

HONORABLE JUDGE ROBERT J. BRYAN

IN THE UNITED STATES DISTRICT COURT
FOR THE WESTERN DISTRICT OF WASHINGTON
AT TACOMA

C. P., by and through his parents,
Patricia Pritchard and Nolle Pritchard;
and PATRICIA PRITCHARD,

Plaintiff,

vs.

BLUE CROSS BLUE SHIELD OF
ILLINOIS,

Defendants.

Case No. 3:20-cv-06145-RJB

**DECLARATION OF GWENDOLYN C.
PAYTON IN SUPPORT OF BLUE CROSS
BLUE SHIELD OF ILLINOIS'S MOTION
TO EXCLUDE PLAINTIFFS' EXPERTS
UNDER *DAUBERT***

NOTE FOR MOTION: November 18, 2022

Pursuant to 28 U.S.C. § 1746, I, Gwendolyn C. Payton, hereby declare as follows:

1. I am an attorney with Kilpatrick Townsend & Stockton LLP in Seattle, Washington. I am counsel of record for Defendant Blue Cross Blue Shield of Illinois ("BCBSIL"). I have personal knowledge of the facts set forth in this declaration.
2. This declaration is filed in support of BCBSIL's Motion to Exclude Plaintiffs' Experts Under *Daubert*, filed herewith.
3. Attached as **Exhibit A** is a true and correct copy of an excerpt of the Zoom Video Deposition Upon Oral Examination of BCBSIL 30(b)(6) witness Telisa Drake.
4. Attached as **Exhibit B** is a true and correct copy of the report of Plaintiffs' expert, Dr. Randi C. Ettner, dated June 16, 2022.

DECLARATION OF GWENDOLYN PAYTON IN SUPPORT OF
BLUE CROSS BLUE SHIELD OF ILLINOIS'S MOTION FOR
SUMMARY JUDGMENT – 1

KILPATRICK TOWNSEND & STOCKTON LLP
1420 FIFTH AVENUE, SUITE 3700
SEATTLE, WA 98101
(206) 626-7713 FAX: (206) 260-8946

1 5. Attached as **Exhibit C** is a true and correct copy of the Zoom Video Deposition
2 Upon Oral Examination of Dr. Randi C. Ettner.

3 6. Attached as **Exhibit D** is a true and correct copy of the report of Plaintiffs' expert,
4 Dr. Loren S. Schechter, dated April 2, 2022.

5 7. Attached as **Exhibit E** is a true and correct copy of the report of Plaintiffs' expert,
6 Dr. Dan H. Karasic, dated June 16, 2022.

7 8. Attached as **Exhibit F** is a true and correct copy of the Zoom Video Deposition
8 Upon Oral Examination of Dr. Dan H. Karasic.

9 9. Attached as **Exhibit G** is a true and correct copy of the expert report of Frank G.
10 Fox, dated August 19, 2022.

11 10. Attached as **Exhibit H** is a true and correct copy of the revised expert report of
12 Frank G. Fox, with addendum, dated September 29, 2022.

13 11. Attached as **Exhibit I** is a true and correct copy of BCBSIL's Fifth Supplemental
14 Responses to Plaintiffs' Second Set of Discovery Requests.

15 12. Attached as **Exhibit J** is a true and correct copy of the expert report of Lawton R.
16 Burns, served June 24, 2022.

17 13. Attached as **Exhibit K** is a true and correct copy of the Zoom Video Deposition
18 Upon Oral Examination of Dr. Loren S. Schechter.

19 14. Attached as **Exhibit L** is a true and correct copy of the November 2017 Endocrine
20 Society Clinical Practice Guideline titled "Endocrine Treatment of Gender-Dysphoric/Gender-
21 Incongruent Persons: An Endocrine Society Clinical Practice Guideline."

22 15. Attached as **Exhibit M** is a true and correct copy of an excerpt of the Zoom Video
23 Deposition Upon Oral Examination of Sharon Booker.

24 16. Attached as **Exhibit N** is a true and correct copy of an excerpt of the Zoom Video
25 Deposition Upon Oral Examination of Sharon Booker.

26 17. Attached as **Exhibit O** is a true and correct copy of an excerpt of the Zoom Video
27 Deposition Upon Oral Examination of Sharon Booker.

19. Attached as **Exhibit Q** is a true and correct copy of the August 30, 2016 Centers for Medicare and Medicaid Services (“CMS”) Decision Memorandum titled “NCA – Gender Dysphoria and Gender Reassignment Surgery (CAG 00446N) – Decision Memo.”

20. Attached as **Exhibit R** is a true and correct copy of the rebuttal expert report of Dr. Michael K. Laidlaw, dated August 3, 2022.

21. Attached as **Exhibit S** is a true and correct copy of the rebuttal expert report of Scott Carr, Ph.D., dated October 21, 2022.

22. I declare, under penalty of perjury under the laws of the United States of America, that the foregoing is true and correct.

DATED this 31st day of October 2022, at Seattle, Washington.

/s/ Gwendolyn C. Payton
Gwendolyn C. Payton

CERTIFICATE OF SERVICE

I certify that on the date indicated below I electronically filed the foregoing, DECLARATION OF GWENDOLYN C. PAYTON IN SUPPORT OF BLUE CROSS BLUE SHIELD OF ILLINOIS'S MOTION TO EXCLUDE PLAINTIFFS' EXPERTS UNDER *DAUBERT* with the Clerk of the Court using the CM/ECF system which sent notification of such filing to the following:

Eleanor Hamburger
SIRIANNI YOUTZ SPOONEMORE HAMBURGER
3101 WESTERN AVENUE STE 350
SEATTLE, WA 98121
206-223-0303
Fax: 206-223-0246
Email: ehamburger@sylaw.com

Jennifer C Pizer
LAMBDA LEGAL DEFENSE AND EDUCATION FUND, INC.
4221 WILSHIRE BLVD., STE 280
LOS ANGELES, CA 90010
213-382-7600
Email: jpizer@lambdalegal.org

Omar Gonzalez-Pagan
LAMBDA LEGAL DEFENSE AND EDUCATION FUND, INC. (NY)
120 WALL STREET
19TH FLOOR
NEW YORK, NY 10005
212-809-8585
Email: ogonzalez-pagan@lambdalegal.org

DATED this 31st day of October, 2022.

Kilpatrick, Townsend & Stockton LLP

By: /s/ Gwendolyn C. Payton
Gwendolyn C. Payton, WSBA #26752
gpayton@kilpatricktownsend.com

*Counsel for Defendant Health Care Service
Corporation, a Mutual Legal Reserve
Company, doing business in Illinois as Blue
Cross and Blue Shield of Illinois*

EXHIBIT A

Page 1

UNITED STATES DISTRICT COURT
WESTERN DISTRICT OF WASHINGTON
AT TACOMA

C.P., by and through his parents,)
Patricia Pritchard and Nolle)
Pritchard and PATRICIA PRITCHARD,)
Plaintiffs,)
vs.) No. 3:20-cv-06145-RJB
BLUE CROSS BLUE SHIELD OF)
ILLINOIS,)
Defendant.)

ZOOM VIDEO DEPOSITION UPON ORAL EXAMINATION
OF
TELISA DRAKE 30(B)(6)

9:30 a.m.

May 13, 2022

REPORTED BY: Pat Lessard, CCR #2104

Page 50	Page 52
1 A. I do. 2 Q. So there is no definition for any word 3 starting with the letter G, correct? 4 A. That is correct. 5 Q. Okay. So it appears that gender 6 reassignment is not a defined term under the standard 7 plan, right? 8 A. That is correct. 9 Q. Okay. And so where would people have to 10 look to know whether a service is considered 11 gender-affirming treatment in the Blue Cross 12 Blue Shield of Illinois standard plan? 13 MS. PAYTON: Object to the form. 14 A. At this point normally members do contact 15 our customer service and we send them to the medical 16 policy which is listed on our public website. 17 MS. HAMBURGER: Okay. I want to turn to 18 Exhibit 2 now, please. 19 (Marked Deposition Exhibit No. 2.) 20 Q. (By Ms. Hamburger) I'm going to stop 21 sharing. 22 A. Okay. 23 Q. I can see you again. 24 All right. Do you know what Exhibit 2 is? 25 A. I do.	1 says "Transgender Reassignment Surgery." 2 Do you see that? 3 A. Yes. 4 Q. And under the chart it has a null sign and 5 it lists page 61. 6 Do you see that? 7 A. I do. 8 Q. And what does that say about transgender 9 reassignment surgery? 10 A. Within the chart it appears that it's saying 11 that it's in the non-covered field. 12 Q. Okay. Then let's go down to -- I think it's 13 page 61. 14 And do you see that Transgender Reassignment 15 Surgery language on page 61? 16 A. Yes, I do. 17 Q. And it says "Not Covered. Benefits shall 18 not be provided for gender reassignment surgery, 19 including, but not limited, to any treatments, drugs, 20 medicines, therapy, counseling services or supplies 21 related to such surgeries." 22 Do you see that? 23 A. I do. 24 Q. And who drafted that? 25 A. Catholic Health Initiatives.
Page 51	Page 53
1 Q. Can you tell me what it is? 2 A. Yes. It is the Catholic Health Initiatives 3 Summary Plan Description. 4 Q. For 2019, correct? 5 A. Yes, this is 2019. 6 Q. Okay. And in 2019 did Blue Cross 7 Blue Shield of Illinois draft this Summary Plan 8 Description? 9 A. No, we did that. 10 Q. But Blue Cross Blue Shield of Illinois 11 administered it, right? 12 A. Yes. We do administer the benefits that are 13 located within this document. 14 Q. Okay. Did Blue Cross Blue Shield of 15 Illinois review this document in order to understand 16 how to administer it? 17 A. Yes, we did. We do match the benefits up to 18 our system to make sure that we're administering as 19 they have depicted to their employees. 20 Q. All right. Let's take a look at the quick 21 reference on page 14. 22 It's page 14. I'm sorry, page twelve in the 23 document itself. Oh, it starts on page twelve but the 24 part I want is page 14. I apologize. 25 I want to draw your attention to where it	1 Q. But Blue Cross Blue Shield of Illinois 2 reviewed and administered it, correct? 3 A. That is correct. 4 Q. And is the term "transgender reassignment 5 surgery" defined? 6 A. Within their documents? 7 Q. Yes. 8 A. It is not. 9 Q. Okay. And where would someone have to go to 10 find what is included as transgender reassignment 11 surgery and the services leading to it? 12 A. That also would result more than likely from 13 a call from the member to our customer advocates, and 14 they would be directed to our medical policy. 15 Q. Okay. And does Blue Cross Blue Shield of 16 Illinois administer the transgender reassignment 17 surgery exclusion -- does it treat the word "gender 18 reassignment surgery" and "transgender reassignment 19 surgery" as the same? 20 MS. PAYTON: Object to the form. 21 A. Can you clarify your question? 22 Q. (By Ms. Hamburger) Yes. From Blue Cross 23 Blue Shield of Illinois's perspective is there a 24 difference between gender reassignment surgery and 25 transgender reassignment surgery?

14 (Pages 50 to 53)

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EXHIBIT B

FILED UNDER SEAL

EXHIBIT C

Transcript of the Testimony of

Randi C. Ettner, Ph.D.

Date: 8/24/2022

C.P., et al. vs Blue Cross Blue Shield



Phone: (425) 866-4250
production@nelsonreporters.com
www.nelsonreporters.com

1 IN THE UNITED STATES DISTRICT COURT
2 FOR THE WESTERN DISTRICT OF WASHINGTON
3 AT TACOMA

4 C.P., by and through his)
5 parents, PATRICIA PRITCHARD)
6 AND NOLLE PRITCHARD; and)
7 PATRICIA PRITCHARD,)
8) No. 3:20-cv-06145-RJB
9)
10) Plaintiffs,)
11)
12) vs.)
13)
14 BLUE CROSS BLUE SHIELD OF)
15 ILLINOIS,)
16)
17) Defendant.)
18

19 REMOTE
20 VIDEOTAPED DEPOSITION UPON ORAL EXAMINATION OF
21 RANDI C. ETTNER, Ph.D.
22 August 24, 2022

23 Taken remotely
24 Witness location: Evanston, Illinois
25

26 KATIE J. NELSON, RPR, CCR #2971
27 NELSON COURT REPORTERS, INC.
28 6513 132nd Avenue NE, #184
29 Kirkland, Washington 98033
30 (425) 866-4250
31 katie@nelsonreporters.com

Nelson Court Reporters, Inc.
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Randi C. Ettner, Ph.D.

8/24/2022

Page 6 1 plaintiffs. 2 THE VIDEOGRAPHER: Thank you. 3 Today's court reporter is Katie Nelson of Nelson 4 Court Reporters. 5 Madam Court Reporter, please swear in the witness. 6 --oOo-- 7 RANDI C. ETTNER, Ph.D., sworn as a witness by the Court 8 Reporter, testified as follows: 9 THE VIDEOGRAPHER: You may proceed. 10 11 EXAMINATION 12 BY ATTY. BEDARD: 13 Q. Good morning, Dr. Ettner. My name is Stephanie 14 Bedard. And as I just mentioned, I represent the defendant 15 in this case, Blue Cross Blue Shield of Illinois. 16 Can you please state and spell your name for the 17 record? 18 A. Randi, R-A-N-D-I, Ettner, E-T-T-N-E-R. 19 Q. Thank you. And you understand you're under oath 20 today? 21 A. I do. 22 Q. So, Dr. Ettner, the plaintiff in this case, the 23 minor plaintiff, his name is [redacted name spoken], but for 24 purposes of establishing the record for your transcript in 25 this case, I'm going to refer to him as C.P. because he is a	Page 8 1 will assume that you have understood the question asked. 2 Is that fair? 3 A. Yes. 4 Q. And by that same token, if there -- at a later 5 point in time in this deposition, if there is a response 6 that you gave that you would like to go back to or help 7 clarify, that is fine as well. Just let me know. 8 Sound good? 9 A. Yes. 10 Q. Dr. Ettner, where do you reside -- where do you 11 currently reside? 12 A. Evanston, Illinois. 13 Q. And is that where you're located today? 14 A. It is. 15 Q. Dr. Ettner, I am going to show you what has been 16 marked as Defendant's Exhibit 1 for this deposition. 17 (Defendant's Exhibit 1 marked.) 18 Q. (By Atty. Bedard) Can you see my screen? 19 A. Yes. 20 Q. I'm going to scroll down so you can see the 21 entirety of the first page. 22 Have you seen this deposition subpoena before 23 today? 24 A. Yes. 25 Q. Great.
Page 7 1 minor. 2 I just wanted to make sure you understood who I was 3 referring to when I use the terminology "C.P." 4 A. I understand. 5 Q. I understand from your expert report, Dr. Ettner, 6 that you have been deposed previously. So some of these 7 ground rules that I'm about to go over will already be 8 familiar to you, but some of them are particularly necessary 9 these days in the age of remote depositions. 10 So because this is being taken down by a court 11 reporter, we'll need a verbal response to every question. 12 So shaking a head yes or no won't work; we'll actually need 13 an affirmative yes or no. Along those same lines, we'll 14 need to make sure not to talk over each other, so I will do 15 my best to allow you to finish any answer you're giving and 16 if you could do your best to let me finish asking every 17 question, that would be great. 18 Throughout the course of the day today, if you need 19 to take a short break, please just let me know and I'd be 20 happy to do so. What I may ask is that we finish a line of 21 questioning or finish discussing a specific exhibit and then 22 we can of course take a break. 23 In terms of other ground rules, you know, if -- if 24 you don't understand my question, please ask me to rephrase 25 and I'll be happy to do so. If you do answer my question, I	Page 9 1 And what did you do to prepare for today? 2 A. I reviewed my notes and I reviewed some of the 3 medical records of C.P. 4 Q. And when you refer to your notes, what notes do you 5 have? 6 A. I have handwritten notes of my interview with C.P. 7 Q. How many pages of notes are they approximately? 8 A. I'm not certain. 9 Q. Okay. And were those notes taken while you were 10 speaking with C.P. or were they also taken afterwards? 11 A. They were taken during my interview. 12 Q. Okay. 13 ATTY. BEDARD: Omar, we have not, I believe, 14 been provided with a copy of those notes. So we would ask 15 that we be given a copy and reserve the right to ask 16 Dr. Ettner additional questions about those notes. 17 ATTY. GONZALEZ-PAGAN: You were provided with 18 a copy of those notes on July 11. 19 ATTY. BEDARD: July 11? 20 ATTY. GONZALEZ-PAGAN: Yes. 21 ATTY. BEDARD: Okay. Could you provide me 22 with the Bates number? 23 ATTY. GONZALEZ-PAGAN: I can look it up, but 24 you have been provided with a copy of Dr. Ettner's notes. 25 ATTY. BEDARD: Great. If you could give me

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Page 10 1 the Bates number and send it to me via e-mail, that would be 2 great. Thank you. 3 Q. (By Atty. Bedard) So, Dr. Ettner, in addition to 4 reviewing some of C.P.'s medical records and reviewing your 5 notes from meeting with C.P., what else did you do to 6 prepare for today? 7 A. Nothing. 8 Q. Did you speak with counsel for plaintiffs? 9 A. Yes. 10 Q. Okay. When did you speak with counsel for 11 plaintiffs? 12 A. Monday. 13 Q. Okay. 14 A. At 3 p.m. Central Time. 15 Q. Monday this week? 16 A. Yes. 17 Q. Was it just one conversation? 18 A. Yes. 19 Q. And have you spoken with plaintiffs' counsel in 20 phone or in person at any other point in time? 21 A. At any other point in time? 22 Q. Correct, but for purposes of this litigation in 23 particular. 24 A. Yes. I received a -- I believe, an e-mail that I 25 was scheduled for an earlier deposition which was then	Page 12 1 A. None. 2 Q. Do you have the exhibits that we circulated 3 yesterday? 4 A. I downloaded those exhibits. 5 Q. Okay. Good. So you'll be able to pull those up on 6 your end and I'll be able to share my screen. 7 Will that work? 8 A. Yes. 9 Q. Okay. Good. 10 ATTY. GONZALEZ-PAGAN: Stephanie, just to 11 follow up, we produced Dr. Ettner's notes, which she 12 collected for us, on Ettner 03958 through Ettner 03969. 13 They were produced on July 11th. And in looking at the 14 access log, I see here that Gwendolyn downloaded a copy. 15 ATTY. BEDARD: Good, thank you. 16 Q. (By Atty. Bedard) Dr. Ettner, have you ever been a 17 plaintiff in a lawsuit before? 18 A. Have I personally been a plaintiff in a lawsuit? 19 Q. Correct. 20 A. Yes. 21 Q. Okay. When was that? 22 A. I believe it was 2001, but I'm not certain about 23 that. It may have been 2000. 24 Q. What was the subject matter of that lawsuit in 25 which you were the plaintiff?
Page 11 1 postponed. 2 Q. And did you speak with plaintiffs' counsel around 3 the time of that earlier scheduled deposition as well? 4 A. I don't recall if I spoke with them or if I just 5 exchanged an e-mail about the -- a possible subsequent date 6 for deposition. 7 Q. And who did you speak with specifically in your 8 call on Monday of this week? 9 A. Mr. Gonzalez-Pagan. 10 Q. Okay. Was anyone else part of that phone call? 11 A. No. 12 Q. Okay. Did you collect documents to provide to 13 plaintiffs' counsel in advance of your deposition today? 14 A. Collect documents? I don't understand the 15 question. 16 Q. So, Dr. Ettner, you received a document subpoena in 17 this case for publications and articles and other materials 18 that you relied on in preparing your report and there was 19 some information produced to us by plaintiffs' counsel. 20 So I'm just trying to understand to what extent you 21 collected some of that information to provide to us. 22 A. I don't believe I collected that information to 23 provide. 24 Q. Okay. And what documents do you have in front of 25 you today?	Page 13 1 A. I was hit from behind in a vehicle accident by some 2 uninsured motorists who had stolen a car. 3 Q. I'm sorry to hear that. 4 A. Thank you. 5 Q. That does not sound like a pleasant experience. 6 Setting aside that lawsuit, which I believe you 7 said was around 2001, have you ever been a plaintiff in a 8 lawsuit against an insurance company before? 9 A. No. 10 Q. Have you ever been a defendant in a lawsuit? 11 A. No. 12 Q. Dr. Ettner, I'm now going to show you what has been 13 marked as Defendant's Exhibit 2. 14 (Defendant's Exhibit 2 marked.) 15 Q. (By Atty. Bedard) I'm going to scroll down so you 16 can see the entirety of the first page. 17 Dr. Ettner, does this appear to be the first page 18 of your expert report? 19 A. Yes. 20 Q. I'm going to go to the end of that report. 21 And this is your signature on Page 25 of the 22 report, right? 23 A. Correct. 24 Q. Dr. Ettner, did you draft this report? 25 A. Yes.

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Page 14 1 Q. Did anyone assist you in preparing it? 2 A. No. 3 Q. Did anyone review a draft of this report before it 4 was finalized? 5 A. Not that I'm aware of. 6 Q. And, Dr. Ettner, you -- you mentioned earlier today 7 that you had previously reviewed some of C.P.'s medical 8 records, medical and mental health records and I believe 9 your report says the same. 10 What specific medical records were you provided? 11 A. I was provided records by Eduardo Garza, records by 12 the surgeon, Dr. Kylo, the records of Kevin Hatfeld or 13 Field. I'm not sure if it's Hatfeld. 14 I was provided with a Ms. Booker's medical report 15 and the comprehensive clinical and neuropsychological 16 evaluation of Dr. Tutty. 17 Q. Were you also provided with any Blue Cross Blue 18 Shield of Illinois specific documents, such as medical 19 policies? 20 A. Yes. 21 Q. And did you review those documents? 22 A. Yes. 23 Q. Now, Dr. Ettner, I understand from your expert 24 report that you have been deposed before today. So let's 25 take a look at that section of your report for a second.	Page 16 1 Q. And what was that Ph.D. in? 2 A. Psychology. 3 Q. Where are you currently employed? 4 A. I'm currently self-employed. 5 Q. Okay. And what is the name of your company or 6 business? 7 A. I do not have a name. I just have a private 8 practice. 9 Q. And where did you work prior to your current 10 private practice? 11 A. I've always maintained a private practice, although 12 I have at times been employed as a consultant, as an 13 educator, as a supervisor. I worked at St. Francis Hospital 14 in the Women's Health Clinic as a psychologist. 15 I have had research projects that have been 16 subsidized, and I was employed as a -- as a -- to do 17 psychological testing at a university -- at a college 18 actually. I believe, although I could verify that by 19 reviewing my CV, that that's some of the paid employment 20 that I've engaged in while simultaneously having a private 21 practice. 22 Q. How many years have you maintained a private 23 practice? 24 A. I would say 35. 25 Q. Would -- did your private practice begin
Page 15 1 I'm going to pull that back up on the screen, Exhibit 2. 2 So we have here on the screen a list of cases in 3 which you've previously provided testimony either by 4 deposition or at trial. Is this list fully accurate to the 5 best of your knowledge? 6 A. Yes. 7 Q. And which of these cases involved gender dysphoria 8 or the provision of transgender-related services? 9 A. All. 10 Q. Now I'm going to scroll down. This paragraph in 11 your report actually extends onto the fifth page, so let me 12 make sure you can see that as well. 13 Is that also true for the cases listed on Page 5 of 14 your expert report? 15 A. Yes. 16 Q. Dr. Ettner, tell us a bit about your educational 17 background, including school and degrees. 18 A. Specifically is there something you'd like me to 19 discuss? 20 Q. So specifically, what degrees have you received and 21 where did you receive them? 22 A. So I received a bachelor's at Indiana University. 23 I received a master's degree in clinical psychology at 24 Roosevelt University in Chicago. I received a Ph.D. at 25 Northwestern University.	Page 17 1 immediately after receiving your Ph.D.? 2 A. No. It began shortly after, but not immediately 3 after. 4 Q. Okay. And you mentioned -- you mentioned a minute 5 ago that you were employed to do psychological testing at a 6 college. 7 Can you tell us more about that? 8 A. Yes. There was a college -- I don't believe it's 9 still in existence -- in Chicago, and a government program 10 hired me to test indigenous people for career occupations. 11 I worked there for a short time immediately after receiving 12 my Ph.D. 13 Q. It sounds from what you're saying that that 14 employment and the scope of that testing was not related to 15 the provision of transgender-related services, right? 16 A. Correct. 17 Q. Okay. What about the -- you mentioned some 18 research projects that had been subsidized. 19 Did any of those research projects relate to gender 20 dysphoria or the provision of transgender-related services? 21 A. All of those did. 22 Q. Okay. And what were the -- what was the scope 23 of -- what was the focus of each research project? 24 A. Well, one which was subsidized by the initial 25 Institutes of Health was on quality of life in -- amongst

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Page 18 1 transgender individuals and that resulted in a publication. 2 The others were supported by and large by either individual 3 donors or the foundation -- the New Health Foundation 4 Worldwide. 5 All of those involved areas of either gender 6 diversity or, in one case, the impact on children whose 7 parents undergo a gender transition. One was -- had to do 8 with the impact of bullying on transgender children. One 9 was a study of tomboys, basically, and the gender 10 trajectories of children who were assigned female at birth 11 and what their ultimate gender and sexual identity 12 trajectories were, to name a few. 13 One was the impact of gender diversity in 14 transgender women and the incidence of hypertension in that 15 cohort. So those are a few that I'm recalling from memory 16 that were subsidized. 17 Q. Have you ever held any fellowship positions? 18 A. Personally, I have not held a fellowship position. 19 I have been the -- there is a Randi and Fred Ettner 20 externally funded transgender health at the University of 21 Minnesota that funds positions for fellows in transgender 22 health. 23 Q. Are you a member of any professional organizations 24 related to gender dysphoria or the provision of 25 transgender-related services?	Page 20 1 And so I had an early, unexpected introduction into 2 what was a very new and apparently at that time thought to 3 be a rarity among rarities, and that was before I actually 4 was a psychologist. There was a surgeon who was performing 5 surgery at Cook County Hospital in the late '70s, and part 6 of what I was asked to do was run groups of individuals who 7 wanted those surgeries. 8 Q. Going back for a minute to your involvement in 9 WPATH, I understand you've been a member of the organization 10 since the '90s. 11 Have you held any leadership roles within WPATH? 12 A. Yes. 13 Q. What roles have you held? 14 A. I was a board member for many years, and I was a -- 15 the secretary for two consecutive terms. And I chair 16 currently and actually initiated the committee for 17 institutionalized persons. I have at times been a member of 18 the scientific committee that reviewed abstracts for our 19 meetings and I was a member of the award committee one year 20 after having received an award. And I believe -- and I've 21 been an author of the Standards of Care and I'm currently an 22 author of the soon-to-be-released 8th version of the 23 Standards of Care. 24 I also was one of the individuals who was an 25 original member of the -- what was known as the Global
Page 19 1 A. I'm a member of the American Psychological 2 Association, which supports gender-affirming care for 3 people, and I'm a member of the World Professional 4 Association for Transgender Health. 5 Q. Which is commonly referred to WPATH, right? 6 A. Yes. 7 Q. Okay. So tell me more about your involvement in 8 WPATH, how long -- 9 Well, first, is it something that you can be a 10 member of, and if so, how long have you been a member for? 11 A. I became a member in the 1990s. 12 Q. And -- go ahead. 13 A. Dr. Lee Schaefer was my mentor and she was the 14 colleague and the keeper of Harry Benjamin, who was the sort 15 of founder of transsexualism. She inherited all of his 16 medical files, which are now the Kinsey Institute. She was 17 his close associate and colleague and she was my mentor. 18 Under her tutelage, I joined WPATH in the '90s. 19 However, as a student in the late '70s, I 20 volunteered at Cook County Hospital, which at that time had 21 a program in what was then referred to as sexual 22 reassignment, and I was the first volunteer they had in the 23 department of psychiatry. So they put me with what they 24 thought were crazy people at the time who wanted to have 25 what was then referred to as sex change.	Page 21 1 Education Initiative, WPATH's educational and certification 2 program. I directed and actually created the foundation and 3 mental health program which was used to educate mental 4 health providers about basic care for transgender persons. 5 Q. And amongst those roles, Dr. Ettner, I believe you 6 mentioned you're the current chair of the committee for 7 institutionalized persons; is that right? 8 A. Correct. 9 Q. Which of those roles, in addition to that chair 10 position, do you currently hold? 11 A. None. 12 Q. Okay. And in addition to WPATH, your report also 13 references The Endocrine Society. 14 Are you involved with The Endocrine Society? 15 A. I'm not involved with The Endocrine Society. 16 Q. And what's your understanding of the difference 17 between these two groups? 18 A. One is composed solely of endocrinologists who 19 chose to join and WPATH is a multidisciplinary organization 20 of individuals who work throughout the world with 21 transgender, gender diverse, gender nonconforming 22 individuals and some of our members are endocrinologists. 23 Many of our members are -- belong -- many of our 24 endocrinology members belong to both societies. WPATH did 25 offer comments on -- on the guidelines for the treatment of

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Page 22 1 gender dysphoria after The Endocrine Society released them. 2 Q. Dr. Ettner, in addition to your involvement with 3 the American Psychological Association as well as WPATH, are 4 there any other organizations or professional groups you're 5 involved in that are related to gender dysphoria or the 6 provision of gender-related care? 7 A. I'm a member of the Society for the Scientific 8 Study of Sexology, known as quad S, which does often have 9 presentations or publish articles, I believe, about gender. 10 But I -- I don't have any active role in that organization. 11 Q. Dr. Ettner, let's turn for a minute to your private 12 practice. 13 You mentioned that you've been in private practice 14 for about 35 years. How many patients do you currently see 15 per year? 16 A. Per year? 17 Q. Yes. 18 A. Well, that's changed significantly due to COVID. 19 Prior to that, I had a very full load of private patients 20 that I saw, not all of whom were -- had gender issues. I 21 also see what I refer to as my civilian casualties, people 22 who just have problems in living. But with COVID, my 23 private practice was intentionally decreased significantly. 24 Q. Okay. So let me approach it then from two ways. 25 First: How many patients on the whole did you see	Page 24 1 identified as transgender? 2 A. Probably closer to 70 percent. 3 Q. So let's do -- let's do the same approach. 4 So currently, what percentage of your patients on 5 the whole would identify as transgender and would also be 6 minors? 7 A. Currently? 8 Q. Currently. 9 A. None are minors currently. 10 Q. And same question for the pre-COVID era. 11 So in 2019, what percentage of your patients who 12 identified as transgender would -- were also minors? 13 A. I would substitute "minors" for adolescents because 14 with children, I would typically see the parents with very 15 young children. So when you say "minors," I would see 16 people who were communicative, you know, not very small 17 children; children either on the cusp of puberty or who were 18 at least school age children, you know, nine, 10, et cetera, 19 eight or -- 20 But for very young children, I would meet with the 21 parents typically and not the child, unless they brought the 22 child, but there's no treatment for a child who can't 23 express themselves verbally. 24 And I would say -- I think the question was what 25 percentage in 2019? I don't know precisely in 2019. I can
Page 23 1 per year prior to COVID, let's say in 2019? 2 A. Well, I don't know on a yearly basis because that 3 would involve some math, but I could tell you on a weekly 4 basis -- 5 Q. Sure. 6 A. -- how many I saw. I would see approximately, I 7 would say -- I worked six days a week typically and I would 8 see probably six people a day, so somewhere around 36 -- 9 between 30 and 40 patients a week was typical. 10 Q. And what is typical for your practice these days 11 post -- well, after the start of COVID? 12 A. Right. Now that I've gone to exclusively Zoom 13 basically or total electronic, I would say I would see 14 probably half that amount. 15 Q. So is your practice completely comprised of Zoom 16 appointments at this point? 17 A. At this point, yes. 18 Q. I guess let's approach this one of two ways then. 19 In your current practice, what percentage of your 20 patients would identify as transgender? 21 A. I would say 30 percent. 22 Q. Would you say that that percentage was different in 23 2019? 24 A. Yes. 25 Q. What percentage of your patients in 2019 would have	Page 25 1 tell you over the entirety of my career seeing transgender 2 people, approximately 25 percent or 30 percent were in that 3 category. 4 Q. So to make sure -- and thank you, by the way, 5 Dr. Ettner, for clarifying my question. 6 To make sure I understand what you're saying, are 7 you saying that historically throughout the course of your 8 private practice, 25 to 30 percent of the transgender 9 patients you have seen are either children or adolescents, 10 or is that 25 to 30 percent of all of the patients that 11 you've seen have been transgender children or adolescents? 12 A. Would you repeat that? 13 Q. Sure. Is -- you said that 25 percent -- 25 to 14 30 percent were children or adolescents who identified as 15 transgender. 16 So I'm just trying to understand: Is that 25 to 17 30 percent of the transgender individuals that you see or 25 18 to 30 percent of all patients that you see? 19 A. 25 to 30 percent of the transgender patients that I 20 see or saw. 21 Q. Okay. 22 A. So several years ago, a Children's Hospital opened 23 in Chicago, the Lurie Children's Hospital, and many young 24 and -- young people and adolescents who lived close to that 25 facility are being seen in that hospital. And so previously

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Page 26 1 before that, I saw more younger people than currently. 2 Q. Oh, I see what you're saying. 3 So because the hospital was built, you actually see 4 fewer minors and adolescents in your current practice than 5 you used to; is that right? 6 A. Yes. People who are regionally situated closer to 7 that hospital will go to that hospital for treatment 8 typically, or consultation or its services. 9 Q. And do you have any affiliation with that hospital? 10 A. I don't. They refer to providers that I work with 11 in a working group, but I don't have any affiliation with 12 them. 13 Q. Okay. And you -- you drew a distinction a minute 14 ago, Dr. Ettner, between children that you've seen in your 15 practice and adolescents that you've seen in your practice. 16 One of the distinctions that you drew was whether or not 17 parents attend a session with -- with the child or 18 adolescent. 19 So are parents typically in attendance for your 20 sessions with children, but not for your sessions with 21 adolescents? 22 ATTY. GONZALEZ-PAGAN: Objection; form. 23 THE WITNESS: Typically parents come with 24 adolescents occasionally. I may interview them first with 25 their child and then ask them to sit in my waiting area	Page 28 1 know, under X age, you would like the parents to be present 2 for the entirety of the session? 3 ATTY. GONZALEZ-PAGAN: Objection; form. 4 THE WITNESS: I would answer that by saying 5 that every situation is on a case-by-case basis. And I 6 don't have any standard age where I insist that a parent be 7 present through the entirety of the session. That often 8 happens. Sometimes parents come in without a child to speak 9 to me about the child. The child may be at camp or away at 10 school and the parents want to discuss the child's progress 11 or some other issues. So parents can come alone as well. 12 Q. (By Atty. Bedard) And, Dr. Ettner, in your private 13 practice, do you diagnose individuals with gender dysphoria? 14 A. In my private practice? If there -- do you mean a 15 diagnosis for the purpose of memorializing that for an 16 insurance purpose or a letter or just in a casual way with 17 the client? 18 Q. Thank you for clarifying. I really mean both 19 frankly. So both as a general matter and for purposes of -- 20 for insurance purposes. 21 A. I have done both, yes. I am capable of diagnosing 22 gender dysphoria. 23 Q. And in the general context, what does the process 24 of diagnosing an individual with gender dysphoria look like? 25 Is there a set process that you would follow?
Page 27 1 while I speak alone with the child. So most -- I'm always 2 seeing the parents at some point or another, but I may 3 interview the child without parents at given times. 4 Q. So for -- to make sure I'm understanding that, for 5 both children and adolescents, parents attend every session, 6 right? 7 A. Well, not necessarily. 8 ATTY. GONZALEZ-PAGAN: Objection; form. 9 Sorry, Dr. Ettner. If you can just give me a pause to... 10 THE WITNESS: Yes. I'm sorry. 11 ATTY. GONZALEZ-PAGAN: Objection; form. 12 Please answer. 13 THE WITNESS: I'm not necessarily seeing the 14 parents at every session. Sometimes an adolescent may come 15 without parents, but I'm always seeing the parents 16 occasionally, or they're waiting in my waiting area and I'm 17 seeing them either before or after the session typically. 18 Q. (By Atty. Bedard) And is there a certain age, 19 based on the age of the child, where you would require or 20 ask the parents to be present for the session? 21 A. Well, I'll always require the parents to be -- 22 initially to attend and then it just depends on what the 23 goal of my contact with the individual is. 24 Q. So there -- let me ask it a different way then. 25 There's not necessarily an age where you say, you	Page 29 1 ATTY. GONZALEZ-PAGAN: Objection; form. 2 THE WITNESS: The criteria for the diagnosis 3 are set forth in the DSM-5. 4 Q. (By Atty. Bedard) And does that process change at 5 all if the purpose of the diagnosis is for submittal to an 6 insurance company? 7 A. The diagnosis remains the same. The purpose may 8 change, for instance, in a correctional facility. 9 Q. And how would that process be different? 10 A. The process would be different because certain 11 correctional facilities may have different -- may have a 12 different standard of -- a policy which does not allow for 13 their clinicians to make the diagnosis. So I would be 14 coming in, not as an employee of the person, but as an 15 outside specialist to make the diagnosis. So there may be 16 some differences in those cases. 17 I would do extensive, for example, testing to rule 18 out any other conflicting diagnosis that an inexperienced 19 correctional officer may have confused with gender 20 dysphoria. 21 Q. And what are those conflicting diagnoses? 22 A. For example, it's not uncommon for incarcerated 23 people to attempt autocastration if they're not receiving 24 adequate care or if they're not receiving -- or if they're 25 receiving inappropriate care. Someone who lacks experience

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Page 30 1 with gender dysphoria may misinterpret that as a borderline 2 personality disorder and not be familiar with the diagnostic 3 criteria for gender dysphoria. 4 And so there may be some training that's involved 5 or some communication that's involved with those individuals 6 and understanding that these attempts are not indicative of 7 borderline personality, but are attempts to remove, in the 8 case of autocastration, the testosterone that's fueling the 9 gender dysphoria. 10 Q. So, Dr. Ettner, taking a step back from the 11 correctional or institutionalized context, are there 12 conflicting diagnoses for the general population of those 13 that identify as transgender? 14 ATTY. GONZALEZ-PAGAN: Objection; form. 15 THE WITNESS: I don't really understand the 16 question as it's phrased. 17 Q. (By Atty. Bedard) Let me rephrase to try to 18 clarify. 19 So you mentioned that in the correctional 20 context -- 21 A. Yes. 22 Q. -- you will sometimes undergo or undertake testing 23 to rule out conflicting diagnoses. And what I'm trying to 24 understand is: In the noncorrectional context, are there 25 also -- is there testing that you would do to rule out	Page 32 1 THE WITNESS: It's very common for people who 2 have gender dysphoria to have attendant depression, anxiety, 3 suicidal ideation or social issues that stem from the gender 4 dysphoria and are attendant to it as explained in the DSM-5. 5 But those -- in those cases, that depression does not 6 respond really to psychotropic medication because it's a 7 result of the gender dysphoria and not a distinct mood 8 disorder. 9 Q. (By Atty. Bedard) So, Dr. Ettner, how do you make 10 that determination? How do you determine that a patient's 11 depression might be stemming from gender dysphoria as 12 compared to being a separate mood disorder? 13 ATTY. GONZALEZ-PAGAN: Objection; form. 14 THE WITNESS: Well, there are several ways. 15 First of all, we look at the criteria for the mood 16 disorder. Second of all, we want to know if they've been 17 treated for the mood disorder, and if so, who's treating 18 them? What's the treatment? What's the duration? What are 19 the symptoms? And third, by getting to know an individual 20 well, this is where clinical judgment comes in. 21 If you treat the gender dysphoria and if the 22 depression stems from the gender dysphoria, it will be 23 attenuated or eliminated when the gender dysphoria is 24 appropriately and adequately treated. 25 Q. (By Atty. Bedard) So I guess in other words, what
Page 31 1 conflicting diagnoses? 2 A. Not conflicting diagnoses. I might rule -- I might 3 want to understand more about co-occurring diagnoses in some 4 of my clients. 5 Q. And what types of co-occurring diagnoses have you 6 seen? 7 A. Well, I have seen individuals who have many 8 co-occurring diagnoses and often they require referral for 9 psychotropic medication, or often they're seeing a 10 psychiatrist who monitors these other conditions. And 11 sometimes I would be the first person who might refer them 12 for medication if they had a co-occurring condition. 13 Q. What are some of those co-occurring conditions 14 themselves? 15 A. Well, they run the gamut. Fifty percent of 16 Americans will be diagnosed with some mental illness during 17 the course of their lifetime and transgender people are no 18 different. They can have other conditions just as an 19 individual can have bronchitis and lupus, so there's no 20 limit to the conditions that an individual can experience as 21 a hazard of living. 22 Q. Are there any co-occurring conditions or diagnoses 23 that you have seen as being particularly prevalent in 24 your -- in the transgender population of your patients? 25 ATTY. GONZALEZ-PAGAN: Objection; form.	Page 33 1 I'm trying to understand is: How would you know, for an 2 individual who has both the gender dysphoria and, say, 3 depression, how would you know whether or not to try 4 medication as compared to bel- -- to independently treat the 5 depression as compared to believing that it stems from the 6 gender dysphoria? 7 ATTY. GONZALEZ-PAGAN: Objection; form. 8 THE WITNESS: Could you rephrase that 9 question, please? 10 Q. (By Atty. Bedard) Sure. For an individual that 11 presents with gender dysphoria and depression, how would you 12 determine whether or not to provide that individual with 13 medication specifically targeting or looking to treat the 14 depression? 15 A. Well, that depends on the phenomenology that the 16 patient describes, which often is expressed over a period of 17 time. And it also depends on if other systems in the body 18 are being impacted by the depression. 19 So, for instance, if a person is experiencing a 20 major mood disorder, they would maybe be having some 21 psychotic elements to it which would not be consistent with 22 gender dysphoria. And largely, it's the client's 23 description of how they experience their life, their gender, 24 their interactions, what areas of their living are -- are 25 they experiencing clinical distress, which is one of the

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Page 34 1 components of the diagnosis of gender dysphoria. 2 So, for instance, if a person is having a 3 reactive-depressive episode -- bereavement, grief -- that's, 4 we know, separate from the gender dysphoria. If a person is 5 saying that I no longer want to go to school because I have 6 to go to the girls' gym locker room and I don't want to go 7 to the girls' gym locker room, et cetera, and they have a 8 narrative that's consistent with the incongruity of their 9 assigned gender and their experienced gender and that is 10 contaminating an area of their life and that's causing them 11 to isolate, we wouldn't necessarily see that as something 12 that required medication. 13 So this is clinical judgment. This is basically 14 what we do over a period of time. Certain disorders, such 15 as bipolar disorder, can take 10 years to diagnose because 16 clinicians usually only see people when they're depressed 17 and so they mistake it for depression and provide 18 antidepressants. 19 So there's experience, training. We can use 20 psychodiagnostic techniques. One of the great tools of 21 psychology is the ability to use psychological tests which 22 very much help in determining whether something is a 23 discrete co-occurring condition. 24 Q. So, Dr. Ettner, I want to circle back to something 25 that you said just a minute ago which related to the	Page 36 1 Q. And when you -- when you do make that diagnosis, 2 when one of your patients is diagnosed with gender 3 dysphoria, is that diagnosis typically made in consultation 4 with other physicians or practitioners? 5 A. Well, very typically the client discloses that they 6 have gender dysphoria, or a medical provider can make that 7 diagnosis if they're experienced with the condition of 8 gender dysphoria. So I'm not always the first person to 9 make that diagnosis. 10 Q. And that's a fair point. 11 So in circumstances where you are the first person 12 making a diagnosis of gender dysphoria, do you typically 13 consult with others before making that diagnosis? 14 A. I consult with the patient and -- 15 Q. What about other practitioners, medical 16 practitioners? 17 A. Only if there's a clinical justification for doing 18 that. So, for instance, if I'm asked to write a referral 19 letter for a medical procedure, or in a -- if a -- when I 20 was working, for instance, at Weiss Gender Confirmation 21 Center, there would be sometimes case consultation meetings 22 where we would discuss an unusual case or a complex case and 23 people would -- it would be an experience where we would 24 share some information, as in ground rounds. I've given 25 grounds rounds or I've talked to the entire staff of a
Page 35 1 frequency with which you might meet with an individual. 2 So prior to diagnosing a patient with gender 3 dysphoria, how many times would you typically meet with that 4 patient? 5 A. That depends, again, on the purpose of my contact 6 with the patient. Some people come in only for an 7 assessment letter -- a letter, a referral for surgery. A 8 second opinion letter is what it's known as in the WPATH 9 standards of care. 10 So I may see an individual who's been followed by a 11 therapist for years, and I may see that individual one time 12 just to provide a second opinion for a referral for 13 particular surgeries as required by the standards of care. 14 So there is no really typical -- some clients I see 15 weekly. Some people previously would come from out of state 16 when possible and I would see them maybe monthly. And a lot 17 of the people that I see or saw prior to COVID, again, were 18 people who had completed their gender transition, were 19 postsurgery and would come just to talk about other issues 20 that they were having in their lives -- the loss of a loved 21 one, an illness that unexpectedly occurred in their life. 22 So as a clinical psychologist, I see people for a 23 variety of reasons and there really is no set specific 24 amount of time that I see an individual, then make a 25 diagnosis, et cetera.	Page 37 1 hospital about cases in gender dysphoria. 2 But when we work in a multidisciplinary way, we 3 consult with medical providers and others, physical 4 therapists, on a case-by-case basis. 5 Q. And have you ever worked with any of the physicians 6 at The Polyclinic? 7 A. No. 8 Q. Are you familiar with Dr. Jeffrey Kylo? 9 A. No. 10 Q. What about Dr. Kevin Hatfield? 11 A. Only by reputation. I know of his name. 12 Q. You've never worked directly with him? 13 A. That's correct. 14 Q. And are you familiar with -- with Sharon Booker, 15 Ms. Booker or the Center for Child & Family Therapy? 16 A. Not personally, no. 17 Q. And, Dr. Ettner, have you reviewed the reports 18 offered by plaintiffs' other experts in this case, Dr. Dan 19 Karasic? 20 A. I reviewed his report, yes. 21 Q. And are you familiar with Dr. Karasic? 22 A. Yes. 23 Q. How do you know him? 24 A. He's a member of WPATH. And he was on the board at 25 one point in time when I was also a board member.

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Page 38 1 Q. Have you ever both served as expert witnesses in a 2 litigation matter before? 3 A. I don't -- I don't know. It's possible. I don't 4 know. 5 Q. And what about Dr. Loren Schechter. Do you know 6 Dr. Schechter? 7 A. Yes. 8 Q. And how do you know Dr. Schechter? 9 A. Dr. Schechter is a surgeon in the Chicago area, and 10 he previously was at Weiss Hospital at the same time that I 11 was a member of the team there. 12 Q. Have you ever referred patients to Dr. Schechter? 13 A. I've written letters referring patients to 14 Dr. Schechter. 15 Q. And what about the reverse situation: Has 16 Dr. Schechter ever referred any patients to you? 17 A. Yes, I believe in the past, he has referred 18 patients to me. Some years ago that would have been. 19 Q. And to the best of your knowledge, have you and 20 Dr. Schechter ever served as expert witnesses in the same 21 litigation dispute? 22 A. Yes. In this case, yes. And I think in -- yes, in 23 a previous case, I believe Dr. Schechter may have been 24 involved. 25 Q. Let me pull up again -- I've got it right in front	Page 40 1 if there is anything more current since I provided that. 2 Q. Let's take a look at that then. 3 Dr. Ettner, this may be a situation where I can 4 both share it on my screen, but given the length of your CV, 5 it may make for sense for you to take a look at Exhibit 2 6 beginning at Page 27. And I'll share my screen as well. 7 A. Is it possible for you to scroll down on your 8 screen? 9 Q. Sure. Let me know when you'd like me to stop. 10 A. Okay. Stop for a moment, please. Continue. And 11 please continue to scroll. And stop. 12 I think this is accurate and current as far as I 13 can tell. 14 Q. Do you need me to continue scrolling to confirm? 15 A. No, this looks fairly current. I don't think that 16 there's anything... 17 Q. Okay. 18 A. It's (inaudible). 19 THE COURT REPORTER: Sorry -- sorry, I didn't 20 hear that, Dr. Ettner. Can you repeat it? 21 THE WITNESS: I think that's an accurate 22 presentation of my CV. 23 ATTY. BEDARD: Dr. Ettner, we've been going 24 for about an hour now. Why don't we take a 10-minute break 25 and come back at -- let me do the mental math. Your
Page 39 1 of me -- your expert report listing your prior testimony in 2 the past four years. 3 A. Yes. 4 Q. Are any of these cases in your expert report what 5 you were referring to as the past matter involving both you 6 and Dr. Schechter? 7 ATTY. GONZALEZ-PAGAN: Objection; form. 8 THE WITNESS: I think Dr. Schechter was an 9 expert, I believe, in Kadel, and as far as I know -- could 10 you scroll down, please. 11 Q. (By Atty. Bedard) Yeah. 12 A. I'm not aware of him being involved in any of these 13 other cases to my knowledge. 14 Q. Dr. Ettner, plaintiffs recently disclosed the 15 report of Dr. Frank Fox. 16 Have you been provided with a copy of that report? 17 A. No. 18 Q. Are you familiar with Dr. Frank Fox? 19 A. No. 20 Q. Dr. Ettner, you provided us with a copy of your CV, 21 or I should say plaintiffs' counsel provided us with a copy 22 of your CV along with your report for this case. 23 Is everything in your CV accurate, to the best of 24 your knowledge? 25 A. I would have to see that CV to review that and see	Page 41 1 12:25 -- 12:27. Let's say 12:27, a full 10 minutes. 2 THE WITNESS: Got it. 3 ATTY. BEDARD: Did I do that right? All 4 right, good. 5 THE VIDEOGRAPHER: The time is 10:17 a.m. We 6 are off the record. 7 (Recess taken from 10:17 to 10:28 a.m.) 8 THE VIDEOGRAPHER: The time is 10:28 a.m. We 9 are back on the record. 10 11 EXAMINATION - (Continuing) 12 BY ATTY. BEDARD: 13 Q. Dr. Ettner, did you speak with anyone about this 14 deposition during our break? 15 A. No. 16 Q. And did you review any documents or materials 17 related to this case during your break? 18 A. No. 19 Q. So in your expert report, you mentioned that you 20 met with the plaintiff, C.P., and his parents on March 19th, 21 right? 22 A. Via Zoom. 23 Q. Via Zoom. 24 Were C.P.'s parents present throughout the course 25 of that meeting?

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Page 42 1 A. No. 2 Q. What portion of that meeting were they present for? 3 A. The final portion. 4 Q. And in addition to C.P.'s parents, was anyone else 5 present during any portion of that interview? 6 A. No. 7 Q. And how long was that meeting via Zoom? 8 A. The entire meeting? 9 Q. Yes. 10 A. Probably a couple of hours. 11 Q. When you say "a couple of hours," do you mean 12 between two and three hours? 13 A. No, I mean two. 14 Q. Two -- 15 A. It was -- 16 Q. -- it was two hours? 17 A. -- closer to two. 18 Q. Okay. 19 And did you review C.P.'s medical and mental health 20 records prior to conducting that interview? 21 A. Yes. 22 Q. Did you speak with anyone about your interview with 23 C.P. after the interview? 24 A. No. 25 Q. Would you consider -- Dr. Ettner, would you	Page 44 1 gender dysphoria, but I myself was not the person who made 2 that diagnosis. 3 Q. And how did you confirm C.P.'s diagnosis of gender 4 dysphoria during your interview? 5 A. It was obvious. C.P. was -- had met and exceeded 6 all of the criteria, and was living and had been living for 7 years in his affirmed gender and not the gender he was 8 assigned at birth. 9 Q. Can you confirm a diagnosis of gender dysphoria 10 without doing any psychological testing? 11 A. Psychological testing cannot confirm a diagnosis of 12 gender dysphoria. 13 Q. So what would then be the purpose of the 14 psychological testing you referred to? 15 ATTY. GONZALEZ-PAGAN: Objection; form. 16 THE WITNESS: Well, I think you -- I asked -- 17 I answered a question about a clinical interview in the 18 broadest terms and said that it might include 19 psychodiagnostic testing, but not in the case of confirming 20 a diagnosis of gender dysphoria. 21 Q. (By Atty. Bedard) Is it your understanding that 22 Dr. Kevin Hatfield was the one to initially diagnose C.P. 23 with gender dysphoria? 24 A. Yes. 25 Q. And that was around the age of 10, right?
Page 43 1 consider your conversation with C.P. to be a clinical 2 interview? 3 A. What are you characterizing -- how are you 4 characterizing a clinical interview? 5 Q. Well, how would you describe a clinical interview? 6 What does a clinical interview mean to you? 7 A. It depends on the purpose of the interview. So it 8 can involve psychological testing. It typically involves 9 observation and interview questioning and a narrative by the 10 client. 11 Q. What do you mean by "narrative by the client"? 12 A. Well, the client discusses their life with the 13 interviewer, with the clinician. 14 Q. I see. Did you perform any psychological testing 15 of C.P.? 16 A. No. 17 Q. And did you provide any diagnoses for C.P.? 18 A. By "provide," do you mean did I make any 19 determination of a diagnosis or did I actually have a 20 written diagnosis that I submitted to someone? 21 Q. Broadly speaking, so not necessarily focused on 22 whether it was submitted to someone else, but did you 23 diagnose C.P. with any condition during the course of your 24 interview? 25 A. The interview confirmed to me C.P.'s diagnosis of	Page 45 1 A. That's my understanding. 2 Q. And in your report, Dr. Ettner, you mentioned that 3 Dr. Hatner [sic] diagnosed -- let me pull up the specific 4 number. 5 Dr. Hatner diagnosed C.P. at Stage Tanner 2 plus. 6 What is Tanner 2 plus? 7 A. I'm sorry. Dr. Hatner? 8 Q. Dr. Hatfield. So let me rephrase my question. 9 You indicated in your report that Dr. Hatfield 10 diagnosed C.P. at a stage of Tanner 2 plus. 11 What is Tanner 2 plus? 12 A. Well, Tanner 2 is one of the stages of development 13 that human beings will evolve through as they go through 14 puberty. I'm not an endocrinologist, so I'm not able to 15 actually opine on what constitutes the different stages of 16 Tanner 2, including Tanner 2. 17 Q. To the best of your knowledge, is there a 18 distinction between Tanner 2 and Tanner 2 plus? 19 A. I believe there is, but again, that would be a 20 distinction that a medical doctor would make. 21 Q. So is the information in your report indicating 22 that C.P. was at Stage Tanner 2 plus, is that based on 23 information you found in Hatfield's records? 24 A. It would be on information I found somewhere in the 25 medical records. I would not have been able to make that

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Page 46 1 determination myself. 2 Q. So, Dr. Ettner, I'm going to show you some of 3 C.P.'s medical records. 4 Dr. Ettner, I'm showing you what has been marked as 5 Defendant's Exhibit 10. I'm going to scroll up to the top 6 of the exhibit. 7 Have you seen these medical records before? 8 (Defendant's Exhibit 10 marked.) 9 THE WITNESS: I believe so. If you'll scroll 10 down further, I can confirm that. 11 Q. (By Atty. Bedard) Absolutely. 12 A. Can you continue to scroll, please. Could you stop 13 momentarily. Yes, I've seen these records. 14 Q. Okay. On the third page of C.P.'s medical records 15 here in Exhibit 10, these are progress notes from Dr. Kevin 16 Hatfield, right? 17 A. Yes. 18 Q. Okay. And in those progress notes, he's indicated 19 phenotypic Tanner Staging 2, right? 20 A. Yes. 21 Q. So based on Hatfield's records, C.P. presented at 22 Tanner Stage 2, not Tanner Stage 2 plus, right? 23 A. That's what it appears. 24 Q. So I'm just trying to understand the basis in your 25 report for indicating that C.P. was at stage Tanner --	Page 48 1 A. Yes. 2 Q. And is it your understanding that C.P. first 3 started testosterone or hormone treatment around that same 4 age? 5 ATTY. GONZALEZ-PAGAN: Objection; form. 6 THE WITNESS: What are you referring to when 7 you say "hormone treatment"? 8 Q. (By Atty. Bedard) Thank you for clarifying. 9 So is it your understanding that C.P. started 10 testosterone cream around the age of 10 or 11? 11 A. Sometime after the Histrelin implant, he received a 12 small dose of the cream. 13 Q. And the Histrelin implant is the Vantas implant, 14 right? 15 A. Yes. 16 Q. And then at some point in time, C.P. switched to 17 testosterone injections, right? 18 A. He was switched, yes. 19 Q. And then C.P. underwent a mastectomy in 2019, 20 right? 21 A. Chest reconstruction surgery, yes -- 22 Q. That's right. 23 A. -- in 2019. 24 Q. Thank you. And that was at age 14? 25 A. Yes.
Page 47 1 Tanner 2 Plus? 2 A. Either I read that somewhere or perhaps it was 3 mentioned to me during the interview. 4 Q. By C.P.? 5 A. Or his parents. 6 Q. Or his parents. 7 Is it your understanding, Dr. Ettner, that C.P. 8 received two Vantas implants throughout the course of his 9 treatment? 10 A. I -- yes, he received the Vantas implants. 11 Q. What is a Vantas implant? 12 A. It's a GNRH, a gonadotropin-releasing hormone 13 analog that is implanted under the skin. 14 Q. Is that a surgical procedure? 15 A. No, it is not necessarily a surgical procedure. It 16 doesn't have to be performed by a surgeon. It can be 17 performed by a dermatologist, not the -- not that procedure, 18 but an implant under the skin -- not the Vantas, but an 19 implant under the skin does not require a surgeon to perform 20 that procedure. 21 Q. But it can be performed by a surgeon? 22 A. It could be. It could be performed by other 23 doctors as well. 24 Q. And is it your understanding that C.P. first 25 received a Vantas implant around the age of 10?	Page 49 1 Q. Dr. Ettner, in your expert report, you refer to 2 C.P. as experiencing early onset gender dysphoria. 3 What would you describe as "early onset gender 4 dysphoria"? 5 A. I would describe that as a child who experiences an 6 incongruity in his or her assigned sex that is experienced, 7 not expressed and begins to actually behave or live in 8 accordance with their affirmed gender identity prior to ever 9 knowing that there is a name for the condition they're 10 experiencing, that there are medical treatments. 11 So it's an individual who very early on shows a -- 12 shows a marked discomfort with the sex assigned at birth. 13 Q. And in your report, Dr. Ettner, you stated that -- 14 and I'm quoting: "Individuals like C.P. diagnosed with 15 early onset gender dysphoria that persists into adolescence 16 typically suffer the most severe expression of the 17 condition," end quote. 18 What is the basis for your statement that 19 individuals with early onset gender dysphoria typically 20 suffer the most severe expression of the condition? 21 A. Clinical experience, and I believe that there is 22 literature that documents that when children state that they 23 are a particular gender as opposed to just saying that they 24 wish they were or they sometimes feel like they were or 25 later experiencing gender dysphoria, they are more likely to

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Page 50 1 have an intractable case of gender dysphoria or persistence. 2 ATTY. BEDARD: Omar, we're receiving a fair 3 amount of feedback on your end while Dr. Ettner is speaking. 4 I think it may be inadvertent. If you could try to -- 5 ATTY. GONZALEZ-PAGAN: I apologize. I had a 6 screen issue. It should be resolved. It literally turned 7 off on me. Sorry. 8 ATTY. BEDARD: Not a problem. Thank you. 9 Q. (By Atty. Bedard) Okay. And you mentioned a 10 second ago, Dr. Ettner, that there is literature supporting 11 the idea that individuals diagnosed with early onset gender 12 dysphoria typically suffer the most severe expression. 13 What literature were you referring to? 14 A. Well, there is -- in our literature, there's a 15 article called "Tomboys Revisited," which talks about 16 retrospective analysis of children who were assigned female 17 at birth, and the trajectory and how those children showed 18 early-on a preference that the children who ultimately came 19 out as lesbians did not show. 20 So they did not persist in their tomboy behavior; 21 whereas, those who had early onset did. And clinically, in 22 my experience and in my colleagues' experience, we've seen 23 that some people, what used to be referred to as primary 24 transsexualism -- and I realize that is an outdated term -- 25 are individuals who never even attempted to live in their	Page 52 1 A. Anything is possible. 2 Q. Dr. Ettner, you indicated that the treatment C.P. 3 received has been appropriate and medically necessary. 4 Is your opinion as to the medical necessity of 5 C.P.'s treatment limited to the mental health treatment that 6 he received? 7 A. No. 8 Q. And what is the basis for your assessment that the 9 surgery C.P. received is medically necessary? 10 A. There's two bases for making that opinion: The 11 first was C.P.'s extreme discomfort with breast buds he 12 began to develop at puberty or as he approached puberty and 13 the discomfort of exposing his chest during swimming and the 14 fear that the breasts would enlarging -- enlarge. And that 15 is one of the criteria for actually administering GNRH 16 analogs, according to standards of care, which is a 17 worsening of distress as puberty approaches or during 18 puberty. 19 Secondly, we know that transmen who have breast 20 development tend to bind their breasts in order to live 21 safely in their affirmed gender because a man with breasts 22 can be a target of victimization, violence, et cetera. And 23 chest-breast binding results in the potential for a number 24 of sometimes serious physical sequelae. 25 Q. Dr. Ettner, in your report -- I'm going to pull up
Page 51 1 assigned gender. 2 So, for example, I had a case of a woman whose own 3 siblings never knew that that person had been assigned male 4 at birth because that person had only ever lived as a 5 female. So it's an extraordinarily longstanding experience 6 of gender dysphoria and those cases do tend to be more 7 persistent and more severe. 8 Q. But it is -- it is possible for gender dysphoria to 9 decrease as one ages, right? 10 A. In adults, gender dysphoria increases with age. 11 Q. And -- 12 A. Cortisol -- 13 Q. Go ahead. 14 A. Cortisol increases with the normal aging, DHEA 15 decreases and that causes a disruption similar to what a -- 16 an analogy might be a cisgender woman who goes through 17 menopause. So as normal aging increases, Cortisol increases 18 and that causes a disruption which may accelerate gender 19 dysphoria. And so we see that individuals who have gender 20 dysphoria, it may intensify at midlife, 40 or 50 years of 21 age. People who often thought they were just cross-dressers 22 or didn't have a severe case of gender dysphoria may 23 experience an intensification and typically do. 24 Q. Is it possible for gender dysphoria to decrease as 25 a person ages?	Page 53 1 the exact language here. 2 In Paragraph 25 of your report, you stated that a 3 growing -- and I quote: "A growing assemblage of research 4 documents that gender identity is immutable and biologically 5 based." 6 Would you agree, Dr. Ettner, that you cannot -- you 7 cannot image a brain to determine an individual's gender 8 identity, right? 9 A. I don't know that I fully agree with that. 10 Q. Why is that? 11 A. Because functional magnetic resonance imaging has 12 displayed four different phenotypes in human brains: 13 Cisgender male, cisgender female, transgender male and 14 transgender female. And I've personally seen that in Madrid 15 when working with a colleague who uses functional magnetic 16 resonance imaging and has published widely on this topic. 17 Q. Is this a topic you published on yourself? 18 A. I published with Antonio Guillaumon and he presented 19 these findings -- well, he presents them around the world, 20 but he presented them at the National Institutes of Health. 21 He was an invited guest to present this. 22 Q. What was the name of that publication? 23 A. What publication? 24 Q. Oh, I'm sorry. I must have misunderstand. I 25 thought you said there was a publication that you released

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Page 54 1 with him. 2 A. We wrote a -- 3 Q. It was a publication? 4 A. We wrote a chapter in a book together on the 5 neurobiological origins of gender dysphoria, and that is in 6 a book called Principles of Transgender Medicine and 7 Surgery. 8 Q. And you referred to four different phenotypes that 9 you said could be used to determine or examine an 10 individual's gender identity; is that right? 11 A. What I said is that there are four different 12 phenotypes that show differences, primarily in the right 13 hemisphere of the brain, in cisgender men, cisgender women, 14 transgender men and transgender women. 15 There's also differences that have been documented 16 in white and gray matter in the brain, in the cortex, the 17 seat of behavior; subcortical structures and in bundles 18 of -- in the microstructure of bundles that connect various 19 regions of the brain. 20 Q. Are there any laboratory tests that could be used 21 to determine an individual's gender identity? 22 A. No. 23 Q. Is there any -- is there any genetic testing that 24 could be used to determine an individual's gender identity? 25 A. There's no genetic testing that's available.	Page 56 1 Q. (By Atty. Bedard) Yes. 2 A. That's an examination of a gland, or what? 3 Q. Let me break down the question. 4 Are there any changes in hormone level that could 5 be examined by physical testing? 6 Could you test someone's hormone level to determine 7 their gender identity? 8 A. Before -- 9 ATTY. GONZALEZ-PAGAN: Object to the form. 10 THE WITNESS: Did you object? I can't hear 11 you, Omar. 12 ATTY. BEDARD: We can't hear you, Omar. 13 ATTY. GONZALEZ-PAGAN: I don't know what's 14 going on. Sorry. I said objection; form. 15 You may answer, Dr. Ettner. 16 ATTY. BEDARD: That's much better. 17 THE WITNESS: Your question doesn't tell me 18 whether or not the person has taken cross-sex hormones or 19 not. 20 Q. (By Atty. Bedard) Okay. So then let me -- let me 21 ask it a different way. 22 Prior to taking any cross-sex hormones, could 23 testing of a hormone level help determine whether or not 24 someone -- help determine an individual's gender identity? 25 A. No.
Page 55 1 Q. Is there any biopsies that could be done to 2 determine an individual's gender identity? 3 A. It's possible that a postmortem autopsy of a brain 4 might reveal that in an individual. Those studies were done 5 in 2000 by Zo [phonetic], et al. 6 Q. Are there any physical changes to a hormone level 7 or to a gland structure that could be examined to determine 8 an individual's gender identity? 9 A. Not -- 10 ATTY. GONZALEZ-PAGAN: (Inaudible.) 11 THE WITNESS: Would you repeat that question, 12 please? 13 THE COURT REPORTER: Omar, did you object? 14 ATTY. GONZALEZ-PAGAN: Yes. 15 THE COURT REPORTER: It came through really 16 quiet. 17 ATTY. GONZALEZ-PAGAN: I'll speak louder. 18 Objection; form. 19 ATTY. BEDARD: Court reporter, could you 20 please read back my question. 21 THE COURT REPORTER: Yes. 22 (Record read by the reporter.) 23 ATTY. GONZALEZ-PAGAN: Same objection. 24 THE WITNESS: Is that the question you want 25 me to answer?	Page 57 1 Q. Dr. Ettner, in your report -- in Paragraph 21 of 2 your report, which -- let me go ahead and pull that up so 3 that we're looking at the same thing. 4 Can you see Paragraph 21? 5 A. Yes. 6 Q. In Paragraph 21 of your report, you state that: "A 7 number of factors go into the determination of a person's 8 sex," and then you go on to list some of those factors, 9 right? 10 A. Yes. 11 Q. And at the end of that list of factors that go into 12 the determination of a person's sex, you list gender 13 identity; is that right? 14 A. Yes. 15 Q. Dr. Ettner, sex chromosomes are not something that 16 can change, right? 17 A. Correct. 18 Q. And sex glands are not something that can change, 19 right? 20 A. I don't know what "sex glands" means. 21 Q. An ovary cannot turn into a testicle and vice 22 versa, right? 23 A. After birth, an ovary cannot turn into a testicle. 24 Q. The same would be true for vice versa? 25 A. Correct.

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Page 58 1 Q. And along the same lines, there's no way for a 2 testicle to produce eggs or for an ovary to produce sperm, 3 right? 4 A. That's correct. 5 Q. So a person's biological sex cannot be changed, 6 right? 7 ATTY. GONZALEZ-PAGAN: Objection; form. 8 THE WITNESS: I would object to the term 9 "biological sex." I would say that a person's reproductive 10 organs cannot be changed and their chromosomes cannot be 11 changed. 12 Q. (By Atty. Bedard) Can the provision of 13 transgender-related services -- can transgender-related 14 services have an impact on fertility? 15 A. Yes. Uh-uh. 16 THE COURT REPORTER: Omar, did you say 17 something? 18 THE WITNESS: Did you object, Omar? I can't 19 hear you. 20 ATTY. GONZALEZ-PAGAN: On that one, I just -- 21 you went too fast for me and I wasn't able to lodge it in, 22 but I would have -- I would have objected on form. I just 23 need you to give me that pause, Dr. Ettner, particularly 24 given the IT issues. 25 THE WITNESS: Okay. If you could speak a	Page 60 1 young to reproduce. 2 Q. And someone who is assigned female at birth who's 3 at Tanner Stage 2 who begins taking puberty blockers, is 4 that person fertile or infertile? 5 ATTY. GONZALEZ-PAGAN: Object to the form. 6 THE WITNESS: I'm not a pediatric 7 endocrinologist and I don't know at what -- at what level a 8 given individual is. I cannot answer a question that's 9 outside of my area of expertise. 10 Q. (By Atty. Bedard) Dr. Ettner, would you agree that 11 a mental health assessment by a qualified professional is a 12 necessary safeguard before any gender-affirming care? 13 ATTY. GONZALEZ-PAGAN: Object to form. 14 THE WITNESS: Not necessarily. No. 15 Q. (By Atty. Bedard) Why not? 16 A. I don't know what interventions you're talking 17 about. I would say that a mental health assessment is 18 required prior to an irrevocable surgical procedure. 19 Q. And what would you consider to be an irrevocable 20 surgical procedure? 21 A. Any procedure that alters the body. 22 Q. Would you consider testosterone injections to be an 23 irrevocable procedure? 24 A. No. 25 Q. And why is that?
Page 59 1 little louder, Omar, because I can't -- 2 ATTY. BEDARD: It's still really difficult to 3 hear you. 4 ATTY. GONZALEZ-PAGAN: I'm sorry. I don't 5 know what's going on with my computer. I'll work through it 6 as much as I can. 7 ATTY. BEDARD: That's fine. 8 THE WITNESS: I'll try to wait a bit just in 9 case you object. 10 ATTY. GONZALEZ-PAGAN: Thank you. Thank you. 11 ATTY. BEDARD: Madam Court Reporter, can you 12 read back the last question, please. 13 (Record read by the reporter.) 14 ATTY. GONZALEZ-PAGAN: Objection; form. 15 Did your hear me or...? 16 THE WITNESS: The -- my -- I heard you, yes, 17 your objection. 18 My answer is some procedures can possibly effect 19 fertility. 20 Q. (By Atty. Bedard) Okay. So let's break that down 21 a bit. 22 Is a person who is assigned female at birth who is 23 at Tanner Stage 2, are they -- would they be fertile or 24 would they be infertile? 25 A. At stanner -- at Tanner Stage 2, they are still too	Page 61 1 A. Because some, not all, of the results of 2 testosterone injections are not permanent if the injections 3 are stopped. Some will be permanent, such as deepening of 4 the voice. 5 Q. So for testosterone injections specifically, what 6 effects would be irrevocable? 7 A. Deepening of the voice is an irrevocable 8 procedure -- is an irrevocable result of testosterone 9 injectable treatment. Depending on length of time that an 10 individual is exposed to testosterone, they may have other 11 effects that are more or less reversible, but that, again, 12 would be on a case-by-case basis, so, for instance, some 13 balding. Other effects will be reversible if they stop the 14 testosterone treatment. 15 Q. Is it possible for testosterone treatment to have 16 an irreversible effect on fertility? 17 A. It's possible, and that's why individuals need to 18 be counseled about fertility and harvesting of eggs and 19 other means of reproduction prior to undergoing any kind of 20 hormonal treatment. 21 Q. Dr. Ettner, are you -- you previously mentioned 22 you're familiar with The Endocrine Society, right? 23 A. Yes. 24 Q. And are you familiar with The Endocrine Society's 25 2017 guidelines?

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Page 62 1 A. I'm aware of those guidelines; I don't know how 2 familiar I am with them. I can't recite them chapter and 3 verse. 4 Q. Well, let me go ahead and pull them up to use as a 5 reference point. 6 Dr. Ettner, I'm going to show you what has been 7 marked as Defendant's Exhibit 5. 8 (Defendant's Exhibit 5 marked.) 9 Q. (By Atty. Bedard) Can you see that document? 10 A. Yes. 11 Q. Would you like me to scroll down so you can 12 familiarize yourself with it or are you already familiar 13 with it? 14 A. Well, all I see at this point are the names of some 15 of my colleagues and their university affiliations. 16 Q. I just want to make sure we're on the same page 17 about what this document is. Are you -- 18 A. Yes. 19 Q. -- comfortable with the fact this is the 2017 20 guidelines? 21 A. Yes. 22 Q. Okay. Great. 23 Dr. Ettner, on Page 8 do you see the paragraph that 24 begins with, "Because of the psychological vulnerability"? 25 A. Yes.	Page 64 1 disruptive or other -- what we call externalizing behaviors 2 or even a child who has internalizing behaviors would 3 require very careful and experienced and usually a 4 multidisciplinary assessment. 5 Q. If a child has depression, for example, would you 6 agree with the 2017 guidelines that a mental health 7 professional with training or experience in child and 8 adolescent gender development should make the diagnosis? 9 ATTY. GONZALEZ-PAGAN: Objection; form. 10 THE WITNESS: If the diagnosis is in order to 11 provide medical services, then a mental health provider 12 should make the assessment. 13 Q. (By Atty. Bedard) Dr. Ettner, based on your review 14 of C.P.'s medical records, did C.P. see a mental health 15 professional with training and experience in child and 16 adolescent gender development before receiving a diagnosis 17 of gender dysphoria? 18 A. He saw an experienced family practice doctor who 19 probably had more experience than most mental health 20 professionals in diagnosing gender dysphoria. 21 Q. Are you referring to Dr. Hatfield? 22 A. I am, yes. 23 Q. And would you consider Dr. Hatfield to be a mental 24 health professional? 25 A. No.
Page 63 1 Q. Could you read that paragraph for me? 2 A. Yes. "Because of the psychological vulnerability 3 of many individuals with GD, slash, gender incongruence, 4 it's important that mental health care is available before, 5 during and sometimes also after transitioning. For children 6 and adolescents, an MHP who has training/experience in child 7 and adolescent gender development, as well as child and 8 adolescent psychopathology, should make the diagnosis 9 because assessing GD/gender incongruence in children and 10 adolescents is often extremely complex." 11 Q. Dr. Ettner, do you agree with that statement? 12 A. I agree that assessing GD in children and 13 adolescents is often extremely complex, yes. 14 Q. Would you agree that a mental health professional 15 with training or experience in child and adolescent gender 16 development should make the diagnosis? 17 A. In complex cases, absolutely. 18 Q. So help me understand the distinction you're 19 drawing there. 20 What would you consider to be a complex case versus 21 a noncomplex case? 22 A. Child who has brain damage. A child who has 23 developmental delays. A child who has Asperger's or is on 24 the spectrum. A child who has -- is intellectually 25 challenged. A child who has some sort of behavioral,	Page 65 1 Q. So C.P. did not see a mental health professional 2 prior to being diagnosed with gender dysphoria, right? 3 A. Correct. 4 Q. Are you aware from your review of medical records 5 or your conversation with C.P. whether C.P. fulfilled the 6 DSM-5 diagnostic criteria for gender dysphoria? 7 A. In my view, he did fulfill the criteria. 8 Q. Okay. And what is your opinion on that based on? 9 A. It's based on the criteria and my interview of 10 C.P., his social transition that he made prior to beginning 11 any medical treatments; the corroboration of his parents, 12 the statements that Dr. Hatfield made and that Ms. Booker 13 made about his longstanding gender dysphoria, his discomfort 14 with his assigned sex, his unwillingness to participate in 15 female activities, et cetera. 16 His desire to have a masculine-appearing body and 17 to live congruently with his affirmed gender even before he 18 was aware that there was a name for that or that there were 19 treatments for that. So he effectively transitioned prior 20 to ever having been diagnosed by anyone. 21 Q. And C.P. did not see a mental health professional 22 prior to starting puberty blockers, right? 23 A. Correct. 24 Q. And C.P. did not see a mental health professional 25 prior to starting testosterone treatment, right?

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Page 66 1 A. Not as far as I'm aware of, no. Although he may 2 have been participating in group therapy at the Gender 3 Spectrum Conferences, I believe, that he attended with his 4 family. 5 Q. Are you surprised that C.P. did not receive any 6 mental health care from a qualified mental health 7 professional prior to undergoing testosterone treatments or 8 a puberty blocker? 9 A. No. 10 ATTY. BEDARD: We've been going for about 11 another hour, so why don't we take a quick break. Mental 12 math here. Let's come back at 1:25, if that works for 13 everyone. 14 THE VIDEOGRAPHER: The time is 11:16 a.m. We 15 are off the record. 16 (Recess taken from 11:16 to 11:28 a.m.) 17 THE VIDEOGRAPHER: Time is 11:28 a.m. We are 18 back on the record. 19 20 E X A M I N A T I O N - (Continuing) 21 BY ATTY. BEDARD: 22 Q. Dr. Ettner, did you speak with anyone about this 23 case during your break? 24 A. No. 25 Q. And did you review any documents relating to this	Page 68 1 Q. And is that something that you discussed with C.P. 2 and his parents? 3 A. I'm not understanding the question. 4 Q. Did you ask C.P. and his parents during the course 5 of your interview with them in March of this year whether 6 C.P. had been diagnosed with any mental health issues? 7 A. As part of every interview, I would ask someone if 8 they've taken psychotropic medication, if they've ever been 9 diagnosed with any psychiatric issues, if they've ever 10 attempted suicide, if they've ever been hospitalized for a 11 psychiatric issue. Those are standard questions that we ask 12 during an interview. 13 Q. Dr. Ettner, are you aware that Ms. Booker indicated 14 that C.P. presented with or exhibited symptoms of 15 depression? 16 A. No. 17 Q. So I'm going to pull up Exhibit 8. I'm sharing 18 what's been marked as Exhibit 8. 19 (Defendant's Exhibit 8 marked.) 20 Q. (By Atty. Bedard) Have you seen these records 21 before today? 22 A. Can you scroll down, please? 23 Q. Sure. 24 A. Could you continue to scroll, please? 25 Q. Sure.
Page 67 1 case during your break? 2 A. No. 3 Q. Prior to your testimony today, Dr. Ettner, did you 4 review the records from Sharon Booker and the Center for 5 Child and Family Therapy? 6 A. Yes. 7 Q. And Ms. Booker is not a clinical psychologist or 8 psychiatrist, right? 9 A. Correct. 10 Q. And Ms. Booker had two sessions with C.P. and then 11 wrote C.P. a letter of recommendation for top surgery, 12 right? 13 A. Yes. 14 Q. Did you review any records showing that Ms. Booker 15 conducted any follow-up assessments with C.P. after that 16 surgery? 17 A. No. 18 Q. Did you review any records showing that C.P. -- 19 that Ms. Booker ever met with C.P. after the surgery? 20 A. No. 21 Q. Dr. Ettner, in your report in Paragraph 80, you 22 indicated that C.P. has never been diagnosed with any mental 23 health issue; is that accurate to the best of your 24 knowledge? 25 A. Yes.	Page 69 1 A. And further. I'm only seeing just the information 2 about the client and not actual records. 3 Q. Okay. 4 A. Yes, I have seen these records before. 5 Q. Okay. And on Page 6 of the records from the Center 6 for Child and Family Therapy, do you see where depression 7 has been checked as a presenting problem or symptom for 8 C.P.? 9 A. Yes. 10 Q. And is C.P.'s -- is the fact that C.P. had 11 presented with or exhibited symptoms of depression something 12 that you discussed in your assessment with C.P.? 13 A. No. Are you referring to this particular document 14 in regards to my discussion with C.P.? 15 Q. Well, you reviewed these medical records prior to 16 meeting with C.P., right? 17 A. Yes. 18 Q. And so my question is: Based on your review of 19 C.P.'s medical records, which indicate that he had presented 20 with or had showed symptoms of depression, my question is 21 whether you discussed that presenting problem or symptom 22 with C.P.? 23 ATTY. GONZALEZ-PAGAN: Objection; form. 24 THE WITNESS: Based on the totality of the 25 medical records that I reviewed, including Ms. Booker's

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Page 70 1 report and particularly the reports by Dr. Garza and Tutty, 2 who did extensive psychological testing and found no 3 evidence of any mood disorder, any depression, any anxiety, 4 nothing that reached clinical significance or even close to 5 the 60 T level cutoff, I presumed that the depression that 6 this was indicating was attendant to the young man's gender 7 dysphoria and would be remediated with the top surgery. 8 Q. (By Atty. Bedard) Did you conduct an assessment of 9 C.P. to determine whether the depression indicated in his 10 medical records was, in fact, attendant to his diagnosis of 11 gender dysphoria? 12 A. C.P. was not aware of what was in this particular 13 medical record, I don't believe, so we didn't speak about 14 this record, per se. He did, however, describe his 15 discomfort with his breasts, his wish that he had started 16 treatment earlier so that he wouldn't have had to undergo 17 top surgery and his overall certainty that his assigned sex 18 was not suitable for him and that he really and 19 authentically believed himself to be male. 20 Q. Dr. Ettner, you said just a second ago that you 21 presumed that the depression was attendant to his diagnosis 22 of gender dysphoria. 23 Did you conduct an assessment to determine whether 24 the depression was, in fact, attendant to C.P.'s diagnosis 25 of gender dysphoria?	Page 72 1 A. Yes. 2 Q. On Page 3 of this document -- one second. 3 On Page 3 of this assessment, C.P. is quoted as 4 having said, "Sometimes I will be angry for no reason. At 5 home, it's more of a problem than anywhere else," end quote. 6 Is that something that you discussed with C.P.? 7 A. No. I don't recall discussing that particular 8 statement. 9 Q. Did you -- do you recall discussing with C.P. any 10 sort of manifestation of anger or agitation as described in 11 this psychological evaluation? 12 A. C.P. did not describe any anger or irritability 13 during our conversation or mention that. This was the only 14 indication of that that I saw or heard throughout my review 15 of records and interview with him. 16 Q. But you reviewed that psychological evaluation 17 prior to meeting with C.P., right? 18 A. Correct. 19 Q. And did you discuss that psychological evaluation 20 with C.P.? 21 A. No. 22 Q. Dr. Ettner, if you are evaluating a patient for a 23 mood disorder, what does that evaluation typically look 24 like? 25 A. It depends on the patient, their age and the
Page 71 1 ATTY. GONZALEZ-PAGAN: Object to the form. 2 THE WITNESS: Well, I did do an assessment of 3 C.P. during that interview, as stated previously, when I 4 reviewed with him his prior psychiatric treatments for which 5 there were none; his suicidal attempts, cutting attempts, 6 which were none; and a review of the major systems, his 7 affect and thought processes, which I describe in the 8 interview, and the contribution of his parents to my -- to 9 inform my opinion that he did not suffer from a separate 10 distinct mood disorder that would meet the criteria of 11 either dysthymia or depression according to the DSM-5. 12 Q. (By Atty. Bedard) You referred a minute ago to a 13 assessment by a Dr. Tutty. 14 Are you referring to a psychological evaluation of 15 C.P. that was done in I think October of 2021? 16 A. Yes. 17 Q. Okay. Let me pull that up. 18 Dr. Ettner, I am showing you what has been marked 19 as Defendant's Exhibit 9. 20 (Defendant's Exhibit 9 marked.) 21 Q. (By Atty. Bedard) Are you familiar with this 22 document? 23 A. Yes. 24 Q. And this is something that was provided to you by 25 plaintiffs' counsel?	Page 73 1 context for which I'm doing the evaluation. 2 Q. I know this is probably different in the post-COVID 3 era, but would you typically do that assessment in person 4 pre-COVID? 5 A. Always pre-COVID, always. 6 Q. By necessity now, it's done via Zoom or do you 7 still try to do those in person? 8 A. I've done some carceral interviews in person. 9 Q. Dr. Ettner, in Paragraph 75 of your report, you 10 indicated that, "There is no evidence of any mood disorders 11 for C.P." 12 Did you conduct an assessment of C.P. for mood 13 disorders? 14 A. No, but Dr. Tutty did. If you'd scroll down on 15 that document you showed me, you'll see that he conducted 16 the Beck Youth Inventory and that none of the T scores on 17 mood disorders were in the range of clinical concern or 18 clinical significance. 19 The highest score, I believe, was a 56, which does 20 not meet the threshold and so he concludes that he does not 21 have any mood disorders. And the only concern clinically is 22 inattention for which he prescribes some remedies that 23 should be implemented in a step-wise way, ultimately even 24 possibly requiring medication if necessary, but mostly 25 around limiting distractibility and allowing for more extra

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Page 74 1 time. 2 Q. So the statement in your report that there is no 3 evidence of any mood disorders is based solely on a previous 4 psychological evaluation of C.P. by Dr. Tutty, right? 5 ATTY. GONZALEZ-PAGAN: Objection; form. 6 THE WITNESS: Well, it's based on 7 psychodiagnostic testing with valid construct content 8 validity and test -- retest reliability in that instrument. 9 So that test was given fairly close in terms of test-retest 10 reliability. 11 And again, in order to have a mood disorder, there 12 would have to be -- the criteria would have to be met, 13 not -- and they were not met. According to the DSM-5, of 14 any mood disorder, there were no symptoms of that that 15 approach diagnostic significance. There's -- and 16 Dr. Eduardo Garza describes in more than one notation that 17 there is no -- there are no indications of any mood 18 disorders; that this young man has friends, is well 19 adjusted, active in sports, does well in school and there's 20 no evidence of any maladjustment. 21 Q. (By Atty. Bedard) But just to clarify: You did 22 not independently conduct an assessment of any mood 23 disorders, right? 24 ATTY. GONZALEZ-PAGAN: Objection; form. 25 THE WITNESS: I conducted an assessment which	Page 76 1 given this is a partially irreversible treatment, we 2 recommend initiating treatment using a gradually increasing 3 dose schedule after a multidisciplinary team of medical and 4 NHPs has confirmed the persistence of GD/gender incongruence 5 and sufficient mental capacity to give informed consent, 6 which most adults" -- "which most adolescents have by age 16 7 years." 8 Q. Dr. Ettner, would you agree with that statement? 9 A. In general, yes. 10 Q. And based on your review of the medical records, do 11 you know whether Dr. Hatfield included a multidisciplinary 12 team of medical professionals and mental health personnel, 13 as the guidelines state, to confirm sufficient mental 14 capacity to give informed consent? 15 A. I didn't see an indication that he consulted a 16 multidisciplinary team. I did, however, see that he had 17 extensive experience and had worked with C.P. over a number 18 of years. I also saw from Dr. Tutty's report that C.P. had 19 exemplary executive functioning which would, in fact, make 20 him competent to understand informed consent. 21 Q. But Dr. Tutty's report is from October of 2021, 22 right? 23 A. Yes. 24 Q. And C.P. received hormone treatment beginning at 25 age 11, right?
Page 75 1 looks for mood disorders. I did not do psychological 2 testing and I wasn't a counselor of C.P. I didn't -- I 3 interviewed him on one occasion, but on that one occasion -- 4 in fact, clinicians are always looking for mood disorders 5 and we're very apt to find them when they exist because all 6 of our training is in determining mood disorders and seeing 7 if affect matches content and whether an individual has any 8 indication or shows any evidence or history of a mood 9 disorder. In this case, there was none. 10 Q. (By Atty. Bedard) Dr. Ettner, I am going to show 11 you, again, Exhibit 5, which are the 2017 Endocrine Society 12 guidelines. 13 Can you see my screen on Exhibit 5? 14 A. Yes. 15 Q. And these are the 2017 Endocrine Society 16 guidelines, right? 17 A. Correct. 18 Q. Okay. And there is a section of those guidelines 19 referring to the treatment of adolescents, right? 20 A. Yes. 21 Q. Okay. And, Dr. Ettner, do you see Paragraphs 2.4 22 and 2.5? 23 A. Yes. 24 Q. Could you read Paragraph 2.4, please. 25 A. "In adolescents who request sex hormone treatment,	Page 77 1 A. Yes. Well, he received blockers, yes. 2 Q. Okay. So he received blockers beginning at age 10 3 or 11; is that right? 4 A. Yes. 5 Q. And that's several years prior to when Dr. Tutty 6 did his psychological evaluation in October of 2021, right? 7 A. Yes. 8 Q. Was C.P. 16 at the time of providing any informed 9 consent for testosterone treatment? 10 A. He was not 16, no. 11 Q. Was C.P. 16 at the time of providing any informed 12 consent for the mastectomy surgery? 13 A. He was not -- 14 ATTY. GONZALEZ-PAGAN: Objection; form. 15 THE WITNESS: He was not 16. 16 Q. (By Atty. Bedard) Should an informed consent for 17 that type of surgery, for a top or keyhole surgery, contain 18 a warning that the patient would lose the ability to 19 breast-feed? 20 A. Informed consent is a process, not merely a 21 signature on a piece of paper, and it should provide 22 individuals and guardians with all of the possible 23 complications and ramifications of any procedure and it 24 should be done over a period of time by the provider who is 25 providing that particular treatment. So it should happen on

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Page 78 1 more than one occasion, depending on what is the step-wise 2 provision of these interventions. 3 Q. And that informed consent process you're describing 4 should include a warning about the impact on the ability to 5 breast-feed, right? 6 A. Yes. 7 Q. And have you seen anything in C.P.'s medical 8 records indicating that C.P. was provided a warning 9 regarding the impact on the ability to breast-feed? 10 A. I saw a statement that they were provided with the 11 implications of the procedures and that they understood -- 12 he and his parents understood the implications of receiving 13 medical and hormonal interventions and surgery. 14 Q. Did the statement you're discussing, did it 15 specifically address the impact on the ability to 16 breast-feed? 17 A. No, but I wouldn't presume that I would see that in 18 a -- in a medical notation, that a doctor would list every 19 possible complication in the notes. I think I would see 20 something just saying that fertility and informed consent 21 and the risks and benefits of the procedure had been 22 discussed. 23 Q. Did C.P. -- when C.P. underwent the top or keyhole 24 procedure at the age of 14, did C.P. have the capacity to 25 consent to that procedure?	Page 80 1 Madam Court Reporter, can you read it back? 2 (Record read by the reporter.) 3 ATTY. GONZALEZ-PAGAN: Same objection. 4 THE WITNESS: That's a hypothetical. I would 5 make a distinction between ideation and suicidal attempts. 6 Q. (By Atty. Bedard) Okay. Thank you for clarifying. 7 Could you answer the question for both categories 8 then, for both suicidal ideations and for suicide attempts? 9 A. Well, suicidal ideation is something that can be 10 transient and something that an individual would have to 11 express and that would depend on the individual, so that I 12 can't make a -- that's a hypothetical I can't comment on 13 because oftentimes, people will say, If I can't get this, 14 I'm going to kill myself, and we don't know if -- we can't 15 take that out of context. 16 A suicide attempt, however, is something that needs 17 to be taken very seriously whether it's a minor or an adult 18 or a geriatric patient. 19 Q. Would you agree that puberty-blocking medication 20 has not been FDA approved for suicide prevention? 21 ATTY. GONZALEZ-PAGAN: Objection; form. 22 Foundation. 23 Q. (By Atty. Bedard) Let me ask the question more 24 broadly. 25 Would you agree that transgender-related services
Page 79 1 A. In my opinion? 2 ATTY. GONZALEZ-PAGAN: Object to form. 3 Go, answer. 4 THE WITNESS: In my opinion, yes. 5 Q. (By Atty. Bedard) Dr. Ettner, I want to circle 6 back to something you mentioned earlier on in your testimony 7 today. 8 Your report discusses the harms resulting from the 9 denial of transgender-related care, right? 10 A. Yes. 11 Q. And one of the harms discussed in your report is 12 suicidality, correct? 13 A. Yes. 14 Q. Specifically in Paragraph 66 of your report, you 15 state that: "Denying gender-affirming care not only 16 frustrates those treatment goals, but exacerbates gender 17 dysphoria and its associated depression and suicidality." 18 Would you agree that any individual, and 19 particularly any minor, who is experiencing suicidal 20 ideations or has attempted suicide should receive immediate 21 and appropriate psychiatric care? 22 ATTY. GONZALEZ-PAGAN: Objection; form. 23 THE WITNESS: Would you repeat the question, 24 please? 25 ATTY. BEDARD: Sure.	Page 81 1 are not an approved treatment for suicidal ideations? 2 ATTY. GONZALEZ-PAGAN: Objection; form. 3 THE WITNESS: I don't understand what you 4 mean by "approved." I would say that every major medical 5 association, including the World Health Organization, the 6 American Psychiatric Association, the American Psychological 7 Association, WPATH, the American Academy of Child and 8 Psychiatric -- and Psychiatry, the American Academy of 9 Pediatrics, all agree that gender-affirming care is -- can 10 be lifesaving. That's not to say that it is a treatment for 11 suicide. I don't know that there is an FDA-approved 12 treatment for suicide qua suicide. 13 Q. Dr. Ettner, are you familiar with the Center for 14 Medicare and Medicaid Services' decision memo on gender 15 dysphoria and gender reassignment surgery? 16 A. I'm aware of it, yes. 17 Q. And have you reviewed it? 18 A. Not recently. 19 Q. Have you ever reviewed it? 20 A. I've seen it, yes. 21 Q. And is that report or decision memo something that 22 you took into consideration in preparing your own report? 23 A. No, because that was a national determination 24 report. And ultimately, like all of medicine, decisions 25 about patient care need to be made on a case-by-case basis.

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Page 82 1 Q. But your report in this case is not based solely on 2 C.P., correct? That there are statements in your report, in 3 other words, that are broader than just the individual 4 treatment that C.P. received? 5 ATTY. GONZALEZ-PAGAN: Objection. 6 THE WITNESS: Yes. 7 ATTY. GONZALEZ-PAGAN: Form. 8 Q. (By Atty. Bedard) You can answer. 9 A. Yes. 10 Q. So did you include the CMS decision memo in the 11 considerations you made in preparing your report for this 12 case on the whole? 13 A. No, because that decision refers to a population, 14 the Medicare population, and there have not been 15 peer-reviewed studies on that population and so that is not 16 something that I considered in this report. 17 I did, however, consider the May 30, 2014, Medicare 18 decision when creating my report. 19 Q. So why did you consider the May 30, 2014, Medicare 20 decision in creating your report if, as you say, that was 21 focused on a -- let me back up. 22 Why did you consider the May 30, 2014, Medicare 23 report? 24 A. Because that was about an exclusion, not a national 25 determination.	Page 84 1 assessment? 2 A. All of -- 3 ATTY. GONZALEZ-PAGAN: Objection; form. 4 THE WITNESS: -- medicine -- all of medicine 5 is done on a case-by-case basis. If a patient is being 6 treated for diabetes, for example, they may not receive the 7 same treatment as another individual who is being treated 8 for diabetes. So all of medicine is based, best 9 practice-wise, on a case-by-case basis. 10 Q. (By Atty. Bedard) I'm going to show you a section 11 of that 2016 CMS decision memo, which is Exhibit 11. 12 Can you see Exhibit 11? 13 A. Yes. 14 (Defendant's Exhibit 11 marked.) 15 Q. (By Atty. Bedard) And are you familiar with this 16 document? 17 A. Yes, although I haven't seen it in a long time. 18 I've seen it previously. 19 Q. There's a section of this decision memo referring 20 to the quality of the studies reviewed, right? 21 A. Yes. 22 Q. In the second paragraph under that section, it 23 states that -- well, first, the decision memo states that 24 the authors for that CMS as a whole reviewed 33 studies, 25 right?
Page 83 1 Q. And what is the distinction between the two? 2 A. Well, the exclusion is relevant in this matter 3 because in 2014, gender-affirming surgery was found to be 4 safe, effective, therapeutic and nonexperimental, and, 5 therefore, should not be excluded. Those studies are still 6 relevant and, in fact, additional and more recent studies 7 have confirmed that. 8 Q. But the 2016 decision memo by CMS -- both reports, 9 I understand, were by CMS. 10 The 2016 decision memo states that CMS was 11 declining to issue a national coverage determination on 12 gender reassignment surgery because the clinical evidence 13 was inconclusive, right? 14 A. Yes. 15 ATTY. GONZALEZ-PAGAN: Objection; form. 16 THE WITNESS: Yes. And, therefore, it should 17 be determined on a case-by-case basis because it's referring 18 to a group of people who are over 65 and more likely to have 19 comorbid medical complications, for example. There is no 20 peer-reviewed literature on that particular population nor 21 is there a national determination for most medical 22 conditions. 23 Q. (By Atty. Bedard) So as a result of those 24 limitations, an assessment would need to be done on a 25 case-by-case basis, right? It would be an individualized	Page 85 1 A. Yes. 2 Q. And in that same paragraph, the decision memo 3 indicates that, "The four best-designed and conducted 4 studies that assessed quality of life before and after 5 surgery, using validated, albeit nonspecific psychometric 6 studies, did not demonstrate clinically significant changes 7 or differences in psychometric test results after GRS." 8 Do you see that? 9 A. Yes. 10 Q. And are you familiar with the four studies cited 11 there: The Heylens study, the Ruppin study, the Smith study 12 and the Udeze study? 13 A. I'm familiar with the Pfafflin study, Smith, et 14 al., those studies. 15 Q. You're familiar with two of the four studies 16 referenced? 17 A. Correct. 18 Q. And those two studies were not specific to the 19 Medicare population, right? 20 A. Correct. 21 Q. And would you agree that those studies did not 22 demonstrate clinically significant changes or differences in 23 psychometric test results before and after surgery? 24 A. I would have to look at those studies. I don't 25 believe Pfafflin used psychometric measures or in -- he did

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Page 86 1 a meta-analysis of studies, so I would have to review those 2 studies and the methodology. 3 Q. As of this moment, you're not aware of whether or 4 not that statement is accurate? 5 A. I don't have an opinion about the accuracy of that 6 statement without being familiar with two of those four 7 studies and reviewing Smith and Pfafflin, who I know were 8 cited in the original Medicare study. 9 Q. When you refer to the original Medicare study -- 10 A. The 2014 study. 11 Q. Understood. Thank you. 12 You're referring to the May 30, 2014, study you 13 referred to a minute -- a minute ago? 14 A. Yes. 15 Q. Okay. Of the two studies that you are familiar 16 with -- the Smith, et al., and the Pfafflin -- am I saying 17 that right, Pfafflin? 18 A. Yes, Pfafflin. 19 Q. Of the two studies you are familiar with, Smith, et 20 al., and Pfafflin, did you consider either of those studies 21 in preparing your report for this case? 22 A. I did not specifically consider those studies. I 23 may have cited those papers in my bibliography or in my 24 report as demonstrating a positive outcome for surgical 25 intervention.	Page 88 1 that there was not sufficient evidence, that the science was 2 unsettled. 3 Q. And again, just to clarify, you have seen and have 4 reviewed the translation of that recommendation? 5 A. I saw the translation. I didn't carefully review 6 it. 7 Q. And what is your response to that recommendation by 8 COHERE Finland? 9 A. My response is that there is evidence that 10 providing gender-affirming care is, in fact, therapeutic in 11 most cases when there is a basis for that provision for 12 people who really have a medical necessity for that care. 13 And the -- my response is informed by the American 14 Academy of Pediatrics, which has stated that no country in 15 Europe has banned providing care entirely and that it will 16 be done in a clinical -- as part of a clinical trial as it 17 is in Sweden. 18 Q. I think this is -- COHERE Finland is in Finland, 19 right? 20 A. Right. 21 Q. Okay. So you're referring to the limitations 22 placed on the treatment of gender dysphoria in Finland? 23 A. Yes, that they're not offering the treatment to 24 minors -- 25 Q. They're not offering the treatment --
Page 87 1 Q. Dr. Ettner, are you familiar with Council for 2 Choices in Health Care in Finland, which is known as COHERE 3 Finland? 4 A. I'm aware of that, yes. 5 Q. And have you ever reviewed any of -- 6 Well, first off, what is COHERE Finland? 7 A. I don't know exactly what it is. I've just seen 8 their -- the statement that they put out, which was recently 9 translated in English. 10 Q. And have you reviewed that statement? 11 A. I've seen that statement, yes. I haven't reviewed 12 it prior to this deposition. 13 Q. And that statement adopts a recommendation on 14 treatment methods for gender dysphoria for minors in 15 particular, right? 16 A. Yes. 17 Q. And what is your understanding of COHERE Finland's 18 assessment or recommendation? 19 A. My understanding is that they will not offer 20 treatment to minors except in -- in very few certain cases. 21 Q. And what is your understanding of why that 22 recommendation was made by COHERE Finland? 23 A. My understanding -- and this was not a 24 peer-reviewed publication; it was a publication that was 25 just put out as a synopsis of a position or policy -- was	Page 89 1 A. -- I think -- except in exceptional cases. 2 Q. And do you reference COHERE Finland's 3 recommendation in your report? 4 A. No. 5 Q. Why not? 6 A. Because it's not a peer-reviewed report of the 7 literature. It's the policy of a particular government 8 position. 9 Q. Did you -- 10 A. It's not -- 11 Q. Go ahead. 12 A. It's not the position in the United States. 13 Q. Did you only cite to peer-reviewed reports or 14 articles in your report? 15 A. No, but I didn't consider a recently translated 16 document from Finland that wasn't peer reviewed in my 17 report. 18 Q. Dr. Ettner, you mentioned Sweden a few minutes ago 19 when we were talking about the COHERE Finland 20 recommendation. 21 Are you familiar with the Swedish at Astrid 22 Lindgren Children's Hospital? 23 A. I'm familiar with, again, the statement that they 24 put out about the position they will be taking in the 25 treatment of minors with gender dysphoria.

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Page 90 1 Q. And what is the position that the Swedish Astrid 2 Lindgren Children's Hospital has taken? 3 A. That that hospital will not be treating minors, 4 offering the treatment. 5 Q. Do you know what treatment they're referring to? 6 A. I believe they're referring to puberty-blocking 7 treatments. 8 Q. Does that include hormone treatments as well? 9 A. Prior to the age of majority. 10 Q. So the position taken by Sweden's Child and 11 Adolescent Gender Clinic is to not provide puberty blockers 12 or hormone treatment under the age of 18; is that right? 13 ATTY. GONZALEZ-PAGAN: Objection; 14 mischaracterizes the document that we're talking -- 15 testimony and what we're talking about. 16 ATTY. BEDARD: I'm sorry. What was the 17 objection? 18 ATTY. GONZALEZ-PAGAN: It mischaracterizes 19 the testimony. The reference has always been to Astrid 20 Lindgren Children's Hospital, not a Swedish -- not a broad 21 Swedish gender clinic. 22 Q. (By Atty. Bedard) Dr. Ettner, to clarify, is it 23 your understanding that there is a gender clinic at Swedish 24 Astrid Lindgren Children's Hospital? 25 A. Can you show me the document that you're referring	Page 92 1 Q. Okay. And on -- in the second paragraph of this 2 document, it states that, "In December 2019, that SBU" -- 3 which is the Swedish Agency for Health Technology Assessment 4 and Assessment of Social Services -- "published an overview 5 of the knowledge base which showed a lack of evidence for 6 both the long-term consequences of the treatments and the 7 reasons for the large influx of patients in recent years." 8 Do you see that? 9 A. Yes -- wait. Yes. I do see that. 10 Q. Okay. And then, the statement goes on to say that, 11 "In October of 2020, the National Institute For Health and 12 Care Excellence in the UK also performed an evidence review 13 of GnRHA (puberty blocker) and cross-sex hormone treatments 14 in children and adolescents..." Right? 15 A. Yes. 16 Q. Are you familiar with both of those studies 17 referred to in this paragraph? 18 A. I'm not familiar with the studies. I'm familiar 19 with the conclusion of the study of these -- these statement 20 I'm familiar with, not the underlying -- I would have to see 21 the underlying studies. 22 Q. But you're familiar with the conclusions reached in 23 the studies referenced in Exhibit 13? 24 A. I don't see studies referenced. In other words, I 25 don't see researchers and dates of studies. I just see the
Page 91 1 to? 2 Q. I'm actually not referring to a document. I'm 3 asking, generally speaking, about the statement or the 4 position taken by Swedish Astrid Lindgren Children's 5 Hospital that you're referring to a minute ago. 6 A. I would need to see the document to see the precise 7 language that they use. My understanding is that they are 8 limiting treatment, but I would like to see that exact 9 statement, if you can provide it to me, and then I can 10 comment more fully. 11 Q. Dr. Ettner, I'm going to show you what has been 12 marked as Defendant's Exhibit 13. 13 (Defendant's Exhibit 13 marked.) 14 Q. (By Atty. Bedard) Can you see this document? 15 A. Yes. 16 Q. And is this the statement you were previously 17 referring to? 18 A. I think it's the statement you were referring to 19 that I was commenting on. 20 Q. Well, a minute ago, Dr. Ettner, you were describing 21 the position taken by Astrid Lindgren Children's Hospital? 22 A. Yes. 23 Q. And what is your understanding of the position 24 taken by Astrid Lindgren Children's Hospital based on? 25 A. It's based on this document that you're showing me.	Page 93 1 conclusion that says the studies conducted are of 2 low-quality evidence. 3 Q. So specifically, the conclusion reached is that -- 4 and I'm quoting from the statement -- "They are small, 5 uncontrolled observational studies providing low-quality 6 evidence that the treatments have the desired effect and 7 that we have very little knowledge about their safety in the 8 long-term," end quote. 9 What is your response to that statement? 10 A. My response to that statement is that one out of 10 11 medical treatments have low-quality evidence, including 12 aspirin and vitamin D. 13 Q. And what about the concern raised in this statement 14 regarding the lack of knowledge about the safety of -- 15 A. No, wait. I said that wrong. Only one out of 10 16 have high-quality evidence, meaning nine out of 10 medical 17 treatments have low-quality evidence. More evidence is 18 desired and needed. But many of our most widely implemented 19 treatments -- some studies say one out of 10, some studies 20 say only one out of 20 is there high-quality evidence for. 21 Q. So like the other examples you provided, like nine 22 out of 10 of other categories, would you agree that more 23 evidence is desired and needed to better understand the 24 long-term effects of transgender-related treatments? 25 A. I think that more research is always desirable,

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Page 94 1 particularly long-term research. There's some long-term 2 research, but there needs to be more and I think funding 3 that research is probably a limitation in why there isn't 4 more. 5 Q. Dr. Ettner, are you -- are you aware of who 6 Dr. Hilary Cass is? 7 A. Yes. In general, I'm aware of who she is. 8 Q. Are you aware that she was appointed by NHS in the 9 UK to chair a review of gender identity services for 10 children and adolescents? 11 A. Yes. 12 Q. And what is your -- well, are you aware that she 13 released an interim report earlier this year? 14 A. Yes. 15 Q. And what is your understanding of the interim 16 conclusions reached in that report? 17 A. My understanding -- and I'm not looking at that 18 report now, but my understanding is she is suggesting more 19 regional facilities and multidisciplinary treatment for 20 young people. And in that sense, again, according to the 21 American Academy of Pediatrics, she's moving closer to our 22 model in the United States in that interim report. 23 Q. Have you reviewed that interim report? 24 A. I saw the interim report on the Internet briefly. 25 Q. There's a lot of information on the Internet, isn't	Page 96 1 evidence showing that gender-affirming care, when 2 appropriate, is -- contributes to the well-being and can be 3 life saving for individuals. And I believe that not 4 providing care is not a neutral option, that there can be 5 negative sequelae to not providing care when it is required. 6 Q. Do you reference the -- this interim report in your 7 report in this case? 8 A. No. 9 Q. And why not? 10 A. Because it doesn't align with my opinions about the 11 literature, the research and my own 30 years or plus of 12 experience. 13 Q. Did you only include references to literature with 14 which you agree in your expert report? 15 A. I included references to literature that was peer 16 reviewed and methodologically sound, not -- 17 Q. But -- 18 A. -- necessarily literature that I re- -- that I 19 agree with or don't agree with. But I did see in that 20 interim report her conviction that children deserve good and 21 adequate care, and what that looks like, she has yet to 22 determine, but that multiregional centers and 23 multidisciplinary teams would be preferable to what was 24 available in the UK, was my understanding of that interim 25 report. And she did add that -- her belief that the science
Page 95 1 there? 2 A. Yes. 3 Q. Let me -- let me show that report to you. I'm 4 showing you what has been marked as Defendant's Exhibit 14. 5 (Defendant's Exhibit 14 marked.) 6 Q. (By Atty. Bedard) Can you see that report? 7 A. Yes. 8 Q. Let me try to -- is that better? 9 A. I can see it. 10 Q. Okay. So in her interim report released earlier 11 this year, on Page 18 of that report, it states, and I 12 quote, "Evidence on the appropriate management of children 13 and young people with gender incongruence and dysphoria is 14 inconclusive both nationally and internationally," end 15 quote. 16 Do you see that statement? 17 A. Yes. 18 Q. And what is your response to that statement? 19 A. I don't really have a response to that statement. 20 That's her view of the evidence. 21 Q. Would you agree that evidence on the appropriate 22 management of children and young people with gender 23 incongruence and dysphoria is inconclusive both nationally 24 and internationally? 25 A. I believe that there is an overwhelming amount of	Page 97 1 was unsettled. 2 Q. We have been going, Dr. Ettner, for, I think, 3 another hour, so why don't we take a short break. 4 Would it work for you if we came back at 2:35? 5 A. Yes. 6 THE VIDEOGRAPHER: Okay. The time is 7 12:29 p.m. We are off the record. 8 (Recess taken from 12:29 to 12:38 p.m.) 9 THE VIDEOGRAPHER: The time is 12:38 p.m. We 10 are back on the record. 11 12 EXAMINATION - (Continuing) 13 BY ATTY. BEDARD: 14 Q. Dr. Ettner, did you review any documents during our 15 most recent break? 16 A. No. 17 Q. And did you speak with or message anyone during our 18 most recent break? 19 A. No. 20 Q. Dr. Ettner, I have no further questions. I 21 appreciate your time today. 22 A. I appreciate all the breaks. Thank you. 23 THE COURT REPORTER: Omar, do you have 24 questions? 25 ATTY. GONZALEZ-PAGAN: I do. I was going

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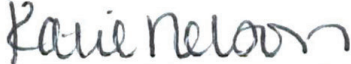
Page 98 1 to -- I was planning on using maybe one exhibit. 2 Should I send that to you via e-mail now? 3 THE COURT REPORTER: Or you could drop it in 4 the chat. 5 ATTY. GONZALEZ-PAGAN: I'll do that. 6 I dropped it in the chat. Let me know if that 7 went through. 8 I'm not using it yet, Dr. Ettner, so you don't 9 need to open it. 10 THE WITNESS: Okay. 11 12 E X A M I N A T I O N 13 BY ATTY. GONZALEZ-PAGAN: 14 Q. All right. Dr. Ettner, you were asked some 15 questions by counsel for defendant regarding a Cass review. 16 Do you recall that? 17 A. Yes. 18 Q. I'm going to show you what's been marked as 19 Defendant's Exhibit 14. 20 I think I'm sharing it but -- okay. Dr. Ettner, do 21 you see the second paragraph in here, in the letter from 22 Dr. Hilary Cass introducing the report? 23 A. I see it. I'd prefer it if it was larger, but I 24 can. I do see it. Thank you. 25 Q. Is that better?	Page 100 1 of inquiry are being pursued, and where there are unanswered 2 questions, that will be addressed more fully during the life 3 of the review. A formal literature review is one strand of 4 the review's commissioned work and this will be reported in 5 full when complete." 6 Did I read that correctly? 7 A. Yes. 8 Q. Does that mean that the literature review by 9 Dr. Cass is as of now still ongoing? 10 A. That's how I would interpret that, yes. 11 Q. I'm moving on to Page 63 of Exhibit 14 by 12 defendants. 13 Do you see the paragraph numbered 5.20? 14 A. Yes. 15 Q. It states, "It should also be recognized that doing 16 nothing cannot be considered a neutral act." 17 Did I read that correctly? 18 A. Yes. 19 Q. Is that consistent with your opinions here today? 20 A. It is. 21 Q. Moving on to Paragraph 5.22, do you see that, in 22 the report? 23 A. I do. 24 Q. Okay. It says, "It is still common that drugs are 25 not specifically licensed for children because the trials
Page 99 1 A. Yes. 2 Q. Okay. Can you read the first three sentences which 3 I have highlighted with my cursor? 4 A. Are you asking me to read them out loud? 5 Q. Yes, please. 6 A. "I have heard that young service users are 7 particularly worried that I will suggest that services 8 should be reduced or stopped. I want to assure you that 9 this is absolutely not the case. The reverse is true. I 10 think that more services are needed for you closer to where 11 you live." 12 Q. And this is consistent with your testimony that 13 Dr. Hilary Cass' review has recommended the availability of 14 more services, not less, with regards to the provision of 15 medical treatment for gender dysphoria; is that right? 16 A. Yes. 17 Q. You were asked some questions about the Cass review 18 assessment of the literature. Do you recall that? 19 A. I do. 20 Q. Okay. I'm going to read this paragraph in -- the 21 following paragraph which is part of the description of what 22 this report is. 23 "It is important to note that the references cited 24 in this report do not constitute a comprehensive literature 25 review and are included only to clarify why specific lines	Page 101 1 have only taken place on adults. This does not preclude 2 their use or make their use inherently unsafe particularly 3 if they are used very commonly in children." 4 Did I read that correctly? 5 A. Yes. 6 Q. Is that consistent with your opinion? 7 A. Yes. 8 Q. I'm going to stop sharing. 9 You were also asked some questions about 10 Exhibit 13, a two-page statement regarding Astrid Lindgren 11 Children's Hospital in Sweden. 12 Do you recall that? 13 A. I do. 14 Q. I'm going to show you the second page. I'm going 15 to share the screen of Defendant's Exhibit 13. 16 The second bullet point states, "The hormonal 17 treatment will only be allowed to take place in a clinical 18 trial setting that receive ethical approval by the EPM 19 (Ethical Review Agency/Swedish Institutional Review Board)." 20 Did I read that correctly? 21 A. Yes. 22 Q. Does this mean that they're not providing any 23 gender-affirming care adolescents in Sweden or that -- or 24 does it mean that they are providing such care in a clinical 25 trial setting?

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Page 102 1 ATTY. BEDARD: Object to form. 2 THE WITNESS: It means that care will only be 3 provided in a clinical setting, but it will be provided. 4 Q. (By Atty. Gonzalez-Pagan) Thank you, Dr. Ettner. 5 Earlier you were asked some questions about whether 6 C.P. had received -- had been assessed by a mental health 7 professional prior to initiating hormones and puberty 8 blockers. 9 Do you recall that line of questioning? 10 A. Yes. 11 Q. You also testified that Dr. Hatfield is not a 12 mental health care -- mental health professional. 13 Do you recall that line of testimony? 14 A. I do. 15 Q. Can family physicians be providers of mental health 16 care? 17 A. They can. 18 Q. And in your opinion, is Dr. Hatfield well qualified 19 in position to conduct an assessment of an adolescent's 20 gender dysphoria? 21 A. Yes. He's very well qualified to do that in my 22 opinion. 23 Q. And I've been -- I'm going to show you what's been 24 marked -- well, let me ask you this: Are you familiar with 25 the American Academy of Family Physicians?	Page 104 1 And, Omar, I would ask that if you're going to ask 2 a witness about an exhibit that she has not seen before, can 3 you show the witness the entirety of the exhibit, please? 4 ATTY. GONZALEZ-PAGAN: What's good for the 5 goose is good for the gander. Sure. I'll ask the same 6 moving forward. 7 Q. (By Atty. Gonzalez-Pagan) I'm going to show you 8 the exhibit again, Dr. Ettner. The first page is blank; 9 that just happens to be how the PDF came out. I'm showing 10 you -- I'm going to zoom out a little bit. 11 It's a position paper. We established that you're 12 familiar with the American Academy of Family Physicians; is 13 that correct? 14 A. Yes. 15 Q. Let me know if you want me to scroll slower or 16 faster or if you want to read this. 17 Dr. Ettner, do you wish to review the exhibit 18 further? 19 A. I'm sorry. Would you repeat that? 20 Q. Do you wish to review the exhibit further? 21 A. No. Thank you. 22 Q. And I had asked you if you agreed with the 23 statement that, "Family physicians are well equipped to 24 provide mental health services and that they are one of the 25 primary sources of mental health care in the United States."
Page 103 1 A. Yes. 2 Q. And you actually reference the American Academy of 3 Family Physicians in your report; is that right? 4 A. Yes. 5 Q. I'm going to show you what's been marked as 6 Plaintiff's Exhibit 1. You can hold on one moment. 7 (Plaintiff's Exhibit 1 marked.) 8 Q. (By Atty. Gonzalez-Pagan) This is a position paper 9 by the American Academy of Family Physicians; is that 10 correct? 11 A. Yes. 12 Q. Have you ever seen this document before? 13 A. I have not. 14 Q. And it is titled, "Mental Health Care Services by 15 Family Physicians"; is that right? 16 A. Yes. 17 Q. I'm going to read the second sentence: "Family 18 physicians are well equipped to provide mental health 19 services and are one of the primary sources for mental 20 health care in the United" -- "in the US." 21 Did I read that correctly? 22 A. Yes. 23 Q. Is that your understanding as well? 24 A. Yes. 25 ATTY. BEDARD: Object to the form.	Page 105 1 Do you agree with that? 2 A. Yes. 3 Q. And you were asked some questions about The 4 Endocrine Society guidelines recommendations. 5 Do you recall that? 6 A. I do. 7 Q. Okay. And those are recommendations; is that 8 correct? 9 A. Yes. They're guidelines. 10 Q. And just to -- I know you answered this in -- in 11 part, but do you believe that Dr. Hatfield is qualified -- 12 sufficiently qualified to make an assessment as to whether 13 an adolescent has gender dysphoria? 14 A. Yes. 15 ATTY. BEDARD: Object to form. 16 Q. (By Atty. Gonzalez-Pagan) And what is the basis of 17 your opinion? 18 A. I reviewed his experience from the medical paper, 19 the medical records provided to me. I had heard of him by 20 reputation. And also, I work with a family physician 21 and when I was part of the gender team at Weiss Memorial 22 Hospital, and they play a very important role. 23 They're often the first people to diagnose gender 24 dysphoria and they work with the families. They see the 25 family over a period of time, and so they're -- they provide

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Page 106 1 a lot of counseling and a lot of mental health. 2 And I'd also like to add that my husband is a 3 family physician. Probably 90 percent of what he does is 4 mental health work. 5 ATTY. GONZALEZ-PAGAN: Thank you, Dr. Ettner. 6 I don't have any further questions. 7 8 FURTHER EXAMINATION 9 BY ATTY. BEDARD: 10 Q. Dr. Ettner, I just have a few quick questions about 11 the exhibit that plaintiffs recently showed to you, so I'm 12 going to put that back up on the screen now, Plaintiff's 13 Exhibit 1. 14 Can you see that document? 15 A. Yes. 16 Q. I know that you had not seen this document before 17 today, but based on your understanding of this document, is 18 this document related to the provision of gender-affirming 19 care or to the treatment of gender dysphoria specifically? 20 A. No, not specifically, as far as what I've seen. 21 And I skimmed the last part that ATTY. Pagan-Gonzalez showed 22 me, but I didn't see any mention specifically of gender 23 dysphoria. 24 Q. Thank you, Dr. Ettner. 25 ATTY. BEDARD: No further questions.	Page 108 1 REPORTER'S CERTIFICATE 2 3 I, KATIE J. NELSON, the undersigned Certified Court 4 Reporter, pursuant to RCW 5.28.010 authorized to administer 5 oaths and affirmations in and for the State of Washington, 6 do hereby certify that the sworn testimony and/or 7 proceedings, a transcript of which is attached, was given 8 before me at the time and place stated therein; that any 9 and/or all witness(es) were duly sworn to testify to the 10 truth; that the sworn testimony and/or proceedings were by 11 me stenographically recorded and transcribed under my 12 supervision, to the best of my ability; that the foregoing 13 transcript contains a full, true, and accurate record of all 14 the sworn testimony and/or proceedings given and occurring 15 at the time and place stated in the transcript; that a 16 review of which was requested; that I am in no way related 17 to any party to the matter, nor to any counsel, nor do I 18 have any financial interest in the event of the cause. 19 WITNESS MY HAND and SIGNATURE this 26th day of 20 August, 2022. 21  22 23 KATIE J. NELSON, RPR, CCR 24 Washington Certified Court Reporter, CCR 2971 25
Page 107 1 THE VIDEOGRAPHER: Should we go off the 2 record and conclude the deposition? 3 ATTY. BEDARD: Yes. 4 THE VIDEOGRAPHER: The time is 12:53 p.m. 5 Pacific Standard Time. This concludes the deposition of 6 Randi C. Ettner. We are off the record. 7 8 (Signature was reserved.) 9 (Deposition concluded at 12:53 p.m.) 10 11 12 13 14 15 16 17 18 19 20 21 22 23 24 25	Page 109 1 Nelson Court Reporters, Inc. 2 6513 132nd Avenue NE, #184 3 Kirkland, Washington 98033 4 production@nelsonreporters.com 5 www.nelsonreporters.com 6 August 26, 2022 7 To: OMAR GONZALEZ-PAGAN 8 LAMBDA LEGAL DEFENSE AND EDUCATION FUND, INC. 9 120 Wall Street, 19th Floor 10 New York, New York 10005-3919 11 ogonzalez-pagan@lambdalegal.org 12 13 Re: C.P., et al. V. Blue Cross Blue Shield of Illinois 14 Deposition of: RANDI C. ETTNER, Ph.D. 15 Date Taken: August 24, 2022 16 Cause No.: 3:20-cv-06145-RJB 17 18 Enclosed are the Correction & Signature page. 19 Instruct the deponent to review the deposition, record any 20 corrections on the Correction page, and sign it. 21 The above referenced transcript must be read and 22 the Correction & Signature page signed within 30 days of 23 this notice or before the trial date, whichever occurs 24 first. 25 If the Correction & Signature page are not signed within that time period, signature will be deemed waived for all purposes. After the Correction & Signature page are signed, please forward to: Nelson Court Reporters Production Department production@nelsonreporters.com Thank you, Katie J. Nelson, RPR, CCR CCR No. 2971

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1 CORRECTION & SIGNATURE PAGE

2 Re: C.P., et al. V. Blue Cross Blue Shield of Illinois
Deposition of: RANDI C. ETTNER, Ph.D.

3 Date Taken: August 24, 2022

4 Cause No.: 3:20-cv-06145-RJB

5 I, RANDI C. ETTNER, Ph.D., have read the within
transcript taken August 24, 2022, and the same is true and
accurate, except for any changes and/or corrections, if
6 any, as follows:

7	PAGE/LINE	CORRECTION	REASON
8			
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21 Signed at _____,
22 on this date: _____.23 _____
24 RANDI C. ETTNER, Ph.D.
25

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EXHIBIT D

The Honorable Robert J. Bryan

**IN THE UNITED STATES DISTRICT COURT
FOR THE WESTERN DISTRICT OF WASHINGTON
AT TACOMA**

C. P., by and through his parents, Patricia
Pritchard and Nolle Pritchard; and PATRICIA
PRITCHARD,

Plaintiffs,

v.

BLUE CROSS BLUE SHIELD OF ILLINOIS,

Defendant.

No. 3:20-cv-06145-RJB

EXPERT REPORT OF LOREN S. SCHECHTER, M.D.

I, Loren S. Schechter, M.D., hereby declare and state as follows:

1. I have been retained by counsel for Plaintiffs as an expert in connection with the above-captioned litigation.

2. I have actual knowledge of the matters stated herein. If called to testify in this matter, I would testify truthfully and based on my expert opinion.

I. PRELIMINARY STATEMENT

3. I am a board-certified plastic surgeon. I specialize in performing gender confirming surgeries (including chest reconstruction surgeries, genital reconstruction surgeries, and other

1 procedures to feminize or masculinize the face and body, as described in more detail below), and I
2 am a recognized expert in this field.

3 4. I have been retained by counsel for Plaintiffs in the above-captioned lawsuit to
4 provide an expert opinion on: 1) the standards of care for treating individuals diagnosed with
5 gender dysphoria; 2) the safety, efficacy, and cost of gender confirming surgeries as treatment for
6 gender dysphoria; 3) the similarities between surgical techniques to treat gender dysphoria with
7 those utilized for surgical treatment of other diagnoses; and 4) whether categorical exclusions of
8 transition-related surgical care administered by Blue Cross Blue Shield of Illinois are consistent
9 with the standards of care for treating transgender individuals diagnosed with gender dysphoria.
10

11 5. I refer to the family of procedures discussed in this report as “gender confirmation,”
12 “gender confirming surgeries,” or “gender affirming surgeries” because they are one of the
13 therapeutic tools used to enable people to be comfortable living in accordance with their gender
14 identities. Out of the myriad of labels I have heard for these procedures—“sex reassignment
15 surgery,” “gender reassignment surgery,” and “sex change operation,” to name but a few—none
16 is as accurate when it comes to describing what is actually taking place as “gender confirmation”
17 or “gender affirmation surgery.” Most, if not all, of the other names used for these procedures
18 suggest that a person is making a choice to switch genders, or that there is a single “surgery”
19 involved. From the hundreds of discussions I have had with patients over the years, nothing could
20 be further from the truth. This is not about choice; it is about using one or more surgical procedures
21 as therapeutic tools to enable people to live authentically.
22

23 **II. BACKGROUND AND QUALIFICATIONS**

24 **A. Qualifications**

25 6. The information provided regarding my professional background, experiences,
26

1 publications, and presentations are detailed in my curriculum vitae (“CV”). A true and correct
2 copy of my most up-to-date CV is attached as **Exhibit A**.

3 7. I received my medical degree from the University of Chicago, Pritzker School of
4 Medicine. I completed my residency and chief residency in plastic and reconstructive surgery and
5 a fellowship in reconstructive microsurgery at the University of Chicago Hospitals.

6 8. I previously served as a Clinical Professor of Surgery at the University of Illinois
7 at Chicago, and resigned that position to become the Director of Gender Affirmation Surgery at
8 Rush University Medical Center beginning April 2022. I will also serve as Professor of Surgery
9 at Rush University Medical Center (pending academic review). I also maintain a clinical practice
10 in plastic surgery in Illinois where I treat patients from around the country, as well as from around
11 the world.
12

13 9. I have been performing gender confirming surgeries for more than 27 years. For
14 at least the past five years, I have been performing approximately 150 gender confirmation
15 procedures every year. I have performed over 1,500 gender confirmation surgeries during my
16 medical career. Currently, approximately 90 percent of the patients in my clinical practice are
17 transgender individuals seeking gender confirmation surgeries.
18

19 10. I was a contributing author to the Seventh Version (current) of the World
20 Professional Association for Transgender Health’s (“WPATH”) Standards of Care for the Health
21 of Transsexual, Transgender, and Gender-Nonconforming People (“Standards of Care”). In
22 particular, I wrote the section focused on the relationship of the surgeon with the treating mental
23 health professional and the physician prescribing hormone therapy. WPATH is in the final stages
24 of drafting the eighth version of the Standards of Care, and I am the co-lead author of the surgical
25 and postoperative care chapter.
26

1 11. The Standards of Care provide clinical guidance for health professionals based on
2 the best available science and expert professional consensus. The purpose of the Standards of Care
3 is to assist health providers in delivering medical care to transgender people in order to provide
4 them with safe and effective pathways to achieving lasting personal comfort with their gendered
5 selves and to maximize their overall health, psychological well-being, and self-fulfillment.

6 12. In addition, I have written a number of peer-reviewed journal articles and chapters
7 in professional textbooks about gender confirmation surgeries. In 2016, I published *Surgical*
8 *Management of the Transgender Patient*, the first surgical atlas (a reference guide for surgeons on
9 how to perform surgical procedures using safe, well-established techniques) dedicated to gender
10 confirming surgeries. In 2020, I published a guide for surgeons entitled *Gender Confirmation*
11 *Surgery: Principles and Techniques for an Emerging Field*. A full and complete list of my
12 publications is included in my CV.

13 13. I am a guest reviewer for several peer-reviewed medical journals, including the
14 Journal of Plastic and Reconstructive Surgery, the Journal of Reconstructive Microsurgery, the
15 Journal of the American College of Plastic Surgeons, the Journal of Plastic and Reconstructive
16 Surgery, the Journal of Plastic and Aesthetic Research, and the Journal of Sexual Medicine. I also
17 serve on the editorial board of both Transgender Health and the International Journal of
18 Transgender Health. Each of these publications is a peer-reviewed medical journal. A full and
19 complete list of my reviewerships and editorial roles is included in my CV.

20 14. I am actively involved in training other surgeons to perform gender confirmation
21 surgeries. In 2017, I started the surgical fellowship in gender surgery, now placed at Rush
22 University Medical Center in Chicago. I am also the Medical Director of the Center for Gender
23 Confirmation Surgery at Weiss Memorial Hospital. I am a co-investigator on a study regarding
24
25
26

uterine transplantation for transgender women.

15. I have given dozens of public addresses, seminars, and lectures on gender confirming surgery, including many through the American Society of Plastic Surgeons. I have also taught a number of courses through WPATH's Gender Education Institute, which provides training courses toward a member certification program in transgender health for practitioners around the world. In addition, in 2018, I co-directed the first live surgery course in gender confirming procedures at Mount Sinai Hospital in New York City, and I am the Director for that live surgery course in 2022. In 2019, I directed the inaugural Gender Affirming Breast, Chest, and Body Master Class for the American Society of Plastic Surgeons.

16. I am also a founding member and president of the American Society of Gender Surgeons; a current member of the Executive Committee of the Board of Directors of the World Professional Association for Transgender Health, where I serve as treasurer; and a former member of the Board of Governors of the American College of Surgeons. I am a guest examiner for the American Board of Plastic Surgery, which involves administering the plastic surgery oral board exam to surgeons who have completed their plastic surgery training and seek board certification. I am the former Chair of the Patient Safety Committee for the American Society of Plastic Surgeons. I have been an invited discussant at the Pentagon regarding transgender servicemembers.

B. Compensation

17. I am being compensated at an hourly rate of \$400/hour plus expenses for my time spent preparing written testimony and reports, and providing local testimony (including deposition or providing hearing testimony by telephone or video-teleconference). I will be compensated a flat daily rate of \$7,500 for any out-of-town deposition or hearing testimony. My compensation

1 does not depend on the outcome of this litigation, the opinions I express, or the testimony I may
2 provide.

3 **C. Previous Testimony**

4 18. Over the past four years, I have given expert testimony at trial or by deposition
5 in the following cases:

- 6 • *Willis v. Flagg*, Cook County, IL (trial)
- 7 • *Bruce v. South Dakota*, D. S.D. (deposition)
- 8 • *Boyden v. State of Wisconsin*, W.D. Wis. (deposition)
- 9 • *Fain v. Crouch*, S.D. W.Va. (deposition)
- 10 • *Kadel v. Folwell*, M.D.N.C. (deposition)
- 11 • *Toomey v. State of Arizona*, D. Ariz. (deposition)

12 To the best of my recollection, I have not given expert testimony at a trial or at a deposition in
13 any other case during this period.
14

15 **III. BASIS FOR OPINIONS**

16 19. My opinions contained in this report are based on all of the following: (1) my
17 clinical experience of over 27 years of caring for transgender individuals; (2) my review and
18 familiarity with relevant peer-reviewed literature;¹ and (3) discussions with colleagues and other
19

20
21
22 ¹ I regularly and routinely perform literature searches as an educator, including in my roles as
23 clinical professor of surgery at the University of Illinois and attending surgeon at Rush University,
24 where I participate in fellow, resident, and student education; Director of the Center for Gender
25 Confirmation Surgery at Weiss Memorial Hospital; lecturer for the Global Education Initiative
26 for WPATH; invited lecturer at national and international conferences; co-lead author of the
surgery and post-operative care chapter of the upcoming WPATH Standards of Care Version 8;
an editor and reviewer for peer-reviewed publications; and a course director for various
educational opportunities for WPATH, American Society of Plastic Surgeons, and other
organizations.

experts in the field, including attendance and participation in various educational conferences both nationally and internationally. The research I relied on in preparing this report is cited in the footnotes and detailed in the reference list attached as **Exhibit B** to this report. I also have reviewed the Amended Class Action Complaint (ECF No. 38) and the court's Order Denying Defendant's Motion to Dismiss (ECF No. 23) in this case.

IV. DISCUSSION

A. Background on Gender Identity and Gender Dysphoria

20. The term "transgender" is used to describe a diverse group of individuals whose gender identity, or internal sense of gender, differs from the sex they were assigned at birth.

21. Many transgender individuals experience gender dysphoria at some point in their lives. Gender dysphoria is a serious medical condition, defined by the Diagnostic and Statistical Manual of Mental Disorders (DSM-V) published by the American Psychiatric Association as "a difference between one's experienced/expressed gender and assigned gender, and significant distress or problems functioning." Gender dysphoria is also recognized by the International Classification of Diseases-11 (ICD-11), under the diagnosis of gender incongruence, and the International Classification of Diseases-10 (ICD-10). Individuals diagnosed with gender dysphoria have an intense and persistent discomfort with the primary and/or secondary sex characteristics of the sex they were assigned at birth. Gender dysphoria can lead to debilitating anxiety and depression, as well as serious incidents of self-harm, including self-mutilation, suicide attempts, and suicide.

22. Appropriate medical care, including mental health services, hormone therapy, and gender confirmation surgeries can help alleviate gender dysphoria. Gender confirmation surgeries, which bring a person's body into better alignment with their gender identity, have been shown to

1 be an effective treatment for gender dysphoria.

2 **B. Gender Confirming Surgeries are Standard, Medically Accepted, and**
 3 **Medically Necessary Treatments for Gender Dysphoria for Transgender**
 4 **People.**

5 23. It is my professional opinion, supported by the prevailing consensus of the medical
 6 community, that procedures used to treat gender dysphoria are medically necessary treatments for
 7 many transgender individuals; these procedures are properly considered as medically necessary,
 8 and are not cosmetic in nature; and these procedures are safe and effective treatments for gender
 9 dysphoria.

10 **1. *Applicable Standards of Care for Treating Gender Dysphoria***

11 24. WPATH is a non-profit professional and educational organization devoted to
 12 transgender health. WPATH's mission is "to promote evidence-based care, education, research,
 13 advocacy, public policy, and respect in transgender health."² WPATH publishes the Standards of
 14 Care. The Standards of Care are based on the best available scientific evidence and expert
 15 professional consensus. WPATH published the first version of the Standards of Care in 1979.
 16 Since that time, the guidelines have been updated through seven versions, reflecting the significant
 17 advances made in the understanding, management, and care of transgender individuals. The
 18 Standards of Care are widely recognized guidelines for the clinical management of transgender
 19 individuals with gender dysphoria. Most surgeons who regularly treat individuals experiencing
 20 gender dysphoria, including myself, practice in accordance with the Standards of Care.
 21

22 25. As indicated in the Standards of Care, effective treatment options for gender
 23 dysphoria include mental health care, hormone therapy, and various surgical procedures to align a
 24
 25

26 ² WPATH, Mission and Vision, <https://www.wpath.org/about/mission-and-vision>.

1 person's primary and/or secondary sex characteristics with the person's gender identity.
2 (Standards of Care at 9-10.) Surgery is often the last and most considered of the treatment options
3 for gender dysphoria in transgender individuals. Not every transgender person may undergo every
4 available surgical procedure. In fact, the Standards of Care note that "[t]he number and sequence
5 of surgical procedures may vary from patient to patient, according to their clinical needs."
6 (Standards of Care at 58.) Evidence shows that while some transgender individuals do not require
7 surgery, "for many others surgery is essential and medically necessary to alleviate their gender
8 dysphoria. For the latter group, relief from gender dysphoria cannot be achieved without
9 modification of their primary and/or secondary sex characteristics to establish greater congruence
10 with their gender identity." (Standards of Care at 54-55.)
11

12 26. The Standards of Care set forth criteria for initiation of surgical treatment. The
13 Endocrine Society—the leading professional organization devoted to research on hormones and
14 the clinical practice of endocrinology—has also issued clinical guidelines for the treatment of
15 transgender individuals.³ The guidelines indicate, that for transgender individuals, gender
16 confirming surgeries often are necessary and effective treatments.⁴
17

18 27. The broader medical community, including the American Medical Association,
19 American Psychological Association, American Psychiatric Association, American College of
20 Obstetricians and Gynecologists, American Academy of Family Physicians, and World Health
21 Organization, recognizes that gender confirming surgeries are standard, appropriate, and often
22
23

24 ³ Wylie C Hembree et al., *Endocrine Treatment of Gender-Dysphoric/Gender-Incongruent*
25 *Persons: An Endocrine Society Clinical Practice Guideline*, 102 J. Clin. Endocrinology &
26 *Metabolism* 3869 (2017).

⁴ *Id.*

necessary treatments for people with gender dysphoria.

2. *Surgical Treatments for Gender Dysphoria*

28. For transgender women and non-binary people assigned male at birth, surgical treatment options that are generally accepted in the medical community and are consistent with the Standards of Care include, but are not limited to:

- Chest reconstruction surgery: augmentation mammoplasty (breast implants);
- Genital reconstruction surgeries: penectomy (removal of the penis), orchiectomy (removal of the testes), vaginoplasty, clitoroplasty, and/or vulvoplasty (creation of female genitalia including the labia minora and majora);
- Non-genital, non-breast surgical interventions: facial feminization surgery, liposuction, lipofilling, voice surgery, thyroid cartilage reduction, gluteal augmentation (implants/lipofilling), and hair reconstruction, among others.

29. For transgender men and non-binary people assigned female at birth, surgical treatment options that are generally accepted in the medical community and are consistent with the Standards of Care include, but are not limited to:

- Chest reconstruction surgery: subcutaneous mastectomy, creation of a male chest;
- Genital surgery: hysterectomy/oophorectomy, reconstruction of the urethra, which can be combined with a metoidioplasty or with a phalloplasty (employing a pedicled or free vascularized flap), vaginectomy, scrotoplasty, and implantation of erection and/or testicular prostheses;
- Non-genital, non-breast surgical interventions: liposuction, lipofilling, pectoral implants, various aesthetic procedures, and sometimes voice surgery (rare).

30. The current version of the Standards of Care recognizes that male chest

1 reconstruction surgery may be indicated for transgender young people under eighteen. As with all
 2 medical care, the standards recommend that clinicians take a case-by-case approach to evaluate
 3 whether and when the procedure is medically necessary for a particular patient. (SOC at 21).
 4 Beyond those recommendations, the standards of care have general criteria for initiation of surgical
 5 treatment. For individuals seeking male chest reconstruction, the criteria are:

- 6 • The patient has the capacity to make fully informed decisions and to consent for
 7 treatment;
- 8 • If the patient has other significant medical or mental health concerns, they are
 9 reasonably well-controlled prior to surgery; and
- 10 • The patient has a referral from at least one mental health professional
 11 documenting the patient's necessity and preparedness for male chest
 12 reconstruction surgery. (SOC at 59).

14 **3. *Gender Confirmation Surgeries are Medically Necessary, Not Cosmetic.***

15 31. The medical community and insurance providers recognize a distinction between
 16 surgery which is medically necessary, and cosmetic surgery, which generally is not. No particular
 17 procedure is inherently cosmetic or inherently medically necessary; rather, the underlying
 18 diagnosis determines whether the procedure is considered cosmetic or medically necessary.
 19

20 32. With respect to surgical treatments for gender dysphoria, the medical community
 21 generally consider those surgeries to be medically necessary. This is true even though the same
 22 surgical procedures might be considered cosmetic when performed on someone without gender
 23 dysphoria. Gender confirming surgeries are not cosmetic because, when performed in accordance
 24 with the Standards of Care, they are clinically indicated to treat the underlying medical condition
 25 of gender dysphoria. Indeed, as explained further below, the surgical procedures listed above to
 26

1 treat gender dysphoria are similar to surgical procedures performed for other diagnoses (e.g., breast
2 cancer). Because these medically necessary procedures help transgender individuals live and
3 present in a manner more consistent with their gender identity and therefore reduce and/or treat
4 their gender dysphoria, the professional medical consensus is that these are appropriately
5 categorized as medically necessary.

6 33. Certain surgical procedures are medically necessary when used to treat gender
7 dysphoria or another medical condition, but are cosmetic when they are used only to alter one's
8 appearance without an underlying medical diagnosis (e.g., a non-transgender woman obtaining a
9 breast augmentation for aesthetic reasons). While the procedures themselves are technically
10 similar, the reasons for performing the procedures are not.

11
12 **C. Gender Confirming Surgeries are Safe, Effective, and Cost Efficient.**

13 34. The prevailing peer-reviewed clinical research, as well as my own clinical
14 expertise as a plastic surgeon specializing in gender confirmation surgeries, shows that surgical
15 procedures for gender dysphoria are safe, effective, and cost efficient; and that many of these
16 procedures are analogous to surgical procedures used to treat other medical conditions.

17
18 **1. Gender Confirming Surgeries are Safe.**

19 35. It is my professional opinion, based on my clinical experience and review of
20 available peer-reviewed research, that gender confirmation surgeries are safe. Notably, when
21 performing gender confirmation surgeries, surgeons use many of the same procedures that they
22 use to treat other medical conditions. The fact that the medical community deems these analogous
23 procedures sufficiently safe to treat conditions other than gender dysphoria is by itself more than
24 sufficient to support the safety of those surgeries to treat gender dysphoria. There is no medical
25 basis to conclude that the same surgical procedures are more or less safe simply because they are
26

1 used to treat gender dysphoria, versus other underlying medical conditions.

2 36. For example, surgeons regularly perform mastectomies and chest/breast
3 reconstruction, hysterectomies/salpingo-oophorectomies (which includes removal of the fallopian
4 tubes and ovaries), and orchiectomies to treat individuals with cancer, or a genetic predisposition
5 to cancer (BRCA 1, 2 genes in the case of prophylactic mastectomy or oophorectomy). Similarly,
6 surgeons perform procedures to reconstruct external genitalia for individuals who have certain
7 medical conditions (e.g., cancer) or who have suffered traumatic injuries or disabling infections to
8 their genitalia. This would include procedures to correct conditions such as hypospadias (a
9 disorder in which the urinary opening is not in the typical location on the glans penis), epispadias
10 (a condition where the urethra is not properly developed), exstrophy (where the bladder develops
11 outside the fetus), fourrier's gangrene (where tissue dies because of an infection), penile webbing,
12 or buried penis (which can occur as a result of obesity, diabetes, or recurrent infections). This
13 would also include procedures to correct conditions such as congenital absence of the vagina or
14 reconstruction of the vagina/vulva following oncologic resection, traumatic injury, or infection.
15

16 **2. Gender Confirmation Surgeries Effectively Treat Gender Dysphoria.**

17 37. It is my professional opinion, based on decades of clinical experience, as well as a
18 substantial body of peer-reviewed research, that standard medical surgical treatments for gender
19 dysphoria are effective when performed in accordance with the Standards of Care.
20

21 38. Peer-reviewed studies find that transgender women who undergo one or more
22 gender confirmation surgeries report positive health outcomes. For example, a peer-reviewed
23 study of transgender women found that those who underwent breast reconstruction surgeries
24
25
26

1 experienced statistically significant improvements in their psychosocial well-being.⁵ Another
 2 peer-reviewed study of transgender women who had vaginoplasty found that study participants'
 3 mean improvement in quality of life after surgery was 7.9 on a scale from one to ten.⁶ Another
 4 study of transgender women found that surgical interventions were highly correlated with
 5 alleviating gender dysphoria.⁷ A recent literature review concluded that in appropriately selected
 6 individuals, gender confirmation surgery is effective at improving quality of life, overall
 7 happiness, and sexual functioning in transgender women who are diagnosed with gender
 8 dysphoria.⁸ Another recent post-operative and six-month follow-up survey of transgender female
 9 patients found improvements in quality of life in a significant majority of patients.⁹

11 39. The available peer-reviewed literature likewise concludes that when performed in
 12 accordance with the prevailing standards of care, male chest reconstruction surgery is safe and
 13 effective in alleviating gender dysphoria. For example, one study found that transgender men who
 14

16 ⁵ Weigert, R., Frison, E., Sessiecq, Q., Mutairi, K. A., & Casoli, V. (2013). Patient Satisfaction
 17 with Breasts and Psychosocial, Sexual, and Physical Well-Being after Breast Augmentation in
 18 Male-to-Female Transsexuals. *Plastic and Reconstructive Surgery*, 132(6), 1421-1429.
 doi:10.1097/01.prs.0000434415.70711.49.

19 ⁶ Horbach, S. E. R., Bouman, M., Smit, J. M., Ozer, M., Buncamper, M. & Mullender, M. G.
 20 (2015). Outcome of Vaginoplasty in Male-to-Female Transgenders: A Systematic Review of
 Surgical Techniques.

21 ⁷ Hess, J., Neto, R., Panic, L., Rubben, H. & Senf, W. (2014). Satisfaction with Male-to-
 22 Female Gender Reassignment Surgery. (Among survey respondents, the majority (90.2%) said
 23 that that their expectations for life as a woman were fulfilled after surgery. A similarly high
 percentage (85.4%) saw themselves as women.)

24 ⁸ Hadj-Moussa, M., et al. Feminizing Genital Gender-Confirmation Surgery, 2018, 1-14. 2018
 Jul;6(3):457-468.e2. doi: 10.1016.

25 ⁹ Papadopoulos, N.A., et al. Male-to-Female Sex Reassignment Surgery Using the Combined
 26 Technique Leads to Increase Quality of Life in a Prospective Study. *Plast Reconstr Surg*. 2017
 Aug;140(2):286-294. doi: 10.1097.

received chest reconstruction experienced few clinical complications and were overwhelmingly satisfied with their surgical outcomes.¹⁰ Another peer-reviewed study of transgender men who received chest reconstruction found that the procedure improved psychosocial well-being and physical well-being among participants.¹¹ Numerous other studies have reached similar conclusions.¹²

40. These findings extend to adolescents; for example, a recent study in JAMA Pediatrics concluded that: “Chest dysphoria was high among presurgical transmasculine youth, and surgical intervention positively affected both minors and young adults.”¹³

41. The overwhelming majority of patients who obtain gender confirmation surgery in a manner consistent with the Standards of Care are both satisfied and experience a reduction of gender dysphoria. For the vast majority of transgender people who seek such surgery, the surgery is successful at treating gender dysphoria and alleviating a lifelong struggle to find peace of mind

¹⁰ Frederick, M. et al., (2017), Chest Surgery in Female to Male Transgender Individuals, *Annals of Plastic Surgery*, 78(3), 249-253.

¹¹ Agarwal, C. et al., (2018). Quality of life improvement after chest wall masculinization in female-to-male transgender patients: A prospective study using the BREAST-Q and Body Uneasiness Test, 71, 651-657.

¹² E.g., Mehringer, J. E., Harrison, J. B., Quain, K. M., Shea, J. A., Hawkins, L. A., & Dowshen, N. L. (2021). Experience of Chest Dysphoria and Masculinizing Chest Surgery in Transmasculine Youth. *Pediatrics*, 147(3), e2020013300. <https://doi.org/10.1542/peds.2020-013300>; Olson-Kennedy, J. et al., (2018), Chest Reconstruction and Chest Dysphoria in Transmasculine Minors and Young Adults, *JAMA Pediatrics*, 172(5), 431-436; Van de Grift, T., et al., (2017), Surgical Indications and Outcomes of Mastectomy in Transmen: A Prospective Study of Technical and Self-Reported Measures. *Plastic and Reconstructive Surgery*, 140(3), 415e-424e. doi:10.1097/PRS.0000000000003607; Berry, M.G. et al., (2012), Female-to-male transgender chest reconstruction: A large consecutive, single-surgeon experience. *Journal of Plastic, Reconstructive & Aesthetic Surgery* 65, 711-719.

¹³ Olson-Kennedy, J. *supra* at n. 12. Additionally, Frederick et al., *supra* at n. 10, included adolescents aged 15-17, as well as adults.

and comfort with their bodies.

3. *Gender Confirmation Surgeries are Cost Efficient.*

42. When billing insurers for reimbursement, health care providers use Current Procedural Terminology (CPT) codes, which are developed and maintained by the American Medical Association. The same code or codes may apply to a particular procedure regardless of whether the procedure is performed on a transgender patient or a non-transgender patient. For example, vaginoplasty may be performed for a non-transgender woman as treatment for congenital absence of the vagina or for a transgender woman with gender dysphoria. The same CPT code(s) may be used for both procedures. The same is true for a subcutaneous mastectomy, which may be performed for a non-transgender woman to reduce her risk of breast cancer or for a transgender man with gender dysphoria.

43. Researchers affiliated with the Johns Hopkins Bloomberg School of Public Health, the Commonwealth of Massachusetts Group Insurance Commission, and the University of Colorado, found access to gender confirmation surgeries through insurance to be a likely cost-effective treatment long-term.¹⁴ Gender confirmation surgery typically results in, at a minimum, a significant reduction of gender dysphoria. Transgender people with gender dysphoria who, for lack of insurance access, are unable to obtain gender confirmation surgeries tend to have higher rates of negative health outcomes such as depression, HIV, drug abuse, and suicidality. These researchers found that the one-time costs of gender confirmation surgeries coupled with standard post-operative care, primary and maintenance care, were overall less expensive at 5- and 10-year

¹⁴ William V Padula, Shiona Heru & Jonathan D Campbell, Societal Implications of Health Insurance Coverage for Medically Necessary Services in the U.S. Transgender Population: A Cost-Effectiveness Analysis, *J Gen Intern Med*, 31(4), 394–401 (2015). doi: 10.1007/s11606-015-3529-6.

1 marks, as compared to the long-term treatment of the negative health outcomes associated with
2 lack of insurance and resulting healthcare access.¹⁵ Similarly, a RAND Corporation study reported
3 findings that due to discrimination, lack of insurance, and problematic interactions with providers,
4 transgender people often avoid seeking treatment for gender dysphoria and other more common
5 health issues. This avoidance resulted in negative healthcare outcomes and greater potential costs
6 related to treating to those outcomes in the long-term.¹⁶ Additionally, this research confirms that
7 coverage for gender confirmation surgeries is affordable and a nominal percentage of the care
8 offered through group health plans.
9

10 **V. SUMMARY OF OPINIONS AND CONCLUSIONS**

11 44. Based on over 27 years of clinical experience performing gender confirmation
12 procedures and caring for transgender individuals, my knowledge of the standards of care and
13 relevant peer-reviewed literature, and my discussions and interactions with experts throughout the
14 world, it is my professional opinion that gender confirmation surgeries are safe, effective, and
15 medically necessary treatments for gender dysphoria in transgender individuals, including
16 adolescents. In my experience, the overwhelming number of individuals who undergo gender
17 confirmation procedures describe relief and/or reduction of their gender dysphoria and
18 improvement in their quality of life and overall functioning.
19

20 45. Furthermore, based on my clinical and professional experience and my ongoing
21 review of the literature, it is my professional opinion that the denial of necessary medical care is
22

23
24 ¹⁵ *Id.* at 398.

25 ¹⁶ Schaefer, Agnes Gereben, Radha Iyengar Plumb, Srikanth Kadiyala, Jennifer Kavanagh,
26 Charles C. Engel, Kayla M. Williams, and Amii M. Kress, *The Implications of Allowing Transgender Personnel to Serve Openly in the U.S. Military*. Santa Monica, CA: RAND Corporation, 2016. https://www.rand.org/pubs/research_briefs/RB9909.html.

1 likely to perpetuate gender dysphoria and create or exacerbate other medical issues, such as
2 depression and anxiety, leading to an increased possibility of self-harm, negative health outcomes,
3 and even suicide.

4 46. In conclusion, it is my professional opinion that the categorical exclusion of
5 transition-related surgical care contained in the Catholic Health Initiatives Medical Plan
6 administered by Blue Cross Blue Shield of Illinois and other similar categorical exclusions
7 transition-related care are 1) inconsistent with the Standards of Care for treating transgender
8 individuals diagnosed with gender dysphoria, 2) inconsistent with the peer-reviewed scientific and
9 medical research demonstrating that gender confirmation surgeries are safe, effective, and more
10 cost efficient treatments for gender dysphoria over the long-term, 3) and inconsistent with expert
11 medical and surgical consensus.
12

13 47. To the extent these exclusions are premised on the assumption that gender
14 confirmation surgical care is not medically necessary, that assumption is wrong. The Standards
15 of Care confirm, based on clinical evidence, that gender confirmation surgeries are medically
16 necessary to help people alleviate the often serious and life-threatening symptoms of gender
17 dysphoria.
18

19 I declare under penalty of perjury under the laws of the United States of America that
20 the foregoing is true and correct.

21 Executed this 2nd day of April, 2022.
22

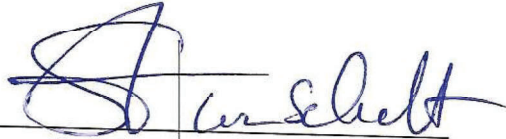
23
24 
25 Loren S. Schechter, M.D.
26

EXHIBIT A

Curriculum Vitae

NAME: LOREN SLONE SCHECHTER, MD, FACS

OFFICE: 4700 Marine Dr.
Suite 515
Chicago, IL 60640
Tel: 847.967.5122
Fax: 847.967.5125

E-MAIL: lorenschechter1@gmail.com

MARITAL STATUS: Married (Rebecca Brown Schechter, MD)

CERTIFICATION: The American Board of Plastic Surgery, 2001
Certificate Number 6271
Date Issued: September 2001
Maintenance of Certification: 2011
Maintenance of Certification: 2021

EDUCATION:

1986-1990	The University of Michigan	BS, 1990
1990-1994	The University of Chicago Pritzker School of Medicine	MD, 1994

POSTGRADUATE TRAINING:

Residency:	The University of Chicago Hospitals 1994-1999 Coordinated Training Program in Plastic and Reconstructive Surgery
Chief Resident:	The University of Chicago Hospitals 1998-1999 Section of Plastic and Reconstructive Surgery
Fellowship:	Reconstructive Microsurgery 1999-2000 The University of Chicago Hospitals Section of Plastic and Reconstructive Surgery

TEACHING APPOINTMENT:

Professor of Surgery, Chief Section of Gender-Affirmation
Surgery, Rush University Medical Center-In Process

Clinical Professor of Surgery, The University of Illinois at
Chicago-resigned to accept position at Rush University

Adjunct Assistant Professor, Dept. of Surgery, Rush University
Medical Center

Associate Professor, Physician Assistant Program, College of
Health Professionals, Rosalind Franklin University

LICENSURE:

Illinois
Illinois Controlled Substance
DEA

STAFF APPOINTMENTS:

Rush University Medical Center
Advocate Lutheran General Hospital
Louis A. Weiss Memorial Hospital
Illinois Sports Medicine and Orthopedic Surgery
Center

HONORS AND AWARDS:

2021	Chicago Magazine Top Doctor-Surgery
2020	The University of Minnesota Program in Human Sexuality, recipient of 50 Distinguished Sexual and Gender Health Revolutionaries
2017-2020	Castle Connolly Top Doctor (Chicago)
2017	Chicago Consumer Checkbook Top Doctor
2015	University of Minnesota Program in Human Sexuality Leadership Council
2014-2015	Rosalind Franklin University of Medicine and Science Chicago Medical School Honors and recognizes for dedication and commitment to teaching
2014	National Center for Lesbian Rights honored guest
2013	Illinois State Bar Association Award for Community Leadership
2010	Advocate Lutheran General 2009 Physicians Philanthropy Leadership Committee-Outstanding Leadership
2009	Advocate Lutheran General Hospital Value Leader (received for compassion)
1994	Doctor of Medicine with Honors
1994	University of Chicago Department of Surgery Award for Outstanding Performance in the Field of Surgery
1994	Catherine Dobson Prize for the Best Oral Presentation Given at the 48 th Annual Senior Scientific Session in The Area of Clinical Investigation
1993	Alpha Omega Alpha

1991	University of Chicago National Institutes Of Health Summer Research Award
1990	Bachelor of Science with High Distinction And Honors in Economics
1990	James B. Angell Award for Academic Distinction
1989	Omicron Delta Epsilon-National Economic Honor Society
1988	College Honors Program Sophomore Honors Award For Academic Distinction
1988	Class Honors (Dean's List)

MEMBERSHIPS:

2018-	The American Association of Plastic Surgeons
2016-	The American Society for Gender Surgeons (founding member and president-elect)
2010-	World Society for Reconstructive Microsurgery
2005-	The University of Chicago Plastic Surgery Alumni Association
2005-	The Chicago Surgical Society
2004-	The American Society for Reconstructive Microsurgery
2003-	The American College of Surgeons
2002-	The American Society of Plastic Surgeons
2001-	Illinois Society of Plastic Surgeons (formerly Chicago Society of Plastic Surgeons)
2001-	The American Society of Maxillofacial Surgeons
2001-	American Burn Association
2001-	Midwest Association of Plastic Surgeons
2001-	WPATH
1994-	The University of Chicago Surgical Society
1994-	The University of Chicago Alumni Association
1992-	American Medical Association
1992-	Illinois State Medical Society
1992-	Chicago Medical Society
1990-	The University of Michigan Alumni Association

CURRENT HOSPITAL COMMITTEES:

Director, Center for Gender Confirmation Surgery,
Louis A. Weiss Memorial Hospital

PROFESSIONAL SOCIETY COMMITTEES:

WPATH Executive Committee

Treasurer, The World Professional Association for Transgender
Health

Chair, Finance and Investment Committee, The American Society of Plastic Surgeons

WPATH 2020 Biennial Meeting Steering Committee

American Society of Breast Surgeons Research Committee, ASPS representative

American Board of Plastic Surgery, Guest Oral Board Examiner

WPATH Ethics Committee

American College of Radiology Committee on Appropriateness Criteria Transgender Breast Imaging Topic, Expert Panel on Breast Imaging: Transgender Breast Cancer Screening Expert Panel on Breast Imaging

American Society of Plastic Surgeons, Finance and Investment Committee

Board of Directors, at-large, The World Professional Association for Transgender Health

PlastyPac, Board of Governors

Medicare Carrier Advisory Committee

OTHER:

American Board of Plastic Surgery-Oral Board Guest Examiner (2020, 2021)

Guest Reviewer, Pain Management

Guest Reviewer, Plastic and Aesthetic Research

Guest Reviewer, European Medical Journal

Guest Reviewer, Open Forum Infectious Diseases

Guest Reviewer, The Journal of The American College of Surgeons

Guest Book Reviewer, Plastic and Reconstructive Surgery

Editorial Board, Transgender Health

Editorial Board (Associate Editor), International Journal of Transgenderism

Fellow of the Maliniac Circle

Guest Reviewer, Journal of Reconstructive Microsurgery

Guest Reviewer, Journal of Plastic and Reconstructive Surgery

Guest Reviewer, Journal of Sexual Medicine

Guest Editor, Clinics in Plastic Surgery, Transgender Surgery (Elsevier Publishing)

Guest Reviewer, The Journal of Plastic and Reconstructive Surgery

PREVIOUS EDITORIAL ROLE:

Guest Reviewer, EPlasty, online Journal

Module Editor for Patient Safety, Plastic Surgery Hyperguide

Editorial Advisory Board, Plastic Surgery Practice

Guest Reviewer, International Journal of Transgenderism

Guest Reviewer, Pediatrics

PREVIOUS ACADEMIC APPOINTMENT:

Visiting Clinical Professor in Surgery, The University of Illinois at Chicago

Chief, Division of Plastic and Reconstructive Surgery, Chicago Medical School, Rosalind Franklin University of Medicine and Science

Associate Professor of Surgery, The College of Health Professionals, Rosalind Franklin University

Clinical Associate in Surgery, The University of Chicago

PREVIOUS HOSPITAL COMMITTEES:

Division Director, Plastic Surgery, Lutheran General Hospital

Division Director, Plastic Surgery, St. Francis Hospital

Medical Staff Executive Committee, Secretary,
Advocate Lutheran General Hospital

Credentials Committee, Lutheran General Hospital

Pharmacy and Therapeutics Committee Lutheran General Hospital

Operating Room Committee, St. Francis Hospital

Cancer Committee, Lutheran General Hospital
-Director of Quality Control

Risk and Safety Assessment Committee, Lutheran General
Hospital

Nominating Committee, Rush North Shore Medical Center

Surgical Advisory Committee, Rush North Shore Medical Center

Section Director, Plastic Surgery, Rush North Shore Medical
Center

PREVIOUS SOCIETY COMMITTEES:

PlastyPac, Chair, Board of Governors

Chair of the Metro Chicago District #2 Committee on Applicants,
American College of Surgeons

American Society of Plastic Surgery, Health Policy Committee

American Society of Plastic Surgery, Patient Safety Committee

American Society of Plastic Surgeons, Coding and Payment Policy
Committee

American Society of Plastic Surgeons, Practice Management
Education Committee

Board of Governors, Governor-at-large, The American College of
Surgeons

American College of Surgeons, International Relations Committee

Chair, Government Affairs Committee, American Society of Plastic Surgeons

President, The Metropolitan Chicago Chapter of The American College of Surgeons

2012 Nominating Committee, American Society of Plastic Surgeons

Program Committee, The World Society for Reconstructive Microsurgery, 2013 Bi-Annual Meeting

President, Illinois Society of Plastic Surgeons

Vice-President, The Illinois Society of Plastic Surgeons (formerly the Chicago Society of Plastic Surgery)

Vice-President, The Metropolitan Chapter of the American College of Surgeons

American Society of Plastic Surgery, Chairman, Patient Safety Committee

2006-2007 Pathways to Leadership, The American Society of Plastic Surgery

2005 & 2006 President, The University of Chicago Plastic Surgery Alumni Association

2003 Leadership Tomorrow Program, The American Society of Plastic Surgery

Senior Residents Mentoring Program, The American Society of Plastic Surgery

American Society of Maxillofacial Surgery, Education Committee

Alternate Councilor, Chicago Medical Society

American Society of Aesthetic Plastic Surgery, Electronic Communications Committee

American Society of Aesthetic Plastic Surgery, Intranet Steering Committee

American Society of Aesthetic Plastic Surgery, International Committee

Membership Coordinator, The Chicago Society of Plastic Surgeons
The Illinois State Medical Society, Governmental Affairs Council

The Illinois State Medical Society, Council on Economics

Chicago Medical Society, Physician Review Committee
-Subcommittee on Fee Mediation

Chairman, Chicago Medical Society, Healthcare Economics Committee

Secretary/Treasurer, The Metropolitan Chicago Chapter of the American College of Surgeons

Scientific Committee, 2007 XX Biennial Symposium WPATH

Local Organizing Committee 2007 WPATH

Secretary, The Chicago Society of Plastic Surgeons

Treasurer, The Chicago Society of Plastic Surgeons

Council Member, The Metropolitan Chicago Chapter of the American College of Surgeons

INTERNATIONAL MEDICAL SERVICE:

Northwest Medical Teams
Manos de Ayuda (Oaxaca, Mexico)

Hospital de Los Ninos (San Juan, Puerto Rico)

COMMUNITY SERVICE:

Alumni Council, The University of Chicago Medical and Biological Sciences Alumni Association

The University of Minnesota Presidents Club Chancellors Society

Board of Directors, Chicago Plastic Surgery Research Foundation

National Center for Gender Spectrum Health Advisory Council

PREVIOUS COMMUNITY SERVICE:

Board of Directors, Committee on Jewish Genetic Diseases, Jewish United Fund, Chicago, Illinois

Governing Council, Lutheran General Hospital, Park Ridge, Il

Lutheran General Hospital Development Council, Park Ridge, Il

Lutheran General Hospital Men's Association, Park Ridge, Il

Advisory Board, Committee on Jewish Genetic Diseases, Cancer Genetics Subcommittee, Jewish United Fund, Chicago, Illinois

Health Care Advisory Board, Congressman Mark Kirk, 10th Congressional District, Illinois

Major Gifts Committee, Saint Francis Hospital Development Council, Evanston, Il

Visiting Professor:

1. University of Utah, Division of Plastic Surgery, November 6-8, 2014.
2. Northwestern University, Division of Plastic Surgery, April 21-22, 2016.
3. The University of North Carolina, Division of Plastic Surgery, March 28-29, 2017
4. Georgetown University, Department of Plastic Surgery, May 17-18, 2017
5. The University of Basel, Basel, Switzerland, August 31-September 1, 2018
6. The Ochsner Health System, New Orleans, LA January 28-January 30, 2019
7. The University of Toronto, Toronto, Ontario, Canada, February 21-22, 2019
8. The University of Michigan, October 3-4, 2019, Ann Arbor, MI,

Invited Discussant:

1. Department of Defense, Military service by people who are transgender, Invitation from Terry Adirim, M.D., M.P.H. Deputy Assistant Secretary of Defense for Health Services Policy & Oversight, The Pentagon, November 9, 2017
2. Aesthetic Surgery Journal, Invited Discussant May 7, 2019, Journal Club. "What is "Nonbinary" and What Do I need to Know? A Primer for Surgeons Providing Chest Surgery for Transgender Patients."

Research Interests:

1. Role of Omental Stem Cells in Wound Healing (Grant: Tawani Foundation)
2. Robotic-Assisted Bilateral Prophylactic Nipple Sparing Mastectomy with Immediate Tissue Expander/Implant Reconstruction (Pending submission to the FDA for Investigational Device Exemption in association with Intuitive Surgical)
3. Transgender Health and Medicine Research Conference, National Institutes of Health, Bethesda, MD May 7-8, 2015
4. Uterine Transplantation, Rush University Medical Center (IRB pending)
5. Gender Affirmation Surgery Prospective Surveys (Rush University-IRB approved)
6. National Network for Gender Affirming Surgeries: Canadian Institute of Health Research, Training Grant – LGBTQ 2S Stigma Reduction & Life Course Mental Wellness (application in process)

BIBLIOGRAPHY:

PEER REVIEWED ARTICLES:

1. E. Wall, D. A. Schoeller, **L. Schechter**, L.J. Gottlieb: Measured Total Energy Requirements of Adult Patients with Burns. *The Journal of Burn Care and Rehabilitation* 20:329, 1999.
2. David C. Cronin, II, **Loren Schechter**, Somchi Limrichramren, Charles G. Winans, Robert Lohman, and J. Michael Millis, Advances in Pediatric Liver Transplantation: Continuous Monitoring of Portal Venous and Hepatic Artery Flow with an Implantable Doppler Probe. *Transplantation* 74(6):887-889, 2002.
3. Robert F. Lohman, **Loren S. Schechter**, Lawrence S. Zachary, Solomon Aronson: Evaluation of Changes in Skeletal Muscle Blood Flow in the Dog with Contrast Ultrasonography Revisited: Has the Technique Been Useful, and Where are We Headed Now? *The Journal of Plastic and Reconstructive Surgery* 111(4):1477-1480, 2003.
4. Alvin B. Cohn, Eric Odessey, Francis Casper, **Loren S. Schechter**: Hereditary Gingival Fibromatosis: Aggressive Two-Stage Surgical Resection in Lieu of Traditional Therapy, *The Annals of Plastic Surgery* Vol 57, Number 5, November 2006.
5. Eric Odessey, Al Cohn, Kenneth Beaman, and **Loren Schechter**: Mucormycosis of the Maxillary Sinus: Extensive Destruction with an Indolent Presentation, *Surgical Infections*, Vol. 9, Number 1, 2008
6. Iris A. Seitz, MD, David Tojo, MD, **Loren S. Schechter**, MD Anatomy of a Medication Error: Inadvertent Intranasal Injection of Neosynephrine During Nasal Surgery – A Case Report

and Review of The Literature *Plast Reconstr Surg*. 2010 Mar;125(3):113e-4e. doi: 10.1097/PRS.0b013e3181cb68f9

7. Iris Seitz, MD Craig Williams, MD, Thomas Weidrich, MD, John Seiler, MD, Ginard Henry, MD, and **Loren S. Schechter, MD**: Omental Free Tissue Transfer for Coverage of Complex Upper Extremity Defects: The Forgotten Flap (*N Y*). 2009 Dec;4(4):397-405. doi: 10.1007/s11552-009-9187-6. Epub 2009 Mar 25.

8. Michael Salvino and **Loren S. Schechter**: Microvascular Reconstruction of Iatrogenic Femoral Artery Thrombus in an Infant: A Case Report and Review of the Literature *ePlasty* Volume 9 ISSN: 19357-5719, E-location ID: e20

9. Phillip C. Haeck, MD, Jennifer A. Swanson, BS, Med, Ronald E. Iverson, MD., **Loren S. Schechter, MD**, Robert Singer, MD, Bob Basu, MD, MPH, Lynn A. Damitz, MD, Scott Bradley Bradley Glasberg, MD, Lawrence S. Glasman, MD, Michael F. McGuire, MD, and the ASPS Patient Safety Committee: Evidence-Based Patient Safety Advisory: Patient Selection and Procedures in Ambulatory Surgery, Supplement to Plastic and Reconstructive Surgery, Volume 124, Number 4s, October Supplement 2009.

10. Philip C. Haeck, MD, Jennifer A. Swanson, BS, Med, **Loren S. Schechter, MD**, Elizabeth J. Hall-Findlay, MD, Noel B. McDevitt, MD, Gary Smotrich, MD, Neal R. Reisman, MD, JD, Scot Bradley Glasberg, MD, and the ASPS Patient Safety Committee: Evidence-Based Patient Safety Advisory: Blood Dyscrasias, Patient Selection and Procedures in Ambulatory Surgery, Supplement to Plastic and Reconstructive Surgery, Volume 124, Number 4s, October Supplement 2009.

11. **Loren S. Schechter, MD**, The Surgeon's Relationship with The Physician Prescribing Hormones and the Mental Health Professional: Review for Version 7 of the World Professional Association of Transgender Health's Standards of Care *International Journal of Transgenderism* 11 (4), p.222-225 Oct-Dec 2009

12. Iris A Seitz, MD, PhD, Craig Williams, MD, **Loren S. Schechter, MD**, Facilitating Harvest of the Serratus Fascial Flap With Ultrasonic Dissection, *Eplasty* 2010 Feb 23;10:e18

13. Seitz, I, Friedewald SM, Rimler, J, **Schechter, LS**, Breast MRI helps define the blood supply to the nipple-areolar complex, *Plastische Chirurgie*, Supplement 1, 10. Jahrgang, September 2010, p. 75

14. Iris A. Seitz, Sally Friedwald, MD; Jonathon Rimler, **Loren S. Schechter**, Breast MRI to Define The Blood Supply to The Nipple-Areolar Complex. *Plast Recon Surg Suppl* 126 (26) p. 27 Oct 2010

15. Kalliainen LK; ASPS Health Policy Committee Evidence-Based Clinical Practice Guidelines: Reduction Mammoplasty, The American Society of Plastic Surgeons *Plast Reconstr Surg*. 2012 Oct;130(4):785-9 **Loren S. Schechter** (member and contributor, ASPS Health Policy Committee)

16. Eli Coleman, Walter Bockting, Marsha Botzer, Peggy Cohen-Kettenis, Griet DeCuypere, Jamie Feldman, Lin Fraser, Jamison Green, Gail Knudson, Walter J. Meyer, Stan Monstrey, Richard K. Adler, George R. Brown, Aaron H. Devor, Randall Ehrbar, Randi Ettner, Evan Eyler, Rob Garofalo, Dan H. Karasic, Arlene Istar Lev, Gal Mayer, Heino Meyer-Bahlburg, Blaine Paxton Hall, Friedmann Pfäfflin, Katherine Rachlin, Bean Robinson, **Loren S. Schechter**, Vin Tangpricha, Mick van Trotsenburg, Anne Vitale, Sam Winter, Stephen Whittle, Kevan R. Wylie & Ken Zucker, Standards of Care for the Health of Transsexual, Transgender, and Gender-Nonconforming People, Version 7, *International Journal of Transgenderism*, 13 (4) p. 165-232, August 2012.

17. Jonathan Bank, M.D., Lucio A. Pavone, M.D., Iris A. Seitz, M.D., Ph.D., Michelle C. Roughton M.D., **Loren S. Schechter M.D.** Case Report and Review of the Literature - Deep Inferior Epigastric Perforator Flap for Breast Reconstruction after Abdominal Recontouring, eplasty Ref.: Ms. No. EPLASTY-D-12-00050R1

18. Seitz IA, Siwinski P, Rioux-Forker D, Pavone L, **Schechter LS** Upper and Lower Limb Salvage with Omental Free Flaps: A Long-Term Functional Outcome Analysis, *Plast Reconstr Surg*. 2014; 134 (4 Suppl 1): 140. Doi: 10.1097/01.prs.0000455514.83516.31. No abstract available. PMID: 25254872 [PubMed - in process]

19. Seitz IA, Friedewald S, **Schechter LS**, “NACsomes”: A Classification system of the blood supply to the nipple areola complex (NAC) based on diagnostic breast MRI exams, accepted for publication, *Plast Reconstr Aesthet Surg*. 2015 Jun;68(6):792-9. doi: 10.1016/j.bjps.2015.02.027. Epub 2015 Feb 19.

20. **Loren S. Schechter**, Gender Confirmation Surgery: An Update for the Primary Care Provider, *Transgender Health*. Jan 2016, 1(1): 32-40.

21. **Loren S. Schechter**, Mimis N. Cohn, Gender Confirmation Surgery: A New Frontier in Plastic Surgery Education, *Journal of Plastic and Reconstructive Surgery*, October 2016, 138 (4): 784 e

22. Berli JU, Knudson G, Fraser L, Tangpricha V, Ettner R, Ettner FM, Safer JD, Graham J, Monstrey S, **Schechter L**, Gender Confirmation Surgery: What Surgeons Need To Know When Providing Care For Transgender Individuals, *JAMA Surg*. 2017 Apr 1;152(4):394-400. doi: 10.1001/jamasurg.2016.5549

23. Seitz, I.A., Lee, J.C., Sulo, S, Shah, V, Shah, M, Jimenez, M, **Schechter, L**, Common characteristics of functional and adverse outcomes in acute lower-extremity trauma reconstruction, *The European Journal of Plastic Surgery*, (2017) doi:10.1007/s00238-016-1268-5

24. **Loren S. Schechter**, Salvatore D’Arpa, Mimis Cohen, Ervin Kocjancic, Karel Claes, Stan Monstrey, Gender Confirmation Surgery: Guiding Principles *J Sex Med*. 2017 Jun;14(6):852-856. doi: 10.1016/j.jsxm.2017.04.001. Epub 2017 May 3

25. Response to Letter to the Editor: "Gender Confirmation Surgery: Guiding Principles". **Schechter LS**. J Sex Med. 2017 Aug;14(8):1067. doi: 10.1016/j.jsxm.2017.06.002. PMID: 28760249
26. Iris A. Seitz, **Loren S. Schechter**, "Successful Tongue Replantation Following Segmental Auto-Amputation Using Supermicrosurgical Technique," J Reconstr Microsurg Open 2017; 02(02): e132-e135 DOI: 10.1055/s-0037-1606584
27. Berli JU, Knudson G, **Schechter L**. Gender Confirmation Surgery and Terminology in Transgender Health-Reply. JAMA Surg. 2017 Nov 1;152(11):1091. doi: 10.1001/jamasurg.2017.2347. PMID: 28724140
28. Randi Ettner, Fred Ettner, Tanya Freise, **Loren Schechter**, Tonya White, "Tomboys Revisited: A retrospective comparison of childhood behavioral patterns in lesbian women and transmen" Journal of Child and Adolescent Psychiatry ISSN: 2643-6655 Volume No: 1 Issue No: 1
29. Editor: **Loren S. Schechter**, Bauback Safa, Gender Confirmation Surgery, Clinics in Plastic Surgery, Vol. 45 (3), July 2018
30. **Loren S. Schechter**, Bauback Safa, Preface: Gender Surgery: A Truly Multidisciplinary Field, Gender Confirmation Surgery, Clinics in Plastic Surgery, Vol. 45 (3), p. xiii July 2018 (editors Loren S. Schechter, Bauback Safa)
31. Introduction to Phalloplasty. **Schechter LS**, Safa B. Clin Plast Surg. 2018 Jul;45(3):387-389. doi: 10.1016/j.cps.2018.03.014. Epub 2018 May 1. Review. PMID: 29908627
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45. ASPS/IQUAM Transatlantic Innovations Meeting, April 4-7, 2009 Mison de la Chimie, Paris, France, “Cost-Effectiveness of Physician Extenders in Plastic Surgery”
46. Midwestern Association of Plastic Surgeons, 47th Annual Meeting, April 18-19, 2009, Chicago, IL, “Microvascular Reconstruction of Iatrogenic Femoral Artery Injury in a Neonate”
47. Midwestern Association of Plastic Surgeons, 47th Annual Meeting, April 18-19, 2009, Chicago, IL, “Two Birds, One Stone: Combining Abdominoplasty with Intra-Abdominal Procedures”

48. The 11th Annual Chicago Trauma Symposium, August 1, 2009, Chicago, IL “Management of Complex Injuries”
49. Societa Italiana Di Microchirurgia, XXIII Congresso Nazionale della Societa Italiana di Microchirurgia, First Atlanto-Pacific Microsurgery Conference, Modena, Italy, October 1-3, 2009, “Omental Free Tissue Transfer for Coverage of Complex Extremity Defects: The Forgotten Flap.”
50. Societa Italiana Di Microchirurgia, XXIII Congresso Nazionale della Societa Italiana di Microchirurgia, First Atlanto-Pacific Microsurgery Conference, Modena, Italy, October 1-3, 2009, “Challenging Cases.”
51. American Society of Plastic Surgeons Annual Meeting, October 23-27, 2009, Seattle, WA, “President’s Panel: The Future of the Solo Practice-Can We, Should We Survive?”
52. The 12th Annual Chicago Trauma Symposium, August 5-8, 2010, Chicago, IL “Management of Complex Injuries”
53. Breast MRI to Define The Blood Supply to the Nipple-Areolar Complex. German Society of Plastic, Reconstructive and Aesthetic Surgery (DGPREAC), Dresden, Germany, September 2010
54. Roundtable Discussion: Electronic Health Records-Implications for Plastic Surgeons, The American Society of Plastic Surgeons Annual Meeting, October 3, 2010, Toronto, CA
55. Breast MRI Helps Define the Blood Supply to the Nipple-Areolar Complex, The American Society of Plastic Surgeons Annual Meeting, October 3, 2010, Toronto, CA.
56. ASPS/ASPSN Joint Patient Safety Panel: Patient Selection and Managing Patient Expectations, The American Society of Plastic Surgeons Annual Meeting, October 4, 2010, Toronto, CA
57. Lunch and Learn: Prevention of VTE in Plastic Surgery Patients, The American Society of Plastic Surgeons Annual Meeting, October 5, 2010, Toronto, CA
58. Breast MRI Helps Define the Blood Supply to the Nipple-Areolar Complex, 16th Congress of The International Confederation for Plastic Reconstructive and Aesthetic Surgery, May 22-27, 2011, Vancouver, Canada
59. Breast MRI Helps Define the Blood Supply to the Nipple-Areolar Complex, The 6th Congress of The World Society for Reconstructive Microsurgery, WSRM 2011, 29 June-2 July, 2011, Helsinki, Finland
60. Applications of the Omentum for Limb Salvage: The Largest Reported Series, The 6th Congress of The World Society for Reconstructive Microsurgery, WSRM 2011, 29 June-2 July, 2011, Helsinki, Finland

61. Successful Tongue Replantation Following Auto-Amputation Using Supermicrosurgical Technique, Poster Session, The 6th Congress of The World Society for Reconstructive Microsurgery, WSRM 2011, 29 June-2 July, 2011, Helsinki, Finland
62. The 13th Annual Chicago Trauma Symposium, August 25-28, 2011, Chicago, IL “Soft Tissue Defects-Getting Coverage”
63. WPATH: Pre-conference Symposium, September 24, 2011, Atlanta, GA “Surgical Options and Decision-Making”
64. American Society of Plastic Surgeons Annual Meeting, September 27, 2011, Denver, CO Closing Session Lunch and Learn: Pathways to Prevention-Avoiding Adverse Events, Part I: Patient Selection and Preventing Adverse Events in the Ambulatory Surgical Setting
65. American Society of Plastic Surgeons Annual Meeting, September 27, 2011, Denver, CO Closing Session Lunch and Learn: Pathways to Prevention-Avoiding Adverse Events, Part III: Preventing VTE
66. XXIV Congresso Nazionale della Societa Italiana di Microchirurgia congiunto con la American Society for Reconstructive Microsurgery, October 20-22, 2011, Palermo, Sicily: 3 Step Approach to Lower Extremity Trauma
67. XXIV Congresso Nazionale della Societa Italiana Microchirurgia congiunto con la American Society for Reconstructive Microsurgery, October 20-22, 2011, Palermo, Sicily: Applications of the Omentum for Limb Salvage: The Largest Reported Series
68. American Society for Reconstructive Microsurgery, Poster Presentation, January 14-17, 2012, Las Vegas, NV: Neonatal Limb Salvage: When Conservative Management is Surgical Intervention
69. The 14th Annual Chicago Trauma Symposium, August 2-5, 2012, Chicago, IL “Soft Tissue Defects-Getting Coverage”
70. The Annual Meeting of The American Society of Plastic Surgeons, October 25th-30, 2012, New Orleans, LA “Reimbursement in Breast Reconstruction”
71. The Annual Meeting of The American Society of Plastic Surgeons, October 25th-30, 2012, New Orleans, LA “Thriving in a New Economic Reality: Business Relationships and Integration in the Marketplace”
72. The 15th Annual Chicago Trauma Symposium, August 2-5, 2013, Chicago, IL “Soft Tissue Defects-Getting Coverage”
73. 2014 WPATH Symposium, Transgender Health from Global Perspectives, February 14-18, 2014, “Short Scar Chest Surgery.”

74. 2014 WPATH Symposium, Transgender Health from Global Perspectives, February 14-18, 2014, “Intestinal Vaginoplasty with Right and Left Colon.”
75. 24th Annual Southern Comfort Conference, September 3-7, 2014, Atlanta, Georgia, “Gender Confirmation Surgery: State of the Art.”
76. The 15th Annual Chicago Trauma Symposium, September 4-7, 2014, Chicago, IL “Soft Tissue Defects-Getting Coverage”
77. The Midwest Association of Plastic Surgeons, May 30, 2015, Chicago, IL “Gender Confirmation Surgery: A Single-Surgeon’s Experience”
78. The Midwest Association of Plastic Surgeons, May 30, 2015, Chicago, IL, Moderator, Gender Reassignment.
79. the American Society of Plastic Surgeons 2015 Professional Liability Insurance and Patient Safety Committee Meeting, July 17, 2015, “Gender Confirmation Surgery.”
80. The American Society of Plastic Surgeons, October 16-20, 2015, Boston, MA. From Fee-for-Service to Bundled Payments
81. The American Society of Plastic Surgeons, October 16-20, 2015, Boston, MA. Moderator, Transgender Surgery
82. The American Society of Plastic Surgeons, October 16-20, 2015, Boston, MA. Efficient Use of Physician Assistants in Plastic Surgery.
83. The American Society of Plastic Surgeons, October 16-20, 2015, Boston, MA. Patient Safety: Prevention of VTE
84. The World Professional Association for Transgender Health, Objective Quality Parameters for Gender Confirmation Surgery, June 18-22, 2016, Amsterdam, Netherlands
85. The World Professional Association for Transgender Health, Resident Education Curriculum for Gender Confirmation Surgery, June 18-22, 2016, Amsterdam, Netherlands
86. The World Professional Association for Transgender Health, Urologic Management of a Reconstructed Urethra(Poster session #195), June 18-22, 2016, Amsterdam, Netherlands
87. The World Professional Association for Transgender Health, Construction of a neovagina for male-to-female gender reassignment surgery using a modified intestinal vaginoplasty technique, poster session (Poster session #198), June 18-22, 2016, Amsterdam, Netherlands
88. Aesthetica Super Symposium, The American Society of Plastic Surgeons, Genital Aesthetics: What are we trying to achieve?, Washington, DC June 23-25, 2016

89. Aesthetica Super Symposium, The American Society of Plastic Surgeons, Female to Male Gender Reassignment, Washington, DC June 23-25, 2016
90. Aesthetica Super Symposium, The American Society of Plastic Surgeons, The journal of retractions, what I no longer do, Washington, DC June 23-25, 2016
91. Aesthetica Super Symposium, The American Society of Plastic Surgeons, The three minute drill, tips and tricks, Washington, DC June 23-25, 2016
92. Aesthetica Super Symposium, The American Society of Plastic Surgeons, Moderator, Mini master class: Male genital plastic surgery, Washington, DC June 23-25, 2016
93. The 16th Annual Chicago Trauma Symposium, August 18-21, 2016, Chicago, IL “Soft Tissue Defects-Getting Coverage”
94. USPATH Poster Session, Feb 2-5, 2017, Los Angeles, CA, Partial Flap Failure Five Weeks Following Radial Forearm Phalloplasty: Case Report and Review of the Literature
95. USPATH Poster Session, Feb 2-5, 2017, Los Angeles, CA, Urethroplasty for Stricture after Phalloplasty in Transmen Surgery for Urethral Stricture Disease after Radial Forearm Flap Phalloplasty—Management Options in Gender Confirmation Surgery
96. USPATH, Feb 2-5, 2017, Los Angeles, CA, Patient Evaluation and Chest Surgery in Transmen: A Pre-operative Classification
97. USPATH, Feb 2-5, 2017, Los Angeles, CA Single Stage Urethral Reconstruction in Flap Phalloplasty: Modification of Technique for Construction of Proximal Urethra
98. USPATH, Feb 2-5, 2017, Los Angeles, CA, Use of Bilayer Wound Matrix on Forearm Donor Site Following Phalloplasty
99. USPATH, Feb 2-5, 2017, Los Angeles, CA, Vaginoplasty: Surgical Techniques
100. USPATH, Feb 2-5, 2017, Los Angeles, CA, Positioning of a Penile Prosthesis with an Acellular Dermal Matrix Wrap following Radial Forearm Phalloplasty
101. USPATH, Feb 2-5, 2017, Los Angeles, CA, Principles for a Gender Surgery Program
102. USPATH, Feb 2-5, 2017, Los Angeles, CA, Construction of a Neovagina Using a Modified Intestinal Vaginoplasty Technique
103. The 18th Annual Chicago Orthopedic Symposium, July 6-9, 2017, Chicago, IL “Soft Tissue Defects-Getting Coverage”

104. The American Society of Plastic Surgeons Annual meeting, October 6-10, 2017, Orlando, FL, Moderator: Genital Surgery Trends for Women
105. The American Society of Plastic Surgeons Annual meeting, October 6-10, 2017, Orlando, FL, Adding Transgender Surgery to Your Practice, Moderator and Speaker
106. The American Society of Plastic Surgeons Annual meeting, October 6-10, 2017, Orlando, FL, Transbottom Surgery
107. 14th Congress of The European Federation of Societies for Microsurgery, Belgrade, May 5-8, 2018 A Novel Approach to IPP Implantation Post Phalloplasty: The Chicago Experience
108. 14th Congress of The European Federation of Societies for Microsurgery, Belgrade, May 5-8, 2018, A Novel Approach for Neovagina Configuration During Vaginoplasty for Gender Confirmation Surgery
109. 14th Congress of The European Federation of Societies for Microsurgery, Belgrade, May 5-8, 2018 Development of a Pelvic Floor Physical Therapy Protocol for Patients Undergoing Vaginoplasty for Gender Confirmation
110. 14th Congress of The European Federation of Societies for Microsurgery, Belgrade, May 5-8, 2018 Establishing Guidelines for Gender Confirmation Surgery: The Perioperative Risk of Asymptomatic Deep Venous Thrombosis for Vaginoplasty
111. The 19th Annual Chicago Trauma Symposium, August 16-19, 2018, Chicago, IL “Soft Tissue Defects-Getting Coverage”
112. Midwest LGBTQ Health Symposium, September 14-15, 2018, Chicago, IL “Quality Parameters in Gender Confirmation Surgery”
113. 25th WPATH Symposium, November 2-6, 2018, Buenos Aires, Argentina, Poster Session, Proposed Guidelines for Medical Tattoo Following Phalloplasty; An Interdisciplinary Approach
114. 25th WPATH Symposium, November 2-6, 2018, Buenos Aires, Argentina, Establishment of the First Gender Confirmation Surgery Fellowship
115. 25th WPATH Symposium, November 2-6, 2018, Buenos Aires, Argentina, ISSM Lecture, The Importance of Surgical Training
116. 25th WPATH Symposium, November 2-6, 2018, Buenos Aires, Argentina, Tracking Patient-Reported Outcomes in Gender Confirmation Surgery
117. “Theorizing the Phantom Penis,” The Psychotherapy Center for Gender and Sexuality’s 6th Biannual Conference, Transformations, March 29-March 30, 2019, NY, NY

INSTRUCTIONAL COURSES:

1. Emory University and WPATH: Contemporary Management of Transgender Patients: Surgical Options and Decision-Making, September 5, 2007 Chicago, IL
2. Craniomaxillofacial Trauma Surgery: An Interdisciplinary Approach, February 16-17, 2008, Burr Ridge, IL
3. Societa Italiana Di Microchirurgia, XXIII Congresso Nazionale della Societa Italiana di Microchirurgia, First Atlanto-Pacific Microsurgery Conference, Modena, Italy, October 1-3, 2009, Moderator: Free Papers, Lower Extremity
4. American Society of Plastic Surgeons Annual Meeting, October 23-27, 2009, Seattle, WA, Moderator: ASPS/ASPSN Patient Panel: Effective Communication-A Key to Patient Safety and Prevention of Malpractice Claims
5. American Society of Plastic Surgeons Annual Meeting, October 23-27, 2009, Seattle, WA, Instructional Course: Strategies to Identify and Prevent Errors and Near Misses in Your Practice
6. American Society of Plastic Surgeons Annual Meeting, October 23-27, 2009, Seattle, WA, Roundtable Discussion: Electronic Health Records-Implications for Plastic Surgeons
7. 10th Congress of The European Federation of Societies for Microsurgery, May 2—22, 2010, Genoa, Italy, “The Mangled Lower Extremities: An Algorithm for Soft Tissue Reconstruction.”
8. Multispecialty Course for Operating Room Personnel-Craniomaxillofacial, Orthopaedics, and Spine, A Team Approach, AO North American, June 26-27, 2010, The Westin Lombard Yorktown Center.
9. Management of Emergency Cases in the Operating Room, The American Society of Plastic Surgeons Annual Meeting, October 4, 2010, Toronto, CA.
10. Surgical Approaches and Techniques in Craniomaxillofacial Trauma, November 6, 2010, Burr Ridge, IL.
11. The Business of Reconstructive Microsurgery: Maximizing Economic value (Chair)The American Society for Reconstructive Microsurgery, January 14-17, 2012, Las Vegas, Nevada.
12. Strategies to Identify and Prevent Errors and Near Misses in Your Practice, The Annual Meeting of The American Society of Plastic Surgeons, October 25th-30th, 2012, New Orleans, LA
13. Strategies to Identify and Prevent Errors and Near Misses in Your Practice, The Annual Meeting of The American Society of Plastic Surgeons, October 11th-15th, 2013, San Diego, CA

14. Mythbusters: Microsurgical Breast Reconstruction in Private Practice, The Annual Meeting of The American Society of Plastic Surgeons, October 11th-15th, 2013, San Diego, CA
15. Minimizing Complications in Perioperative Care, The American Society for Reconstructive Microsurgery, January 11-14, 2014, Kauai, Hawaii
16. Genitourinary and Perineal Reconstruction, The American Society for Reconstructive Microsurgery, January 11-14, 2014, Kauai, Hawaii
17. Transgender Breast Surgery, The American Society of Plastic Surgeons, October 16-20, 2015, Boston, MA
18. Gender Confirmation Surgery, The School of the Art Institute (recipient of American College Health Fund's Gallagher Koster Innovative Practices in College Health Award), October 27, 2015, Chicago, IL
19. Transgender Health: Best Practices in Medical and Mental Health Care. A WPATH Certified Training Course, November 5-7, 2015, Chicago, IL Overview of Surgical Treatment Options
20. Transgender Health: Best Practices in Medical and Mental Health Care. A WPATH Certified Training Course, November 5-7, 2015 Chicago, IL Surgical Procedures
21. Transgender Health: Best Practices in Medical and Mental Health Care. A WPATH Certified Training Course, November 5-7, 2015, Chicago, IL Surgical Complications
22. Transgender Health: Best Practices in Medical and Mental Health Care. A WPATH Certified Training Course, November 5-7, 2015, Chicago, IL Post-operative Care
23. Transgender Health: Best Practices in Medical and Mental Health Care. A WPATH Certified Training Course, November 5-7, 2015, Chicago, IL Case Discussions: The Multidisciplinary Team
24. Transgender Health: Best Practices in Medical and Mental Health Care. A WPATH Certified Training Course, January 20-23, 2016, Atlanta, GA Overview of Surgical Treatment Options
25. Transgender Health: Best Practices in Medical and Mental Health Care. A WPATH Certified Training Course, January 20-23, 2016, Atlanta, GA Surgical Treatment Options
26. Transgender Health: Best Practices in Medical and Mental Health Care. A WPATH Certified Training Course, March 30-April 1, 2016, Springfield, MO, Surgical Treatment Options.

27. Transgender Health: Best Practices in Medical and Mental Health Care. A WPATH Certified Training Course, March 30-April 1, 2016, Springfield, MO, Multi-disciplinary Case Discussion.
28. Introduction to Transgender Surgery, ASPS Breast Surgery and Body Contouring Symposium, Santa Fe, NM, August 25-27, 2016
29. Transgender Health: Best Practices in Medical and Mental Health Care. A WPATH Global Education Initiative Advanced Training Course, September 28, 2016, Ft. Lauderdale, FL.
30. Cirugias de Confirmacion de Sexo Paso a Paso, XXXV Congreso Confederacion Americana de Urologia (CAU), Panama City, Panama, October 4-8, 2016.
31. Transgender Health: Best Practices in Medical and Mental Health Care. A WPATH Global Education Initiative Advanced Training Course, December 3, 2016, Arlington, VA.
32. PSEN (sponsored by ASPS and endorsed by WPATH), Transgender 101 for Surgeons, January 2017-March 2017
33. Surgical Anatomy and Surgical Approaches to M-to-F Genital Gender Affirming Surgery and the Management of the Patient Before, During and After Surgery: A Human Cadaver Based Course, Orange County, CA, Feb. 1, 2017
34. Gender Confirmation Surgery, ALAPP, 2 Congreso Internacional de la Asociacion Latinoamericana de Piso Pelvico, Sao Paulo, Brasil, 9-11 de marzo de 2017
35. Transgender Health: Best Practices in Medical and Mental Health Care. A WPATH Global Education Initiative Foundations Training Course, Overview of Surgical Treatment, March 31-April 2, 2017, Minneapolis Minnesota.
36. Transgender Health: Best Practices in Medical and Mental Health Care. A WPATH Global Education Initiative Foundations Training Course, The Multi-Disciplinary Team Case Discussions, March 31-April 2, 2017, Minneapolis Minnesota.
37. Transfeminine Cadaver Course, WPATH, May 19-20, 2017, Chicago, IL
38. Transgender/Penile Reconstruction-Penile Reconstruction: Radial Forearm Flap Vs. Anterolateral Thigh Flap, Moderator and Presenter, The World Society for Reconstructive Microsurgery, June 14-17, 2017, Seoul, Korea
39. Primer of Transgender Breast Surgery, ASPS Breast Surgery and Body Contouring Symposium, San Diego, CA, August 10-12, 2017
40. Confirmation Surgery in Gender Dysphoria: current state and future developments, International Continence Society, Florence, Italy, September 12-15, 2017

41. The American Society of Plastic Surgeons Annual meeting, October 6-10, 2017, Orlando, FL, ASPS/WPATH Joint Session, Session Planner and Moderator
42. Transgender Health: Best Practices in Medical and Mental Health Care. A WPATH Global Education Initiative Foundations Training Course: Overview of Surgical Treatment, Columbus, OH, October 20-21, 2017
43. Transgender Health: Best Practices in Medical and Mental Health Care. A WPATH Global Education Initiative Advanced Training Course: Medical Care in the Perioperative Period, Aftercare: Identifying Potential Complications, Columbus, OH, October 20-21, 2017
44. Webinar: Gender Affirming Surgeries 101: Explore The Latest Topics in Gender Affirmation Surgery, PSEN, April 18, 2018
45. Course Director: MT. Sinai/WPATH Live Surgery Training Course for Gender Affirmation Procedures, April 26-28, 2018, New York, NY
46. Philadelphia Trans Wellness Conference, Perioperative Care of the Transgender Woman Undergoing Vaginoplasty (Workshop), Philadelphia, PA, August 3, 2018
47. Philadelphia Trans Wellness Conference, Gender Confirmation Surgery (Workshop), Philadelphia, PA, August 3, 2018
48. Gender Confirmation Surgery, 2018 Oral and Written Board Preparation Course, The American Society of Plastic Surgeons, August 16-18, 2018, Rosemont, IL
49. Confirmation Surgery in Gender Dysphoria: Current State and Future Developments, The International Continence Society, Philadelphia, PA August 28, 2018
50. WPATH Global Education Initiative, Foundations Training Course, "Overview of Surgical Treatment," Cincinnati, OH, September 14-15, 2018
51. WPATH Global Education Initiative, Foundations Training Course, "The Multi-Disciplinary Team: Case Discussions," Cincinnati, OH, September 14-15, 2018
52. WPATH Global Education Initiative, Advanced Training Course, "Medical Care in the Perioperative Period After Care: Identifying Potential Complications," Cincinnati, OH, September 14-15, 2018
53. 25th WPATH Symposium, Surgeons Conference, November 1, 2018, Buenos Aires, Argentina, Moderator
54. 25th WPATH Symposium, November 2-6, 2018, Buenos Aires, Argentina, Global Education Initiative (GEI): Surgery and Ethics

55. WPATH GEI: Best Practices in Medical and Mental Health Care, Foundations in Surgery, New Orleans, March 22, 2019
56. WPATH GEI: Best Practices in Medical and Mental Health Care, Advanced Surgery, New Orleans, March 22, 2019
57. Program Chair: ASPS/WPATH GEI Inaugural Gender-Affirming Breast, Chest, and Body Master Class, Miami, Fl, July 20, 2019
58. Overview of Surgical Management and The Standards of Care (WPATH, v. 7) ASPS/WPATH GEI Inaugural Gender-Affirming Breast, Chest, and Body Master Class, Miami, Fl, July 20, 2019
59. Program Director, Gender Affirming Breast, Chest, and Body Master Class, The American Society of Plastic Surgeons, Miami, Fl, July 20, 2019
60. Gender Confirmation Surgery, The American Society of Plastic Surgeons Oral and Written Board Preparation Course, August 15, 2019, Rosemont, Il
61. Upper Surgeries (chest surgery & breast augmentation), WPATH, Global Education Initiative, September 4-5, 2019, Washington, DC
62. Preparing for Upper Surgeries-Case Based (chest surgery & breast augmentation), WPATH, Global Education Initiative, September 4-5, 2019, Washington, DC
63. Preparing for Feminizing Lower Surgeries-Case Based (vaginoplasty), WPATH, Global Education Initiative, September 4-5, 2019, Washington, DC
64. Lower Surgeries-Masculinizing (phalloplasty & metoidioplasty), WPATH, Global Education Initiative, September 4-5, 2019, Washington, DC
65. Preparing for Masculinizing Lower Surgeries-Case Based (phalloplasty & metoidioplasty), WPATH, Global Education Initiative, September 4-5, 2019, Washington, DC
66. Panel Discussion about Ethics in Surgery and Interdisciplinary Care, WPATH, Global Education Initiative, September 4-5, 2019, Washington, DC
67. Discussion about Ethics and Tensions in Child and Adolescent Care, WPATH, Global Education Initiative, September 4-5, 2019, Washington, DC
68. Transgender Health: Best Practices in Medical and Mental Health Care Foundation Training Courses, Hanoi, Viet Nam, Jan 14-17, 2020 (Foundations in Surgery, Advanced Medical-surgery and complicated case studies), Planning & Documentation (upper surgeries-chest surgery and breast augmentation, preparing for upper surgeries-case based (chest surgery and breast augmentation), lower surgeries (feminizing-vaginoplasty), preparing for feminizing lower surgeries-case based, lower surgeries-masculinizing (phalloplasty and metoidioplasty), preparing

for masculinizing lower surgeries-case-based (phalloplasty and metoidioplasty), Ethics-panel discussion about ethics in surgery and interdisciplinary care)

69. WPATH GEI Panel Cases Discussion, via Webinar, May 29, 30, 31, 2020
70. WPATH GEI: Illinois Dept. of Corrections, Foundations in Surgery, November 20, 2020
71. WPATH GEI: Illinois Dept. of Corrections, Ethical Considerations in Transgender Healthcare, November 20, 2020
72. WPATH GEI: Illinois Dept. of Corrections, Foundations in Surgery, February 26, 2021
73. WPATH GEI: Illinois Dept. of Corrections, Ethical Considerations in Transgender Healthcare, February 26, 2021.
74. Current Concepts in Gender Affirming Surgery for Women in Transition, March 11-12, 2021 (online event), Moderator, Transgender Health.
75. GEI Foundations Course, Live Q&A, March 21, 2021
76. GEI Foundations Course, Live Case Panel Discussion, March 23, 2021
77. GEI Advanced Ethics Workshop; Surgical and Interdisciplinary care ethics panel, May 1, 2021 (virtual)
78. Wpath GEI Foundations course for the Illinois Dept of Corrections, Foundations in Surgery, May 21, 2021
79. Wpath GEI, Foundations course for the Illinois Dept of Corrections, Ethical considerations in Transgender Healthcare, May 21, 2021
80. WPATH GEI, Online GEI Foundations Course, Moderator, August 31, 2001.
81. WPATH Health Plan Provider (HPP) Training, Q&A Panel, September 13, 14, 21 2021, via Zoom
82. WPATH, GEI Advanced Medical Course, Upper and Lower Surgery (via zoom), December 9, 2021

SYMPOSIA:

1. Program Director, 2011 Chicago Breast Symposium, October 15, 2011, The Chicago Plastic Surgery Research Foundation and The Chicago Medical School at Rosalind Franklin University, North Chicago, IL,

2. Fundamentals of Evidence-Based Medicine & How to Incorporate it Into Your Practice, Challenging Complications in Plastic Surgery: Successful Management Strategies, The American Society of Plastic Surgeons, July 13-14, 2012 Washington, DC
3. Understanding Outcome Measures in Breast & Body Contouring Surgery, Challenging Complications in Plastic Surgery: Successful Management Strategies, The American Society of Plastic Surgeons, July 13-14, 2012 Washington, DC
4. Benchmarking Complications: What We Know About Body Contouring Complication Rates from Established Databases, Challenging Complications in Plastic Surgery: Successful Management Strategies, The American Society of Plastic Surgeons, July 13-14, 2012 Washington, DC
5. Special Lecture: VTE Prophylaxis for Plastic Surgery in 2011, Challenging Complications in Plastic Surgery: Successful Management Strategies, The American Society of Plastic Surgeons, July 13-14, 2012 Washington, DC
6. Nipple Sparing Mastectomy: Unexpected Outcomes, Challenging Complications in Plastic Surgery: Successful Management Strategies, The American Society of Plastic Surgeons, July 13-14, 2012 Washington, DC
7. Program Director, 2011 Chicago Breast Symposium, October 13-14, 2012, The Chicago Plastic Surgery Research Foundation and The Chicago Medical School at Rosalind Franklin University, North Chicago, IL
8. Practice Strategies in a Changing Healthcare Environment, Moderator, Midwestern Association of Plastic Surgeons, April 27-28, 2013, Chicago, IL
9. Moderator: Breast Scientific Paper Session, The Annual Meeting of The American Society of Plastic Surgery, October 12, 2014, Chicago, IL.
10. Moderator: The World Professional Association for Transgender Health, Tuesday, June 21, Surgical Session (0945-1045), June 18-22, 2016, Amsterdam, Netherlands
11. Course Director: Transmale Genital Surgery: WPATH Gender Education Initiative, October 21-22, 2016 Chicago, IL
12. Co-Chair and Moderator: Surgeon's Only Session, USPATH, Los Angeles, CA, Feb. 2, 2017
13. Vascular Anastomosis: Options for Lengthening Vascular Pedicle, Surgeon's Only Session, USPATH, Los Angeles, CA, Feb. 2, 2017
14. Transgender Healthcare Mini-Symposium, Chicago Medical School of Rosalind Franklin University, North Chicago, IL March 10, 2017.

15. Moderator: Penile Transplant: Genito-urinary trauma/penile cancer, The European Association of Urologists, Meeting of the EAU Section of Genito-Urinary Reconstructive Surgeons (ESGURS), London, United Kingdom, March 23-26, 2017
16. 25th WPATH Symposium, November 2-6, 2018, Buenos Aires, Argentina, Mini-Symposium: A Comprehensive Approach to Gender Confirming Surgery
17. Program Director, 2nd Annual Live Surgery Conference for Gender Affirmation Procedures, Ichan School of Medicine at Mt. Sinai, NY, NY February 28, 2019-March 2, 2019.
18. Moderator, “Genital Reassignment for Adolescents: Considerations and Conundrums,” Discussions on gender affirmation: surgery and beyond, Dignity Health Saint Francis Memorial Hospital and WPATH GEI, San Francisco, CA, May 30-June 1, 2019
19. Moderator, “Reconstructive Urology and Genitourinary Options in Gender Affirming Surgery,” Discussions on gender affirmation: surgery and beyond, Dignity Health Saint Francis Memorial Hospital and WPATH GEI, San Francisco, CA, May 30-June 1, 2019
20. Moderator, “Complications in Masculinizing Genital Reconstruction Surgery,” Dignity Health Saint Francis Memorial Hospital and WPATH GEI, San Francisco, CA, May 30-June 1, 2019
21. Moderator, “Preparing for Surgery and Recovery,” Dignity Health Saint Francis Memorial Hospital and WPATH GEI, San Francisco, CA, May 30-June 1, 2019
22. Discussant, “WPATH Standards of Care Version 8 Preview,” Dignity Health Saint Francis Memorial Hospital and WPATH GEI, San Francisco, CA, May 30-June 1, 2019
23. Program Coordinator, Surgeon’s Only Course, USPATH, September 5, 2019, Washington, DC
24. Master Series in Transgender Surgery 2020: Vaginoplasty and Top Surgery, course co-director, Mayo Clinic, Rochester, MN, August 7-8, 2020
25. WPATH 2020 Surgeons’ Program, Co-Chair, November 6-7, 2020, Virtual Symposium (due to covid-19 cancellation of Hong Kong meeting)
26. WPATH Journal Club #3, Uterine Transplantation and Donation in Transgender Individuals; Proof of Concept, December 13, 2021 (Zoom)

FACULTY SPONSORED RESEARCH:

1. Societa Italiana Di Microchirurgia, XXIII Congresso Nazionale della Societa Italiana di Microchirurgia, First Atlanto-Pacific Microsurgery Conference, Modena, Italy, October 1-3, 2009, “Free Tissue Transfer in the Treatment of Zygomycosis.” Presented by Michelle Roughton, MD

2. Hines/North Chicago VA Research Day, Edward Hines, Jr., VA Hospital, Maywood, IL, April 29, 2010, "Breast MRI Helps to Define the Blood Supply to the Nipple-Areolar Complex." Presented by Iris A. Seitz, MD, PhD.
3. Advocate Research Forum, Advocate Lutheran General Hospital, May 5, 2010, "Breast MRI Helps to Define the Blood Supply to the Nipple-Areolar Complex." Presented by Iris A. Seitz, MD, PhD.
4. Advocate Research Forum, Advocate Lutheran General Hospital, May 5, 2010, "Achieving Soft Tissue Coverage of Complex Upper and Lower Extremity Defects with Omental Free Tissue Transfer." Presented by Iris A. Seitz, MD, PhD.
5. Advocate Research Forum, Advocate Lutheran General Hospital, May 5, 2010, "Facilitating Harvest of the Serratus Fascial Flap with Ultrasonic Dissection." Presented by Iris A. Seitz, MD, PhD.
6. Advocate Research Forum, Advocate Lutheran General Hospital, May 5, 2010, "Patient Safety: Abdominoplasty and Intra-Abdominal Procedures." Presented by Michelle Roughton, MD
7. The Midwestern Association of Plastic Surgeons, 49th Annual Scientific Meeting, May 15th, 2010, "Breast MRI Helps Define The Blood Supply to the Nipple-Areolar Complex." Presented by Iris A. Seitz, MD, PhD.
8. Jonathan M. Hagedorn, BA, **Loren S. Schechter**, MD, FACS, Dr. Manoj R. Shah, MD, FACS, Matthew L. Jimenez, MD, Justine Lee, MD, PhD, Varun Shah. Re-examining the Indications for Limb Salvage, 2011 All School Research Consortium at Rosalind Franklin University. Chicago Medical School of Rosalind Franklin University, 3/16/11.
9. Jonathan Bank, MD, Lucio A. Pavone, MD, Iris A. Seitz, Michelle C. Roughton, MD, Loren S. Schechter, MD Deep Inferior Epigastric Perforator Flap for Breast Reconstruction after Abdominoplasty The Midwestern Association of Plastic Surgeons, 51st Annual Educational Meeting, April 21-22, 2012, Northwestern Memorial Hospital, Chicago, Illinois
10. Samuel Lake, Iris A. Seitz, MD, PhD, Loren S. Schechter, MD, Daniel Peterson, PhD Omentum and Subcutaneous Fat Derived Cell Populations Contain hMSCs Comparable to Bone Marrow-Derived hMSCs First Place, Rosalind Franklin University Summer Research Poster Session
11. J. Siwinski, MS II, Iris A. Seitz, MD PhD, Dana Rioux Forker, MD, Lucio A. Pavone, MD, Loren S. Schechter, MD FACS. Upper and Lower Limb Salvage With Omental Free Flaps: A Long-Term Functional Outcome Analysis. Annual Dr. Kenneth A. Suarez Research Day, Midwestern University, Downers Grove, IL, May 2014

12. Whitehead DM, Kocjancic E, Iacovelli V, Morgantini LA, **Schechter LS**. A Case Report: Penile Prosthesis With an Alloderm Wrap Positioned After Radial Forearm Phalloplasty. Poster session presented at: American Society for Reconstructive Microsurgery Annual Meeting, 2018 Jan 13-16; Phoenix, AZ.

13. Whitehead DM, Kocjancic E, Iacovelli V, Morgantini LA, **Schechter LS**. An Innovative Technique: Single Stage Urethral Reconstruction in Female-to-Male Patients. Poster session presented at: American Society for Reconstructive Microsurgery Annual Meeting, 2018 Jan 13-16; Phoenix, AZ.

14. Whitehead, DM Inflatable Penile Prosthesis Implantation Post Phalloplasty: Surgical Technique, Challenges, and Outcomes, MAPS 2018 Annual Scientific Meeting, April 14, 2018, Chicago, IL

15. Whitehead, DM, Inverted Penile Skin With Scrotal Graft And Omission of Sacrospinal Fixation: Our Novel Vaginoplasty Technique MAPS 2018 Annual Scientific Meeting, April 14, 2018, Chicago, IL

16. S. Marecik, J. Singh. **L. Schechter**, M. Abdulhai, K. Kochar, J. Park, Robotic Repair of a Recto-Neovaginal Fistula in a Transgender Patient Utilizing Intestinal Vaginoplasty, The American College of Surgeons Clinical Congress 2020, October 7, 20

Keynote Address:

1. University of Utah, Gender Confirmation Surgery, Transgender Provider Summit, November 8, 2014

INVITED LECTURES:

1. Management of Soft Tissue Injuries of the Face, Grand Rounds, Emergency Medicine, The University of Chicago, August, 1999

2. Case Report: Excision of a Giant Neurofibroma, Operating Room Staff Lecture Series, Continuing Education Series, St. Francis Hospital, Evanston, IL March 2000

3. Wounds, Lincolnwood Family Practice, Lincolnwood, IL April 2000

4. The Junior Attending, Grand Rounds, Plastic and Reconstructive Surgery, The University of Chicago, June 2000

5. Case Report: Excision of a Giant Neurofibroma, Department of Medicine Grand Rounds, St. Francis Hospital, Evanston, IL June 2000

6. Facial Trauma, Resurrection Medical Center Emergency Medicine Residency, September 2000

7. Plastic Surgery of the Breast and Abdomen, Grand Rounds, Dept. of Obstetrics and Gynecology, Evanston Hospital, September, 2000
8. Change of Face; Is Cosmetic Surgery for You?, Adult Education Series, Rush North Shore Medical Center, October, 2000
9. Reconstructive Surgery of the Breast, Professional Lecture Series on Breast Cancer, St. Francis Hospital, October, 2000
10. Plastic Surgery of the Breast and Abdomen, Grand Rounds, Dept. of Obstetrics and Gynecology, Lutheran General Hospital, December, 2000
11. Change of Face; Is Cosmetic Surgery for You?, Adult Education Series, Lutheran General Hospital and The Arlington Heights Public Library, December, 2000
12. Updates in Breast Reconstruction, The Breast Center, Lutheran General Hospital, January 2001
13. Abdominal Wall Reconstruction, Trauma Conference, Lutheran General Hospital, February 2001
14. Wound Care, Rush North Shore Medical Center, March 2001
15. Breast Reconstruction, Diagnosis and Treatment Updates on Breast Cancer, Lutheran General Hospital, April 2001
16. Wound Care and V.A.C. Therapy, Double Tree Hotel, Skokie, IL October 2001
17. The Role of the V.A.C. in Reconstructive Surgery, LaCrosse, WI November 2001
18. Dressing for Success: The Role of the V.A.C. in Reconstructive Surgery, Grand Rounds, The University of Minnesota Section of Plastic and Reconstructive, Minneapolis, MN January, 2002
19. The Vacuum Assisted Closure Device in the Management of Complex Soft Tissue Defects, Eau Claire, WI February, 2002
20. The Vacuum Assisted Closure Device in Acute & Traumatic Soft Tissue Injuries, Orland Park, IL March, 2002
21. Body Contouring After Weight Loss, The Gurnee Weight Loss Support Group, Gurnee, IL April, 2002
22. An Algorithm to Complex Soft Tissue Reconstruction With Negative Pressure Therapy, Owensboro Mercy Medical Center, Owensboro, KY, April, 2002

23. Breast and Body Contouring, St. Francis Hospital Weight Loss Support Group, Evanston, Il April, 2002
24. The Wound Closure Ladder vs. The Reconstructive Elevator, Surgical Grand Rounds, Lutheran General Hospital, Park Ridge, Il, May, 2002.
25. An Algorithm for Complex Soft Tissue Reconstruction with the Vacuum Assisted Closure Device, The Field Museum, Chicago,Il, May, 2002
26. The Role of Negative Pressure Wound Therapy in Reconstructive Surgery, Kinetic Concepts, Inc. San Antonio, Texas, July 31, 2002
27. Management of Complex Soft Tissue Injuries of the Lower Extremity, Chicago Trauma Symposium, August 2-5, 2002, Chicago, Illinois:
28. Wound Bed Preparation, Smith Nephew, Oak Brook, Il, August 6, 2002
29. Getting Under Your Skin...Is Cosmetic Surgery for You?, Rush North Shore Adult Continuing Education Series, Skokie, Il August 28, 2002.
30. The Role of Negative Pressure Therapy in Complex Soft Tissue Wounds, Columbia/St. Mary's Wound, Ostomy, and Continence Nurse Program, Milwaukee, Wi, September 17, 2002
31. A Systematic Approach to Functional Restoration, Grand Rounds, Dept. of Physical Therapy and Rehabilitation Medicine, Lutheran General Hospital, September 19, 2002
32. The Role of Negative Pressure Wound Therapy in Reconstructive Surgery, Ann Arbor, Mi September 26, 2002
33. Dressing for Success: The Role of the Vacuum Assisted Closure Device in Plastic Surgery, Indianapolis, In November 11, 2002
34. The Wound Closure Ladder Versus the Reconstructive Elevator, Crystal Lake, Il November 21, 2002
35. A Systematic Approach to Functional Restoration, Grand Rounds, Dept. of Physical Therapy, Evanston Northwestern Healthcare, Evanston, Il February 13, 2003
36. Case Studies in Traumatic Wound Reconstruction, American Association of Critical Care Nurses, Northwest Chicago Area Chapter, Park Ridge, Il February 19, 2003
37. Reconstruction of Complex Soft Tissue Injuries of the Lower Extremity, Podiatry Lecture Series, Rush North Shore Medical Center, Skokie, Il March 5, 2003
38. The Use of Negative Pressure Wound Therapy in Reconstructive Surgery, Kalamazoo, Mi March 19, 2003

39. Updates in Breast Reconstruction, The Midwest Clinical Conference, The Chicago Medical Society, Chicago, Il March 21, 2003
40. Updates of Vacuum Assisted Closure, Grand Rounds, The Medical College of Wisconsin, Department of Plastic Surgery, Milwaukee, Wi March 26, 2003
41. Breast Reconstruction, Surgical Grand Rounds, Lutheran General Hospital, Park Ridge, Il March 27, 2003
42. Decision-Making in Breast Reconstruction: Plastic Surgeons as Members of a Multi-Disciplinary Team, 1st Annual Advocate Lutheran General Hospital Breast Cancer Symposium, Rosemont, Il, April 11, 2003
43. The Wound Closure Ladder Versus The Reconstructive Elevator, Duluth, Mn, April 24, 2003
44. Dressing For Success: The Role of The Wound VAC in Reconstructive Surgery, Detroit, Mi, May 9, 2003
45. Plastic Surgery Pearls, Grand Rounds Orthopedic Surgery Physician Assistants Lutheran General Hospital and Finch University of Health Sciences, Park Ridge, Il, June 5, 2003
46. A Systematic Approach to Complex Reconstruction, 12th Annual Vendor Fair “Surgical Innovations,” October 18, 2003, Lutheran General Hospital, Park Ridge, Il 2003
47. Dressing For Success: The Role of the Wound VAC in Reconstructive Surgery, American Society of Plastic Surgery, October 26, 2003, San Diego, CA
48. Beautiful You: From Botox to Weekend Surgeries, 21st Century Cosmetic Considerations, March 21, 2004 Hadassah Women’s Health Symposium, Skokie, Il
49. Updates in Breast Reconstruction, The 2nd Annual Breast Cancer Symposium, Advocate Lutheran General, Hyatt Rosemont, April 2, 2004
50. Head and Neck Reconstruction, Grand Rounds, The University of Illinois Metropolitan Group Hospitals Residency in General Surgery, Advocate Lutheran General Hospital, May 6, 2004
51. Abdominal Wall Reconstruction, Surgeons Forum, LifeCell Corporation, May 15, 2004, Chicago, Il
52. 4th Annual Chicagoland Day of Sharing for Breast Cancer Awareness, Saturday, October 2, 2004, Hoffman Estates, Il

53. Abdominal Wall Reconstruction, University of Illinois Metropolitan Group Hospitals Residency in General Surgery, November 19, 2004, Skokie, Il
54. Advances in Wound Care, Wound and Skin Care Survival Skills, Advocate Good Samaritan Hospital, Tuesday, February 8, 2005, Downer's Grove, Il
55. Plastic Surgery: A Five Year Perspective in Practice, Grand Rounds, The University of Chicago, May 18, 2005, Chicago, Il
56. New Techniques in Breast Reconstruction, The Cancer Wellness Center, October 11, 2005 Northbrook, Il
57. Principles of Plastic Surgery; Soft Tissue Reconstruction of the Hand, Rehab Connections, Inc., Hand, Wrist, and Elbow Forum, October 28, 2005, Homer Glen, Il
58. Principles of Plastic Surgery, Lutheran General Hospital Quarterly Trauma Conference, November 9, 2005, Park Ridge, Il
59. Principles of Plastic Surgery, Continuing Medical Education, St. Francis Hospital, November 15, 2005, Evanston, Il
60. Dressing for Success: A Seven Year Experience with Negative Pressure Wound Therapy, Kinetic Concepts Inc, November 30, 2005, Glenview, Il.
61. Breast Reconstruction: The Next Generation, Breast Tumor Conference, Lutheran General Hospital, May 9, 2006.
62. Complex Wound Care: Skin Grafts, Flaps, and Reconstruction, The Elizabeth D. Wick Symposium on Wound Care, *Current Concepts in Advanced Healing: An Update*, Rush North Shore Medical Center, November 4, 2006.
63. An Approach to Maxillofacial Trauma: Grand Rounds, Lutheran General Hospital/Univ. of Illinois Metropolitan Group Hospital Residency in General Surgery, November 9, 2006.
64. "From Paris to Park Ridge", Northern Trust and Advocate Lutheran General Hospital, Northern Trust Bank, June 7, 2007.
65. "Private Practice Plastic Surgery: A Seven Year Perspective," Grand Rounds, The University of Chicago, Section of Plastic Surgery.
66. "Meet the Experts on Breast Cancer," 7th Annual Chicagoland Day of Sharing, Sunday, April 13th, 2008
67. Gender Confirmation Surgery: Surgical Options and Decision-Making, The University of Minnesota, Division of Human Sexuality, May 10, 2008, Minneapolis, Minnesota.

68. "Private Practice Plastic Surgery: A Seven Year Perspective," Grand Rounds, Loyola University, 2008 Section of Plastic Surgery.
69. "Management of Lower Extremity Trauma," Grand Rounds, The University of Chicago, Section of Plastic Surgery, October, 8, 2008.
70. "Concepts in Plastic Surgery: A Multi-Disciplinary Approach," Frontline Surgical Advancements, Lutheran General Hospital, November 1, 2008
71. "Surgical Techniques-New Surgical Techniques/Plastic Surgery/Prosthetics," Caldwell Breast Center CME Series, Advocate Lutheran General Hospital, November 12, 2008
72. "Genetics: *A Family Affair*" Panel Discussion: Predictive Genetic Testing, 23rd Annual Illinois Department of Public Health Conference, Oak Brook Hills Marriott Resort, Oak Brook, IL, March 18, 2009
73. "Gender Confirmation Surgery" Minnesota TransHealth and Wellness Conference, May 15, 2009, Metropolitan State University, Saint Paul, MN.
74. "The Role of Plastic Surgery in Wound Care, " Practical Wound Care A Multidisciplinary Approach, Advocate Lutheran General Hospital, October 9-10, 2009, Park Ridge, IL.
75. "In The Family," Panel, General Session III, 2009 Illinois Women's Health Conference, Illinois Dept. of Health, Office of Women's Health October 28-29, 2009, Oak Brook, IL.
76. "Patient Safety in Plastic Surgery," The University of Chicago, Section of Plastic Surgery, Grand Rounds, November 18, 2009.
77. "Compartment Syndrome," 6th Annual Advocate Injury Institute Symposium, Trauma 2009: Yes We Can!, November 19-20, 2009.
78. "Maxillofacial Trauma," 6th Annual Advocate Injury Institute Symposium, Trauma 2009: Yes We Can!, November 19-20, 2009.
79. "Management of Complex Lower Extremity Injuries," Grand Rounds, The Section of Plastic Surgery, The University of Chicago, December 16, 2009, Chicago, IL.
80. "Gender-Confirming MTF Surgery: Indications and Techniques," Working Group on Gender, New York State Psychiatric Institute, March 12, 2010
81. "Gender-Confirmation Surgery," Minnesota Trans Health and Wellness Conference, Metropolitan State University, St. Paul Campus, May 14th, 2010
82. "Physical Injuries and Impairments," Heroes Welcome Home The Chicago Association of Realtors, Rosemont, Illinois, May 25th, 2010.

83. "Genetics and Your Health," Hadassah Heals: Healing Mind, Body, & Soul, Wellness Fair, 2010, August 29, 2010, Wilmette, Illinois.
84. "GCS," Southern Comfort Conference 2010, September 6-11, 2010, Atlanta, GA.
85. "Gender Confirming Surgery," The Center, The LGBT Community Center, October 22, 2010 New York, NY.
86. "Gender Confirming Surgery," the Center, The LGBT Community Center, May 20, 2011, New York, NY.
87. "Gender Confirming Surgery," Roosevelt-St. Lukes Hospital, May 20, 2011, New York, NY
88. "Principles of Plastic Surgery," Learn about Ortho, Lutheran General Hospital, May 25, 2011, Park Ridge, Il.
89. "Forging Multidisciplinary Relationships in Private Practice," Chicago Breast Reconstruction Symposium 2011, September 9, 2011, Chicago, Il
90. "Gender Confirming Surgery," Minnesota TransHealth and Wellness Conference, Diverse Families: Health Through Community, September 10, 2011, Minneapolis, Minnesota
91. "Gender Confirming Surgery," University of Chicago, Pritzker School of Medicine, Anatomy Class, September 16, 2011, Chicago, Il
92. "Facial Trauma," 8th Annual Advocate Injury Institute Symposium, Trauma 2011: 40 years in the Making, Wyndham Lisle-Chicago, November 9-10, 2011
93. "Establishing a Community-Based Microsurgical Practice," QMP Reconstructive Symposium, November 18-20, 2011, Chicago, Il
94. "Surgery for Gender Identity Disorder," Grand Rounds, Dept. of Obstetrics and Gynecology, Northshore University Health System, December 7, 2011
95. "Managing Facial Fractures," Trauma Grand Rounds, Lutheran General Hospital, Park Ridge, Il July 17, 2012
96. "Principles of Transgender Medicine," The University of Chicago Pritzker School of Medicine, Chicago, Il, September 7, 2012
97. "State of the art breast reconstruction," Advocate Health Care, 11th Breast Imaging Symposium, January 26, 2013, Park Ridge, Il.
98. "State of the art breast reconstruction," Grand Rounds, Dept. of Surgery, Mount Sinai Hospital, April 25, 2013, Chicago, Il.

99. "Getting under your skin: is cosmetic surgery right for you?" Lutheran General Hospital community lecture series, May 7, 2013, Park Ridge, Il.
100. "Gender Confirming Surgery," University of Chicago, Pritzker School of Medicine, Anatomy Class, September 27, 2013, Chicago, Il
101. "State of the Art Breast Reconstruction," Edward Cancer Center, Edward Hospital, October 22, 2013, Naperville, Il
102. "Transgender Medicine and Ministry," Pastoral Voice, Advocate Lutheran General Hospital, October 23, 2013, Park Ridge, Il
103. "Principles of Transgender Medicine and Surgery," The University of Illinois at Chicago College of Medicine, January 28, 2014, Chicago, Il
104. "Principles of Transgender Medicine and Surgery," Latest Surgical Innovations and Considerations, 22nd Annual Educational Workshop, Advocate Lutheran General Hospital, March 1, 2014, Park Ridge, Il.
105. "Principles of Transgender Medicine: Gender Confirming Surgery," Loyola University Medical Center, March 12, 2014.
106. "Principles of Plastic Surgery," Grand Rounds, Dept. of Obstetrics and Gynecology, Lutheran General Hospital, September 12, 2014.
107. "Gender Confirmation Surgery," The University of Chicago, Pritzker School of Medicine, October 3, 2014
108. "Private Practice: Is There a Future?" The Annual Meeting of The American Society of Plastic Surgical Administrators/The American Society of Plastic Surgery Assistants, Chicago, Il, October 11, 2014.
109. "Private Practice: Is There a Future?" The Annual Meeting of The American Society of Plastic Surgery Nurses, Chicago, Il, October 12, 2014.
110. "Gender Confirmation Surgery" Grand Rounds, The University of Minnesota, Dept. of Plastic Surgery, Minneapolis, MN, October 29, 2014.
111. "Body Contour After Massive Weight Loss," The Bariatric Support Group, Advocate Lutheran General Hospital, February 5, 2015, Lutheran General Hospital, Park Ridge, Il.
112. "Gender Confirmation Surgery," The School of the Art Institute of Chicago, February 1, 2015, Chicago, Il.

113. "Gender Confirmation Surgery," The Community Kinship Life/Bronx Lebanon Department of Family Medicine, Bronx, NY, March 6, 2015
114. "Gender Confirmation Surgery," Educational Inservice, Lutheran General Hospital, Park Ridge, Il, April 20, 2015
115. "Principles of Plastic Surgery, " Surgical Trends, Lutheran General Hospital, Park Ridge, Il, May 16, 2015
116. "Updates on Gender Confirmation Surgery, " Surgical Trends, Lutheran General Hospital, Park Ridge, Il, May 16, 2015
117. "Gender Confirmation Surgery," Lurie Childrens' Hospital, Chicago, Il, May 18, 2015, Chicago, Il 2015.
118. "Gender Confirmation Surgery," TransClinical Care and Management Track Philadelphia Trans-Health Conference, June 5, 2015, Philadelphia, Pa.
119. "Gender Confirmation Surgery: A Fifteen Year Experience," Grand Rounds, The University of Minnesota, Plastic and Reconstructive Surgery and the Program in Human Sexuality, July 30, 2015, Minneapolis, Mn
120. "Gender Confirmation Surgery," Grand Rounds, Tel Aviv Medical Center, Tel Aviv, Israel, August 13, 2015
121. "Gender Confirmation Surgery," Grand Rounds, University of Illinois, Dept of Family Medicine, September 2, 2015
122. "Principles of Plastic Surgery," Grand Rounds, St. Francis Hospital, Evanston, Il September 18, 2015
123. "Gender Confirmation Surgery," Midwest LGBTQ Health Symposium, Chicago, Il, October 2, 2015
124. "Gender Confirmation Surgery," Southern Comfort Conference, Weston, Fl, October 3, 2015
125. "Surgical Transitions for Transgender Patients," Transgender Health Training Institute, Rush University Medical Center, Chicago, Il, October 8, 2015
126. "Gender Confirmation Surgery," The Transgender Health Education Peach State Conference, Atlanta, GA, October 30, 2015
127. "Gender Confirmation Surgery," Weiss Memorial Medical Center, November 4, 2015, Chicago, Il

128. "Gender Confirmation Surgery," University of Illinois at Chicago, Operating Room Staff Inservice, November 18, 2015, Chicago, IL
129. "Gender Confirmation Surgery," University of Illinois at Chicago, Plastic Surgery and Urology Inservice, November 18, 2015, Chicago, IL
130. "Gender Confirmation Surgery," Weiss Memorial Medical Center, November 19, 2015, Chicago, IL
131. "Gender Confirmation Surgery," Section of Plastic Surgery, The University of Illinois at Chicago, January 13, 2016, Chicago, IL
132. "Gender Confirmation Surgery," Dept. of Medicine, Louis A. Weiss Memorial Hospital, February 18, 2016, Chicago, IL
133. "Gender Confirmation Surgery," BCBSIL Managed Care Roundtable March 2, 2016 Chicago, IL
134. "Gender Confirmation Surgery-MtF," Keystone Conference, March 10, 2016, Harrisburg, PA
135. "Gender Confirmation Surgery-FtM," Keystone Conference, March 10, 2016, Harrisburg, PA
136. "Gender Confirmation Surgery," Grand Rounds, Dept. of Ob-Gyn, March 25, 2016, Lutheran General Hospital, Park Ridge, IL 60068
137. "Surgical Management of the Transgender Patient," Spring Meeting, The New York Regional Society of Plastic Surgeons, April 16, 2016, New York, NY
138. "A Three Step Approach to Complex Lower Extremity Trauma," University of Illinois at Chicago, April 27, 2016, Chicago, IL.
139. "Gender Confirmation Surgery," Howard Brown Health Center, July 12, 2016, Chicago, IL
140. "Creating the Transgender Breast M-F; F-M", ASPS Breast surgery and Body Contouring Symposium, Santa Fe, NM, August 25-27, 2016
141. "Overview of Transgender Breast Surgery," ASPS Breast surgery and Body Contouring Symposium, Santa Fe, NM, August 25-27, 2016
142. "VTE Chemoprophylaxis in Cosmetic Breast and Body Surgery: Science or Myth", ASPS Breast surgery and Body Contouring Symposium, Santa Fe, NM, August 25-27, 2016
143. "Gender Confirmation Surgery," Gender Program, Lurie Childrens', Parent Group, September 20, 201, 467 W. Deming, Chicago, IL

144. "Gender Confirmation Surgery," The American Society of Plastic Surgeons Expo, September 24, 2016, Los Angeles, CA
145. Transgender Surgery, Management of the Transgender Patient, Female to Male Surgery, Overview and Phalloplasty, The American College of Surgeons, Clinical Congress 2016 October 16-20, 2016 Washington, DC
146. "Gender Confirmation Surgery," The Department of Anesthesia, The University of Illinois at Chicago, November 9, 2016
147. "Gender Confirmation Surgery," The Division of Plastic Surgery, The University of Illinois at Chicago, December 14, 2016
148. "Gender Confirmation Surgery," Nursing Education, The University of Illinois at Chicago, January 10, 2017
149. "F2M-Radial Forearm Total Phalloplasty: Plastic Surgeon's Point of View," The European Association of Urologists, Meeting of the EAU Section of Genito-Urinary Reconstructive Surgeons (ESGURS), London, United Kingdom, March 23-26, 2017
150. "Gender Confirmation Surgery," Grand Rounds, The Department of Surgery, The University of North Carolina, March 29, 2017.
151. "Transgender Facial Surgery," *The Aesthetic Meeting 2017 – 50 Years of Aesthetics* - in San Diego, California April 27– May 2, 2017.
152. "Gender Confirmation Surgery: A New Surgical Frontier," 15th Annual Morristown Surgical Symposium Gender and Surgery, Morristown, NJ, May 5, 2017.
153. "Gender Confirmation Surgery: A New Surgical Frontier," Dept. of Obstetrics and Gynecology, The Medical College of Wisconsin, May 24, 2017
154. "Gender Confirmation Surgery: A New Surgical Frontier," Dept. of Obstetrics and Gynecology, Howard Brown Health Center, August 8, 2017
155. "Current State of the Art: Gynecomastia," ASPS Breast Surgery and Body Contouring Symposium, San Diego, CA, August 10-12, 2017
156. "Gender Confirmation Surgery-An Overview," ASPS Breast Surgery and Body Contouring Symposium, San Diego, CA, August 10-12, 2017
157. "Gender Confirmation Surgery," Grand Rounds, Dept. of Obstetrics and Gynecology, The University of Chicago, August 25, 2017

158. "Gender Confirmation Surgery," Wake Forest School of Medicine, Transgender Health Conference, Winston-Salem, NC, September 28-29, 2017
159. "Phalloplasty," Brazilian Professional Association for Transgender Health, Teatro Marcos Lindenberg, Universidade Federal de São Paulo (Unifesp), November 1-4, 2017
160. "Gender Confirmation Surgery," Brazilian Professional Association for Transgender Health/WPATH Session, Teatro Marcos Lindenberg, Universidade Federal de São Paulo (Unifesp), November 1-4, 2017
161. "Gender Confirmation Surgery," The Division of Plastic Surgery, The University of Illinois at Chicago, December 13, 2017, Chicago, IL
162. "Gender Confirmation Surgery," Gender and Sex Development Program, Ann and Robert H. Lurie Children's Hospital of Chicago, December 18, 2017, Chicago, IL
163. "Transgender Breast Augmentation," 34th Annual Atlanta Breast Surgery Symposium, January 19-21, 2018, Atlanta, GA
164. "Top Surgery: Transmasculine Chest Contouring," 34th Annual Atlanta Breast Surgery Symposium, January 19-21, 2018, Atlanta, GA
165. "Gender Confirmation Surgery," The 17th International Congress of Plastic and Reconstructive Surgery in Shanghai, March 18-25, 2018, Shanghai, China
166. "Gender Confirmation Surgery: Facial Feminization and Metoidioplasty," 97th Meeting of the American Association of Plastic Surgeons, Reconstructive Symposium, April 7-10, 2018, Seattle, WA
167. Moderator: "Gender Confirmation Surgery: Top Surgery", The Annual Meeting of The American Society of Aesthetic Plastic Surgery, April 26-May 1, 2018, New York, NY
168. "Gender Confirmation Surgery," Econsult monthly meeting, Dept. of Veterans' Affairs, May 24, 2018
169. "Gender Confirmation Surgery," Transgender Care Conference: Improving Care Across the Lifespan, Moses Cone Hospital, Greensboro, NC, June 8, 2018
170. "WPATH State of the Art," 1st Swiss Consensus Meeting on the Standardization of Sex Reassignment Surgery, The University of Basel, August 31, 2018-September 1, 2018
171. "Facial Feminization Surgery: The New Frontier?" 1st Swiss Consensus Meeting on the Standardization of Sex Reassignment Surgery, The University of Basel, August 31, 2018-September 1, 2018

172. “Current Techniques and Results in Mastectomies,” 1st Swiss Consensus Meeting on the Standardization of Sex Reassignment Surgery, The University of Basel, August 31, 2018-September 1, 2018
173. “Gender Confirmation Surgery,” The University of Chicago, Pritzker School of Medicine, September 7, 2018, Chicago, IL.
174. The Business End: Incorporating Gender Confirmation Surgery, Plastic Surgery The Meeting, Annual Meeting of The American Society of Plastic Surgeons, September 29, 2018, Chicago, IL
175. Body Contouring in Men, Gynecomastia, Plastic Surgery The Meeting, Annual Meeting of The American Society of Plastic Surgeons, September 30, 2018, Chicago, IL
176. Moderator: Breast Augmentation and Chest Surgery in Gender Diverse Individuals, Plastic Surgery The Meeting, Annual Meeting of The American Society of Plastic Surgeons, October 1, 2018, Chicago, IL
177. Moderator: Aesthetic Surgery of The Male Genitalia, Plastic Surgery The Meeting, Annual Meeting of The American Society of Plastic Surgeons, October 1, 2018, Chicago, IL
178. Moderator: Gender Confirmation Surgeries: The Standards of Care and Development of Gender Identity, Plastic Surgery The Meeting, Annual Meeting of The American Society of Plastic Surgeons, October 1, 2018, Chicago, IL
179. The Center for Gender Confirmation Surgery Lecture Series, “Introduction to Gender Confirmation Surgery,” Weiss Memorial Hospital, October 17, 2018, Chicago, IL
180. Institute 3: Gender Dysphoria Across Development: Multidisciplinary Perspectives on the Evidence, Ethics, and Efficacy of Gender Transition, Gender Confirming Care in Adolescence: Evidence, Timing, Options, and Outcomes, The American Academy of Child and Adolescent Psychiatry, 65th Annual Meeting, October 22-27, 2018, Seattle, WA
181. Gender Confirmation Surgery, Combined Endocrine Grand Rounds, The University of Illinois at Chicago, Rush University, Cook County Hospital, January 8, 2019
182. Gender Confirmation Surgery: An Update, Division of Plastic Surgery, The University of Illinois at Chicago, January 23, 2019
183. Gender Confirmation Surgery from Top to Bottom: A 20 Year Experience, Grand Rounds, The Department of Surgery, Ochsner Health System, January 30, 2019, New Orleans, LA
184. Master Series of Microsurgery: Battle of the Masters
One Reconstructive Problem – Two Masters with Two Different Approaches, Gender Affirmation, Male-to-Female Vaginoplasty: Intestinal Vaginoplasty, The American Society for Reconstructive Microsurgery, Palm Desert, California, February 2, 2019

185. Gender Confirmation Surgery: From Top to Bottom, The University of Toronto, Toronto, Canada, February 21, 2019
186. Gender Confirmation Surgery: Where are We, The University of Toronto, Toronto, Canada, February 21, 2019
187. Professors' Rounds: Gender Confirmation Surgery: A Twenty Year Experience, Princess Margaret Hospital, Toronto, Canada, February 22, 2019
188. A 3 Step Approach to Lower Extremity Trauma, Plastic Surgery at The Red Sea, Eilat, Israel, March 6-9, 2019.
189. Gender Surgery: Where are We Now?, Plastic Surgery at The Red Sea, Eilat, Israel, March 6-9, 2019.
190. Gender Confirmation Surgery, A Single Surgeon's 20 Year Experience, Plastic Surgery at The Red Sea, Eilat, Israel, March 6-9, 2019.
191. Gender Confirmation Surgery: Where We Have Been and Where We Are Going, Grand Rounds, The University of Chicago, Section of Plastic Surgery, March 13, 2019
192. Gender Confirmation Surgery: From Top To Bottom, Resident Core Curriculum Conference, The University of Chicago, Section of Plastic Surgery, March 13, 2019.
193. "Gender Confirmation Surgery," WPATH/AMSA Medical School Trans Health Elective, Webinar, March 13, 2019
194. Robotic Vaginoplasty: An Alternative to Penile Inversion Vaginoplasty in Cases of Insufficient Skin, Vaginal Stenosis, and Rectovaginal Fistula. The European Professional Association for Transgender Health, April 9-13, Rome, Italy
195. Current State of Gender-Affirming Surgery in the US and Beyond, Gender-affirming genital surgery presented by the American Urologic Association in collaboration with the Society for Genitourinary Reconstructive Surgeons (GURS), May 2, 2019, Chicago, IL
196. Surgical Training-How Can I get it, The Aesthetic Meeting 2019, New Orleans, LA, May 20, 2019
197. What is the Standard of Care in This New Frontier, The Aesthetic Meeting 2019, New Orleans, LA, May 20, 2019
198. The 20th Annual Chicago Orthopedic Symposium, August 15-18, 2019, Chicago, IL "Soft Tissue Defects-Getting Coverage"

199. Gender Confirmation Surgery, The Potocsnak Family Division of Adolescent and Young Adult Medicine, Ann & Robert H. Lurie Children's Hospital of Chicago, August 19, 2019
200. Anatomy, Embryology, and Surgery, The University of Chicago, First Year Medical Student Anatomy Lecture, September 9, 2019, The University of Chicago, Chicago, IL.
201. Gender Confirmation Surgery, Howard Brown Health Center Gender Affirming Learning Series, September 13, 2019, Chicago, IL.
202. Moderator, Patient Selection in Gender Affirming Surgery, 88th Annual Meeting of The American Society of Plastic Surgeons, September 20-23, 2019, San Diego, CA
203. Breast Augmentation in Transwomen: Optimizing Aesthetics and Avoiding Revisions, 88th Annual Meeting of The American Society of Plastic Surgeons, September 20-23, 2019, San Diego, CA
204. Breast Reconstruction, State of the Art, NYU-Langone Health, NYU School of Medicine, Standards of Care and Insurance Coverage, Saturday, November 23, 2019, New York, NY.
205. ASRM Masters Series in Microsurgery: Think Big, Act Small: The Building Blocks for Success, "Building a Microsurgery Private Practice from the Ground Up", 2020 ASRM Annual Meeting, Ft. Lauderdale, Florida, January 10-14, 2020
206. ASPS/ASRM Combined Panel II: Gender Affirmation Surgery: Reconstruction Challenges of Function and Sensation, 2020 ASRM Annual Meeting, Ft. Lauderdale, Florida, January 10-14, 2020
207. Rush University Medical Center, Division of Urology, Grand Rounds, "Gender Confirmation Surgery: A Single Surgeon's Experience," January 22, 2020
208. Rush University Medical Center, Department of General Surgery, Grand Rounds, "Gender Confirmation Surgery: A Single Surgeon's Experience," February 5, 2020.
209. WPATH/AMSA (American Medical Association) Gender Scholar Course, Webinar, March 11, 2020
210. Rush University Medical Center, Division of Plastic Surgery, Weekly Presentation, Gender Confirmation Surgery: Can a Surgeon Provide Informed Consent?, April 29, 2020
211. Legal Issues Faced by the Transgender Community, ISBA Standing Committee on Women and The Law and the ISBA Standing Committee on Sexual Orientation and Gender Identity, Co-Sponsored by the National Association of Women Judges District 8, Live Webinar, May 28, 2020
212. Principles of Transgender Surgery, National Association of Women's Judges, District 8, Webinar, June 4, 2020

- 213. Gender-Affirming Surgery, National Association of Women's Judges, District 8, Webinar, July 8, 2020
- 214. Gender-Affirming Surgery, The University of Chicago, Pritzker School of Medicine, 1st year Anatomy, September 15, 2020
- 215. Gender-Affirming Surgery, Rush University Medical School, 2nd year Genitourinary Anatomy, September 16, 2020.
- 216. Surgical Management of the Transgender Patient, Rosalind Franklin University, The Chicago Medical School, Plastic Surgery Interest Group, October 7, 2020
- 217. Breast Augmentation in Transgender Individuals, The American Society of Plastic Surgeons Spring Meeting, March 20, 2021
- 218. International Continence Society Institute of Physiotherapy Podcast 5-Pelvic Floor Most Common Disorders and Transgender Patients (recorded April 30, 2021)
- 219. The American Association of Plastic Surgeons Annual Meeting, Reconstructive Symposium, Gender Affirmation Panel, Complications of GCS, Miami, FL, May 15, 2021 (presented virtually)
- 220. Gender Confirmation Surgery, Grand Rounds, Rush University, Section of Urology, June 8, 2021.
- 221. Genitourinary introduction lecture, M2, Rush University School of Medicine, September 2, 2021 (by Zoom)
- 222. Demystifying Gender: Fostering Gender Friendly Healthcare, Gender Affirmative Care in Adults, Querencia (lady hardinge medical college, WHO Collaborating Center for Adolescent Health, Dept of Paediatrics, JSCH & LHMC, New Delhi, WPATH September 5, 2021 (by zoom)
- 223. Gender Confirmation Surgery, The University of Chicago Pritzker School of Medicine, MS-1, Anatomy lecture, September, 14, 2021, Chicago Il.
- 224. Gender Confirmation Surgery, A Single Surgeon's 22 Year Experience: Where are We Now?, Research Seminar, Section of Endocrinology, The University of Chicago, Chicago, Il, October 4, 2011 (by Zoom)
- 225. Chest Surgery, The Illinois Dept. of Corrections (by zoom), October 13, 2021.
- 226. Vaginoplasty, The Illinois Dept. of Corrections (by zoom), October 15, 2021.
- 227. International Continence Society, 20th Physioforum, Pelvic Floor Physical Therapy and Gender-Affirming Surgery, October 16, 2021, Melbourne, Australia (by Zoom)

228. Rush University Division of Plastic Surgery, Gender Affirmation Surgery: Where Are We Now?, educational conference, November 23, 2021, Chicago, IL

229. 51 Congreso Argentino de Cirugia Plastica, Microsurgery Symposium, SACPER-FILACP, 3 Step Approach to Lower Extremity Trauma, November 29, 2021, Mar del Plata, Argentina

230. 51 Congreso Argentino de Cirugia Plastica, Genital Aesthetics and Gender Confirmation Surgery I, “Gestión Quirúrgica de la Disforia de Género: Descripción general del manejo quirúrgico y los estándares de atención,”
December 1, 2021, Mar del Plata, Argentina

231. 51 Congreso Argentino de Cirugia Plastica, Genital Aesthetics and Gender Confirmation Surgery II, Cirugía Genital Masculinizante (Metoidioplastia y Faloplastia), December 2, 2021, Mar del Plata, Argentina

232. 51 Congreso Argentino de Cirugia Plastica, Genital Aesthetics and Gender Confirmation Surgery III, Faloplastia: optimización de resultados y reducción de complicaciones, December 2, 2021, Mar del Plata, Argentina

233. Government of India, Ministry of Health and Welfare, National AIDS Control Organization, Meeting with AIIMS on Gender Affirmation Care (GAC) Clinic Pilot Intervention, December 21, 2021, New Delhi (virtual)

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EXHIBIT E

FILED UNDER SEAL

EXHIBIT F

Transcript of the Testimony of

Dan H. Karasic, MD

Date: 7/13/2022

C.P. vs BLUE CROSS BLUE SHIELD OF ILLINOIS



Phone: (425) 866-4250
production@nelsonreporters.com
www.nelsonreporters.com

IN THE UNITED STATES DISTRICT COURT
FOR THE WESTERN DISTRICT OF WASHINGTON
AT TACOMA

C. P., by and through his	)	
parents, Patricia Pritchard,	)	
and Nolle Pritchard; and	)	
PATRICIA PRITCHARD,	)	
	)	
Plaintiffs,	)	
	)	
vs.	)	No. 3:20-cv-06145-RJB
	)	
BLUE CROSS BLUE SHIELD OF	)	
ILLINOIS,	)	
	)	
Defendant.	)	

REMOTE
VIDEOTAPED DEPOSITION UPON ORAL EXAMINATION OF
DAN H. KARASIC, MD
Wednesday, July 13, 2022 at 9:00 a.m.

Via Zoom Remote Videoconference
Witness location: San Francisco, California

SIERRA ZANGHI, RSR, CCR #22004202
NELSON COURT REPORTERS, INC.
6513 132nd Avenue NE, #184
Kirkland, Washington 98033
(425) 866-4250
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Dan H. Karasic, MD

7/13/2022

Page 2 1 A P P E A R A N C E S 2 3 FOR THE PLAINTIFFS: 4 OMAR GONZALEZ-PAGAN (Via videoconference) 5 Lambda Legal Defense and Education Fund, Inc. 6 120 Wall Street, 19th Floor 7 New York, NY 10005-3919 8 ogonzalez-pagan@lambdalegal.com 9 10 ELEANOR HAMBURGER (Via videoconference) 11 Sirianni Youtz Spoonemore Hamburger 12 3101 Western Avenue, Suite 350 13 Seattle, WA 98121 14 206-223-0303 15 ehamburger@sylaw.com 16 17 FOR THE DEFENDANT: 18 STEPHANIE N. BEDARD (Via videoconference) 19 Kilpatrick Townsend & Stockton LLP 20 1100 Peachtree NE, Suite 2800 21 Atlanta, Georgia 30309 22 sbedard@kilpatricktownsend.com 23 404-815-6039 24 25 ALSO PRESENT: 26 KURT SCHULTZ (Via videoconference) 27 Videographer 28 29 REED FERGUSON (Via videoconference) 30 Summer associate observing from Plaintiff's side	Page 4 1 E X H I B I T S (cont'd) 2 Exhibit 9, 12/6/2021 Psychological evaluation by 64 3 Steve Tutty, MA, PhD, Bates No. PLA 4 003064-003075 plus handwritten notes, 25 pages 5 Exhibit 10, Polyclinic records, Bates No. 78 6 Pritchard POL 000001-000078, 78 pages 7 Exhibit 11, 8/30/2016 CMS Decision Memo, 101 8 111 pages 9 Exhibit 12, 6/16/2020 Recommendation by COHERE 106 10 Finland, 2 pages 11 Exhibit 13, 5/1/2021 Guideline Regarding 110 12 Hormonal Treatment of Minors with Gender 13 Dysphoria at Tema Barn - Astrid Lindgren 14 Children's Hospital, 3 pages 15 Exhibit 14, February 2022, The Cass Review, 120 16 112 pages 17 Exhibit 15, June 2022 Florida Medicaid - 123 18 Generally Accepted Professional Medical 19 Standards Determination on the Treatment of 20 Gender Dysphoria, 46 pages 21 22 23 24 25
Page 3 1 I N D E X 2 Pritchard, et al, v. Blue Cross Blue Shield of Illinois 3 NO. 3:20-CV-06145-RJB 4 July 13, 2022 5 6 T E S T I M O N Y 7 DAN H. KARASIC, MD PAGE NO. 8 Examination by Atty. Bedard 6 9 Examination by Atty. Gonzalez-Pagan 131 10 11 12 E X H I B I T S 13 Exhibit 1, Deposition subpoena duces tecum to 8 14 Dan H. Karasic, M.D. for 7/13/2022, 9 pages 15 Exhibit 2, 6/16/2022 Expert Report of Dan H. 17 16 Karasic, M.D., 50 pages 17 Exhibit 3, Records from the Polyclinic, T-Scan 21 18 Corporation, Bates No. Pritchard POL 19 000112-000155, 46 pages 20 Exhibit 5, November 2017 Clinical Practice 50 21 Guideline by the Endocrine Society, from 22 the Journal of Clinical Endocrinology and 23 Metabolism, 35 pages 24 Exhibit 7, Medical Records from the Center for 56 25 Child and Family Therapy and the 26 Polyclinic, Bates No. PLA 000982-001003, 27 22 pages 28 Exhibit 8, Records from the Center for Child and 61 29 Family Therapy, Bates No. Pritchard 30 CFT 000001-000011, 11 pages 31 (Exhibits cont'd on next page)	Page 5 1 BE IT REMEMBERED that on Wednesday, July 13, 2 2022, in San Francisco, California, at 9:00 a.m., 3 via Zoom remote videoconference, the deposition of 4 DAN H. KARASIC, MD was taken before Sierra Zanghi, 5 Certified Court Reporter. The following proceedings 6 took place: 7 --o0o-- 8 THE VIDEOGRAPHER: Today is July 13th, 2022. 9 The time is 9:01 a.m. This is Volume I in the 10 deposition of Dr. Dan Karasic in the U.S. District 11 Court for the Western District in Tacoma in the 12 matter of C. P., et al, v. Blue Cross Blue Shield of 13 Illinois, Cause No. 3:20-cv-06145-RJB. 14 This is a remote Zoom deposition noticed by 15 Defense Attorney Stephanie Bedard. My name is Kurt 16 Schultz. I'm contracted by Royal Video Productions, 17 whose principal place of business is 950 Northwest 18 Firwood Boulevard, Issaquah, Washington 98027. The 19 phone number is 425-391-6809. 20 At this time, I would ask counsel to identify 21 themselves. 22 ATTY. BEDARD: Good morning. My name is 23 Stephanie Bedard. I'm counsel for Blue Cross Blue 24 Shield of Illinois. 25 ATTY. GONZALEZ-PAGAN: Good morning. Omar

Dan H. Karasic, MD

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Page 6 1 Gonzalez-Pagan, counsel for the plaintiffs with 2 Lambda Legal. 3 THE VIDEOGRAPHER: Thank you. Today's court 4 reporter is Sierra Zanghi of Nelson Court Reporters. 5 You may swear the witness in. 6 7 DAN H. KARASIC, being first duly sworn to tell 8 the truth, the whole truth, 9 and nothing but the truth 10 testified as follows: 11 12 EXAMINATION 13 BY ATTY. BEDARD: 14 Q. Good morning, Dr. Karasic. As you may have heard a 15 minute ago, my name is Stephanie Bedard, and I 16 represented Blue Cross Blue Shield of Illinois. 17 Before I say anything further, am I pronouncing your 18 name correctly, "Karasic"? 19 A. Yes. 20 Q. Okay, good. I just wanted to make sure. So as you 21 know, the plaintiff -- one of the plaintiffs in this 22 case is Casey Pritchard, but because Casey is a 23 minor, I'm going to be referring to him throughout 24 this deposition as "C. P." I just wanted to make 25 sure you understood who I was referring to when I	Page 8 1 questioning or finish asking you about a specific 2 exhibit, but then we can certainly take a break. 3 A. Yes. 4 Q. Okay. Great. And I also, you know, I tend to try 5 to give everyone a break every hour or so. But 6 again, if you need something more frequent or 7 between those times, that's perfectly fine. 8 So if I ask you a question and you are confused 9 by it, please feel to ask me to rephrase. Does that 10 make sense? 11 A. Yes. 12 Q. Okay. Great. And by that same token, if you answer 13 my question, I will assume you have understood the 14 question asked. Does that make sense? 15 A. Yes. 16 Q. Great. Dr. Karasic, what is your current address? 17 Where do you currently reside? 18 A. 86 Montezuma Street, San Francisco, California 19 94110. 20 Q. And is that where you're located today? 21 A. Yes. 22 ATTY. BEDARD: Dr. Karasic, I am going to share 23 my screen and share with you what has been marked 24 as Defendant's Exhibit 1. 25 (Exhibit 1 marked for identification.)
Page 7 1 said that. 2 A. Yes. 3 Q. Okay. Great. And you understand you're under oath 4 today? 5 A. Yes. 6 Q. Well, I understand you've had your deposition taken 7 before, but I don't know if that was in our Zoom 8 remote deposition era or not, so I'm going to go 9 over a few ground rules that will be particularly 10 important in this Zoom era. 11 And the first is to do our absolute best to try 12 not to talk over each other. It's easy to do in 13 person, and it's even easier to do via Zoom. So I 14 will do my best not to speak over you, and I would 15 ask that you do the same; does that work? 16 A. Yes. 17 Q. Okay, great. And also, because this is a remote 18 deposition, we'll need you to affirmatively answer 19 every question. Simply shaking your head yes or no, 20 while on the video, won't be picked up by the court 21 reporter. Does that make sense? 22 A. Yes. 23 Q. And if you need a break at any time through the 24 course of your deposition, feel free to raise your 25 hand, flag me down. I may finish a line of	Page 9 1 Q. (BY ATTY. BEDARD) Can you see that exhibit? 2 A. Yes. 3 Q. Great. Have you seen this deposition subpoena 4 before today? 5 A. Yes. 6 Q. And how did you prepare for today? 7 A. I reviewed my statement, reviewed a few of the 8 papers listed in my report, and I had two meetings 9 with counsel. 10 Q. When were those meetings? 11 A. One was on -- it would have been July 10th, and the 12 other one was July 8th. 13 Q. And when you refer to your counsel, are you 14 referring to Mr. Gonzalez-Pagan who's sitting here 15 today? 16 A. Yes. 17 Q. Okay. Was anyone present during the course of your 18 meetings, other than the two of you? 19 A. There were other members of the legal team. 20 Q. Okay. Do you remember their names? 21 A. No. 22 Q. Was Ele Hamburger a part of that meeting as well? 23 A. Yes. 24 Q. Okay. Was there anyone in the meeting who was not 25 legal counsel?

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Page 10 1 A. No, I don't believe so. 2 Q. And did you collect documents to provide to 3 plaintiff's counsel in advance of your deposition 4 today? 5 A. Yes. Well, I provided them with references to my 6 statement and the bibliography. 7 Q. And are there any -- first, Dr. Karasic, when you're 8 referring to your "statement" -- I just want to make 9 sure we're on the same page -- this is your expert 10 disclosure that was disclosed to defense counsel on 11 June 27th, right? 12 A. Yes. 13 Q. Okay, great. Just want to make sure we're talking 14 about the same document here. So when you were 15 preparing and drafting your statement or your 16 disclosure, are there any documents that you 17 reviewed that you did not provide to plaintiff's 18 counsel? 19 A. I'm sure -- I mean, I, you know, read widely in the 20 field of transgender health, and so there may be 21 other documents that shaped my opinion. But the 22 kind of primary documents that I'm basing my opinion 23 on are in my report. 24 Q. Okay. And are there -- would you say that the 25 documents that you collected to provide to	Page 12 1 report that you have previously been deposed. How 2 many times have you been deposed before today? 3 A. So as I list in that document, in recent years, I've 4 been deposed three times. I was also deposed 5 in 2014. And a couple of times relating -- I was 6 deposed relating to patient care. And each time, it 7 was a patient of mine in my practice many years ago 8 who was involved in a lawsuit where I was deposed 9 related to that lawsuit. 10 Q. Okay. So just to break down what I understand 11 you're saying, Dr. Karasic, let's start first with 12 the three times that you've recently been deposed. 13 For each of those three times, were you deposed as a 14 treating physician on behalf of someone you'd seen 15 in your practice? 16 A. No. The three times -- 17 Q. So -- 18 A. The three times -- 19 Q. I apologize, go ahead. 20 A. The three times that are listed in my expert report 21 are the three times I was deposed as an expert. 22 Q. Okay. And what were the names of those three cases, 23 if you can recall? 24 (Atty. Hamburger joined the proceedings.) 25 A. Sure. So one is Kadel v. Folwell, and one is Fain
Page 11 1 plaintiff's counsel, would those represent the 2 primary documents you relied on in your report? 3 A. Yes. 4 Q. Okay. And what documents do you have in front of 5 you today? 6 A. The only document I have in front of me is I have a 7 paper copy of my expert report for convenience, if 8 we refer to it. 9 ATTY. GONZALEZ-PAGAN: And just to clarify for 10 the record, Stephanie, and completeness, Dr. Karasic 11 provided some documents. We also collected some of 12 them ourselves from his bibliography that he 13 provided to us. So I just wanted to make sure 14 there's clarity on the record. 15 ATTY. BEDARD: Okay. And just to clarify, the 16 production that was provided to defense counsel that 17 begins with Bates No. "KARASIC" includes those -- 18 ATTY. GONZALEZ-PAGAN: Right. Well, it 19 includes the full body, yes. 20 Q. (BY ATTY. BEDARD) Okay, great. And then 21 Dr. Karasic, just to circle back, the only paper 22 document you have in front of you today is your 23 expert report, right? 24 A. Yes. 25 Q. Okay. And Dr. Karasic, I understand from that	Page 13 1 v. Crouch, and one is Brandt v. Rutledge. 2 Q. And in your capacity as an expert in each of those 3 three cases, were you providing expert testimony on 4 gender-related issues, gender-related care? 5 A. Yes. 6 Q. Okay. So then in addition to those three cases in 7 which you were deposed that are included in your 8 expert report, you also mentioned just now that you 9 have previously been deposed as a treating 10 physician. Can you walk us through each of those 11 times? 12 A. Sure. So they were many years ago. I don't 13 remember all the details. One was a patient that -- 14 of mine at San Francisco General who was suing the 15 San Francisco Police Department for being injured by 16 a police officer. 17 And another as a treating physician was a 18 patient of mine who was engaged in litigation, and I 19 think I was essentially asked about the emotional 20 effect of the litigation on that person. 21 So those are the two that I can recall. And 22 yeah, so that's the treating physician. 23 Q. Did either of those two cases involve gender-related 24 issues? 25 A. No.

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Page 14 1 Q. And those two cases are the only cases you recall 2 providing deposition testimony in a treating 3 capacity, right? 4 A. Yes. 5 Q. Okay. And are these three cases where you discussed 6 providing deposition testimony in an expert 7 capacity, are those the only three cases where you 8 have provided deposition testimony in an expert 9 capacity? 10 A. No. I mentioned there was one in 2014 where I was 11 deposed as an expert. 12 Q. Okay. Can you tell us more about that case, 13 including the case name, if you remember? 14 A. Sure. It was Cabading v. Cal Baptist University. 15 Q. And what do you recall about that case? 16 A. Sure. So there was a transgender woman who had been 17 admitted to Cal Baptist, to their nursing school, 18 and shortly prior to starting school, they found out 19 that she was transgender, and they revoked her 20 admission. 21 Q. And you provided expert opinion in that case on 22 behalf of the plaintiff you referenced? 23 A. Yes. Yeah. 24 Q. Okay. In addition to the 2014 case you just 25 mentioned and the three cases we've already	Page 16 1 ATTY. GONZALEZ-PAGAN: Objection to form. 2 A. Yes. 3 Q. (BY ATTY. BEDARD) Were there any other instances in 4 which you testified in a Canadian court or tribunal? 5 A. I did an expert statement in a case, CF v. Alberta, 6 but I did not -- I was not deposed, and I didn't 7 testify. I just provided an expert statement which 8 was accepted. 9 Q. Okay. So just to backtrack a little bit. Setting 10 aside the appearance in front of the Canadian Human 11 Rights Tribunal, we've previously discussed the 12 instances in which you provided deposition 13 testimony, either as an expert or as a treating 14 physician. Can you please walk me now through any 15 instances in which you provided trial or other live 16 or in-court testimony? Again, either as a treating 17 or as an expert -- treating physician or expert 18 witness. 19 A. So I have not -- in the US, I have not provided live 20 in-court testimony. 21 Q. Is there any other testimony you've provided in any 22 capacity that we have not yet talked about? 23 A. Meaning deposition or live court testimony? 24 Q. Good question. Let me clarify. Let me extend it as 25 well to expert reports. Are there any expert
Page 15 1 discussed, are there any other cases where you 2 provided testimony in an expert capacity? 3 A. It wasn't as a -- in a deposition format, but I did 4 testify in the Province of Ontario, XY v. Ontario. 5 I testified in 2010. I believe the case was -- the 6 decision was in 2012. And it was before the 7 Province of Ontario Tribunal of Human Rights -- a 8 human rights court that some Canadian provinces 9 have. 10 THE VIDEOGRAPHER: Stephanie, you're still 11 sharing that Exhibit. 12 ATTY. BEDARD: That's fine. Thank you. 13 THE VIDEOGRAPHER: Okay. 14 ATTY. BEDARD: I appreciate the reminder. I do 15 tend to leave them up sometimes. 16 Q. (BY ATTY. BEDARD) So Dr. Karasic, in the XY case you 17 just mentioned, you were testifying in an expert 18 capacity, right? 19 A. Yes. 20 Q. And that was in court? 21 A. It was in a human rights court, which they have in 22 Ontario. I don't believe there is an equivalent in 23 the US. 24 Q. But you were testifying in an expert capacity in 25 front of that tribunal?	Page 17 1 reports you've provided in any case other than those 2 in which we've already spoken about today? 3 A. Yes. I did an expert report in a case in Ohio. I 4 don't recall the name of the case right now, but I 5 did an expert report on that case. And that would 6 have been in 2020, I think. I think it may be on 7 my -- the case name may be on my CV. Yeah, Drew 8 Glass v. City of Forest Park, 2021. And so, yeah, 9 it's mentioned on my -- in my report. 10 Q. And in that case, Dr. Karasic, you provided an 11 expert report, but you were not deposed, and you did 12 not or have not testified in court? 13 A. Yes. 14 Q. Okay. Great. And have you ever personally been 15 involved in litigation before, as a plaintiff? 16 A. No. 17 Q. What about as a defendant? 18 A. No. 19 Q. Dr. Karasic, I am now going to show you what has 20 been marked as Defendant's Exhibit 2. 21 (Exhibit 2 marked for identification.) 22 Q. (BY ATTY. BEDARD) Defendant's Exhibit 2 is the 23 expert disclosure that you have made in this case, 24 which you've been referring to as a statement, which 25 is fine. Can you see that okay?

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Page 18 1 A. Yes, I was just pulling it up on my big screen. 2 Yes. 3 Q. Are you able to see the one that I'm actually 4 sharing? The reason I ask is I may scroll through 5 it. 6 A. Oh, okay. Yes. 7 Q. Okay. Great. It'll probably just be easiest if 8 we're all looking at the same one, same page, same 9 paragraph, that type of thing. Did you draft this 10 report? 11 ATTY. GONZALEZ-PAGAN: And just for clarity of 12 what's been shown on the screen, it only shows the 13 caption. It doesn't show the document title. 14 Thanks. 15 THE WITNESS: Yes. 16 ATTY. BEDARD: So Omar, can you see the exhibit 17 now? 18 ATTY. GONZALEZ-PAGAN: Yes, yes. Now it shows, 19 thank you. 20 ATTY. BEDARD: Okay, great. 21 Q. (BY ATTY. BEDARD) So Dr. Karasic, I'm going to 22 repeat my question again: Did you draft and prepare 23 this report? 24 A. Yes. 25 Q. Did anyone assist you in preparing it?	Page 20 1 But certainly I reviewed a number of the papers I 2 cited in the report. 3 Q. So in addition to medical literature on 4 gender-related issues, what documents did you review 5 that were specific to the plaintiff, C. P.? 6 ATTY. GONZALEZ-PAGAN: Objection to form. 7 A. So I reviewed medical records that were provided to 8 me -- C. P.'s medical records. 9 Q. (BY ATTY. BEDARD) Did those include medical records 10 from CHI Franciscan Health and Dr. Garza? 11 A. They were from, as I recall, from Polyclinic, from 12 Dr. Hatfield; there was Dr. Garza, I believe; and 13 there was a -- I believe her name was Sharon Booker. 14 There was a mental health social worker's letter 15 that I reviewed. 16 Q. It's my understanding, by the way, that Ms. Booker 17 works at the Center for Child and Family Therapy. 18 So I may refer to those records either as her 19 records or that facility's records. 20 A. Sure. 21 Q. Are there any other C. P.-specific records that you 22 reviewed? 23 A. Not that I can recall. 24 Q. Did you review a psychological evaluation of C. P. 25 from 2021?
Page 19 1 A. Yes. 2 Q. Who was that? 3 A. So Omar Gonzalez-Pagan assisted me. We had -- I'd 4 been an expert in a case that Omar had been involved 5 in, Kadel. And I had done another case, Fain, with 6 Lambda Legal. And so there are aspects of the 7 report that have kind of carried through from prior 8 reports, and Omar assisted in -- in that aspect of 9 kind of carrying over what I had provided as an 10 expert in these prior cases, working with Lambda 11 Legal. 12 Q. And other than Omar and other individuals at Lambda 13 Legal, is there anyone else who assisted you in 14 preparing the report? 15 A. No. 16 Q. Did anyone other than Omar or someone at Lambda 17 Legal review the report before it was finalized? 18 A. No. 19 Q. And what documents did you review in preparing this 20 report? 21 A. So I reviewed quite a number of documents. I don't 22 think I could list them in any complete way, but I'm 23 always reading, you know, in transgender health. 24 And so any review for this, you know, just overlaps 25 with, you know, my reading in transgender health.	Page 21 1 A. Oh, yes. I did. The one -- I think it was in 2 regards to ADHD. 3 Q. Okay. And did you review any records from Blue 4 Cross Blue Shield of Illinois in preparing your 5 report? 6 A. The only material I reviewed from Blue Cross Blue 7 Shield of Illinois that I can recall was their 8 statement of provision of transgender care for their 9 policies that are not for self-insurance. 10 Q. And Dr. Karasic, there were some new documents we 11 received from the Polyclinic recently, and recently 12 provided those to plaintiff's counsel. I don't know 13 whether you have seen these yet today. I'm going to 14 show them to you so that you can see them now. 15 A. Okay. 16 Q. Let me know if you've seen them previously. 17 A. I don't know if I've seen them previously. 18 Q. Okay. 19 ATTY. GONZALEZ-PAGAN: Stephanie, you're not -- 20 you stopped sharing. Thank you. 21 (Exhibit 3 marked for identification.) 22 Q. (BY ATTY. BEDARD) So Dr. Karasic, can you see the 23 document I'm showing you now that says "T-Scan 24 Corporation" at the top? 25 A. Yes.

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Page 22 1 Q. I'm introducing what's been marked as Defendant's 2 Exhibit 3. These are those new records from the 3 Polyclinic we received this week and which have been 4 provided to plaintiff's counsel. We'll go through 5 these later today, but I just wanted to give you a 6 frame of reference of what I was talking about when 7 I refer to the "new Polyclinic records," as compared 8 to what you've previously reviewed. 9 A. Okay. 10 Q. And in particular, I wanted to draw your attention 11 to the PDF Page 30. Do you see here where it says 12 "CONSENT FOR SURGERY" up at the top? 13 A. Yeah. Let me pull it up on a larger screen, because 14 the Zoom screen is a small one, so it's a little 15 hard for me to see. 16 Q. Dr. Karasic, I'm happy to zoom in on my screen if 17 need be. It will be easier if we can ensure we're 18 looking at the same document the whole time, rather 19 than you looking at your own version. 20 A. Okay. 21 Q. But if you can't see it, just let me know, we can 22 come up with another solution. Is that better 23 there? Can you see that? 24 A. Okay. Yeah. 25 Q. Okay, great. So do you see where it says "CONSENT	Page 24 1 And then I trained in psychiatry at the UCLA 2 Neuropsychiatric Institute. The last year of my 3 residency overlapped with an NIMH fellowship. And 4 then in 1991, I started working as faculty at 5 University of California, San Francisco. 6 Q. Okay. And are you currently still employed as 7 faculty at UCSF? 8 A. So I am an emeritus professor of psychiatry. I 9 retired from being full-time employed by UCSF 10 in 2020. Since then, I've done a small amount of 11 work for UCSF as recall faculty, which is something 12 I expect to continue, but just a very small amount 13 of, you know, paid work for UCSF, since 2020. 14 Q. And since you obtained your psychiatry degree, have 15 you also been in private practice since that time? 16 A. Yes. So while I was at UCSF, as part of my work, I 17 did a faculty practice in addition to the clinics I 18 worked in. And then in 2020, when I retired, I 19 started a private practice. And that's my primary 20 employment now. 21 Q. What is the name of that private practice? 22 A. Just "Dan Karasic, MD." 23 Q. Are there any other physicians within that private 24 practice with you? 25 A. No.
Page 23 1 FOR SURGERY"? 2 A. Yes. 3 Q. And that this is a record for C. P.? 4 A. Yes. 5 Q. I'm scrolling down. It says that this consent 6 authorizes Dr. Jeffrey Kylo to perform a bilateral 7 mastectomy? 8 A. Yes. 9 Q. Okay, great. And we'll come back to this, but do 10 you see at the bottom where it says "Patient 11 Signature," and it has C. P.'s signature as the 12 patient signature? 13 A. Yes. 14 Q. With a witness signature as well, right? 15 A. Of the parent, yes. 16 Q. Yes. Okay. All right. 17 So Dr. Karasic, we've reviewed a bit of your 18 educational background and qualifications from 19 what's in your report, but if you would for a moment 20 tell me a bit about your educational background 21 first. Can you let me know any schools you attended 22 and any degrees you received? 23 A. Sure. I received my bachelor's degree from 24 Occidental College in Los Angeles, and then went to 25 Yale University School of Medicine in New Haven.	Page 25 1 Q. And you previously mentioned that you had testified 2 as a treating physician in the past. So at those 3 times, where was your private practice located? 4 ATTY. GONZALEZ-PAGAN: Objection. Form. 5 A. So at that time I was not in private practice. I 6 did something like a private practice that was 7 called a faculty practice, because the money would 8 go to UCSF. But most of my work while I worked at 9 UCSF was in various clinics. So it was at a UCSF 10 clinic in each of those two cases where a patient in 11 that clinic was involved in litigation, and I was 12 deposed as a treating physician. 13 Q. (BY ATTY. BEDARD) So essentially, when we talk about 14 something along the lines of private practice, you 15 were in a faculty practice from the time that you 16 achieved your degree in psychiatry until 2020, and 17 it was in 2020 when you began your own private 18 practice outside of your faculty practice, right? 19 A. Yeah. I mean, the faculty practice refers to 20 something that is structured somewhat like a private 21 practice. But I also -- much of my work was in -- 22 as a psychiatrist in various clinics, various UCSF 23 and San Francisco Department of Public Health 24 clinics where it wasn't really like a private 25 practice. It was going into a medical or mental

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Page 26 1 health clinic and consulting or taking care of 2 patients. 3 Q. And were any of those clinics specifically focused 4 on the provision of transgender-related or 5 gender-related care? 6 A. Yes. So I was the psychiatrist for the Dimensions 7 Clinic for trans youth from 2003 until 2020, when I 8 retired. And I was also the co-lead and co-founder 9 of the gender team at UCSF Gender Alliance Health 10 Project, and that gender team started around 2011. 11 But even before that, we were not with a formal 12 team, we were taking care of transgender people. 13 UCSF Alliance Health Project is a mental health 14 clinic of UCSF that provides mental health care for 15 LGBTQ patients. 16 Q. And you also previously mentioned a fellowship. Was 17 there a specific specialty for that fellowship? 18 A. Yes. It was in mental health services for people 19 with HIV/AIDS. 20 Q. And are you a member of any professional 21 organizations? 22 A. Yes. I am a distinguished life fellow of the 23 American Psychiatric Association, and I am a member 24 of the World Professional Association for 25 Transgender Health.	Page 28 1 to organizing conferences, to providing trainings to 2 healthcare providers inside and outside of the US. 3 We provided consultation to international 4 organizations and government and governments outside 5 of the US, as well as the US. And so it was an 6 active time in that regard. I also -- we were 7 restructuring the organization to have regional 8 chapters, and I was the conference chair for the 9 first USPATH conference in 2017, which was 10 organized, actually, by WPATH because the USPATH 11 board wasn't elected until 2018. 12 Q. (BY ATTY. BEDARD) And I understand you were on the 13 board of WPATH from 2014 to 2018. So from 2018 to 14 the present, would you consider your involvement in 15 WPATH to be as a member or in a different capacity? 16 ATTY. GONZALEZ-PAGAN: Object to form. 17 A. So I'm a member. I've also been the chapter lead 18 for the mental health chapter, which involves mental 19 health care for adults in Standards of Care 8. 20 Q. (BY ATTY. BEDARD) What does it mean to be a chapter 21 lead? 22 A. So I guess I would say in addition to that, I'm on 23 the larger committee for Standards of Care 8. But 24 within the chapter, it involved, with the editors of 25 SOC 8, selecting other authors for the chapter, and
Page 27 1 Q. Is that commonly referred to as WPATH? 2 A. Yes. 3 Q. So walk me through, if you can, your involvement 4 with WPATH. Are you a member? Are you on the 5 board? What's been the extent of your involvement 6 over the years? 7 ATTY. GONZALEZ-PAGAN: Objection. Form. 8 A. Sure. So I first joined as a member in 2001. I 9 became involved in the late 2000s with committees 10 relating to DSM and ICD diagnoses WPATH committees. 11 And then I became involved as a co-author of WPATH's 12 Standards of Care, Version 7, which was written, I 13 would say, between 2009 and 2011. 14 And then from 2014 to 2018, I was on the board 15 of directors of WPATH. 16 THE COURT REPORTER: And Counsel 17 Gonzalez-Pagan, did you have an objection? 18 ATTY. GONZALEZ-PAGAN: Yes. I said objection 19 to form prior to his answer. 20 THE COURT REPORTER: Thank you. 21 Q. (BY ATTY. BEDARD) And Dr. Karasic, what does -- what 22 was the extent of your involvement on the board of 23 directors of WPATH? 24 A. We had a very active board, and so we had addressed 25 quite a number of issues relating to -- especially	Page 29 1 then writing possible statements for Delphi 2 approval, which was a way of achieving kind of a 3 supermajority approval of each statement, and then 4 writing explanatory text. And so the chapter lead 5 is the equivalent of a first author on a paper. The 6 chapter was ultimately my responsibility, but I 7 worked with the other authors on the chapter. 8 Q. And did you say that after you finished drafting a 9 chapter, it went for Delphi approval? Did I hear 10 you correctly? 11 A. Yes. Delphi approval was not for the whole chapter, 12 but the previous standards of care were the -- 13 standards of care had approval by consensus. 14 Standards of Care 8 grew too large for that, so 15 there would be -- there's a process which is called 16 Delphi process for coming to agreement on kind of 17 central statements of a document. 18 And so our chapter, with the editors, ended up 19 coming down to ten statements that we submitted for 20 Delphi approval from the 120 to 140 people involved 21 with Standards of Care 8 -- the other authors of 22 Standards of Care 8. And a statement could receive 23 75-percent approval to be an approved statement. 24 If it received less than that, for each 25 statement, each reviewer, which was the 120 to 140

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Page 30 1 people, could put down comments. And particularly, 2 if a statement received less than 75 percent, there 3 was an opportunity to modify the statement and bring 4 it back to Delphi. 5 Q. Okay. So to make sure I understand how this process 6 works, there would be one or more primary drafters 7 of a specific statement in the next Standards of 8 Care version, and then it would go then out for 9 Delphi approval. And Delphi approval means weigh-in 10 on that statement by the 120 to 140 members who are 11 weighing in on that statement, right? 12 ATTY. GONZALEZ-PAGAN: Object to form. 13 A. Yes -- yes, who are part of the Standards of Care 8 14 Committee, really, the authors of Standards of Care 15 8. So Standards of Care 8 is a much larger document 16 than the previous Standards of Care. And so there 17 were about 20 chapters. And so each chapter had 18 probably five to seven members, at least. 19 And so all of those people who were involved in 20 any of the chapters could -- were given a link to 21 weigh in and comment on each statement that may have 22 been drafted by a group. 23 So the statement would originally be drafted by 24 perhaps five to 17 people, led by a chapter lead, in 25 consultation with the three editors, and then that	Page 32 1 Committee. So when I was referring to those members 2 of Standards of Care 8 Committee, people had to 3 apply with a CV and a statement. And so it was a 4 competitive process to be on one of the chapters of 5 Standards of Care 8. 6 To be a member of WPATH, one has to apply to 7 WPATH. To be a full member, one is supposed to be a 8 health professional or health-related academic. 9 There are a few lawyers who work with the interface 10 of the law and transgender health, I think, who are 11 full members. But otherwise, people are health 12 professionals, some who are also health academics, 13 some are -- many of the members are clinicians. 14 Q. Is there any sort of degree requirement to be a 15 member of WPATH? 16 A. So there's not a -- to be a full member of WPATH, 17 there's not a degree requirement, but to be a health 18 professional that would, you know, or an academic, 19 you would need a degree, certainly. 20 So there are student members. So there are 21 people who are working on degrees as student 22 members. They're not full members of WPATH. And 23 there is some associate membership -- I believe it's 24 a nonvoting membership that people can get who are 25 not health professionals.
Page 31 1 statement would be sent out to all of the authors. 2 And it was considered agreed upon if 75 percent of 3 people agreed upon it. If it was not agreed upon, 4 then the authors -- the original authors of the 5 statement had all of the comments, what people 6 disagreed with about the statement, and could -- had 7 an opportunity to later go back to the Delphi 8 process with a modified statement to see if that 9 would be approved. 10 Q. (BY ATTY. BEDARD) So what is the current status of 11 the Standards of Care 8? 12 A. My understanding is that it's done, and that it is 13 going to be released imminently. We have -- I was 14 asked to give a talk about the mental health chapter 15 at the WPATH conference in Montreal, which is in 16 September of this year. And so I don't know whether 17 they plan to do a public release during the 18 conference, but I would imagine -- or if the release 19 will be before that -- but I would imagine that the 20 document would be released by September. 21 Q. And just taking a quick step back, we've discussed 22 membership in WPATH. Who is eligible to be a member 23 of WPATH? 24 A. So yes. We discussed membership in WPATH, which is 25 different from membership on the Standards of Care 8	Page 33 1 Q. And Dr. Karasic, in addition to WPATH, are you also 2 familiar with the Endocrine Society? 3 A. Yes. 4 Q. And what is that? 5 A. So it's -- the Endocrine Society is a professional 6 organization of endocrinology. 7 Q. Is it specifically focused on gender-related issues? 8 A. No. The Endocrine Society deals with endocrinology 9 and other aspects, aside from gender care. 10 Q. So to make sure I understand this correctly, then, 11 the Endocrine Society looks at gender-related issues 12 but also has a scope that is broader than just 13 gender-related issues? 14 A. Yes. Gender-related issues are just one of many 15 issues that the Endocrine Society addresses. 16 Q. And to be a member of the Endocrine Society, do you 17 need to have a degree in endocrinology? 18 A. So I'm not a member of the Endocrine Society, and I 19 can't say I know what their criteria are. But my 20 understanding is it's an organization of 21 endocrinologists, so largely people who have trained 22 first in internal medicine, and then in 23 endocrinology, or first to pediatrics and then in 24 pediatric endocrinology. 25 Q. But is there some overlap between the two groups in

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Page 34 1 terms of the subject matter that they cover? 2 A. Yes. In terms of the Endocrine Society and WPATH? 3 Q. Correct. 4 A. Yeah. So most people in WPATH are also part of 5 another organization. So for example, I've been 6 active in the American Psychiatric Association as a 7 psychiatrist. Somebody who's a family medicine 8 doctor might be in the American Academy of Family 9 Medicine; or a pediatrician, the American Academy of 10 Pediatrics. And so endocrinologists who work in 11 gender health may well be a member of the Endocrine 12 Society, which -- related to endocrinology more 13 generally -- as well as being endocrinologists 14 within WPATH. 15 Q. And you actually read my mind with what was going to 16 be my next question, which is -- since you're a 17 member of WPATH, you're a member of American 18 Psychology Association, I believe you said -- are 19 there any other professional organizations that you 20 are a member of? 21 ATTY. GONZALEZ-PAGAN: Objection. 22 A. So I'm a member -- 23 THE COURT REPORTER: Counsel -- one moment. 24 Counsel Gonzalez-Pagan, did you have an objection? 25 I wasn't able to hear it.	Page 36 1 current patients identify as transgender? 2 A. So that was something I did look at, just a typical 3 week, and -- a little while back. And about 4 two-thirds of my patients are transgender. 5 Q. And how many of those transgender patients are 6 minors? 7 A. And so about half of my transgender patients are 8 minors, or I started seeing as minors in 2020. Some 9 may have turned 18 since then. But when I -- the 10 reason I give those numbers is at one point I just 11 looked at my schedule, and just for a given week, 12 and saw it was about one-third transgender minors, 13 about one-third transgender adults, and about 14 one-third cisgender patients, mostly adults. 15 Q. And throughout the course of your career and your 16 practice, have you ever worked with any physicians 17 from the Polyclinic? 18 A. No. 19 Q. Prior to reviewing C. P.'s medical records, were you 20 familiar with Dr. Kevin Hatfield? 21 A. No. 22 Q. And what about Dr. Jeffrey Kylo? 23 A. No. 24 Q. The same question for Ms. Sharon Booker with the 25 Center for Child and Family Therapy. Are you
Page 35 1 ATTY. GONZALEZ-PAGAN: Objection to form. 2 THE COURT REPORTER: Thank you. 3 A. So I'm not a member of the American Psychological 4 Association, I'm a member of the American 5 Psychiatric Association. And currently, I am only a 6 member of the American Psychiatric Association and 7 WPATH. 8 Q. (BY ATTY. BEDARD) And Dr. Karasic, let's talk for a 9 minute about what your current private practice 10 looks like. So -- and I understand that your 11 private practice was first started in about 2020. 12 How many patients do you currently see per year? 13 A. I don't have -- I don't have those numbers off the 14 top of my head. Yeah. I don't think I can tell 15 you. I don't keep those statistics, although I 16 suppose I could, you know, review how many charts I 17 have, but I haven't. 18 Q. Would you say that it's over 100 patients? 19 A. Yes. 20 Q. And somewhere less than 250 patients? 21 A. I just hesitate to speculate under oath, in that I 22 don't know what the numbers are. 23 Q. Understood. That's fine. We're not going to hold 24 you to a specific number today. 25 To the best of your knowledge, how many of your	Page 37 1 familiar with that practice group? 2 A. No. 3 Q. And are you familiar with Ms. Booker? 4 A. No. 5 Q. And have you reviewed the reports of plaintiff's two 6 other experts in this case, Dr. Ettner and 7 Dr. Schechter? 8 A. I actually don't believe I have. 9 Q. Are you aware that Dr. Ettner and Dr. Schechter have 10 provided expert disclosures in this case? 11 A. Yes. 12 Q. And have you ever worked with either of them 13 previously? 14 A. Yes. I was on the WPATH board with both 15 Dr. Schechter and Dr. Ettner. So I've not worked 16 clinically with them. I've worked with both of them 17 on the board, and we have worked together on 18 educational projects -- on projects to train 19 healthcare providers in transgender health. 20 Q. What about Dr. Frank Fox, who we understand has or 21 will also be disclosed as an expert? It's Frank G. 22 Fox. 23 A. No. 24 Q. And as we talk about your practice and the number of 25 transgender -- the patients you see who identify as

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Page 38 1 transgender, I'm assuming transgender-related 2 issues, gender-related issues are something that you 3 would consider to be a specialty, right? 4 A. Yes. 5 Q. Did you receive any specialized training in 6 gender-related issues? 7 ATTY. GONZALEZ-PAGAN: Sorry, just before you 8 finish the question, Dr. Karasic, if you can hold 9 off just a couple of seconds for me to lodge an 10 objection, I know that it's just -- I believe the 11 court reporter may appreciate it. I would 12 appreciate it. So if you just kind of hold off a 13 couple of seconds before answering. 14 THE WITNESS: Yes, I will -- I will try. 15 Sorry. 16 ATTY. GONZALEZ-PAGAN: Apologies, Stephanie. 17 Please. I didn't mean to interrupt. 18 ATTY. BEDARD: That's all right. I'll repeat 19 my question. We can have the weighted pause. 20 Q. (BY ATTY. BEDARD) Dr. Karasic, did you receive any 21 specialized training in gender-related issues? 22 A. Yes. I did my psychiatry residency at UCLA, UCLA 23 Neuropsychiatric Institute, and I received my first 24 training in transgender care there with Robert 25 Stoller, who coined the term "gender identity." He	Page 40 1 of your knowledge? 2 A. I believe so. 3 Q. And is everything listed in your CV attached to your 4 expert disclosure accurate, to the best of your 5 knowledge? 6 A. I believe so. 7 Q. Are there any recent updates to your background or 8 qualifications that do not currently appear on your 9 CV? 10 A. Well, I recently went from being a distinguished 11 fellow of the American Psychiatric Association to a 12 distinguished life fellow of the American 13 Psychiatric Association, which was just an 14 achievement I guess I got by surviving. And I 15 don't -- since updating my CV -- since I'd worked 16 for one employer my entire career, it was always a 17 challenge updating my CV. And since I retired 18 in 2020, it's not something I do very often. I've 19 added some legal cases with expert witness work that 20 I've done since retirement. But there's no doubt 21 that there are things that I've done that are not 22 listed on my CV. 23 Q. Well, hopefully the recent change in your 24 designation for the APA means you no longer have to 25 pay dues.
Page 39 1 had been working with transgender people at UCLA 2 since the 1950s. 3 And I also worked with -- received training 4 from Richard Green, who was a psychiatrist at UCLA 5 at that time. He did the Feminine Boy Study at 6 UCLA. And so I received training about 7 gender-nonconforming boys from his work. 8 Q. Anything else? 9 A. Well, yes. So much of what I did as a faculty 10 member were trainings that I organized, of which 11 there were many. I probably organized more 12 trainings on transgender health -- and more 13 educational sessions on transgender health over this 14 last 30 years at American Psychiatric Association 15 meetings, probably than anyone else. 16 But even if I were the chair of a session, I 17 was one of a panel of presenters. And so I received 18 training, certainly, by -- from my peer 19 psychiatrists. 20 I was also faculty on an American Psychiatric 21 Association CME training with fellow psychiatrists. 22 So there were many opportunities over the years to 23 be educated by my peers as well. 24 Q. And Dr. Karasic, is everything in the qualifications 25 section of your expert report accurate to the best	Page 41 1 A. I used to, but they changed that. So now they have, 2 like, a semi-retired status. But it was, until a 3 couple years ago, that when you reached that status, 4 that you no longer had to pay dues. But the APA 5 decided -- I think psychiatrists are getting so old 6 that they decided that that was not a viable 7 proposition indefinitely. 8 Q. Understood. 9 ATTY. BEDARD: Omar, I am about to go into a 10 series of questions about a specific exhibit. It 11 may be a good time to take a quick five-minute 12 break. We're right at a hour mark, if that works 13 for everyone? 14 ATTY. GONZALEZ-PAGAN: Yeah. Five minutes is 15 fine. 16 THE VIDEOGRAPHER: Okay. We are going off the 17 record at 10:03. 18 (Break from 10:04 a.m. to 10:10 a.m.) 19 THE VIDEOGRAPHER: We are back on the record at 20 10:10. 21 ATTY. BEDARD: Dr. Karasic, I'm going to go 22 back now to Exhibit 2, which is your expert 23 disclosure, and I'm going to share my screen with 24 you. 25 THE WITNESS: Okay.

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Page 42 1 Q. (BY ATTY. BEDARD) Can you see my screen? 2 A. Yes. 3 Q. So I'm going to go now in your expert report to 4 Paragraph 17. And in Paragraph 17, I understand 5 from your disclosure that you conducted an interview 6 with C. P. on March 18th of 2022; is that correct? 7 A. Yes. 8 Q. And it was via Zoom? 9 A. Yes. 10 Q. And were C. P.'s parents present for part or all of 11 that interview? 12 A. Yes. C. P.'s parents were present at the beginning 13 and at the end, and in the middle portion of the two 14 hours, I was just with C. P. 15 Q. And had you reviewed C. P.'s medical records prior 16 to that March meeting with C. P.? 17 A. Yes. 18 Q. What about the records from Sharon Booker and the 19 Center for Child and Family Therapy? 20 A. Yes. 21 Q. And based on your review of those records and your 22 meeting with C. P., is it your understanding that 23 C. P. first met with Dr. Hatfield in 2016? 24 A. Yes. 25 Q. And C. P. was ten years old at that time, right?	Page 44 1 around -- I think shortly after C. P. turned 13. 2 The -- I have reviewed the -- saw the record of when 3 the testosterone injections started, but I can't 4 remember whether C. P. was 13 or 14 at the time of 5 the first injection. 6 Q. And then C. P. also received a bilateral mastectomy, 7 right? 8 A. Yes. 9 Q. And that was in 2019? 10 A. And that was in 20- -- let's see. I think that 11 the -- yeah, I think it was maybe December of 2019. 12 Yeah, I think so. 13 Q. Let's take a look further down in your expert 14 report. 15 ATTY. GONZALEZ-PAGAN: Stephanie, just for the 16 sake of completeness, I believe, like, your Adobe 17 panel on the -- what would be right-hand side is 18 blocking a bit of the text. Do you see the arrow in 19 the middle? It can be collapsed. 20 ATTY. BEDARD: Thank you. Is that better? 21 ATTY. GONZALEZ-PAGAN: Yes. 22 Q. (BY ATTY. BEDARD) Dr. Karasic, can you see the full 23 text of the document I'm showing you right now? 24 A. No. Should I hide thumbnail video? 25 Q. Is the Zoom screen blocking it?
Page 43 1 A. C. P. in 2016 may have been 11. I think 2016 -- 2 C. P.'s year of birth is 2005 -- early 2005. So 10 3 or 11. 4 Q. And C. P. first received a puberty blocker that same 5 year, right? 6 A. Yes. 7 Q. And that was age 10 or 11? 8 A. Yes. I believe that was age 11 that C. P. received 9 the puberty blocker. 10 Q. And then is it your understanding that C. P. then 11 started testosterone cream in 2017 at the age of 11 12 or 12? 13 A. I think the testosterone cream was started just when 14 C. P. turned 13, is my recollection, so around 15 early 2018. 16 Q. Is it your understanding that there was a period of 17 time in which C. P. was prescribed testosterone 18 cream, and then at one point switched to 19 testosterone injections? 20 A. Yes. 21 Q. Do you recall, from your review of the records and 22 meeting with C. P., when that was? In other words, 23 how old C. P. was when he began the testosterone 24 injections? 25 A. Let's see. The testosterone cream was right	Page 45 1 A. Yes, partially. 2 Q. You can move the Zoom screen portion around. 3 A. Okay. All right. Okay. Let's see. I moved it 4 down, and it brought it down to the lower part of 5 the screen, so I'll just ask you to scroll up if you 6 need -- if I need -- 7 Q. Sure. I'd be happy to do so. So Dr. Karasic, I'm 8 looking at Paragraph 70 and 71 of your expert 9 report. Does this help refresh your recollection as 10 to the dates of the various procedures and C. P.'s 11 age for each of those procedures? 12 A. Yes. 13 Q. And do you see in Paragraph 71, and I'm going to 14 read from your report now, where it says, "[C. P.] 15 states that Dr. Hatfield discussed the risks and 16 benefits of each intervention extensively with 17 [C. P.] and his parents." Do you see that? 18 A. Yes. 19 Q. And would you agree with that statement? 20 A. That is what I was told by Casey and his parents. 21 Q. And I guess my question though, Dr. Karasic, is 22 understanding that that's what Casey told you -- 23 what C. P. told you, would you agree with the 24 statement that Dr. Hatfield discussed the risks and 25 benefits of each intervention extensively with C. P.

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Page 46 1 and his parents? 2 ATTY. GONZALEZ-PAGAN: Objection to form. 3 A. Well, the sentence says, "Casey states that 4 Dr. Hatfield discussed risks and benefits of each 5 intervention." So when I was doing my expert 6 statement, it was what Casey had told me. 7 But my recollection is, in reviewing the 8 medical records of Dr. Hatfield, that Dr. Hatfield 9 also documented having discussed risks and benefits 10 of interventions with C. P. and C. P.'s parents. 11 Q. (BY ATTY. BEDARD) And would you agree that that was 12 an extensive discussion of the risks and benefits? 13 ATTY. GONZALEZ-PAGAN: Objection. Form. 14 A. So the word "extensively" was from my discussion 15 with Casey and Casey's parents. 16 Q. (BY ATTY. BEDARD) Understood. But I'm asking you a 17 slightly separate question, perhaps inartfully. I'm 18 asking whether you agree that Dr. Hatfield's 19 discussion of the risks and benefits with C. P. and 20 his parents was extensive? 21 ATTY. GONZALEZ-PAGAN: Objection. Form. 22 A. My recollection is that there is documentation of 23 risks and benefits, including bone health and 24 fertility, that Dr. Hatfield charted. But the 25 characterization comes from the interview. I did	Page 48 1 Q. (BY ATTY. BEDARD) And part of what that mental 2 health professional would be assessing is the 3 patient's capacity to consent and whether those 4 risks and benefits are adequately understood by the 5 patient, right? 6 A. Yes. Now, in the case of a minor, the minor is 7 assenting and the parents are giving the informed 8 consent. And so the health professional should be 9 meeting with the patient and parents, in terms of 10 making sure they understand the risks and benefits 11 of the care being provided. 12 Q. And I'm looking now, Dr. Karasic, at Paragraph 75 of 13 your expert disclosure. Can you see that? 14 A. Yes. 15 Q. Now, I just want to make sure I understand what you 16 mean by this first sentence. You said, "No mental 17 health history other than gender dysphoria and 18 seeing a mental health professional before 19 gender-affirming care." What does that mean, 20 exactly? 21 A. So there was no history, for example, of C. P. being 22 treated with psychiatric medications or -- other 23 than there was mention of, I think in Dr. Hatfield's 24 note, of seeing a mental health person before and 25 being in a group before Dr. Hatfield saw C. P.
Page 47 1 not interview Dr. Hatfield to ask, you know, how 2 extensive the discussion of risks and benefits was. 3 I'm only relying on -- that it is documented in the 4 medical record. 5 Q. Let's turn now to paragraph 50 of your expert 6 report. Can you see that? 7 A. Yes. 8 Q. Good. And in Paragraph 50, you stated in your 9 report that, "As part of the treatment process for 10 gender dysphoria, patients provide informed consent 11 to their care." And you went on to state that, 12 "However, for gender-affirming medical care, there 13 is the additional safeguard of the assessment by a 14 mental health professional, who in addition to 15 diagnosing gender dysphoria, also assesses capacity 16 to consent and reviews the risks and benefits of 17 treatment with the patient," right? 18 A. Yes. 19 Q. So in other words, in any circumstance, patients 20 should provide informed consent to their care. But 21 when it comes to gender-affirming medical care, you 22 look for this additional safeguard of an assessment 23 by a mental health professional, right? 24 ATTY. GONZALEZ-PAGAN: Objection. Form. 25 A. Yes.	Page 49 1 But -- so I said, "seeing a mental health 2 professional," also including Sharon Booker for the 3 assessment for surgery. So that was the extent. 4 There was an assessment for attention deficit 5 hyperactivity disorder done in 2021. But there had 6 not been any treatment for that. In my -- 7 Q. And other than -- sorry, Dr. Karasic, go ahead. 8 A. Oh, I said, "in my recollection." That C. P. was 9 not being treated for that at the time of my 10 interview. 11 Q. Okay. Thank you. So other than the evaluation for 12 ADHD in 2021, is there any record in the medical 13 records you reviewed of C. P. ever meeting with a 14 psychiatrist? 15 A. No. 16 Q. Is there any record in the medical records that you 17 reviewed -- any evidence that C. P. met with a 18 psychologist either prior to, during, or after 19 receiving treatment? 20 A. I don't know Dr. Tutty's -- you know, what 21 Dr. Tutty's PhD was in. So I don't think I can 22 answer that part. 23 The one set of -- I believe that Sharon -- the 24 letter that I saw, Sharon Booker, is an LCSW. 25 Q. In other words, Sharon Booker is not a psychiatrist,

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Page 50 1 right? 2 A. Correct. 3 Q. And Ms. Booker is also not a psychologist, right? 4 A. Correct. 5 Q. And what is the LCSW degree? What does that stand 6 for? 7 A. That's a licensed clinical social worker. 8 Q. And what does that degree entail? 9 ATTY. GONZALEZ-PAGAN: Objection. Form. 10 A. So -- 11 ATTY. GONZALEZ-PAGAN: Outside the scope. 12 A. So becoming an LCSW means getting a master's degree 13 in social work and then doing many, many hours of 14 supervised work before being able to become 15 licensed. So typically, a licensed clinical social 16 worker is somebody who is a mental health 17 professional. Once they're licensed, they can do 18 that work as a mental health professional 19 independently. 20 ATTY. BEDARD: Dr. Karasic, I am now going to 21 show you what has been marked as Defendant's 22 Exhibit 5. 23 (Exhibit 5 marked for identification.) 24 Q. (BY ATTY. BEDARD) Can you see this exhibit? 25 A. Yes.	Page 52 1 on Page 8 that begins with, "Because of the 2 psychological"? 3 A. Yes. 4 Q. Dr. Karasic, could you read that paragraph for me, 5 please? 6 A. Yes. "Because of the psychological vulnerability of 7 many individuals with [gender dysphoria or] gender 8 incongruence, it is important that mental health 9 care is available before, during, and sometimes 10 after transitioning. For children and adolescents, 11 a [mental health professional] who has 12 training/expertise in child and adolescent gender 13 development (as well as child and adolescent 14 psychopathology) should make the diagnosis, because 15 assessing GD/gender incongruence in children and 16 adolescents is often extremely complex." 17 Q. So Dr. Karasic, for the record, you just read a 18 paragraph from the Endocrine Society guidelines. 19 And I'll repeat my question, which was: Do you 20 agree with the statement that you just read? 21 A. In large part, I would say "yes." I would say that 22 mental health professionals can include kind of 23 primary care providers as well. So the WPATH has 24 kind of moved to having less distinguishing of 25 health professional versus mental health
Page 51 1 Q. And I'm going to scroll down just so you can see the 2 entirety of the first page. 3 A. Okay. 4 Q. Have you seen this exhibit or this document before? 5 A. Yes. 6 Q. And what is it? 7 A. So the Endocrine Society -- a committee of the 8 Endocrine Society wrote clinical practice guidelines 9 for endocrine treatment of people with gender 10 dysphoria. 11 Q. Are there different versions of those guidelines? 12 A. These are the guidelines that I'm familiar with. 13 Q. What I meant was, you know, with the Standards of 14 Care for WPATH, you've got Version 6, Version 7, 15 Version 8. For the Endocrine Society, are there 16 similar versions? 17 A. I don't recall whether a committee of the Endocrine 18 Society had done guidelines before this. 19 Q. But to the best of your knowledge, these are the 20 current guidelines for the Endocrine Society, 21 correct? 22 A. Yes. 23 Q. I'm turning now to Page 8 of Exhibit 5. One second. 24 Turning now to Page 15 of Exhibit 5, do you see 25 the -- one second. Okay. Do you see the paragraph	Page 53 1 professional, in that primary care providers also 2 are providers of mental health care. 3 Q. Dr. Karasic, did C. P. see a mental health 4 professional who has training or experience in child 5 and adolescent gender development as well as child 6 and adolescent psychopathology, as the guidelines 7 describe, before receiving a diagnosis of gender 8 dysphoria? 9 ATTY. GONZALEZ-PAGAN: Object to form. 10 A. Yes, I believe so. Family medicine doctors consider 11 themselves mental health professionals, and if 12 you -- their, like, American Academy of Family 13 Physicians, I think it's called -- their 14 professional organizations make the point that most 15 mental healthcare providers -- most mental health 16 care is provided in primary care settings, and not 17 by psychiatrists. 18 And so a -- someone in family -- who is 19 board-certified in family medicine has received 20 extensive mental health training. And so we 21 consider family medicine doctors as mental health 22 professionals. And so in that regard, I would say 23 "yes" to your question. 24 Q. (BY ATTY. BEDARD) Dr. Karasic, based on your review 25 of C. P.'s medical records and your discussion with

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Page 54 1 C. P., who diagnosed C. P. with gender dysphoria? 2 A. So the -- C. P. was diagnosed by Dr. Hatfield, later 3 was diagnosed by Sharon Booker, and I think was 4 diagnosed -- I think may have been charted by 5 Dr. Garza in some other medical records that I saw. 6 But I think the initial diagnosis was from 7 Dr. Hatfield. 8 Q. And at the time of initial diagnosis by 9 Dr. Hatfield, was C. P. seeing a mental health 10 professional with training and experience in child 11 and adolescent psychopathology? 12 A. So if -- that was part of my prior answer, that 13 family medicine doctors are considered mental health 14 professionals. They are generalists, but they do 15 have expertise in internal medicine, pediatrics, and 16 psychiatry as part of their training. 17 Q. Do you know whether Dr. Hatfield, specifically, has 18 training in child and adolescent psychopathology? 19 A. I would assume that he does, because he's 20 board-certified in family medicine, and -- or I 21 assume he's board-certified in family medicine. But 22 board certification in family medicine includes, as 23 well as board certification in any specialty, 24 requirements of extensive training. And family 25 medicine doctors have that training in working with	Page 56 1 A. Yes. 2 Q. Great. Just wanted to make sure we're on the same 3 page. So in your opinion, Dr. Karasic, was C. P. 4 evaluated by a qualified mental health professional 5 before starting the puberty-blocking medication? 6 A. Yes. 7 Q. And who was that? 8 A. That was Dr. Hatfield. 9 Q. And was C. P. evaluated by a qualified mental health 10 professional before starting any testosterone 11 treatment? 12 A. Yes. 13 Q. And who was that? 14 A. That was Dr. Hatfield. 15 ATTY. BEDARD: Okay. I'm going to show you 16 what has been marked as Defendant's Exhibit 7. 17 (Exhibit 7 marked for identification.) 18 Q. (BY ATTY. BEDARD) Can you see that document? 19 A. Yes. 20 Q. And have you seen these medical records previously? 21 A. Yes. 22 Q. I'll be referring throughout the course of this 23 deposition, if I haven't yet, to the numbers that 24 appear either at the bottom middle or bottom 25 right-hand side of the page. Those are referred to
Page 55 1 adults and working with children and in providing 2 mental health care. 3 Q. And Dr. Karasic, did C. P. fulfill DSM-5 diagnostic 4 criteria for gender dysphoria? 5 A. Yes, I believe so. Remember, I am doing this 6 assessment not at the time that C. P. received these 7 interventions. But it's my opinion that he did have 8 a DSM-5 diagnosis of gender dysphoria. 9 Q. And what is your opinion based on? 10 A. So C. P. had had persistent discomfort with his 11 gender role, with how he was perceived by others, 12 and with his body. And that dysphoria had persisted 13 for more than six months. And that the -- that the 14 distress was clinically significant, by -- as 15 described in the DSM. 16 Q. Is there any other evidence from C. P.'s medical 17 records or from your interview with C. P. that 18 supports your opinion that C. P. fulfilled the DSM-5 19 diagnostic criteria for gender dysphoria? 20 A. Yes. I go into greater detail in my summary of my 21 examination of C. P. 22 Q. And when you refer to the summary of your 23 examination of C. P., you're referring to the 24 section of your expert disclosure that discusses 25 that examination of C. P.?	Page 57 1 as Bates numbers. Do you understand what I'm saying 2 when I say "Bates number"? 3 A. Yes. 4 Q. Okay, great. So I'm scrolling now to Plaintiff's 5 Bates No. 990. 6 Have you previously reviewed this medical 7 record? 8 A. I believe so, yes. 9 Q. And this is a medical record from Dr. Jeffrey Kylo 10 with the Polyclinic, right? 11 A. Yes. 12 Q. And this specific entry, this specific progress note 13 is dated April 30th of 2019, right? 14 A. Yes. 15 Q. I'm scrolling down within that consult note from 16 Dr. Kylo. It states that C. P. is being referred 17 by Dr. Hatfield for possible top surgery, right? 18 A. Yes. 19 Q. And do you see where it says further down in that 20 paragraph, "Has not had mental healthcare counseling 21 at this point"? 22 A. Yes. 23 Q. And at this point, C. P. had been taking puberty 24 blockers for several years, right? 25 A. Yes.

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Page 58 1 Q. And C. P. had been on some form of testosterone for 2 several years, right? 3 A. For -- well, for less time than that, for I think 4 over a year. And this says gel at age 11 and 5 injections three months ago. 6 But one thing I would just distinguish is 7 between mental health counseling, which is 8 psychotherapy, versus having had a mental health 9 assessment. And WPATH make that -- distinguishes 10 those two: A mental health assessment is required 11 by WPATH; but psychotherapy is not required. 12 Q. So tell me a bit about that distinction. What is 13 the distinction, in your opinion, between mental 14 health counseling and a mental health assessment? 15 A. Sure. So by "counseling," I might use the word 16 "psychotherapy," because that's in -- certainly in 17 WPATH, makes a distinction between an assessment and 18 psychotherapy. And both in Standards of Care 7 and 19 the upcoming Standards of Care 8, assessments are 20 required, but very specially WPATH says that 21 psychotherapy is not a requirement. 22 And so the assessment is done by the health 23 professional to make sure that the person has 24 persistent gender dysphoria, typically a 25 diagnosis -- DSM diagnosis of gender dysphoria, and	Page 60 1 A. So it depends on the patient. 2 Q. It's a sort of case-by-case analysis? 3 A. Yes. 4 Q. And what might it depend on? What factors might it 5 depend on? 6 A. It might depend on whether or not there's 7 co-occurring mental health concerns, and it might 8 depend on whether there is ambivalence, for example, 9 on the part of the patient. So there are -- there 10 are certainly indicators of why psychotherapy might 11 be particularly important. 12 It -- you know, there are many people who can 13 benefit from psychotherapy anyway, but there's a 14 distinction between, you know, a recommendation or a 15 suggestion and a requirement of psychotherapy before 16 someone is given a letter to a surgeon, supporting 17 surgery. 18 Q. And Dr. Karasic, do you typically recommend 19 psychotherapy prior to any hormone treatment, 20 including testosterone cream or injections? 21 ATTY. GONZALEZ-PAGAN: Object to form. 22 A. It's, again, on a case-by-case basis. Now, I would 23 just say that in my practice as a psychiatrist, I 24 tend to see people who have co-occurred mental 25 illness. And so very often, mental health care is
Page 59 1 that they understand the risks and benefits of 2 treatment, and that there's not a mental health or 3 medical condition that stands in the way of their 4 getting a good result from care. So that's all part 5 of the assessment. 6 Psychotherapy is, you know, is a separate 7 process, though certainly some psychotherapists will 8 do mental health assessments. 9 Q. And is it your understanding, based on your review 10 of the medical records, that Dr. Kylo required 11 C. P. to undergo mental healthcare counseling prior 12 to his top surgery? 13 A. I did not have that impression when I read that. I 14 don't know if there's more to the document than what 15 is said here, but again, there's a distinction 16 between a mental health assessment and mental health 17 counseling, or mental health assessment and 18 psychotherapy. And so, you know, I don't know 19 exactly in this context what the word "counseling" 20 is being used to refer to. But commonly it refers 21 to psychotherapy, which is not a requirement to have 22 surgery. 23 Q. Dr. Karasic, do you, in your practice, typically 24 recommend psychotherapy for transgender minors who 25 receive top surgery?	Page 61 1 necessary for co-occurring mental illness. 2 Q. (BY ATTY. BEDARD) And Dr. Karasic, I appreciate you 3 walking me through the distinction that you've drawn 4 between mental health counseling and a mental health 5 assessment. For the assessment portion of that, 6 which you have said is required by WPATH, does that 7 assessment need to follow certain specific criteria 8 that would be the same in every case? Or is that an 9 individualized assessment? 10 ATTY. GONZALEZ-PAGAN: Objection. Form. 11 A. So there are recommendations that are made in 12 trainings, for example, for what should be asked in 13 an assessment. But ultimately, it is obtaining the 14 information that is required for a letter in 15 accordance of Standards of Care 7. 16 ATTY. BEDARD: Dr. Karasic, I'm now going to 17 show you what has been marked as Defendant's 18 Exhibit 8. 19 (Exhibit 8 marked for identification.) 20 Q. (BY ATTY. BEDARD) Can you see this document? 21 A. Yes. 22 Q. And do you see that these are records from the 23 Center for Child and Family Therapy? 24 A. Yes. 25 Q. Dr. Karasic, I am now on Bates No. Pritchard CFT

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Page 62 1 00005 [sic]. Do you see that? 2 A. Yes. 3 Q. And this is an intake form from the Center of Child 4 and Family Therapy, correct? 5 A. Yes. 6 Q. And did you review this intake form prior to today? 7 A. I don't recall. 8 Q. But you reviewed the records for C. P. from the 9 Center of Child and Family Therapy as a whole, prior 10 to forming your expert opinion, right? 11 A. Yes, that's my recollection. 12 Q. So halfway through this intake form, do you see the 13 section that says "Reason for Referral"? 14 A. Yes. 15 Q. And what was the reason for the referral of C. P. to 16 Ms. Booker? 17 A. It says, "assessment letter for reconstructive chest 18 surgery." 19 Q. So in other words, the assessment letter was the 20 purpose of the visit? That's your understanding? 21 A. Yes. 22 Q. And then I'm scrolling down to the next page. Do 23 you see where it says, "Treatment Goals"? 24 A. Yes. 25 Q. And what are the treatment goals listed?	Page 64 1 involvement that was considered or happened with 2 Sharon Booker afterwards, but I don't recall that 3 from the medical records. 4 Q. Did you review any records showing that Ms. Booker 5 ever met with C. P. again after the surgery? 6 A. I did not see any medical records regarding that. 7 ATTY. BEDARD: All right. Dr. Karasic, I am 8 now going to show you what has been marked as 9 Defendant's Exhibit 9. 10 (Exhibit 9 marked for identification.) 11 Q. (BY ATTY. BEDARD) Can you see this document? 12 A. Yes. 13 Q. And have you seen this document before today? 14 A. I believe so, yes. 15 Q. Did you review this psychological evaluation of 16 C. P. in forming your expert opinion in this case? 17 A. Yes. I believe I've reviewed it prior to -- right 18 prior to forming my expert opinion. 19 Q. And for this type of evaluation, for something 20 entitled a "psychologist evaluation," is this 21 something where a physician would typically refer 22 C. P. for this type of evaluation? 23 A. So my recollection is that this is related to 24 treatment of -- for attention deficit hyperactivity 25 disorder, and very commonly someone does get an
Page 63 1 A. "Provide an assessment [...] letter for gender 2 affirming reconstructive surgery." 3 Q. So Dr. Karasic, writing a letter is not a treatment 4 goal, right? 5 A. Well, it's -- there is -- it is providing an 6 assessment for care, which could be part of a 7 treatment plan, even if it's not -- and I mean, the 8 totality of, you know, of someone's care can be one 9 component, which it sounds like this -- in this 10 particular intake, was focused on that component. 11 Q. And Dr. Karasic, is it your understanding, based on 12 speaking with C. P. and the review of his records, 13 particularly his records with the Center for Child 14 and Family Therapy, that he had two therapy sessions 15 with Ms. Booker? 16 A. So yes. My understanding is that there were two 17 sessions for the assessment for surgery. 18 Q. And after those two sessions, Ms. Booker then wrote 19 a letter of support for his reconstructive surgery? 20 A. Yes. 21 Q. Did you review any records showing that Ms. Booker 22 conducted any follow-up assessments after the 23 surgery? 24 A. I don't recall that from the records. I think the 25 parents might have said something about some	Page 65 1 evaluation from a psychologist for ADHD prior to 2 initiating treatment. 3 ATTY. BEDARD: Omar, just as a sidebar, we may 4 be getting some background feedback from you again. 5 ATTY. GONZALEZ-PAGAN: I apologize. I'm 6 literally on vacation, so the connection is not the 7 best, but I apologize for the feedback. 8 ATTY. BEDARD: No, that's okay. It's a 9 reverberating sound. I don't know how to describe 10 it. 11 ATTY. GONZALEZ-PAGAN: I was writing. It's a 12 tiny little desk. 13 Q. (BY ATTY. BEDARD) Yeah. Okay. So for this type of 14 psychological evaluation, is this the type of 15 evaluation that you might see before someone 16 receives a diagnosis of gender dysphoria as well? 17 A. My recollection of this evaluation is that it was 18 for attention deficit hyperactivity disorder, ADHD. 19 Q. Understood. That was the specific purpose for C. P. 20 I think I'm asking, perhaps inartfully, a broader 21 question which is: Is this type of psychological 22 evaluation something that you might see prior to or 23 at the initiation of a diagnosis of gender 24 dysphoria? 25 A. No, not typically. So a general neuropsychological

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Page 66 1 evaluation is not typically what you see prior to 2 care; rather, one might see an assessment that is 3 focused on the care that's being considered. 4 Q. And Dr. Karasic, I'm going back now to your expert 5 report and paragraph 75, specifically, of that 6 expert report. 7 A. Yeah. 8 Q. And in that second sentence of Paragraph 75, you 9 said, "Casey's ADHD diagnosis does not impact the 10 diagnosis of gender dysphoria nor the medical 11 necessity of treatment." What is the basis for that 12 opinion? 13 A. Sure. So when one is making a diagnosis of gender 14 dysphoria, it's based on the DSM criteria of gender 15 dysphoria. It's based on the symptoms of gender 16 dysphoria. And many people have ADHD. Some people 17 with ADHD also have gender dysphoria. Many do not. 18 Having ADHD does not, you know, mean that you can't 19 also have a diagnosis of gender dysphoria, and 20 indeed, many people have both. 21 And similarly, if somebody has gender 22 dysphoria, having ADHD does not mean that treatment 23 of gender dysphoria is not medically necessary. 24 Q. Dr. Karasic, we're at another hour mark, but before 25 we go off the record, I'm hearing what appear to be,	Page 68 1 questions." So kind of typical lawyer 2 reinforcement. 3 Q. Did he say anything else? 4 A. He did not say anything else, and I didn't say 5 anything as well. It was a, you know, extremely 6 brief communication during the break. 7 Q. Did you discuss any documents when you were speaking 8 with plaintiff's counsel? 9 A. No. 10 ATTY. BEDARD: Okay. If we want to take a 11 short break, it's two -- sorry -- 11:03 Pacific. Do 12 you want to come back at 11:10? 13 ATTY. GONZALEZ-PAGAN: That works. 14 THE VIDEOGRAPHER: We are going off the record 15 at 11:04. 16 (Break from 11:04 a.m. to 11:13 a.m.) 17 THE VIDEOGRAPHER: We are back on the record at 18 11:13. 19 Q. (BY ATTY. BEDARD) Dr. Karasic, we've just taken a 20 short break. Did you speak with anyone during the 21 break? 22 A. No. 23 Q. Did you communicate with anyone via phone or email? 24 A. No. 25 ATTY. GONZALEZ-PAGAN: Objection to form.
Page 67 1 like, instant messaging sounds. Do you have any 2 sort of message system in front of you right now? 3 A. I do not. 4 ATTY. GONZALEZ-PAGAN: Stephanie, those may be 5 my computer. 6 ATTY. BEDARD: Okay. So Omar, I don't know if 7 you're able to turn -- 8 ATTY. GONZALEZ-PAGAN: I'll try to turn them 9 off. 10 ATTY. BEDARD: Yeah. If you could turn the 11 sounds off, that would be great. 12 Q. (BY ATTY. BEDARD) And Dr. Karasic, just before we go 13 off the record, have you communicated with anyone 14 during the course of the deposition so far today? 15 A. Not during the course of the deposition. During the 16 break, Omar called me and said, "You're doing 17 great." And that's pretty much, you know. But 18 during the -- while during -- you know, while we 19 were doing the deposition, I have received no 20 instant messages or any other communication. 21 Q. Understood. And did plaintiff's counsel say 22 anything to you during the break other than, "You're 23 doing great?" 24 A. I think he said maybe something to the effect of, 25 "You're doing great. Remember just answer the	Page 69 1 A. No. 2 Q. (BY ATTY. BEDARD) Did you review any documents 3 during the break? 4 A. No. 5 Q. Let's turn now to -- back to Exhibit 2, your expert 6 disclosure. And I'm looking specifically at 7 paragraphs 38 and 39. Can you see that document? 8 A. Yes. 9 Q. So in Paragraphs 38 and 39 of your report, you 10 discuss the reversibility or the irreversibility of 11 treatment. So Dr. Karasic, is it your expert 12 opinion that certain gender-related treatment are 13 reversible and others are irreversible? 14 A. Yes. 15 Q. So let's talk about that for a minute and sort of go 16 through some of these different procedures. 17 So first, for puberty blocking, is it your 18 understanding that puberty -- the impact of puberty 19 blockers is reversible? 20 A. Yes. 21 ATTY. GONZALEZ-PAGAN: Objection to form. 22 A. Yes. 23 Q. (BY ATTY. BEDARD) And in your report, you stated 24 that "once stopped, a patient immediately returns to 25 the stage of pubertal development that had begun

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Page 70 1 when the treatment was initiated"; is that right? 2 A. Yes. 3 Q. So just so I understand this -- if a patient goes on 4 puberty blockers, do they immediately start puberty 5 again once they go off the blockers, or is there 6 typically a period of time before puberty would 7 start again? 8 ATTY. GONZALEZ-PAGAN: Objection to form. 9 A. Well, if -- if they go off puberty blockers, then 10 they can then have initiation of production of 11 hormones that can start the changes of puberty that, 12 you know, would have happened if puberty had not 13 been paused by the puberty blockers. 14 Q. (BY ATTY. BEDARD) Understood. But I guess what I'm 15 asking is if a patient goes off puberty blockers -- 16 to the extent we know, if a patient goes off puberty 17 blockers, is there typically a delay before that 18 patient would begin puberty again? 19 A. Well, they've already begun puberty, in that puberty 20 blockers are started at Tanner Stage II. So 21 presumably, they would again be at -- when puberty 22 blockers are discontinued, they would be at Tanner 23 Stage II. And then with their own production of sex 24 hormones, they could then progress in puberty. 25 Q. So let me ask it a slightly different way, then.	Page 72 1 Q. (BY ATTY. BEDARD) And then in your report, you also 2 discussed how certain treatments are irreversible. 3 And which treatment would you consider to be 4 irreversible? 5 A. Well, WPATH labels partially reversible and 6 reversible treatments. And hormones are -- can be 7 partially reversible, up to a point, in that 8 somebody who stops hormones could then -- for 9 example, if someone stopped puberty blockers and 10 hormones, could then proceed in puberty of their sex 11 assigned at birth, but they may have some changes 12 related to -- relating to having been on cross-sex 13 hormones. 14 And then surgery being mostly irreversible, you 15 know, there can be some attempts to reverse the 16 cosmetic result with chest surgery. Certainly, 17 genital surgery is irreversible. 18 Q. And a minute ago, Dr. Karasic, you mentioned Tanner 19 Stage II. So what is Tanner staging? 20 A. So Tanner staging is a I-to-V scale relating to 21 puberty, where Tanner Stage II is the start of 22 puberty, and people assigned female at birth, that 23 the development of breast buds is usually the 24 indicator. And Tanner Stage V is having completed 25 puberty. So pediatricians and pediatric
Page 71 1 Let's say a patient goes onto puberty blockers and 2 then goes back off those puberty blockers. You 3 testified that it is a reversible treatment, and the 4 patient will immediately go back to where they 5 started. What I'm trying to understand is, is it an 6 immediate process? So if someone goes off of 7 puberty blockers, will they immediately restart 8 where they previously left off in their puberty 9 development? Or does it typically take some time 10 for puberty to restart? 11 ATTY. GONZALEZ-PAGAN: Objection to form. 12 A. So puberty is a process of development. And so 13 the -- but the development of puberty can continue 14 again once the person has stopped puberty blockers. 15 There's certainly data -- you know, more data, 16 people starting and stopping puberty blockers, from 17 the treatment of central precocious puberty, in 18 which case people are on puberty blockers to delay 19 puberty so that the patient undergoes puberty with 20 their peers, and so when they have reached that 21 time, they're taken off puberty blockers, and then 22 they can proceed in puberty with their peers. 23 But of course, any development that they've had 24 before starting puberty blockers, you know, could 25 still be there.	Page 73 1 endocrinologists stage where people are in puberty 2 on that I-to-V scale. 3 Q. And what was the Tanner stage of C. P. at the 4 initial presentation to Dr. Hatfield? 5 A. So because Casey -- so I did not examine Casey at 6 that time, but Casey had reported the very earliest 7 breast development, and -- around that time. And so 8 with -- even though I saw somewhere in the medical 9 records, and I don't know, but from Casey's report, 10 there was -- it sounded like breast bud development, 11 which would have been Tanner Stage II, as Casey 12 started to have some discomfort with development in 13 his chest. 14 Q. And was there some discrepancy you're referencing in 15 the medical records about the progression of breast 16 development? 17 A. Yeah. There was somewhere, I think, where breast -- 18 where it may have said no breast buds. I can't 19 remember where that was in the medical record. But 20 clearly the impetus, as described by Casey, for 21 going to the doctor was starting to have these 22 changes. 23 And when you start to have those changes, 24 breast bud development specifically, that puts you 25 in Tanner Stage II. Before that, Casey did not

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Page 74 1 have, you know, discomfort with his chest. 2 Q. And for someone who starts taking puberty blockers 3 at Tanner Stage II, are they considered to be 4 fertile or infertile at that point? 5 A. So -- 6 ATTY. GONZALEZ-PAGAN: Objection to form. 7 A. So my understanding is that fertility develops with 8 the progression of puberty, that there has been 9 concern about fertility if you, you know, if 10 somebody halts at Tanner Stage II, but really only 11 if they're going on to cross-sex hormones. If 12 somebody stops puberty blockers, they just continue 13 progressing in puberty. And when we look at people 14 with central precocious puberty, they still have 15 fertility, you know, after they have gone off of 16 puberty blockers. 17 Q. (BY ATTY. BEDARD) And just in layman's terms for 18 myself, when we talk about central precocious 19 puberty, is that when someone starts undergoing 20 puberty at an earlier age than their peers, and 21 takes a puberty blocker? 22 A. Yes. 23 Q. Okay. So you mentioned a second ago the impact on 24 fertility of taking some sort of hormone treatment 25 like testosterone. So is someone who presents at	Page 76 1 Q. And you mentioned that there have been some concerns 2 in the medical and scientific community about the 3 impact on fertility. Can you talk a little bit more 4 about that? 5 ATTY. GONZALEZ-PAGAN: Objection to form. 6 A. So just that if -- that the patient and their 7 parents are well informed that this course of 8 treatment of puberty blockers that are not halted 9 but then progressing on to cross-sex hormones, that 10 that may affect the person's fertility. And so it's 11 important for the provider to have a discussion with 12 the patient and parents. 13 Q. (BY ATTY. BEDARD) Dr. Karasic, I am now going to 14 show you what has been marked -- reshow you what has 15 previously been marked as Defendant's Exhibit 5. 16 Do you see the Paragraph -- I'm sorry, let me 17 back up. 18 This is what has previously been marked as 19 Defendant's Exhibit 5, and it is the 2017 Endocrine 20 Society guidelines. Do you understand that? 21 A. Yes. 22 Q. Okay. And do you see the section on Page 11 that 23 starts with "Remarks"? 24 A. Yes. 25 Q. Okay. Could you read that paragraph, please -- that
Page 75 1 Tanner Stage II and starts taking puberty blockers 2 and then goes on to take testosterone, are they 3 considered fertile at that point? 4 A. So my understanding is that fertility can persist if 5 somebody has gone a little bit further into puberty. 6 But I also know that there have been trans men who 7 have been told they were not going to be fertile who 8 later had babies. And so, you know, it may be a 9 determination of how far into puberty it's required 10 for them to, you know, to be fertile. 11 But there certainly is counseling of people if 12 they start puberty blockers, you know, early, that 13 if then they continue in transition, that that might 14 affect their -- you know, with hormonal transition, 15 that might affect their fertility. 16 Q. Okay. So in other words, when someone is about to 17 take puberty blockers, you would advise that there 18 be an informed consent process about the potential 19 impacts on fertility? 20 A. Yes. 21 Q. And the same would be true for hormone treatment 22 like testosterone, that there should be a process of 23 informed consent about that treatment and the 24 impacts on fertility? 25 A. Yes.	Page 77 1 first paragraph after "Remarks"? 2 A. "Persons considering hormone use for gender 3 affirmation need adequate information about this 4 treatment in general and about fertility effects of 5 hormone treatment in particular to make an informed 6 and balanced decision. Because young adolescents 7 may not feel qualified to make decisions about 8 fertility and may not fully understand the potential 9 effects of hormone interventions, informed consent 10 and protocol education should include parents, the 11 referring [mental health professionals], and other 12 members of the adolescent's support group. To our 13 knowledge, there are no formally evaluated decision 14 aids available to assist in the discussion and 15 decision regarding the future fertility of 16 adolescents or adults beginning gender-affirming 17 treatment." 18 Q. Do you agree with that statement, Dr. Karasic? 19 A. Yes. 20 Q. And do you agree specifically with the portion of 21 this statement from the Endocrine Society that says 22 "consent and protocol education should include 23 parents as well as the referring [mental health 24 professionals]"? 25 A. Yes.

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Page 78 1 Q. Based on your review of the medical records and your 2 discussion with C. P., did Dr. Hatfield include a 3 referring mental health provider in his discussion 4 and decision-making about fertility with C. P.? 5 ATTY. GONZALEZ-PAGAN: Object to form. 6 A. Dr. Hatfield was the referring mental health 7 provider. 8 Q. (BY ATTY. BEDARD) So let me ask it a different way, 9 then: Did you see any discussion or any evidence in 10 the medical records, that Dr. Hatfield discussed the 11 impacts on fertility of starting puberty blockers? 12 A. Yes. It's my recollection that there was 13 documentation that there was a discussion about 14 fertility. 15 ATTY. BEDARD: Let me pull up those records for 16 you. 17 (Exhibit 10 marked for identification.) 18 Q. (BY ATTY. BEDARD) So Dr. Karasic, can you see the 19 document that says, "CERTIFICATION OF THE AGENT FOR 20 THE CUSTODIAN OF RECORDS"? 21 A. Yes. 22 Q. And these are the documents -- the medical records 23 from the Polyclinic that you previously reviewed for 24 C. P.? 25 A. Well, I can only see the little top part of it, but	Page 80 1 position was that he had no interest in ever bearing 2 children. 3 Q. Dr. Karasic, what are the effects of puberty 4 blockers on bone density? 5 A. So the data on that are really a mixed bag. There 6 is concern if someone is on puberty blockers for too 7 long that that can affect bone density. But 8 overall, bone density data on young people is kind 9 of mixed. There was some data I recall reading that 10 people assigned male at birth who were transgender 11 had lower bone density before starting puberty 12 blockers. Perhaps they were less physically active 13 than their cisgender peers. 14 So there is concern with bone density, and 15 particularly concern if people are on puberty 16 blockers for a very long time. And there's concern 17 in adults for people who have hormone-blocking 18 without cross-sex hormones. 19 But when -- the long-range data that there's 20 been, like the Dutch have followed people over ten 21 years and concluded that there are transgender 22 people -- patients who receive cross-sex hormones -- 23 presumably some have had puberty blockers first -- 24 that they had -- that there was no effect that they 25 saw in the ten-year period on bone density.
Page 79 1 I'm assuming -- 2 Q. Let me scroll down a bit. 3 A. Okay. Yes, that looks like the documents -- part of 4 the documents that I reviewed. 5 Q. Do you recall where specifically in these medical 6 records Dr. Hatfield discussed the impacts on 7 fertility with C. P. and his parents? 8 A. No. And I don't remember whether it was in notes 9 from Dr. Hatfield or with Dr. Garza. I just, you 10 know, I've reviewed these a while back, but my 11 recollection was somewhere there was a charting of a 12 fertility discussion. And that's just my 13 recollection. 14 Q. Do you recall anything else about that discussion? 15 A. No. I was not present for the discussion, so I 16 can't really say anything about it -- 17 Q. Understood. 18 A. -- except the records that you have as well. 19 Q. And in your conversation with C. P. in March of this 20 year, did you discuss with him whether there had 21 been a prior discussion with any of his providers 22 about the impact on fertility? 23 A. Yes. And C. P. had specifically said that he had no 24 interest in bearing children. And so that he had 25 had that discussion with his providers, and his	Page 81 1 So there have been some reports of effects, but 2 I think that the general consensus is that then if 3 people are moving on to cross-sex hormones, that 4 that is not a long-range -- a long-term problem for 5 them. 6 Q. Okay. So to make sure I understand that, the 7 concern, at least in part, might stem from someone 8 who is on a puberty blocker for a long time that 9 does not then start cross-sex hormones, right? 10 A. Yes. 11 Q. But the initiation of cross-sex hormones means that 12 the treatment at that point becomes at least 13 partially irreversible, right? 14 ATTY. GONZALEZ-PAGAN: Objection to form. 15 A. At least partially, yes. 16 Q. (BY ATTY. BEDARD) So any impact on bone density that 17 occurred on puberty blockers alone is not something 18 that could then be reversed; is that right? 19 ATTY. GONZALEZ-PAGAN: Objection. 20 A. No, that's not true. Because first of all, the data 21 about bone density and development, is kind of all 22 over the place. And then people given cross-sex 23 hormones, and it appears that their bone density is 24 stable in long-term follow-ups on cross-sex 25 hormones.

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Page 82 1 And so while there's concern in that, you know, 2 it might be listed as a potential side effect in 3 given informed consent, and there are concerns some 4 people have had in reviewing some data; in fact the 5 data is kind of all over the place, and the 6 long-term impact on transgender people is, at least 7 according to the Dutch, that study of long-term -- 8 that there is not an impact of, you know, long-term 9 cross-sex hormones on bone health. 10 Q. (BY ATTY. BEDARD) Which is the Dutch study? Who 11 were the authors of that study? 12 A. So there were a couple studies where the first 13 author -- so it was a big Dutch group. It was 14 Wiepjes. Wiepjes, W-i-e-p-j-e-s, was the author of 15 a couple of articles about a long-term follow-up on 16 bone health in patients who have transitioned in 17 Holland. 18 Q. And have those studies focused on the impact of 19 minors taking puberty blockers? 20 A. No. Those were focused on impact in adults. And at 21 least Wiepjes's. I don't think -- I think there's 22 maybe a little bit of data that the Dutch might be 23 publishing at some point on the group that went 24 through puberty blockers and then hormones and then 25 surgery. And perhaps that will include bone health.	Page 84 1 A. So we certainly have experience with, you know, with 2 trans people who have had puberty blockers, as well 3 as cisgendered people who have puberty blockers. 4 But, you know, certainly more research, you know, is 5 something that I think, you know, could happen. 6 The issue is that people are on puberty 7 blockers typically for just a short period of time, 8 and so it might be even difficult to, you know, to 9 kind of measure, because then they're moving on to 10 cross-sex hormones. 11 Q. Okay. But to make sure I understand that, at least 12 in this case for C. P., C. P. first had a Vantas 13 implant and then actually received a second Vantas 14 implant, right? So the puberty blockers actually 15 continued throughout the course of the hormone 16 treatment as well. It's not something that stopped 17 when hormone treatment began, right? 18 A. That's true. There's often overlap. And -- but I 19 think when -- once somebody is receiving cross-sex 20 hormones, once C. P. was receiving testosterone, 21 C. P. was having the influence of testosterone on 22 development. And so the fact that estrogen was 23 being suppressed was not maybe as much of a, you 24 know, concern, in that people assigned male at birth 25 have predominantly testosterone and lower amounts of
Page 83 1 But I think Wiepjes looked at, like, ten years of 2 hormone treatment in adults. 3 Q. So what data is out there, then, about the impact of 4 puberty blockers on minors in terms of the impacts 5 on bone density? 6 A. So I don't think I can provide you with a literature 7 review of it. I can say my impressions and, you 8 know, maybe having looked at reviews, that different 9 people who have looked at it maybe have had somewhat 10 different results in terms of effect on bone 11 density; and that people who then progressed to 12 cross-sex hormones or, you know, presumably if 13 people stop cross-sex hormones and they get their -- 14 the hormones from the sex they were assigned at 15 birth, that they have healthy bones. 16 The one thing I saw -- I think it was from 17 Wiepjes's, like, perhaps in -- trans women over 50 18 have bone health issues similar to cisgender women 19 over 50, as opposed to cisgender men over 50. But, 20 like, fracture rates were similar to cisgender 21 women. And before that, I think there was not a 22 difference. Yes. 23 Q. So switching gears slightly. So when a minor starts 24 taking a puberty blocker, do we know the long-term 25 impacts on brain development?	Page 85 1 estrogen in their system during puberty. 2 Q. So I have a similar question about a different 3 effect: If a minor starts taking a puberty blocker, 4 do we know the long-term impacts on body 5 composition -- body fat composition, I should say? 6 A. So I don't know -- I don't think I could tell you 7 the studies on body fat composition, you know, for 8 people on puberty blockers. Certainly if people -- 9 if somebody gets -- if somebody's assigned female at 10 birth, and then they start on testosterone later, 11 after starting on testosterone, they can have both a 12 building of muscle and a redistribution of fat that 13 could affect body fat content. 14 Q. Dr. Karasic, I'm going to show you again Defendant's 15 Exhibit 5. 16 Can you see that screen? 17 A. Yes. 18 Q. And we are, again, looking at the 2017 Endocrine 19 Society guidelines, right? 20 A. Yes. 21 Q. Okay. On Page 3 of the Endocrine Society 22 guidelines, do you see the paragraph that's marked 23 2.4 -- Paragraph 2.4? 24 A. Yes. 25 Q. Okay. Could you read that paragraph, please?

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Page 86 1 A. "In adolescents who request sex hormone treatment 2 (given that this is a partly irreversible 3 treatment), we recommend initiating treatment using 4 a gradually increasing dose schedule after a 5 multidisciplinary team of medical and MHPs has 6 confirmed the persistence of GD/gender incongruence 7 and sufficient mental capacity to give informed 8 consent, which most adolescents have by age 16." 9 Q. Dr. Karasic, do you agree with that statement? 10 A. Well, I am a psychiatrist and not an 11 endocrinologist, but this is my understanding of 12 the, you know, consensus of the endocrinologists who 13 wrote this statement. 14 Q. Based on your review of C. P.'s medical records and 15 your conversation with C. P., did Dr. Hatfield 16 follow this guideline and include a 17 multidisciplinary team of medical and MHPs to 18 confirm the persistence of gender incongruence and 19 sufficient mental capacity to give informed consent? 20 A. So it's been a little while since I've reviewed the 21 entire guidelines, but I believe elsewhere they 22 say -- they speak to a preference for a 23 multidisciplinary team, but also recognize that 24 multidisciplinary teams are not always available. 25 And I think it speaks to a difference between	Page 88 1 and so my answer would be "no." 2 Q. And do you know the grading of evidence for a 3 mastectomy procedure for adolescent trans males in 4 the ESG? 5 A. I can't tell you what the grades given in the 6 Endocrine Society guidelines. 7 Q. And do you believe, in your opinion, that an 8 11-year-old would have the capacity and maturity and 9 judgment to understand what it is like to be 10 sterilized as an adult? 11 ATTY. GONZALEZ-PAGAN: Object to form. 12 A. So remember that the parents are providing consent 13 certainly with the assent of the minor, and with 14 discussion of the rest of the team. But I would 15 also say that starting a puberty blocker at age 11 16 isn't in and of itself sterilizing. 17 It could be sterilizing if somebody were 18 transitioning further. But an 11-year-old could 19 start puberty blockers and then go off of puberty 20 blockers and still be fertile. 21 Q. (BY ATTY. BEDARD) So thinking more about this 22 informed consent for a mastectomy in particular, 23 would a proper informed consent form for that 24 surgical procedure contain a warning that a patient 25 is likely to lose the ability to breast-feed?
Page 87 1 the European gender clinics and, to some extent, 2 perhaps academic medical centers that have gender 3 teams in the US. But in the US, most transgender 4 care is provided in private practice settings, and 5 there is no multidisciplinary team present. There 6 can be referrals to people from other disciplines, 7 but just health care is structured a little bit 8 differently than in the European gender clinics. 9 Q. Was C. P. 16 years or older at the time of providing 10 consent to testosterone therapy? 11 A. No. But remember, C. P.'s parents consented and 12 C. P. assented. 13 Q. Was C. P. 16 years or older at the time of providing 14 consent for the bilateral mastectomy surgery? 15 A. No. 16 Q. What is the grading of evidence for a reference 17 range of 320 to 1000 MGDs for testosterone for 18 trans males in the Endocrine Society guidelines? 19 A. Well, I would ask you to repeat your question, but I 20 don't really think that it's my place to be reciting 21 back what's in the endocrine guidelines. 22 Q. Are you aware of the grading of evidence? 23 A. There is a grading of evidence. You were asking for 24 a specific grade on a specific question within that 25 and asking if I know that off the top of my head,	Page 89 1 A. So I don't know what might be on a given form, but I 2 think that, you know, it's reasonable for that to be 3 part of a discussion of anyone who has a mastectomy, 4 whether they're transgender or cisgender. You know, 5 just that they know that they, you know, may very 6 well not be able to breast-feed, whether that's a 7 cisgender woman who is having a mastectomy for, you 8 know, for whatever medical reason, or a transgender 9 person. 10 Q. But in other words, you would recommend, in your 11 professional judgment, that an informed consent form 12 for a mastectomy, regardless of the circumstances, 13 should include information that the patient is 14 likely to lose the ability to breast-feed, right? 15 ATTY. GONZALEZ-PAGAN: Objection. 16 Mischaracterizes testimony. 17 A. Yeah. I think I said in my testimony I don't know 18 about construction of a form, but I think that 19 should be part of the discussion in informed 20 consent, you know, making clear that the person, you 21 know, won't be able to breast-feed. 22 In the case of C. P., C. P. was very clear that 23 he never wanted to parent. And even now, as an 24 older teen, continues to be very clear about that. 25 And I doubt he would be breast-feeding anyone else's

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Page 90 1 baby. 2 And so in this case, you know, it should be 3 part of the discussion, but it's not necessarily, 4 you know, a kind of a deal-breaker for an individual 5 patient if they're not thinking of parenting. And, 6 you know, of course people can parent and feed their 7 infants in other ways. 8 ATTY. BEDARD: Dr. Karasic, I am going to show 9 you what has previously been marked as Defendant's 10 Exhibit 3. And these are the Polyclinic records 11 that were recently produced to us and then produced 12 to plaintiffs. 13 Q. (BY ATTY. BEDARD) And I'm going to scroll in, 14 because I can see you squinting here. I don't want 15 you to have to do that. Can you see that okay? 16 A. Yes. 17 Q. Okay. And this is the page we previously discussed. 18 That is C. P.'s informed consent for his bilateral 19 mastectomy, correct? 20 A. Yes. 21 Q. Okay. I'm going to scroll down to the different 22 provisions in the consent form. And let me know 23 when you want me to keep scrolling so that you've 24 been able to review the entire form. 25 A. Okay. Okay. Yeah, I can only see down to Line 6,	Page 92 1 record of that. 2 And given that C. P. was -- has been pretty 3 emphatic from early on about never wanting to bear 4 children, my guess is that there wasn't -- it was 5 not, you know -- I would say hopefully it was 6 discussed, but it was not, you know, a consideration 7 by C. P. or C. P.'s parents in making the decision. 8 Q. And at the bottom of the page here for this consent 9 form for the bilateral mastectomy, do you see the 10 date is December 10th of 2019? 11 A. Yes. 12 Q. And C. P. was 14 years old at that point in time, 13 right? 14 A. Yes. About three months, I think, before becoming 15 15. 16 Q. So at age 14, C. P. signed the consent form for the 17 mastectomy procedure, right? 18 A. And one of C. P.'s parents. 19 Q. Signed as a witness, right? 20 A. Well, that's how this particular -- it looks like 21 this is a form that was -- the one that was signed 22 may well have been one meant for adults, because the 23 parent is not just a witness when there's consent 24 for any care by a minor. 25 So the, you know, the form does say "Witness
Page 91 1 so if you could scroll up after that. 2 Q. Sure. 3 A. Okay. I've read it. 4 Q. Okay. Was C. P. informed, prior to the bilateral 5 mastectomy, that he would lose the ability to 6 breast-feed? 7 A. So one can't tell from the form. This was a form 8 that was signed, but it does not necessarily say 9 everything that was part of a discussion. C. P. did 10 have a discussion with Sharon Booker and presumably 11 with Dr. Hatfield. And so hopefully there, you 12 know, was a thorough discussion of the risks and 13 benefits of surgery, but not everything is listed on 14 this form. 15 Q. So Dr. Karasic, I hear you saying "hopefully" that 16 those conversations took place. 17 A. Mm-hmm. 18 Q. But is there any evidence in the medical records 19 themselves that any of C. P.'s providers discussed 20 the impact on C. P.'s ability to breast-feed? 21 A. I don't recall. When I talked with C. P. about -- 22 C. P. and C. P.'s parents had said that there was a 23 thorough discussion of risks and benefits of the 24 treatments they received, but I don't recall whether 25 there was documentation elsewhere in the medical	Page 93 1 Signature," but in fact, the informed consent was 2 really being given by the parent. 3 Q. And Dr. Karasic, have you seen any evidence in the 4 medical records that C. P. was evaluated to ensure 5 that there was capacity to make fully informed 6 decisions and specifically to consent to surgical 7 treatment? 8 A. So that, I don't recall. But remember, the consent 9 is being given by the parent. And the minor is -- 10 is assenting. And so they should have an 11 understanding of what's happening, but the informed 12 consent is being given by the adult parent. 13 Q. So I understand that typically a minor would be 14 assenting and the parent would be consenting. But 15 as we sit here looking at this consent form, 16 Casey -- sorry, C. P., the minor, is the one who 17 actually signed the form on the patient signature 18 line, right? 19 A. Well, you have the same form that, you know, you're 20 showing me the form. I see where it was signed. 21 But I think they just used a form to be signed that 22 was a stock form for adults, I assume, because it 23 says "patient" and "witness." If this was a form 24 that was meant for minors, it's not a 25 well-constructed form, because the consent is -- the

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Page 94 1 informed consent is done by the parent and the 2 patient assents. And if the form was constructed 3 some other way, it's not the best, you know, 4 constructed form. 5 Q. So Dr. Karasic, we're about at that hour mark again. 6 Do you want to keep going? Do you want to keep 7 plugging away? Would you prefer to take a break? 8 What's your preference? 9 A. Well, how many more hours are you guessing this is 10 going to be? 11 ATTY. GONZALEZ-PAGAN: Can we go off the 12 record, Stephanie, just to discuss? 13 ATTY. BEDARD: Sure. That's fine. 14 THE VIDEOGRAPHER: We're going off the record 15 at 12:03. 16 (Break from 12:03 p.m. to 12:47 p.m.) 17 THE VIDEOGRAPHER: We are back on the record at 18 12:47. 19 Q. (BY ATTY. BEDARD) Great. Dr. Karasic, did you speak 20 with anyone during the break? 21 A. No. 22 Q. And did you review any documents during the break? 23 A. No. 24 Q. All right. So I'm going to show you what has been 25 marked as Defendant's Exhibit 10. Can you see that	Page 96 1 making that decision. So perhaps better to ask 2 Dr. Hatfield. 3 Q. Understood. So let me try to ask it a different 4 way. What hormone is primarily responsible for the 5 growth of breast tissue? 6 A. So breast tissue is primarily a response to 7 estrogen. 8 Q. Okay. And what hormone, then, is important for 9 ensuring things like normal bone growth and bone 10 density that we previously discussed? 11 ATTY. GONZALEZ-PAGAN: Objection. Form. 12 A. So both testosterone and estradiol can support bone 13 health. 14 Q. (BY ATTY. BEDARD) And am I correct in understanding 15 that testosterone is converted into estradiol in the 16 bone? 17 A. I'm not -- I don't think I'm going to extend my 18 expertise into the effects -- the relative effects 19 of estradiol and testosterone on bone health and 20 bone growth. 21 Q. Okay. So you are not offering any opinion in this 22 case on any testosterone levels that C. P. may have 23 had? 24 ATTY. GONZALEZ-PAGAN: Objection. Form. 25 A. I'm not offering expertise in this case on the
Page 95 1 document? 2 A. Yes. 3 Q. Great. And just as a refresher, Defendant's 4 Exhibit 10 are the records from the Polyclinic that 5 we previously discussed during your deposition. So 6 I'm turning now to Bates No. 13. 7 So Dr. Karasic, do you see the progress note in 8 the middle of the page from Dr. Hatfield from 9 June 9th of 2018? 10 A. Yes. 11 Q. And it appears from this progress note that 12 Dr. Hatfield had tested C. P.'s testosterone levels, 13 right? 14 A. Yes. 15 Q. After undertaking that test, did he prescribe any 16 medication for C. P.? 17 A. It looks like from the note, yes. 18 Q. And what was that medication? 19 A. Well, it looks like it was a testosterone cream. 20 And he also said, "We will also include a small 21 amount of estradiol to improve bone growth." 22 Q. And what is your understanding of why estradiol 23 would be prescribed in these circumstances? 24 A. So I don't think I can comment on that. I'm a 25 psychiatrist, and I wasn't -- also wasn't the person	Page 97 1 proper approach, hormonally, related to bone growth. 2 Q. (BY ATTY. BEDARD) Well, I guess I'm asking a 3 slightly different question: Are you offering an 4 opinion in this case as to whether the medications 5 provided to C. P. were appropriate under his 6 specific circumstances? 7 A. Yes. 8 Q. Okay. So are lab reference ranges important for a 9 physician to use to determine if a lab value is 10 normal or abnormal? 11 ATTY. GONZALEZ-PAGAN: Objection. Form. 12 A. Yes. Lab values are important, and also clinical 13 effect. 14 Q. (BY ATTY. BEDARD) And do lab ranges differ for males 15 and females? 16 A. Yes. 17 Q. And does a person's gender identity change what's 18 the normal range of their lab values? 19 A. In one regard, which is when people have 20 transitioned. And certainly I know in adults who 21 have transitioned, there are target ranges by their 22 primary care physicians of bringing hormones into -- 23 within the target range of the gender to which they 24 identify, as opposed to the sex assigned at birth. 25 Q. And can erythrocytosis -- am I pronouncing it

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Page 98 1 correctly if I say "erythrocytosis," Dr. Karasic? 2 ATTY. GONZALEZ-PAGAN: Stephanie, I apologize, 3 you spoke fairly quickly there, and I was having a 4 hard time understanding you. So I don't know -- at 5 least for my edification, I couldn't understand what 6 you just asked. 7 ATTY. BEDARD: Sure. 8 Q. (BY ATTY. BEDARD) Let me ask it this way: 9 Dr. Karasic, what is the medical term for someone 10 with a high red blood cell count? 11 A. Oh, okay. So you were -- it sounds like you were 12 referring to erythrocytosis when you were asking -- 13 I think that's the word that you were using? 14 Q. It is, yes. I just wanted to make sure I was 15 pronouncing it correctly. 16 A. Yeah, okay. 17 Q. So erythrocytosis? 18 A. Yes. 19 Q. Okay. So can erythrocytosis be dangerous to a 20 patient? 21 A. Yes. If somebody has, like, a polycythemia -- if 22 somebody has a really high red blood cell count, 23 that can be harmful. 24 Q. And can testosterone cause erythrocytosis? 25 A. So yeah, it can cause polycythemia, I think is how	Page 100 1 A. Well, the reference range from this lab on the 2 result says 37.5 to 51. So I think the reference 3 range can vary by lab. 4 Q. What's your understanding of the normal reference 5 range? 6 A. Somewhere around that. I think there's a 7 different -- slightly different reference range 8 for -- for men and women. And -- but yeah, I guess 9 I would... 10 Q. And are you aware of the condition known as 11 polycystic ovarian syndrome, or PCOS? 12 A. Yes. 13 Q. And is it your understanding that PCOS has been 14 associated with things like insulin resistance or 15 metabolic syndromes or diabetes? 16 ATTY. GONZALEZ-PAGAN: Objection to form. 17 A. Yes. 18 Q. (BY ATTY. BEDARD) And would it be important for a 19 physician to help a patient with PCOS lower their 20 testosterone levels to prevent those complications? 21 A. I don't think I'm going to comment as an expert on 22 the best treatments of PCOS. 23 Q. One second, Dr. Karasic. Okay. 24 Dr. Karasic, are you aware that in 2019, the 25 Centers for Medicare and Medicaid Services issued a
Page 99 1 they would refer to it. But yes, testosterone can 2 cause an increase in red blood cell count, and that 3 has risk. 4 Q. And are you aware that in the Framington [sic] 5 study, the younger female group hematocrit levels 6 above 45 had an increased risk of cardiovascular 7 disease, myocardial infection, and death? 8 ATTY. GONZALEZ-PAGAN: Objection. Lack of 9 foundation. 10 A. Yeah, I am not aware of the details of the 11 Framingham study, in terms of red blood cell count. 12 I guess I'll leave it at that. 13 Q. (BY ATTY. BEDARD) If a patient does develop 14 erythrocytosis, should the amount of testosterone 15 given to that patient be decreased? 16 A. It depends in -- at least where I've seen it happen 17 has been in adult patients, and usually the 18 recommendation is to give blood regularly. And that 19 brings it down to the normal range. 20 Q. So turning back now to Exhibit 10. I'm looking now 21 at the lab notes at the top of the page. Do you see 22 where it says 45.5 percent? 23 A. Yes. 24 Q. And is it your understanding that the normal 25 reference range is between 35 to 44 percent?	Page 101 1 decision memo on gender dysphoria and gender 2 reassignment surgery? 3 A. What year did you say? 4 Q. 2019. 5 A. That the -- that CMS -- well, CMS has made a few 6 statements. So you might need to show me which one 7 that is in 2019. I know that they made a statement 8 in 2015. 9 ATTY. BEDARD: Sure. Let's take a look at it. 10 So I'm showing you what has been marked 11 as Defendant's Exhibit 11. 12 (Exhibit 11 marked for identification.) 13 Q. (BY ATTY. BEDARD) Can you see this document? 14 A. Yes. Yeah, I believe this was -- 15 Q. And all -- 16 A. I believe this was 2015 that this decision was made. 17 Q. Oh, you know what? Thank you, Dr. Karasic. The 18 date on here is August 30th of 2016. Do you see 19 that? 20 A. Oh, okay. 2016, I'm sorry. 21 Q. We were both wrong, so. You were closer than I was. 22 A. Yeah. 23 Q. So now that we know we're talking about the same 24 document here, have you seen this same document 25 previously?

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Page 102 1 A. Yes. 2 Q. Okay. And you've had the opportunity to previously 3 review it? 4 A. Not lately. 5 Q. So I'm going to go down to the Decision section of 6 this exhibit. And do you see where it says section 7 "IX. Decision"? 8 A. Yes. 9 Q. Okay. Could you please, Dr. Karasic, read the first 10 full paragraph, starting with "Currently"? 11 A. "Currently, the local Medicare Administrative 12 Contractors determine coverage of gender 13 reassignment surgery on a case-by-case basis. We 14 have received a complete, formal request to make a 15 national coverage determination on surgical remedies 16 for gender identity disorder (GID), now known as 17 gender dysphoria. The Centers for Medicare & 18 Medicaid Services (CMS) is not issuing a National 19 Coverage Determination (NCD) at this time on gender 20 reassignment surgery for Medicare beneficiaries with 21 gender dysphoria because the clinical evidence is 22 inconclusive for the Medicare population." 23 Q. And what's your response to that statement, that the 24 clinical evidence is inconclusive? 25 A. Yes. So I remembered it -- yeah, now it would	Page 104 1 Q. I'm looking now at the section of this decision memo 2 titled "Quality of Studies Reviewed." And let's 3 look now at the second full paragraph discussing the 4 studies reviewed. Could you read that paragraph for 5 me that starts with "Of the 33 studies reviewed"? 6 A. Okay. "Of the 33rd studies reviewed, published 7 results were conflicting -- some were positive; 8 [some] were negative. Collectively, the evidence is 9 inconclusive for the Medicare population. The 10 majority of studies were non-longitudinal, 11 exploratory type studies (i.e. in a preliminary 12 state of investigation or hypothesis generating), or 13 did not include concurrent controls or testing prior 14 to and after surgery. Several reported positive 15 results but the potential issues noted (...) reduced 16 strength and confidence. After careful assessment, 17 we identified six studies that could provide useful 18 information. Of these, the four best designed and 19 conducted studies that assessed quality of life 20 before and after surgery using validated (albeit 21 non-specific) psychometric studies did not 22 demonstrate clinically significant changes or 23 differences in psychometric test results after GRS." 24 Q. Thank you, Dr. Karasic. So while I understand you 25 were saying that CMS's decision is specific to the
Page 103 1 be 2016, actually -- because I was part of a group 2 that responded when this came out. We were at the 3 WPATH conference in Amsterdam in 2016 when it came 4 out and we disagreed. Of note, the CMS had lifted 5 the categorical exclusion transgender care two years 6 earlier, in 2014. 7 In this statement, they say that clinical 8 evidence is inconclusive for the Medicare 9 population, which is primarily the elderly, but also 10 disabled -- some disabled people. And indeed, there 11 was not a lot of research on people with Medicare, 12 because people with Medicare had difficulty 13 accessing surgery at this time. 14 So I do think that within that paragraph, 15 noting that they're talking about Medicare 16 beneficiaries -- which are specifically the elderly 17 and some disabled people. Whereas they had, two 18 years earlier, lifted the CMS exclusion overall on 19 payment, they were asking to do this on a -- 20 continue doing it on a case-by-case basis for now 21 while more information is gathered on -- for 22 gender-affirming surgery in people on Medicare. 23 Q. Let's look for a second, then, at the studies 24 referenced in this decision. 25 A. Mm-hmm.	Page 105 1 Medicare population, at least this specific 2 decision, the concerns voiced in this paragraph 3 don't have to do with the fact that the studies were 4 related or were not related to Medicare, right? 5 ATTY. GONZALEZ-PAGAN: Objection. 6 Mischaracterizes the document. 7 A. It says "collectively the evidence is inconclusive 8 for the Medicare population." And you know, because 9 until two years earlier there was a specific 10 exclusion of paying for transgender care in the 11 Medicare population, it wouldn't have been possible 12 for there to be studies of that. 13 However, some of the studies they cite are from 14 other countries. And since then, there have been 15 more studies about effects of gender-affirming care. 16 And so I wouldn't say that these -- the studies they 17 cite are the totality of evidence. 18 I would also say that the differences in 19 psychometric test results, I would certainly have to 20 look at each study to see what they meant by that, 21 but there has been evidence of people having 22 improved body image, less gender dysphoria, and less 23 depression, less suicidality in a number of studies 24 since then. So I wouldn't say this is an exhaustive 25 review of the studies in that regard.

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Page 106 1 Q. (BY ATTY. BEDARD) And Dr. Karasic, do you reference 2 this CMS decision memo in your report? 3 A. No. It's not original research. It was, you know, 4 some members of the CMS staff, not people involved 5 in transgender care, who had come up with this. And 6 there was some communication between our group and 7 theirs. But it was not original research, it was 8 one, you know, review that was focused on the 9 Medicare population at that time in 2016. 10 ATTY. BEDARD: Dr. Karasic, I'm now going to 11 show you what has been marked as Defendant's 12 Exhibit 12. 13 (Exhibit 12 marked for identification.) 14 Q. (BY ATTY. BEDARD) Can you see that document? 15 A. Yes. 16 Q. And have you seen this document before? 17 A. Yes. 18 Q. What is this document? 19 A. This is a document, it says, by the Counsel for 20 Choices in Health Care in Finland. 21 Q. And what is your understanding of the Counsel for 22 Choices in Health Care in Finland? 23 A. It's a committee in Finland. 24 Q. And did that committee adopt a recommendation on 25 treatment methods for gender dysphoria for minors?	Page 108 1 children and youth. There is also a need for more 2 information on the disadvantages of procedures and 3 on people who regret them." 4 Q. Dr. Karasic, what is your response to this 5 recommendation by COHERE Finland? 6 A. You know, health care across the world is diverse, 7 and different places take different approaches. I 8 know that in the wake of some maybe controversies 9 and like Bell v. Tavistock in the UK, that there was 10 questioning of care for minors. And that -- and 11 this Finish committee seems to be responding to 12 that. But it also is -- it's just one committee's 13 response. 14 Q. Would you agree that research data on the treatment 15 dysphoria due to gender identity conflicts in minors 16 is limited? 17 A. I think that there's -- there is quite a bit of 18 data, and so it just depends how one defines 19 "limited." Always great to have more data, but we 20 also do have a substantial amount of information, 21 not only from studies, but from many decades of 22 minors receiving gender-affirming care. 23 Q. Would you agree that there is a need for more 24 information on the disadvantages of procedures and 25 on people who regret them?
Page 107 1 A. My understanding -- and I guess from reading the 2 full document as well -- that they had -- that they 3 did make some recommendations. 4 Q. Okay. Well, I'm going to scroll down here and ask 5 you to read the second-to-last paragraph, beginning 6 with "Surgical treatments." 7 A. Yes. Now, I don't know in this case -- 8 Q. If you could actually read it for the record, that 9 would be great. 10 A. Okay. "Surgical treatments are not part of the 11 treatment methods for dysphoria caused by 12 gender-related conflicts in minors. The initiation 13 and monitoring, like, of hormonal treatments must be 14 centralized at the research clinics on gender 15 identity at HUS and TAYS. 16 "Research data" -- do you want the 17 remainder? -- "Research data on the treatment of 18 gender dysphoria due to gender identity conflicts in 19 minors is limited. COHERE considers that, moving 20 forward, multi-professional clinics specializing in 21 the diagnostics and treatment of gender identity 22 conflicts at HUS and TAYS should collect extensive 23 information on the diagnostic process and the 24 effects of different treatment methods on the mental 25 wellbeing, social capacity and quality of life of	Page 109 1 A. Well, we have a lot of information showing very 2 little regret. It's, of course, always good to have 3 more information. I cite in my report a study by 4 Bustos of several thousand -- a review of several 5 thousand cases within various studies, showing a 6 regret rate of about 1 percent. 7 Kaiser of Northern California reviewed recently 8 all of its cases of chest surgery in transmasculine 9 youth since 2013, and there were two cases of regret 10 out of, I think, just over 200 surgeries that 11 they've done. So about 1 percent. 12 So we know that regret exists, and it's good 13 for us to have more knowledge about regret. But we 14 also know that it is relatively uncommon. 15 Q. Dr. Karasic, this report from COHERE Finland is 16 dated from 2020, right? 17 A. Yes. 18 Q. Did you include that report or reference it in your 19 disclosure? 20 A. No, I didn't -- I don't know if there would be any 21 reason to. It was not original research of any 22 sort; it was one committee's view on how to proceed 23 in Finland. 24 Q. Did you include any other committee position 25 statements in your report?

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Page 110 1 A. I included the fact that many large American 2 organizations, like the American Medical 3 Association, American Psychiatric Association, 4 American Psychological Association, support 5 gender-affirming care. That within the US, there is 6 widespread support for gender-affirming care for 7 both minors and adults. 8 Q. But in other words, the fact that a position is made 9 by a professional organization as compared to 10 original research was not a reason to not include 11 something in your report, right? 12 A. Well, that's true -- 13 ATTY. GONZALEZ-PAGAN: Object to form. 14 A. -- but I view something a little bit different in 15 terms of -- a policy statement for two clinics in 16 Finland doesn't, to me, seem to have the same weight 17 as, for example, WPATH, which includes experts from 18 around the world, including many from Europe. 19 Q. (BY ATTY. BEDARD) Dr. Karasic, I'm going to show you 20 what has now been marked as -- hold please, one 21 second -- Defendant's Exhibit 13. 22 (Exhibit 13 marked for identification.) 23 Q. (BY ATTY. BEDARD) Can you see this document? 24 A. Yes. 25 Q. Have you seen this document before?	Page 112 1 was also a real shortage of staff. And a decision 2 was made -- so there were already long waits -- a 3 decision was made that they would only continue -- 4 they would continue providing care to people who had 5 already started puberty blockers. So people who 6 were already enrolled in care could continue in 7 care. 8 That new patients, in order to receive care, 9 would have to join a study. And the study was to 10 gather more information, basically, on 11 gender-affirming care in minors. 12 Q. And you've referenced a couple of times, 13 Dr. Karasic, the Bell v. Tavistock decision. Can 14 you tell us more about that? 15 A. Yeah. So my understanding of the case was that it 16 related to the ability of minors to consent in the 17 UK. And there was a person who I think had 18 de-transitioned who was, I think, Keira Bell. 19 And there was an initial court case about the 20 validity of consent that put an effective halt for a 21 little while on minors getting care in the UK, and 22 then it was reversed. And so a higher court, I 23 presume, reversed the case. And so it no longer has 24 any effect -- any legal effect in the UK. 25 Q. Were you personally involved in that case in the UK?
Page 111 1 A. Yes. 2 Q. And what is this document? 3 A. So this was -- this is a document regarding the 4 treatment of gender dysphoria in minors at a 5 hospital called Astrid Lindgren in the Stockholm 6 area. 7 Q. And what is your understanding of the Astrid 8 Lindgren Children's Hospital role in the provision 9 of gender care? 10 A. Okay. So I know a little bit more about Sweden than 11 Finland. I -- in my -- the Standards of Care 8 12 mental health chapter that I led, we do have -- one 13 of the experts is from Sweden. 14 So -- and when I was there in -- either 15 speaking in the clinic in 2009, or I was a keynote 16 speaker at the Scandinavian Transgender Health 17 Conference that included Swedish and Finish people 18 in 2013, I did meet a psychologist from Astrid 19 Lindgren. So -- but my understanding is that they 20 were providing transgender care to minors, and then 21 there was some controversy in Sweden, both regarding 22 Bell v. Tavistock, and I think there was a TV show 23 in Sweden. 24 And according to my colleague, who's head of 25 the gender program at Karolinska Institute, there	Page 113 1 A. No. 2 Q. And it's your understanding that the current status 3 of that case is that there is no longer a block or 4 ban or halt on the provision of gender-related care 5 for minors? 6 A. In the UK, right. 7 Q. In the UK? 8 A. Yeah. Yes. 9 Q. And you have referenced that case in the context of 10 several other European studies that we've also 11 discussed. And so what is your understanding of how 12 that case may have impacted -- may have impacted the 13 provision of gender-related care for minors in other 14 countries? 15 ATTY. GONZALEZ-PAGAN: Objection to form. 16 Misrepresents the nature of the exhibits. 17 A. Okay. Well, I say that just because that was my 18 understanding, having talked to the -- you know, I 19 was already in discussion, regular discussion with 20 my Standards of Care 8 chapter, with the head of the 21 gender clinic at Karolinska Institute, which was the 22 clinic for adults. She had previously introduced me 23 to somebody from Astrid Lindgren years ago. And so 24 in our conversations, I just -- you know, I asked 25 what was going on in Sweden while this was

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Page 114 1 happening, so a while back. 2 And she had said that there was, you know, as 3 head of her program, that there was political 4 pressure that was related to this lawsuit in the UK. 5 I think as well as a television program -- an 6 episode of a television program in Sweden. And so 7 she had said this was -- what happened at Astrid 8 Lindgren was reactive to those things going on. 9 Q. (BY ATTY. BEDARD) So circling back, then, to the 10 Astrid Lindgren decision -- 11 A. Mm-hmm. 12 Q. -- is your understanding, is that decision is to no 13 longer provide puberty blockers, testosterone or 14 hormone treatment, and gender-care related surgery 15 to minors outside of the clinical trial setting? 16 A. So my understanding is that they were continuing -- 17 they will continue -- they would continue to provide 18 care to anyone who had already been admitted to 19 their program. 20 So anyone already part of their program would 21 continue to get puberty blockers and hormones. And 22 that new patients, in order to access care at Astrid 23 Lindgren, would have to enroll in a clinical trial. 24 Basically, they would get their care, but it would 25 be observed, you know, data would be collected in	Page 116 1 A. Or if you mean that paragraph, I think that -- well, 2 I disagree with it. And I think that even the, you 3 know, director of the gender program at Karolinska 4 Institute would disagree. 5 That because there are -- it lists things 6 that -- where there is controversy or discussion 7 perhaps in adults but certainly not in youth, 8 there's no evidence of increased cardiovascular 9 disease in youth; osteoporosis, while there's, you 10 know, variable data in terms of bone density, 11 osteoporosis is really a disease of much older 12 people; infertility, you know, we've discussed, is 13 something that can happen with, you know, people 14 over the course of transitioning, but is not 15 necessarily, you know, something if somebody's 16 entering a program for puberty blockers that could 17 still be fertile if they stopped the puberty 18 blockers; increased cancer risk, there's no evidence 19 of that in minors; or thrombosis. 20 And so each of these are potential side effects 21 of concern that are, you know, discussed and 22 followed in adults. And certainly in adults, one, 23 you know, discusses risks and benefits of treatment, 24 like any treatment. But they're not really 25 applicable to minors, nor are they more of a concern
Page 115 1 that clinical trial. 2 Q. Understood. Okay. So let's go back, then, to that 3 exhibit, to the Astrid Lindgren guidelines. Can you 4 see the document again, Exhibit 13? 5 A. Yes. 6 Q. And I'm going to direct you to the last full 7 paragraph on the first page from the guidelines that 8 begins with "these treatments." Do you see that 9 paragraph? 10 A. "These treatments" -- okay. 11 Q. Yeah, I'll scroll up. 12 A. Yeah. 13 Q. Okay. Could you read that photograph for us? 14 A. "These treatments are potentially fraught with 15 extensive and irreversible adverse consequences such 16 as cardiovascular disease, osteoporosis, 17 infertility, increased cancer risk, and thrombosis. 18 This makes it challenging to assess the risk/benefit 19 for the individual patient, and even more 20 challenging for minors or their guardians to be in 21 the position of an informed stance regarding these 22 treatments." 23 Q. So Dr. Karasic, what is your response to this 24 guideline? 25 ATTY. GONZALEZ-PAGAN: Objection to form.	Page 117 1 than -- or a concern that necessarily outweighs the 2 benefits of treatment, such that certainly 3 transgender care in adults. One weighs risks and 4 benefits, and, you know, and people have been 5 consenting, you know, to that as adults to that 6 care. 7 But this conflates the various potential 8 concerns of adverse consequences in adults with a 9 decision in youth. 10 Q. (BY ATTY. BEDARD) Well, Dr. Karasic, I think what I 11 understand you saying is that some of these side 12 effects, such as cardiovascular disease or 13 osteoporosis, typically present in adults rather 14 than in minors, right? 15 A. Yes. 16 Q. Okay. So let me ask it this way, then. Let's take 17 cardiovascular disease, for example. Are there 18 studies of adults who received gender-related 19 treatments, therapies, as minors on the long-term 20 impacts of those treatments once they become adults? 21 A. Well, the Dutch are saying they're going to be 22 releasing more long-term research as it happens. 23 Long-term research of, let's say, somebody -- if 24 somebody started on puberty blockers when they're 12 25 years old. And hip fractures don't tend to happen

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Page 118 1 until people are at least in their 50s. So we would 2 have to wait 40 years before someone's enrolled in 3 the study and when we might have a full picture of 4 its impact on hip fractures. 5 So it's difficult to -- to say, with the 6 exception of the Dutch, because they did start some 7 people on puberty blockers in the 1980s, you know, 8 that we need to wait for, you know, 40 years to see. 9 But for example, in adults, I mentioned the 10 Wiepjes study that, you know, that in terms of bone 11 fractures, there doesn't seem to be an impact before 12 age 50. And then in -- or in people -- or in trans 13 men. And that for trans women, their risk is closer 14 to cisgender women as opposed to cisgender men once 15 they're in their 50s. 16 But we're not, from our -- you know, American 17 longitudinal research is going to take quite a long 18 time before we can see the people started on puberty 19 blockers in America at age 12, whether -- what, you 20 know, what all -- all of, you know, like, the 21 research into what happens when they're elderly. So 22 in the meantime, we try to explain risks and 23 benefits of interventions to people. 24 There has been mixed data on cardiovascular 25 disease in trans people. Some of it may be related	Page 120 1 A. Yeah. So it's -- my understanding is that she is 2 doing a -- that she's done an interim report with 3 recommendations for improving and even expanding 4 care in the UK. And so it's not original research, 5 in terms of providing outcomes of interventions, but 6 she's trying to make an assessment of care as it is 7 in the UK and how it might be improved. 8 Q. And she was appointed by the NHS to make that 9 assessment and to provide that report, right? 10 A. That's my understanding. 11 ATTY. GONZALEZ-PAGAN: Objection. Form. 12 ATTY. BEDARD: Let's take a look at that 13 report. 14 (Exhibit 14 marked for identification.) 15 Q. (BY ATTY. BEDARD) I'm showing you what's been marked 16 as Defendant's Exhibit 14. Can you see that? 17 A. Yes. 18 Q. And is this the interim report you were referring 19 to? 20 A. Yes. 21 Q. It's dated February of this year, of 2022, right? 22 A. Yes. 23 Q. Do you see the section starting with "Existing 24 evidence base," on the bottom of Page 18? 25 A. Yes. I see just the first part of the sentence
Page 119 1 to things other than hormones, like increased 2 smoking. I know one study. 3 And so, you know, these are all areas of 4 interest or areas of research, but the -- the fact 5 that there could be potential long-term side effects 6 of one particular intervention has to be weighed 7 against the benefits, like we do for anything. You 8 know, we know that serotonin reuptake inhibitors, 9 long-term use of them can increase the use of hip 10 fractures. But it's rare that people are given 11 informed consent, even for that with SSRIs. 12 So, you know, this is part of the work that we 13 do with all of our patients whenever we prescribe 14 anything, is to try to give them a full picture of 15 the risks and benefits. 16 Q. Dr. Karasic, I'm going to show you now what has been 17 marked as Defendant's Exhibit 14. As I get this 18 pulled up, are you aware of who Dr. Hilary Cass is? 19 A. Yes. 20 Q. And who is she? 21 A. My understanding is that she is leading an ongoing 22 process of evaluating transgender care for minors in 23 the UK. 24 Q. And have you reviewed any reports released from her 25 research?	Page 121 1 there, because the lower -- 2 Q. Okay. 3 A. Yeah, okay. 4 Q. And can you read that first paragraph for me, 5 beginning with 1.23? 6 A. Yes. "Evidence on the appropriate management of 7 children and young people with gender incongruence 8 and dysphoria is inconclusive both nationally and 9 internationally." 10 Q. And what is your response to this statement and 11 Dr. Cass's interim report? 12 A. Well, she says "inconclusive," and the question is 13 inconclusive as to what? 14 Q. Well, you have read this interim report, right? 15 A. Well, I don't remember everything that was said, but 16 it sounds like -- well, it says that she says that 17 it's inconclusive. 18 So the question as to what -- when I say 19 appropriate -- it's saying "evidence on the 20 appropriate management," so that doesn't necessarily 21 mean that's inconclusive whether or not to provide 22 care or not to provide care. It's -- the question 23 is, "What's the appropriate course? What's the 24 appropriate strategy to provide care?" And I 25 believe elsewhere in the study, it refers to, for

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Page 122 1 example, the long waits to get care. So appropriate 2 management might be easing access to care, not just 3 restricting it. 4 Q. And do you reference Dr. Cass's interim report in 5 your disclosure? 6 A. No. 7 Q. Okay. And why not? 8 A. It's not -- it's a government review of transgender 9 care for minors in the UK. It's not a study of the, 10 you know, of interventions or their response, or of 11 surveys in their response to -- of trans people to 12 get care. A government -- 13 Q. But, Dr. Karasic -- 14 A. It's an interim government report that mostly is 15 talking about, like, how to proceed in the UK. 16 Q. But Dr. Karasic, you do not fully rely on what you 17 refer to as "original studies" in your report, 18 right? 19 A. Well, I also rely on 30 years of clinical experience 20 and the experience of my peers. We have been 21 working with transgender youth for decades, using 22 the information that was available at the time. 23 Each additional bit of information is interesting 24 and helpful, but we don't rely on one particular 25 study or report.	Page 124 1 Q. So let me show you what's been marked as Defendant's 2 Exhibit 15. Is this the report you're referring to? 3 A. Yeah, I think so. I saw something on it where it 4 listed the people who were doing individual reports. 5 And so -- but I assume that that was it. 6 Q. Okay. Well, let me scroll down, because I do want 7 to make sure we are talking about the same report. 8 Is there a specific section of this report that 9 would be helpful to look at? 10 A. No, I can't say I reviewed the whole report in 11 detail, because just looking at it, as I said, I 12 saw -- from what I saw, it did not seem like anyone 13 who was involved, that I could see, were people who 14 had something to contribute to the discussion in 15 transgender health. But rather, it was really more 16 of a political scheme. 17 Q. So Dr. Karasic, I guess I'm just -- I'm trying to 18 understand. The criticisms that I have heard you 19 voice today are in part -- of this specific report, 20 are in part based on the contributors to the report, 21 right? 22 A. Right. I may have skimmed over a little bit of the 23 contents, but I can't say I've read the whole thing 24 in detail, nor that it would -- that there would be 25 a reason for me to do so, in terms of -- you know,
Page 123 1 ATTY. BEDARD: Dr. Karasic, I'm now going to 2 show you what has been marked at Defendant's 3 Exhibit 15. 4 (Exhibit 15 marked for identification.) 5 Q. (BY ATTY. BEDARD) And as I do so, have you -- let me 6 back up. 7 Are you aware that this year, the State of 8 Florida released a Medicaid report on gender 9 dysphoria? 10 A. Yes. 11 Q. And have you reviewed that report? 12 A. Just very superficially. I looked at who was 13 involved, and it seemed to me that it was really a 14 political sham as opposed to any serious report. It 15 was -- one of the reports was from a Canadian 16 dentist, and another was from an expert on 17 pedophilia, who has admitted in court that he has 18 never cared for a transgender minor. 19 And so it seemed like they were selecting 20 people from Canada who had never cared for -- never 21 provided transgender care, to justify a political 22 maneuver that had nothing to do with trans care. So 23 it really didn't seem worth my while to read it in 24 any more detail. I thought it was a ridiculous 25 effort.	Page 125 1 certainly in terms of the -- even the original 2 expert report that I provided, I believe, was before 3 this came out. And I can't imagine that there's 4 anything there that, because -- yeah, I did, you 5 know, there was, like, a little update recently, but 6 I had done the expert statement a while back, before 7 this came out, and there wasn't anything that 8 seemed, you know, that it would contribute to any 9 change in my opinion. 10 Q. So just so we're on the same page, Dr. Karasic, are 11 the comments that you've made about the document 12 that's in front of us as Exhibit 15 specifically, or 13 are you not sure whether or not you have previously 14 reviewed this exhibit prior to today? 15 ATTY. GONZALEZ-PAGAN: Object to form. Asked 16 and answered. 17 A. As I said, I think I reviewed it very briefly, but 18 did not -- you know, to see if there was anything 19 useful in there, and concluded that there wasn't. 20 You can feel free to bring up a paragraph, if you'd 21 like, and I'm happy to comment on that paragraph. 22 Q. (BY ATTY. BEDARD) Sure. And before I do so, I do 23 want to better understand, because I think part of 24 the -- some of the comments that you've made today 25 have to do with the contributors to this report or

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1 to a similar report. So is there a section of this 2 report you looked at that describes who contributed 3 to the report? 4 A. I did -- I read something where it looked like there 5 was a pair of contributors that were led by a 6 Canadian dentist, and then there was one by James 7 Cantor who -- James Cantor is an expert on 8 pedophilia, but has not provided, as he's admitted 9 in court, has not ever provided transgender care. 10 So here, when you go to Attachment C and 11 Attachment D: Attachment C is from the dentist, the 12 Canadian dentist; and Attachment D is from James 13 Cantor, a Canadian pedophilia researcher and maybe 14 advocate for understanding and acceptance? And -- 15 which seemed a curious choice of expert, because he 16 has never provided care for any transgender minors, 17 as he has, you know, admitted in court. 18 Q. And are you familiar with the assessments cited as 19 Attachments E, F, and G? 20 A. Well, Dr. Lappert, I believe, was involved, I think 21 in making an expert statement on a previous case. 22 And -- but also it just -- it seemed to me that 23 these were political choices, as opposed to anyone 24 who's ever done, you know, people who have actually 25 taken care of a trans person or done actual research	1 A. I don't know who G. Kevin Donovan is. Never heard 2 of Quentin Van Meter. 3 Q. Understood. So I'm scrolling down now to Page 3 of 4 this report, Dr. Karasic. 5 A. Yes. 6 Q. And there is a paragraph starting with, "Following a 7 review." Could you read that paragraph for us? 8 A. "Following a review of available literature, 9 clinical guidelines, and coverage by other insurers 10 and nations, Florida Medicaid has determined that 11 the research supporting sex reassignment surgery is 12 insufficient to demonstrate efficacy and safety. In 13 addition, numerous studies, including the reports 14 provided by the clinical and technical experts 15 listed above, identify poor methods and the 16 certainty of irreversible physical changes. 17 Considering the weak evidence supporting the use of 18 puberty suppression, cross-sex hormones, and 19 surgical procedures when compared to stronger 20 research demonstrating the permanent effects they 21 cause, these treatments do not conform to GAPMS and 22 are experimental and investigational." 23 Q. And Dr. Karasic, what is your response to that 24 statement? 25 A. I think this entire report is just ridiculous. It's
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1 working with trans people. It seemed like a -- not 2 a serious document, to me. 3 Q. So for the -- for the doctors referenced in 4 Attachments E, F, and G -- so Dr. Van Meter, 5 Dr. Lappert, and Dr. Donovan -- do you know whether 6 they have ever treated patients who have -- 7 A. So first of all, I did want -- I did want to say -- 8 Q. Sorry, Dr. Karasic, if you can just wait one second 9 until I finish my question before you answer, that 10 would be great. 11 A. Sorry. 12 Q. I know it's tough, with the remote depo in 13 particular. Just -- I'll restate my question. 14 For Dr. Van Meter, Dr. Lappert, and 15 Dr. Donovan, do you know whether they treat patients 16 who identify as transgender? 17 A. So I'm sorry I interrupted, I had wanted to finish 18 my comment about the previous authors, which I do 19 believe I read enough of it that James Cantor did 20 support transgender care for adults -- that he was 21 raising questions about transgender care for youth. 22 Lappert, I think, was an expert in a case I was 23 involved in. You'll have to move everything up a 24 little bit for me to see more. 25 Q. Sure.	1 not a serious effort, from even skimming over it. 2 There's nothing serious about it. It is -- it was 3 an attempt by Governor DeSantis to shut down 4 transgender care in a purely political move in the 5 same way that Florida has been playing politics on 6 LGBT issues more broadly. 7 And it's a shame that low-income people, the 8 people on Medicaid in Florida, have to suffer 9 because of this political grandstanding. And that 10 they couldn't find any real experts, and so they 11 found these fake experts to back this up. 12 Q. If we could take -- 13 A. I mean, I think it's kind of even -- I think it's 14 even kind of shameful for you to, like, present this 15 to me as a serious document, because it so obviously 16 is not. So I mean, obviously you can present 17 whatever you want, but this -- you know, the Cass 18 report or Finland -- you know, people have their own 19 point of views. But what's going on in Florida is 20 not -- nothing in that paragraph has any meaning 21 beyond the politics of what's going on in Florida 22 right now. 23 ATTY. BEDARD: Dr. Karasic, why don't we take a 24 five-minute break? Let's reconvene at 5:00 p.m. 25 Eastern, 2:00 p.m. Pacific.

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Page 130 1 THE WITNESS: Okay. 2 ATTY. BEDARD: Does that work for everyone 3 else? 4 THE VIDEOGRAPHER: Okay. We're going off the 5 record at 1:53. 6 (Break from 1:53 p.m. to 2:01 p.m.) 7 THE VIDEOGRAPHER: We are back on the record at 8 2:01. 9 Q. (BY ATTY. BEDARD) Dr. Karasic, did you look at any 10 documents during our most recent break? 11 A. No. 12 Q. And did you speak with anyone via phone, email, text 13 during our most recent break? 14 A. No. 15 Q. And is there anything you'd like to clarify in your 16 deposition testimony today? 17 A. Not that I can think of. 18 Q. I have no further questions, Dr. Karasic. I 19 appreciate your time today, and enjoyed speaking 20 with you. 21 A. Great. Thank you. 22 ATTY. GONZALEZ-PAGAN: Thank you, Stephanie. 23 Dr. Karasic, I'm going to have a couple of follow-up 24 questions on redirect just now, if you will. 25	Page 132 1 going to be able to respond to the growing demand in 2 a timely way." 3 Q. Dr. Karasic, from that statement, does it seem that 4 Dr. Cass is recommending that care be reduced or 5 stopped for gender-dysphoric youth in the 6 United Kingdom? 7 A. No. 8 Q. I'm going to just move to another page, if you will. 9 This is Page 15 of the PDF. Dr. Karasic, do you see 10 the paragraph that's numbered 1.5? 11 A. Yes. 12 Q. Do you mind reading that into the record? 13 A. "The review is not able to provide definitive advice 14 on the use of puberty blockers and 15 feminizing/masculinising [sic] hormones at this 16 stage, due to gaps in the evidence base; however, 17 recommendations will be developed as our research 18 programme progresses." 19 Q. Dr. Karasic, is it your understanding that the Cass 20 review from February of 2022 is making any 21 recommendations as to the provision of 22 gender-affirming care, such as puberty blockers and 23 hormones at this time? 24 A. My understanding is they are not. 25 Q. Okay. And is it your understanding that the review
Page 131 1 EXAMINATION 2 BY ATTY. GONZALEZ-PAGAN: 3 Q. You were shown an exhibit, I believe it is 4 Exhibit 14, from the defendants, a Cass -- a 5 preliminary report by Dr. Hilary Cass in the UK. Do 6 you recall that? 7 A. Yes. 8 Q. Okay. I'm going to try to share my screen here. 9 Can you see the screen, Dr. Karasic? 10 A. Yes. 11 Q. I'll try to zoom a bit here. And Dr. Karasic, if 12 you can read the second paragraph that begins with 13 "I have heard." 14 A. "I have heard that young service users are 15 particularly worried that I will suggest that 16 services should be reduced or stopped. I want to 17 assure you that this is absolutely not the case -- 18 the reverse the true. I think that more services 19 are needed for you, closer to where you live. The 20 GIDS staff are working incredibly hard and doing 21 their very best to see you as quickly as possible, 22 but providing supportive care is not something that 23 can be rushed -- each young person needs enough time 24 and space for their personal needs to be met. So 25 with the best will in the world, one service is not	Page 133 1 is actually ongoing? 2 A. Yes. 3 Q. Dr. Karasic, you were previously shown what's been 4 marked as Defendant's Exhibit 13, where -- 5 pertaining to a statement by the Astrid Lindgren 6 Children's Hospital. Do you recall that? 7 A. Yes. 8 Q. To your knowledge, is that statement peer-reviewed? 9 A. No. 10 Q. And that statement pertains to solely one hospital; 11 is that correct? 12 A. That statement is specific to Astrid Lindgren 13 Hospital. 14 Q. Okay. And do you recall discussing side effects 15 from hormone treatments such as cardiovascular 16 disease, osteoporosis, infertility, increased cancer 17 risk, and thrombosis? 18 A. That was brought up in this deposition, yes. 19 Q. Okay. Dr. Karasic, are the side effects of the 20 provision of hormones unique when -- because they're 21 being provided for the treatment of gender 22 dysphoria? 23 A. No. So hormones that are provided for other 24 purposes also can cause side effects. As a matter 25 of fact, almost everything we prescribe has a

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Page 134 1 potential for side effects. 2 THE WITNESS: I lost you for a moment. 3 ATTY. GONZALEZ-PAGAN: Apologies. 4 Q. (BY ATTY. GONZALEZ-PAGAN) Every medical treatment 5 has risks and benefits; is that right? 6 A. Yes. 7 Q. Dr. Karasic, to your knowledge, is the -- well, let 8 me go back. 9 Dr. Karasic, do you recall reviewing a summary 10 of a recommendation by COHERE? Do you recall that? 11 A. Yes. 12 Q. Okay. That is a summary of a report; is that 13 correct? 14 A. Yes. 15 Q. Okay. But it's not the full report; is that right? 16 A. Yes. 17 Q. That is also -- is the summary of the recommendation 18 by COHERE peer-reviewed? 19 A. No. 20 Q. Okay. And COHERE is a governmental entity in 21 Finland; is that correct? 22 A. That's my understanding, is it's a governmental 23 committee of some sort. 24 Q. All right. Dr. Karasic, do you recall going through 25 Exhibit 10 -- where is Exhibit 10? -- an informed	Page 136 1 ATTY. GONZALEZ-PAGAN: It's all right. I 2 can -- if you wouldn't mind, stop sharing. I have 3 it in front of me. I apologize. 4 ATTY. BEDARD: Okay. 5 Q. (BY ATTY. GONZALEZ-PAGAN) Dr. Karasic, do you 6 remember being shown a Consent for Surgery form from 7 the Polyclinic earlier today? 8 A. Yes. 9 Q. I'm going to share my screen with you. Can you see 10 that? 11 A. Yes. 12 Q. Okay. Dr. Karasic, and I know that it's a bit 13 fuzzy, but if you could read Paragraph 11? 14 A. "The above treatment or procedure has been explained 15 to me in a way that I understand. I realize that 16 there may be alternative procedures or methods of 17 treatment, and that there are risks to the procedure 18 or treatment proposed." 19 Q. Thank you. From your understanding, is it -- 20 actually, and if you don't mind reading the next 21 sentence thereafter, beginning "in signing"? 22 A. "In signing this consent, you acknowledge that you 23 have been informed about the risks and benefits for 24 this surgery/procedure, and accept responsibility 25 for the clinical decisions that were made along with
Page 135 1 consent form, a consent form regarding surgery? 2 A. Yes. 3 ATTY. GONZALEZ-PAGAN: Stephanie, I apologize. 4 If you can recall for me which exhibit it is, that 5 ASA informed consent form, it might make it move 6 faster. But if not, I can find it. 7 ATTY. BEDARD: No, that's fine. I can pull it 8 up for you, if you'd like. 9 ATTY. GONZALEZ-PAGAN: That'd be great. Thank 10 you. I really appreciate it. 11 ATTY. BEDARD: It's the most recent Polyclinic 12 records. 13 ATTY. GONZALEZ-PAGAN: Correct, yeah. I'm not 14 sure if it's 5 or 10. 15 ATTY. BEDARD: No, it's 10. Do you want me to 16 share my screen? 17 ATTY. GONZALEZ-PAGAN: If you don't mind, that 18 would be appreciated. 19 ATTY. BEDARD: Sure. No, it's not 10. It's 3. 20 ATTY. GONZALEZ-PAGAN: Yeah, it's 3. Yeah, 21 okay, that's what I was -- 22 ATTY. BEDARD: It's 3, and I'm happy to share 23 my screen. I will be the one with control -- I 24 don't think I can share control, so you'll just have 25 to let me know where you want to go.	Page 137 1 the financial costs of all future treatments." 2 Q. Based on your review of this document and those 3 sentences, is it your understanding that risk and 4 consequences of the surgery -- in this case, a 5 bilateral mastectomy -- were discussed with C. P. 6 and his parents? 7 A. Yes. It seems like there's an acknowledgment of it. 8 The form is a fairly generic form, but it 9 includes -- they're acknowledging that there has 10 been a discussion. So I wouldn't view the form as a 11 discussion, but rather the acknowledgment that a 12 discussion has taken place. 13 Q. Thank you. And earlier, you were asked some 14 questions about the fact that C. P.'s father signed 15 under the "Witness Signature" line. Do you recall 16 that? 17 A. Yes. 18 Q. Isn't it true that there's a third signature just 19 below the witness signature for a Sue 20 Harrington, RN? 21 A. Yes. Can you scroll up? Just because it's being 22 blocked by my -- 23 Q. Can you see that now? 24 A. Yeah. So it looks like there's a witness signature 25 below, on the third line. And so, again, it was a

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Page 138 1 stock form, I assume, for adults. So it didn't have 2 a parent signature like forms typically do when 3 they're for procedures on minors. 4 Q. Is it your understanding, then, that there's at 5 least a parent who could provide consent, a minor 6 who could provide assent, and a distinct witness, 7 all of whom have signed this form? 8 A. Yes. 9 Q. All right. Dr. Karasic, earlier you were asked some 10 questions about the effects of puberty blockers on 11 bone density. Do you recall that? 12 A. Yes. 13 Q. Are the effects of puberty blockers on bone density 14 primarily a concern when the production of sex 15 hormones is being blocked and no other sex hormones 16 are being provided? 17 A. It's primarily a concern -- 18 ATTY. BEDARD: Object to form. 19 A. It's primarily a concern when there is long-term 20 use. For example, some adults who might be without 21 either testosterone or estrogen, there can be a 22 long-term concern for osteoporosis. And so the data 23 for short-term use in youth were not generally -- 24 even if there's some change in bone density where 25 the data's mixed, we're not -- it's not really a	Page 140 1 ATTY. GONZALEZ-PAGAN: We will read. 2 THE COURT REPORTER: And orders, Counsel? 3 ATTY. BEDARD: Let's say non-expedited for now, 4 and if need be, I'll circle up with our team and let 5 you know as soon as possible if that changes. 6 ATTY. GONZALEZ-PAGAN: The same for us. 7 (Deposition concluded at 2:17 p.m.) 8 (Signature reserved.) 9 ----- 10 11 12 13 14 15 16 17 18 19 20 21 22 23 24 25
Page 139 1 concern in terms of the function of the bone, then, 2 because from the data we have, fractures don't 3 become an issue for people until -- fractures due to 4 osteoporosis become an issue for people much later 5 in life. 6 Q. (BY ATTY. GONZALEZ-PAGAN) Does the provision of sex 7 hormones, whether because the puberty blockers have 8 been stopped or they've been provided in an 9 exogenous manner, dissipate the concern about bone 10 density? 11 ATTY. BEDARD: Object to form. 12 A. Yeah. So as I said, there's variable data in terms 13 of what happened in bone density in people provided 14 puberty blockers. And -- but bone density tends to 15 increase again with the start of gender-affirming 16 hormones, such that people have bone growth that 17 appears equivalent to that of the gender to which 18 they've transitioned. 19 ATTY. GONZALEZ-PAGAN: Thank you, Dr. Karasic. 20 No more questions, and I'll stop sharing the screen. 21 ATTY. BEDARD: I have no further questions 22 either. 23 THE VIDEOGRAPHER: Okay. That concludes the 24 deposition. The time is 2:16 p.m. We are going off 25 the record.	Page 141 1 Nelson Court Reporters, Inc. 2 6513 132nd Avenue NE, #184 3 Kirkland, Washington 98033 4 production@nelsonreporters.com 5 www.nelsonreporters.com 6 July 25, 2022 7 To: Omar Gonzalez-Pagan 8 Lambda Legal Defense and Education Fund, Inc. 9 120 Wall Street, 19th Floor 10 New York, NY 10005-3919 11 Re: Pritchard, et al, v. BCBS of Illinois 12 Deposition of: Dan H. Karasic, MD 13 Date Taken: July 13, 2022 14 Cause No.: 3:20-cv-06145-RJB 15 16 Enclosed are the Correction & Signature page. 17 Instruct the deponent to review the deposition, record 18 any corrections on the Correction page, and sign it. 19 The above referenced transcript must be read 20 and the Correction & Signature page signed within 30 21 days of this notice or before the trial date, whichever 22 occurs first. 23 If the Correction & Signature page are not 24 signed within that time period, signature will be deemed 25 waived for all purposes. After the Correction & Signature page are signed, please forward to: Nelson Court Reporters Production Department production@nelsonreporters.com Thank you, Sierra Zanghi, RSR, CCR CCR No. 22004202

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EXHIBIT G

The Honorable Robert J. Bryan

UNITED STATES DISTRICT COURT
WESTERN DISTRICT OF WASHINGTON
AT TACOMA

C.P., by and through his parents, Patricia
Pritchard and Nolle Pritchard; and
PATRICIA PRITCHARD,

Plaintiffs,

v.

BLUE CROSS BLUE SHIELD OF ILLINOIS,

Defendant.

NO. 3:20-cv-06145-RJB

DECLARATION OF FRANK G. FOX IN
SUPPORT OF PLAINTIFFS' MOTION
FOR CLASS CERTIFICATION

I, Frank. G. Fox, Ph.D., declare under penalty of perjury and in accordance with
the laws of the State of Washington and the United States that:

1. I am over the age of 18, not a party in the case and competent to testify to
all matters stated herein. All statements are made upon my personal knowledge.

2. I am an economist with expertise in quantitative health care planning,
statistics and financial modeling.

3. *Exhibit A* attached hereto is a true and accurate copy of my Curriculum
Vitae that details my professional background in health planning, statistics and finances.

4. My educational experience is as follows:

1977 Ph.D., University of Washington, Seattle, WA
(Economics)

1972 M.A. , University of Washington, Seattle, WA
(Economics)

1970 B.A., University of Washington, Seattle, WA
(Economics)

5. I have owned and operated my own consulting firm since 1996, specializing in healthcare statistical analysis and the development of utilization and financial modeling and forecasting. I began my career in econometric modeling in the defense industry, preparing stochastic forecast models. I moved into health care economics in the early 1980s, first working in research and development, then in a large hospital organization as a health care planner, then in applied research and development. Since I have had my own consulting practice, I have provided healthcare planning, statistical analysis and financial simulation modeling to many of the hospitals in the State of Washington and in other parts of the country. I have also been engaged by numerous physician practices as an expert in health economics and financial/statistical modeling.

6. I have extensive experience with forecasting the need for hospital acute care beds, kidney dialysis centers, heart and liver transplant services, home health and hospice services, ambulatory surgery cases, clinical procedures such as GI procedures, cardiac surgery, epilepsy procedures, etc., and evaluating financial performance of health care entities. I have prepared a large number of simulation models for healthcare organizations to forecast utilization and financial performance for new technologies such as MRIs, linear accelerators and minimally invasive surgery, and for discrete projects such as new hospitals, ambulatory surgery centers, urgent care centers, imaging centers, and emergency departments. I have also prepared a large number of business plans for many hospital services and programs. I have extensive experience in designing primary research studies to ensure that the quantitative results generated from those studies

1 provide statistically meaningful results, *i.e.*, provide results that can be generalized to
 2 the larger universe in a statistically valid way.

3 7. I have been qualified and have testified as a statistical expert, an expert in
 4 health economics and a healthcare planning expert in the following court cases:
 5 (1) Florida, 1985; (2) Oregon Federal District Court (2006); (3) Seattle WA Superior Court
 6 (2004); (4) in twenty-one separate Washington Department of Health Administrative
 7 Law Judge (“DOH ALJ”) Hearings – one in 2004, 2008, 2010, two cases in 2011, two cases
 8 in 2012, two cases in 2013, four cases in 2014, one case in 2015, two cases in 2016, two
 9 cases in 2018; two cases in 2020 and one case in 2021; and (5) in two hearings before the
 10 Alaska Office of Administrative Hearings, one in 2016 and another in 2017. These cases
 11 also included expert deposition testimony. In addition, I have been deposed as an expert
 12 in a number of additional cases that were settled before trial. I have also acted as an
 13 expert consultant in the following cases: (1) numerous cases involving the acute care bed
 14 need methodology required by the Washington Department of Health under the
 15 certificate-of-need rules; (2) an anti-trust case in Oregon (2008); (3) ambulatory surgery
 16 center certificate-of-need cases in Washington; (4) kidney dialysis certificate-of need
 17 cases in Washington; and (5) nursing home and hospice certificate-of-need cases in
 18 Washington.

19 8. At the request of Plaintiffs’ attorneys, I created a statistical model using
 20 data sources that are publicly available, as well as information from discovery produced
 21 by Defendant. Based on my expert opinion, this information can be reliably used to
 22 prepare statistically robust estimates of the number of enrollees who have been or are
 23 participants or beneficiaries in Blue Cross Blue Shield of Illinois (“BCBSIL”) administered ERISA self-funded group health plans from January 1, 2016 to the present,
 24 who required or require treatment with excluded gender affirming health care services.
 25
 26

9. Discovery from Defendant BCBSIL identified at least 505 unique enrollees in BCBSIL-administered ERISA group health plans that contained gender affirming care exclusions who had claims denied under such exclusions during the proposed class period.

10. Apart from this 505-enrollee figure, which alone, provides numerosity in this matter, Defendant provided the number of enrollees in each ERISA self-funded plan administered by BCBSIL that contained a gender affirming care exclusion, by year, over the time period 2016-2021. As explained in my Report, a true and correct copy of which is attached as *Exhibit B* to this declaration, I prepared and utilized simulation models over the 2016-2021 period to estimate the number of enrollees by plan year, who would be expected to utilize medically necessary treatment for gender dysphoria in BCBSIL administered ERISA self-funded group health plans.

11. In summary, in my expert opinion, utilizing either estimating approach (1) direct counts of enrollees in BCBSIL-administered ERISA group health plans who submitted claims for treatment for gender dysphoria that were denied; or (2) simulation models to estimate utilization of medically necessary treatment for gender dysphoria in the same plans over the same class period, indicates that the number of these individuals who are likely to have required or require gender affirming care in these plans during the proposed class period significantly exceeds 40 enrollees.

DATED: August 19, 2022, at Seattle, Washington.

Frank G. Fox, Ph.D.

Exhibit A

FRANK G. FOX, JR.

Contact Information: frankgfox@comcast.net

Telephone: 206.366.1550

Website: <https://healthtrends.consulting/>

Education

1977	Ph.D., University of Washington, Seattle, WA (Economics)
1972	M.A., University of Washington, Seattle, WA (Economics)
1970	B.A., University of Washington, Seattle, WA (Economics)

Professional Experience

May 1996 - Present **HealthTrends, Shoreline, WA**

Principal

Direct work with health care organizations in the development and implementation of actions to improve performance. This work is principally quantitative analysis and simulation modeling.

Projects include demand and financial modeling, including future year budget forecasts and business plan development; statistical survey research and analysis; strategic plan development; asset and program/service valuation, including physician practices and other businesses; new business development; joint ventures; compilation and analysis of information defining internal and market actions; medical staff development plans; technology acquisition/implementation; and expert consultation with clients regarding quantitative analysis and modeling, including evaluation of new technology. Significant expert testimony consultations regarding statistical and health care economics. Engagements have included:

- Development of demand and financial models for organization business planning and future year budgets. Includes developing databases and preparing models that simultaneously link “dependent” and “independent” variables that combined simulate utilization and financial projections. Includes preparing sensitivity analyses to test the effect of changes in key model variables on projected outcomes

- Development of financial statements, including income and expense, cash flow, asset depreciation and balance sheets. These schedules are used to define prior performance and model future growth. Includes engagements assisting small business “start-up” operations, including serving as chief financial officer, but in a consultant role
- Expert consultation regarding statistical/mathematical issues associated with clients’ surveys and other sampling work
- Primary and secondary survey research. Includes formulating best research design, developing survey questionnaires, utilizing in-person or other survey approach(es), preparing statistical analysis of survey responses and report preparation
- Preparation of volume and financial performance models for free-standing emergency departments, urgent care centers, medical clinics, imaging centers and ambulatory surgery centers. Includes preparation of demand and revenue forecasts by type of service, program or physician sub-specialty. Also includes estimation of direct and indirect expenses of business operations, including FTE (“full-time equivalent”) employment forecasts and capital expenditure modeling. Designed to identify key performance statistics and provide risk analysis of alternative utilization, reimbursement and expense scenarios
- Preparation of demand and financial models to define, evaluate and model demand and financial performance for new programs and technologies, e.g., transplantation programs including liver and pancreas transplantation; Gamma Knife program; PET scanner; minimally invasive surgery; and transcranial magnetic stimulation (“TMS”).
- Preparation of demand and financial models to evaluate current performance and prepare service/program forecasts. Representative projects include: imaging centers, including forecasts for all key modalities; emergency services; cardiac services; obstetrics and women’s’ services; sleep lab; oncology programs, including medical oncology and radiation therapy; and ambulatory surgery centers.
- Preparation of medical staff development plans, including integration of quantitative estimates of demand by specialty, current and projected supply, financial modeling, and qualitative interview research. Designed to assist organizations’ alignment/integration with physicians.
- Preparation of performance analyses, where client benchmarks are established and performance, measured. Examples include emergency department physicians, or

practicing physicians in a single or multi-specialty clinic. Work has included development and implementation of “production-based” compensation models.

- Preparation of valuation studies, which require assessment of “fair market value.” This has included contractual arrangements, where buyers must meet fair market value standard for federal statutes. It has also included preparation of fair market value estimates of physician practices.
- Preparation of strategic plans, including market demographic and economic profiles, organization performance data across key services/programs, including portfolio analysis, competitor analysis, and identification and prioritization of goals, strategies and implementation actions.
- Preparation of marketplace statistics on population, utilization and market share figures to assist organizations’ strategic planning and marketing programs.
- Expert testimony and deposition. I have been qualified and have testified as a statistical expert, an expert in economics and health economics, and a healthcare planning expert in a large number of courts-of-law. This includes deposition and expert testimony in the following: (1) Florida, Federal District Court, 1985; (2) Oregon Federal District Court (2006); (3) Seattle WA Superior Court (2004); (4) in twenty-one separate Washington Department of Health Administrative Law Judge (“DOH ALJ”) Hearings—one in 2004, 2008, 2010, two cases in 2011, two cases in 2012, two cases in 2013, four cases in 2014, one case in 2015, two cases in 2016, two cases in 2018, two cases in 2020 and one case in 2021; and (5) in two hearings before the Alaska Office of Administrative Hearings, one in 2016 and another in 2017.
- Expert consultation. I have acted as an expert consultant in the following cases: (1) numerous cases involving the acute care bed need methodology required by the Washington Department of Health under the certificate-of-need rules; (2) an anti-trust case in Oregon (2008); (3) ambulatory surgery center certificate-of-need cases in Washington; (4) kidney dialysis certificate-of-need cases in Washington; and (5) nursing home and hospice certificate-of-need cases in Washington.
- Depositions, Expert Declarations, Expert Reports and Rebuttal Reports. I have provided expert declarations and/or expert reports and rebuttals in the following cases: (1) In 2018, I provided an expert declaration (“Declaration”) valuing the injunctive relief in a class action settlement in support of the motion for preliminary approval of that settlement in *Kerr v. Kaiser Foundation Health Plan*, Los Angeles Superior Court Case No. BC556863. (2) In May 2019, I provided a Declaration regarding models I prepared estimating utilization and cost for selected treatments for patients with diagnoses identified in the California Mental Health Parity Act and substance abuse in *Ames v. Anthem Blue Cross Life & Health Insurance Company*, Los Angeles Superior Court Case No. BC591623. (3)

In May 2019, I provided Declaration regarding estimates of the number of Plan insureds with a prevalence of Autism Spectrum Disorder (“ASD”) who utilized and expended monies for applied behavior therapy (“ABA”) in *JR v. CHI et.al.*, United States District Court, Western District of Washington, Seattle, No. 2:18:cv-01191-JLR. (4) In June 2019, I prepared an Expert Report in *DT v. NECA/IBEW Family Medical Plan, Civil Action No. 2:17-cv-00004 (RAJ)*, which estimated utilization and expenditures for ABA and/or physical therapy (“PT”), occupational therapy (“OT”) or speech therapy, for Plan insureds with a prevalence of ASD. (5) In July 2019, I prepared a series of Rebuttal Reports in *DT v. NECA/IBEW Family Medical Plan, Civil Action No. 2:17-cv-00004 (RAJ)*. (6) In January 2020, I provided a Declaration valuing coverage for residential treatment for insureds with eating disorders in a class action case in *Rea v. Blue Shield of California, Los Angeles Superior Court Case No. B468900*. (7) In July 2020, I prepared an Expert Report in *Crosby v. Blue Shield of California, Magellan Health, et. al., Case No.: 8:17-CV-01970-CJC-JDE*; (8) In August 2020, I prepared a Rebuttal Report also for *Crosby v. Blue Shield of California, Magellan Health, et. al., Case No.: 8:17-CV-01970-CJC-JDE*; (9) In October 2020, I prepared a Declaration in support of a motion for summary adjudication of Health Net’s fifth cause of action for intentional interference with contractual relations in *Dual Diagnosis Treatment Center Inc., v. Health Net, Los Angeles Superior Court, Case No. LC104357*; (10) November 2020, I provided a supplemental Declaration in *Rea v. Blue Shield of California, Los Angeles Superior Court Case No. B468900*; (11) In January 2022, I was deposed in in *Dual Diagnosis Treatment Center Inc., v. Health Net, Los Angeles Superior Court, Case No. LC104357*; (12) In June 2022, I was deposed in *Decision by the Department of Health Regarding Two Certificate of Need Applications Proposing to Establish Medicare and Medicaid Certified Hospice Services in Thurston County, No. M2021-923*.

- Preparation of Certificate of Need applications. Projects have included: (1) the development and operation of freestanding ambulatory surgery centers;(2) the purchase and sale of two hospitals in Eastern Washington in Spring 2003; (3) the development and operation of St. Anthony Hospital in Gig Harbor Washington in Fall 2003; (4) the development of a liver transplant program for Swedish Health Services in Seattle WA in Summer 2003; (5) the preparation of 3 kidney dialysis center applications in Spokane County, WA in fall 2003; (6) the preparation of a kidney dialysis center application in Clark County, WA in spring 2005; (7) the development and operation of a new hospital—Swedish Issaquah Hospital—in Issaquah Washington, submitted in 2004; (8) the development and operation of a freestanding hospital in Eugene Oregon, submitted in December 2005; (9) the expansion of acute care beds for St. Francis Hospital, Federal Way, WA submitted in late Fall 2006; (10) the build-out of a hospital tower and the expansion of licensed capacity by 166 acute care beds for Providence Regional Medical Center in Everett WA this represented the largest expansion project in Washington CN history), also submitted in late Fall 2006; (11) the preparation of a certificate of need application for a 152-bed expansion and 21-bed NICU expansion for Sacred Heart Medical Center in Spokane WA, completed in February 2009; (12 & 13) the preparation of two certificate of need applications for percutaneous coronary intervention (PCI) programs

at Stevens Hospital, Edmonds WA and Valley Medical Center, Renton WA—both applications were submitted in February 2009; (14) the preparation of a certificate-of-need application for a 27-bed NICU expansion Kadlec Medical Center, Richland WA, submitted in August 2009; (15) preparation of a certificate of need application for a 114-bed expansion project for Kadlec Medical Center, Richland WA, submitted November 2009; (16) preparation of a certificate of need application for a new 58-bed hospital in the Southeast Planning Area, submitted in December 2009; (17) preparation of a certificate of need request for Swedish Health Services' Lease of Stevens Hospital in Edmonds WA, submitted in May 2010; (18) preparation of a certificate of need for a 25-bed expansion of Mary Bridge Children's Hospital, submitted in July 2010; (19) preparation of a certificate of need request for pancreatic transplantation at Sacred Heart Medical Center; (20) preparation of a certificate-of-need request for a 20-bed expansion of Tacoma General Hospital's Neonatal Intensive Care Unit ("NICU"); (21) preparation of a certificate-of-need request for a 4-bed expansion of Tacoma General Hospital's Intermediate Care Nursery ("ICN"); (22) preparation of a certificate-of-need request for a 16-bed Intermediate Care Nursery ("ICN") at Swedish/Issaquah, submitted in January 2011; (23) preparation of a certificate-of-need request to operate an elective percutaneous coronary intervention ("PCI") program at Swedish/Issaquah; (24) preparation of a certificate-of-need request for an 11-bed expansion of Good Samaritan Hospital, submitted in June 2011; (25) preparation of a certificate of need for a 20-bed expansion of Mary Bridge Children's Hospital, submitted in October, 2011; (26) preparation of a certificate-of-need request for an ambulatory surgery center in Gig Harbor, Washington, submitted October 2011 (27) preparation of a certificate-of-need request for a new 30-bed psychiatric hospital in Everett, Washington, submitted November 2011; (28) preparation of a certificate-of-need request to operate an elective percutaneous coronary intervention ("PCI") program at Swedish/First Hill, submitted in February 2012; (29) preparation of a certificate-of-need request for an additional Level I rehabilitation beds at Providence St. Peter Hospital, submitted in March 2012; (30) preparation of a certificate-of-need request to lease Wenatchee Valley Hospital, submitted in September 2012; (31) preparation of a certificate-of-need request to lease United General Hospital, submitted November 2012; (32) preparation of a certificate of need to operate an ambulatory surgery facility, submitted in July, 2013; (33) preparation of a certificate of need application to operate three additional Level I rehabilitation bed at PeaceHealth St. Joseph Medical Center, Bellingham Washington, September 2013; (34) preparation of a certificate of need application to operate a kidney dialysis facility, submitted in January 2014; (35) preparation of a certificate of need to operate an ambulatory surgery facility, submitted in February 2014; (36) preparation of a certificate-of-need request for a new 34-bed psychiatric hospital in Monroe, Washington, submitted November 2013; (37) preparation of a certificate of need to operate a kidney dialysis facility, submitted in May 2014; (38) preparation of a certificate of need for Level I rehabilitation beds for Wenatchee Valley Hospital, submitted November 2014; (39 and 40) preparation of two separate certificate of need applications to operate kidney dialysis facilities in different planning areas, submitted in November 2014; (41) preparation of a certificate of need application for a 120 bed psychiatric hospital, Tacoma Washington, submitted December 2014; (42) preparation of

a certificate of need application to operate a kidney dialysis facility in Pierce County, submitted in February 2015; (43) preparation of a certificate of need application for an ambulatory surgery center for Swedish Health Services and Proliance, submitted in March 2015; (44) preparation of a certificate of need application for a 100-bed psychiatric hospital, Spokane County, submitted in June 2015; (45) preparation of a certificate of need to operate an ambulatory surgery center in Bellevue in East King Planning Area (2015); (46) preparation of a certificate of need to operate an ambulatory surgery center in Issaquah in East King Planning Area (2015); (47) preparation of a certificate of need to operate an ambulatory surgery center in Seattle in the North King Planning Area (2015); (48) preparation and submittal of a certificate of need application for MultiCare Good Samaritan Hospital for additional Level I rehabilitation beds (2015); (49) preparation and submittal of a certificate of need application for MultiCare Good Samaritan Hospital for additional acute care beds (2015); (50) preparation and submittal of a 100-bed psychiatric hospital certificate of need (Oregon) (2016); (51) preparation and submittal of a certificate of need to operate a kidney dialysis facility in Pierce County (2016); (52) preparation and submittal of a certificate of need to operate an 85-bed psychiatric hospital in Thurston County (2016); (53) preparation of a certificate of need to operate an ambulatory surgery center in Everett in the Central Snohomish Planning Area (2016); (54) preparation of a certificate of need to operate an ambulatory surgery center in the Grant County Planning Area (2016); (55) preparation of a certificate of need to operate an ambulatory surgery center in Okanogan County Planning Area (2016); (56) preparation of a certificate of need for approval of the purchase of Deaconess Hospital in the Spokane Planning Area (2017); (57) preparation of a certificate of need for approval of the purchase of Valley Hospital in the Spokane Planning Area (2017); (58) preparation of a certificate of need to operate an ambulatory surgery center in the Spokane County Planning Area (2017); (59) preparation of a certificate of need to operate an ambulatory surgery center in Central King County Planning Area (2017); (60) preparation and submittal of a certificate of need to expand a kidney dialysis facility in Grays Harbor County (2017); (61) preparation and submittal of a certificate of need to relocate and expand a kidney dialysis facility in Grant County (2017); (62) preparation and submittal of a certificate of need to operate an ambulatory surgery center in the East King Planning Area (2017); (63) preparation and submittal of a certificate of need to expand MultiCare Tacoma General Hospital's Level IV Neonatal Intensive Care Unit (NICU) (2018); (64, 65, 66, 67, 68, 69) preparation and submittal of six separate certificates of need to expand kidney dialysis facilities in Pierce County (2018); (70 & 71) preparation and submittal of certificates of need to expand kidney dialysis facilities in Thurston County (2018); (72) preparation and submittal of a certificate of need to establish a kidney dialysis facility in Clark County (2018); (73) preparation and submittal of a certificate of need to expand a kidney dialysis facility in Grant County (2018); (74) preparation and submittal of a certificate of need to develop a kidney dialysis facility in King County (2018); (75) preparation and submittal of a certificate of need to develop a kidney dialysis facility in Cowlitz County (2018); (76) preparation and submittal of a certificate of need to expand a kidney dialysis facility in Adams County (2018); (77) preparation and submittal of a certificate of need to expand a kidney dialysis facility in Okanogan Count (2018); (78) preparation and submittal of a

certificate of need to expand a kidney dialysis facility in Mason County (2018); (79) preparation and submittal of a certificate of need to expand a kidney dialysis facility Thurston County (2019); (80) preparation and submittal of a certificate of need to develop a kidney dialysis facility in King County (2019); (81) preparation and submittal of a certificate of need to expand a kidney dialysis facility (Benton County (2019); (82) preparation and submittal of a certificate of need to operate an ambulatory surgery center in the East King Planning Area (2019); (83) preparation and submittal of a 100-bed psychiatric hospital certificate of need (Oregon) (2019); (84) preparation and submittal of a certificate of need to expand an ambulatory surgery facility in East Pierce Planning Area (2019); (85)) preparation and submittal of a certificate of need to expand an ambulatory surgery facility in the East Pierce Planning Area (2019); (86) preparation and submittal of a certificate of need to expand an ambulatory surgery facility in East King Planning Area (2019); (87) preparation and submittal of a certificate of need to expand an ambulatory surgery facility in the Central Pierce Planning Area (2020); (88) preparation and submittal of a certificate of need to develop an elective PCI program in the Spokane County Planning Area (2020); (89) preparation and submittal of a certificate of need to relocate and expand a kidney dialysis facility Thurston County (2020); (90) preparation and submittal of a certificate of need to develop and operate a kidney dialysis facility in Yakima County (2020); (90) preparation and submittal of a certificate of need to relocate a dialysis facility in Mason County (2020); (92) preparation and submittal to expand a dialysis facility in Cowlitz County (2020); (93) Preparation and submittal to expand a dialysis facility in Stevens County; (94) preparation and submittal of a certificate of need to establish an ambulatory surgery facility in the East Pierce Planning Area (2020); (95) preparation and submittal of a certificate of need to operate a hospice agency in Spokane County (2020); (96) preparation and submittal of a certificate of need to operate a hospice agency in Thurston County Washington (2021); (97) preparation of a certificate of need application to relocate MultiCare Mary Bridge Children's Hospital in Tacoma Washington (2021); (98) preparations and submittal of a certificate of need application for the purchase of Capital Medical Center, Olympia (2021); (99) preparation and submittal of a certificate of need to establish an ambulatory surgery facility in the Spokane Planning Area (2021); (100) preparation and submittal to expand a dialysis facility in Grays Harbor County WA (2021); (101) preparation and submittal of a certificate of need to develop and operate a kidney dialysis facility in Yakima County (2021); (102) preparation and submittal to expand a dialysis facility in Cowlitz County (2021); (103) preparation and submittal of a certificate of need to purchase MPT ownership in Capital Medical Center building (2021); (104) preparation and submittal of a certificate of need to operate a hospice agency in Spokane County (105) preparation and submittal of a certificate of need to add licensed NICU bassinets to Mary Bridge Children's Hospital (2022); (106) preparation and submittal to add OR capacity to an ambulatory surgical facility in East Pierce County (2022;; (107) preparation and submittal for certificate of need approval to operate a Two OR ambulatory surgery facility in Thurston County; (108) preparation and submittal of a certificate of need request to add 160 licensed acute care beds to Good Samaritan Hospital in Puyallup WA.

- These projects included preparation of detailed utilization and financial performance

models, including income and expense, cash flow statements, asset depreciation schedules and balance sheets. They also included preparation and submittal of complete applications to Washington Department of Health.

July 2001-July 2002 ClearMedical, Bellevue WA

Vice President, Finance and Chief Financial Officer

Financial stewardship for ClearMedical, Inc. This included developing and properly using financial reports and performance information, in aggregate, and at the product/service level, to monitor and improve company performance. Performance was measured for contribution margin, cash flow and return on investment. As the company's financial leader, responsible for daily fiscal activities and longer term financial viability and growth. Responsibilities included:

- Preparation of weekly and monthly financial reports for the chief executive officer, the Board of Directors, and other members of the executive team. Financial reports include income and expense statements, cash flow and balance sheet statements. These reports were compiled for year-to-date and annualized estimates.
- Preparation of monthly departmental budgets, then monitoring actual expenditures against budget estimates. Also responsible for budget forecasts, used to guide departmental growth.
- Preparation of 5 year forecast models to estimate financial performance and resource requirements.
- Correct daily operation of accounts payable and accounts receivable activities, as well as company payroll and other routine financial operations
- Monitoring company performance against financial performance forecasts and "key performance indicators" (KPIs) included in the Strategic Plan. This included implementing corrective actions to better assure actual performance matches forecasts and benchmarks.
- Monitoring overall company performance against its Strategic Plan, as defined by performance benchmarks. Responsible for providing annual revisions/updates to the ClearMedical Strategic Plan.

1993 - April 1996 Franciscan Health System (FHS), Aston, PA

Vice President, Research and Development

Responsible for FHS research and development. This included all research to support focused technology and other studies. Selected studies included:

- Stereotactic breast biopsy technology
- Minimally invasive surgery technology

- Advanced healthcare practitioners
- Alternative medicine (healing/wholistic medicine)
- Genetic engineering
- Patient-focused care

Responsible for leadership and staff support to the FHS Technology Steering Committee, a multidisciplinary group, including numerous physicians, that had responsibility for identifying and making technology implementation recommendations across FHS.

Responsible for strategic planning, including the compilation of information, the development of market goals and strategies, and the preparation of focused strategic plans. This also included seminars and workshops to prepare and present plans.

Responsible for compilation, analysis and presentation of quantitative and qualitative information on FHS products, services and markets, including:

- Utilization forecast models, by service line, for each FHS hospital, to model the effect of managed care.
- The development of emergency department care delivery models.
- The development of an ambulatory surgery model.
- Preparation of market share and service line projections.

Responsible for service and program integration/consolidation across 3 FHS-West hospitals, including outsourcing all transcription, saving \$750,000 annually, and consolidating laboratory services, saving \$3 million over five years.

Responsible for the development and implementation of a Community Health Model for FHS organizations.

1988 - 1993 Franciscan Health Services - Washington, Tacoma, WA

Vice President, Research and Development

Responsible for new product and service identification and development, including the development of a research process, the Technology Model, which was later implemented throughout Franciscan Health System.

Studies included:

- Magnetic resonance imaging
- Laser technologies
- Imaging, including ultrasound, SPECT cameras and CT
- Continuous quality improvement models
- Optical disk technologies
- Flow cytometry equipment

Responsible for the feasibility study, design and implementation of an MRI service at 4 FHS-West hospitals, including:

- Business and operations plan development
- Acquisition of three MRI systems and service contracts, which represented over \$8 million in capital and operating expenses
- Recruitment of staff, and day-to-day operational responsibility for the MRI department with an annual budget of \$4 million, for two years

1985 - 1988 Franciscan Health Services - Washington, Tacoma, WA

Director, Planning and Research

Responsible for utilization and financial projections for numerous program/services, as key elements of business plan preparation.

Responsible for all regulatory interface, including all certificate-of-need applications, and work with local and state planning agencies.

Responsible for all utilization and service area forecasts and competitor analysis for annual hospital strategic plans and budgets.

Responsible for all primary and secondary market research, including both internal survey projects, e.g., patient satisfaction surveys, and external research, e.g., large, community-wide, surveys.

1984-1985 Washington State Hospital Commission, Olympia, WA

Associate Director, Program Planning and Research

Responsible for technical and staff management of Program Planning and Research Division for the Hospital Commission, including:

- Design, development and management of the Commission Hospital Abstract Reporting System (CHARS), which is still used to compile and analyze patient discharge data from every hospital in the state.
- Design and development of target revenue estimates for statewide hospital revenues, required by the Washington Legislature. This task required compilation and analysis of very large data sets containing cost and revenue data for each Washington hospital.
- Development and implementation of charity care definitions and policies across all Washington hospitals.
- Management of Hospital Commission Certificate-of-Need reviews.

1983 SysteMetrics, Inc., Santa Barbara, CA

Senior Health Care Economist

Responsible for acquisition/development of health care data and forecasting models.

1977-1983 HDR Systems, Santa Barbara, CA

Senior Economist/Project Manager

Project management of numerous military studies. Responsibilities included proposal preparation, study definition, milestone and budget scheduling. This included: Publication scheduling and deadlines; assignment and coordination of interdisciplinary staff input; and technical review and edit.

Developed and implemented econometric forecasting models. These models forecast key economic and demographic parameters, e.g., employment/unemployment, wage levels, and population, for a defined geographic region.

Responsible for development and analysis of other economic technical studies, including development and use of regional inter-industry (input-output) models.

1971-1977 University of Washington, Seattle, WA

Instructor

Taught courses in micro and macroeconomics.

Computer Language Experience

Statistical Analysis System (SAS)

Statistical Package for the Social Sciences (SPSS)

STATA

Access

Honors and Awards

Phi Beta Kappa

Omicron Delta Epsilon (Economics Honor Society)

Magna Cum Laude Graduate

Memberships

American College of Health Executives

Washington State Hospital Association

Published Articles and Presentations

Publications

“Developing A Model for Technology Assessment,” Frank Fox, Ph.D. and Ellen Barron, Health Progress, pages 50-58, January-February 1993.

“Linking Technology with Strategic and Financial Plans: A Case Study of Franciscan Health System,” Frank Fox, Ph.D. and Ellen Barron, American Hospital Association, Hospital Technology Special Report, Volume 14, Number 11, September 1995.

Presentations

“Assessing Marketplace Impact of Future Clinical Technologies,” Technology and Healthcare Marketing--Future Vision Conference, The Alliance for Healthcare Strategy and Marketing, November 10-12, 1996.

“Smart Technology,” Real Solutions for Healthcare Materials Management—Annual Conference, American Society for Healthcare Materials Management, August 11-13, 1996.

“Smart Technology,” 16th Annual Meeting—Strategy Forum, Society for Healthcare Planning and Marketing, American Hospital Association, April 24-27, 1994.

Exhibit B

The Honorable Robert J. Bryan

UNITED STATES DISTRICT COURT
WESTERN DISTRICT OF WASHINGTON
AT TACOMA

C.P., by and through his parents, Patricia
Pritchard and Nolle Pritchard; and PATRICIA
PRITCHARD,

NO. 3:20-cv-06145-RJB

Plaintiffs,

v.

BLUE CROSS BLUE SHIELD OF ILLINOIS,

Defendant.

REPORT OF FRANK G. FOX, Ph.D.

A. Scope of Request

1. At request of counsel, I have been asked to prepare estimates of the number of persons who:

(1) Identify as transgender and gender diverse (“TGD”);

(2) Are enrolled in an ERISA self-funded “group health plan” (as defined in 29 U.S.C. § 1167(1)) administered by Blue Cross Blue Shield Illinois

(“BCBSIL”) that contains a categorical exclusion denying or limiting coverage for gender affirming health care;¹ and

(3) Whose enrollment occurred within the Study Period, defined to include January 1, 2016, to December 31, 2021, as provided by legal counsel.²

2. This analysis is based on BCBSIL enrollment counts obtained from discovery, as provided by legal counsel.³ For each year of the Study Period, I have been provided two sets of enrollment files. Based on further discovery and guidance from legal counsel, I have utilized the enrollment data across the two sets of enrollment files, for each year of the Study Period,⁴ and calculated a merged enrollment figure, by year. From these merged enrollment figures, I prepare estimates of the likely number of TGD persons in these BCBSIL ERISA self-funded group health plans which include categorical exclusions denying or limiting coverage for gender-affirming health care. In addition, I also estimate the subset of those persons likely to seek gender-affirming care.

3. Based on the methodology outlined below I estimate that, annually, on average, persons enrolled in the affected BCBSIL plans included about 1,740 TGD persons. Of these TGD insureds, I estimate that about 17.5% would have sought gender-affirming care in any given year. This corresponds to, on average, about 300 TGD persons seeking care in each of the relevant years. In my opinion, based on information provided to me and current scientific literature, these are reasonable estimates of these two populations.

¹ See Paragraphs 90 and 91 Class Definitions, *C.P. v. Blue Cross Blue Shield of Illinois*, Amended Complaint (Class Action), No. 3-20-cv-06145-RJB, United States District Court Western District of Washington at Tacoma, November 11, 2021.

² Telephone discussion with Ms. Ele Hamburger, August 1, 2022.

³ E-mail from Ms. Ele Hamburger, August 1, 2022.

⁴ Based on instruction from Ms. Payton, Kilpatrick Townsend & Stockton LLP, to Ms. Hamburger in an e-mail exchange, August 10, 2022, we used unique plan counts across the two separate enrollment counts, by plan, by year.

B. Background

4. Gender dysphoria is a serious medical condition recognized in the American Psychiatric Association’s Diagnostic and Statistical Manual of Mental Disorders, Fifth Edition (“DSM-5”);⁵ the World Health Organization’s International Classification of Diseases, which is the diagnostic and coding compendia for medical professionals;⁶ and by other leading medical and mental health professional groups, including the American Medical Association (“AMA”);⁷ and the American Psychological Association (“APA”).⁸

5. Transgender people often undertake a series of individualized steps to live in a manner consistent with their gender identity, rather than the sex they were assigned at birth. These steps, known as transitioning, typically include social, legal, and medical transitions. The social transition entails a transgender individual living in accordance with their gender identity, the legal transition involves steps to formally align a transgender individual’s legal identity with their gender identity, and the medical transition includes gender-affirming care that brings the sex-specific characteristics of a transgender person’s body into alignment with their gender. Gender-affirming care can involve counseling to obtain a diagnosis of gender dysphoria, hormone replacement therapy, surgical care, or other medically necessary treatments for gender dysphoria.

⁵ American Psychiatric Association. 2013. *Diagnostic and Statistical Manual of Mental Disorders, 5th Edition*. American Psychiatric Association, Arlington, VA.

⁶ World Health Organization. 2022. *International Classification of Diseases, 11th Revision*. <https://icd.who.int/en>, Last Accessed August 17, 2022.

⁷ American Medical Association. 2019. *AMA: Leading medical organizations fight for transgender Americans*. AMA Press Releases, July 10, 2019. <https://www.ama-assn.org/press-center/press-releases/ama-leading-medical-organizations-fight-transgender-americans>, Last Accessed August 17, 2022.

⁸ American Psychological Association. 2022. *Patients and Families: Mental Health Topics*. <https://www.psychiatry.org/patients-families>, Last Accessed August 17, 2022.

6. In estimating TGD populations, there exist large differences between survey-based self-reported transgender identity and treatment- or diagnosis-based results.⁹

7. Survey-based estimates of transgender prevalence include those from the Williams Institute, UCLA School of Law, which uses data from the CDC's Behavior Risk Factor Surveillance System ("BRFSS") and Youth Risk Behavior Survey ("YRBS") to estimate the population, age distribution, and ethnic distribution of TGD persons for U.S. states.¹⁰ The most recent publication by the Williams Institute, in June 2022, indicates that about 0.52% of persons across the U.S identify as transgender, and that this proportion is highest among the adolescent (13-17; 1.43%) and young adult (18-24; 1.31%) age groups.¹¹

8. Treatment- or diagnosis-based estimates of transgender prevalence come from health care providers or health systems where patients have either sought body or hormonal modifications or have been otherwise compelled to disclose their TGD identity to access clinical services. These estimates reflect a subset of the TGD population who are actively seeking gender-affirming health care.¹² Thus, diagnosis-based estimates should be understood as estimates of TGD persons actively seeking health care services related to their transgender identity.

9. Perhaps the best set of diagnosis-based estimates comes from Kaiser Permanente health plans in Georgia ("KPGA"), Southern California ("KPSC"), and Northern California ("KPNC").¹³ These plans provide health services to approximately 8 million members, enrolled

⁹ World Professional Association for Transgender Health ("WPATH"). 2021. *Standards of Care: Epidemiology*. <https://www.wpath.org/publications/soc>, Last Accessed August 17, 2022. See also Collin, Lindsay, Sari L. Reisner, Vin Tangpricha, and Michael Goodman. 2016. *Prevalence of Transgender Depends on the "Case" Definition: A Systematic Review*. The Journal of Sexual Medicine, Vol 13: 613-626.

¹⁰ Herman, Jody L., Andrew R. Flores, and Kathryn K. O'Neill. June 2022. *How Many Adults and Youth Identify as Transgender in the United States?* The Williams Institute, UCLA School of Law. This is the most recent research publication by the Williams Institute. There were also research studies published in 2016, 2017 and 2020.

¹¹ *Ibid.*, p. 10.

¹² Meier, Stacy C. and Christine M. Labuski. 2013. *The Demographics of the Transgender Population*. In: International Handbook on the Demography of Sexuality: Springer, 289-327.

¹³ Quinn et al. 2017. *Cohort profile: Study of Transition, Outcomes and Gender (STRONG) to assess health status of transgender people*. BMJ Open, 7: e018121.

1 through employers or state or federal programs such as Medicare or Medicaid, so represent a large
 2 sample across a diverse set of insureds. Through analysis of diagnosis codes and free-text clinical
 3 notes, researchers estimated that the prevalence of transgender status ranged from .038% (KPGA)
 4 to .075% (KPNC) of Kaiser enrollees.¹⁴ Based off how transgender status was determined, these
 5 proportions represent enrollees who sought care related to their transgender identity, a subset of
 6 Kaiser TGD enrollees.

7 **C. Analysis**

8 **1. Plan enrollment estimates**

9 10. The number of persons enrolled in BCBSIL ERISA self-funded plans and subject
 10 to the gender affirming health care exclusion was provided for the period 2016 to 2021 by counsel
 11 in the files BCBSIL_CP_0020594, BCBSIL_CP_0020595, BCBSIL_CP_0020596,
 12 BCBSIL_CP_0020597, BCBSIL_CP_0020598, BCBSIL_CP_0020599.¹⁵

13 11. These files contained enrollment by plan, for two sets of plans. The first set was
 14 titled "Account_CP matched to Acct_Nbr," and the second "Account_CP matched to
 15 Group_Nbr." For convenience I label the enrollment from the first set of plans "P1" and
 16 enrollment from the second set of plans "P2." Annual enrollment counts by year for P1 and P2
 17 are presented in Table 1.

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 25 ¹⁴ *Ibid*, p. 9. These figures are from 2014 statistics. The proportions were 38 per 100,000 enrollees at KPGA,
 44 per 100,000 enrollees at KPSC and 75 per 100,000 enrollees at KPNC.

26 ¹⁵ E-mail with attachments, from Ms. Ele Hamburger, August 1, 2022. It is my understanding these files were
 produced during the discovery process.

Table 1: BCBSIL Enrollment in ERISA Self-Funded Plans Subject to Gender Affirming Health Care Exclusion						
	2016	2017	2018	2019	2020	2021
Enrollment						
Account_CP matched to Acct Nbr (P1)	149,409	159,831	164,679	151,309	148,063	140,621
Account_CP matched to Group Nbr (P2)	271,865	271,698	292,921	295,289	283,796	273,993
Sources: BCBSIL_CP_0020594, BCBSIL_CP_0020595, BCBSIL_CP_0020596, BCBSIL_CP_0020597, BCBSIL_CP_0020598						

12. The enrollment counts from P1 reflect enrollment across about 20 different plans, while enrollment counts from P2 reflect enrollment across about 283 different plans.¹⁶ Thus, while there is some overlap in the included plans between the two estimates of enrollment, most plans included in P2 do not appear in P1.

13. Separating enrollment in P2 between those plans which are included in P1, I present enrollment within “overlapping” plans and “non-overlapping” plans in Table 2.

Table 2: P2 Enrollment in Separating by Overlap Status						
	2016	2017	2018	2019	2020	2021
Enrollment						
P2 – Non-Overlapping Plans	241,708	245,447	262,317	266,306	252,779	244,090
P2 – Overlapping Plans	30,157	26,251	30,604	28,983	31,017	29,903
Sources: BCBSIL_CP_0020594, BCBSIL_CP_0020595, BCBSIL_CP_0020596, BCBSIL_CP_0020597, BCBSIL_CP_0020598						
Notes: P2 – Non-Overlapping Plans includes enrollment from plans present in P2, but not present in P1. P2 – Overlapping Plans includes P2 enrollment for plans present in both P1 and P2.						

14. Merging P1 and P2, and excluding P2 enrollment for overlapping plans, gives annual enrollment counts for BCBSIL ERISA self-funded plans subject to the gender affirming health care exclusion. This additional step was identified and requested by plaintiffs’ counsel for

¹⁶ These figures are apparently less than the number of BCBSIL ERISA self-funded plans that have gender-affirming care exclusions. In its response to Interrogatory Question #6, attorneys for the defendant stated there are 398 such plans that meet this definition. See response to Interrogatory #6, p. 5, *Fifth Supplemental Responses and Objections to Plaintiffs’ Second Discovery Request to Defendant Blue Cross and Blue Shield of Illinois*, Case No. 3:20-cv-06145-RJB, July 29, 2022.

complete plan enrollment figures. An alternative method of combining P1 and P2 would be to add the enrollment counts together, however I have taken the above approach for accuracy and conservativeness. From this method, I present merged enrollment totals in Table 3.

Table 3: BCBSIL Merged Plan Enrollment

	2016	2017	2018	2019	2020	2021
Enrollment						
Merged plan enrollment	391,117	405,278	426,996	417,615	400,842	384,711

Sources: BCBSIL_CP_0020594, BCBSIL_CP_0020595, BCBSIL_CP_0020596, BCBSIL_CP_0020597, BCBSIL_CP_0020598

Notes: Merged enrollment includes all plans from P1, plus non-overlapping plans from P2.

2. Methodology to Estimate the Number of Enrolled TGD Persons

15. From the enrollment counts in Table 3, I apply age-specific population estimates of the proportion of persons who identify as TGD to population by age, where the age distribution is assumed to equal that of Illinois overall for each of the given years.¹⁷ Estimates of the overall number of TGD persons by year, from Table 3, is presented in Table 4.

Table 4: Population Weighted Estimates of Affected Insureds

Year	Row	2016	2017	2018	2019	2020	2021
Enrollment Counts	1	391,117	405,278	426,996	417,615	400,842	384,711
Population Proportions by Age (Illinois Population Structure)							
0 to 12	2	16.30%	16.12%	15.96%	15.79%	15.62%	15.62%
13 to 17	3	6.62%	6.59%	6.54%	6.50%	6.50%	6.50%
18 to 24	4	9.34%	9.21%	9.12%	9.03%	8.94%	8.94%
25 to 64	5	52.95%	52.86%	52.71%	52.52%	52.31%	52.31%
65 and older	6	14.79%	15.21%	15.67%	16.16%	16.63%	16.63%
Proportion by Age							
0 to 12	7	N/A	N/A	N/A	N/A	N/A	N/A
13 to 17	8	0.65%	0.65%	0.65%	0.65%	0.65%	0.65%

¹⁷ I do not know where BSBCIL insureds in these plans reside so have assumed, for purposes of modeling, the majority live in the state of Illinois.

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25 to 64	10	0.50%	0.50%	0.50%	0.50%	0.50%	0.50%
65 and older	11	0.46%	0.46%	0.46%	0.46%	0.46%	0.46%
Numerosity	12	1,678	1,741	1,837	1,799	1,729	1,659
Average Proportion	13	0.43%	0.43%	0.43%	0.43%	0.43%	0.43%

Sources:

Row 1: BCBSIL_CP_0020594, BCBSIL_CP_0020595, BCBSIL_CP_0020596, BCBSIL_CP_0020597, BCBSIL_CP_0020598. See Table 3.

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Row 12: Weighted sum of merged enrollment, distributed according to rows 2-6 and weighted by rows 7-11.

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16. From the methodology in Table 4, I estimate about 1,740 TGD persons per year were enrolled in one of the BCBSIL affected plans. These estimates represent the number of BCBSIL insureds who met the definition of gender-affirming care and were included in such plans that had plan exclusions for such care. Below, I estimate the proportion of these insureds who are estimated to have sought gender-affirming care, based on current scientific literature.¹⁸

Table 5: Estimates of TGD Insureds, Health Care Users Only

Year	Row	2016	2017	2018	2019	2020	2021
Numerosity	12	1,678	1,741	1,837	1,799	1,729	1,659
Average Proportion	13	0.43%	0.43%	0.43%	0.43%	0.43%	0.43%
Population Proportion From Study of Health Care Users Only	14	0.075%	0.075%	0.075%	0.075%	0.075%	0.075%
Ratio of Health Care Users to Overall Population Proportion	15	17.5%	17.5%	17.4%	17.4%	17.4%	17.4%

¹⁸ Quinn et al. 2017.

Numerosity, Health Care Users Only	16	293	304	320	313	301	289
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17. From Table 5, of the TGD persons estimated to have been enrolled in the identified BCBSIL plans, I estimate about 17.5% would be likely to seek gender-affirming care in any given year. This indicates that, on average, about 300 persons would have been expected to seek gender-affirming care each year.

Dated: August 19, 2022, in Seattle, Washington.



Frank Fox, PhD.

APPENDIX A – RATE AND LITIGATION EXPERIENCE

I am paid at the rate of \$275 per hour in this litigation.

Depositions, Expert Declarations, Expert Reports and Rebuttal Reports.

I have provided expert declarations and/or expert and rebuttal reports in the following cases over the past four years: (1) In 2018, I provided a declaration (“Declaration”) valuing the injunctive relief in a class action settlement in support of the motion for preliminary approval of that settlement in *Kerr v. Kaiser Foundation Health Plan*, Los Angeles Superior Court Case No. BC556863. (2) In May 2019, I provided a Declaration regarding models I prepared estimating utilization and cost for selected treatments for patients with diagnoses identified in the California Mental Health Parity Act and substance abuse in *Ames v. Anthem Blue Cross Life & Health Insurance Company*, Los Angeles Superior Court Case No. BC591623. (3) In May 2019, I provided Declaration regarding estimates of the number of Plan insureds with a prevalence of Autism Spectrum Disorder (“ASD”) who utilized and expended monies for applied behavior therapy (“ABA”) in *JR v. CHI et.al.*, United States District Court, Western District of Washington, Seattle, No. 2:18:cv-01191-JLR. (4) In June 2019, I prepared an Expert Report in *DT v. NECA/IBEW Family Medical Plan, Civil Action No. 2:17-cv-00004 (RAJ)*, which estimated utilization and expenditures for ABA and/or physical therapy (“PT”), occupational therapy (“OT”) or speech therapy, for Plan insureds with a prevalence of ASD. (5) In July 2019, I prepared a series of Rebuttal Reports in *DT v. NECA/IBEW Family Medical Plan, Civil Action No. 2:17-cv-00004 (RAJ)*. (6) In January 2020, I provided a Declaration valuing coverage for residential treatment for insureds with eating disorders in a class action case in *Rea v. Blue Shield of California, Los Angeles Superior Court Case No. B468900*. (7) In July 2020, I prepared an Expert Report in *Crosby v. Blue Shield of California, Magellan Health, et. al., Case No. 8:17-CV-01970-CJC-JDE*. (8) In August 2020, I prepared a Rebuttal Report also for *Crosby v. Blue Shield of California, Magellan Health, et. al., Case No. 8:17-CV-01970-CJC-JDE*. (9) In October 2020, I prepared a Declaration in support of a motion for summary adjudication of Health Net’s

1 fifth cause of action for intentional interference with contractual relations in *Dual Diagnosis*
2 *Treatment Center Inc., v. Health Net, Los Angeles Superior Court, Case No. LC104357*. (10) In
3 November 2020, I provided a supplemental Declaration in *Rea v. Blue Shield of California, Los*
4 *Angeles Superior Court Case No. B468900*. (11) In January 2022, I was deposed in in *Dual*
5 *Diagnosis Treatment Center Inc., v. Health Net, Los Angeles Superior Court, Case No.*
6 *LC104357*. (12) In June 2022, I was deposed in *Decision by the Department of Health Regarding*
7 *Two Certificate of Need Applications Proposing to Establish Medicare and Medicaid Certified*
8 *Hospice Services in Thurston County, No. M2021-923*.

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3 [releases/ama-leading-medical-organizations-fight-transgender-americans,](https://www.ama-assn.org/press-center/press-releases/ama-leading-medical-organizations-fight-transgender-americans) Last Accessed
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- 12 Herman, Jody L., Andrew R. Flores, and Kathryn K. O’Neill. 2022. How Many Adults and Youth
13 Identify as Transgender in the United States? The Williams Institute, UCLA School of Law.
- 14 Meier, Stacy C. and Christine M. Labuski. 2013. The Demographics of the Transgender
15 Population. In: International Handbook on the Demography of Sexuality: Springer, 289-327.
- 16 Quinn et al. 2017. Cohort profile: Study of Transition, Outcomes and Gender (STRONG) to assess
17 health status of transgender people. BMJ Open, 7: e018121.
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19 <https://icd.who.int/en>, Last Accessed August 17, 2022.
- 20 WPATH. 2021. Standards of Care: Epidemiology. <https://www.wpath.org/publications/soc>, Last
21 Accessed August 17, 2022.

EXHIBIT H

The Honorable Robert J. Bryan

UNITED STATES DISTRICT COURT
WESTERN DISTRICT OF WASHINGTON
AT TACOMA

C.P., by and through his parents, Patricia
Pritchard and Nolle Pritchard; and PATRICIA
PRITCHARD,

NO. 3:20-cv-06145-RJB

Plaintiffs,

v.

BLUE CROSS BLUE SHIELD OF ILLINOIS,

Defendant.

REPORT OF FRANK G. FOX, Ph.D.

A. Scope of Request

1. At request of counsel, I have been asked to prepare estimates of the number of persons who:

(1) Identify as transgender and gender diverse (“TGD”);

(2) Are enrolled in an ERISA self-funded “group health plan” (as defined in 29 U.S.C. § 1167(1)) administered by Blue Cross Blue Shield Illinois

(“BCBSIL”) that contains a categorical exclusion denying or limiting coverage for gender affirming health care;¹ and

(3) Whose enrollment occurred within the Study Period, defined to include January 1, 2016, to December 31, 2021, as provided by legal counsel.²

2. This analysis is based on BCBSIL enrollment counts obtained from discovery, as provided by legal counsel.³ For each year of the Study Period, I have been provided two sets of enrollment files. Based on further discovery and guidance from legal counsel, I have utilized the enrollment data across the two sets of enrollment files, for each year of the Study Period,⁴ and calculated a merged enrollment figure, by year. From these merged enrollment figures, I prepare estimates of the likely number of TGD persons in these BCBSIL ERISA self-funded group health plans which include categorical exclusions denying or limiting coverage for gender-affirming health care. In addition, I also estimate the subset of those persons likely to seek gender-affirming care.

3. Based on the methodology outlined below I estimate that, annually, on average, persons enrolled in the affected BCBSIL plans included about 1,740 TGD persons. Of these TGD insureds, I estimate that about 17.5% would have sought gender-affirming care in any given year. This corresponds to, on average, about 300 TGD persons seeking care in each of the relevant years. In my opinion, based on information provided to me and current scientific literature, these are reasonable estimates of these two populations.

¹ See Paragraphs 90 and 91 Class Definitions, *C.P. v. Blue Cross Blue Shield of Illinois*, Amended Complaint (Class Action), No. 3-20-cv-06145-RJB, United States District Court Western District of Washington at Tacoma, November 11, 2021.

² Telephone discussion with Ms. Ele Hamburger, August 1, 2022.

³ E-mail from Ms. Ele Hamburger, August 1, 2022.

⁴ Based on instruction from Ms. Payton, Kilpatrick Townsend & Stockton LLP, to Ms. Hamburger in an e-mail exchange, August 10, 2022, we used unique plan counts across the two separate enrollment counts, by plan, by year.

B. Background

4. Gender dysphoria is a serious medical condition recognized in the American Psychiatric Association’s Diagnostic and Statistical Manual of Mental Disorders, Fifth Edition (“DSM-5”);⁵ the World Health Organization’s International Classification of Diseases, which is the diagnostic and coding compendia for medical professionals;⁶ and by other leading medical and mental health professional groups, including the American Medical Association (“AMA”);⁷ and the American Psychological Association (“APA”).⁸

5. Transgender people often undertake a series of individualized steps to live in a manner consistent with their gender identity, rather than the sex they were assigned at birth. These steps, known as transitioning, typically include social, legal, and medical transitions. The social transition entails a transgender individual living in accordance with their gender identity, the legal transition involves steps to formally align a transgender individual’s legal identity with their gender identity, and the medical transition includes gender-affirming care that brings the sex-specific characteristics of a transgender person’s body into alignment with their gender. Gender-affirming care can involve counseling to obtain a diagnosis of gender dysphoria, hormone replacement therapy, surgical care, or other medically necessary treatments for gender dysphoria.

⁵ American Psychiatric Association. 2013. *Diagnostic and Statistical Manual of Mental Disorders, 5th Edition*. American Psychiatric Association, Arlington, VA.

⁶ World Health Organization. 2022. *International Classification of Diseases, 11th Revision*. <https://icd.who.int/en>, Last Accessed August 17, 2022.

⁷ American Medical Association. 2019. *AMA: Leading medical organizations fight for transgender Americans*. AMA Press Releases, July 10, 2019. <https://www.ama-assn.org/press-center/press-releases/ama-leading-medical-organizations-fight-transgender-americans>, Last Accessed August 17, 2022.

⁸ American Psychological Association. 2022. *Patients and Families: Mental Health Topics*. <https://www.psychiatry.org/patients-families>, Last Accessed August 17, 2022.

1 6. In estimating TGD populations, there exist large differences between survey-based
2 self-reported transgender identity and treatment- or diagnosis-based results.⁹

3 7. Survey-based estimates of transgender prevalence include those from the Williams
4 Institute, UCLA School of Law, which uses data from the CDC's Behavior Risk Factor
5 Surveillance System ("BRFSS") and Youth Risk Behavior Survey ("YRBS") to estimate the
6 population, age distribution, and ethnic distribution of TGD persons for U.S. states.¹⁰ The most
7 recent publication by the Williams Institute, in June 2022, indicates that about 0.52% of persons
8 across the U.S identify as transgender, and that this proportion is highest among the adolescent
9 (13-17; 1.43%) and young adult (18-24; 1.31%) age groups.¹¹

10 8. Treatment- or diagnosis-based estimates of transgender prevalence come from
11 health care providers or health systems where patients have either sought body or hormonal
12 modifications or have been otherwise compelled to disclose their TGD identity to access clinical
13 services. These estimates reflect a subset of the TGD population who are actively seeking gender-
14 affirming health care.¹² Thus, diagnosis-based estimates should be understood as estimates of
15 TGD persons actively seeking health care services related to their transgender identity.

16 9. Perhaps the best set of diagnosis-based estimates comes from Kaiser Permanente
17 health plans in Georgia ("KPGA"), Southern California ("KPSC"), and Northern California
18 ("KPNC").¹³ These plans provide health services to approximately 8 million members, enrolled
19

20 ⁹ World Professional Association for Transgender Health ("WPATH"). 2021. *Standards of Care: Epidemiology*.
21 <https://www.wpath.org/publications/soc>, Last Accessed August 17, 2022. See also Collin, Lindsay, Sari L. Reisner,
22 Vin Tangpricha, and Michael Goodman. 2016. *Prevalence of Transgender Depends on the "Case" Definition: A Systematic Review*. The Journal of Sexual Medicine, Vol 13: 613-626.

23 ¹⁰ Herman, Jody L., Andrew R. Flores, and Kathryn K. O'Neill. June 2022. *How Many Adults and Youth Identify as Transgender in the United States?* The Williams Institute, UCLA School of Law. This is the most recent research publication by the Williams Institute. There were also research studies published in 2016, 2017 and 2020.

24 ¹¹ *Ibid.*, p. 10.

25 ¹² Meier, Stacy C. and Christine M. Labuski. 2013. *The Demographics of the Transgender Population*. In: International Handbook on the Demography of Sexuality: Springer, 289-327.

26 ¹³ Quinn et al. 2017. *Cohort profile: Study of Transition, Outcomes and Gender (STRONG) to assess health status of transgender people*. BMJ Open, 7: e018121.

1 through employers or state or federal programs such as Medicare or Medicaid, so represent a large
 2 sample across a diverse set of insureds. Through analysis of diagnosis codes and free-text clinical
 3 notes, researchers estimated that the prevalence of transgender status ranged from .038% (KPGA)
 4 to .075% (KPNC) of Kaiser enrollees.¹⁴ Based off how transgender status was determined, these
 5 proportions represent enrollees who sought care related to their transgender identity, a subset of
 6 Kaiser TGD enrollees.

7 **C. Analysis**

8 **1. Plan enrollment estimates**

9 10. The number of persons enrolled in BCBSIL ERISA self-funded plans and subject
 10 to the gender affirming health care exclusion was provided for the period 2016 to 2021 by counsel
 11 in the files BCBSIL_CP_0020594, BCBSIL_CP_0020595, BCBSIL_CP_0020596,
 12 BCBSIL_CP_0020597, BCBSIL_CP_0020598, BCBSIL_CP_0020599.¹⁵

13 11. These files contained enrollment by plan, for two sets of plans. The first set was
 14 titled "Account_CP matched to Acct_Nbr," and the second "Account_CP matched to
 15 Group_Nbr." For convenience I label the enrollment from the first set of plans "P1" and
 16 enrollment from the second set of plans "P2." Annual enrollment counts by year for P1 and P2
 17 are presented in Table 1.

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19
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21
22
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24
25 ¹⁴ *Ibid*, p. 9. These figures are from 2014 statistics. The proportions were 38 per 100,000 enrollees at KPGA,
 44 per 100,000 enrollees at KPSC and 75 per 100,000 enrollees at KPNC.

26 ¹⁵ E-mail with attachments, from Ms. Ele Hamburger, August 1, 2022. It is my understanding these files were
 produced during the discovery process.

Table 1: BCBSIL Enrollment in ERISA Self-Funded Plans Subject to Gender Affirming Health Care Exclusion						
	2016	2017	2018	2019	2020	2021
Enrollment						
Account_CP matched to Acct Nbr (P1)	149,409	159,831	164,679	151,309	148,063	140,621
Account_CP matched to Group Nbr (P2)	271,865	271,698	292,921	295,289	283,796	273,993
Sources: BCBSIL_CP_0020594, BCBSIL_CP_0020595, BCBSIL_CP_0020596, BCBSIL_CP_0020597, BCBSIL_CP_0020598						

12. The enrollment counts from P1 reflect enrollment across about 20 different plans, while enrollment counts from P2 reflect enrollment across about 283 different plans.¹⁶ Thus, while there is some overlap in the included plans between the two estimates of enrollment, most plans included in P2 do not appear in P1.

13. Separating enrollment in P2 between those plans which are included in P1, I present enrollment within “overlapping” plans and “non-overlapping” plans in Table 2.

Table 2: P2 Enrollment in Separating by Overlap Status						
	2016	2017	2018	2019	2020	2021
Enrollment						
P2 – Non-Overlapping Plans	241,708	245,447	262,317	266,306	252,779	244,090
P2 – Overlapping Plans	30,157	26,251	30,604	28,983	31,017	29,903
Sources: BCBSIL_CP_0020594, BCBSIL_CP_0020595, BCBSIL_CP_0020596, BCBSIL_CP_0020597, BCBSIL_CP_0020598						
Notes: P2 – Non-Overlapping Plans includes enrollment from plans present in P2, but not present in P1. P2 – Overlapping Plans includes P2 enrollment for plans present in both P1 and P2.						

14. Merging P1 and P2, and excluding P2 enrollment for overlapping plans, gives annual enrollment counts for BCBSIL ERISA self-funded plans subject to the gender affirming health care exclusion. This additional step was identified and requested by plaintiffs’ counsel for

¹⁶ These figures are apparently less than the number of BCBSIL ERISA self-funded plans that have gender-affirming care exclusions. In its response to Interrogatory Question #6, attorneys for the defendant stated there are 398 such plans that meet this definition. See response to Interrogatory #6, p. 5, *Fifth Supplemental Responses and Objections to Plaintiffs’ Second Discovery Request to Defendant Blue Cross and Blue Shield of Illinois*, Case No. 3:20-cv-06145-RJB, July 29, 2022.

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Dated: August 19, 2022, in Seattle, Washington.



Frank Fox, PhD.

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I am paid at the rate of \$275 per hour in this litigation.

Depositions, Expert Declarations, Expert Reports and Rebuttal Reports.

I have provided expert declarations and/or expert and rebuttal reports in the following cases over the past four years: (1) In 2018, I provided a declaration (“Declaration”) valuing the injunctive relief in a class action settlement in support of the motion for preliminary approval of that settlement in *Kerr v. Kaiser Foundation Health Plan*, Los Angeles Superior Court Case No. BC556863. (2) In May 2019, I provided a Declaration regarding models I prepared estimating utilization and cost for selected treatments for patients with diagnoses identified in the California Mental Health Parity Act and substance abuse in *Ames v. Anthem Blue Cross Life & Health Insurance Company*, Los Angeles Superior Court Case No. BC591623. (3) In May 2019, I provided Declaration regarding estimates of the number of Plan insureds with a prevalence of Autism Spectrum Disorder (“ASD”) who utilized and expended monies for applied behavior therapy (“ABA”) in *JR v. CHI et.al.*, United States District Court, Western District of Washington, Seattle, No. 2:18:cv-01191-JLR. (4) In June 2019, I prepared an Expert Report in *DT v. NECA/IBEW Family Medical Plan, Civil Action No. 2:17-cv-00004 (RAJ)*, which estimated utilization and expenditures for ABA and/or physical therapy (“PT”), occupational therapy (“OT”) or speech therapy, for Plan insureds with a prevalence of ASD. (5) In July 2019, I prepared a series of Rebuttal Reports in *DT v. NECA/IBEW Family Medical Plan, Civil Action No. 2:17-cv-00004 (RAJ)*. (6) In January 2020, I provided a Declaration valuing coverage for residential treatment for insureds with eating disorders in a class action case in *Rea v. Blue Shield of California, Los Angeles Superior Court Case No. B468900*. (7) In July 2020, I prepared an Expert Report in *Crosby v. Blue Shield of California, Magellan Health, et. al., Case No. 8:17-CV-01970-CJC-JDE*. (8) In August 2020, I prepared a Rebuttal Report also for *Crosby v. Blue Shield of California, Magellan Health, et. al., Case No. 8:17-CV-01970-CJC-JDE*. (9) In October 2020, I prepared a Declaration in support of a motion for summary adjudication of Health Net’s

1 fifth cause of action for intentional interference with contractual relations in *Dual Diagnosis*
2 *Treatment Center Inc., v. Health Net, Los Angeles Superior Court, Case No. LC104357*. (10) In
3 November 2020, I provided a supplemental Declaration in *Rea v. Blue Shield of California, Los*
4 *Angeles Superior Court Case No. B468900*. (11) In January 2022, I was deposed in in *Dual*
5 *Diagnosis Treatment Center Inc., v. Health Net, Los Angeles Superior Court, Case No.*
6 *LC104357*. (12) In June 2022, I was deposed in *Decision by the Department of Health Regarding*
7 *Two Certificate of Need Applications Proposing to Establish Medicare and Medicaid Certified*
8 *Hospice Services in Thurston County, No. M2021-923*.

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Addendum—Report of Frank G. Fox, Ph.D

Upon reviewing my Report, I have identified a revision to Tables 4 and 5 of my Report based on updated 2022 statistics from The Williams Institute, upon whose population estimates I rely.¹ These revisions are provided below and should be used to substitute the prior tables in my earlier Report.

Updated Table 1: Population Weighted Estimates of Affected Insureds							
Year	Row	2016	2017	2018	2019	2020	2021
Enrollment Counts	1	391,117	405,278	426,996	417,615	400,842	384,711
Population Proportions by Age (Illinois Population Structure)							
0 to 12	2	16.30%	16.12%	15.96%	15.79%	15.62%	15.62%
13 to 17	3	6.62%	6.59%	6.54%	6.50%	6.50%	6.50%
18 to 24	4	9.34%	9.21%	9.12%	9.03%	8.94%	8.94%
25 to 64	5	52.95%	52.86%	52.71%	52.52%	52.31%	52.31%
65 and older	6	14.79%	15.21%	15.67%	16.16%	16.63%	16.63%
Proportion by Age							
0 to 12	7	N/A	N/A	N/A	N/A	N/A	N/A
13 to 17	8	1.66%	1.66%	1.66%	1.66%	1.66%	1.66%
18 to 24	9	1.94%	1.94%	1.94%	1.94%	1.94%	1.94%
25 to 64	10	0.24%	0.24%	0.24%	0.24%	0.24%	0.24%
65 and older	11	0.24%	0.24%	0.24%	0.24%	0.24%	0.24%
Numerosity	12	1,774	1,830	1,920	1,871	1,791	1,719
Average Proportion	13	0.45%	0.45%	0.45%	0.45%	0.45%	0.45%
Sources:							
Row 1: BCBSIL_CP_0020594, BCBSIL_CP_0020595, BCBSIL_CP_0020596, BCBSIL_CP_0020597, BCBSIL_CP_0020598. See Table 3.							

¹ The updated source is the following: Herman, Jody L., Andrew R. Flores, and Kathryn K. O'Neill. 2022. *How Many Adults and Youth Identify as Transgender in the United States?* The Williams Institute, UCLA School of Law.

Row 2 – Row 6: SC-EST2020-AGESEX-CIV: Annual Estimates of the Civilian Population by Single Year of Age and Sex for the United States, States, and the District of Columbia: April 1, 2010, to July 1, 2020.

Row 7 – Row 11: Herman, Jody L., Andrew R. Flores, and Kathryn K. O’Neill. 2022. *How Many Adults and Youth Identify as Transgender in the United States?* The Williams Institute, UCLA School of Law.

Row 12: Weighted sum of merged enrollment, distributed according to rows 2-6 and weighted by rows 7-11.

Row 13: Row 12 divided by Row 1.

Table 5 utilizes Table 4 TGD insureds’ prevalence estimates. Thus, Table 5 is also revised. It is presented below. Revisions to Table 5 include Rows 12 and 13, which are directly from Table 4, as well as Rows 15 and 16. They follow from the revisions to numerosity calculations in Table 4, shown in Rows 12 and 13.

Updated Table 5: Estimates of TGD Insureds, Health Care Users Only							
Year	Row	2016	2017	2018	2019	2020	2021
Numerosity	12	1,774	1,830	1,920	1,871	1,791	1,719
Average Proportion	13	0.45%	0.45%	0.45%	0.45%	0.45%	0.45%
Population Proportion From Study of Health Care Users Only	14	0.075%	0.075%	0.075%	0.075%	0.075%	0.075%
Ratio of Health Care Users to Overall Population Proportion	15	16.5%	16.6%	16.7%	16.7%	16.8%	16.8%
Numerosity, Health Care Users Only	16	293	304	320	313	301	289

Sources:

Row 12-13: Table 1.

Row 14: Quinn et al. (2017). *Cohort profile: Study of Transition, Outcomes and Gender (STRONG) to assess health status of transgender people*. BMJ Open, 7: e018121. This 0.075% estimate is for Northern California Kaiser enrollees.

Row 15: Row 14 divided by Row 13.

Row 16: Row 12 multiplied by Row 15.

Al Fox, PhD

Frank Fox, PhD.

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EXHIBIT I

HONORABLE JUDGE ROBERT J. BRYAN

IN THE UNITED STATES DISTRICT COURT
FOR THE WESTERN DISTRICT OF WASHINGTON
AT TACOMA

C. P., by and through his parents,
Patricia Pritchard and Nolle Pritchard;
and PATRICIA PRITCHARD,

Plaintiff,

vs.

BLUE CROSS BLUE SHIELD OF
ILLINOIS,

Defendants.

Case No. 3:20-cv-06145-RJB

**FIFTH SUPPLEMENTAL RESPONSES
AND OBJECTIONS TO PLAINTIFFS'
SECOND DISCOVERY REQUESTS TO
DEFENDANT BLUE CROSS AND BLUE
SHIELD OF ILLINOIS**

TO: Plaintiffs C. P., Patricia Pritchard, and Nolle Pritchard.

AND TO: SIRIANNI YOUTZ SPOONEMORE HAMBURGER PLLC and LAMBDA
LEGAL DEFENSE AND EDUCATION FUND, INC., their attorneys.

Pursuant to Federal Rules of Civil Procedure 26, 33, and 34, Defendant Blue Cross Blue
Shield of Illinois ("BCBSIL") hereby objects and responds to Plaintiffs' Second Discovery
Requests (the "Requests") as follows:

A. GENERAL OBJECTIONS

1. BCBSIL objects to the Requests to the extent they are overly broad, unduly
burdensome, oppressive, redundant, vague, ambiguous, and/or seek to impose on BCBSIL
obligations greater than or different from those imposed by the Federal Rules of Civil Procedure.

2. BCBSIL objects to the Requests to the extent they impose a burden on it that is

disproportionate to the needs of the litigation.

3. BCBSIL interprets the Requests as excluding documents and information subject to the attorney-client privilege, work-product privilege, joint-defense/common-interest privilege, and any other applicable privileges or protections.

5. BCBSIL objects to the Requests to the extent they require BCBSIL to use more than reasonable diligence in preparing their objections and responses based on an examination of those files that reasonably may be expected to yield responsive information and an inquiry of those persons who reasonably may be expected to possess responsive information.

6. BCBSIL objects to the Requests to the extent the discovery sought is unreasonably cumulative, duplicative, or obtainable from some other source that is more convenient, less burdensome, or less expensive, including if the discovery sought is already in the Plaintiffs' possession.

7. BCBSIL objects to each and every Request to the extent it seeks to require BCBSIL to identify or produce documents not currently in their possession, custody, or control, on the grounds that such a request seeks to require more of BCBSIL than any obligation imposed by law, would subject it to unreasonable and undue annoyance, oppression, burden, and expense, or would seek to impose upon it an obligation to discover information or materials from third parties or sources that are equally accessible to the Plaintiffs.

8. BCBSIL objects to the Requests to the extent they seek information outside the applicable three-year statute of limitations for Plaintiffs' Section 1557 claims. *See Smith v. Highland Hosp. of Rochester*, No. 17-CV-6781-CJS, 2018 WL 4748187, at *3 (W.D.N.Y. Oct. 2, 2018); *Solis v. Our Lady of the Lake Ascension Cmty. Hosp., Inc.*, No. CV 18-56-SDD-RLB, 2020 WL 2754917, at *4 (M.D. La. May 27, 2020); *Ward v. Our Lady of the Lake Hosp., Inc.*, No. CV 18-00454-BAJ-RLB, 2020 WL 414457, at *2 (M.D. La. Jan. 24, 2020); RCW 4.16.080(2). Moreover, Plaintiffs' class claims, added via amended complaint, do not relate back to the filing of the initial complaint because BCBSIL was not put on sufficient notice at the time that Plaintiffs intended to seek relief on a class-wide basis. *See McClelland v. Deluxe Fin. Servs.*,

1 *Inc.*, 431 F. App'x 718, 731 (10th Cir. 2011); *Corns v. Laborers Int'l Union of N. Am.*, No. 09-
 2 CV-4403 YGR, 2014 WL 1319363, at *5 (N.D. Cal. Mar. 31, 2014) (finding the notice
 3 requirement unmet where the original complaint did not give "clear notice" of plaintiff's intent to
 4 allege and certify a class); *Perry v. Beneficial Finance Co. of N.Y.*, 81 F.R.D. 490, 495
 5 (W.D.N.Y. 1979) (amended complaint adding class claims did not relate back to initial
 6 individual complaint). Nonetheless, per the agreement between the parties and for discovery
 7 purposes only, BCBSIL will conduct and produce discovery from November 23, 2016 to the
 8 present.

9 10. BCBSIL incorporates by reference these "General Objections" into each of the
 10 Specific Responses and Objections set forth below, as if fully set forth therein

11 **B. OBJECTIONS TO INSTRUCTIONS**

12 1. BCBSIL objects to Instruction One because it purports to require BCBSIL to
 13 provide documents or information outside of its own possession, custody or control. BCBSIL will
 14 interpret these Requests to require BCBSIL to draw upon the information reasonably ascertainable
 15 to it, in accordance with the Federal Rules of Civil Procedure.

16 2. BCBSIL objects to Instruction Two because it purports to require BCBSIL to
 17 provide documents or information outside of its own possession, custody or control. BCBSIL will
 18 interpret these Requests to require BCBSIL to draw upon the information reasonably ascertainable
 19 to it, in accordance with the Federal Rules of Civil Procedure.

20 **C. OBJECTIONS TO DEFINITIONS**

21 1. BCBSIL objects to the terms "Defendant," "you" or "your," as overly broad and as
 22 calling for information outside of its own possession, custody, or control. BCBSIL also objects
 23 that these terms as defined seek information protected by the attorney-client privilege, work
 24 product doctrine, or any other applicable privilege or protection.

25 2. BCBSIL further objects that the term "Plan," as defined, fails to identify a specific
 26 policy year. BCBSIL interprets this term to mean the Summary Plan Description, with an effective
 27

1 date of January 1, 2019, attached as Appendix A to the Amended Complaint (Doc. 38, the
2 “Complaint”).

3 **D. REQUESTS FOR ADMISSION**

4 **REQUEST FOR ADMISSION NO. 1:** Admit that there are at least 40 persons who
5 fit the class definition found at paragraph 91 of the Amended Complaint (Dkt. No. 38).

6 **INITIAL ANSWER:** BCBSIL objects to this Interrogatory in that the class definition is
7 vague, ambiguous and not easily ascertainable. BCBSIL is still investigating this request and will
8 supplement this response upon completion of the investigation.

9 **SUPPLEMENTAL ANSWER:** BCBSIL objects that the class definition found at
10 Paragraph 91 of the Amended Complaint is vague, ambiguous, and not easily ascertainable.
11 BCBSIL specifically objects that the proposed class definition hypothetically includes all
12 individuals who “will be participants” and who “will be denied pre-authorization of coverage.”

13 Notwithstanding the foregoing objections, BCBSIL admits that there are at least 40 persons
14 who may fit the class definition found at paragraph 91 of the Amended Complaint.

15 **E. INTERROGATORIES**

16 **INTERROGATORY NO. 6:** Please identify any other plans for which BCBSIL
17 administers a gender-affirming care exclusion.

18 **INITIAL ANSWER:** BCBSIL objects to this Interrogatory as overly broad, unduly
19 burdensome, and not reasonably calculated to lead to the discovery of admissible evidence in
20 seeking “any other plans” for which BCBSIL administers a “gender-affirming care exclusion,”
21 without regard to the materiality of such plans to the fact as issue in this lawsuit as alleged in the
22 Complaint.
23

24 Notwithstanding the foregoing objections, BCBSIL states that it will produce responsive
25 Documents sufficient to show the relevant language and number of ERISA self-funded group
26 health plans pursuant to Rule 33(d) of the Federal Rules of Civil Procedure.

27 **SUPPLEMENTAL ANSWER:** BCBSIL objects to this Interrogatory as overly broad,

1 unduly burdensome, and not reasonably calculated to lead to the discovery of admissible evidence
 2 in seeking “any other plans” for which BCBSIL administers a “gender-affirming care exclusion,”
 3 without regard to the materiality of such plans to the fact as issue in this lawsuit as alleged in the
 4 Complaint.

5 Notwithstanding the foregoing objections, BCBSIL preliminarily states that there are 398
 6 ERISA self-funded group health plans for which BCBSIL administers a gender-affirming care
 7 exclusion. Discovery is ongoing.

8 SECOND SUPPLEMENTAL ANSWER: *See* revised Addendum A.

9 THIRD SUPPLEMENTAL ANSWER: BCBSIL incorporates by references its prior and
 10 supplemental responses to Interrogatory No. 6. BCBSIL further states that of the 398 ERISA self-
 11 funded group health plans for which BCBSIL administers a gender-affirming care exclusion, some
 12 employers who offer a plan containing a gender-affirming care exclusion offer one or more plans
 13 in the same year that do not contain a gender-affirming care exclusion. *See, e.g.,*
 14 BCBSIL_CP_0020053-BCBSIL_CP_0020593.

15
 16 **INTERROGATORY NO. 7: Please identify the total population of enrollees, by year,**
 17 **in the CHI Plan and each of the plans identified in the responses to Interrogatories Nos. 3**
 18 **and 6.**

19 INITIAL ANSWER: BCBSIL incorporates by reference its responses and objections to
 20 Interrogatory Nos. 3 and 6. Notwithstanding the foregoing objections, BCBSIL states that it will
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1 meet and confer with Plaintiffs regarding the relevance of this request to the allegations in the
2 complaint.

3 SUPPLEMENTAL ANSWER: BCBSIL states that the average number of enrollees in the
4 CHI Medical Plan is as follows:

5	January 2016-December 2016	35,802
6	January 2017-December 2017	34,437
7	January 2018-December 2018	34,224
8	January 2019-December 2019	34,883
9	January 2020-December 2020	37,641
10	January 2021-December 2021	37,222

11 *See* BCBSIL_CP_0010824.

12
13 **INTERROGATORY NO. 8:** Please identify the total number of unique enrollees in
14 each plan administered by BCBSIL that contains a gender-affirming care exclusion as
15 identified in response to Interrogatory No. 6, or an exclusion that is the same or similar to
16 the Transgender Reassignment Surgery exclusion as identified in response to Interrogatory
17 No. 3, who have received a denial based on such exclusion from BCBSIL at any time since
18 November 23, 2014.

19 INITIAL ANSWER: BCBSIL incorporates by reference its responses and objections to
20 Interrogatory Nos. 3 and 6. BCBSIL further objects to the term “same or similar” as vague and
21 ambiguous. BCBSIL also objects to the time frame set forth in this Interrogatory as seeking
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1 irrelevant information beyond the applicable statute of limitations. For the reasons stated above,
 2 BCBSIL will conduct and produce discovery from November 23, 2016 to the present.

3 Notwithstanding the foregoing objections, BCBSIL states that it will produce responsive
 4 Documents sufficient to show the requested information from November 23, 2016 to the present,
 5 to the degree it exists.

6 SUPPLEMENTAL ANSWER: BCBSIL incorporates by reference its responses and
 7 objections to Interrogatory Nos. 3 and 6. BCBSIL further objects to the term “same or similar” as
 8 vague and ambiguous. BCBSIL also objects to the time frame set forth in this Interrogatory as
 9 seeking irrelevant information beyond the applicable statute of limitations. For the reasons stated
 10 above, BCBSIL will conduct and produce discovery from November 23, 2016 to the present.

11 Notwithstanding the foregoing objections, BCBSIL preliminarily states that of the ERISA
 12 self-funded group health plans BCBSIL administers, there are approximately 505 unique members
 13 of 200 plans who have received a denial based on such an exclusion, for a total claim count of
 14 1,952 claims and a total billed charges amount of \$1,326,779.00. BCBSIL reasonably anticipates
 15 that these numbers are overinclusive. Discovery is ongoing, and BCBSIL will supplement these
 16 preliminary numbers as its internal review and investigation proceeds.

17
 18 **INTERROGATORY NO. 9:** For each of the plans identified in response to
 19 Interrogatories Nos. 3 and 6, please identify all individuals who participated in any way in
 20 the creation, drafting and/or preparation of the Benefit Program Application provision on
 21 coverage of treatment for gender dysphoria and/or the gender-affirming care exclusion,
 22 whether employed by BCBSIL or another entity.

23 **ANSWER:** BCBSIL incorporates by reference its responses and objections to
 24 Interrogatory Nos. 3 and 6. BCBSIL objects that the terms “creation” and “preparation” are vague
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1 and ambiguous. Notwithstanding the foregoing objections, BCBSIL states that it will meet and
2 confer with Plaintiffs regarding the relevance of this request to the allegations in the complaint.

3
4 **INTERROGATORY NO. 10:** To the extent that BCBSIL's response to Request for
5 Admission No. 1 is not a complete admission, please identify the complete factual bases for
6 BCBSIL's denial, either in whole or in part, including the source of the factual bases for the
7 denial.

8 ANSWER: BCBSIL has admitted Request for Admission No. 1.

9 **F. REQUESTS FOR PRODUCTION**

10 **REQUEST FOR PRODUCTION NO. 12:** All contracts, Benefit Program
11 Applications or other kinds of applications or agreements between BCBSIL and any other
12 entity, including the self-funded plans and/or the self-funded plans' sponsors, pertaining to
13 the plans identified in response to Interrogatories Nos. 3 and 6 in effect as of January 1, 2014,
14 up to and including the present.

15 INITIAL RESPONSE: BCBSIL incorporates by reference its responses and objections to
16 Interrogatory Nos. 3 and 6. BCBSIL objects to this Request as unduly burdensome and not
17 reasonably calculated to lead to the discovery of admissible evidence in seeking "all contracts,
18 Benefit Program Applications or other kinds of applications or agreements" between BCBSIL and
19 "any other entity," without regard to the materiality of such documents to the facts at issue in this
20 lawsuit. For example, this Request as drafted could encompass agreements between BCBSIL and
21 a whole number of third parties that have nothing to do with coverage for any beneficiaries.
22 BCBSIL further objects to the time frame set forth in this Request as seeking irrelevant information
23 beyond the applicable statute of limitations.

24 Notwithstanding the foregoing objections, BCBSIL states that it will meet and confer with
25 Plaintiffs regarding the relevance of this request to the allegations in the complaint.

26 SUPPLEMENTAL RESPONSE: BCBSIL has produced its Administrative Services
27 Agreement, *see* BCBSIL_CP_0003912. BCBSIL has also produced a number of responsive

Benefit Program Applications from 2013-2021, *see, e.g.*, BCBSIL_CP_0008556; BCBSIL_CP_0010652; BCBSIL_CP_0011135; BCBSIL_CP_0011147; BCBSIL_CP_0008567; BCBSIL_CP_0010664; BCBSIL_CP_0008419; BCBSIL_CP_0010632; and BCBSIL_CP_0010621.

REQUEST FOR PRODUCTION NO. 13: All documents, emails, and other communications relating to covering or excluding treatment related to gender dysphoria and/or a gender-affirming care exclusion with regards to any plan identified in response to Interrogatories Nos. 3 and 6, including but not limited to, treatment with puberty blockers, hormone treatment, and/or surgery.

RESPONSE: BCBSIL incorporates by reference its responses and objections to Interrogatory Nos. 3 and 6. BCBSIL also objects to this Interrogatory to the extent it seeks information protected by the attorney-client privilege, the work product doctrine, and/or other applicable privileges. BCBSIL further objects to this Request as unduly burdensome and not reasonably calculated to lead to the discovery of admissible evidence in seeking “all documents, emails, and other communications” without regard to the materiality of such documents to the facts at issue in this lawsuit. For example, this Request as drafted could encompass documents, emails, and communications related to the plans identified in response to Interrogatory Nos. 3 and 6 but which do not directly concern treatment for gender dysphoria and/or a gender-affirming care exclusion.

Notwithstanding the foregoing objections, BCBSIL states that it will meet and confer with Plaintiffs regarding the relevance of this request to the allegations in the complaint.

REQUEST FOR PRODUCTION NO. 14: To the extent not already provided, please produce all copies of the “Benefit Program Application” submitted to BCBSIL in relation to

any plan identified in response to Interrogatories No. 3 and 6, at any time since January 1, 2014.

RESPONSE: BCBSIL incorporates by reference its responses and objections to Interrogatory Nos. 3 and 6. BCBSIL further objects to the time frame set forth in this Request as seeking irrelevant information beyond the applicable statute of limitations.

Notwithstanding the foregoing objections, BCBSIL states that it will meet and confer with Plaintiffs regarding the relevance of this request to the allegations in the complaint.

REQUEST FOR PRODUCTION NO. 15: To the extent not already provided, please produce all documents relating to any plan identified in response to Interrogatories Nos. 3 and 6 which reflect any determination that BCBSIL could administer such plan in a manner that did not and/or does not comply with the Affordable Care Act's Section 1557, 42 U.S.C. § 18116.

RESPONSE: BCBSIL incorporates by reference its responses and objections to Interrogatory Nos. 3 and 6. BCBSIL also objects to this Request to the extent it implicates attorney-client privilege, work-product privilege, or any other applicable privileges or protections.

BCBSIL incorporates by reference its responses and objections to Interrogatory Nos. 3 and 6. Notwithstanding the foregoing objections, BCBSIL states that it will meet and confer with Plaintiffs regarding the relevance of this request to the allegations in the complaint.

DATED this 29th day of July, 2022.

KILPATRICK TOWNSEND & STOCKTON LLP

By /s/ Gwendolyn C. Payton
Gwendolyn C. Payton, WSBA No. 26752
gpayton@kilpatricktownsend.com
1420 Fifth Ave., Suite 3700
Seattle, WA 98101
Telephone: (206) 626-7714
Facsimile: (206) 623-6793

Counsel for Defendant Health Care Service

*Corporation, a Mutual Legal Reserve
Company, doing business in Illinois as Blue
Cross and Blue Shield of Illinois*

CERTIFICATE OF SERVICE

I certify that on the date indicated below I caused a copy of the foregoing document, FIFTH SUPPLEMENTAL RESPONSES AND OBJECTIONS TO PLAINTIFFS' SECOND DISCOVERY REQUESTS TO DEFENDANT BLUE CROSS AND BLUE SHIELD OF ILLINOIS has been sent via e-mail to the following attorneys of record:

Eleanor Hamburger
SIRIANNI YOUTZ SPOONEMORE HAMBURGER
3101 WESTERN AVENUE STE 350
SEATTLE, WA 98121
206-223-0303
Fax: 206-223-0246
Email: ehamburger@sylaw.com

Jennifer C Pizer
LAMBDA LEGAL DEFENSE AND EDUCATION FUND, INC.
4221 WILSHIRE BLVD., STE 280
LOS ANGELES, CA 90010
213-382-7600
Email: jpizer@lambdalegal.org

Omar Gonzalez-Pagan
LAMBDA LEGAL DEFENSE AND EDUCATION FUND, INC. (NY)
120 WALL STREET
19TH FLOOR
NEW YORK, NY 10005
212-809-8585
Email: ogonzalez-pagan@lambdalegal.org

DATED this 29th day of July, 2022.

Kilpatrick, Townsend & Stockton LLP

By: /s/ Gwendolyn C. Payton
Gwendolyn C. Payton, WSBA #26752
gpayton@kilpatricktownsend.com

*Counsel for Defendant Health Care Service
Corporation, a Mutual Legal Reserve
Company, doing business in Illinois as Blue
Cross and Blue Shield of Illinois*

ADDENDUM A

Effective Date	Exclusion/Limitation Language
1/01/2017	["Exclusions - What is Not Covered"] "Gender reassignment Surgery (also referred to as transsexual Surgery, sex reassignment Surgery or intersex Surgery), including related services and supplies."
1/1/2019	["Exclusions"] "This Plan does not cover services, supplies or treatment relating to, arising out of, or given in connection with the following: . . . Treatment or services, except for the initial diagnosis, for a primary diagnosis of Mental Retardation, Learning, Motor Skills and Communication Disorders, Conduct Disorder, Dementia, Sexual, Paraphilia and Gender Dysphoria, and Personality Disorders, as well as other mental illnesses that will not substantially improve beyond the current level of functioning, or that are not subject to modification or management according to prevailing national standards of clinical practice, as reasonably determined by Blue Cross and Blue Shield of Illinois." ["Short Term Disability Benefits"] "This Plan will not cover any disability . . . a gender change, including, but not limited to, any operation, drug therapy or any other procedure related to a gender change." ["Long Term Disability Benefits"] "This Plan will not cover any disability: . . . a gender change, including, but not limited to, any operation, drug therapy or any other procedure related to a gender change."
1/01/2020	[GENDER REASSIGNMENT SURGERY] Benefits will be provided for Covered Services for gender reassignment the same as any other for persons 18 and older. Benefits for gender reassignment Surgery will be limited to a lifetime maximum of \$75, 000. Gender reassignment Surgery will be provided when all of the following criteria are met: 1. The Individual is at least 18 years of age; 2. The individual has been diagnosed with the Gender Identity Disorder (GID) of transsexualism; 3. The individual has undergone a minimum of 12 months of continuous hormonal therapy when recommended by a mental health professional and such therapy is provided under the supervision of a Physician; 4. The individual has completed a minimum of 12 months of successful continuous full time real-life experience in their new gender, with no returning to their original gender; 5. A letter from the individual's physician and mental health provider, who has treated the individual for a minimum of 18 months, documenting the treatment and that the treatment is Medically Necessary. Coverage will also be provided for cosmetic Surgery. The following surgeries

are considered cosmetic and will be covered for an individual who has undergone or is planning to undergo gender reassignment Surgery:

1. Reduction thyroid chondroplasty;
2. Liposuction;
3. Rhinoplasty;
4. Facial bone reconstruction;
5. Face lift;
6. Blepharoplasty;
7. Voice modification surgery;
8. Hair removal/hairplasty; and/or
9. Breast augmentation.

However, no benefits will be provided for transportation or lodging expenses or for any reversal of gender reassignment Surgery.

[EXCLUSIONS – WHAT IS NOT COVERED]

- Transportation and lodging expenses for gender reassignment Surgery
- Reversal of gender reassignment surgery.

1/1/2016	["What is Not Covered by the Medical Plan"] "Transsexual surgery or any treatment of gender identity disorders."
1/1/2013	[Gender Reassignment Surgery] "Benefit is provided to associates only. All of the following criteria must be met: - Associate is at least 18 years old; - Associate has met criteria for the diagnosis of "true" transsexualism, including: - A sense of estrangement from one's own body, so that any evidence of one's own biological sex is regarded as repugnant;- A stable transsexual orientation evidenced by a desire to be rid of one's genitals and to live in society as a member of the other sex for at least 2 years, that is, not limited to periods of stress; - Absence of physical inter-sex of genetic abnormality; - Does not gain sexual arousal from cross-dressing; - Life-long sense of belonging to the opposite sex and of having been born into the wrong sex, often since childhood; - Not due to another biological, chromosomal or associated psychiatric disorder, such as schizophrenia; - Wishes to make his or her body as congruent as possible with the preferred sex through surgery and hormone treatment; and - Associate has completed a recognized program of transgender identity treatment as evidenced by all of the following: - A qualified mental health professional*who has been acquainted with the member for at least 18 months recommends sex reassignment surgery documented in the form of a written comprehensive evaluation; - For genital surgical sex reassignment, a second concurring recommendation by another qualified mental health professional * must be documented in the form of a written expert opinion**;

1 -For genital surgical sex reassignment, member has undergone a urological
 2 examination for the purpose of identifying and perhaps treating abnormalities of
 3 the genitourinary tract, since genital surgical sex reassignment includes the
 4 invasion of, and the alteration of, the genitourinary tract (urological examination
 5 is not required for persons not undergoing genital reassignment);
 6 - Associate has demonstrated an understanding of the proposed male-to-female
 7 or female-to-male sex reassignment surgery with its attendant costs, required
 8 lengths of hospitalization, likely complications, and post-surgical rehabilitation
 9 requirements of the planned surgery; - Psychotherapy is not an absolute
 10 requirement for surgery unless the mental health professional's initial assessment
 11 leads to a recommendation for psychotherapy that specifies the goals of
 12 treatment, estimates its frequency and duration throughout the real life
 13 experience (usually a minimum of 3 months);
 14 - The associate has successfully lived and worked within the desired gender role
 15 full-time for at least 12 months(so-called real-life experience), without periods
 16 of returning to the original gender; and
 17 - Unless medically contraindicated, associate has received at least 12 months of
 18 continuous hormonal sex reassignment therapy recommended by a mental health
 19 professional and carried out by an endocrinologist (which can be simultaneous
 20 with the real-life experience)."

21 "At least one of the two clinical behavioral scientists making the favorable
 22 recommendation for surgical (genital) sex reassignment must possess a doctoral
 23 degree (e.g., Ph.D., Ed.D., D.Sc., D.S.W., Psy.D., or M.D.).

24 Note: Evaluation of candidacy for sex reassignment surgery by a mental health
 25 professional is covered under the member's medical benefit, unless the services
 26 of a mental health professional are necessary to evaluate and treat a mental
 27 health problem, in which case the mental health professional's services are
 covered under the associate's behavioral health benefit. Please check benefit
 plan descriptions."

**Either two separate letters or one letter with two signatures is acceptable.

"Notes:

(1) Medically necessary core surgical procedures for female to male persons
 include: mastectomy, hysterectomy, vaginectomy, salpingo-oophorectomy,
 metoidioplasty, phalloplasty, urethroplasty, scrotoplasty and placement of
 testicular prostheses, and erectile prostheses.

(2) Medically necessary core surgical procedure for male to female persons
 include: penectomy, orchidectomy, vaginoplasty, clitoroplasty, and labiaplasty.

(3) Rhinoplasty ,face-lifting, lip enhancement, facial bone reduction,
 blepharoplasty, breast augmentation, liposuction of the waist (body contouring),
 reduction thyroid chondroplasty, hair"

"Gender Reassignment Surgery- Travel & Lodging Gender reassignment surgery

	is performed at limited locations in the United States, and most patients will need to travel outside their immediate home area. If travel is required for surgery because it is not offered in your immediate home area, travel to an in-network surgery provider and lodging expenses will be reimbursed up to a maximum of \$10,000. To be eligible for reimbursement: - Travel must be over 100 miles away from your home and must be by air, rail, bus or car. The \$10,000 covers you and one caretaker to travel with you for in-network surgery only. - You are only allowed to travel in-network within the 48 contiguous United States. - Lodging expenses include hotel or motel room, car rental, tips and cost of meals while you are not hospitalized and for your caretaker. - Itemized receipts will be required.”
1/1/2015	[Schedule of Benefits Gender Reassignment Surgery] LIFETIME MAXIMUM OF \$75,000 PPO 85% after deductible 60% of eligible charges after deductible HRA 85% after deductible 60% of eligible charges after deductible HSA 85% after deductible 60% of eligible charges after deductible. Gender reassignment surgery benefits will be provided for covered services rendered to persons age 18 and over. Conditions for coverage apply: •The individual is at least 18 years of age• The individual has been diagnosed with the gender identity disorder (GID) of trans-sexualism •The individual has undergone a minimum of 12 months of continuous hormonal therapy when recommended by a mental health professional and provided under the supervision of a physician •The individual has completed a minimum of 12 months of successful continuous full time real-life experience in their new gender, with no returning to their original gender •A letter from the individual’s physician or mental health provider documenting treatments and medical necessity [Exclusions] Benefits for gender reassignment surgery exclude transportation and lodging expenses, reversals, and surgeries that are considered to be cosmetic. The following surgeries are considered cosmetic and will not be covered for an individual who has undergone or is planning to undergo gender reassignment surgery: reduction thyroid, chondroplasty, liposuction, rhinoplasty, facial bone reconstruction, face lift, blepharoplasty, voice modification surgery, hair removal/hairplasty and breast augmentation. [STD Exclusions] Cosmetic surgery (defined as procedures or services that change or improve appearance without significantly improving physiological function) except for reconstructive surgery or gender reassignment surgery and the subsequent cosmetic surgery to enhance the transformation, as determined by Leave Administration and the medical plan.

1	6/1/2021	["Exclusions - What is Not Covered"] "Gender reassignment Surgery (also referred to as transsexual Surgery, sex reassignment Surgery or intersex Surgery), including related services and supplies." ["Exclusions - What is Not Covered"] Transgender Coverage"
2	1/1/2022	["Other Covered Services"] Gender reassignment—Benefits will be provided for services and supplies related to gender reassignment but excluding surgery.
3	1/1/2019	["Other Plan Exclusions and Limitations"] "Services related to gender reassignment"
4	1/1/2016	["Gender Reassignment Surgery"] "Benefits will be provided for the gender reassignment surgery for persons age 18 and over with a Gender Identity Disorder, undergone a minimum of 12 months of continuous hormonal therapy when recommended by a mental health professional and provided under the supervision of a physician. Benefits for gender reassignment will be limited to a lifetime maximum of \$75,000." Gender Reassignment Surgery is covered; with the exception of the following: - Transportation and lodging expenses relating to gender reassignment surgery; - Reversals of gender reassignment Surgery.
5	1/1/2015	["Participating Provider"] "When you receive Covered Services for gender reassignment Surgery (also referred to as transsexual Surgery, sex reassignment Surgery or intersex Surgery) and counseling and related services and supplies, from a Participating Provider, benefits will be provided at 90% of the Maximum Allowance or 90% of the Eligible Charge after you have met your program deductible. However, benefits for gender reassignment Surgery, including counseling, related services and supplies, are subject to a lifetime maximum of \$75,000." ["Non-Participating Provider"] "When you receive Covered Services for gender reassignment Surgery (also referred to as transsexual Surgery, sex reassignment Surgery or intersex Surgery) and counseling and related services and supplies, from a Non- Participating Provider, benefits will be provided at 70% of the Maximum Allowance or 70% of the Eligible Charge after you have met your program deductible. However, benefits for gender reassignment Surgery, including counseling, related services and supplies, are subject to a lifetime maximum of \$75,000."

1		[EXCLUSIONS – WHAT IS NOT COVERED]
2		"Reversal of gender reassignment surgery (also referred to as transsexual
3		Surgery, sex reassignment Surgery or intersex Surgery), including related
4	1/1/2014	services and supplies."
5		["Participating Provider"]
6		"When you receive Covered Services for gender reassignment Surgery (also
7		referred to as transsexual Surgery, sex reassignment Surgery or intersex Surgery)
8		and counseling and related services and supplies, from a Participating Provider,
9		benefits will be provided at 80% of the Maximum Allowance or 80% of the
10		Eligible Charge after you have met your program deductible.
11		However, benefits for gender reassignment Surgery, including counseling,
12		related services and supplies, are subject to a lifetime maximum of \$75,000."
13		["Non-Participating Provider"]
14		"When you receive Covered Services for gender reassignment Surgery (also
15		referred to as transsexual Surgery, sex reassignment Surgery or intersex Surgery)
16		and counseling and related services and supplies, from a Non- Participating
17		Provider, benefits will be provided at 60% of the Maximum Allowance or 60%
18		of the Eligible Charge after you have met your program deductible.
19		However, benefits for gender reassignment Surgery, including counseling,
20		related services and supplies, are subject to a lifetime maximum of \$75,000."
21		["Exclusions - What is Not Covered"]
22		"Reversal of gender reassignment Surgery (also referred to as transsexual
23		Surgery, sex reassignment Surgery or intersex Surgery), including related
24		services and supplies."
25	1/1/2014	["Participating Provider"]
26		"When you receive Covered Services for gender reassignment Surgery (also
27		referred to as transsexual Surgery, sex reassignment Surgery or intersex Surgery)
		and counseling and related services and supplies, from a Participating Provider,
		benefits will be provided at 100% of the Maximum Allowance or 100% of the
		Eligible Charge after you have met your program deductible.
		However, benefits for gender reassignment Surgery, including counseling,
		related services and supplies, are subject to a lifetime maximum of \$75,000."
		["Non-Participating Provider"]
		"When you receive Covered Services for gender reassignment Surgery (also
		referred to as transsexual Surgery, sex reassignment Surgery or intersex Surgery)
		and counseling and related services and supplies, from a Non- Participating
		Provider, benefits will be provided at 70% of the Maximum Allowance or 70%
		of the Eligible Charge after you have met your program deductible.

1		However, benefits for gender reassignment Surgery, including counseling, related services and supplies, are subject to a lifetime maximum of \$75,000."
2		
3		["Exclusions - What is Not Covered"]
4		"Reversal of gender reassignment Surgery (also referred to as transsexual Surgery, sex reassignment Surgery or intersex Surgery), including related services and supplies."
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6	1/1/2018	[EXCLUSIONS – WHAT IS NOT COVERED]
7		"Reversal of gender reassignment surgery (also referred to as transsexual Surgery, sex reassignment Surgery or intersex Surgery), including related services and supplies."
8	1/1/2016	The following exclusions apply generally to all services, drugs and supplies for BCBSIL and CVS Caremark. Specific limitations and exclusions related to certain types of care also appear in the Schedule of Benefits. Please refer to the Schedule of Benefits for specific coverage, limitations and exclusions.
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10		***
11		10. Charges for sex transformation surgery, hormones related to the surgery, and any related expenses.
12		
13	1/1/2022	[Gender Reassignment Surgery]
14		"Benefits will be provided for gender reassignment surgery for persons age 18 and over with gender dysphoria, Gender dysphoria (formerly known as ‘gender identity disorder’) is a condition recognized by the Diagnostic and Statistical Manual (DSM) of Mental Disorders and commonly known as transsexualism. The diagnostic criteria describe many individuals who experience dissonance between their sex at birth and personal gender identity, which is not the same as having ambiguous genitalia. Gender reassignment surgery-- also known as transsexual surgery or sex reassignment surgery-- and related services may be considered medically necessary when meeting the criteria for gender dysphoria listed below. Otherwise, gender reassignment surgery and related services will be considered not medically necessary. Benefits for gender reassignment surgery will be unlimited. Benefits for gender reassignment surgery are the same as benefits for any other condition. Benefits will be provided for Covered services rendered to persons age 18 and over. Criteria for Coverage of Gender Reassignment Surgery and Related Services: The individual being considered for surgery and related services must meet ALL the following criteria. The individual must have: Reached the age of majority- at least 18 years of age AND The capacity to make a fully informed decision and to consent for treatment; AND Been diagnosed with persistent, well-documented gender dysphoria, AND Undergone a minimum of 12 months of continuous hormonal therapy when recommended by a mental health professional and provided under the supervision of a physician. Completed a minimum of 12 months of successful continuous full time real-life experience in their new gender, with no returning
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	to their original gender. A letter from the individual's physician or mental health provider documenting treatments and medical necessity. Has the required referrals prior to any surgery or related service(s): o Prior to feminizing or masculinizing hormonal therapy, one required referral from the individual's qualified mental health professionals competent in the assessment and treatment of gender dysphoria; and/or o Prior to breast/chest surgery, e.g., mastectomy, chest reconstruction, or breast augmentation, one required referral from the individual's qualified mental health professionals competent in the assessment and treatment of gender dysphoria; and/or o Prior to any genital surgery, e.g., hysterectomy, salpingoophorectomy, orchiectomy, and/or other genital reconstructive procedures, two separate required independent referrals (or one signed by both referring providers) from the individual's qualified mental health professionals competent in the assessment, treatment of gender dysphoria, and addressing the identical/same surgery to be performed. Gender Reassignment Surgeries and Related Services: Procedures or services to create and maintain gender specific characteristics (masculinization or feminization) as part of the overall desired gender reassignment services treatment plan may be considered medically necessary for the treatment of gender dysphoria ONLY. These procedures may include the following: Abdominoplasty; • Blepharoplasty; • Brow lift; • Calf implants; • Cheek implants; • Chin or nose implants; • External penile prosthesis (vacuum erection devices); • Face lift (rhytidectomy); • Facial bone reconstruction/sculpturing/reduction, includes jaw shortening; • Forehead lift or contouring; • Hair removal (may include donor skin sites) or hair transplantation (electrolysis or hairplasty); • Laryngoplasty; • Lip reduction or lip enhancement; • Liposuction/lipofilling or body contouring or modeling of waist, buttocks, hips, and thighs reduction; • Neck tightening; • Pectoral implants; • Reduction thyroid chondroplasty or trachea shaving (reduction of Adam's apple); • Redundant/excessive skin removal; • Rhinoplasty (nose correction); • Skin resurfacing; Benefits for gender reassignment surgery exclude: Transportation and lodging expenses, Reversals [Not payable under the plan] "Gender Reassignment Surgery is covered; with the exception of the following: Transportation and lodging expenses relating to gender reassignment surgery; reversals of gender reassignment surgery."
1/1/2016	["Specific Limits, Criteria and Exclusions"] Gender Identity Disorder Treatment Benefit Limits: Network only - 50% \$75,000 per Member Lifetime Maximum Non-Network– 0% Includes psychotherapy, continuous hormone replacement(not oral – see Prescription Drug Details section) (including laboratory testing to monitor safety), Genital Surgery, Surgery to Change Secondary Sex Characteristics.

Excludes:- reversal of genital surgery or reversal of surgery to revise secondary sex characteristics; -sperm preservation in advance of hormone treatment or gender surgery; -cryopreservation of fertilized embryos.

- voice modification surgery; -facial feminization surgery, including but not limited to: facial bone reduction, face “lift”, facial hair removal, and certain facial plastic procedures; -suction-assisted lipoplasty of the waist; -drugs for hair loss or growth;-drugs for sexual performance or Cosmetic purposes (except for hormone therapy described above); -voice therapy; and - transportation, meals, lodging or similar expenses.

Criteria for Coverage of Continuous Hormone Replacement. In order to receive hormones (not oral– see Prescription Drug Section) of the desired gender, the Member must: - have a diagnosed Gender Identity Disorder; - be at least age 18; -demonstrate knowledge of what hormones medically can and cannot do and their social benefits and risks; and -have already had completed:

- a documented real-life experience living as the desired gender of at least three months; and

- a period of psychotherapy of a duration specified by the Mental Health Professional after the initial evaluation (usually a minimum of three months).

Gender Identity Disorder means a disorder characterized by the following diagnostic criteria: -a strong and persistent cross-gender identification (not merely a desire for any perceived cultural advantages of being the other sex); - the member’s persistent discomfort with his or her sex or sense of inappropriateness in the gender role of that sex; -the disturbance is not concurrent with a physical intersex condition; and -the disturbance causes clinically significant distress or impairment in social, occupational, or other important areas of functioning.

Criteria for Coverage of Surgery. In order to receive Genital Surgery or Surgery to Change Secondary Sex Characteristics: -the Member must have a diagnosed Gender Identity Disorder;-the Surgery must be performed by a Provider at a Hospital or Alternate Facility with a history of treating persons with Gender Identity Disorder; - the treatment plan must conform to the World Professional Association for Transgender Health Association (WPATH, an advocacy group) standards; - the Member must be at least age 18 years or older for irreversible surgical interventions; - the Member must complete 12 months of Continuous Hormone Therapy for those without contraindications; and - the Member must complete 12 months of successful continuous full time real life experience in the desired gender.

Genital Surgery means one of the following: complete hysterectomy, orchiectomy, penectomy, vaginoplasty, vaginectomy, clitoroplasty, labiaplasty, salpingo-oophorectomy, metoidioplasty, scrotoplasty, urethroplasty, placement of testicular prosthesis, phalloplasty.

1/1/2013	“Gender reassignment surgery – Benefits will be provided for gender reassignment Surgery for persons diagnosed with a Gender Identity Disorder and will be limited to a lifetime maximum of \$75,000.” "Gender reassignment Surgery is covered; with the exception of the following: ffl Transportation and lodging expenses relating to gender reassignment Surgery; ffl Reversals of gender reassignment Surgery; ffl Surgeries which a reconsidered to be cosmetic including, but not limited to, reduction thyroid chondroplasty, liposuction, rhinoplasty, facial bone reconstruction, face lift, blepharoplasty, voice modification Surgery, hair removal/hairsplasty, and breast augmentation."
1/1/2013	["Exclusions - What is not covered"] "Gender reassignment Surgery (also referred to as transsexual Surgery, sex reassignment Surgery or intersex Surgery), including related services and supplies. This exclusion includes medications, implants, hormone therapy, surgery, medical or psychiatric treatment."

EXHIBIT J

HONORABLE JUDGE ROBERT J. BRYAN

**IN THE UNITED STATES DISTRICT COURT
FOR THE WESTERN DISTRICT OF WASHINGTON
AT TACOMA**

C. P., by and through his parents,
Patricia Pritchard and Nolle Pritchard;
and PATRICIA PRITCHARD,

Plaintiff,

vs.

BLUE CROSS BLUE SHIELD OF
ILLINOIS,

Defendants.

Case No. 3:20-cv-06145-RJB

DECLARATION OF LAWTON R. BURNS

I. Expert Witness Background & Qualifications

1. My name is Lawton R. Burns. I am the James Joo-Jin Kim Professor at the Wharton School of the University of Pennsylvania, where I am a Professor in the Departments of Health Care Management and Management. For seven years (2007–2014), I also served as the Chair of the Health Care Management Department. Currently, I am the Co-Director of the Roy and Diana Vagelos Program in Life Sciences and Management at the University of Pennsylvania. I have taught at Wharton since 1994. Prior to Wharton, I taught in the health administration programs of two other business schools: the Graduate School of Business at the University of Chicago and the College of Business and Public Administration at the University

DECLARATION OF LAWTON R. BURNS - 1

KILPATRICK TOWNSEND & STOCKTON LLP
1420 FIFTH AVENUE, SUITE 3700
SEATTLE, WA 98101
(206) 626-7713 FAX: (206) 260-8946

KILPATRICK TOWNSEND 76135937 2

1 of Arizona. I have also taught in the healthcare management programs at the Indian School of
2 Business in Hyderabad and the Guanghua School of Management at Peking University.

3 2. At Wharton, I teach the first-year course, “Introduction to the U.S. Health Care
4 System” to graduate students. The course covers the entire value chain of health care, including
5 hospital/physician providers, managed care organizations and insurers who contract with and
6 reimburse providers for their services, and employers, individuals, and governmental bodies who
7 ultimately pay for those services. I have taught this course at Wharton in the daytime MBA
8 program for over twenty years. I have also taught the same course to the weekend MBA program
9 on both the East and West coast campuses for over a decade. I have taught various versions of
10 this course at each of the Universities I have worked at since 1981.

11 3. Between 1998 and 2013, I also taught a graduate business elective course on
12 “Managed Care and the Industrial Organization of Healthcare.” I resumed teaching this course
13 in 2017. The course covers (a) the horizontal integration of physicians, hospitals, and insurers;
14 and (b) the vertical integration between physicians, hospitals, and insurers. The course also
15 covers the contractual and bargaining relationships between physicians, hospitals, and insurers—
16 and the strategies those three parties have undertaken to align with and/or negotiate with one
17 another. I taught an earlier, but parallel version of this course between 1998–2002 to physicians
18 pursuing a masters’ degree in the Administrative Medicine Program at the University of
19 Wisconsin School of Medicine.

20 4. I have testified on these and related topics (*e.g.*, economic and clinical integration)
21 to the Federal Trade Commission (FTC) on several occasions and have served as an expert
22 witness for both the FTC and the Department of Justice (DOJ) on issues concerning horizontal
23 integration, vertical integration, and payer-provider contracting. Most of these cases involved
24 horizontal mergers of physician practices and vertical integration of physicians with hospital
25 systems. In all of these cases, I opined on whether there was sufficient economic and/or clinical
26 integration benefits to potentially offset the consumer welfare loss from consolidation and
27

DECLARATION OF LAWTON R. BURNS - 2

KILPATRICK TOWNSEND & STOCKTON LLP
1420 FIFTH AVENUE, SUITE 3700
SEATTLE, WA 98101
(206) 626-7713 FAX: (206) 260-8946

KILPATRICK TOWNSEND 76135937 2

1 reduced competition. A list of cases in which I have testified at trial or deposition during the
2 past four years is attached as Appendix 1.

3 5. I received my Ph.D. in organizational sociology (in 1981) and my Masters in
4 Business Administration in hospital administration (in 1984), both from the University of
5 Chicago. During my MBA training, I interned with the Hospital Corporation of America
6 (“HCA”), the largest for-profit chain of hospitals in the US. I also completed a one-year
7 residency with Jackson Park Hospital in Chicago. For both institutions, I served as the Assistant
8 to the Administrator. I have spent my career since that time seeking to use (a) the theory and
9 research of management, corporate strategy, and industrial organization to (b) analyze healthcare
10 delivery and (c) improve observed patterns of physician and hospital behavior that serve to
11 decrease costs while maintaining or improving quality.

12 6. Throughout my career, I have focused much of my research on the hospital
13 industry and the medical profession. Earlier research examined:

- 14 • hospital-sponsored primary care
- 15 • physicians’ use of hospitals (*e.g.*, admitting patterns and loyalty)
- 16 • historical transformation of the hospital from a philanthropic to a business base
- 17 • hospital adoption of reengineering
- 18 • medical group practices
- 19 • medical staff organization
- 20 • physician-hospital relationships and conflicts
- 21 • physician-hospital alignment
- 22 • physician-hospital alliances (*e.g.*, PHOs, MSOs, IPAs, etc.)
- 23 • integrated delivery networks (IDNs)
- 24 • hospital supply of community benefits
- 25 • hospital performance (*e.g.*, operating costs, profitability)
- 26 • formation of hospital systems
- 27 • hospital mergers
- hospital bankruptcies
- hospital competition
- hospital-managed care bargaining
- capitated contracting between hospitals and health plans
- hospital ownership conversions, and
- alternative delivery systems (non-hospital based).

DECLARATION OF LAWTON R. BURNS - 3

KILPATRICK TOWNSEND & STOCKTON LLP
1420 FIFTH AVENUE, SUITE 3700
SEATTLE, WA 98101
(206) 626-7713 FAX: (206) 260-8946

KILPATRICK TOWNSEND 76135937 2

1 In recognition of this research, the American Hospital Association awarded me the Edwin
 2 Crosby Memorial Fellowship to study physician-hospital relationships in 1992–1993. In 2015,
 3 the Academy of Management and its Health Care Administration Division awarded me the
 4 Distinguished Scholar Award.

5 7. In terms of management topics, I have focused much of my attention on
 6 organization structures, organization processes (*e.g.*, participation in decision-making), and
 7 employee behavior (*e.g.*, collaboration, conflict, satisfaction, loyalty and commitment to the
 8 organization, citizenship behaviors, etc.). In terms of corporate strategy and industrial
 9 organization topics, I have focused on “governance decisions” (*e.g.*, make-in-house versus buy
 10 from the market), horizontal and vertical integration, diversification, strategic alliances and
 11 networks, and value-chain alliances.

12 8. In terms of healthcare topics, I have focused much of my attention on organized
 13 delivery systems. These include physician group practices; physician practice management
 14 companies (“PPMCs”); ambulatory surgery centers (“ASCs”); and a variety of integrated
 15 delivery networks (“IDNs”), such as physician-hospital organizations (“PHOs”), management
 16 services organizations (“MSOs”), clinically integrated networks (“CINs”), accountable care
 17 organizations (“ACOs”); and economic and clinical integration. Many of these centered on the
 18 integration within physician organizations and the integration between physician organizations
 19 and hospitals. During this period, I have conducted mail surveys of thousands of physicians,
 20 personally interviewed hundreds of physicians and executives in IDNs, received numerous grants
 21 and research contracts to study physicians and IDNs, written or co-written five case studies of
 22 IDNs, and published multiple articles and book chapters relating to the topic of physician-
 23 hospital integration.

24 9. I have written extensively on healthcare related topics.¹ I have written about both
 25 professional service agreements and the different contractual arrangements among physicians

26 ¹ Lawton R. Burns and Douglas R. Wholey. “Responding to a Consolidating Healthcare System: Options for
 27 Physician Organizations.” In *Advances in Health Care Management* Volume 1 (New York: Elsevier): 273-335.
 2000. Lawton R. Burns and Ralph Muller. “Hospital-Physician Collaboration: Landscape of Economic Integration
 DECLARATION OF LAWTON R. BURNS - 4

1 and between physicians and other parties, such as hospitals and practice management
2 companies.²

3 10. I have two new books. The first is an introductory textbook to the entire U.S.
4 healthcare ecosystem. The second is an analysis of the harmful effects of consolidation among
5 healthcare providers and the historical chronicle of consolidation efforts stretching back from the
6 1990s into the present. The latter covers both horizontal and vertical integration involving
7 hospitals and physicians.³

8 11. I have published over one hundred and fifty articles and book chapters on these
9 topics. I have also published several books in the same areas. Exhibit 1 contains my curriculum
10 vitae.

11 **II. Summary of Work Performed**

12 12. I have been asked to analyze the effect of Blue Cross of Illinois (“BCBSIL”)’s
13 practice of administering self-funded health plans that contain exclusions from gender affirming
14 care.

17 and Impact on Clinical Integration.” *Milbank Quarterly* 86(3):375-434. 2008. Lawton R. Burns, Jeff C. Goldsmith,
18 and Ralph Muller. “History of Hospital/Physician Relationships: Obstacles, Opportunities, and Issues.” In Jay
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20 2010. Lawton R Burns and Mark V Pauly. “Accountable Care Organizations May Have Difficulty Avoiding The
21 Failures of Integrated Delivery Networks of The 1990s.” *Health Affairs* 31(11): 2407-2416. 2012. Lawton R. Burns,
22 Jeff Goldsmith, and Aditi Sen. “Horizontal and Vertical Integration of Physicians: A Tale of Two Tails.” In *Annual
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Care Management*, Volume 15: 39-117. (Emerald Group Publishing). 2013. Lawton R. Burns and Mark V. Pauly.
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109.

² Burns and Muller. 2008. Lawton R. Burns and Darrell P. Thorpe. “Trends and Models in Physician-Hospital
Organization.” *Health Care Management Review* 18(4): 7-20. 1993. Jeffrey Alexander, Thomas Vaughn, Lawton R.
Burns et al. “Organizational Approaches to Integrated Healthcare Delivery: A Taxonomic Analysis of Physician
Organization Arrangements.” *Medical Care Research and Review* 53(1): 71-93. 1996. Lawton R. Burns. “Physician
Practice Management Companies.” *Health Care Management Review* 22(4):32-46. 1997. Lawton R. Burns, Jeffrey
Alexander, and Ronald Andersen. “How Different Governance Models May Impact Physician-Hospital Alignment.”
Health Care Management Review. Forthcoming.

³ Lawton R. Burns. *The U.S. Healthcare Ecosystem: Payers, Providers, Producers* (McGraw-Hill, 2021). David
Dranove and Lawton R. Burns. *Big Med: Megaproviders and the High Cost of Health Care in America* (Chicago,
IL: University of Chicago Press, 2021).

DECLARATION OF LAWTON R. BURNS - 5

KILPATRICK TOWNSEND & STOCKTON LLP
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SEATTLE, WA 98101
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1 13. I have also been asked to determine whether the elimination of BCBSIL's to
2 administer plans with varying designs, including designs that exclude gender affirming care, will
3 harm employers and consumers.

4 14. I have reached opinions on these matters in my report based on a combination of
5 (a) knowledge developed over nearly forty years of conducting academic research on health care
6 delivery networks; (b) knowledge developed over the past thirty years of conducting
7 extramurally-funded research; (c) knowledge acquired over the past twenty years in expert
8 witness work on related cases; (d) evidence gleaned from depositions and documents produced
9 in this litigation; and (e) the broader literature on medical groups, professional service
10 agreements, including prior research and rulings and advisories by the FTC. My work on this
11 matter is continuing, and I reserve the right to amend my opinions and testimony, including in
12 response to any of plaintiffs' experts.

13 15. I am compensated at the rate of \$900 per hour for performing my work on this
14 matter. I am paid this rate regardless of the opinions I reach in connection with my work.

15 **III. Summary of Opinions**

- 16 i. Plan designs that contain various iterations of exclusion for gender
17 affirming care are common;
- 18 ii. These Plan designs allow greater economic flexibility for employers and
19 further their ability to make health care coverage available at customized
20 price-points;
- 21 iii. Eliminating the ability to purchase health plans with gender-affirming care
22 exclusions would be harmful to consumers.
- iv. Individuals will ultimately bear the burden of price increases.

23 **IV. Background Regarding the Healthcare Industry.**

24 16. Individuals not eligible for public insurance, such as Medicare or Medicaid, can
25 obtain health insurance coverage in two ways. First, they can buy insurance on their own on the
26 individual market (the self-employed, those working for firms that do not offer coverage, early
27

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1 retirees). Second, like the majority of the population, they can obtain coverage on the group
 2 market through their, or a family member's, employer. Group coverage can include both small
 3 group (defined as firms with less than 50–100 workers, depending on the state) as well as large
 4 group (firms with 100+ workers).

5 17. Employers are often referred to as ERISA plan sponsors. Employers sponsor
 6 insurance for their workers in one of two ways. Some employers purchase it. In this situation,
 7 the employer purchases insurance from a company such as BCBSIL. These employers are
 8 referred to as “fully insured” because the insurance risk rests with the insurer. Other employers,
 9 especially the majority of large employers, directly assume financial responsibility for
 10 employees' medical claims and administrative costs and use their own money to pay health care
 11 costs. These employers are known as “self-insured.” Most self-insured employers hire
 12 companies such as BCBSIL to assemble a network of providers, process claims, and handle
 13 provider billing.

14 18. Generally, self-insured ERISA plans design their own coverages. In other words,
 15 the employer chooses what it will cover for employees and then hires an administrator to provide
 16 employees with a network of providers and process the claims. In order to price these products,
 17 parties need to employ actuaries and underwriters. These staff estimate the likely cost of a given
 18 plan based on the utilization of its enrollees over a future period and then derive an annual
 19 premium to cover the plan's cost, including medical and administrative costs.

20 **A. When Health Care Costs Rise, Consumers Are Adversely Affected.**

21 19. When the amount that employers pay for health care goes up, the end consumer
 22 ultimately feels the impact. As in other segments of the health care value chain (*e.g.*, rising drug
 23 prices), rising fees upstream (*e.g.*, the prices charged by providers) are passed along to the health
 24 plans, the employers who sponsor those plans, and ultimately to the workers who enroll in these
 25 plans.

26 20. Consumers generally have what are called cost-sharing obligations for their health
 27 care. These obligations span deductibles, co-pays, and co-insurance. Monies to cover these
 DECLARATION OF LAWTON R. BURNS - 7

obligations come directly from the consumer's own pocket. Individuals who obtain insurance through their employer also pay higher premiums directly, if their employer requires them to contribute to premiums or plan costs through a payroll deduction. But even when an employer nominally pays for health coverage, the employee ultimately bears the burden of overall higher prices for health services.⁴

21. To attract more and better-qualified labor, employers offer prospective employees a combination of salary and benefits. Together, salary and benefits are considered the employee's total compensation and the employee's money. Employer payments for health insurance premiums ultimately come out of what would otherwise have been paid to workers as money wages. As of the mid-1990s, consultants estimated that 88% of premiums were offset by money wage reductions. Thus, it is the employee, and not the employer, who pays for the increased health insurance premium.⁵

22. Employees may bear the burden of higher prices in two ways. First, some employers will stop offering insurance to their employees entirely.⁶ This leaves the employee either uninsured, and thus fully exposed to the financial risk of medical costs, or in the position where they need to purchase coverage on their own in the individual market at a much higher price. Second, those employers who do continue to offer insurance will offset the increased cost through higher premiums, higher cost-sharing, and lower wages.

23. The 2017 Annual Survey of Employer Health Benefits published by the Kaiser Family Foundation ("KFF") and the Health Research & Educational Trust ("HRET") highlights the ways in which rising healthcare costs are passed on to end-consumers:

⁴ Carlin CS, Feldman R, Dowd B, *The Impact of Provider Consolidation on Physician Prices*, 26 HEALTH ECONOMICS 1789 (2017)

⁵ Mark V. Pauly. *Health Benefits at Work* (Ann Arbor: University of Michigan Press, 1997). Lewin-VHI. *The Financial Impact of the Health Security Act* (Fairfax, VA: Lewin-VHI, 1993).

⁶ Fronstin P, Sources of Health Insurance Coverage: *A Look at Changes Between 2013 and 2014 from the March 2014 and 2015 Current Population Survey, 2015*, EMPLOYEE BENEFIT RESEARCH INSTITUTE ISSUE BRIEF 419, available at https://www.ebri.org/pdf/briefspdf/EBRI_IB_419.0ct15.Sources.pdf, accessed October 23, 2018.

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- Increased premiums. Average annual premiums for employer-sponsored family coverage reached \$18,764 in 2017, up 55% from \$12,106 in 2007.⁷ This is an average growth rate of 4.4% per year. The worker contribution increased 74%, from \$3,281 in 2007 to \$5,714 in 2017.⁸
- Increased deductibles. The percentage of covered workers enrolled in a plan with an annual deductible of \$1,000 or more increased from 34% in 2012 to 51% in 2017 (for single coverage plans).⁹
- Increased percentage of premium paid by workers. For single coverage, employees in 2017 paid 18% of the total premium, up from 16% in 2007; for family coverage, the employee share of the total premium increased from 28% to 31% over the same period.¹⁰

24. Among firms with between 3 and 199 employees that do not offer insurance coverage, the high cost of health insurance was the most commonly cited reason for not offering coverage.¹¹ Professors Katherine Baicker of UCLA and Amitabh Chandra of Harvard University have studied the effects of increased health insurance premiums and have concluded that workers, as opposed to employers, bear the brunt of such increases.¹² Specifically, they estimate that, on average, the effects of a 10% economy-wide increase in insurance premiums include the following:

- A 1.2 percentage point reduction in the aggregate probability of employment;
- Among the employed population, a 1.9 percentage point reduction in the probability of working full time instead of part time;
- A 2.4% reduction in hours worked; and

⁷ *Kaiser/HRET 2017 Survey*, Figure B. Overall, this is attributable primarily to rising payments for healthcare services rather than to higher administrative costs or health plan profits. From 2007 to 2016, between 86% and 89% of all premiums collected were paid out in the form of health benefits. US Centers for Medicare & Medicaid Services, “Table 20 Private Health Insurance Premiums, Benefits and Net Cost; Levels, Annual Percent Change and Percent Distribution, Selected Calendar Years 1960–2016,” <http://www.cms.gov/Research-Statistics-Data-and-Systems/Statistics-Trends-and-Reports/NationalHealthExpendData/Downloads/Tables.zip>.

⁸ *Id.* Figure B.

⁹ *Id.* Figure E.

¹⁰ *Id.* Figure 6.1.

¹¹ *Id.* Figure 2.22.

¹² Katherine Baicker and Amitabh Chandra, *The Labor Market Effects of Rising Health Insurance Premiums*, 24 JOURNAL OF LABOR ECONOMICS 609, 629–31 (2006).

- Among workers who have employer provided insurance coverage, a 2.3% decrease in wages.¹³

25. In self-insured plans, employers pay for claims directly, and higher prices from health care providers translate dollar-for-dollar into higher expenditures by employers. In fully-insured plans, higher prices lead to higher premiums for individuals and employers. If group expenditures are uncertain, including as a result of uncertain medical reimbursement, employers may face the cost of supplemental stop-loss insurance or may decide not to self-insure. Both fully-insured and self-insured plans would have a limited ability to make changes mid-year in response to changes to reimbursement rates demanded by physician groups. For example, fully-insured plans have regulatory limits on premium increases and medical loss ratios. Fully-insured and self-insured plans would also face limits to their ability to change plan benefits, provider networks and individual premium contributions.

26. When self-insured plans are unable to change premiums in response to unanticipated increases in medical expenditures, due either to utilization or price increases, ongoing plan losses are not sustainable and can lead either to eventual increases in plan premiums or to plan exit.

F. Loss of Choice in Plan Design Harms Employers and Consumers.

27. I understand from BCBSIL that many of their self-funded ERISA groups offer plans with exclusions for some or all gender-affirming care. I also understand from BCBSIL that many of these employers also offer a plan design to employees that includes coverage for these services, so that employees can chose what plan design is right for their circumstances.

27. Employers and consumers bear the burden of higher prices several ways. First, higher health care costs translate into higher premiums. Second, members' cost share payments immediately increase. Third, as health care prices rise, some employers will stop offering

¹³ *Id.* at 609. This means that increases in health insurance premiums come out of wages close to dollar for dollar. For example, if premiums for a family of four are \$14,000, then a 10% increase would be \$1,400. If that family has wage income of \$60,000, then a 2.3% offsetting wage reduction would be \$1,380.

insurance to their employees entirely. Fourth, those employers who do continue to offer insurance will offset the increased cost through lower wages.

G. I declare under penalty of perjury under the laws of the State of Washington that the foregoing is true and correct to the best of my knowledge and belief.

at Bryn Mawr, Pennsylvania.

By
Lawton R. Burns

Hulton R. Burns

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KILPATRICK TOWNSEND & STOCKTON LLP
1420 FIFTH AVENUE, SUITE 3700
SEATTLE, WA 98101
(206) 626-7713 FAX: (206) 260-8946

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APPENDIX 1

Lawton Robert Burns, PhD, MBA

**The James Joo-Jin Kim Professor
Professor - Health Care Management
Professor – Management
Co-Director - Roy & Diana Vagelos Program in Life Sciences and Management
The Wharton School**

CURRICULUM VITAE (February 2022)

Office Address:

Health Care Management Department
The Wharton School
203 Colonial Penn Center
3641 Locust Walk
Philadelphia, PA 19104

Phone: 215-898-3711
Fax: 215-573-2157
Cell: 610-247-0902
Email: burnsL@wharton.upenn.edu
<http://hcmg.wharton.upenn.edu/burnsL>

HONORS AND FELLOWSHIPS

Teaching Excellence Award. The Wharton School. 2020.

Midland Lecture, Ohio State University, March 2017

Teaching Excellence Award, Wharton Weekend MBA Program, Class of 2017.

Distinguished Scholar Award, Academy of Management – Health Care Administration Division, August 2015.

Outstanding Author Contribution Award. Emerald Literati Network. 2012.

Institute of Medicine Committee on Evaluation of the Lovell Federal Health Center Merger (2011-2012)

Outstanding Author Contribution Award. Emerald Literati Network. 2010.

Wharton Faculty Seminar: Beijing and Shanghai, August 2009

Board of Institute of Medicine (IOM) – Health Services Section. 2003-2006.

Paul A. Gross Distinguished Leadership Lecture, Virginia Commonwealth University. 2002.

Election to Life Fellow, Clare Hall, University of Cambridge. 2001.

Arthur Andersen Distinguished Visiting Professor, Judge Institute of Management Studies, University of Cambridge. 2001.

Invited Lecture Series, National University of Singapore (NUS). 2000.

James Joo-Jin Kim Professorship (Endowed Chair). 1999.

Teacher of the Year, Administrative Medicine Program, University of Wisconsin School of Medicine. 1999.

Invited Lecture Series. Catholic University of Rome, LUISS, & National Agency Health Care Services (Italy). 1997.
Edwin L. Crosby Memorial Fellowship, Hospital Research and Educational Trust, Chicago IL. 1992-1993.

Udall Fellowship in Public Policy, Udall Center for Studies in Public Policy, University of Arizona. 1990-1991.
Graduate Training Fellowship, Kaiser Family Foundation and the Graduate School of Business, University of Chicago. 1982-1984.

Post-Doctoral Research Fellowship, Graduate School of Business, University of Chicago. 1981-1982.

Doctoral Research Fellowship, Kaiser Family Foundation and the Graduate School of Business, University of Chicago. 1979-1980.

Doctoral Research Fellowship, National Health Care Management Center, University of Pennsylvania. 1979-1980.

Ernest W. Burgess Fellowship, Department of Sociology, University of Chicago. 1975-1976.

EDUCATION

MBA, Graduate School of Business, University of Chicago, Chicago, Illinois, 1984
Specialization in Hospital Administration & Marketing.

Ph.D. Sociology, University of Chicago, Chicago, Illinois, 1981
- Dissertation: "The Adoption and Diffusion of Decentralized Management in Hospitals."
- Committee: James Coleman, Edward Laumann, Charles Bidwell

M.A. Sociology, University of Chicago, Chicago, Illinois, 1976

B.A. Sociology and Anthropology, cum laude, Haverford College, Haverford, Pennsylvania, 1973

MAJOR FIELDS OF INTEREST

- Health Care Management	- Strategic Management
- Integrated Health Care	- Formal Organizations
- Strategic Alliances	- Evaluation Research
- Organizational Change	- Strategic Implementation
- Health Care Systems of India & China	- Health Systems Science (School of Medicine)

ACADEMIC POSITIONS

Co-Director, Vagelos Life Sciences & Management Program (LSMP). 2013 – Present

Area Leader, Health Care Management Program, India School of Business. 2010 – 2017.

Chair, Department of Health Care Management. 2007 – 2014.

Arthur Andersen Distinguished Visiting Professor, Judge Institute of Management Studies, University of

Cambridge, 2001

James Joo-Jin Kim Professor, University of Pennsylvania, 1999-Present

Director, Wharton Center for Health Management and Economics, 1999-2020

Professor of Health Care Systems, The Wharton School, 1998-Present

Visiting Professor, Department of Preventive Medicine, University of Wisconsin Medical School, 1997-Present

Director of Research, Leonard Davis Institute of Health Economics, University of Pennsylvania, 1996-2000

Associate Professor of Health Care Systems, The Wharton School, University of Pennsylvania, Philadelphia PA (Tenured), 1994-1998

Associate Professor, College of Business and Public Administration, University of Arizona, Tucson, Arizona. Joint Appointments in Management & Policy, Public Administration & Policy, Psychology, 1992-1994

Assistant Professor, College of Business, Univ. of Arizona, 1985-1991

Administrative Practicum, Jackson Park Hospital, Chicago, Illinois, 1983-1984

Assistant to the Administrator, Medical Plaza Hospital, Ft Worth, 1983

Lecturer in Health Administration, Graduate School of Business, University of Chicago, 1981-1984

Post-Doctoral Fellow, Graduate School of Business, Univ. of Chicago, 1981-1982

GRANTS AWARDED

2017-2018	“Physician Consolidation and its Effect on Specialist Care: A Causal Analysis with Machine Learning.” Robert Wood Johnson Foundation. Co-Investigator.
2014	American Hospital Association. “Purchasing Executives' Perspective on Group Purchasing Organizations,” \$138,000.
2011-2012	University of Pennsylvania Health System, “Accountable Care Organizations (ACOs): Stakeholder Analysis in the Philadelphia Market,” \$45,000.
2009-2011	Understanding the Role of Clinician Collaborators in Medical Device Innovation. InHealth. Award: \$380,000.
2007-2008	Retail Medical Clinics and Their Impact on Physician-Hospital Relationships. Center For Health Management Research. Award: \$97,000
2006-2007	Guanghua - Wharton Joint Research Initiative. "Informal Payments in China's Health Care Sector."
2004-2006	National Science Foundation. "Inventory and Distribution in Integrated Delivery Networks." Co-Principal Investigator. Award: \$200,000
2004-2006	Robert Wood Johnson Foundation, HCFO Initiative. "Co-Evolution in HMO and Hospital Markets." (With Robert Town)
2003-2004	IBM Global Services. "Trends in the Pharmaceutical Outsourcing Market." Award: \$50,000.

2000-2001	Robert Wood Johnson Investigator Award in Health Policy Research. "Implementing and Sustaining Fundamental Change in Health Care Organizations." (With Gloria Bazzoli). Award: \$250,000.
1999-2001	Wharton Program on Pharmaceutical Policy, Economics, and Management." Research Grant from Merck Award: \$200,000.
1998-2000	"Hospital Ownership Conversions." Robert Wood Johnson Foundation. Award: \$349,000. (Co-Investigator; PI: Frank Sloan).
1998-1999	"Provision of Community Benefits among FAHS Member Hospitals." Federation of American Health Systems. Award: \$120,000. (Co-Investigator; PI: Mark Pauly).
1998-2000	"Impact of Hospital Consolidation on Supplier-Provider Contracting: Value Chain Analysis." Center for Health Management Research. Award: \$183,000. (Principal Investigator).
1996-1999	"Aligning Physician Groups and Health Systems." National Science Foundation and Center for Organized Delivery Systems. Award: \$840,000. (Co-Investigator; PI: Steve Shortell). Analyze success factors in strategic alliances between integrated delivery systems and physician group practices.
1996-1999	"Referrals to Specialists in HMOs". Agency for Health Care Policy & Research (AHCPR). Award: \$250,000. (Co-Investigator). Measure rates and types of referrals in midwestern HMO.
1996-1997	"Physician-Organization Arrangements: Impact on Integration and Managed Care." Robert Wood Johnson Foundation. Award: \$232,394. (Co-Principal Investigator). Assess impact of integrated delivery systems on primary care and managed care infrastructure in hospitals.
1995-1997	"HMO Impact on Integrated Networks and Services." Grant from Agency for Health Care Policy & Research. Award: \$288,157 (Principal Investigator). Assess impact of HMO prevalence and penetration on development of integrated systems in local markets.
1995-1997	"Managed Care and Hospital-Physician Integration." Grant from Agency for Health Care Policy & Research. Award: \$313,482 (Co- Investigator). Assess impact of managed care on specific mechanisms used by hospitals to integrate their medical staffs.
1994-1997	"Managing Uncertainty to Promote Self-Help in Breast Cancer." Grant from National Cancer Institute. Award: \$990,000. (Co-Investigator). Evaluation of efficacy of nursing intervention to promote self-care and self-help in treatment for breast cancer.
1993-1995	"A Comprehensive Evaluation of Physician-Hospital Arrangements." Grant from the Industry/University Cooperative Research Center for Health Management. Award: \$200,000. (Co-Investigator). Evaluation of physician-hospital networks forming in response to managed competition and managed care contracting.
1991-1992	"Impact of State Subsidies for Liability Insurance on the Delivery of Obstetrical Care by Rural Physicians." Grant from Office for Rural Health Policy, Health Resources & Services Administration (USPHS). Award: \$ 6,000. (Principal Investigator). Evaluation of impact of stipend award and stipend amount on decisions by rural physicians to continue obstetrical practice.
1990-1993	"Interdisciplinary Training for Rural Health Action." Grant from Bureau of Health Professions. Award: \$891,000. Department of Family and Community Medicine, College of Medicine, University of Arizona. (Faculty Trainer).

- 1990-1991 "Structure and Outcomes of Joint-Venture Relationships Between Physicians and Hospitals." Grant from Health Care Management and Technology Assessment Center, University of Arizona. Award: \$ 6,700. (Principal Investigator). Survey of joint ventures between Arizona physicians & hospitals and their impact on utilization of hospitals.
- 1989-1991 "Nursing Interventions Promoting Self-Help to Cancer." Grant from the National Cancer Institute. Award: \$1.2 million. College of Nursing, University of Arizona. (Co-Investigator). Experimental Design to study the clinical- and cost-effectiveness of three nursing interventions to improve self-care knowledge and behaviors among 360 women with breast cancer.

RESEARCH CONTRACTS

- 2020-2021 Private Equity and Nurse Practitioners. Funded by the American Medical Association.
- 2006 "Determinants of Small Device Firm Survival and Growth." Funded by C.R. Bard.
- 2005- 2006 "Assessment and Restructuring of the University of Pennsylvania Health System Supply Chain." Funded by UPHS.
- 2005 "Physician Preference Among Surgical Products." Funded by Broadlane.
- 2004 "Buyer-Supplier Contracting." Funded by Johnson & Johnson Health Care Systems.
- 2000 "Using Network Analysis to Understand Change in Local Healthcare Markets." Funded by Center for Studying Health System Change. (With Douglas Wholey)
- 1998-1999 "The Rise and Fall of AHERF: Lessons for Academic Medical Centers." Funded by Association of Professors of Medicine.
- 1995-1997 "Development of Integrated Delivery Systems in Illinois." Funded by Illinois Hospital and Health Systems Association. Statewide study of integrated system development in community and academic medical centers. With Institute of Medicine.
- 1997 "Impact of Physician Practice Management Companies on Hospital-Based Integrated Delivery Systems." Center for Health Management Research. With James C. Robinson.
- 1992-1993 "Physicians' Decisions Concerning Resource Allocation by Hospitals." Funded by Tucson Medical Center, Tucson AZ. County-wide study of physician estimates regarding the areas to which hospitals should allocate their scarce resources.
- 1992 "Patient Care Restructuring Project." Funded by University Medical Center, Tucson AZ. Evaluation of new personnel roles on inpatient units to relieve nurses of nonprofessional tasks and improve patient management.
- 1992 "Decentralization of the Veterans Administration Hospital System." Funded by the VA Medical Center, Boston, MA. Study to develop models for the decentralized operation of the VA hospital system. Reviewer.
- 1991-1992 "Clinical and Cost Outcomes of Nurse Case Management in a Medicare HMO Setting." Funded by Carondelet-St. Mary's Hospital/Health System, Tucson AZ.
- 1989-1990 "Access and Quality of Care Outcomes in Medicaid HMOs." Funded by Joint Commission on Accreditation of Healthcare Organizations. Analysis of the adherence of Medicaid HMOs to JCAHO accreditation criteria.

PUBLICATIONS

Books:

Mark Pauly, David Asch, Lawton R. Burns, et al. *Seemed Like a Good Idea: Alchemy versus Evidence-Based Approaches to Healthcare Management Innovation*. (Cambridge, UK: Cambridge University Press, 2022).

Lawton R. Burns. *The U.S. Healthcare Ecosystem: Payers, Providers, Producers* (New York: McGraw-Hill, 2021).

David Dranove and Lawton R. Burns. *Big Med: Megaproviders and the High Cost of Healthcare in America*. (Chicago, IL: University of Chicago Press, Forthcoming 2021).

Lawton Burns. *The Business of Healthcare Innovation* – 3rd Edition. (Cambridge, UK: Cambridge University Press). 2020. Prior editions in 2005 and 2012.

Lawton R. Burns, Elizabeth Bradley, and Bryan Weiner (Eds.), Shortell & Kaluzny's *Health Care Management: Organization Design and Behavior* - Seventh Edition. (Delmar). 2019. Prior edition in 2011.

Philip Rea, Mark V. Pauly, and Lawton R. Burns (Eds.). *Managing Discovery: Harnessing Creativity to Drive Biomedical Innovation* (Cambridge, UK: Cambridge University Press, 2018).

Lawton R. Burns and Gordon Liu. *China's Healthcare System and Reform* (Cambridge, UK: Cambridge University Press, 2017).

Lawton R. Burns. *India's Healthcare Industry: Innovation in Delivery, Financing, and Manufacturing* (Cambridge, UK: Cambridge University Press, 2014).

Rosemary Stevens, Charles Rosenberg, and Lawton R. Burns (Eds.), *Health Care History and Policy in the United States* (New Brunswick, NJ: Rutgers University Press). 2006.

Lawton R. Burns & Wharton School Colleagues. *The Health Care Value Chain: Producers, Purchasers, and Providers* (San Francisco: Jossey-Bass). 2002.

Articles/Book Chapters:

Lawton R. Burns, Ingrid M. Nembhard, and Stephen Shortell. "Integrating Network Theory into the Study of Integrated Healthcare." *Social Science and Medicine* (2022). <https://doi.org/10.1016/j.socscimed.2021.114664>

Lawton R. Burns, David Asch, and Ralph Muller. "Vertical Integration of Physicians and Hospitals: Three Decades of Futility?" in Mark V. Pauly (Ed.), *Seemed Like a Good Idea: Alchemy versus Evidence-Based Approaches to Healthcare Management Innovation* (Cambridge, UK: Cambridge University Press, 2022).

Lawton R. Burns and Rachel M. Werner. "Care Coordination," in Mark V. Pauly (Ed.), *Seemed Like a Good Idea: Alchemy versus Evidence-Based Approaches to Healthcare Management Innovation* (Cambridge, UK: Cambridge University Press, 2022).

Lawton R. Burns, Howard Forman, and Carolyn Watts. "Teaching the Introductory Course on the U.S. Healthcare System: Issues, Challenges, and Lessons." *Journal of Health Administration Education* (forthcoming 2022).

Akshat Kumar, Rohit Gupta, and Lawton R. Burns. "Strategic Analysis of India's Private Hospital Sector," in Ali Mehdi and Irudaya Rajan (Eds.), *Health of the Nation: Perspectives for a New India*. (Oxford University Press 2020): 223-239.

Gregory Kruse, Lawton R. Burns, and Ralph Muller. "Health Care Inc." in James Schaefer, Richard M. Mizelle, Jr., & Helen K. Valier (Eds.), *Oxford Handbook of American Medical History*. Chapter 16. Forthcoming 2020.

Mark V. Pauly and Lawton R. Burns. "When is Medical Care Price Transparency a Good Thing (And When Isn't It)?" in Jennifer Hefner and Mona Al-Amin (Eds.), *Advances in Health Care Management – Transforming Health: A Focus on Consumerism and Profitability*. Volume 19 (Emerald Press, 2020): 75-97.

Ann Kutney-Lee, Douglas Sloane, Kathryn Bowles, Lawton R. Burns, & Linda Aiken. (2019). "Electronic Health Record Adoption and Nurse Reports of Usability and Quality of Care: The Role of Work Environment. *Applied Clinical Informatics*. <https://doi.org/10.1055/s-0039-1678551>. 10(1) (2019): 129-139.

Lawton R. Burns and Allison Briggs. "Hospital Purchasing Alliances: Ten Years After." *Health Care Management Review*. Forthcoming.

Lawton R. Burns, Jeffrey Alexander, and Ronald Andersen. "How Different Governance Models May Impact Physician-Hospital Alignment." *Health Care Management Review*. Forthcoming.

Lawton R. Burns and Mark V. Pauly. "Transformation of the Healthcare Industry: Curb Your Enthusiasm?" *Milbank Quarterly*. (March 2018) 96(1): 57-109.

Edward Zajac, Thomas D'Aunno, and Lawton R. Burns. "Managing Strategic Alliances: Neither Make nor Buy but Ally," in L.R. Burns, E. Bradley, & B. Weiner (Eds.), *Health Care Management: Organization Design & Behavior*. 7th Edition. (Delmar Cengage Learning, forthcoming).

Lawton R. Burns, Elizabeth Bradley, & Bryan Weiner. "The Management Challenge of Delivering Value in Health Care: Global and U.S. Perspectives," in L.R. Burns, E. Bradley, & B. Weiner (Eds.), *Health Care Management: Organization Design & Behavior*. 7th Edition. (Delmar Cengage Learning, forthcoming).

Lawton R. Burns and Gordon G. Liu. "Health, Disease, and Medical Care," in Weiping Wu and Mark Frazier (Eds.), *The SAGE Handbook of Contemporary China* (Sage, 2018).

Lawton R. Burns, Alex Rosen, Philip Rea et al. "Regeneron: Agility, Resilience, and Balance." Forthcoming in Philip Rea, Mark V. Pauly, and Lawton R. Burns (Eds.), *Managing Discovery in the Life Sciences*. (Cambridge, UK: Cambridge University Press, 2018).

Lawton R. Burns and Philip Rea. "Organization of the Discovery Process." Forthcoming in Philip Rea, Mark V. Pauly, and Lawton R. Burns (Eds.), *Managing Discovery in the Life Sciences*. (Cambridge, UK: Cambridge University Press, 2018).

Simon Bassey, Sourav Bose, Lawton R. Burns, and Chris Groskaufmanis. "The Development of Percutaneous Transluminal Coronary Angioplasty." Forthcoming in Philip Rea, Mark V. Pauly, and Lawton R. Burns (Eds.), *Managing Discovery in the Life Sciences*. (Cambridge, UK: Cambridge University Press, 2018).

Lawton R. Burns, Michael Housman, Robert Booth, and Aaron Koenig. "Physician Preference Items: What Factors Matter to Surgeons? Does the Vendor Matter?" *Medical Devices: Evidence and Research* 11 (2018): 39-49.

Karen B Lasater, Michael R Richards, Nikila Dandapani, Lawton R Burns, and Matthew D McHugh. "Magnet Hospital Recognition in Hospital Systems Over Time," *Health Care Management Review*. 42 (2017):

Mirko Noordegraaf and Lawton R. Burns. "Paradoxes of Leading and Managing Healthcare Professionals to Integrate Healthcare Services," in Gary Young, Kathleen Sutcliffe, and Tim Hoff (Eds.), *The Healthcare Professional Work Force: New Directions in Theory and Practice* (Oxford, UK: Oxford University Press, 2016).

Lawton R. Burns, Jeffrey McCullough, Douglas Wholey, Peter Kralovec, Gregory Kruse, and Ralph Muller. "Is the System Really the Solution? Operating Costs in Hospital Systems," *Medical Care Research and Review* 72(3) (2015): 247-272.

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Allison Briggs and Lawton R. Burns. "Do Group Purchasing Organizations Help Hospitals to Reduce Supply Costs?"

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Jeffrey McCullough, Ira Moscovice, and Lawton R. Burns. "Integration and Competition in Physician Markets: Urban versus Rural Effects."

Lawton R. Burns, Mark V. Pauly, and Philip Rea. "How to Manage Scientific Innovation: Penn's Program in Life Sciences & Management (LSM)."

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INDUSTRY PRESENTATIONS

Palo Alto Medical Foundation (Palo Alto), July 1994

Western Network for Healthcare Education (Berkeley, CA), August 1994

Berlex Laboratories (NJ), January 1995

Main Line Health (Radnor, PA), January 1995

Medical Group Management Association, January 1995
St. Luke's Medical Center (K.C.), January 1995
Center for Physician Development, Beth Israel Hospital (Boston), May 1995
Johnson & Johnson Wharton Fellows Program, June 1995
American Healthcare Radiology Administrators (Nashville, TN), August 1995
Orthopedics in a Managed Care Environment (Scottsdale, AZ), October 1995
Massachusetts Health Data Consortium (Boston), September 1995
Berlex Laboratories (NJ), January 1996
Geisinger Medical Center (Danville, PA), January 1996
American Society of Ophthalmic Administrators, February 1996
Main Line Health (Radnor, PA), February 1996
Geisinger Medical Center (Danville, PA), May 1996
Johnson & Johnson Wharton Fellows Program, June 1996
American Society of Cataract and Refractive Surgery (Nashville), July 1996
VA/VISN 11 Task Force (An Arbor), November 1996
Health Strategy Network (Philadelphia), December 1996
American Society of Ophthalmic Administrators, January 1997
Main Line Health (Radnor, PA), February 1997
UNUM Insurance, March 1997
AHA Center for Health Care Leadership (Chicago), June 1997
Johnson & Johnson Wharton Fellows Program, June 1997
Prime Care/Merck (Staten Island), June 1997
Association of Professors of Medicine (Philadelphia), July 1997
University of Alabama Alumni of Health Administration (Fort Walton Beach), August 1997
HRET Future Focus Forum (Boston), September 1997
Illinois Hospital & Health Systems Association (Chicago), October 1997
Brazilian Social Security Cultural Institute, November 1997
Catholic University of Rome (Rome), November 1997
Italian National Agency for Health Care Services (Rome), November 1997
Memorial Health System (Springfield, IL), November 1997
Main Line Health (Radnor, PA), December 1997
American Society of Ophthalmic Administrators, January 1998
Association of Professors of Medicine (Scottsdale), February 1998
American Organization of Nurse Executives, March 1998 (San Diego)
American Society of Cataract and Refractive Surgery (Phoenix), March 1998
University of Alabama Executive Education Program for Physicians, March 1998
UNUM Insurance, March 1998
Johnson & Johnson Wharton Fellows Program, June 1998
Riverview Medical Center (Red Bank, NJ), June 1998
Smithkline Beecham, June 1998
Small & Rural Hospitals Constituency Section, IHHA (Springfield, IL), September 1998
National Association of Children's Hospitals (Houston), October 1998
Meridian Health System (NJ), October 1998
University of Alabama Executive Education Program for Physicians, October 1998
Premier Health Alliance (Chicago), November 1998
Martins Point Health Care (Portland, ME), January 1999
Association of Professors of Medicine (Scottsdale), February 1999
Children's Hospital (Columbus, OH), February 1999
Children's Memorial Hospital (Chicago, IL), February 1999
Christiana Care Physicians Organization (Wilmington, DE), February 1999
Johnson & Johnson (New Brunswick, NJ), February 1999
Martins Point Health Care (Portland, ME), February 1999
Integrated Healthcare 2000 (Vail, CO), March 1999
IBM Global Services (Palm Beach), April 1999
Interurban Clinical Club (Philadelphia), April 1999
East Coast Health Care Executive Summit (Boston), June 1999

Johnson & Johnson Wharton Fellows Program, June 1999
Premier Practice Management (Charlotte), June 1999
Annual Symposium on Governing Integrated Healthcare Systems (Aspen, CO), August 1999
University of Alabama Alumni of Health Administration (Fort Walton Beach), August 1999
Wisconsin Health & Hospital Association Convention (Lake Geneva), September 1999
Austral University (Argentina), October 1999
IBM Global Services (Palm Beach), October 1999
The Global Rx Supply Chain Conference (Philadelphia), October 1999
University of Alabama Executive Education Program for Physicians, October 1999
Symposium for Governing Healthcare Systems (Palm Springs), November 1999
Symposium on Governing/Managing Integrated Health Systems (Naples), January 2000
Annual Winter Symposium on Integrated Healthcare (Aspen), March 2000
Centocor/Johnson & Johnson (Cincinnati), April 2000
INSEAD, Seminar on Healthcare Management (Fontainebleau), May 2000
Merck Advisory Board (Chicago), May 2000
National Association of Children's Hospitals (Philadelphia), September 2000
SmithKline Beecham (Philadelphia), September 2000
University of Alabama Physician Leadership Institute (Birmingham), October 2000
Johnson & Johnson Hospital Program/National University of Singapore, November 2000
Sparrow Hospital and Health System (Lansing, MI), November 2000
Glaxo SmithKline Industry Conference, (Raleigh, NC), May 2001
J&J Wharton CEO Program in Health Care Leadership (Philadelphia), October 2001
Johnson & Johnson Hospital Program/National University of Singapore, November 2001
Johnson & Johnson Health System CEO Forum (Philadelphia, PA), December 2001
Ochsner Clinic Foundation (New Orleans, LA), December 2001
Chestnut Hill Health Care - Board Retreat (Philadelphia), February 2002
Glaxo SmithKline Pharmacy Leaders (Philadelphia), February 2002
Health Industry Distributors Association (Tucson, AZ), March 2002
College of Surgeons (Philadelphia), "Lessons from the Allegheny Bankruptcy," April 2002
Center for Health Management Research CHMR Value Chain," May 2002
Goldman Sachs Institutional Investors (NYC), "Improving the Health Care Value Chain," May 2002
Health Industry Group Purchasing Association Global Summit (Amsterdam), May 2002
Putnam Institutional Investors (Boston), "Improving the Health Care Value Chain," May 2002
Accenture Conference on Supply Chain Excellence (London, UK), June 2002
Association for Health Services Research and Policy (Washington D.C.), June 2002
Johnson & Johnson Nurse Fellows Program, "Integrated Delivery Networks," June 2002
American Society of Ophthalmic Administrators and American Society of Corrective and Refractive Surgeons (ASOA/ASCRS), August 2002
Association for Health Resource and Materials Management (San Antonio), August 2002
IDN Summit (Atlanta), "Improving the Health Care Value Chain," September 2002
UniMED (Sao Paulo), September 2002
VHA West Materials Managers Meeting, September 2002
Workshop on Antitrust in Health Care. Federal Trade Commission (Washington D.C.), "Group Purchasing Organizations and Antitrust Implications," September 2002
Health Industry Group Purchasing Association (Orlando), October 2002
Healthcare Marketing and Manufacturers Council (Chicago), November 2002
Johnson & Johnson Hospital Management Program (Singapore), November 2002
Premier 2002 Partnerships Meeting (Chicago), November 2002
Dade Behring (Fort Lauderdale), January 2003
Premier Governance Education Conference (Naples), January 2003
NCI Conference on Hospital Systems (Orlando), January 2003
International Pharmaceutical Wholesalers Conference (New York), February 2003
Aventis Pharmaceuticals (Philadelphia), April 2003
Inova Health Systems (Virginia), April 2003
VHA Leadership Conference (Boston), April 2003
Premier Leadership Conference (Las Vegas), May 2003

Humana (Philadelphia), June 2003
Association of Biotechnology Financial Officers (Scottsdale), June 2003
UniMED (Sao Paolo), July 2003
Dade Behring Executive Team (Philadelphia), July 2003
Association of Healthcare Resource and Materials Managers (San Diego), August 2003
McKesson Corporation (Atlanta), August 2003
W.L. Gore & Associates (Maryland), August 2003
UNIMED (Philadelphia), September 2003
Kettering Medical Center Network (Dayton), October 2003
DePuy, November 2003
Johnson & Johnson Hospital Management Program (Singapore), November 2003
Ethicon (Somerville, NJ), January 2004
Health Industry Distributors Association (Amelia Island Plantation), March 2004
Lehigh Valley Health System (Allentown), March 2004
Heritage Valley Health System (Beaver, PA), April 2004
New England Health Care Assembly (Worcester, MA), April 2004
Ohio State Medical Society (Cincinnati), May 2004
Inova Health System (Virginia), May 2004
American Medical Association - HMSS Section (Chicago), June 2004
Johnson & Johnson Contract Excellence (Princeton), September 2004
Chesapeake General Hospital (Williamsburg), September 2004
Biosciences Forum (Philadelphia), October 2004
Cooper Heart Institute (Voorhees, NJ), October 2004
Adventist Health Care (Nemacolin, PA), October 2004
Christiana Care (Wilmington, DE), November 2004
Christiana Care (Wilmington, DE), January 2005
Cooper University Hospital (Camden, NJ), May 2005
Cerner Corporation May 2005
HDMA (Orlando, FL), June 2005
Johnson & Johnson Wharton Nurse Fellows Program, June 2005
Maine Health (Bar Harbor, ME), October 2005
Greater New York Hospital Association (NYC), October 2005
DePuy (Puerto Rico), January 2006
Broadlane Annual Client Summit (Dallas), March 2006
Owens & Minor Board Retreat (Richmond), March 2006
Johnson & Johnson/ Wharton Executive Management Academy, April 2006
Cooper University Hospital - Heart Institute Advisory Board, May 2006
Medtronic Marketing Leader Program (Minneapolis), May 2006
Johnson & Johnson/Wharton Nurse Fellows Program, June 2006
Medtronic Directors Program, July 2006
Sisters of Charity of Leavenworth Health System (San Diego), October 2006
Health Industry Group Purchasing Association (HIGPA), 2006 Expo, October 2006
National Federation of Municipal Analysts. (Washington, D.C.), November 2006
ECRI Conference on "Confronting Dilemmas of Risk in Healthcare" (Plymouth Meeting, PA), November 2006
Greater New York Hospital Association (NYC), November 2006
Johnson and Johnson/ Wharton Hospital CEO Program, November 2006
South Jersey Healthcare, December 2006
Medtronic Director Development Program, January 2007
World Congress Summit on Healthcare Supply Chain Management, January 2007
Johnson & Johnson Health Care Systems National Meeting, February 2007
Lancaster General Hospital Leadership Conference, April 2007
Medtronic Directors Program, May 2007
United Healthcare (Minneapolis), May 2007
Cooper Health System, June 2007
Healthcare Distribution Management Association, June 2007
Johnson & Johnson/ Wharton Nurse Fellows Program, June 2007

Teva Pharmaceuticals, June 2007
Eisai Pharmaceuticals, July 2007, August 2007
Hospital & Healthcare Association of Pennsylvania, July 2007
Novartis, July 2007
United HealthCare, July 2007
Medtronic Directors Program, August 2007
University of Miami / Humana Health Services Research Center, January 2008
United Healthcare, January 2008
Kaiser Permanente Institute for Health Policy, February 2008
United HealthCare, April 2008
Cooper University Hospital, May 2008
Trinity College - Dublin, June 2008
Health Services Executive, Republic of Ireland, June 2008
Johnson & Johnson / Wharton Nurse Fellows Program, June 2008
Medtronic Directors Program, June 2008
Lehigh Valley Health System, June 2008
Health Industry Group Purchasing Association (HIGPA), October 2008
Ephrata Community Hospital, September 2008
American Health & Drug Benefits Conference, October 2008
World Health Care Information Technology Congress, December 2008
Novartis, February 2009
Astra-Zeneca, March 2009.
LeHigh Valley Health System, April 2009
West Penn Allegheny Health System, April 2009
McKesson, April 2009
West Penn Allegheny Health System, June 2009
Boston Scientific, June 2009
Cooper Heart Institute, June 2009
Johnson & Johnson / Wharton Nurse Fellows Program, July 2009
Beijing University, August 2009
Anesthesia Business Group, September 2009
American Health & Drug Benefits Conference, October 2009
Indian School of Business, Hyderabad, January 2010
World Economic Forum, Davos (Switzerland), January 2010
West Penn Allegheny Health System, March 2010
Medtronic, March 2010
Universal Health Services, March 2010
Wheaton Franciscan Health System, April 2010
Johnson & Johnson/Wharton Nurse Fellows, June 2010
Anesthesia Business Group, September 2010
Sanofi/Aventis, September 2010
Cooper Heart Institute, September 2010
Academy Health and Research Insights, December 2010 and February 2011
Methodist Health System, February 2011
Lockheed Martin, March 2011
Becton Dickinson, April 2011
Association of Health Journalists, April 2011
VHA Leadership Conference, May 2011
MacEachern Symposium/Kellogg Graduate School of Management, May 2011
West Penn Allegheny Health System, June 2011
Johnson & Johnson, June 2011
Harkness Fellows Program, September 2011
APAX Partners, October 2011
Anesthesia Business Group, January 2012
PricewaterhouseCoopers, March 2012
Morgan Stanley, May 2012

US-China Biopharma Congress 2012 & SAPA-GP 10th Annual Conference, June 2012
HealthTrust, July 2012
Rite-Aid, August 2012
Edwards Life Sciences, December 2012
Anesthesia Business Group, January 2013
Astra-Zeneca, January 2013
US Congressional Staffers & Health Industry Group Purchasing Association, January 2013
Edwards Life Sciences, April/May 2013
Rite-Aid, August 2013
Edwards Life Sciences, August 2013
Novo Nordisk, December 2013
Anesthesia Business Group, January 2014
Novo Nordisk, January 2014
Securities Industry Institute, March 2014
Novo Nordisk, April 2014
World Bank, April 2014
Wharton Global Forum – Beijing , June 2014
Novo Nordisk, October 2014
Novartis, October 2014
Edwards Life Sciences, October 2014
Vertex Pharmaceuticals, November 2014
Edwards Life Sciences, November 2014
Webinar on India's Healthcare System, November 2014
Penn Medicine - University of Pennsylvania, January 2015
Anesthesia Business Group, January 2015
McKesson, February 2015
Vertex Pharmaceuticals, February 2015
Edwards Life Sciences, March 2015
Securities Industry Institute, March 2015
Princeton Healthcare Conference, May 2015
Genentech, July 2015
Mayo Clinic, September 2015
Genentech, October 2015
Bristol-Myers Squibb, October 2015
Novartis, November 2015
The Health Industry Forum, November 2015
Anesthesia Business Group, February 2016
Securities Industry Institute, March 2016
Novo Nordisk – China, April 2016
Genentech, April 2016
Edwards Life Sciences, May 2016
Sino-American Pharmaceutical Professionals Association (SAPA), June 2016
Janssen Pharmaceuticals, August 2016
Cooper Health System, September 2016
Edwards Life Sciences, November 2016
Massachusetts Association of Health Plans, November 2016
Webinar on China, December 2016
Anesthesia Business Group, February 2017
Center for Therapeutic Effectiveness Research, April 2017
China – U.S. Business Leaders Roundtable, NYC, April 2017
Edwards Life Sciences, April 2017
Lehigh Valley Business Coalition, May 2017
Central Pennsylvania Business Group on Health, September 2017
Healthcare Executives Leadership Network, January 2018
Securities Industry Institute, March 2018
Population Health Colloquium, Jefferson Health, March 2019

Securities Industry Institute, March 2019
Physician Group Practice Strategic Transactions, NYC, April 2019
Novo Nordisk, Philadelphia, June 2019
Veterinary Trends, Philadelphia, June 2019
Association of Academic Health Centers, Boston, July 2019
Teva Pharmaceuticals, September 2019
Central Pennsylvania Business Group on Health, October 2019
Pharma & Healthcare Business Summit, University of the Sciences, February 2021
Securities Industry Institute, March 2021
Medtronic, July 2021

ACADEMIC DIRECTOR - EXECUTIVE EDUCATION PROGRAMS

American Society of Ophthalmic Administrators (ASOA), August 2002

Johnson & Johnson Health Care Systems, April 2003

Aventis Pharmaceuticals, January 2003, April 2003, October 2003, February 2004

Humana, June 2003

Eisai Pharmaceuticals, July - December 2007

Novo Nordisk, October 2014

Bristol-Myers Squibb, October 2015

American Association of Orthodontists, Spring-Summer 2021

FEDERAL/STATE GOVERNMENT: EXPERT WITNESS TESTIMONY

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Expert Witness, Department of Justice, United States and State of Michigan vs. Hillsdale Community Health Center and Allegiance Health, 2016

Expert Witness, Department of Justice, United States V. Aetna and Humana, 2016

Expert Witness, Attorney General, State of Washington, State of Washington v. Franciscan Health System, 2017-18

Expert Witness, Attorney General, State of Rhode Island, Rhode Island Attorney General v. Lifespan/Care New England

PRIVATE SECTOR: EXPERT WITNESS TESTIMONY

Cravath, Swaine, and Moore. *Unsecured Creditors of Allegheny Health, Education and Research Foundation v. PricewaterhouseCoopers*. 2004-2005.

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Boies, Schiller & Flexner. *Spartanburg Regional Healthcare System v. Hillenbrand Industries*. 2005.

Winston and Strawn. *Rochester Medical Corporation v. C.R. Bard*. 2006.

ECRI v. Guidant, 2007

Goodwin Proctor. *USA v. Richard Lane*, 2008.

Winston and Strawn. *Southeast Missouri Hospital and Saint Francis Medical Center v. C.R. Bard*, 2009.

Venable. *Retractable Technologies Inc. v. Abbott Laboratories*, 2009-2010.

Baker and McKenzie. *Medtronic Inc. v. IRS Commissioner*, 2010.

Morgan, Lewis and Bockius. *USA v. Amgen*, 2011.

Greenberg Traurig. *Freedom Medical v. Universal Hospital Services*, 2011.

Akin Gump Hauer Strauss and Feld. *Lenox MacLaren v. Medtronic*, 2012, 2015.

Lewis & Gellen. *Fabiszak v. Silver Cross Hospital*, 2013.

Bubb, Grogan, and Cocca, *AHS Hospital Corporation v. Town of Morristown*, 2013.

Buchanan Ingersoll & Rooney. *Aetna Life Insurance v. Foundation Surgical Associates*, 2015.

Dykema. *Kerrins v. Palos Community Hospital*, 2016.

Hamstead Williams & Shook, Wiles v. West Virginia University Hospitals, 2017-2018

Lowenstein Sandler, Appraisal of Team Health Holdings, 2018

Lowenstein Sandler, Brigade Capital v. Kindred Healthcare, 2018-2019

American Medical Association. CVS Health / Aetna Merger. 2018

Dorsey & Whitney, *Consolidated Class Action Lawsuit – EpiPen ERISA Litigation*, 2019-2020.

Lieff, Cabraser, Heimann & Bernstein. The Hospital Authority of Metropolitan Government of Nashville & American Federation of State, County, and Municipal Employees District Council 37 Health and Security Plan. 2019.

Kirkpatrick Townsend. *Premiera v. The Everett Clinic, Eastside Family Medical Clinic*. 2020.

Oxley Rich Sammons. *Jane Doe and West Virginia Residents v. Steven Matulis*. 2021.

Wilmer Cutler Pickering Hale & Dorr, *Vascular Solutions v. Medtronic* 2021-2022

PROFESSIONAL ACTIVITIES

Editorial Board:

Health Care Management Review (1992-2000). Associate Editor (1994-2000)

Health Services Research (1994-Present)

AUPHA / Health Administration Press

Governmental Research Review Committees:

Agency for Health Care Policy & Research:

Health Services Research Review Subcommittee (1994-1998)

Consulting Reviewer (Journals):

Academy of Management Journal

Administrative Science Quarterly

Health Affairs

Health Care Management Review

Inquiry

Journal of American Medical Association

Journal of Health Economics

Journal of Management Studies

Medical Care

Milbank Fund Quarterly

Social Science and Medicine

Strategic Management Journal

Consulting Reviewer (Grants):

Agency for Health Care Policy and Research (Rockville, MD)

Health Care Financing Administration (Baltimore, MD)

Robert Wood Johnson Foundation

Veterans Administration (Washington, DC)

Affiliations:

Academy of Management

American Hospital Association

Association for Health Services Research

TEACHING

Integrated Delivery Systems
Analysis of Health Systems
Comparative Health Care Management
Organizational Behavior
Health Care Strategy
Organizational Change
Innovation in India's Health Care System
Life Sciences & Management

Seminar on the Professions
Health Care Policy
Evaluation Research
Issues in Rural Health Care
Managed Care & Industrial Organization of Healthcare
Strategic Implementation
China's Healthcare System & Reform
Health Systems Science

EXHIBIT K

Transcript of the Testimony of

Loren S. Schechter, M.D.

Date: 8/2/2022

C.P., et al. vs Blue Cross Blue Shield



Phone: (425) 866-4250
production@nelsonreporters.com
www.nelsonreporters.com

Loren S. Schechter, M.D.

8/2/2022

1 A P P E A R A N C E S Page 2 2 FOR THE PLAINTIFFS: 3 ELEANOR HAMBURGER 4 SIRIANNI YOUTZ SPOONEMORE HAMBURGER 5 3101 Western Avenue, Suite 350 6 Seattle, Washington 98121 7 (206) 223-0303 8 ehamburger@syllaw.com 9 10 OMAR GONZALEZ-PAGAN 11 LAMBDA LEGAL DEFENSE AND EDUCATION 12 FUND, INC. 13 120 Wall Street, 19th Floor 14 New York, New York 10005-3919 15 ogonzalez-pagan@lamdalegal.org 16 FOR THE DEFENDANT: 17 STEPHANIE N. BEDARD 18 KILPATRICK TOWNSEND & STOCKTON LLP 19 1100 Peachtree NE, Suite 2800 20 Atlanta, Georgia 30309 21 (404) 815-6039 22 sbedard@kilpatricktownsend.com 23 ALSO PRESENT: Lindsey Lewis, videographer 24 Maggie Wells, associate 25 Kilpatrick Townsend & Stockton	Page 4 1 BE IT REMEMBERED THAT on August 2, 2022, in Highland 2 Park, Illinois, at 9:03 a.m., before Katie J. Nelson, RPR, 3 CCR, appearing remotely, LOREN S. SCHECHTER, M.D., appeared 4 herein; 5 6 THE VIDEOGRAPHER: We're now on the record. 7 Today's date is August 2, 2022. The time is now 9:31 a.m. 8 This is the video-recorded deposition of Loren S. 9 Schechter, M.D., in the matter of C.P., Patricia Pritchard 10 and Nolle Pritchard, et al., vs. Blue Cross Blue Shield of 11 Illinois, et al., pending in the United States District 12 Court, Western District of Washington at Tacoma. Case 13 Number 3:20-cv-06145-RJB. This deposition is at the request 14 of the defense. 15 My name is Lindsey Lewis, I'm your videographer, 16 here with Katie Nelson, your court reporter. We represent 17 Nelson Court Reporters. This deposition is taking place via 18 Zoom. 19 Will counsel please identify and state your 20 appearances for the record. 21 MS. BEDARD: Yes. Good morning. My name is 22 Stephanie Bedard, I'm with Kilpatrick Townsend & Stockton 23 and we represent the defendant, Blue Cross Blue Shield of 24 Illinois. 25 MR. GONZALEZ-PAGAN: Good morning, Omar
Page 3 1 LOREN S. SCHECHTER, M.D. - August 2, 2022 2 I N D E X 3 EXAMINATION BY: Page(s) 4 Ms. Bedard 5 5 Mr. Gonzalez-Pagan 70 6 Ms. Bedard 72 7 8 * * * 9 EXHIBITS FOR IDENTIFICATION: 10 Exhibit 1 Subpoena to Testify 7 11 Exhibit 2 Expert Report of Loren S. 10 12 Schechter, M.D. 13 Exhibit 3 Article in the Journal of Clinical 45 14 Endocrinology and Metabolism 15 Exhibit 4 Final Decision Memorandum on Gender 57 16 Reassignment Surgery for Medicare 17 Beneficiaries with Gender Dysphoria 18 Exhibit 5 (exhibit not introduced) -- 19 Exhibit 6 Guideline Regarding Hormonal 63 20 Treatment of Minors with Gender 21 Dysphoria at Tema Barn - Astrid 22 Lindgren Children's Hospital 23 Exhibit 7 (exhibit not introduced) -- 24 Exhibit 8 Florida Medicaid June 2022 report 67 25	Page 5 1 Gonzalez-Pagan with Lambda Legal representing the plaintiff. 2 MS. HAMBURGER: This is Ele Hamburger from 3 Sirianni Youtz Spoonemore Hamburger also representing the 4 plaintiff. 5 THE VIDEOGRAPHER: Will the court reporter 6 please administer the oath. 7 --o0o-- 8 LOREN S. SCHECHTER, M.D., sworn as a witness by the Court 9 Reporter, testified as follows: 10 11 E X A M I N A T I O N 12 BY MS. BEDARD: 13 Q. Good morning, Dr. Schechter. Thank you for being 14 with us here today. 15 As I mentioned a minute ago, my name is Stephanie 16 Bedard. I'm one of the attorneys for the defendant in this 17 case, Blue Cross Blue Shield of Illinois. 18 The plaintiff in this action is named (plaintiff 19 name spoken) but because he is a minor, I'm going to be 20 referring to him throughout the course of this deposition as 21 "C.P." I just wanted to give you a heads-up on that so you 22 know to whom I was referring when I said that. 23 Does that sound good? 24 A. Thank you. Yes. 25 Q. Okay. Great.

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Page 6 1 And you understand you're under oath today? 2 A. I do. 3 Q. And I understand from your CV that you have 4 previously been deposed before, so I'm going to go over just 5 a few ground rules. Some of these have changed or are 6 particularly important now that we're in the remote 7 deposition era. 8 So the first is, of course, since there is a court 9 reporter taking down everything we're saying, when you 10 respond to a question I ask, make sure that it is an 11 affirmative response, you know, a yes or no, rather than 12 just a shaking of the head. 13 Does that sound good? 14 A. Yes. 15 Q. Okay. And along those lines, particularly because 16 this is via video, we'll need to do our absolute best not to 17 talk over each other, so I will do my best not to speak over 18 you and I would appreciate it if you could do the same. 19 If I ask you a question and you don't understand 20 what it is I'm asking you, please feel free to ask me to 21 rephrase the question. And just by that same token, if I 22 ask you a question and you do not ask me to rephrase, I will 23 assume that you have understood the question. 24 Sound good? 25 A. Yes.	Page 8 1 A. Possible. I don't recall. 2 Q. Well, I'll scroll down. 3 There's an amended subpoena to testify at a 4 deposition in a civil action directed towards you for 5 today's date, right? 6 A. Yes. 7 Q. Great. And how did you prepare for today's 8 deposition? 9 A. I reviewed my declaration. I reviewed declaration 10 of Dr. Ettner and Dr. Karasic, as well as the amended 11 complaint, and I've spoken with Mr. Gonzalez-Pagan. 12 Q. When did you speak with Mr. Gonzalez-Pagan? 13 A. Sunday evening and Monday evening. 14 Q. And for how long did you speak to him each time? 15 A. Approximately 45 minutes to an hour. 16 Q. Did you discuss any documents other than the 17 documents that you just mentioned, so the declarations of 18 Ettner and Karasic and the amended complaint? 19 MR. GONZALEZ-PAGAN: I'll just instruct the 20 witness not to provide any discussion, but to identify any 21 documents that he may have reviewed. 22 THE WITNESS: I've not reviewed any other 23 documents. 24 Q. (By Ms. Bedard) Did you discuss any other 25 documents with Mr. Gonzalez-Pagan?
Page 7 1 Q. And if there's -- at any point in time, if you 2 realize that a previous answer that you've given wasn't 3 complete or isn't accurate or you would like to supplement 4 it, please just let me know and we can certainly go back and 5 do that. 6 And if you would like to take a short break at any 7 time, that's perfectly fine. What I'll just ask is that I 8 finish a line of questioning or finish discussing a specific 9 exhibit with you, and then we can of course take a short 10 break whenever you would like to. 11 And I also, just as a general practice, like to 12 take a break on the hour if we haven't taken one yet, you 13 know, just quick bathroom breaks, that type of thing. 14 Okay. Great. Any questions about those 15 instructions? 16 A. No. 17 Q. Dr. Schechter, where do you currently live? 18 A. I live in Highland Park, Illinois. 19 Q. And is that where you are today? 20 A. It is. 21 Q. Dr. Schechter, I'm going to show you what has been 22 marked as Defendant's Exhibit 1. 23 (Exhibit 1 marked.) 24 Q. (By Ms. Bedard) Have you seen this deposition 25 subpoena before today?	Page 9 1 A. I have discussed what was in the bibliography to my 2 re- -- to my declaration. 3 Q. And have you reviewed at any point in time any 4 deposition transcripts from this case? 5 A. No. 6 Q. Did you speak with anyone about this case other 7 than Mr. Gonzalez-Pagan on those two occasions? 8 A. No. I may -- I spoke with Mr. Gonzalez-Pagan I 9 think before I agreed to do the case, but not more than 10 that. 11 Q. Okay. When was that, if you remember? 12 A. I don't re- -- prior to my report, but I don't 13 recall. 14 Q. Did you -- when you spoke with Mr. Gonzalez-Pagan, 15 was anyone else a part of those conversations? 16 A. I don't believe so. 17 Q. And did you collect any documents to provide to 18 plaintiffs' counsel in advance of today's deposition? 19 A. No. 20 Q. So, Dr. Schechter, we discussed this a minute ago, 21 but I understand that you have previously been deposed. 22 How many times have you been deposed in the past? 23 A. Probably 60, perhaps, plus or minus. 24 Q. Did you say 60? 25 A. 6-0, yes.

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Page 10 1 Q. 6-0, okay. And how many of those were from the 2 past four or five years? 3 A. Perhaps 10 to 12 as an estimate, but maybe up to 4 15. 5 Q. And of those 60 depositions, how many of those 6 cases related to the provision of gender-related care? 7 A. Only the cases that I've listed in my report as far 8 as the federal depositions -- or federal cases. I don't 9 believe that any others have. 10 Q. Okay. So let's take a look at your report because 11 I want to make sure I'm looking at the right section here. 12 Dr. Schechter, I'm going to share with you what has 13 been marked as Defendant's Exhibit 2. 14 (Exhibit 2 marked.) 15 Q. (By Ms. Bedard) Can you see that? 16 A. I can. 17 Q. Okay. Great. There's a section of your report 18 here on Page 6 that refers to previous testimony from the 19 past four years. Do you see that? 20 A. Yes. 21 MR. GONZALEZ-PAGAN: Stephanie, just for 22 clarity of the record, when you showed the exhibit 23 originally, you just showed the top half which doesn't show 24 the title, just the caption, and so -- we haven't 25 established that this is his report yet, so I just wanted to	Page 12 1 that some may be insurance. It may not be direct clinical 2 care in which I was a treating physician. 3 Q. Help me understand that distinction you're drawing 4 better. 5 A. In other words, I don't -- I wasn't a treating 6 physician in these cases; they pertain to issues related to 7 gender-affirming care. But when you say "provision of 8 care," I don't want to confuse it that these were 9 necessarily patients that I've provided med- -- direct 10 medical care. 11 Q. Understood. Okay. So let me take a step back. 12 For each of these six cases listed here, you were 13 appearing in an expert capacity in those cases, right? 14 A. That's correct. 15 Q. And not as a treating physician? 16 A. That's correct. 17 Q. Okay. Did the expert opinion you provided in these 18 six cases relate to gender-affirming care? 19 A. Yes. 20 Q. And to make sure I understand your testimony from a 21 minute ago, are these six cases the only cases related to 22 gender-affirming care where you have provided testimony as 23 an expert? 24 A. That's correct. 25 Q. And for these six cases, I see here that you have
Page 11 1 make that clear if you want to go back. 2 MS. BEDARD: Sure. 3 Q. (By Ms. Bedard) Dr. Schechter, I'm going to go to 4 the top of Exhibit 2. Is this -- 5 A. Okay. 6 Q. -- the expert report that you produced in this 7 case? 8 A. I suppose for completeness, maybe we can look at 9 the signature page, but... 10 Q. Absolutely. Let's go down there. 11 A. Yes, that looks like it's it. 12 Q. Okay. Exhibit 2 is the expert report that you have 13 provided in this case? 14 A. Yes. 15 Q. Great. And on Page 6 of this report, there's a 16 section titled "Previous Testimony," and it states that this 17 is expert testimony you have given at trial or by deposition 18 in the past four years, right? 19 A. I don't see where it says four years, but I see 20 it -- oh, over the past, yes. 21 Q. Okay. So we have six cases listed here where you 22 provided testimony at trial or by deposition. 23 Did each of these cases relate to the provision of 24 gender-related care? 25 A. They relate to gender-related care in the sense	Page 13 1 indicated that five of the six, it was deposition testimony, 2 and that for the sixth case you provided trial testimony, 3 right? 4 A. Oh, let me -- the first case is not 5 gender-affirming care. I was an expert for a physician in a 6 medical negligence case that had -- that was not pertaining 7 to gender-affirming care. 8 Q. So then for the five other cases, Bruce vs. South 9 Dakota, Boyden vs. State of Wisconsin, Fain v. Crouch, Kadel 10 v. Folwell, and Toomey v. State of Arizona, you provided 11 deposition testimony in an expert capacity in each of those 12 cases, right? 13 A. Yes. 14 Q. Did you also provide trial testimony in any of 15 those cases? 16 A. I do not believe so with the exception of the first 17 case listed. 18 Q. Understood. And that case did not relate to 19 gender-affirming care? 20 A. That is correct. 21 Q. And, Dr. Schechter, what documents do you have in 22 front of you today? 23 A. None. 24 Q. Do you have a laptop in front of you? 25 A. I do.

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Page 14 1 Q. And do you have any sort of e-mail or chat open on 2 that laptop? 3 A. I do not. 4 Q. What about a cell phone? Do you have a cell phone 5 in front of you? 6 A. I do. 7 Q. So, Dr. Schechter, let's change subjects for a bit 8 and discuss your prior involvement in any litigation. 9 Have you ever personally been involved in 10 litigation before? 11 A. Yes. 12 Q. Tell me about that. 13 A. Sure. I was in a medical liability trial which 14 ended June 7th of this year. Prior to that, I was probably 15 20 years ago named in a medical negligence case which 16 dropped. There may have been some cases regarding bill 17 collections from practice, but I don't specifically recall 18 any specific cases. 19 Q. Okay. So let's start with the medical liability 20 trial that just wrapped up. 21 What was the subject matter of that trial? 22 A. A woman -- cisgender woman who claimed a nerve 23 injury to her foot following an abdominoplasty -- tummy 24 tuck -- and liposuction. 25 Q. And for that trial, were you acting in an expert	Page 16 1 infection of the joint and needed soft tissue coverage over 2 his knee. 3 Q. So, Dr. Schechter, let's go back to your report 4 we've been looking at, which is Exhibit 2. 5 Did you draft this report? 6 A. This is my -- these are my opinions. It may have 7 been memorialized by the attorney, but these are my 8 opinions. 9 Q. So did anyone assist you in drafting this report 10 other than plaintiffs' counsel? 11 A. No. 12 Q. And when you refer to "your attorney," are you 13 referring to plaintiffs' counsel? 14 A. I'm sorry. You're correct, yes. To plaintiffs' 15 counsel. 16 Q. Did anyone review this report before it was 17 finalized other than plaintiffs' counsel? 18 A. No. 19 Q. And did plaintiffs' counsel review this report 20 before it was finalized? 21 A. Probably, but I don't recall. 22 Q. And what documents did you review in preparing this 23 report, Dr. Schechter? 24 A. They would be listed in my bibliography. 25 Q. Is that Exhibit B to your report?
Page 15 1 capacity or in a capacity of a treating physician? 2 A. I was the named defendant. 3 Q. You were the named defendant? 4 A. Yes. 5 Q. Okay. Have you ever been a plaintiff in a lawsuit? 6 A. Probably for some bill collections, but I don't 7 believe other than that. 8 Q. Have you ever brought suit against an insurance 9 company before? 10 A. Suit? I can't recall. I've had billing disputes 11 with insurance companies. I can't recall bringing suit. 12 Q. And by "suit," I meant lawsuit -- 13 A. I -- that's right. 14 Q. -- just to clarify. 15 A. Yes, that's how I interpret it. 16 Q. Good. Thank you. 17 And going back just a second to the second case you 18 mentioned in which you were a party to a lawsuit as a 19 defendant, I believe you mentioned that was a medical 20 negligence case from about 20 years ago that dropped. 21 What did you mean by "dropped"? 22 A. Never -- the case was dropped. Dismissed. 23 Q. What was the subject matter of that lawsuit? 24 A. An elderly cisgender man who had, I believe, a 25 revision or multiple revision knee prostheses with an	Page 17 1 A. I have -- I don't recall. If you have it, I can 2 look at it. 3 Q. I'll scroll down to that then. 4 I'm showing you Exhibit B to your expert report, 5 Dr. Schechter. 6 This appears to be the bibliography to that report, 7 right? 8 A. It does, yes. 9 Q. Are there any reports or articles or literature 10 that you reviewed in preparing your report other than what 11 is listed in the bibliography here? 12 A. I routinely review literature in my teaching 13 capacity and my clinical capacity as guest editor and an 14 editor for a number of journals, but none specific to 15 preparing this report. 16 Q. And you mentioned you also reviewed the complaint, 17 right? 18 A. I believe it was listed as an amended complaint. 19 Q. Did you review any other pleadings from this case? 20 A. No. 21 Q. Did you review any medical records for the 22 plaintiff C.P.? 23 A. No. 24 Q. Did you review any of Blue Cross Blue Shield of 25 Illinois medical policies?

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Page 18 1 A. Only what was contained within the amended 2 complaint. 3 Q. Did you review any other policies or materials 4 prepared or authored by Blue Cross Blue Shield of Illinois 5 other than what is attached to the amended complaint? 6 A. Nothing outside of the amended complaint. 7 Q. So, Dr. Schechter, I'd appreciate if we could talk 8 for a second about your educational background. 9 Where did you get your medical degree? 10 A. University of Chicago Pritzker School of Medicine. 11 Q. You've been in the Chicago area for a while then? 12 A. I have, yes. 13 Q. What about your residency? 14 A. Residency in general surgery, plastic surgery and 15 fellowship in reconstructive microsurgery, all at the 16 University of Chicago. 17 Q. Did you undertake any fellowships in addition to 18 those residencies? 19 A. The fellowship in reconstructive microsurgery. 20 Q. Was that also in Chicago? 21 A. Also at the University of Chicago. 22 Q. And do you have any specialized training or 23 education in the field of mental health disorders? 24 A. I'm a -- 25 MR. GONZALEZ-PAGAN: Objection; form.	Page 20 1 pending professorship, if I understand that right? 2 A. I don't know that I would describe them as 3 different roles. My major focus is in gender affirmation 4 surgery and genitourinary reconstruction within the division 5 of plastic surgery. 6 Q. Let me ask it a different way then. 7 How much of your career at this point is academic 8 versus clinical? 9 A. Well, it's -- they're intertwined. It's an 10 academic practice, so my practice involves both treating 11 patients on a clinical basis as well as teaching, research 12 and education. 13 Q. And where were you employed prior to your current 14 role at the Rush University Medical Center? 15 A. For five years prior to that, I was employed by 16 Weiss Memorial Hospital in Chicago. 17 Q. Is that "Weiss"? 18 A. W-E-I-S-S, Weiss. 19 Q. And what was your role at Weiss? 20 A. Plastic surgeon. I also held a -- 21 Q. Were you -- 22 A. -- director- -- yes, I also had a directorship of 23 their center for gender confirmation surgery. 24 Q. So both an academic and clinical role again; is 25 that right?
Page 19 1 You may answer. 2 THE WITNESS: Thank you. I'm a licensed 3 physician and surgeon. 4 Q. (By Ms. Bedard) So what training have you received 5 related to mental health care? 6 MR. GONZALEZ-PAGAN: Objection; form. 7 THE WITNESS: My board certification and 8 expertise is in surgery. Mental health care is a part of 9 medical education. I also routinely teach and attend and 10 lecture at multidisciplinary conferences which involve and 11 include an interdisciplinary and multidisciplinary team, 12 which involves mental health and behavioral health 13 professionals. 14 Q. (By Ms. Bedard) And where are you currently 15 employed? 16 A. Rush University Medical Center. 17 Q. How long have you been employed there? 18 A. Started April of this year. 19 Q. And what is your role at Rush University Medical 20 Center? 21 A. I'm director of gender affirmation surgery. I'm 22 within the division of plastic surgery with -- my pending 23 appointment is professor of surgery. 24 Q. So two different roles technically: You're the 25 director of gender affirmation surgery and you also have a	Page 21 1 A. My academic appointment prior to that was at the 2 University of Illinois at Chicago. 3 Q. I see. So your time at Weiss, was that purely 4 clinical or was that academic as well as clinical? 5 A. It was both. I served as director of our 6 fellowship in gender-confirming surgery, so I had an 7 academic -- or I had an administrative and a clinical role, 8 but my academic appointment was at the University of 9 Illinois at Chicago. 10 Q. Understood. Okay. What about prior to that? 11 A. Prior to that, I was employed by a practice, 12 University Plastic Surgery. 13 Q. Is that a private practice? 14 A. It was a private practice, yes. 15 Q. Do you still maintain a private practice today? 16 A. All my clinical work is through Rush University. 17 Q. And for how long did you maintain that private 18 practice? 19 A. From 2000 to 2003, I was employed by a senior 20 plastic surgeon who retired. From 2003 to 2017, I was in 21 private practice. 22 Q. And what about prior to 2000? 23 A. I was in my fellowship at the University of Chicago 24 from -- excuse me -- 1999 till 2000. 25 Q. Now, let's skip back forward to the present time.

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1 How many patients do you currently see per year in 2 your practice at Rush University? 3 A. I probably -- probably see 20 to 30 -- probably 20 4 to 40 patients per week. 5 Q. Are you going to get me to do math now to try to 6 figure out how many that is per year? I can figure it out 7 eventually. 8 A. So, you know, I probably operate on upwards of 200 9 patients per year. Yeah, I'd have to figure -- I mean, so 10 probably -- so that's probably 150 to 200 patients per 11 month, so a thousand to 2,000 patients per year. 12 Q. Thank you. 13 A. Mm-hm. 14 Q. Do you -- in your practice, do you diagnose gender 15 dysphoria? 16 A. I do not. 17 Q. And how many surgeries do you perform per year 18 related to gender care? 19 MR. GONZALEZ-PAGAN: Objection; form. 20 THE WITNESS: And by "gender care," can you 21 be more specific? 22 Q. (By Ms. Bedard) Well, you previously used the term 23 "gender-affirming care" a minute ago. You've also used the 24 term "gender confirmation care," I believe, prior today. 25 How do you typically refer to that type of care?	1 A. I would estimate perhaps somewhere between 10 to 2 20 percent. 3 Q. All right. So I'm going to try to do some math 4 here again and you tell me if I'm wrong. 5 So if you perform between 150 and 200 surgeries per 6 year related to the treatment of gender dysphoria and 7 approximately 10 to 20 percent of those are for minors, then 8 we're looking at approximately 20 to 25 surgeries per year 9 for transgender minors? 10 A. Yeah. So I think you said 150 to 200. I believe I 11 said 150 to 250. 12 Q. Thank you -- 13 A. Those are surgery -- 14 Q. -- for clarifying. 15 A. Not all patients I see are patients of -- upon whom 16 I perform surgery, so I see more patients per year than I do 17 perform surgery. In terms of surgical procedures on 18 individuals under the age of 18, that would probably be 10 19 to 25 people per year depending on the year. 20 Q. That's 10 to 25 surgeries performed per year on 21 transgender minors? 22 A. That would be 10 to 25 people upon whom I would 23 perform surgery. I suppose if we get into the weeds, there 24 may be staged procedures, so they may not be distinct 25 individuals. In other words, someone may have a secondary
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1 A. So I would refer to that type of care as either 2 gender-affirming or gender-confirming care. I also continue 3 to perform genitourinary reconstruction for a variety of 4 conditions that are not related to gender dysphoria, and I 5 also have no limitation on my privileges within the division 6 of plastic surgery in terms of performing general plastic 7 surgery and reconstructive microsurgery. 8 Q. Understood. Okay. So perhaps the best way for me 9 to say it then to encompass all those different types of 10 treatments would be surgeries for the treatment of gender 11 dysphoria. Does that make sense? 12 A. Yes. 13 Q. Okay. So how many surgeries do you perform per 14 year related to the treatment of gender dysphoria? 15 A. Between 150 and 250. 16 Q. So 150 to 250 of the surgeries you perform per year 17 are related to the treatment of gender dysphoria. 18 How many surgeries are you performing per year then 19 that are not related to the treatment of gender dysphoria? 20 A. Probably 25 to 50. 21 Q. And how many of your patients, current patients 22 identify as transgender? 23 A. Approximately 85 to 90 percent. 24 Q. And how many of your current transgender patients 25 are minors?	1 procedure. 2 Q. Fair point. Thank you for clarifying. 3 Okay. And have you ever worked, Dr. Schechter, 4 with any of the physicians from The Polyclinic? 5 A. No. 6 Q. Have you ever spoken with Dr. Kevin Hatfield from 7 The Polyclinic? 8 A. Not to my knowledge. It's possible I've met him. 9 I don't recall that name, but I attend many conferences. I 10 have no independent recollection of meeting or speaking with 11 him. 12 Q. What about Dr. Jeffrey Kylo with The Polyclinic? 13 A. Same response. No independent recollection. 14 Q. And are you familiar with the Center for Child and 15 Family Therapy in the area? 16 A. In which area? 17 Q. I'm sorry. In the Seattle area. 18 A. Not -- not off the top of my head, no. 19 Q. And have you ever spoken with Sharon Booker with 20 the Center for Child and Family Therapy? 21 A. Similarly, I have no independent recollection. I 22 suppose it's possible that we have crossed paths at some 23 point, but I don't recall that. 24 Q. And, Dr. Schechter, you mentioned that you reviewed 25 the expert reports prepared by two of plaintiffs' other

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Page 26 1 experts in this case, Drs. Ettner and Karasic. 2 Have you ever worked with Dr. Ettner before? 3 A. Yes. 4 Q. And how do you know Dr. Ettner? 5 A. I know Dr. Ettner in her clinical capacity as a 6 clinical and forensic psychologist. I also know her 7 professionally for probably 25 years, perhaps more. 8 Q. And how have you run into her in a professional 9 capacity outside of the clinical context? 10 A. So I've spoken on panels with her, presented at 11 meetings with her, published papers with her, conducted 12 clinical research with her. 13 Q. And in the clinical context, how have you 14 interacted with each other? 15 A. We've shared patients in common. 16 Q. And what is Dr. Ettner's specialty? 17 A. I believe clinical and forensic psychologist. 18 Q. Do you refer patients to each other? 19 A. We have in the past. 20 Q. How many patients would you say you have referred 21 to Dr. Ettner? 22 A. Over the years, perhaps somewhere between 10 to 25 23 perhaps. 24 Q. And what about patients referred from Dr. Ettner to 25 you?	Page 28 1 Q. So who is eligible to be a member of WPATH? 2 A. Professionals in the field are eligible to be full 3 members. There may be corresponding categories. 4 Q. What do you mean by "corresponding categories"? 5 A. There may be individuals who don't have voting 6 rights, but I'd have to review the bylaws to answer that. 7 Q. So to make sure I understand what you're saying, 8 there are professionals, medical professionals who are full 9 members of WPATH and then there are also members who are not 10 full members who do not have voting rights in WPATH; is that 11 right? 12 A. I'd have to look -- 13 MR. GONZALEZ-PAGAN: Objection; form. 14 THE WITNESS: I'd have to see the specifics 15 of the bylaws to answer that accurately. 16 Q. (By Ms. Bedard) And what is your current 17 involvement with WPATH? 18 A. I serve as treasurer and a member -- a member of 19 the executive committee. 20 Q. What do both of those roles involve? 21 A. So the executive committee is a member of the board 22 of directors. As treasurer, I review financials, work in 23 conjunction with the administrative team and the board in 24 terms of preparing budgets and so forth. 25 Q. How long have you served in each of those roles?
Page 27 1 A. I would estimate 25 to 75 perhaps. 2 Q. So for Dr. Karasic, I understand that you reviewed 3 his report as well. 4 Have you previously spoken with Dr. Karasic before? 5 A. Not about this, but I have spoken with Dr. Karasic. 6 We served on the WPATH board together. We've been at 7 meetings together. He has authored articles in either 8 textbooks or journals that I've been -- either edited -- an 9 editor or guest editor in. 10 Q. Have you ever worked with Dr. Karasic in a clinical 11 capacity? 12 A. I don't believe so. It's conceivable I've seen a 13 patient from him, but I don't recall offhand. 14 Q. And have you spoken with either Dr. Ettner or 15 Dr. Karasic about this case? 16 A. No. 17 Q. Have you reviewed either of their deposition 18 transcripts? 19 A. No. 20 Q. So you mentioned for Dr. Karasic that you served on 21 the WPATH board with him. What is WPATH? 22 A. World Professional Association for Transgender 23 Health. 24 Q. And are you a member of WPATH? 25 A. I am.	Page 29 1 A. I've been ending my two-year term as treasurer now. 2 Prior to that, it may have been four or six years -- I don't 3 recall specifically -- as a member of the board. 4 Q. Prior to your current role on executive committee 5 and as treasurer, did you hold any other positions within 6 WPATH? 7 A. I have -- I serve on several committees and have 8 had several roles. Dating back to 2007, I was the local 9 host, one of the local hosts for the biennial meeting when 10 it was hosted in Chicago. I began the -- what's called the 11 Surgeons Only Program beginning in 2007. I've been the 12 director of multiple different educational offerings 13 including the global education institute and various other 14 educational conferences. I serve as a member on the ethics 15 committee. There may have been some others, but I'd have to 16 look at my CV. 17 Q. And are you involved with the preparation or 18 production of various versions of the WPATH standards of 19 care? 20 A. I serve as colead for the surgery and after-care 21 chapter for the forthcoming Standard of Care 8. Prior to 22 that, I was one of the authors for Standards of Care 7 as 23 well. 24 Q. For the same sections? 25 A. The sections have -- we combined surgery and after

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Page 30 1 care for Standard of Care 8. In Standard of Care 7, my 2 focus was on the relationship of the surgeon with the mental 3 health professional and the professional providing -- 4 prescribing hormones. 5 Q. And has Standard of Care 8 been released to the 6 public yet? 7 A. There was a version released for public comment, I 8 believe, around December. I may have that date a little bit 9 off. It has not been otherwise released as of yet. 10 Q. And, Dr. Schechter, are you also familiar with The 11 Endocrine Society? 12 A. With The Endocrine Society? 13 Q. Yes. 14 A. I believe there are several different endocrine 15 societies. There's clinical -- I think they have several 16 different societies. 17 Q. When you say "they" have several different 18 societies, what do you mean exactly? 19 A. Endocrinologists. 20 Q. So are you a member of any of the endocrine 21 societies? 22 A. I am not. 23 Q. In addition to WPATH, are you involved in any other 24 societies or professional organizations that relate to the 25 treatment of gender dysphoria?	Page 32 1 on the care of individuals under the age of 18 who have been 2 diagnosed with gender dysphoria? 3 A. And by "academic practice," I'm not sure the 4 distinction you're... 5 Q. Fair point. Thank you for asking. 6 I'm distinguishing it from your clinical practice. 7 So in other words, I'm not asking number of patients you see 8 who are under the age of 18, but rather your nonclinical 9 work. 10 How much of your nonclinical work is focused on 11 transgender minors? 12 A. So in terms of -- so I -- that sort of work would 13 include writing, preparation of manuscripts, presentations 14 at local, regional, national, international meetings. 15 There's not always a bright line between, for example, in a 16 conference, care of an adolescent or an individual under the 17 age of 18 versus some over the age of 18. So there's quite 18 a bit of overlap in most of that work. 19 Q. Have you conducted any research that is focused on 20 minors experiencing gender dysphoria? 21 A. I believe that my clinical research involves 22 predominantly individuals over the age of 18. They're 23 perhaps, in terms of research, case reports and/or case 24 presentations that pertain to individuals under the age of 25 18.
Page 31 1 A. So I'm involved in numerous surgical societies. 2 For example, American Society of Plastic Surgeons, American 3 Society for Reconstructive Microsurgery, the American 4 College of Surgeons. All of those organizations have had -- 5 excuse me -- educational offerings pertaining to gender 6 affirming -- affirming surgery. 7 I'm a member of the American Medical Association. 8 I think I've participated in some educational offerings 9 from -- from that organization, perhaps some of the others. 10 I'd have to go through my CV to say specifically. 11 Q. Are you involved in any organizations that relate 12 to treatment for minors with gender dysphoria? 13 A. So, again, American Society of Plastic Surgeons, 14 American Society for Reconstructive Microsurgery, American 15 Medical Association. I have participated in educational 16 offerings. I'm sorry. 17 Did you say member or participated in? 18 Q. Why don't you answer both if you can. 19 A. Sure. So I've presented at the American -- I don't 20 recall their specific name, but the child and adolescent 21 psychiatry association. So those other organizations that 22 I've named where surgical care is discussed also involve 23 discussions pertaining to care of individuals under the age 24 of 18. 25 Q. And how much of your academic practice is focused	Page 33 1 Q. What about articles that you have authored? Have 2 you authored any articles that are specifically focused on 3 treatment for minors experiencing gender dysphoria? 4 A. Yeah. So the majority of articles and those that 5 would focus on surgical technique would not necessarily 6 exclude or draw a distinction necessarily on -- only on age. 7 So a number of the articles may involve individuals under 8 the age of 18, but are not exclusive to individuals under 9 the age of 18. 10 Q. So to ask it a different way: You have not 11 authored any articles that are focused exclusively on those 12 under the age of 18? 13 A. So my -- my work would focus -- my academic work, 14 which may also mirror much of my clinical work, would 15 include individuals under the age of 18. 16 Q. And is everything in your CV, Dr. Schechter, 17 updated and accurate to the best of your knowledge? 18 A. I'm -- you know, I update it probably on a monthly 19 basis, so you may not have -- I don't know when that was 20 produced. If it was with the report, there are probably 21 some updates. 22 Q. Are there any updates that should be added to your 23 CV from the last three months that relate to the provision 24 of care or treatment for those diagnosed with gender 25 dysphoria?

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Page 34 1 A. It's possible, again, in the sense that the 2 academic work would mirror my clinical work, so in the sense 3 that there have been publications accepted and I have 4 presentations that have discussed clinical care of 5 individuals under the age of 18. 6 Q. So I was actually asking more broadly about 7 treatment of gender dysphoria on the whole, not just for 8 those under the age of 18, although that's helpful to know 9 as well. 10 So what would the updates be from the past few 11 months to your CV related to the provision of care for the 12 treatment of those with gender dysphoria? 13 A. So I've had a publication accepted to the Journal 14 of Plastic and Reconstructive Surgery regarding the 15 relationship between the surgeon and mental health 16 professional. That article explores the issue of informed 17 consent. I don't believe we specifically highlight -- there 18 may be references to adolescent care, but looks at the topic 19 of surgery for gender incongruence or gender dysphoria more 20 broadly. 21 There would be presentations including grand 22 rounds. I was a visiting professor at Georgetown within the 23 last several weeks. There were discussions regarding 24 provision of care adolescents, so in that sense, there would 25 be updates to my CV.	Page 36 1 record I saw was contained either in the amended complaint 2 and then in the declarations by Dr. Ettner or Karasic. I've 3 seen nothing outside of that. I don't recall specifically 4 if there were other medical information contained within the 5 amended complaint outside of Dr. Hatfield's letter and the 6 letter by Booker. 7 Q. (By Ms. Bedard) So other than what was attached to 8 the complaint or referenced or attached to the reports of 9 other experts in this case, you have not independently 10 reviewed any medical records for C.P., right? 11 MR. GONZALEZ-PAGAN: Objection; asked and 12 answered. 13 THE WITNESS: That's correct. 14 Q. (By Ms. Bedard) And you have not reviewed any 15 records related to mental health treatment for C.P.; is that 16 right? 17 A. Nothing outside of what we've just referenced. 18 Q. And do you have an opinion as to whether any 19 treatment for gender dysphoria was medically necessary for 20 C.P. specifically? 21 A. I haven't reviewed his medical records, so I can't 22 speak specifically to -- to those treatments. 23 Q. And do you have an opinion on whether C.P.'s 24 treating physician discussed the risks and benefits of 25 treatments with C.P. and his parents?
Page 35 1 Q. And, Dr. Schechter, in preparing your report, you 2 did not meet or speak with the plaintiff C.P., right? 3 A. I did not. 4 Q. And you did not meet or speak with his parents 5 either, right? 6 A. That is correct. I did not. 7 Q. And are you aware of any of the treatments that 8 C.P. received? 9 A. So I've reviewed Dr. Ettner and Dr. Karasic's 10 declarations. And I believe contained within the complaint, 11 there was a letter from, I believe, Dr. Hatfield and his -- 12 I think it was Sharon Booker. 13 Q. And what's your understanding of those letters? 14 A. It's my understanding that those letters were -- or 15 assessments were provided to support the decision by the 16 surgeon to move forward with gender-affirming surgery, also 17 with the goal of obtaining insurance coverage for those 18 procedures. 19 Q. So you have not reviewed any of the medical records 20 provided by Dr. Hatfield, right? 21 A. I believe the only -- 22 MR. GONZALEZ-PAGAN: One second. 23 Objection; form. 24 Go ahead, Doctor. 25 THE WITNESS: I believe the only -- the only	Page 37 1 A. I have not reviewed those records -- any medical 2 records. 3 Q. Dr. Schechter, we are right at the hour mark, so my 4 suggestion would be that we take a quick five-minute break 5 or so and then get started back. 6 Does that work for everyone else? 7 MR. GONZALEZ-PAGAN: So at the 35 mark? 8 MS. BEDARD: 35 mark. 9 THE WITNESS: Okay. 10 THE VIDEOGRAPHER: We're now going off the 11 record. The time is 10:30 a.m. 12 (Recess taken from 10:30 to 10:35 a.m.) 13 THE VIDEOGRAPHER: We're now back on the 14 record. The time is 10:35 a.m. 15 16 E X A M I N A T I O N - (Continuing) 17 BY MS. BEDARD: 18 Q. Dr. Schechter, I'm going to show you again what has 19 been marked as Defendant's Exhibit 2, which is your expert 20 report. Can you see my screen? 21 A. I can. 22 Q. And can you read for me Paragraph 23 of your 23 report. 24 A. "It is my professional opinion, supported by the 25 prevailing consensus of the medical community, that

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Page 38 1 procedures used to treat gender dysphoria are medically 2 necessary treatments for many transgender individuals; these 3 procedures are properly considered as medically necessary 4 and are not cosmetic in nature; and these procedures are 5 safe and effective treatments for gender dysphoria." 6 Q. So, Dr. Schechter, your opinion states that 7 "...procedures used to treat gender dysphoria are medically 8 necessary treatments for many transgender individuals." 9 Are there certain circumstances where treatments -- 10 procedures used to treat gender dysphoria would not be 11 medically necessary for transgender individuals? 12 A. Well, the point of this statement is that not all 13 transgender individuals necessarily undergo surgical 14 procedures. 15 Q. Understood. And when you say that "...these 16 procedures are properly considered as medically necessary 17 and are not cosmetic in nature," what is the distinction 18 that you are drawing between medically necessary procedures 19 and cosmetic procedures? 20 A. Medically necessary would be used to treat, 21 evaluate, diagnose a medical condition. 22 Q. Are there any procedures used to treat gender 23 dysphoria that you would consider to be cosmetic? 24 A. So my -- my area of expertise is in surgery. I 25 can't necessarily speak to all procedures in terms of	Page 40 1 none to, as the Paragraph 22 says, mental health services, 2 medical services and surgical services. 3 Q. And is part of the reason to undertake mental 4 health services to determine whether the individual has the 5 capacity to consent to the treatment? 6 A. I would say that the prevailing opinion, current 7 opinion is that mental health or behavioral health can be a 8 useful adjunct in many individuals to help consider whether 9 or not a particular surgical intervention is appropriate for 10 them. 11 Q. Dr. Schechter, can you now read for me -- I'm not 12 going to ask you to read it out loud because it's longer, 13 but Paragraph 30 of your report. I'm at the top here, and 14 let me know when you'd like me to scroll down. 15 A. All right. Okay. You can scroll, please. 16 Okay. 17 Q. So is it your opinion, Dr. Schechter, that 18 clinicians should take a case-by-case approach to evaluate 19 whether a procedure is medically necessary for a particular 20 patient? 21 A. I think that's consistent the general practice of 22 surgery. We would -- with the exception of an emergent 23 life-threatening situation, meet with the patient, perform a 24 history and physical examination, discuss treatment options, 25 obtain whatever consultative services we require and work
Page 39 1 medical pro- -- nonsurgical procedures, medical procedures 2 and so forth. As to whether a procedure is considered 3 medically necessary would depend upon the clinical 4 circumstances in question. 5 Q. So in other words, whether a specific procedure is 6 medically necessary is -- it depends on the specific facts, 7 it depends on the specific individual, right? 8 A. It would depend on the specific clinical 9 circumstances. 10 Q. It would be a case-by-case basis in other words? 11 A. Any decision to move forward with a surgical 12 treatment is done on a case-by-case basis. 13 Q. Dr. Schechter, could you now read for me 14 Paragraph 22 of your report? 15 A. Excuse me. "Appropriate medical care, including 16 mental health services, hormone therapy, and gender 17 confirmation surgeries can help alleviate gender dysphoria. 18 Gender confirmation surgeries, which bring a person's body 19 into better alignment with their gender identity, have been 20 shown to be an effective treatment for gender dysphoria." 21 Q. Dr. Schechter, is it your opinion that mental 22 health services are part of the treatment options available 23 to alleviate gender dysphoria? 24 A. Individuals with gender dysphoria may have a 25 variety of treatment options available to them ranging from	Page 41 1 with the patient to determine what would be most appropriate 2 for them, but ultimately it's the decision of the patient as 3 to whether or not to proceed. 4 Q. And one of the criteria in that case-by-case 5 approach is whether or not the patient has the capacity to 6 make fully informed decisions, right? 7 A. Yes. 8 Q. And whether or not the patient has the capacity to 9 consent to treatment, right? 10 A. The patient has the capacity or, in the case of 11 individuals under the age of 18, assent to the procedure and 12 then provide legal consent from parent or guardian. 13 Q. Understood. And another criteria you would look at 14 in that case-by-case approach is whether the patient has 15 other significant mental health or medical concerns, right? 16 A. As we would with anyone undergoing surgery, we 17 would take a history and that history would include medical 18 and/or relevant mental health concerns. 19 Q. And, Dr. Schechter, what did you mean in your 20 report when you said that you would look to whether those 21 mental health concerns are reasonably well controlled prior 22 to surgery? 23 A. So many people, whether seeking gender-affirming 24 treatment or general surgical care for any number of 25 conditions may have mental health conditions. The standards

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Page 42 1 of care go a step further and explicitly indicate that those 2 concerns be reasonably well controlled, meaning that if an 3 individual has a mental health condition, that does not 4 necessarily preclude them from a surgical intervention. 5 Q. But what does "reasonably well controlled" mean in 6 this context? 7 A. It -- the specifics would depend on the clinical 8 situation at hand. 9 Q. Dr. Schechter, do you recommend counseling for 10 individuals experiencing gender dysphoria prior to surgical 11 treatment? 12 A. Again, it would depend on the specifics of the 13 clinical condition. There are cases where I have 14 recommended counseling prior to gender-affirming surgical 15 interventions. 16 Q. Do you recommend counseling prior to implantation 17 of a hormone blocker? 18 A. I don't perform implantation of hormone blockers. 19 Q. Do you recommend counseling prior to a mastectomy 20 that is performed for the treatment of gender dysphoria? 21 A. And by "counseling," what -- can you be more 22 specific? 23 Q. Sure, mental health care. 24 Do you recommend mental health care counseling 25 prior to performing a mastectomy for the treatment of gender	Page 44 1 You do require that some sort of mental health 2 assessment be performed prior to the provision -- prior to 3 performing a top surgery? 4 A. Assessments required. As to who performs that 5 assessment may depend on the clinical circumstances. A 6 primary care professional may in certain circumstances be 7 the primary person performing mental health services 8 depending upon who that person is and the scope of their 9 practice. It may be -- we've talked about a number of 10 different mental health and behavioral health specialists 11 such as psychologists, psychiatrists, social workers, 12 therapists. 13 Q. And when you require that mental health assessment 14 and your patient undergoes that mental health assessment, do 15 you review the results of that mental health assessment 16 yourself prior to performing any surgery? 17 A. Most often, and I work in my -- my personal 18 practice, we have a social worker and various clinical 19 navigators. We work as a team. We'll typically all -- we 20 will all discuss and review the assessment and the 21 individual. If any additional consultation is required, 22 then I will request a referral or make a referral to 23 additional professionals. 24 Q. Dr. Schechter, I'm now going to show you what has 25 been marked as Defendant's Exhibit 3.
Page 43 1 dysphoria? 2 A. So prior to performing a surgical intervention, I 3 do receive assessments. Those assessments may be from 4 primary care professionals and/or behavioral health and/or 5 mental health professionals. 6 Q. I think I'm asking a slightly different question. 7 Let me rephrase. 8 Do you require that your patients see a mental 9 health care counselor, psychiatrist or psychologist prior to 10 you performing a mastectomy for the provision of 11 gender-related care? 12 MR. GONZALEZ-PAGAN: Objection; form. 13 THE WITNESS: I require an assessment. That 14 assessment may be from a combination of primary care 15 professional, depending on in what capacity they serve. It 16 may be from a mental health or behavioral health 17 professional; that may be a psychologist, a psychiatrist, a 18 therapist, and there are other -- other individuals who 19 perform mental health services who may perform the 20 assessment. I'm blanking on every possibility right now, 21 but there are others. 22 Q. (By Ms. Bedard) There's a certain criteria for a 23 type of mental health care that you would require prior 24 to -- let me back up. I'm trying to be as precise as 25 possible in the way I'm asking about this.	Page 45 1 (Exhibit 3 marked.) 2 Q. (By Ms. Bedard) Can you see this exhibit? 3 A. I can. 4 Q. And have you seen this exhibit before? 5 A. I believe -- can you just -- just let me see -- if 6 you can scroll to the top, let me just see the title, I 7 believe these -- yeah, and that's -- can you just scroll 8 down so I can see the -- okay. Yes. Yes. 9 Q. What is this document? 10 A. This is an article in the Journal of Clinical 11 Endocrinology and Metabolism. I believe that's the full 12 title. 13 Q. And what is the date on the document? 14 A. This article is dated November of 2017. 15 Q. And have you seen this Clinical Practice Guideline 16 before today? 17 A. Yes. 18 Q. And this is from The Endocrine Society, correct? 19 A. Can you scroll down. If you can -- yeah, just keep 20 going and just scroll down, if you would. I know there are 21 different endocrine societies, so I don't want to miss- -- 22 mislabel it as to the authorship of -- perhaps the last page 23 would be the -- have the final. I'm sorry, the last page of 24 the manuscript. Oh, and -- so it says "The Endocrine 25 Society."

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Page 46 1 Q. Dr. Schechter, I'm now going to show you Page 8 of 2 these clinical guidelines. 3 A. Okay. 4 Q. One second. Dr. Schechter, I'm showing Exhibit 3 5 to you again. I'm on PDF Page 8. 6 Do you see the paragraph beginning with, "Because 7 of the psychological vulnerability..."? 8 A. Yeah. I just have to move my thumbnails here. 9 Yes. 10 Q. Could you read that paragraph for me, please. 11 A. "Because of the psychological vulnerability of many 12 individuals with GD, slash, gender incongruence, it is 13 important that mental health care is available before, 14 during and sometimes also after transitioning. For children 15 and adolescents, an MHP who has training, slash, experience 16 in child and adolescent gender development, parentheses, (as 17 well as child and adolescent psychopathology) close 18 parentheses, should make the diagnosis, because assessing 19 GD, slash, gender incongruence in children and adolescents 20 is often extremely complex." 21 Q. Dr. Schechter, do you agree with that statement? 22 A. I would agree that people regardless of age should 23 have mental health care available to them before, during and 24 after transitioning. 25 Q. What about the second sentence of that paragraph?	Page 48 1 Q. So outside of the expert reports of other experts 2 that you reviewed in this case, you don't have an 3 independent opinion as to whether C.P. fulfilled the 4 diagnostic criteria for gender dysphoria, right? 5 MR. GONZALEZ-PAGAN: Objection; form. 6 THE WITNESS: That is correct. I just -- I'm 7 getting feedback. I don't know if -- it could be on my end. 8 I just want to... 9 MS. BEDARD: Omar, I think that may be on 10 your end. 11 MR. GONZALEZ-PAGAN: I am muted, so... 12 THE WITNESS: Okay. 13 MS. BEDARD: Okay. 14 THE WITNESS: I think that's better. 15 MS. BEDARD: I'll ask the question again. 16 Hopefully it doesn't continue. There we go. 17 Q. (By Ms. Bedard) So just to ask the question again 18 for the record: Outside of the reports from other experts 19 that you've reviewed in this case as well as what is 20 attached to the amended complaint, do you have an 21 independent opinion as to whether C.P. fulfilled the 22 diagnostic criteria for gender dysphoria? 23 A. I do not. 24 Q. And do you have an independent opinion as to 25 whether C.P. was evaluated by a qualified mental health
Page 47 1 A. I don't make the diagnosis of gender dysphoria, but 2 I think that access to mental health and other medically 3 necessary treatments when indicated, primary care, 4 endocrine, are all important in the multidisciplinary 5 treatment of individuals with gender incongruence or gender 6 dysphoria. 7 Q. Do you have an opinion as to whether the plaintiff 8 in this case, C.P., saw a mental health provider who has 9 training or experience in child and adolescent gender 10 development specifically? 11 A. The clinical information that I saw was contained 12 within the -- outside of Dr. Ettner and Dr. Karasic's report 13 was contained within the amended complaint. That included 14 Dr. Hatfield's note, I believe -- I don't have it in front 15 of me -- Dr. Hatfield referenced his experience in caring 16 for individuals with gender incongruence and gender 17 dysphoria, which was quite extensive. 18 Q. And do you have an opinion as to whether C.P. 19 fulfilled the diagnostic criteria for gender dysphoria? 20 A. Based on what I recall of Dr. Hatfield and of 21 Dr. Ettner and Karasic 's report, the answer was -- is yes. 22 I -- I did not -- I'm sorry. Is there -- I thought I heard 23 an echo. 24 I did not review any other medical information 25 outside of that.	Page 49 1 professional before starting puberty blocking medication? 2 MR. GONZALEZ-PAGAN: Objection; form. 3 THE WITNESS: Before starting puberty 4 blocking medication? 5 Q. (By Ms. Bedard) Correct. 6 A. I did not review the medical records, so I don't -- 7 I don't know the answer to that question. 8 Q. So your answer would be the same about starting -- 9 when C.P. started testosterone, right? 10 MR. GONZALEZ-PAGAN: Objection; form. 11 THE WITNESS: The answer would be I have not 12 reviewed the medical records so I can't speak to the care he 13 received prior to starting testosterone. 14 Q. (By Ms. Bedard) Dr. Schechter, do you consider 15 certain treatment options for the treatment of gender 16 dysphoria to be reversible? 17 A. Are you speaking from a surgical perspective? 18 Q. Well, more broadly, are certain treatments 19 reversible and other treatments irreversible? 20 MR. GONZALEZ-PAGAN: Objection; form. 21 THE WITNESS: So my area of -- my specific 22 area of expertise is in surgery and surgical treatments for 23 gender dysphoria. I do work, participate in educational 24 sessions more collaboratively in a multidisciplinary fashion 25 with medical professionals endocrinologists, mental health

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Page 50 1 professionals and so forth. So while I don't prescribe, for 2 example, hormones, it is my understanding that some 3 components of hormone -- hormones may be reversible. Others 4 may not. 5 Q. And do you have an opinion as to whether puberty 6 blockers are a reversible or irreversible treatment? 7 A. I do not prescribe puberty blockers. I would defer 8 that to the endocrinology and primary care people. 9 Q. Are you aware of what the plaintiff C.P.'s Tanner 10 stage was at his initial presentation to his treating 11 physician, Dr. Hatfield? 12 A. I'd have to look specifically at the one letter 13 that I saw in the amended complaint. I don't recall 14 offhand. 15 Q. Dr. Schechter, I am going to show you Exhibit 3 16 again, which are The Endocrine Society guidelines. 17 Do you see the section here beginning with 18 "Remarks"? 19 A. I do. 20 Q. And can you read that paragraph for me. 21 A. "Persons considering hormone use for gender 22 affirmation need adequate information about this treatment 23 in general and about fertility effects of hormone treatment 24 in particular to make an informed and balanced decision. 25 "Because young adolescents may not feel qualified	Page 52 1 agree with that. I would agree that -- 2 Q. And in the context -- 3 A. -- not only -- go ahead. I'm sorry. 4 Q. No, that's all right. Go ahead. 5 A. I would agree that not only adolescents, but -- but 6 all individuals should have medically necessary and quality 7 health care available to them when needed to make medical 8 decisions. 9 Q. So when an adolescent is considering treatment for 10 gender dysphoria, what should that informed-consent process 11 look like? What types of information should an adolescent 12 receive? 13 MR. GONZALEZ-PAGAN: Objection; form. 14 THE WITNESS: What -- to what type of 15 treatment are you referring? I -- I don't prescribe, for 16 example, pubertal blocking agents. 17 Q. (By Ms. Bedard) In other words, you don't have an 18 opinion on what would constitute an informed and balanced 19 decision for the effects of hormone treatment, right? 20 MR. GONZALEZ-PAGAN: Objection; form. 21 THE WITNESS: I would not -- I would not 22 offer an opinion as to specific risks and benefits of 23 hormone therapy or pubertal blockers to an individual. 24 Q. (By Ms. Bedard) What about for surgical treatment 25 for gender dysphoria? What would constitute an informed and
Page 51 1 to make decisions about fertility and may not fully 2 understand the potential effects of hormonal interventions, 3 consent and protocol education" -- "consent and protocol 4 education should include parents, the referring MHPs and 5 other members of the adolescent's support group. To our 6 knowledge, there are no formally evaluated decision aids 7 available to assist in the discussion and decision regarding 8 the future fertility of adolescents or adults beginning 9 gender-affirming treatment." 10 Q. Dr. Schechter, do you agree with that statement? 11 A. Well, I would say that in terms of care for an 12 individual, it would depend on the clinical circumstances of 13 a case. Do I agree that individuals should receive 14 information and enlist the help of health care professionals 15 and consultative services on an as-needed basis? Yes, I 16 think that's generally good medical care, not only in 17 gender-affirming care, but -- but in many aspects of 18 medicine and surgery. 19 Q. This paragraph, though, is focused specifically on 20 informed consent for adolescents, right? 21 A. I don't know that it's specifically an informed 22 consent. I'm looking at, you know, one paragraph. I don't 23 know in which it's -- section of this document it's 24 contained. What the document says is that persons 25 considering hormone use need adequate information. I would	Page 53 1 balanced decision for surgical treatment? 2 A. And for what -- what type of -- is there a specific 3 treatment? 4 Q. Let's start with if I use the term "top surgery," 5 what does that term mean to you? 6 A. Most often that would refer -- to me, would refer 7 to mastectomy. It may have other connotations, but to me, 8 typically that would mean mastectomy. 9 Q. Okay. So what would be the types of information 10 that a patient should receive in order to make an informed 11 and balanced decision prior to receiving top surgery? 12 A. Well, so first and foremost, we would perform -- as 13 a surgeon, I would perform a history and physical exam. I 14 would listen to the goals and expectations of the 15 individual. Here I'll assume we're speaking about an 16 individual over the age of 18. Is that fair or...? 17 Q. Sure. 18 A. Okay. I would conduct a -- perform a physical 19 examination. I would discuss treatment options in a shared 20 decision-making manner with the individual. That shared 21 decision-making process involves me understanding the 22 individual's goals and expectations. It often involves the 23 use of decisional aids. That can be patient education -- 24 written patient education material, it can be representative 25 photographs. It would be a discussion of the risks of

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Page 54 1 surgery, the benefits of surgery, the options available, 2 which may include no surgical intervention. 3 And then encourage the individual to consider our 4 discussion, to discuss it with whomever is relevant in their 5 sphere in terms of their decision-making. Prior to 6 proceeding with surgery, as we've discussed, we would obtain 7 additional information in the form of an assessment from a 8 primary care professional and/or behavioral health and 9 mental health professional. 10 Q. And, Dr. Schechter, do the criteria that you have 11 just described that are a part of a patient making an 12 informed and balanced decision prior to top surgery, are 13 there any additional criteria you would add for an 14 individual under the age of 18 so that they make an informed 15 and balanced decision? 16 A. So that would incorporate or include the 17 individual's parents and/or guardians in -- in that process. 18 Q. Are there any other additional steps you might take 19 to ensure that an individual under the age of 18 is 20 adequately informed and has provided informed consent prior 21 to top surgery? 22 A. So that would -- again, it would depend upon the 23 individual circumstance, the base -- the assessments that I 24 received and a determination as to whether any additional 25 consultative services or referrals are required.	Page 56 1 and any particular form memorializes that discussion. So 2 many of these discussions are undertaken between -- with the 3 patient and their surgeon and then a consent form is signed 4 memorializing that discussion. 5 Q. And do you believe the informed-consent process 6 should advise the patient that the patient would lose the 7 ability to breast-feed if they receive a top surgery. 8 A. So that is a part -- removal of the mammary gland 9 removes the ability to breast-feed. As to the specific 10 discussion between the patient and the surgeon, I'm not 11 privileged to that. 12 In my particular practice, not only with 13 mastectomy, but with any surgery on the breast, cisgender or 14 transgender, there's typically a discussion of the inability 15 or the potential for loss of ability to breast-feed. So, 16 for example, that may also include a cisgender young 17 adolescent woman seeking a breast reduction for large -- 18 painful, large breasts, what we call symptomatic 19 macromastia, and so forth. 20 Q. And, Dr. Schechter, do you believe that a 21 14-year-old patient would have the capacity to consent to a 22 top surgery? 23 A. So that would depend on the clinical circumstances 24 in the individual patient. 25 Q. Case-by-case basis, in other words?
Page 55 1 Q. And do you have an opinion as to whether the 2 plaintiff C.P. was fully informed of different surgical 3 techniques available? 4 A. I've not reviewed the medical record. 5 Q. And do you have an opinion as to whether C.P. was 6 fully informed of the risks and complications associated 7 with top surgery? 8 A. Once again, I've not reviewed any of the medical 9 records, so I haven't seen any discussions between C.P. and 10 the surgeon or any of the other information contained 11 outside of the amended complaint and Dr. Ettner and 12 Karasic's reports. 13 Q. Dr. Schechter, is it your opinion that, when we 14 talk about a consent form -- let me back up. 15 Do you ask your patients to fill out a consent form 16 prior to undergoing top surgery? 17 A. So informed consent is -- is the process. There is 18 documentation memorializing that process. There may be 19 various consent forms that are signed that memorialize 20 typically the discussions that we've just referred to, 21 risks, benefits, options and so forth. 22 Q. And should a consent form for top surgery contain a 23 warning that the patient would lose the ability to 24 breast-feed? 25 A. Again, the process -- informed consent is a process	Page 57 1 A. It would be a case-by-case basis. 2 Q. Dr. Schechter, I am now going to show you what has 3 been marked as Defendant's Exhibit 4. 4 (Exhibit 4 marked.) 5 Q. (By Ms. Bedard) Can you see this exhibit? 6 A. Yeah, I can. I'm just trying to get my thumbnail 7 off the -- okay. 8 Q. Take your time. 9 A. Okay. 10 Q. Let me know if you'd like me to scroll down. 11 A. Okay. I see -- I see the document. 12 Q. Do you need me to scroll down so you can 13 familiarize yourself with the document? 14 A. Sure, sure. If you could just go down a bit more, 15 but I think -- okay. I think I'm familiar with this 16 document. 17 Q. What is this document? 18 A. Can you go back -- well, it's -- the subject says, 19 "Final Decision Memorandum on Gender Reassignment Surgery 20 for Medicare Beneficiaries with Gender Dysphoria." 21 Q. And have you seen this document before today? 22 A. I believe so, or a version of it, yes. 23 Q. On Page 49 of this document, do you see the first 24 paragraph beginning with "currently"? 25 A. Yes.

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Page 58 1 Q. Could you read me that paragraph, please? 2 A. "Currently, the local Medicare Administrative 3 Contractors determine coverage of gender reassignment 4 surgery on a case-by-case basis. We have received a 5 complete, formal request to make a national coverage 6 determination on surgical remedies for gender identity 7 disorder, parentheses, (GID), now known as gender dysphoria. 8 The Centers for Medicare and Medicaid Services, parentheses, 9 (CMS), is not issuing a national coverage determination, 10 parentheses, (NCD), at this time on gender reassignment 11 surgery for Medicare beneficiaries with gender dysphoria 12 because the clinical evidence is inconclusive for the 13 Medicare population." 14 Q. So, Dr. Schechter, CMS in 2016 made a determination 15 not to issue a national coverage determination because the 16 clinical evidence was inconclusive to the Medicare 17 population, right? 18 A. To the Medicare population, that is correct. 19 Q. And I'm going to turn now to Page 46 of that 20 decision memo. 21 And on Page 46, do you see the paragraph beginning 22 with, "Of the 33 studies reviewed"? 23 A. Yes. 24 Q. Could you read me that paragraph as well, please? 25 A. Sure. Hold on. Just trying to move this	Page 60 1 So in this CMS decision memo, they indicated that 2 CMS reviewed 33 studies, right? 3 A. Yes. 4 Q. And CMS determined that the published results of 5 those studies were conflicting; that some were positive and 6 some were negative, right? 7 A. Yes. So Medicare looked at -- or CMS looked at the 8 data with regard to the Medicare population, and as we know, 9 it wasn't until 2014 when Medicare removed their 10 across-the-board ban on gender affirm- -- on reimbursement 11 for gender-affirming surgeries. So the issue that evidence 12 is limited is not surprising when people have been denied 13 medically necessary care. That's one issue. 14 Also our issue or our indication for surgery is for 15 the medical condition of gender incongruence or gender 16 dysphoria. So while psychometric studies may be one 17 assessment or one review, in most of the studies, the 18 overwhelming majority of the studies demonstrate improvement 19 in health outcomes. This does not speak to the primary 20 indication for surgery, which is treatment of gender 21 incongruence or gender dysphoria. 22 Q. And why -- why is that? Why does it not speak to 23 the provision of treatment for gender incongruence or gender 24 dysphoria? 25 A. It does not specifically indicate that it
Page 59 1 thumbnail. Hold on. 2 "Of the 33 studies reviewed, published results were 3 conflicting - some were positive; others were negative. 4 Collectively, the evidence is inconclusive for the Medicare 5 population. The majority of studies were nonlongitudinal 6 exploratory-type studies, parentheses, (i.e., in a 7 preliminary state of investigation or hypothesis 8 generating), or did not conclude concurrent controls or 9 testing prior to and after surgery. Several reported 10 positive results, but the potential issues noted above 11 reduced strength and confidence. After careful assessment, 12 we identified six studies that could provide useful 13 information, parentheses, (Figure 1). Of these, the four 14 best designed and conducted studies that assessed quality of 15 life before and after surgery using validated, parentheses, 16 (albeit non-specific) psychometric studies did not 17 demonstrate clinically significant changes or differences in 18 psychometric test results after GRS." 19 My thumbnail's right at the bottom. Can you just 20 scroll -- scroll up a little if you need me to read those 21 references? Thanks. 22 "Parentheses, Heylens, et al., 2014; Ruppin, 23 Pfafflin, 2015; Smith, et al., 2005; Udeze, et al., 2008, 24 parentheses, (Appendix C, Panel A and Appendix G)." 25 Q. Thank you, Dr. Schechter.	Page 61 1 evaluates -- that this -- the 33 studies who look at 2 gender -- I'm sorry. I'm getting an echo again. 3 MS. BEDARD: I am too. 4 MR. GONZALEZ-PAGAN: It might be me -- 5 MS. BEDARD: Okay. 6 MR. GONZALEZ-PAGAN: -- it gave me a warning 7 slow resources, I'll mute. 8 MS. BEDARD: I think it's yours. 9 THE WITNESS: This paragraph looks at 10 psychometric studies, does not look at the effect on gender 11 incongruence specifically, the alignment of one's body with 12 their identity. 13 Q. (By Ms. Bedard) And what is your response, 14 Dr. Schechter, to this decision memo? 15 A. Well, first of all, in plastic surgery, most of the 16 surgeries we performed do not have a national coverage 17 determination. So once again, it's completely unsurprising 18 to me because most often patients, upon -- who we -- 19 patients who we care for aren't or have conditions that 20 aren't covered under national coverage determination, so 21 this is very much consistent with the overall practice of 22 plastic surgery. 23 Q. And do you reference this decision memo in your 24 expert report in this case? 25 A. I do not believe so.

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Page 62 1 Q. And why not? 2 A. Well, as I just said, because it's entirely 3 unsurprising and consistent with plastic surgery in general. 4 Most of our procedures don't have national coverage 5 determinations, so it's really the norm. 6 Q. And, Dr. Schechter, are you aware that in 2020, the 7 Council for Choices in Health Care in Finland, which I 8 understand is known as COHERE Finland -- are you aware that 9 they adopted a recommendation on medical treatment methods 10 for gender dysphoria in minors? 11 A. I've heard of -- of treatments or -- or treatment 12 policies in Finland. 13 Q. Have you reviewed any of those treatment policies 14 prior to today? 15 A. I have never received a full translated copy of the 16 decision for their policy. 17 Q. And Dr. Schechter, are you aware that in 2021, 18 Sweden's largest adolescent gender clinic announced that it 19 was no longer going to prescribe puberty blockers or 20 hormones to youths under 18 outside of clinical trials? 21 A. I've heard of issues in Sweden at -- at one 22 hospital, yes. Again, I haven't seen the full translated 23 policy. 24 Q. Dr. Schechter, I'm going to show you what has been 25 marked as Defendant's Exhibit 6.	Page 64 1 Internet is cutting out a little bit. Is that anyone else? 2 MR. GONZALEZ-PAGAN: Yeah, I've been -- it's 3 coming in and out for me too. 4 THE WITNESS: Okay. Should I start from the 5 beginning or would you like me to start? 6 MR. GONZALEZ-PAGAN: I'll leave it to 7 Stephanie. 8 Q. (By Ms. Bedard) Dr. Schechter, are you still 9 receiving a message that your WiFi connection is weak? 10 A. No, I'm back. Can you hear me? 11 Q. Yes. 12 A. Okay. 13 Q. Yes. We did have some breakup in your feed there, 14 so if you could start over, that would be great, and also if 15 you see that message in the future, just flag us down and 16 let us know and we'll -- we'll work on a solution. 17 A. Great. 18 "In December 2019, the SBU, parentheses, (Swedish 19 Agency for Health Technology Assessment and Assessment of 20 Social Services) published an overview of the knowledge base 21 which showed a lack of evidence for both the long-term 22 consequences of the treatments and the reasons for the large 23 influx of patients in recent years. 24 "In October 2020, NICE, parentheses, (The National 25 Institute for Health and Care Excellence UK), also performed
Page 63 1 (Exhibit 6 marked.) 2 THE WITNESS: Okay. 3 Q. (By Ms. Bedard) Would you like me to scroll down? 4 A. Please. Okay. And can you just go back up to the 5 top, if you... Okay. 6 Q. Are you familiar with the Astrid Lindgren 7 Children's Hospital? 8 A. Only in name. 9 Q. And could you read the second paragraph for me, 10 please, beginning with, "In December 2019"? 11 A. "In December 2019, the SBU (Swedish Agency for 12 Health Technology Assessment and Assessment of Social 13 Services) published an over"-- overview -- I'm sorry. I'm 14 getting an unstable internet. 15 "...published an overview of the knowledge base 16 which showed a lack of evidence for both the long-term 17 consequences of the treatments and the reasons for the large 18 influx of patients in recent years. In October of 2020, 19 NICE, parentheses, (The National Institute for Health and 20 Care Excellence, UK)" -- excuse me -- "also performed an 21 evidence review of GnRHa, parentheses, (puberty blocker) and 22 of cross-sex hormone treatments of children and adolescents 23 with gender dysphoria. Taken together, they show that the 24 studies conducted are small, uncontrolled observational" -- 25 THE COURT REPORTER: Sorry, sir. Your	Page 65 1 an evidence review of GnRHa, parentheses, (puberty blocker) 2 and of cross-sex hormone treatments of children and 3 adolescents with gender dysphoria. 4 "Taken together, they show that the studies 5 conducted to date are small, uncontrolled observational 6 studies providing low quality evidence that the treatments 7 have the desired effect and that we have very little 8 knowledge about their safety in the long-term." 9 Q. Dr. Schechter, are you familiar with either of the 10 publications referenced in this paragraph namely, the 2019 11 Swedish Agency for Health Technology Assessment and 12 Assessment of Social Services Overview and the October 2020 13 National Institute for Health and Care Excellence Evidence 14 Review? 15 MR. GONZALEZ-PAGAN: Objection; form. 16 THE WITNESS: I have seen the -- I believe 17 the 2020 NICE. I don't believe I've seen the SBU report. 18 Q. (By Ms. Bedard) Would you agree that the 2020 NICE 19 report demonstrates that there is little knowledge about the 20 safety of these treatments in the long-term? 21 A. So by "these treatments," this seems to refer to 22 GnRH analogs and pubertal blockers. Again, I don't 23 prescribe those and so I wouldn't necessarily agree with 24 that statement. 25 Q. You would not agree or disagree with that statement

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Page 66 1 because you do not prescribe puberty blockers, right? 2 A. I do not prescribe puberty blockers. You know, my 3 area of expertise, again, is -- is in surgery, and, of 4 course, while I work with pediatricians, child and 5 adolescent psychiatrists and psychologists and social 6 workers, my opinions here focus on surgery. 7 Q. Dr. Schechter, why don't we take another quick 8 break, we're at the hour mark again. 9 A. Okay. 10 Q. It is 32 now. Why don't we come back in 10 minutes 11 at 42? 12 A. Great. 13 Q. Okay. 14 MS. BEDARD: Thank you, everyone. Off the 15 record. 16 THE VIDEOGRAPHER: We're now going off the 17 record. The time is 11:32 a.m. 18 (Recess taken from 11:32 to 11:43 a.m.) 19 THE VIDEOGRAPHER: We're now back on the 20 record. The time is 11:43 a.m. 21 22 EXAMINATION - (Continuing) 23 BY MS. BEDARD: 24 Q. Dr. Schechter, are you aware of who Dr. Hilary Cass 25 is?	Page 68 1 Q. Could you read that paragraph for me, please. 2 A. "Following a review of available literature, 3 clinical guidelines, and coverage by other insurers and 4 nations, Florida Medicaid has determined that the research 5 supporting sex reassignment treatment is insufficient to 6 demonstrate efficacy and safety. In addition, numerous 7 studies, including the reports provided by the clinical and 8 technical experts listed above" -- "listed above identify 9 poor methods and the certainty of irreversible physical 10 changes. 11 "Considering the weak evidence supporting the use 12 of puberty suppression, cross-sex hormones and surgical 13 procedures when compared to the stronger research 14 demonstrating the permanent effects they cause, these 15 treatments do not conform to the GAPMS and are experimental 16 and investigational." 17 Q. Dr. Schechter, what is your response to the 18 statement you just read in this report? 19 A. I completely disagree with it, but can I ask you to 20 scroll up because I'd like to see who the authors or 21 consultants are. 22 Q. Yes. 23 A. Okay. I'm sorry. So let's -- okay. Can we scroll 24 down? Okay. Keep going. 25 Q. Okay.
Page 67 1 A. No. 2 Q. Are you aware of an interim report prepared in 3 February of this year concerning a review of gender identity 4 services for children in the UK? 5 A. No. 6 Q. And, Dr. Schechter, are you aware that in June of 7 this year, June 2022, Florida Medicaid services released a 8 report on gender dysphoria? 9 A. I'm aware of issues regarding gender-affirming 10 treatment in Florida. I don't recall if it was Medicaid or 11 what agency released it. 12 Q. Dr. Schechter, I'm going to show you what has been 13 marked as Defendant's Exhibit 8. 14 (Exhibit 8 marked.) 15 Q. (By Ms. Bedard) Can you see that document? 16 A. Yes, I can. 17 Q. And what is the title of that document? 18 A. Florida Medicaid Generally Accepted Professional 19 Medical Standards Determination on the Treatment of Gender 20 Dysphoria dated June of 2022. 21 Q. Have you reviewed this document before today? 22 A. No. 23 Q. Do you see the paragraph beginning with, "Following 24 a review"? 25 A. Yes.	Page 69 1 A. Hold on. Let's see. Okay. Well, I see one 2 attachment from a Dr. Lappert, who I don't consider in any 3 way to be able to provide an expert opinion on 4 gender-affirming surgery. He's nonboarded in plastic 5 surgery. To my knowledge, he does not have hospital 6 privileges and I'm not sure that he even performs surgery at 7 this point. To my knowledge, he has no presentations or 8 publications in peer-reviewed medical journals. I've never 9 encountered him at any -- nor is he a member of any 10 professional surgical organizations that are widely 11 accepted. I've never heard him speak outside of what I 12 believe are theologic discussions regarding gender-affirming 13 surgery. 14 So if they're basing their decision on an expert 15 report by Dr. Lappert, I don't put much stock in this at 16 all. 17 Q. And you do not reference this 2022 Florida Medicaid 18 report in your expert report, correct? 19 A. Based on what I just said, I don't think it's 20 worthwhile to reference in my report. I think this holds no 21 value. 22 Q. Dr. Schechter, today we took a couple of breaks. 23 Did you review any documents today during any break? 24 A. No. 25 Q. And did you speak with anyone during any of the

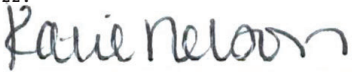
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Page 70 1 breaks that we took today? 2 A. No. 3 Q. Did you e-mail or message with anyone during any of 4 the breaks? 5 A. No. I received a text from our fellow and PA 6 regarding a clinical situation, but nothing regarding this 7 case. 8 Q. Not related to this case? 9 A. Nothing related to this case. 10 Q. And is there anything you'd like to clarify in your 11 testimony today? 12 A. I don't believe so. 13 Q. Okay. I have no further questions. Dr. Schechter, 14 thank you for your time. 15 A. Thank you very much. 16 MR. GONZALEZ-PAGAN: Thank you. 17 Dr. Schechter, I may -- I just have two quick questions. 18 19 EXAMINATION 20 BY MR. GONZALEZ-PAGAN: 21 Q. At the beginning of the -- your deposition, do you 22 recall discussing the cases listed on Paragraph 18 of your 23 report in which you have provided deposition or trial 24 testimony? 25 A. I do.	Page 72 1 FURTHER EXAMINATION 2 BY MS. BEDARD: 3 Q. Dr. Schechter, I'm going to show you Defendant's 4 Exhibit 2, which is your expert report. 5 Can you see that report? 6 A. I can. 7 Q. And counsel for plaintiffs helpfully clarified that 8 you -- you provided testimony today indicating that the -- 9 five of the six cases listed here are the only cases in 10 which you have provided an expert opinion related to the 11 treatment of gender dysphoria in the past four years, 12 correct? 13 A. That is correct. 14 Q. Are there other cases earlier than the past four 15 years in which you provided expert testimony regarding 16 treatment for gender dysphoria? 17 A. Yes. 18 Q. Do you recall the names of those cases? 19 A. There was a case in Massachusetts, an inmate by the 20 last name of Kosilek -- K-O-S, I believe, I-L-E-K. That's 21 going back, oh, probably 15 years or so. I don't remember 22 specifically. That's all I can recall. It's possible there 23 may have been one other, but I can't recall anything else. 24 Q. So as far as you can recall, Dr. Schechter, in 25 addition to the case you just described, the Kosilek case
Page 71 1 Q. Okay. And at some point, counsel asked you if 2 these were the only cases you have provided expert testimony 3 regarding gender-affirming care. 4 Do you recall that? 5 A. Yes. 6 Q. Okay. I just want to clarify: Is that pertaining 7 to the last four years or overall? 8 A. Last four years. 9 Q. Thank you. 10 Dr. Schechter, you were asked some questions about 11 providing informed consent and discussing the inability to 12 breast-feed with regards to top surgery. 13 Do you recall that discussion? 14 A. I do. 15 Q. Okay. Does an informed consent form need to 16 explicitly list the inability to breast-feed as a 17 consequence of top surgery in order for informed consent to 18 have occurred in a particular case? 19 A. No. I don't believe so. 20 MR. GONZALEZ-PAGAN: Those are all the 21 questions. Thank you, Dr. Schechter. 22 MS. BEDARD: Dr. Schechter, I do have a 23 follow-up question related to a question that 24 Mr. Gonzales-Pagan asked you about -- about your expert 25 report so let's turn back to that.	Page 73 1 from about 15 years ago, and then the five cases listed in 2 your expert report from the past four years, are those the 3 totality of the cases in which you have provided an expert 4 opinion in a case relating to treatment for gender 5 dysphoria? 6 A. That is correct. 7 Q. And are there any cases -- not just from the past 8 four years, but throughout the course of your practice where 9 you have provided an opinion as a treating physician related 10 to treatment for gender dysphoria? 11 A. I have served as an expert for both defense and 12 plaintiff in -- and plaintiffs in the clinical -- in the 13 surgical treatment of gender dysphoria. I don't believe 14 that I've ever been deposed in any of those cases. 15 Q. Well, I guess I'm trying to ask a different 16 question, probably inartfully. 17 So I'm drawing a distinction between when you 18 appear in a case in an expert capacity, when you've been 19 retained as an expert, and then when you -- you were a 20 treating surgeon for a patient and you provided surgical 21 treatment to a patient and then were deposed in a case 22 related to that treatment. 23 Have you ever been deposed in a case related to 24 surgical treatment you provided for a patient related to 25 gender dysphoria?

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1 A. I don't believe so. Not that I can recall. 2 Q. Thank you, Dr. Schechter. I have no further 3 questions. 4 A. Thank you. 5 MR. GONZALEZ-PAGAN: Thank you. 6 THE VIDEOGRAPHER: All right. This concludes 7 the videotape deposition of Loren S. Schechter. 8 We're now going off the record. The time is 9 11:55 a.m. 10 (Signature was reserved.) 11 (Deposition concluded at 11:55 a.m.)	1 Nelson Court Reporters, Inc. 2 6513 132nd Avenue NE, #184 3 Kirkland, Washington 98033 4 production@nelsonreporters.com 5 www.nelsonreporters.com 6 August 11, 2022 7 To: OMAR GONZALEZ-PAGAN 8 LAMBDA LEGAL DEFENSE AND EDUCATION FUND, INC. 9 120 Wall Street, 19th Floor 10 New York, New York 10005-3919 11 ogonzalez-pagan@lamdalegal.org 12 Re: C.P. v. Blue Cross Blue Shield 13 Deposition of: LOREN S. SCHECHTER, M.D. 14 Date Taken: August 2, 2022 15 Cause No.: 3:20-cv-06145-RJB 16 Enclosed are the Correction & Signature page. 17 Instruct the deponent to review the deposition, record any 18 corrections on the Correction page, and sign it. 19 The above referenced transcript must be read and 20 the Correction & Signature page signed within 30 days of 21 this notice or before the trial date, whichever occurs 22 first. 23 If the Correction & Signature page are not signed 24 within that time period, signature will be deemed waived for 25 all purposes. After the Correction & Signature page are signed, please forward to: Nelson Court Reporters Production Department production@nelsonreporters.com Thank you, Katie J. Nelson, RPR, CCR CCR No. 2971																																																									
Page 75 1 REPORTER'S CERTIFICATE 2 3 I, KATIE J. NELSON, the undersigned Certified Court 4 Reporter, pursuant to RCW 5.28.010 authorized to administer 5 oaths and affirmations in and for the State of Washington, 6 do hereby certify that the sworn testimony and/or 7 proceedings, a transcript of which is attached, was given 8 before me at the time and place stated therein; that any 9 and/or all witness(es) were duly sworn to testify to the 10 truth; that the sworn testimony and/or proceedings were by 11 me stenographically recorded and transcribed under my 12 supervision, to the best of my ability; that the foregoing 13 transcript contains a full, true, and accurate record of all 14 the sworn testimony and/or proceedings given and occurring 15 at the time and place stated in the transcript; that a 16 review of which was requested; that I am in no way related 17 to any party to the matter, nor to any counsel, nor do I 18 have any financial interest in the event of the cause. 19 WITNESS MY HAND and SIGNATURE this 11th day of 20 August, 2022. 21  22 23 KATIE J. NELSON, RPR, CCR 24 Washington Certified Court Reporter, CCR 2971 25	Page 77 1 CORRECTION & SIGNATURE PAGE 2 Re: C.P. v. Blue Cross Blue Shield 3 Deposition of: LOREN S. SCHECHTER, M.D. 4 Date Taken: August 2, 2022 5 Cause No.: 3:20-cv-06145-RJB 6 I, LOREN S. SCHECHTER, M.D., have read the within 7 transcript taken August 2, 2022, and the same is true and 8 accurate, except for any changes and/or corrections, if 9 any, as follows: <table border="1"> <thead> <tr> <th>PAGE/LINE</th> <th>CORRECTION</th> <th>REASON</th> </tr> </thead> <tbody> <tr><td>8</td><td></td><td></td></tr> <tr><td>9</td><td></td><td></td></tr> <tr><td>10</td><td></td><td></td></tr> <tr><td>11</td><td></td><td></td></tr> <tr><td>12</td><td></td><td></td></tr> <tr><td>13</td><td></td><td></td></tr> <tr><td>14</td><td></td><td></td></tr> <tr><td>15</td><td></td><td></td></tr> <tr><td>16</td><td></td><td></td></tr> <tr><td>17</td><td></td><td></td></tr> <tr><td>18</td><td></td><td></td></tr> <tr><td>19</td><td></td><td></td></tr> <tr><td>20</td><td></td><td></td></tr> <tr><td>21</td><td></td><td></td></tr> <tr><td>22</td><td></td><td></td></tr> <tr><td>23</td><td></td><td></td></tr> <tr><td>24</td><td></td><td></td></tr> <tr><td>25</td><td></td><td></td></tr> </tbody> </table> Signed at _____, on this date: _____. LOREN S. SCHECHTER, M.D.	PAGE/LINE	CORRECTION	REASON	8			9			10			11			12			13			14			15			16			17			18			19			20			21			22			23			24			25		
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EXHIBIT L

Endocrine Treatment of Gender-Dysphoric/ Gender-Incongruent Persons: An Endocrine Society* Clinical Practice Guideline

Wylie C. Hembree,¹ Peggy T. Cohen-Kettenis,² Louis Gooren,³ Sabine E. Hannema,⁴ Walter J. Meyer,⁵ M. Hassan Murad,⁶ Stephen M. Rosenthal,⁷ Joshua D. Safer,⁸ Vin Tangpricha,⁹ and Guy G. T'Sjoen¹⁰

¹New York Presbyterian Hospital, Columbia University Medical Center, New York, New York 10032 (Retired); ²VU University Medical Center, 1007 MB Amsterdam, Netherlands (Retired); ³VU University Medical Center, 1007 MB Amsterdam, Netherlands (Retired); ⁴Leiden University Medical Center, 2300 RC Leiden, Netherlands; ⁵University of Texas Medical Branch, Galveston, Texas 77555; ⁶Mayo Clinic Evidence-Based Practice Center, Rochester, Minnesota 55905; ⁷University of California San Francisco, Benioff Children's Hospital, San Francisco, California 94143; ⁸Boston University School of Medicine, Boston, Massachusetts 02118; ⁹Emory University School of Medicine and the Atlanta VA Medical Center, Atlanta, Georgia 30322; and ¹⁰Ghent University Hospital, 9000 Ghent, Belgium

***Cosponsoring Associations:** American Association of Clinical Endocrinologists, American Society of Andrology, European Society for Pediatric Endocrinology, European Society of Endocrinology, Pediatric Endocrine Society, and World Professional Association for Transgender Health.

Objective: To update the "Endocrine Treatment of Transsexual Persons: An Endocrine Society Clinical Practice Guideline," published by the Endocrine Society in 2009.

Participants: The participants include an Endocrine Society-appointed task force of nine experts, a methodologist, and a medical writer.

Evidence: This evidence-based guideline was developed using the Grading of Recommendations, Assessment, Development, and Evaluation approach to describe the strength of recommendations and the quality of evidence. The task force commissioned two systematic reviews and used the best available evidence from other published systematic reviews and individual studies.

Consensus Process: Group meetings, conference calls, and e-mail communications enabled consensus. Endocrine Society committees, members and cosponsoring organizations reviewed and commented on preliminary drafts of the guidelines.

Conclusion: Gender affirmation is multidisciplinary treatment in which endocrinologists play an important role. Gender-dysphoric/gender-incongruent persons seek and/or are referred to endocrinologists to develop the physical characteristics of the affirmed gender. They require a safe and effective hormone regimen that will (1) suppress endogenous sex hormone secretion determined by the person's genetic/gonadal sex and (2) maintain sex hormone levels within the normal range for the person's affirmed gender. Hormone treatment is not recommended for prepubertal gender-dysphoric/gender-incongruent persons. Those clinicians who recommend gender-affirming endocrine treatments—appropriately trained diagnosing clinicians (required), a mental health provider for adolescents (required) and mental health

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Abbreviations: BMD, bone mineral density; DSD, disorder/difference of sex development; DSM, Diagnostic and Statistical Manual of Mental Disorders; GD, gender dysphoria; GnRH, gonadotropin-releasing hormone; ICD, International Statistical Classification of Diseases and Related Health Problems; MHP, mental health professional; VTE, venous thromboembolism.

professional for adults (recommended)—should be knowledgeable about the diagnostic criteria and criteria for gender-affirming treatment, have sufficient training and experience in assessing psychopathology, and be willing to participate in the ongoing care throughout the endocrine transition. We recommend treating gender-dysphoric/gender-incongruent adolescents who have entered puberty at Tanner Stage G2/B2 by suppression with gonadotropin-releasing hormone agonists. Clinicians may add gender-affirming hormones after a multidisciplinary team has confirmed the persistence of gender dysphoria/gender incongruence and sufficient mental capacity to give informed consent to this partially irreversible treatment. Most adolescents have this capacity by age 16 years old. We recognize that there may be compelling reasons to initiate sex hormone treatment prior to age 16 years, although there is minimal published experience treating prior to 13.5 to 14 years of age. For the care of peripubertal youths and older adolescents, we recommend that an expert multidisciplinary team comprised of medical professionals and mental health professionals manage this treatment. The treating physician must confirm the criteria for treatment used by the referring mental health practitioner and collaborate with them in decisions about gender-affirming surgery in older adolescents. For adult gender-dysphoric/gender-incongruent persons, the treating clinicians (collectively) should have expertise in transgender-specific diagnostic criteria, mental health, primary care, hormone treatment, and surgery, as needed by the patient. We suggest maintaining physiologic levels of gender-appropriate hormones and monitoring for known risks and complications. When high doses of sex steroids are required to suppress endogenous sex steroids and/or in advanced age, clinicians may consider surgically removing natal gonads along with reducing sex steroid treatment. Clinicians should monitor both transgender males (female to male) and transgender females (male to female) for reproductive organ cancer risk when surgical removal is incomplete. Additionally, clinicians should persistently monitor adverse effects of sex steroids. For gender-affirming surgeries in adults, the treating physician must collaborate with and confirm the criteria for treatment used by the referring physician. Clinicians should avoid harming individuals (via hormone treatment) who have conditions other than gender dysphoria/gender incongruence and who may not benefit from the physical changes associated with this treatment. (*J Clin Endocrinol Metab* 102: 3869–3903, 2017)

Summary of Recommendations

1.0 Evaluation of youth and adults

- 1.1. We advise that only trained mental health professionals (MHPs) who meet the following criteria should diagnose gender dysphoria (GD)/gender incongruence in adults: (1) competence in using the Diagnostic and Statistical Manual of Mental Disorders (DSM) and/or the International Statistical Classification of Diseases and Related Health Problems (ICD) for diagnostic purposes, (2) the ability to diagnose GD/gender incongruence and make a distinction between GD/gender incongruence and conditions that have similar features (e.g., body dysmorphic disorder), (3) training in diagnosing psychiatric conditions, (4) the ability to undertake or refer for appropriate treatment, (5) the ability to psychosocially assess the person's understanding, mental health, and social conditions that can impact gender-affirming hormone therapy, and (6) a practice of regularly attending relevant professional meetings. (Ungraded Good Practice Statement)
- 1.2. We advise that only MHPs who meet the following criteria should diagnose GD/gender incongruence in children and adolescents: (1) training in child and adolescent developmental psychology and psychopathology, (2) competence in using the DSM and/or the ICD for diagnostic purposes, (3) the ability to make a distinction between GD/gender incongruence and conditions that have similar features (e.g., body dysmorphic disorder), (4) training in diagnosing psychiatric conditions, (5) the ability to undertake or refer for appropriate treatment, (6) the ability to psychosocially assess the person's understanding and social conditions that can impact gender-affirming hormone therapy, (7) a practice of regularly attending relevant professional meetings, and (8) knowledge of the criteria for puberty blocking and gender-affirming hormone treatment in adolescents. (Ungraded Good Practice Statement)
- 1.3. We advise that decisions regarding the social transition of prepubertal youths with GD/gender incongruence are made with the assistance of an MHP or another experienced professional. (Ungraded Good Practice Statement).

- 1.4. We recommend against puberty blocking and gender-affirming hormone treatment in pre-pubertal children with GD/gender incongruence. (1 ⊕⊕○○)
- 1.5. We recommend that clinicians inform and counsel all individuals seeking gender-affirming medical treatment regarding options for fertility preservation prior to initiating puberty suppression in adolescents and prior to treating with hormonal therapy of the affirmed gender in both adolescents and adults. (1 ⊕⊕⊕○)

2.0 Treatment of adolescents

- 2.1. We suggest that adolescents who meet diagnostic criteria for GD/gender incongruence, fulfill criteria for treatment, and are requesting treatment should initially undergo treatment to suppress pubertal development. (2 ⊕⊕○○)
- 2.2. We suggest that clinicians begin pubertal hormone suppression after girls and boys first exhibit physical changes of puberty. (2 ⊕⊕○○)
- 2.3. We recommend that, where indicated, GnRH analogues are used to suppress pubertal hormones. (1 ⊕⊕○○)
- 2.4. In adolescents who request sex hormone treatment (given this is a partly irreversible treatment), we recommend initiating treatment using a gradually increasing dose schedule after a multidisciplinary team of medical and MHPs has confirmed the persistence of GD/gender incongruence and sufficient mental capacity to give informed consent, which most adolescents have by age 16 years. (1 ⊕⊕○○).
- 2.5. We recognize that there may be compelling reasons to initiate sex hormone treatment prior to the age of 16 years in some adolescents with GD/gender incongruence, even though there are minimal published studies of gender-affirming hormone treatments administered before age 13.5 to 14 years. As with the care of adolescents ≥16 years of age, we recommend that an expert multidisciplinary team of medical and MHPs manage this treatment. (1 ⊕○○○)
- 2.6. We suggest monitoring clinical pubertal development every 3 to 6 months and laboratory parameters every 6 to 12 months during sex hormone treatment. (2 ⊕⊕○○)

3.0 Hormonal therapy for transgender adults

- 3.1. We recommend that clinicians confirm the diagnostic criteria of GD/gender incongruence and

- the criteria for the endocrine phase of gender transition before beginning treatment. (1 ⊕⊕⊕○)
- 3.2. We recommend that clinicians evaluate and address medical conditions that can be exacerbated by hormone depletion and treatment with sex hormones of the affirmed gender before beginning treatment. (1 ⊕⊕⊕○)
- 3.3. We suggest that clinicians measure hormone levels during treatment to ensure that endogenous sex steroids are suppressed and administered sex steroids are maintained in the normal physiologic range for the affirmed gender. (2 ⊕⊕○○)
- 3.4. We suggest that endocrinologists provide education to transgender individuals undergoing treatment about the onset and time course of physical changes induced by sex hormone treatment. (2 ⊕○○○)

4.0 Adverse outcome prevention and long-term care

- 4.1. We suggest regular clinical evaluation for physical changes and potential adverse changes in response to sex steroid hormones and laboratory monitoring of sex steroid hormone levels every 3 months during the first year of hormone therapy for transgender males and females and then once or twice yearly. (2 ⊕⊕○○)
- 4.2. We suggest periodically monitoring prolactin levels in transgender females treated with estrogens. (2 ⊕⊕○○)
- 4.3. We suggest that clinicians evaluate transgender persons treated with hormones for cardiovascular risk factors using fasting lipid profiles, diabetes screening, and/or other diagnostic tools. (2 ⊕⊕○○)
- 4.4. We recommend that clinicians obtain bone mineral density (BMD) measurements when risk factors for osteoporosis exist, specifically in those who stop sex hormone therapy after gonadectomy. (1 ⊕⊕○○)
- 4.5. We suggest that transgender females with no known increased risk of breast cancer follow breast-screening guidelines recommended for non-transgender females. (2 ⊕⊕○○)
- 4.6. We suggest that transgender females treated with estrogens follow individualized screening according to personal risk for prostatic disease and prostate cancer. (2 ⊕○○○)
- 4.7. We advise that clinicians determine the medical necessity of including a total hysterectomy and oophorectomy as part of gender-affirming surgery. (Ungraded Good Practice Statement)

5.0 Surgery for sex reassignment and gender confirmation

- 5.1. We recommend that a patient pursue genital gender-affirming surgery only after the MHP and the clinician responsible for endocrine transition therapy both agree that surgery is medically necessary and would benefit the patient's overall health and/or well-being. (1 ⊕⊕○○)
- 5.2. We advise that clinicians approve genital gender-affirming surgery only after completion of at least 1 year of consistent and compliant hormone treatment, unless hormone therapy is not desired or medically contraindicated. (Ungraded Good Practice Statement)
- 5.3. We advise that the clinician responsible for endocrine treatment and the primary care provider ensure appropriate medical clearance of transgender individuals for genital gender-affirming surgery and collaborate with the surgeon regarding hormone use during and after surgery. (Ungraded Good Practice Statement)
- 5.4. We recommend that clinicians refer hormone-treated transgender individuals for genital surgery when: (1) the individual has had a satisfactory social role change, (2) the individual is satisfied about the hormonal effects, and (3) the individual desires definitive surgical changes. (1 ⊕○○○)
- 5.5. We suggest that clinicians delay gender-affirming genital surgery involving gonadectomy and/or hysterectomy until the patient is at least 18 years old or legal age of majority in his or her country. (2 ⊕⊕○○)
- 5.6. We suggest that clinicians determine the timing of breast surgery for transgender males based upon the physical and mental health status of the individual. There is insufficient evidence to recommend a specific age requirement. (2 ⊕○○○)

Changes Since the Previous Guideline

Both the current guideline and the one published in 2009 contain similar sections. Listed here are the sections contained in the current guideline and the corresponding number of recommendations: Introduction, Evaluation of Youth and Adults (5), Treatment of Adolescents (6), Hormonal Therapy for Transgender Adults (4), Adverse Outcomes Prevention and Long-term Care (7), and Surgery for Sex Reassignment and Gender Confirmation (6). The current introduction updates the diagnostic classification of “gender dysphoria/gender incongruence.” It also reviews the development of “gender identity” and summarizes its natural development. The section on

clinical evaluation of both youth and adults, defines in detail the professional qualifications required of those who diagnose and treat both adolescents and adults. We advise that decisions regarding the social transition of prepubertal youth are made with the assistance of a mental health professional or similarly experienced professional. We recommend against puberty blocking followed by gender-affirming hormone treatment of prepubertal children. Clinicians should inform pubertal children, adolescents, and adults seeking gender-confirming treatment of their options for fertility preservation. Prior to treatment, clinicians should evaluate the presence of medical conditions that may be worsened by hormone depletion and/or treatment. A multidisciplinary team, preferably composed of medical and mental health professionals, should monitor treatments. Clinicians evaluating transgender adults for endocrine treatment should confirm the diagnosis of persistent gender dysphoria/gender incongruence. Physicians should educate transgender persons regarding the time course of steroid-induced physical changes. Treatment should include periodic monitoring of hormone levels and metabolic parameters, as well as assessments of bone density and the impact upon prostate, gonads, and uterus. We also make recommendations for transgender persons who plan genital gender-affirming surgery.

Method of Development of Evidence-Based Clinical Practice Guidelines

The Clinical Guidelines Subcommittee (CGS) of the Endocrine Society deemed the diagnosis and treatment of individuals with GD/gender incongruence a priority area for revision and appointed a task force to formulate evidence-based recommendations. The task force followed the approach recommended by the Grading of Recommendations, Assessment, Development, and Evaluation group, an international group with expertise in the development and implementation of evidence-based guidelines (1). A detailed description of the grading scheme has been published elsewhere (2). The task force used the best available research evidence to develop the recommendations. The task force also used consistent language and graphical descriptions of both the strength of a recommendation and the quality of evidence. In terms of the strength of the recommendation, strong recommendations use the phrase “we recommend” and the number 1, and weak recommendations use the phrase “we suggest” and the number 2. Cross-filled circles indicate the quality of the evidence, such that ⊕○○○ denotes very low-quality evidence; ⊕⊕○○, low quality; ⊕⊕⊕○, moderate quality; and ⊕⊕⊕⊕, high quality. The task force has confidence that persons who receive care according to the strong recommendations will derive, on average, more benefit than harm. Weak recommendations require more careful consideration of the person's circumstances, values, and preferences to determine the best course of action. Linked to each recommendation is a description of the evidence and the

values that the task force considered in making the recommendation. In some instances, there are remarks in which the task force offers technical suggestions for testing conditions, dosing, and monitoring. These technical comments reflect the best available evidence applied to a typical person being treated. Often this evidence comes from the unsystematic observations of the task force and their preferences; therefore, one should consider these remarks as suggestions.

In this guideline, the task force made several statements to emphasize the importance of shared decision-making, general preventive care measures, and basic principles of the treatment of transgender persons. They labeled these “Ungraded Good Practice Statement.” Direct evidence for these statements was either unavailable or not systematically appraised and considered out of the scope of this guideline. The intention of these statements is to draw attention to these principles.

The Endocrine Society maintains a rigorous conflict-of-interest review process for developing clinical practice guidelines. All task force members must declare any potential conflicts of interest by completing a conflict-of-interest form. The CGS reviews all conflicts of interest before the Society’s Council approves the members to participate on the task force and periodically during the development of the guideline. All others participating in the guideline’s development must also disclose any conflicts of interest in the matter under study, and most of these participants must be without any conflicts of interest. The CGS and the task force have reviewed all disclosures for this guideline and resolved or managed all identified conflicts of interest.

Conflicts of interest are defined as remuneration in any amount from commercial interests; grants; research support; consulting fees; salary; ownership interests [e.g., stocks and stock options (excluding diversified mutual funds)]; honoraria and other payments for participation in speakers’ bureaus, advisory boards, or boards of directors; and all other financial benefits. Completed forms are available through the Endocrine Society office.

The Endocrine Society provided the funding for this guideline; the task force received no funding or remuneration from commercial or other entities.

Commissioned Systematic Review

The task force commissioned two systematic reviews to support this guideline. The first one aimed to summarize the available evidence on the effect of sex steroid use in transgender individuals on lipids and cardiovascular outcomes. The review identified 29 eligible studies at moderate risk of bias. In transgender males (female to male), sex steroid therapy was associated with a statistically significant increase in serum triglycerides and low-density lipoprotein cholesterol levels. High-density lipoprotein cholesterol levels decreased significantly across all follow-up time periods. In transgender females (male to female), serum triglycerides were significantly higher without any changes in other parameters. Few myocardial infarction, stroke, venous thromboembolism (VTE), and death events were reported. These events were more frequent in transgender females. However, the

quality of the evidence was low. The second review summarized the available evidence regarding the effect of sex steroids on bone health in transgender individuals and identified 13 studies. In transgender males, there was no statistically significant difference in the lumbar spine, femoral neck, or total hip BMD at 12 and 24 months compared with baseline values before initiating masculinizing hormone therapy. In transgender females, there was a statistically significant increase in lumbar spine BMD at 12 months and 24 months compared with baseline values before initiation of feminizing hormone therapy. There was minimal information on fracture rates. The quality of evidence was also low.

Introduction

Throughout recorded history (in the absence of an endocrine disorder) some men and women have experienced confusion and anguish resulting from rigid, forced conformity to sexual dimorphism. In modern history, there have been numerous ongoing biological, psychological, cultural, political, and sociological debates over various aspects of gender variance. The 20th century marked the emergence of a social awakening for men and women with the belief that they are “trapped” in the wrong body (3). Magnus Hirschfeld and Harry Benjamin, among others, pioneered the medical responses to those who sought relief from and a resolution to their profound discomfort. Although the term transsexual became widely known after Benjamin wrote “The Transsexual Phenomenon” (4), it was Hirschfeld who coined the term “transsexual” in 1923 to describe people who want to live a life that corresponds with their experienced gender vs their designated gender (5). Magnus Hirschfeld (6) and others (4, 7) have described other types of trans phenomena besides transsexualism. These early researchers proposed that the gender identity of these people was located somewhere along a unidimensional continuum. This continuum ranged from all male through “something in between” to all female. Yet such a classification does not take into account that people may have gender identities outside this continuum. For instance, some experience themselves as having both a male and female gender identity, whereas others completely renounce any gender classification (8, 9). There are also reports of individuals experiencing a continuous and rapid involuntary alternation between a male and female identity (10) or men who do not experience themselves as men but do not want to live as women (11, 12). In some countries, (e.g., Nepal, Bangladesh, and Australia), these nonmale or nonfemale genders are officially recognized (13). Specific treatment protocols, however, have not yet been developed for these groups.

Instead of the term transsexualism, the current classification system of the American Psychiatric Association uses the term gender dysphoria in its diagnosis of persons who are not satisfied with their designated gender (14). The current version of the World Health Organization's ICD-10 still uses the term transsexualism when diagnosing adolescents and adults. However, for the ICD-11, the World Health Organization has proposed using the term "gender incongruence" (15).

Treating persons with GD/gender incongruence (15) was previously limited to relatively ineffective elixirs or creams. However, more effective endocrinology-based treatments became possible with the availability of testosterone in 1935 and diethylstilbestrol in 1938. Reports of individuals with GD/gender incongruence who were treated with hormones and gender-affirming surgery appeared in the press during the second half of the 20th century. The Harry Benjamin International Gender Dysphoria Association was founded in September 1979 and is now called the World Professional Association for Transgender Health (WPATH). WPATH published its first Standards of Care in 1979. These standards have since been regularly updated, providing guidance for treating persons with GD/gender incongruence (16).

Prior to 1975, few peer-reviewed articles were published concerning endocrine treatment of transgender persons. Since then, more than two thousand articles about various aspects of transgender care have appeared.

It is the purpose of this guideline to make detailed recommendations and suggestions, based on existing medical literature and clinical experience, that will enable treating physicians to maximize benefit and minimize risk when caring for individuals diagnosed with GD/gender incongruence.

In the future, we need more rigorous evaluations of the effectiveness and safety of endocrine and surgical protocols. Specifically, endocrine treatment protocols for GD/gender incongruence should include the careful assessment of the following: (1) the effects of prolonged delay of puberty in adolescents on bone health, gonadal function, and the brain (including effects on cognitive, emotional, social, and sexual development); (2) the effects of treatment in adults on sex hormone levels; (3) the requirement for and the effects of progestins and other agents used to suppress endogenous sex steroids during treatment; and (4) the risks and benefits of gender-affirming hormone treatment in older transgender people.

To successfully establish and enact these protocols, a commitment of mental health and endocrine investigators is required to collaborate in long-term, large-scale

studies across countries that use the same diagnostic and inclusion criteria, medications, assay methods, and response assessment tools (e.g., the European Network for the Investigation of Gender Incongruence) (17, 18).

Terminology and its use vary and continue to evolve. Table 1 contains the definitions of terms as they are used throughout this guideline.

Biological Determinants of Gender Identity Development

One's self-awareness as male or female changes gradually during infant life and childhood. This process of cognitive and affective learning evolves with interactions with parents, peers, and environment. A fairly accurate timetable exists outlining the steps in this process (19). Normative psychological literature, however, does not address if and when gender identity becomes crystallized and what factors contribute to the development of a gender identity that is not congruent with the gender of rearing. Results of studies from a variety of biomedical disciplines—genetic, endocrine, and neuroanatomic—support the concept that gender identity and/or gender expression (20) likely reflect a complex interplay of biological, environmental, and cultural factors (21, 22).

With respect to endocrine considerations, studies have failed to find differences in circulating levels of sex steroids between transgender and nontransgender individuals (23). However, studies in individuals with a disorder/difference of sex development (DSD) have informed our understanding of the role that hormones may play in gender identity outcome, even though most persons with GD/gender incongruence do not have a DSD. For example, although most 46,XX adult individuals with virilizing congenital adrenal hyperplasia caused by mutations in *CYP21A2* reported a female gender identity, the prevalence of GD/gender incongruence was much greater in this group than in the general population without a DSD. This supports the concept that there is a role for prenatal/postnatal androgens in gender development (24–26), although some studies indicate that prenatal androgens are more likely to affect gender behavior and sexual orientation rather than gender identity *per se* (27, 28).

Researchers have made similar observations regarding the potential role of androgens in the development of gender identity in other individuals with DSD. For example, a review of two groups of 46,XY persons, each with androgen synthesis deficiencies and female raised, reported transgender male (female-to-male) gender role changes in 56% to 63% and 39% to 64% of patients, respectively (29). Also, in 46,XY female-raised individuals with cloacal

Table 1. Definitions of Terms Used in This Guideline

<i>Biological sex, biological male or female:</i> These terms refer to physical aspects of maleness and femaleness. As these may not be in line with each other (e.g., a person with XY chromosomes may have female-appearing genitalia), the terms biological sex and biological male or female are imprecise and should be avoided.
<i>Cisgender:</i> This means not transgender. An alternative way to describe individuals who are not transgender is “non-transgender people.”
<i>Gender-affirming (hormone) treatment:</i> See “gender reassignment”
<i>Gender dysphoria:</i> This is the distress and unease experienced if gender identity and designated gender are not completely congruent (see Table 2). In 2013, the American Psychiatric Association released the fifth edition of the DSM-5, which replaced “gender identity disorder” with “gender dysphoria” and changed the criteria for diagnosis.
<i>Gender expression:</i> This refers to external manifestations of gender, expressed through one’s name, pronouns, clothing, haircut, behavior, voice, or body characteristics. Typically, transgender people seek to make their gender expression align with their gender identity, rather than their designated gender.
<i>Gender identity/experienced gender:</i> This refers to one’s internal, deeply held sense of gender. For transgender people, their gender identity does not match their sex designated at birth. Most people have a gender identity of man or woman (or boy or girl). For some people, their gender identity does not fit neatly into one of those two choices. Unlike gender expression (see below), gender identity is not visible to others.
<i>Gender identity disorder:</i> This is the term used for GD/gender incongruence in previous versions of DSM (see “gender dysphoria”). The ICD-10 still uses the term for diagnosing child diagnoses, but the upcoming ICD-11 has proposed using “gender incongruence of childhood.”
<i>Gender incongruence:</i> This is an umbrella term used when the gender identity and/or gender expression differs from what is typically associated with the designated gender. Gender incongruence is also the proposed name of the gender identity–related diagnoses in ICD-11. Not all individuals with gender incongruence have gender dysphoria or seek treatment.
<i>Gender variance:</i> See “gender incongruence”
<i>Gender reassignment:</i> This refers to the treatment procedure for those who want to adapt their bodies to the experienced gender by means of hormones and/or surgery. This is also called gender-confirming or gender-affirming treatment.
<i>Gender-reassignment surgery (gender-confirming/gender-affirming surgery):</i> These terms refer only to the surgical part of gender-confirming/gender-affirming treatment.
<i>Gender role:</i> This refers to behaviors, attitudes, and personality traits that a society (in a given culture and historical period) designates as masculine or feminine and/or that society associates with or considers typical of the social role of men or women.
<i>Sex designated at birth:</i> This refers to sex assigned at birth, usually based on genital anatomy.
<i>Sex:</i> This refers to attributes that characterize biological maleness or femaleness. The best known attributes include the sex-determining genes, the sex chromosomes, the H-Y antigen, the gonads, sex hormones, internal and external genitalia, and secondary sex characteristics.
<i>Sexual orientation:</i> This term describes an individual’s enduring physical and emotional attraction to another person. Gender identity and sexual orientation are not the same. Irrespective of their gender identity, transgender people may be attracted to women (gynephilic), attracted to men (androphilic), bisexual, asexual, or queer.
<i>Transgender:</i> This is an umbrella term for people whose gender identity and/or gender expression differs from what is typically associated with their sex designated at birth. Not all transgender individuals seek treatment.
<i>Transgender male (also: trans man, female-to-male, transgender male):</i> This refers to individuals assigned female at birth but who identify and live as men.
<i>Transgender woman (also: trans woman, male-to-female, transgender female):</i> This refers to individuals assigned male at birth but who identify and live as women.
<i>Transition:</i> This refers to the process during which transgender persons change their physical, social, and/or legal characteristics consistent with the affirmed gender identity. Prepubertal children may choose to transition socially.
<i>Transsexual:</i> This is an older term that originated in the medical and psychological communities to refer to individuals who have permanently transitioned through medical interventions or desired to do so.

exstrophy and penile agenesis, the occurrence of transgender male changes was significantly more prevalent than in the general population (30, 31). However, the fact that a high percentage of individuals with the same conditions did not change gender suggests that cultural factors may play a role as well.

With respect to genetics and gender identity, several studies have suggested heritability of GD/gender incongruence (32, 33). In particular, a study by Heylens *et al.* (33) demonstrated a 39.1% concordance rate for gender identity disorder (based on the DSM-IV criteria) in 23 monozygotic twin pairs but no concordance in 21 same-sex dizygotic or seven opposite-sex twin pairs. Although numerous investigators have sought to identify

specific genes associated with GD/gender incongruence, such studies have been inconsistent and without strong statistical significance (34–38).

Studies focusing on brain structure suggest that the brain phenotypes of people with GD/gender incongruence differ in various ways from control males and females, but that there is not a complete sex reversal in brain structures (39).

In summary, although there is much that is still unknown with respect to gender identity and its expression, compelling studies support the concept that biologic factors, in addition to environmental factors, contribute to this fundamental aspect of human development.

Natural History of Children With GD/Gender Incongruence

With current knowledge, we cannot predict the psychosexual outcome for any specific child. Prospective follow-up studies show that childhood GD/gender incongruence does not invariably persist into adolescence and adulthood (so-called “desisters”). Combining all outcome studies to date, the GD/gender incongruence of a minority of prepubertal children appears to persist in adolescence (20, 40). In adolescence, a significant number of these desisters identify as homosexual or bisexual. It may be that children who only showed some gender nonconforming characteristics have been included in the follow-up studies, because the DSM-IV text revision criteria for a diagnosis were rather broad. However, the persistence of GD/gender incongruence into adolescence is more likely if it had been extreme in childhood (41, 42). With the newer, stricter criteria of the DSM-5 (Table 2), persistence rates may well be different in future studies.

1.0 Evaluation of Youth and Adults

Gender-affirming treatment is a multidisciplinary effort. After evaluation, education, and diagnosis, treatment may include mental health care, hormone therapy, and/or surgical therapy. Together with an MHP, hormone-prescribing clinicians should examine the psychosocial impact of the potential changes on people’s lives, including mental health, friends, family, jobs, and their role in society. Transgender individuals should be encouraged to experience living in the new gender role and assess whether

this improves their quality of life. Although the focus of this guideline is gender-affirming hormone therapy, collaboration with appropriate professionals responsible for each aspect of treatment maximizes a successful outcome.

Diagnostic assessment and mental health care

GD/gender incongruence may be accompanied with psychological or psychiatric problems (43–51). It is therefore necessary that clinicians who prescribe hormones and are involved in diagnosis and psychosocial assessment meet the following criteria: (1) are competent in using the DSM and/or the ICD for diagnostic purposes, (2) are able to diagnose GD/gender incongruence and make a distinction between GD/gender incongruence and conditions that have similar features (e.g., body dysmorphic disorder), (3) are trained in diagnosing psychiatric conditions, (4) undertake or refer for appropriate treatment, (5) are able to do a psychosocial assessment of the patient’s understanding, mental health, and social conditions that can impact gender-affirming hormone therapy, and (6) regularly attend relevant professional meetings.

Because of the psychological vulnerability of many individuals with GD/gender incongruence, it is important that mental health care is available before, during, and sometimes also after transitioning. For children and adolescents, an MHP who has training/experience in child and adolescent gender development (as well as child and adolescent psychopathology) should make the diagnosis, because assessing GD/gender incongruence in children and adolescents is often extremely complex.

During assessment, the clinician obtains information from the individual seeking gender-affirming treatment. In the case

Table 2. DSM-5 Criteria for Gender Dysphoria in Adolescents and Adults

- A. A marked incongruence between one’s experienced/expressed gender and natal gender of at least 6 mo in duration, as manifested by at least two of the following:
 1. A marked incongruence between one’s experienced/expressed gender and primary and/or secondary sex characteristics (or in young adolescents, the anticipated secondary sex characteristics)
 2. A strong desire to be rid of one’s primary and/or secondary sex characteristics because of a marked incongruence with one’s experienced/expressed gender (or in young adolescents, a desire to prevent the development of the anticipated secondary sex characteristics)
 3. A strong desire for the primary and/or secondary sex characteristics of the other gender
 4. A strong desire to be of the other gender (or some alternative gender different from one’s designated gender)
 5. A strong desire to be treated as the other gender (or some alternative gender different from one’s designated gender)
 6. A strong conviction that one has the typical feelings and reactions of the other gender (or some alternative gender different from one’s designated gender)
 - B. The condition is associated with clinically significant distress or impairment in social, occupational, or other important areas of functioning.
- Specify if:
1. The condition exists with a disorder of sex development.
 2. The condition is posttransitional, in that the individual has transitioned to full-time living in the desired gender (with or without legalization of gender change) and has undergone (or is preparing to have) at least one sex-related medical procedure or treatment regimen—namely, regular sex hormone treatment or gender reassignment surgery confirming the desired gender (e.g., penectomy, vaginoplasty in natal males; mastectomy or phalloplasty in natal females).

Reference: American Psychiatric Association (14).

of adolescents, the clinician also obtains information from the parents or guardians regarding various aspects of the child's general and psychosexual development and current functioning. On the basis of this information, the clinician:

- decides whether the individual fulfills criteria for treatment (see Tables 2 and 3) for GD/gender incongruence (DSM-5) or transsexualism (DSM-5 and/or ICD-10);
- informs the individual about the possibilities and limitations of various kinds of treatment (hormonal/surgical and nonhormonal), and if medical treatment is desired, provides correct information to prevent unrealistically high expectations;
- assesses whether medical interventions may result in unfavorable psychological and social outcomes.

In cases in which severe psychopathology, circumstances, or both seriously interfere with the diagnostic work or make satisfactory treatment unlikely, clinicians should assist the adolescent in managing these other issues. Literature on postoperative regret suggests that besides poor quality of surgery, severe psychiatric comorbidity and lack of support may interfere with positive outcomes (52–56).

For adolescents, the diagnostic procedure usually includes a complete psychodiagnostic assessment (57) and an assessment of the decision-making capability of the youth. An evaluation to assess the family's ability to endure stress, give support, and deal with the complexities of the adolescent's situation should be part of the diagnostic phase (58).

Social transitioning

A change in gender expression and role (which may involve living part time or full time in another gender role that is consistent with one's gender identity) may test the person's resolve, the capacity to function in the affirmed gender, and the adequacy of social, economic, and psychological supports. It assists both the individual and the clinician in their judgments about how to proceed (16). During social transitioning, the person's feelings about the social transformation (including coping with the responses of others) is a major focus of the counseling. The optimal timing for social transitioning may differ between individuals. Sometimes people wait until they

start gender-affirming hormone treatment to make social transitioning easier, but individuals increasingly start social transitioning long before they receive medically supervised, gender-affirming hormone treatment.

Criteria

Adolescents and adults seeking gender-affirming hormone treatment and surgery should satisfy certain criteria before proceeding (16). Criteria for gender-affirming hormone therapy for adults are in Table 4, and criteria for gender-affirming hormone therapy for adolescents are in Table 5. Follow-up studies in adults meeting these criteria indicate a high satisfaction rate with treatment (59). However, the quality of evidence is usually low. A few follow-up studies on adolescents who fulfilled these criteria also indicated good treatment results (60–63).

Recommendations for Those Involved in the Gender-Affirming Hormone Treatment of Individuals With GD/Gender Incongruence

- 1.1. We advise that only trained MHPs who meet the following criteria should diagnose GD/gender incongruence in adults: (1) competence in using the DSM and/or the ICD for diagnostic purposes, (2) the ability to diagnose GD/gender incongruence and make a distinction between GD/gender incongruence and conditions that have similar features (*e.g.*, body dysmorphic disorder), (3) training in diagnosing psychiatric conditions, (4) the ability to undertake or refer for appropriate treatment, (5) the ability to psychosocially assess the person's understanding, mental health, and social conditions that can impact gender-affirming hormone therapy, and (6) a practice of regularly attending relevant professional meetings. (Ungraded Good Practice Statement)
- 1.2. We advise that only MHPs who meet the following criteria should diagnose GD/gender incongruence in children and adolescents: (1) training in child and adolescent developmental psychology and psychopathology, (2) competence in using the DSM and/or ICD for diagnostic

Table 3. ICD-10 Criteria for Transsexualism

Transsexualism (F64.0) has three criteria:

1. The desire to live and be accepted as a member of the opposite sex, usually accompanied by the wish to make his or her body as congruent as possible with the preferred sex through surgery and hormone treatments.
2. The transsexual identity has been present persistently for at least 2 y.
3. The disorder is not a symptom of another mental disorder or a genetic, DSD, or chromosomal abnormality.

Table 4. Criteria for Gender-Affirming Hormone Therapy for Adults

1. Persistent, well-documented gender dysphoria/gender incongruence
2. The capacity to make a fully informed decision and to consent for treatment
3. The age of majority in a given country (if younger, follow the criteria for adolescents)
4. Mental health concerns, if present, must be reasonably well controlled

Reproduced from World Professional Association for Transgender Health (16).

purposes, (3) the ability to make a distinction between GD/gender incongruence and conditions that have similar features (e.g., body dysmorphic disorder), (4) training in diagnosing psychiatric conditions, (5) the ability to undertake or refer for appropriate treatment, (6) the ability to psychosocially assess the person's understanding and social conditions that can impact gender-affirming hormone therapy, (7) a practice of regularly attending relevant professional meetings, and (8) knowledge of the criteria for puberty blocking and gender-affirming hormone treatment in adolescents. (Ungraded Good Practice Statement)

Evidence

Individuals with gender identity issues may have psychological or psychiatric problems (43–48, 50, 51, 64, 65). It is therefore necessary that clinicians making the diagnosis are able to make a distinction between GD/gender incongruence and conditions that have similar features. Examples of conditions with similar features are body dysmorphic disorder, body identity integrity disorder (a condition in which individuals have a sense that their anatomical configuration as an able-bodied person is somehow wrong or inappropriate) (66), or certain forms of eunuchism (in which a person is preoccupied with or engages in castration and/or penectomy for

Table 5. Criteria for Gender-Affirming Hormone Therapy for Adolescents

Adolescents are eligible for GnRH agonist treatment if:

1. A qualified MHP has confirmed that:
 - the adolescent has demonstrated a long-lasting and intense pattern of gender nonconformity or gender dysphoria (whether suppressed or expressed),
 - gender dysphoria worsened with the onset of puberty,
 - any coexisting psychological, medical, or social problems that could interfere with treatment (e.g., that may compromise treatment adherence) have been addressed, such that the adolescent's situation and functioning are stable enough to start treatment,
 - the adolescent has sufficient mental capacity to give informed consent to this (reversible) treatment,
2. And the adolescent:
 - has been informed of the effects and side effects of treatment (including potential loss of fertility if the individual subsequently continues with sex hormone treatment) and options to preserve fertility,
 - has given informed consent and (particularly when the adolescent has not reached the age of legal medical consent, depending on applicable legislation) the parents or other caretakers or guardians have consented to the treatment and are involved in supporting the adolescent throughout the treatment process,
3. And a pediatric endocrinologist or other clinician experienced in pubertal assessment:
 - agrees with the indication for GnRH agonist treatment,
 - has confirmed that puberty has started in the adolescent (Tanner stage $\geq$ G2/B2),
 - has confirmed that there are no medical contraindications to GnRH agonist treatment.

Adolescents are eligible for subsequent sex hormone treatment if:

1. A qualified MHP has confirmed:
 - the persistence of gender dysphoria,
 - any coexisting psychological, medical, or social problems that could interfere with treatment (e.g., that may compromise treatment adherence) have been addressed, such that the adolescent's situation and functioning are stable enough to start sex hormone treatment,
 - the adolescent has sufficient mental capacity (which most adolescents have by age 16 years) to estimate the consequences of this (partly) irreversible treatment, weigh the benefits and risks, and give informed consent to this (partly) irreversible treatment,
2. And the adolescent:
 - has been informed of the (irreversible) effects and side effects of treatment (including potential loss of fertility and options to preserve fertility),
 - has given informed consent and (particularly when the adolescent has not reached the age of legal medical consent, depending on applicable legislation) the parents or other caretakers or guardians have consented to the treatment and are involved in supporting the adolescent throughout the treatment process,
3. And a pediatric endocrinologist or other clinician experienced in pubertal induction:
 - agrees with the indication for sex hormone treatment,
 - has confirmed that there are no medical contraindications to sex hormone treatment.

Reproduced from World Professional Association for Transgender Health (16).

reasons that are not gender identity related) (11). Clinicians should also be able to diagnose psychiatric conditions accurately and ensure that these conditions are treated appropriately, particularly when the conditions may complicate treatment, affect the outcome of gender-affirming treatment, or be affected by hormone use.

Values and preferences

The task force placed a very high value on avoiding harm from hormone treatment in individuals who have conditions other than GD/gender incongruence and who may not benefit from the physical changes associated with this treatment and placed a low value on any potential benefit these persons believe they may derive from hormone treatment. This justifies the good practice statement.

- 1.3. We advise that decisions regarding the social transition of prepubertal youths with GD/gender incongruence are made with the assistance of an MHP or another experienced professional. (Ungraded Good Practice Statement).
- 1.4. We recommend against puberty blocking and gender-affirming hormone treatment in prepubertal children with GD/gender incongruence. (1 ⊕⊕○○)

Evidence

In most children diagnosed with GD/gender incongruence, it did not persist into adolescence. The percentages differed among studies, probably dependent on which version of the DSM clinicians used, the patient's age, the recruitment criteria, and perhaps cultural factors. However, the large majority (about 85%) of prepubertal children with a childhood diagnosis did not remain GD/gender incongruent in adolescence (20). If children have completely socially transitioned, they may have great difficulty in returning to the original gender role upon entering puberty (40). Social transition is associated with the persistence of GD/gender incongruence as a child progresses into adolescence. It may be that the presence of GD/gender incongruence in prepubertal children is the earliest sign that a child is destined to be transgender as an adolescent/adult (20). However, social transition (in addition to GD/gender incongruence) has been found to contribute to the likelihood of persistence.

This recommendation, however, does not imply that children should be discouraged from showing gender-variant behaviors or should be punished for exhibiting such behaviors. In individual cases, an early complete social transition may result in a more favorable outcome, but there are currently no criteria to identify the

GD/gender-incongruent children to whom this applies. At the present time, clinical experience suggests that persistence of GD/gender incongruence can only be reliably assessed after the first signs of puberty.

Values and preferences

The task force placed a high value on avoiding harm with gender-affirming hormone therapy in prepubertal children with GD/gender incongruence. This justifies the strong recommendation in the face of low-quality evidence.

- 1.5. We recommend that clinicians inform and counsel all individuals seeking gender-affirming medical treatment regarding options for fertility preservation prior to initiating puberty suppression in adolescents and prior to treating with hormonal therapy of the affirmed gender in both adolescents and adults. (1 ⊕⊕⊕○)

Remarks

Persons considering hormone use for gender affirmation need adequate information about this treatment in general and about fertility effects of hormone treatment in particular to make an informed and balanced decision (67, 68). Because young adolescents may not feel qualified to make decisions about fertility and may not fully understand the potential effects of hormonal interventions, consent and protocol education should include parents, the referring MHP(s), and other members of the adolescent's support group. To our knowledge, there are no formally evaluated decision aids available to assist in the discussion and decision regarding the future fertility of adolescents or adults beginning gender-affirming treatment.

Treating early pubertal youth with GnRH analogs will temporarily impair spermatogenesis and oocyte maturation. Given that an increasing number of transgender youth want to preserve fertility potential, delaying or temporarily discontinuing GnRH analogs to promote gamete maturation is an option. This option is often not preferred, because mature sperm production is associated with later stages of puberty and with the significant development of secondary sex characteristics.

For those designated male at birth with GD/gender incongruence and who are in early puberty, sperm production and the development of the reproductive tract are insufficient for the cryopreservation of sperm. However, prolonged pubertal suppression using GnRH analogs is reversible and clinicians should inform these individuals that sperm production can be initiated following prolonged gonadotropin suppression. This can be accomplished by spontaneous gonadotropin recovery after

cessation of GnRH analogs or by gonadotropin treatment and will probably be associated with physical manifestations of testosterone production, as stated above. Note that there are no data in this population concerning the time required for sufficient spermatogenesis to collect enough sperm for later fertility. In males treated for precocious puberty, spermarche was reported 0.7 to 3 years after cessation of GnRH analogs (69). In adult men with gonadotropin deficiency, sperm are noted in seminal fluid by 6 to 12 months of gonadotropin treatment. However, sperm numbers when partners of these patients conceive are far below the “normal range” (70, 71).

In girls, no studies have reported long-term, adverse effects of pubertal suppression on ovarian function after treatment cessation (72, 73). Clinicians should inform adolescents that no data are available regarding either time to spontaneous ovulation after cessation of GnRH analogs or the response to ovulation induction following prolonged gonadotropin suppression.

In males with GD/gender incongruence, when medical treatment is started in a later phase of puberty or in adulthood, spermatogenesis is sufficient for cryopreservation and storage of sperm. *In vitro* spermatogenesis is currently under investigation. Restoration of spermatogenesis after prolonged estrogen treatment has not been studied.

In females with GD/gender incongruence, the effect of prolonged treatment with exogenous testosterone on ovarian function is uncertain. There have been reports of an increased incidence of polycystic ovaries in transgender males, both prior to and as a result of androgen treatment (74–77), although these reports were not confirmed by others (78). Pregnancy has been reported in transgender males who have had prolonged androgen treatment and have discontinued testosterone but have not had genital surgery (79, 80). A reproductive endocrine gynecologist can counsel patients before gender-affirming hormone treatment or surgery regarding potential fertility options (81). Techniques for cryopreservation of oocytes, embryos, and ovarian tissue continue to improve, and oocyte maturation of immature tissue is being studied (82).

2.0 Treatment of Adolescents

During the past decade, clinicians have progressively acknowledged the suffering of young adolescents with GD/gender incongruence. In some forms of GD/gender incongruence, psychological interventions may be useful and sufficient. However, for many adolescents with GD/gender incongruence, the pubertal physical changes are unbearable. As early medical intervention may prevent

psychological harm, various clinics have decided to start treating young adolescents with GD/gender incongruence with puberty-suppressing medication (a GnRH analog). As compared with starting gender-affirming treatment long after the first phases of puberty, a benefit of pubertal suppression at early puberty may be a better psychological and physical outcome.

In girls, the first physical sign of puberty is the budding of the breasts followed by an increase in breast and fat tissue. Breast development is also associated with the pubertal growth spurt, and menarche occurs ~2 years later. In boys, the first physical change is testicular growth. A testicular volume ≥ 4 mL is seen as consistent with the initiation of physical puberty. At the beginning of puberty, estradiol and testosterone levels are still low and are best measured in the early morning with an ultrasensitive assay. From a testicular volume of 10 mL, daytime testosterone levels increase, leading to virilization (83). Note that pubic hair and/or axillary hair/odor may not reflect the onset of gonadarche; instead, it may reflect adrenarche alone.

- 2.1. We suggest that adolescents who meet diagnostic criteria for GD/gender incongruence, fulfill criteria for treatment (Table 5), and are requesting treatment should initially undergo treatment to suppress pubertal development. (2 $\oplus\oplus\oplus\oplus$)
- 2.2. We suggest that clinicians begin pubertal hormone suppression after girls and boys first exhibit physical changes of puberty (Tanner stages G2/B2). (2 $\oplus\oplus\oplus\oplus$)

Evidence

Pubertal suppression can expand the diagnostic phase by a long period, giving the subject more time to explore options and to live in the experienced gender before making a decision to proceed with gender-affirming sex hormone treatments and/or surgery, some of which is irreversible (84, 85). Pubertal suppression is fully reversible, enabling full pubertal development in the natal gender, after cessation of treatment, if appropriate. The experience of full endogenous puberty is an undesirable condition for the GD/gender-incongruent individual and may seriously interfere with healthy psychological functioning and well-being. Treating GD/gender-incongruent adolescents entering puberty with GnRH analogs has been shown to improve psychological functioning in several domains (86).

Another reason to start blocking pubertal hormones early in puberty is that the physical outcome is improved compared with initiating physical transition after puberty has been completed (60, 62). Looking like a man or woman when living as the opposite sex creates difficult

barriers with enormous life-long disadvantages. We therefore advise starting suppression in early puberty to prevent the irreversible development of undesirable secondary sex characteristics. However, adolescents with GD/gender incongruence should experience the first changes of their endogenous spontaneous puberty, because their emotional reaction to these first physical changes has diagnostic value in establishing the persistence of GD/gender incongruence (85). Thus, Tanner stage 2 is the optimal time to start pubertal suppression. However, pubertal suppression treatment in early puberty will limit the growth of the penis and scrotum, which will have a potential effect on future surgical treatments (87).

Clinicians can also use pubertal suppression in adolescents in later pubertal stages to stop menses in transgender males and prevent facial hair growth in transgender females. However, in contrast to the effects in early pubertal adolescents, physical sex characteristics (such as more advanced breast development in transgender boys and lowering of the voice and outgrowth of the jaw and brow in transgender girls) are not reversible.

Values and preferences

These recommendations place a high value on avoiding an unsatisfactory physical outcome when secondary sex characteristics have become manifest and irreversible, a higher value on psychological well-being, and a lower value on avoiding potential harm from early pubertal suppression.

Remarks

Table 6 lists the Tanner stages of breast and male genital development. Careful documentation of hallmarks of pubertal development will ensure precise timing when initiating pubertal suppression once puberty has started. Clinicians can use pubertal LH and sex steroid levels to confirm that puberty has progressed sufficiently before starting pubertal suppression (88). Reference

ranges for sex steroids by Tanner stage may vary depending on the assay used. Ultrasensitive sex steroid and gonadotropin assays will help clinicians document early pubertal changes.

Irreversible and, for GD/gender-incongruent adolescents, undesirable sex characteristics in female puberty are breasts, female body habitus, and, in some cases, relative short stature. In male puberty, they are a prominent Adam's apple; low voice; male bone configuration, such as a large jaw, big feet and hands, and tall stature; and male hair pattern on the face and extremities.

- 2.3. We recommend that, where indicated, GnRH analogues are used to suppress pubertal hormones. (1 ⊕⊕○○)

Evidence

Clinicians can suppress pubertal development and gonadal function most effectively via gonadotropin suppression using GnRH analogs. GnRH analogs are long-acting agonists that suppress gonadotropins by GnRH receptor desensitization after an initial increase of gonadotropins during ~10 days after the first and (to a lesser degree) the second injection (89). Antagonists immediately suppress pituitary gonadotropin secretion (90, 91). Long-acting GnRH analogs are the currently preferred treatment option. Clinicians may consider long-acting GnRH antagonists when evidence on their safety and efficacy in adolescents becomes available.

During GnRH analog treatment, slight development of secondary sex characteristics may regress, and in a later phase of pubertal development, it will stop. In girls, breast tissue will become atrophic, and menses will stop. In boys, virilization will stop, and testicular volume may decrease (92).

An advantage of using GnRH analogs is the reversibility of the intervention. If, after extensive exploration of his/her transition wish, the individual no longer desires transition, they can discontinue pubertal suppression. In subjects with

Table 6. Tanner Stages of Breast Development and Male External Genitalia

The description of Tanner stages for breast development:

1. Prepubertal
2. Breast and papilla elevated as small mound; areolar diameter increased
3. Breast and areola enlarged, no contour separation
4. Areola and papilla form secondary mound
5. Mature; nipple projects, areola part of general breast contour

For penis and testes:

1. Prepubertal, testicular volume <4 mL
2. Slight enlargement of penis; enlarged scrotum, pink, texture altered, testes 4–6 mL
3. Penis longer, testes larger (8–12 mL)
4. Penis and glans larger, including increase in breadth; testes larger (12–15 mL), scrotum dark
5. Penis adult size; testicular volume > 15 mL

Adapted from Lawrence (56).

precocious puberty, spontaneous pubertal development has been shown to resume after patients discontinue taking GnRH analogs (93).

Recommendations 2.1 to 2.3 are supported by a prospective follow-up study from The Netherlands. This report assessed mental health outcomes in 55 transgender adolescents/young adults (22 transgender females and 33 transgender males) at three time points: (1) before the start of GnRH agonist (average age of 14.8 years at start of treatment), (2) at initiation of gender-affirming hormones (average age of 16.7 years at start of treatment), and (3) 1 year after “gender-reassignment surgery” (average age of 20.7 years) (63). Despite a decrease in depression and an improvement in general mental health functioning, GD/gender incongruence persisted through pubertal suppression, as previously reported (86). However, following sex hormone treatment and gender-reassignment surgery, GD/gender incongruence was resolved and psychological functioning steadily improved (63). Furthermore, well-being was similar to or better than that reported by age-matched young adults from the general population, and none of the study participants regretted treatment. This study represents the first long-term follow-up of individuals managed according to currently existing clinical practice guidelines for transgender youth, and it underscores the benefit of the multidisciplinary approach pioneered in The Netherlands; however, further studies are needed.

Side effects

The primary risks of pubertal suppression in GD/gender-incongruent adolescents may include adverse effects on bone mineralization (which can theoretically be reversed with sex hormone treatment), compromised fertility if the person subsequently is treated with sex hormones, and unknown effects on brain development. Few data are available on the effect of GnRH analogs on BMD in adolescents with GD/gender incongruence. Initial data in GD/gender-incongruent subjects demonstrated no change of absolute areal BMD during 2 years of GnRH analog therapy but a decrease in BMD *z* scores (85). A recent study also suggested suboptimal bone mineral accrual during GnRH analog treatment. The study reported a decrease in areal BMD *z* scores and of bone mineral apparent density *z* scores (which takes the size of the bone into account) in 19 transgender males treated with GnRH analogs from a mean age of 15.0 years (standard deviation = 2.0 years) for a median duration of 1.5 years (0.3 to 5.2 years) and in 15 transgender females treated from 14.9 (± 1.9) years for 1.3 years (0.5 to 3.8 years), although not all changes were statistically significant (94). There was incomplete catch-up at age 22 years after sex hormone treatment from age 16.6 (± 1.4)

years for a median duration of 5.8 years (3.0 to 8.0 years) in transgender females and from age 16.4 (± 2.3) years for 5.4 years (2.8 to 7.8 years) in transgender males. Little is known about more prolonged use of GnRH analogs. Researchers reported normal BMD *z* scores at age 35 years in one individual who used GnRH analogs from age 13.7 years until age 18.6 years before initiating sex hormone treatment (65).

Additional data are available from individuals with late puberty or GnRH analog treatment of other indications. Some studies reported that men with constitutionally delayed puberty have decreased BMD in adulthood (95). However, other studies reported that these men have normal BMD (96, 97). Treating adults with GnRH analogs results in a decrease of BMD (98). In children with central precocious puberty, treatment with GnRH analogs has been found to result in a decrease of BMD during treatment by some (99) but not others (100). Studies have reported normal BMD after discontinuing therapy (69, 72, 73, 101, 102). In adolescents treated with growth hormone who are small for gestational age and have normal pubertal timing, 2-year GnRH analog treatments did not adversely affect BMD (103). Calcium supplementation may be beneficial in optimizing bone health in GnRH analog-treated individuals (104). There are no studies of vitamin D supplementation in this context, but clinicians should offer supplements to vitamin D-deficient adolescents. Physical activity, especially during growth, is important for bone mass in healthy individuals (103) and is therefore likely to be beneficial for bone health in GnRH analog-treated subjects.

GnRH analogs did not induce a change in body mass index standard deviation score in GD/gender-incongruent adolescents (94) but caused an increase in fat mass and decrease in lean body mass percentage (92). Studies in girls treated for precocious puberty also reported a stable body mass index standard deviation score during treatment (72) and body mass index and body composition comparable to controls after treatment (73).

Arterial hypertension has been reported as an adverse effect in a few girls treated with GnRH analogs for precocious/early puberty (105, 106). Blood pressure monitoring before and during treatment is recommended.

Individuals may also experience hot flashes, fatigue, and mood alterations as a consequence of pubertal suppression. There is no consensus on treatment of these side effects in this context.

It is recommended that any use of pubertal blockers (and subsequent use of sex hormones, as detailed below) include a discussion about implications for fertility (see recommendation 1.3). Transgender adolescents may

want to preserve fertility, which may be otherwise compromised if puberty is suppressed at an early stage and the individual completes phenotypic transition with the use of sex hormones.

Limited data are available regarding the effects of GnRH analogs on brain development. A single cross-sectional study demonstrated no compromise of executive function (107), but animal data suggest there may be an effect of GnRH analogs on cognitive function (108).

Values and preferences

Our recommendation of GnRH analogs places a higher value on the superior efficacy, safety, and reversibility of the pubertal hormone suppression achieved (as compared with the alternatives) and a relatively lower value on limiting the cost of therapy. Of the available alternatives, depot and oral progestin preparations are effective. Experience with this treatment dates back prior to the emergence of GnRH analogs for treating precocious puberty in papers from the 1960s and early 1970s (109–112). These compounds are usually safe, but some side effects have been reported (113–115). Only two recent studies involved transgender youth (116, 117). One of these studies described the use of oral lynestrenol monotherapy followed by the addition of testosterone treatment in transgender boys who were at Tanner stage B4 or further at the start of treatment (117). They found lynestrenol safe, but gonadotropins were not fully suppressed. The study reported metrorrhagia in approximately half of the individuals, mainly in the first 6 months. Acne, headache, hot flashes, and fatigue were other frequent side effects. Another progestin that has been studied in the United States is medroxyprogesterone. This agent is not as effective as GnRH analogs in lowering endogenous sex hormones either and may be associated with other side effects (116). Progestin preparations may be an acceptable treatment for persons without access to GnRH analogs or with a needle phobia. If GnRH analog treatment is not available (insurance denial, prohibitive cost, or other reasons), postpubertal, transgender female adolescents may be treated with an antiandrogen that directly suppresses androgen synthesis or action (see adult section).

Remarks

Measurements of gonadotropin and sex steroid levels give precise information about gonadal axis suppression, although there is insufficient evidence for any specific short-term monitoring scheme in children treated with GnRH analogs (88). If the gonadal axis is not completely suppressed—as evidenced by (for example) menses, erections, or progressive hair growth—the interval of GnRH analog treatment can be shortened or the dose increased. During treatment, adolescents should be monitored for negative effects of delaying puberty, including a halted growth spurt and impaired bone mineral accretion. Table 7 illustrates a suggested clinical protocol.

Anthropometric measurements and X-rays of the left hand to monitor bone age are informative for evaluating growth. To assess BMD, clinicians can perform dual-energy X-ray absorptiometry scans.

- 2.4. In adolescents who request sex hormone treatment (given this is a partly irreversible treatment), we recommend initiating treatment using a gradually increasing dose schedule (see Table 8) after a multidisciplinary team of medical and MHPs has confirmed the persistence of GD/gender incongruence and sufficient mental capacity to give informed consent, which most adolescents have by age 16 years (Table 5). (1 |⊕⊕○○)
- 2.5. We recognize that there may be compelling reasons to initiate sex hormone treatment prior to the age of 16 years in some adolescents with GD/gender incongruence, even though there are minimal published studies of gender-affirming hormone treatments administered before age 13.5 to 14 years. As with the care of adolescents ≥16 years of age, we recommend that an expert multidisciplinary team of medical and MHPs manage this treatment. (1 |⊕○○○)
- 2.6. We suggest monitoring clinical pubertal development every 3 to 6 months and laboratory parameters every 6 to 12 months during sex hormone treatment (Table 9). (2 |⊕⊕○○)

Table 7. Baseline and Follow-Up Protocol During Suppression of Puberty

Every 3–6 mo
Anthropometry: height, weight, sitting height, blood pressure, Tanner stages
Every 6–12 mo
Laboratory: LH, FSH, E2/T, 25OH vitamin D
Every 1–2 y
Bone density using DXA
Bone age on X-ray of the left hand (if clinically indicated)

Adapted from Hembree *et al.* (118).
Abbreviations: DXA, dual-energy X-ray absorptiometry; E2, estradiol; FSH, follicle stimulating hormone; LH, luteinizing hormone; T, testosterone;

Table 8. Protocol Induction of Puberty

Induction of female puberty with oral 17β -estradiol, increasing the dose every 6 mo:

5 $\mu\text{g/kg/d}$

10 $\mu\text{g/kg/d}$

15 $\mu\text{g/kg/d}$

20 $\mu\text{g/kg/d}$

Adult dose = 2–6 mg/d

In postpubertal transgender female adolescents, the dose of 17β -estradiol can be increased more rapidly:

1 mg/d for 6 mo

2 mg/d

Induction of female puberty with transdermal 17β -estradiol, increasing the dose every 6 mo (new patch is placed every 3.5 d):

6.25–12.5 $\mu\text{g/24 h}$ (cut 25- μg patch into quarters, then halves)

25 $\mu\text{g/24 h}$

37.5 $\mu\text{g/24 h}$

Adult dose = 50–200 $\mu\text{g/24 h}$

For alternatives once at adult dose, see Table 11.

Adjust maintenance dose to mimic physiological estradiol levels (see Table 15).

Induction of male puberty with testosterone esters increasing the dose every 6 mo (IM or SC):

25 $\text{mg/m}^2/2 \text{ wk}$ (or alternatively, half this dose weekly, or double the dose every 4 wk)

50 $\text{mg/m}^2/2 \text{ wk}$

75 $\text{mg/m}^2/2 \text{ wk}$

100 $\text{mg/m}^2/2 \text{ wk}$

Adult dose = 100–200 mg every 2 wk

In postpubertal transgender male adolescents the dose of testosterone esters can be increased more rapidly:

75 mg/2 wk for 6 mo

125 mg/2 wk

For alternatives once at adult dose, see Table 11.

Adjust maintenance dose to mimic physiological testosterone levels (see Table 14).

Adapted from Hembree et al. (118).

Abbreviations: IM, intramuscularly; SC, subcutaneously.

Evidence

Adolescents develop competence in decision making at their own pace. Ideally, the supervising medical professionals should individually assess this competence, although no objective tools to make such an assessment are currently available.

Many adolescents have achieved a reasonable level of competence by age 15 to 16 years (119), and in many countries 16-year-olds are legally competent with regard to medical decision making (120). However, others believe that although some capacities are generally achieved before age 16 years, other abilities (such as good risk

assessment) do not develop until well after 18 years (121). They suggest that health care procedures should be divided along a matrix of relative risk, so that younger adolescents can be allowed to decide about low-risk procedures, such as most diagnostic tests and common therapies, but not about high-risk procedures, such as most surgical procedures (121).

Currently available data from transgender adolescents support treatment with sex hormones starting at age 16 years (63, 122). However, some patients may incur potential risks by waiting until age 16 years. These include the potential risk to bone health if puberty is suppressed

Table 9. Baseline and Follow-up Protocol During Induction of Puberty

Every 3–6 mo

•Anthropometry: height, weight, sitting height, blood pressure, Tanner stages

Every 6–12 mo

•In transgender males: hemoglobin/hematocrit, lipids, testosterone, 25OH vitamin D

•In transgender females: prolactin, estradiol, 25OH vitamin D

Every 1–2 y

•BMD using DXA

•Bone age on X-ray of the left hand (if clinically indicated)

BMD should be monitored into adulthood (until the age of 25–30 y or until peak bone mass has been reached).

For recommendations on monitoring once pubertal induction has been completed, see Tables 14 and 15.

Adapted from Hembree et al. (118).

Abbreviation: DXA, dual-energy X-ray absorptiometry.

for 6 to 7 years before initiating sex hormones (*e.g.*, if someone reached Tanner stage 2 at age 9-10 years old). Additionally, there may be concerns about inappropriate height and potential harm to mental health (emotional and social isolation) if initiation of secondary sex characteristics must wait until the person has reached 16 years of age. However, only minimal data supporting earlier use of gender-affirming hormones in transgender adolescents currently exist (63). Clearly, long-term studies are needed to determine the optimal age of sex hormone treatment in GD/gender-incongruent adolescents.

The MHP who has followed the adolescent during GnRH analog treatment plays an essential role in assessing whether the adolescent is eligible to start sex hormone therapy and capable of consenting to this treatment (Table 5). Support of the family/environment is essential. Prior to the start of sex hormones, clinicians should discuss the implications for fertility (see recommendation 1.5). Throughout pubertal induction, an MHP and a pediatric endocrinologist (or other clinician competent in the evaluation and induction of pubertal development) should monitor the adolescent. In addition to monitoring therapy, it is also important to pay attention to general adolescent health issues, including healthy life style choices, such as not smoking, contraception, and appropriate vaccinations (*e.g.*, human papillomavirus).

For the induction of puberty, clinicians can use a similar dose scheme for hypogonadal adolescents with GD/gender incongruence as they use in other individuals with hypogonadism, carefully monitoring for desired and undesired effects (Table 8). In transgender female adolescents, transdermal 17β -estradiol may be an alternative for oral 17β -estradiol. It is increasingly used for pubertal induction in hypogonadal females. However, the absence of low-dose estrogen patches may be a problem. As a result, individuals may need to cut patches to size themselves to achieve appropriate dosing (123). In transgender male adolescents, clinicians can give testosterone injections intramuscularly or subcutaneously (124, 125).

When puberty is initiated with a gradually increasing schedule of sex steroid doses, the initial levels will not be high enough to suppress endogenous sex steroid secretion. Gonadotropin secretion and endogenous production of testosterone may resume and interfere with the effectiveness of estrogen treatment, in transgender female adolescents (126, 127). Therefore, continuation of GnRH analog treatment is advised until gonadectomy. Given that GD/gender-incongruent adolescents may opt not to have gonadectomy, long-term studies are necessary to examine the potential risks of prolonged GnRH analog treatment. Alternatively, in transgender male adolescents, GnRH analog treatment can be discontinued once an

adult dose of testosterone has been reached and the individual is well virilized. If uterine bleeding occurs, a progestin can be added. However, the combined use of a GnRH analog (for ovarian suppression) and testosterone may enable phenotypic transition with a lower dose of testosterone in comparison with testosterone alone. If there is a wish or need to discontinue GnRH analog treatment in transgender female adolescents, they may be treated with an antiandrogen that directly suppresses androgen synthesis or action (see section 3.0 "Hormonal Therapy for Transgender Adults").

Values and preferences

The recommendation to initiate pubertal induction only when the individual has sufficient mental capacity (roughly age 16 years) to give informed consent for this partly irreversible treatment places a higher value on the ability of the adolescent to fully understand and oversee the partially irreversible consequences of sex hormone treatment and to give informed consent. It places a lower value on the possible negative effects of delayed puberty. We may not currently have the means to weigh adequately the potential benefits of waiting until around age 16 years to initiate sex hormones vs the potential risks/harm to BMD and the sense of social isolation from having the timing of puberty be so out of sync with peers (128).

Remarks

Before starting sex hormone treatment, effects on fertility and options for fertility preservation should be discussed. Adult height may be a concern in transgender adolescents. In a transgender female adolescent, clinicians may consider higher doses of estrogen or a more rapid tempo of dose escalation during pubertal induction. There are no established treatments yet to augment adult height in a transgender male adolescent with open epiphyses during pubertal induction. It is not uncommon for transgender adolescents to present for clinical services after having completed or nearly completed puberty. In such cases, induction of puberty with sex hormones can be done more rapidly (see Table 8). Additionally, an adult dose of testosterone in transgender male adolescents may suffice to suppress the gonadal axis without the need to use a separate agent. At the appropriate time, the multidisciplinary team should adequately prepare the adolescent for transition to adult care.

3.0 Hormonal Therapy for Transgender Adults

The two major goals of hormonal therapy are (1) to reduce endogenous sex hormone levels, and thus reduce

the secondary sex characteristics of the individual's designated gender, and (2) to replace endogenous sex hormone levels consistent with the individual's gender identity by using the principles of hormone replacement treatment of hypogonadal patients. The timing of these two goals and the age at which to begin treatment with the sex hormones of the chosen gender is codetermined in collaboration with both the person pursuing transition and the health care providers. The treatment team should include a medical provider knowledgeable in transgender hormone therapy, an MHP knowledgeable in GD/gender incongruence and the mental health concerns of transition, and a primary care provider able to provide care appropriate for transgender individuals. The physical changes induced by this sex hormone transition are usually accompanied by an improvement in mental well-being (129, 130).

- 3.1. We recommend that clinicians confirm the diagnostic criteria of GD/gender incongruence and the criteria for the endocrine phase of gender transition before beginning treatment. (1 ⊕⊕⊕⊕)
- 3.2. We recommend that clinicians evaluate and address medical conditions that can be exacerbated by hormone depletion and treatment with sex hormones of the affirmed gender before beginning treatment (Table 10). (1 ⊕⊕⊕⊕)
- 3.3. We suggest that clinicians measure hormone levels during treatment to ensure that endogenous sex steroids are suppressed and administered sex steroids are maintained in the normal physiologic range for the affirmed gender. (2 ⊕⊕○○)

Evidence

It is the responsibility of the treating clinician to confirm that the person fulfills criteria for treatment. The treating clinician should become familiar with the terms and criteria presented in Tables 1–5 and take a thorough history from the patient in collaboration with the other members of the treatment team. The treating clinician must ensure that the desire for transition is appropriate; the consequences, risks, and benefits of treatment are well understood; and the desire for transition persists. They also need to discuss fertility preservation options (see recommendation 1.3) (67, 68).

Transgender males

Clinical studies have demonstrated the efficacy of several different androgen preparations to induce masculinization in transgender males (Appendix A) (113, 114, 131–134). Regimens to change secondary sex characteristics follow the general principle of hormone replacement treatment of male hypogonadism (135). Clinicians can use either parenteral or transdermal preparations to achieve testosterone values in the normal male range (this is dependent on the specific assay, but is typically 320 to 1000 ng/dL) (Table 11) (136). Sustained supraphysiologic levels of testosterone increase the risk of adverse reactions (see section 4.0 “Adverse Outcome Prevention and Long-Term Care”) and should be avoided.

Similar to androgen therapy in hypogonadal men, testosterone treatment in transgender males results in increased muscle mass and decreased fat mass, increased facial hair and acne, male pattern baldness in those genetically predisposed, and increased sexual desire (137).

Table 10. Medical Risks Associated With Sex Hormone Therapy

Transgender female: estrogen

Very high risk of adverse outcomes:

- Thromboembolic disease

Moderate risk of adverse outcomes:

- Macroprolactinoma
- Breast cancer
- Coronary artery disease
- Cerebrovascular disease
- Cholelithiasis
- Hypertriglyceridemia

Transgender male: testosterone

Very high risk of adverse outcomes:

- Erythrocytosis (hematocrit > 50%)

Moderate risk of adverse outcomes:

- Severe liver dysfunction (transaminases > threefold upper limit of normal)
- Coronary artery disease
- Cerebrovascular disease
- Hypertension
- Breast or uterine cancer

Table 11. Hormone Regimens in Transgender Persons

Transgender females ^a	
Estrogen	
Oral	
Estradiol	2.0–6.0 mg/d
Transdermal	
Estradiol transdermal patch (New patch placed every 3–5 d)	0.025–0.2 mg/d
Parenteral	
Estradiol valerate or cypionate	5–30 mg IM every 2 wk 2–10 mg IM every week
Anti-androgens	
Spironolactone	100–300 mg/d
Cyproterone acetate ^b	25–50 mg/d
GnRH agonist	3.75 mg SQ (SC) monthly 11.25 mg SQ (SC) 3-monthly
Transgender males	
Testosterone	
Parenteral testosterone	
Testosterone enanthate or cypionate	100–200 mg SQ (IM) every 2 wk or SQ (SC) 50% per week
Testosterone undecanoate ^c	1000 mg every 12 wk
Transdermal testosterone	
Testosterone gel 1.6% ^d	50–100 mg/d
Testosterone transdermal patch	2.5–7.5 mg/d

Abbreviations: IM, intramuscularly; SQ, sequentially; SC, subcutaneously.

^aEstrogens used with or without antiandrogens or GnRH agonist.

^bNot available in the United States.

^cOne thousand milligrams initially followed by an injection at 6 wk then at 12-wk intervals.

^dAvoid cutaneous transfer to other individuals.

In transgender males, testosterone will result in clitoromegaly, temporary or permanent decreased fertility, deepening of the voice, cessation of menses (usually), and a significant increase in body hair, particularly on the face, chest, and abdomen. Cessation of menses may occur within a few months with testosterone treatment alone, although high doses of testosterone may be required. If uterine bleeding continues, clinicians may consider the addition of a progestational agent or endometrial ablation (138). Clinicians may also administer GnRH analogs or depot medroxyprogesterone to stop menses prior to testosterone treatment.

Transgender females

The hormone regimen for transgender females is more complex than the transgender male regimen (Appendix B). Treatment with physiologic doses of estrogen alone is insufficient to suppress testosterone levels into the normal range for females (139). Most published clinical studies report the need for adjunctive therapy to achieve testosterone levels in the female range (21, 113, 114, 132–134, 139, 140).

Multiple adjunctive medications are available, such as progestins with antiandrogen activity and GnRH agonists (141). Spironolactone works by directly blocking androgens during their interaction with the androgen

receptor (114, 133, 142). It may also have estrogenic activity (143). Cyproterone acetate, a progestational compound with antiandrogenic properties (113, 132, 144), is widely used in Europe. 5 α -Reductase inhibitors do not reduce testosterone levels and have adverse effects (145).

Dittrich *et al.* (141) reported that monthly doses of the GnRH agonist goserelin acetate in combination with estrogen were effective in reducing testosterone levels with a low incidence of adverse reactions in 60 transgender females. Leuprolide and transdermal estrogen were as effective as cyproterone and transdermal estrogen in a comparative retrospective study (146).

Patients can take estrogen as oral conjugated estrogens, oral 17 β -estradiol, or transdermal 17 β -estradiol. Among estrogen options, the increased risk of thromboembolic events associated with estrogens in general seems most concerning with ethinyl estradiol specifically (134, 140, 141), which is why we specifically suggest that it not be used in any transgender treatment plan. Data distinguishing among other estrogen options are less well established although there is some thought that oral routes of administration are more thrombogenic due to the “first pass effect” than are transdermal and parenteral routes, and that the risk of thromboembolic events is dose-dependent. Injectable estrogen and sublingual

estrogen may benefit from avoiding the first pass effect, but they can result in more rapid peaks with greater overall periodicity and thus are more difficult to monitor (147, 148). However, there are no data demonstrating that increased periodicity is harmful otherwise.

Clinicians can use serum estradiol levels to monitor oral, transdermal, and intramuscular estradiol. Blood tests cannot monitor conjugated estrogens or synthetic estrogen use. Clinicians should measure serum estradiol and serum testosterone and maintain them at the level for premenopausal females (100 to 200 pg/mL and <50 ng/dL, respectively). The transdermal preparations and injectable estradiol cypionate or valerate preparations may confer an advantage in older transgender females who may be at higher risk for thromboembolic disease (149).

Values

Our recommendation to maintain levels of gender-affirming hormones in the normal adult range places a high value on the avoidance of the long-term complications of pharmacologic doses. Those patients receiving endocrine treatment who have relative contraindications to hormones should have an in-depth discussion with their physician to balance the risks and benefits of therapy.

Remarks

Clinicians should inform all endocrine-treated individuals of all risks and benefits of gender-affirming hormones prior to initiating therapy. Clinicians should strongly encourage tobacco use cessation in transgender females to avoid increased risk of VTE and cardiovascular complications. We strongly discourage the unsupervised use of hormone therapy (150).

Not all individuals with GD/gender incongruence seek treatment as described (*e.g.*, male-to-eunuchs and individuals seeking partial transition). Tailoring current protocols to the individual may be done within the context of accepted safety guidelines using a multidisciplinary approach including mental health. No evidence-based protocols are available for these groups (151). We need prospective studies to better understand treatment options for these persons.

- 3.4. We suggest that endocrinologists provide education to transgender individuals undergoing treatment about the onset and time course of physical changes induced by sex hormone treatment. (2 ⊕○○○)

Evidence

Transgender males

Physical changes that are expected to occur during the first 1 to 6 months of testosterone therapy include

cessation of menses, increased sexual desire, increased facial and body hair, increased oiliness of skin, increased muscle, and redistribution of fat mass. Changes that occur within the first year of testosterone therapy include deepening of the voice (152, 153), clitoromegaly, and male pattern hair loss (in some cases) (114, 144, 154, 155) (Table 12).

Transgender females

Physical changes that may occur in transgender females in the first 3 to 12 months of estrogen and anti-androgen therapy include decreased sexual desire, decreased spontaneous erections, decreased facial and body hair (usually mild), decreased oiliness of skin, increased breast tissue growth, and redistribution of fat mass (114, 139, 149, 154, 155, 161) (Table 13). Breast development is generally maximal at 2 years after initiating hormones (114, 139, 149, 155). Over a long period of time, the prostate gland and testicles will undergo atrophy.

Although the time course of breast development in transgender females has been studied (150), precise information about other changes induced by sex hormones is lacking (141). There is a great deal of variability among individuals, as evidenced during pubertal development. We all know that a major concern for transgender females is breast development. If we work with estrogens, the result will be often not what the transgender female expects.

Alternatively, there are transgender females who report an anecdotal improved breast development, mood, or sexual desire with the use of progestogens. However, there have been no well-designed studies of the role of progestogens in feminizing hormone regimens, so the question is still open.

Our knowledge concerning the natural history and effects of different cross-sex hormone therapies on breast

Table 12. Masculinizing Effects in Transgender Males

Effect	Onset	Maximum
Skin oiliness/acne	1–6 mo	1–2 y
Facial/body hair growth	6–12 mo	4–5 y
Scalp hair loss	6–12 mo	— ^a
Increased muscle mass/strength	6–12 mo	2–5 y
Fat redistribution	1–6 mo	2–5 y
Cessation of menses	1–6 mo	— ^b
Clitoral enlargement	1–6 mo	1–2 y
Vaginal atrophy	1–6 mo	1–2 y
Deepening of voice	6–12 mo	1–2 y

Estimates represent clinical observations: Toorians *et al.* (149), Assche-man *et al.* (156), Gooren *et al.* (157), Wierckx *et al.* (158).

^aPrevention and treatment as recommended for biological men.

^bMenorrhagia requires diagnosis and treatment by a gynecologist.

Table 13. Feminizing Effects in Transgender Females

Effect	Onset	Maximum
Redistribution of body fat	3–6 mo	2–3 y
Decrease in muscle mass and strength	3–6 mo	1–2 y
Softening of skin/decreased oiliness	3–6 mo	Unknown
Decreased sexual desire	1–3 mo	3–6 mo
Decreased spontaneous erections	1–3 mo	3–6 mo
Male sexual dysfunction	Variable	Variable
Breast growth	3–6 mo	2–3 y
Decreased testicular volume	3–6 mo	2–3 y
Decreased sperm production	Unknown	>3 y
Decreased terminal hair growth	6–12 mo	>3 y ^a
Scalp hair	Variable	— ^b
Voice changes	None	— ^c

Estimates represent clinical observations: Toorians *et al.* (149), Asscheman *et al.* (156), Gooren *et al.* (157).

^aComplete removal of male sexual hair requires electrolysis or laser treatment or both.

^bFamilial scalp hair loss may occur if estrogens are stopped.

^cTreatment by speech pathologists for voice training is most effective.

development in transgender females is extremely sparse and based on the low quality of evidence. Current evidence does not indicate that progestogens enhance breast development in transgender females, nor does evidence prove the absence of such an effect. This prevents us from drawing any firm conclusion at this moment and demonstrates the need for further research to clarify these important clinical questions (162).

Values and preferences

Transgender persons have very high expectations regarding the physical changes of hormone treatment and are aware that body changes can be enhanced by surgical procedures (*e.g.*, breast, face, and body habitus). Clear expectations for the extent and timing of sex hormone-induced changes may prevent the potential harm and expense of unnecessary procedures.

4.0 Adverse Outcome Prevention and Long-Term Care

Hormone therapy for transgender males and females confers many of the same risks associated with sex hormone replacement therapy in nontransgender persons. The risks arise from and are worsened by inadvertent or intentional use of supraphysiologic doses of sex hormones, as well as use of inadequate doses of sex hormones to maintain normal physiology (131, 139).

- 4.1. We suggest regular clinical evaluation for physical changes and potential adverse changes in response to sex steroid hormones and laboratory monitoring of sex steroid hormone levels every

3 months during the first year of hormone therapy for transgender males and females and then once or twice yearly. (2 ⊕⊕○○)

Evidence

Pretreatment screening and appropriate regular medical monitoring are recommended for both transgender males and females during the endocrine transition and periodically thereafter (26, 155). Clinicians should monitor weight and blood pressure, conduct physical exams, and assess routine health questions, such as tobacco use, symptoms of depression, and risk of adverse events such as deep vein thrombosis/pulmonary embolism and other adverse effects of sex steroids.

Transgender males

Table 14 contains a standard monitoring plan for transgender males on testosterone therapy (154, 159). Key issues include maintaining testosterone levels in the physiologic normal male range and avoiding adverse events resulting from excess testosterone therapy, particularly erythrocytosis, sleep apnea, hypertension, excessive weight gain, salt retention, lipid changes, and excessive or cystic acne (135).

Because oral 17-alkylated testosterone is not recommended, serious hepatic toxicity is not anticipated with parenteral or transdermal testosterone use (163, 164). Past concerns regarding liver toxicity with testosterone have been alleviated with subsequent reports that indicate the risk of serious liver disease is minimal (144, 165, 166).

Transgender females

Table 15 contains a standard monitoring plan for transgender females on estrogens, gonadotropin suppression, or antiandrogens (160). Key issues include avoiding supraphysiologic doses or blood levels of estrogen that may lead to increased risk for thromboembolic disease, liver dysfunction, and hypertension. Clinicians should monitor serum estradiol levels using laboratories participating in external quality control, as measurements of estradiol in blood can be very challenging (167).

VTE may be a serious complication. A study reported a 20-fold increase in venous thromboembolic disease in a large cohort of Dutch transgender subjects (161). This increase may have been associated with the use of the synthetic estrogen, ethinyl estradiol (149). The incidence decreased when clinicians stopped administering ethinyl estradiol (161). Thus, the use of synthetic estrogens and conjugated estrogens is undesirable because of the inability to regulate doses by measuring serum levels and the risk of thromboembolic disease. In a German gender clinic, deep vein thrombosis occurred in 1 of 60 of transgender females treated with a GnRH analog and oral

Table 14. Monitoring of Transgender Persons on Gender-Affirming Hormone Therapy: Transgender Male

1. Evaluate patient every 3 mo in the first year and then one to two times per year to monitor for appropriate signs of virilization and for development of adverse reactions.
2. Measure serum testosterone every 3 mo until levels are in the normal physiologic male range:^a
 - a. For testosterone enanthate/cypionate injections, the testosterone level should be measured midway between injections. The target level is 400–700 ng/dL to 400 ng/dL. Alternatively, measure peak and trough levels to ensure levels remain in the normal male range.
 - b. For parenteral testosterone undecanoate, testosterone should be measured just before the following injection. If the level is <400 ng/dL, adjust dosing interval.
 - c. For transdermal testosterone, the testosterone level can be measured no sooner than after 1 wk of daily application (at least 2 h after application).
3. Measure hematocrit or hemoglobin at baseline and every 3 mo for the first year and then one to two times a year. Monitor weight, blood pressure, and lipids at regular intervals.
4. Screening for osteoporosis should be conducted in those who stop testosterone treatment, are not compliant with hormone therapy, or who develop risks for bone loss.
5. If cervical tissue is present, monitoring as recommended by the American College of Obstetricians and Gynecologists.
6. Ovariectomy can be considered after completion of hormone transition.
7. Conduct sub- and periareolar annual breast examinations if mastectomy performed. If mastectomy is not performed, then consider mammograms as recommended by the American Cancer Society.

^aAdapted from Lapauw *et al.* (154) and Ott *et al.* (159).

estradiol (141). The patient who developed a deep vein thrombosis was found to have a homozygous C677 T mutation in the methylenetetrahydrofolate reductase gene. In an Austrian gender clinic, administering gender-affirming hormones to 162 transgender females and 89 transgender males was not associated with VTE, despite an 8.0% and 5.6% incidence of thrombophilia (159). A more recent multinational study reported only 10 cases of VTE from a cohort of 1073 subjects (168). Thrombophilia screening of transgender persons initiating hormone treatment should be restricted to those with a personal or family history of VTE (159). Monitoring D-dimer levels during treatment is not recommended (169).

- 4.2. We suggest periodically monitoring prolactin levels in transgender females treated with estrogens. (2 ⊕⊕○○)

Evidence

Estrogen therapy can increase the growth of pituitary lactotroph cells. There have been several reports of prolactinomas occurring after long-term, high-dose

estrogen therapy (170–173). Up to 20% of transgender females treated with estrogens may have elevations in prolactin levels associated with enlargement of the pituitary gland (156). In most cases, the serum prolactin levels will return to the normal range with a reduction or discontinuation of the estrogen therapy or discontinuation of cyproterone acetate (157, 174, 175).

The onset and time course of hyperprolactinemia during estrogen treatment are not known. Clinicians should measure prolactin levels at baseline and then at least annually during the transition period and every 2 years thereafter. Given that only a few case studies reported prolactinomas, and prolactinomas were not reported in large cohorts of estrogen-treated persons, the risk is likely to be very low. Because the major presenting findings of microprolactinomas (hypogonadism and sometimes gynecomastia) are not apparent in transgender females, clinicians may perform radiologic examinations of the pituitary in those patients whose prolactin levels persistently increase despite stable or reduced estrogen levels. Some transgender individuals receive psychotropic medications that can increase prolactin levels (174).

Table 15. Monitoring of Transgender Persons on Gender-Affirming Hormone Therapy: Transgender Female

1. Evaluate patient every 3 mo in the first year and then one to two times per year to monitor for appropriate signs of feminization and for development of adverse reactions.
2. Measure serum testosterone and estradiol every 3 mo.
 - a. Serum testosterone levels should be <50 ng/dL.
 - b. Serum estradiol should not exceed the peak physiologic range: 100–200 pg/mL.
3. For individuals on spironolactone, serum electrolytes, particularly potassium, should be monitored every 3 mo in the first year and annually thereafter.
4. Routine cancer screening is recommended, as in nontransgender individuals (all tissues present).
5. Consider BMD testing at baseline (160). In individuals at low risk, screening for osteoporosis should be conducted at age 60 years or in those who are not compliant with hormone therapy.

This table presents strong recommendations and does not include lower level recommendations.

- 4.3. We suggest that clinicians evaluate transgender persons treated with hormones for cardiovascular risk factors using fasting lipid profiles, diabetes screening, and/or other diagnostic tools. (2 ⊕⊕○○)

Evidence

Transgender males

Administering testosterone to transgender males results in a more atherogenic lipid profile with lowered high-density lipoprotein cholesterol and higher triglyceride and low-density lipoprotein cholesterol values (176–179). Studies of the effect of testosterone on insulin sensitivity have mixed results (178, 180). A randomized, open-label uncontrolled safety study of transgender males treated with testosterone undecanoate demonstrated no insulin resistance after 1 year (181, 182). Numerous studies have demonstrated the effects of sex hormone treatment on the cardiovascular system (160, 179, 183, 184). Long-term studies from The Netherlands found no increased risk for cardiovascular mortality (161). Likewise, a meta-analysis of 19 randomized trials in nontransgender males on testosterone replacement showed no increased incidence of cardiovascular events (185). A systematic review of the literature found that data were insufficient (due to very low-quality evidence) to allow a meaningful assessment of patient-important outcomes, such as death, stroke, myocardial infarction, or VTE in transgender males (176). Future research is needed to ascertain the potential harm of hormonal therapies (176). Clinicians should manage cardiovascular risk factors as they emerge according to established guidelines (186).

Transgender females

A prospective study of transgender females found favorable changes in lipid parameters with increased high-density lipoprotein and decreased low-density lipoprotein concentrations (178). However, increased weight, blood pressure, and markers of insulin resistance attenuated these favorable lipid changes. In a meta-analysis, only serum triglycerides were higher at ≥24 months without changes in other parameters (187). The largest cohort of transgender females (mean age 41 years, followed for a mean of 10 years) showed no increase in cardiovascular mortality despite a 32% rate of tobacco use (161).

Thus, there is limited evidence to determine whether estrogen is protective or detrimental on lipid and glucose metabolism in transgender females (176). With aging, there is usually an increase of body weight. Therefore, as with nontransgender individuals, clinicians should

monitor and manage glucose and lipid metabolism and blood pressure regularly according to established guidelines (186).

- 4.4. We recommend that clinicians obtain BMD measurements when risk factors for osteoporosis exist, specifically in those who stop sex hormone therapy after gonadectomy. (1 ⊕⊕○○)

Evidence

Transgender males

Baseline bone mineral measurements in transgender males are generally in the expected range for their pre-treatment gender (188). However, adequate dosing of testosterone is important to maintain bone mass in transgender males (189, 190). In one study (190), serum LH levels were inversely related to BMD, suggesting that low levels of sex hormones were associated with bone loss. Thus, LH levels in the normal range may serve as an indicator of the adequacy of sex steroid administration to preserve bone mass. The protective effect of testosterone may be mediated by peripheral conversion to estradiol, both systemically and locally in the bone.

Transgender females

A baseline study of BMD reported T scores less than −2.5 in 16% of transgender females (191). In aging males, studies suggest that serum estradiol more positively correlates with BMD than does testosterone (192, 193) and is more important for peak bone mass (194). Estrogen preserves BMD in transgender females who continue on estrogen and antiandrogen therapies (188, 190, 191, 195, 196).

Fracture data in transgender males and females are not available. Transgender persons who have undergone gonadectomy may choose not to continue consistent sex steroid treatment after hormonal and surgical sex reassignment, thereby becoming at risk for bone loss. There have been no studies to determine whether clinicians should use the sex assigned at birth or affirmed gender for assessing osteoporosis (e.g., when using the FRAX tool). Although some researchers use the sex assigned at birth (with the assumption that bone mass has usually peaked for transgender people who initiate hormones in early adulthood), this should be assessed on a case-by-case basis until there are more data available. This assumption will be further complicated by the increasing prevalence of transgender people who undergo hormonal transition at a pubertal age or soon after puberty. Sex for comparison within risk assessment tools may be based on the age at which hormones were initiated and the length of exposure to hormones. In some cases, it may be

reasonable to assess risk using both the male and female calculators and using an intermediate value. Because all subjects underwent normal pubertal development, with known effects on bone size, reference values for birth sex were used for all participants (154).

- 4.5. We suggest that transgender females with no known increased risk of breast cancer follow breast-screening guidelines recommended for those designated female at birth. (2 ⊕⊕○○)
- 4.6. We suggest that transgender females treated with estrogens follow individualized screening according to personal risk for prostatic disease and prostate cancer. (2 ⊕○○○)

Evidence

Studies have reported a few cases of breast cancer in transgender females (197–200). A Dutch study of 1800 transgender females followed for a mean of 15 years (range of 1–30 years) found one case of breast cancer. The Women's Health Initiative study reported that females taking conjugated equine estrogen without progesterone for 7 years did not have an increased risk of breast cancer as compared with females taking placebo (137).

In transgender males, a large retrospective study conducted at the U.S. Veterans Affairs medical health system identified seven breast cancers (194). The authors reported that this was not above the expected rate of breast cancers in cisgender females in this cohort. Furthermore, they did report one breast cancer that developed in a transgender male patient after mastectomy, supporting the fact that breast cancer can occur even after mastectomy. Indeed, there have been case reports of breast cancer developing in subareolar tissue in transgender males, which occurred after mastectomy (201, 202).

Women with primary hypogonadism (Turner syndrome) treated with estrogen replacement exhibited a significantly decreased incidence of breast cancer as compared with national standardized incidence ratios (203, 204). These studies suggest that estrogen therapy does not increase the risk of breast cancer in the short term (<20 to 30 years). We need long-term studies to determine the actual risk, as well as the role of screening mammograms. Regular examinations and gynecologic advice should determine monitoring for breast cancer.

Prostate cancer is very rare before the age of 40, especially with androgen deprivation therapy (205). Childhood or pubertal castration results in regression of the prostate and adult castration reverses benign prostate hypertrophy (206). Although van Kesteren *et al.* (207) reported that estrogen therapy does not induce hypertrophy or premalignant changes in the prostates of

transgender females, studies have reported cases of benign prostatic hyperplasia in transgender females treated with estrogens for 20 to 25 years (208, 209). Studies have also reported a few cases of prostate carcinoma in transgender females (210–214).

Transgender females may feel uncomfortable scheduling regular prostate examinations. Gynecologists are not trained to screen for prostate cancer or to monitor prostate growth. Thus, it may be reasonable for transgender females who transitioned after age 20 years to have annual screening digital rectal examinations after age 50 years and prostate-specific antigen tests consistent with U.S. Preventive Services Task Force Guidelines (215).

- 4.7. We advise that clinicians determine the medical necessity of including a total hysterectomy and oophorectomy as part of gender-affirming surgery. (Ungraded Good Practice Statement)

Evidence

Although aromatization of testosterone to estradiol in transgender males has been suggested as a risk factor for endometrial cancer (216), no cases have been reported. When transgender males undergo hysterectomy, the uterus is small and there is endometrial atrophy (217, 218). Studies have reported cases of ovarian cancer (219, 220). Although there is limited evidence for increased risk of reproductive tract cancers in transgender males, health care providers should determine the medical necessity of a laparoscopic total hysterectomy as part of a gender-affirming surgery to prevent reproductive tract cancer (221).

Values

Given the discomfort that transgender males experience accessing gynecologic care, our recommendation for the medical necessity of total hysterectomy and oophorectomy places a high value on eliminating the risks of female reproductive tract disease and cancer and a lower value on avoiding the risks of these surgical procedures (related to the surgery and to the potential undesirable health consequences of oophorectomy) and their associated costs.

Remarks

The sexual orientation and type of sexual practices will determine the need and types of gynecologic care required following transition. Additionally, in certain countries, the approval required to change the sex in a birth certificate for transgender males may be dependent on having a complete hysterectomy. Clinicians should help patients research nonmedical administrative criteria and

provide counseling. If individuals decide not to undergo hysterectomy, screening for cervical cancer is the same as all other females.

5.0 Surgery for Sex Reassignment and Gender Confirmation

For many transgender adults, genital gender-affirming surgery may be the necessary step toward achieving their ultimate goal of living successfully in their desired gender role. The type of surgery falls into two main categories: (1) those that directly affect fertility and (2) those that do not. Those that change fertility (previously called sex reassignment surgery) include genital surgery to remove the penis and gonads in the male and removal of the uterus and gonads in the female. The surgeries that effect fertility are often governed by the legal system of the state or country in which they are performed. Other gender-conforming surgeries that do not directly affect fertility are not so tightly governed.

Gender-affirming surgical techniques have improved markedly during the past 10 years. Reconstructive genital surgery that preserves neurologic sensation is now the standard. The satisfaction rate with surgical reassignment of sex is now very high (187). Additionally, the mental health of the individual seems to be improved by participating in a treatment program that defines a pathway of gender-affirming treatment that includes hormones and surgery (130, 144) (Table 16).

Surgery that affects fertility is irreversible. The World Professional Association for Transgender Health Standards of Care (222) emphasizes that the “threshold of 18 should not be seen as an indication in itself for active intervention.” If the social transition has not been satisfactory, if the person is not satisfied with or is ambivalent about the effects of sex hormone treatment, or if the person is ambivalent about surgery then the individual should not be referred for surgery (223, 224).

Gender-affirming genital surgeries for transgender females that affect fertility include gonadectomy, penectomy, and creation of a neovagina (225, 226). Surgeons often invert the skin of the penis to form the wall of the vagina, and several literatures reviews have

reported on outcomes (227). Sometimes there is inadequate tissue to form a full neovagina, so clinicians have revisited using intestine and found it to be successful (87, 228, 229). Some newer vaginoplasty techniques may involve autologous oral epithelial cells (230, 231).

The scrotum becomes the labia majora. Surgeons use reconstructive surgery to fashion the clitoris and its hood, preserving the neurovascular bundle at the tip of the penis as the neurosensory supply to the clitoris. Some surgeons are also creating a sensate pedicled-spot adding a G spot to the neovagina to increase sensation (232). Most recently, plastic surgeons have developed techniques to fashion labia minora. To further complete the feminization, uterine transplants have been proposed and even attempted (233).

Neovaginal prolapse, rectovaginal fistula, delayed healing, vaginal stenosis, and other complications do sometimes occur (234, 235). Clinicians should strongly remind the transgender person to use their dilators to maintain the depth and width of the vagina throughout the postoperative period. Genital sexual responsivity and other aspects of sexual function are usually preserved following genital gender-affirming surgery (236, 237).

Ancillary surgeries for more feminine or masculine appearance are not within the scope of this guideline. Voice therapy by a speech language pathologist is available to transform speech patterns to the affirmed gender (148). Spontaneous voice deepening occurs during testosterone treatment of transgender males (152, 238). No studies have compared the effectiveness of speech therapy, laryngeal surgery, or combined treatment.

Breast surgery is a good example of gender-confirming surgery that does not affect fertility. In all females, breast size exhibits a very broad spectrum. For transgender females to make the best informed decision, clinicians should delay breast augmentation surgery until the patient has completed at least 2 years of estrogen therapy, because the breasts continue to grow during that time (141, 155).

Another major procedure is the removal of facial and masculine-appearing body hair using either electrolysis or

Table 16. Criteria for Gender-Affirming Surgery, Which Affects Fertility

1. Persistent, well-documented gender dysphoria
2. Legal age of majority in the given country
3. Having continuously and responsibly used gender-affirming hormones for 12 mo (if there is no medical contraindication to receiving such therapy)
4. Successful continuous full-time living in the new gender role for 12 mo
5. If significant medical or mental health concerns are present, they must be well controlled
6. Demonstrable knowledge of all practical aspects of surgery (e.g., cost, required lengths of hospitalizations, likely complications, postsurgical rehabilitation)

laser treatments. Other feminizing surgeries, such as that to feminize the face, are now becoming more popular (239–241).

In transgender males, clinicians usually delay gender-affirming genital surgeries until after a few years of androgen therapy. Those surgeries that affect fertility in this group include oophorectomy, vaginectomy, and complete hysterectomy. Surgeons can safely perform them vaginally with laparoscopy. These are sometimes done in conjunction with the creation of a neopenis. The cosmetic appearance of a neopenis is now very good, but the surgery is multistage and very expensive (242, 243). Radial forearm flap seems to be the most satisfactory procedure (228, 244). Other flaps also exist (245). Surgeons can make neopenile erections possible by reinnervation of the flap and subsequent contraction of the muscle, leading to stiffening of the neopenis (246, 247), but results are inconsistent (248). Surgeons can also stiffen the penis by imbedding some mechanical device (*e.g.*, a rod or some inflatable apparatus) (249, 250). Because of these limitations, the creation of a neopenis has often been less than satisfactory. Recently, penis transplants are being proposed (233).

In fact, most transgender males do not have any external genital surgery because of the lack of access, high cost, and significant potential complications. Some choose a metaoidioplasty that brings forward the clitoris, thereby allowing them to void in a standing position without wetting themselves (251, 252). Surgeons can create the scrotum from the labia majora with good cosmetic effect and can implant testicular prostheses (253).

The most important masculinizing surgery for the transgender male is mastectomy, and it does not affect fertility. Breast size only partially regresses with androgen therapy (155). In adults, discussions about mastectomy usually take place after androgen therapy has started. Because some transgender male adolescents present after significant breast development has occurred, they may also consider mastectomy 2 years after they begin androgen therapy and before age 18 years. Clinicians should individualize treatment based on the physical and mental health status of the individual. There are now newer approaches to mastectomy with better outcomes (254, 255). These often involve chest contouring (256). Mastectomy is often necessary for living comfortably in the new gender (256).

- 5.1. We recommend that a patient pursue genital gender-affirming surgery only after the MHP and the clinician responsible for endocrine transition therapy both agree that surgery is medically

necessary and would benefit the patient's overall health and/or well-being. (1 ⊕⊕○○)

- 5.2. We advise that clinicians approve genital gender-affirming surgery only after completion of at least 1 year of consistent and compliant hormone treatment, unless hormone therapy is not desired or medically contraindicated. (Ungraded Good Practice Statement)
- 5.3. We advise that the clinician responsible for endocrine treatment and the primary care provider ensure appropriate medical clearance of transgender individuals for genital gender-affirming surgery and collaborate with the surgeon regarding hormone use during and after surgery. (Ungraded Good Practice Statement)
- 5.4. We recommend that clinicians refer hormone-treated transgender individuals for genital surgery when: (1) the individual has had a satisfactory social role change, (2) the individual is satisfied about the hormonal effects, and (3) the individual desires definitive surgical changes. (1 ⊕○○○)
- 5.5. We suggest that clinicians delay gender-affirming genital surgery involving gonadectomy and/or hysterectomy until the patient is at least 18 years old or legal age of majority in his or her country. (2 ⊕⊕○○)
- 5.6. We suggest that clinicians determine the timing of breast surgery for transgender males based upon the physical and mental health status of the individual. There is insufficient evidence to recommend a specific age requirement. (2 ⊕○○○)

Evidence

Owing to the lack of controlled studies, incomplete follow-up, and lack of valid assessment measures, evaluating various surgical approaches and techniques is difficult. However, one systematic review including a large numbers of studies reported satisfactory cosmetic and functional results for vaginoplasty/neovagina construction (257). For transgender males, the outcomes are less certain. However, the problems are now better understood (258). Several postoperative studies report significant long-term psychological and psychiatric pathology (259–261). One study showed satisfaction with breasts, genitals, and femininity increased significantly and showed the importance of surgical treatment as a key therapeutic option for transgender females (262). Another analysis demonstrated that, despite the young average age at death following surgery and the relatively larger number of individuals with somatic morbidity, the study does not allow for determination of

causal relationships between, for example, specific types of hormonal or surgical treatment received and somatic morbidity and mortality (263). Reversal surgery in regretful male-to-female transsexuals after sexual reassignment surgery represents a complex, multistage procedure with satisfactory outcomes. Further insight into the characteristics of persons who regret their decision postoperatively would facilitate better future selection of applicants eligible for sexual reassignment surgery. We need more studies with appropriate controls that examine long-term quality of life, psychosocial outcomes, and psychiatric outcomes to determine the long-term benefits of surgical treatment.

When a transgender individual decides to have gender-affirming surgery, both the hormone prescribing clinician and the MHP must certify that the patient satisfies criteria for gender-affirming surgery (Table 16).

There is some concern that estrogen therapy may cause an increased risk for venous thrombosis during or following surgery (176). For this reason, the surgeon and the hormone-prescribing clinician should collaborate in making a decision about the use of hormones before and following surgery. One study suggests that preoperative factors (such as compliance) are less important for patient satisfaction than are the physical postoperative results (56). However, other studies and clinical experience dictate that individuals who do not follow medical instructions and do not work with their physicians toward a common goal do not achieve treatment goals (264) and experience higher rates of postoperative infections and other complications (265, 266). It is also important that the person requesting surgery feels comfortable with the anatomical changes that have occurred during hormone therapy. Dissatisfaction with social and physical outcomes during the hormone transition may be a contraindication to surgery (223).

An endocrinologist or experienced medical provider should monitor transgender individuals after surgery. Those who undergo gonadectomy will require hormone replacement therapy, surveillance, or both to prevent adverse effects of chronic hormone deficiency.

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Correspondence and Reprint Requests: The Endocrine Society, 2055 L Street NW, Suite 600, Washington, DC 20036. E-mail: publications@endocrine.org; Phone: 202971-3636.

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EXHIBIT M

IN THE UNITED STATES DISTRICT COURT
FOR THE WESTERN DISTRICT OF WASHINGTON
AT TACOMA

C.P., by and through his)
parents, PATRICIA PRITCHARD)
AND NOLLE PRITCHARD; and)
PATRICIA PRITCHARD,)
) No. 3:20-cv-06145-RJB
Plaintiffs,)
)
vs.)
)
BLUE CROSS BLUE SHIELD OF)
ILLINOIS,)
)
Defendant.)

REMOTE
VIDEOTAPED DEPOSITION UPON ORAL EXAMINATION OF
SHARON BOOKER, MA, LMHC
May 6, 2022

Witness location: Poulsbo, Washington

KATIE J. NELSON, RPR, CCR #2971
NELSON COURT REPORTERS, INC.
6513 132nd Avenue NE, #184
Kirkland, Washington 98033
(425) 866-4250
production@nelsonreporters.com

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Page 38 1 Our practice has a huge reputation in the 2 community. We've -- we've always had a large presence, you 3 know, for the last 25 years. And so -- so this is what we 4 do at these, you know, quarterly meetings is we -- we let 5 each other -- we give trainings on what each other does so 6 that we can get -- refer people to proper care. So I'm just 7 one of those people and she's one of those people and that's 8 how we know each other. 9 Q. What is the name of the networking group? 10 A. Oh, it's terrible. It's the -- it's the Kitsap 11 Mental Health Education and Training Group, but that's not 12 exactly. It gets changed. It's too long, too blah. I can 13 never remember it. 14 Q. There's no good acronym in other words? 15 A. No. It's mainly about -- it's mainly about 16 training and it's mainly about referrals. And it's Kitsap 17 County. 18 Q. And this is a group that -- both you and Pattie 19 Pritchard are involved in? 20 A. Yes. We have a huge number of providers, both 21 medical, mental health, psychiatrist, everyone, so that 22 everybody has a clear idea what others do. And we -- it has 23 printouts and has descriptions of what people do so that we 24 can give good referrals. 25 Q. So in addition to C.P., do you have any other	Page 40 1 Q. How many -- 2 A. -- I haven't worked with that surgeon before. 3 Q. But you had worked with Dr. Hatfield before? 4 A. Yes. Well, yes, been in the chain. Not directly. 5 I've never spoken to him. 6 Q. So you've never -- you've never spoken directly to 7 Dr. Hatfield? 8 A. No. 9 Q. Have you ever e-mailed with him? 10 A. To give a copy of what I had done, get a copy of 11 what he'd done, you know, anything -- maybe exchange on that 12 kind of pertinent information. But no, I don't get 13 medical -- I didn't ask for medical records, all of the 14 medical records, and he doesn't either. I don't really 15 encourage that because I don't want to give out my medical 16 records to people because they're very private. 17 MS. HAMBURGER: Stephanie, how -- I don't 18 want to interrupt your line of thought, if we can, in the 19 next 10 minutes, take a break. 20 MS. BEDARD: Yes. I think 10 minutes from 21 now will be perfect. 22 Q. (By Ms. Bedard) Ms. Booker, how many times did you 23 see C.P. as a patient, or I should say client? 24 A. Okay. I -- I want to give you the process. I did 25 an intake -- initial intake with the parent, which I always
Page 39 1 clients who have come to you as a result of your 2 participation in the networking group? 3 A. Oh, yeah, lots. I'm well known because I've 4 been -- I'm on the steering community and I've been on it 5 since, like I said, 2003 or something, 2004. So I'm pretty 6 well known. 7 Q. So just to clarify, C.P. did not first come to see 8 you as a result of any referral from a medical provider? 9 A. I don't know. 10 Q. Was there a specific reason that C.P. came to see 11 you? 12 A. Yes, because there's a second letter that's 13 required and -- and that is also from a mental health 14 provider. 15 Q. Who is the letter required by? 16 A. WPATH, World Association of Transgender Health. 17 You know what I mean. 18 Q. Who would you submit the letter to? 19 A. Well, I would give a copy back to Hatfield and I 20 would give -- I had a copy mainly to the surgeon. 21 Q. And who was that? 22 A. I knew you were going to ask me and I can't 23 remember. You have my letter and assessment; I do not. 24 It's a short name; I can't remember. That's -- yeah, I 25 don't have --	Page 41 1 do when it's a minor, okay? 2 So an intake with Pattie Pritchard, then I met with 3 C.P. for an hour; then I met with both C.P. and Pattie for 4 an hour as part of doing the assessment letter. 5 Q. So do -- you met with C.P. for a total of two 6 hours? 7 A. Correct. 8 Q. And after that second session, did you meet with 9 C.P. again? 10 A. No. 11 Q. How old was C.P. when you first met with him? 12 A. 15. 13 Q. And for those two-hour-long sessions -- oh, each 14 session was an hour total, right? 15 A. Correct. 16 Q. For the session -- the first session where you met 17 with C.P., was his mother with him or was he by himself? 18 A. He was by himself. 19 Q. And that's pretty typical for your minor patients 20 that you would have one just -- one session just with the 21 minor and then one session with the minor and their parent? 22 A. This was for an assessment. This is different than 23 my normal practice. 24 Q. So tell me a bit more about that. 25 What do you mean by an "assessment"? What does the

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REMOTE
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SHARON BOOKER, MA, LMHC
May 6, 2022

Witness location: Poulsbo, Washington

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Page 58 1 the bottom of it. 2 A. Yes. 3 Q. Our office only received Page 1 of this document. 4 MS. BEDARD: And so, Ms. Hamburger, I would 5 ask that to the extent there are additional pages of this 6 document -- the Bates number is Pritchard CFT 00002, that we 7 could receive the additional pages of this document to the 8 extent they exist. 9 MS. HAMBURGER: We'll -- we'll take a look 10 again to see if there are any missing pages that are not 11 produced, and if there are, we'll let you know. 12 THE WITNESS: Well -- 13 Q. (By Ms. Bedard) Thank you. 14 A. Can I say something? 15 Q. Yes. 16 A. You looked at the disclosure already, so that was 17 part of it, okay? So the -- I think there are two pages for 18 disclosure. The other page is just the signature page about 19 permission for billing insurances, you know, permission to 20 contact medical people, if necessary, and to agree to, you 21 know, services. So those don't really -- those aren't 22 filled out; they're just paperwork. But if you want copies 23 of them, fine. 24 Q. Thank you for clarifying. 25 Just out of an abundance of caution, we would like	Page 60 1 Q. And so was it your understanding that the purpose 2 of the visit was to obtain a letter supporting 3 gender-reaffirming surgery? 4 A. Correct. 5 Q. Ms. Booker, I'm now going to show you what has been 6 marked as Defendant's Exhibit 10. 7 (Exhibit 10 marked.) 8 Q. (By Ms. Bedard) What is this document? 9 A. These are the medical notes, which are very 10 specifically what is needed by the state for our sessions. 11 It is not to -- it is not -- it is -- it's just what is 12 required for every client medical -- 13 Q. And did you -- 14 THE COURT REPORTER: Crosstalk. Please 15 repeat that, Ms. Booker. 16 MS. BEDARD: Apologies. 17 THE WITNESS: A medical note is different 18 than a therapy note. It's specific kind of information that 19 needs to be included: The date, you know, the coding, these 20 are very specific questions. 21 Q. (By Ms. Bedard) Did you fill out this form? 22 A. Yes. 23 Q. And as I look at this form, it appears that there 24 are notes -- medical notes for three separate sessions. 25 A. Correct.
Page 59 1 to see the document in its entirety as it appears in your 2 record. 3 A. Okay. 4 Q. So, going back to this first page of the document, 5 though, it says that C.P.'s primary care physician is 6 Dr. Garza. 7 Did you ever consult with Dr. Garza about C.P.? 8 A. No. 9 Q. And then I'm scrolling down on same page. It says: 10 "Please describe the main problems that led you to therapy," 11 and filled out on the form, it says: "Assessment for gender 12 dysphoria to obtain letter supporting gender-reaffirming 13 surgery." 14 Is that right? 15 A. Yes. 16 Q. Are there any problems listed here in addition to 17 the need to obtain a letter supporting gender-reaffirming 18 surgery? 19 A. Just gender -- well, no. No, it's -- that's what 20 they came for; that's what I was aware of during the intake. 21 Q. So going into your session with C.P., you would 22 have reviewed this document in advance? 23 A. This document? 24 Q. This document. 25 A. Of course.	Page 61 1 Q. So at the top of the page, there is a date for 2 December 20th of 2019? 3 A. Yeah. As you see is -- 4 Q. In the middle of the -- if you could just let me 5 finish, that would be helpful. 6 A. Okay. 7 Q. Thank you. 8 So at the top of the page, there is a note for 9 December 20th of 2019. 10 A. Mm-hm. 11 Q. Middle of the page is June 20th of 2019, and at the 12 bottom of the page is July 23rd of 2019; is that right? 13 A. Yes. If you look at it, you'll see that the first 14 one is an intake, okay, a parent intake, and that's -- 15 that's what I designated. That's what I was telling you, 16 and that's typical for me. 17 Q. Why is the date of the parent intake after the 18 other two sessions? 19 A. Hum? Huh? 20 Q. Am I reading that correctly? It's a -- oh, right. 21 A. That could be a mistake. I'm not sure. I'd have 22 to go back and look. 23 Q. Okay. But for the -- 24 A. That would have been in February. 25 Q. -- parent intake --

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Page 66 1 about -- and are you talking about primary letters or 2 secondary letters? There's a big difference between -- 3 Q. Thank you for -- 4 A. -- the two. 5 Q. Thank you for clarifying. 6 So let's -- let's start big picture: How many 7 letters, primary or secondary, have you been asked to write 8 for chest reconstructive surgery for adults or minors? 9 A. I don't have a specific count. Maybe 15, you know, 10 around. Don't know specifically. 11 Q. And -- 12 A. Again, I don't track this. 13 Q. And of those approximately 15 letters that you've 14 been asked to write for reconstructive chest surgery for 15 adults or minors, did you write a letter on every occasion? 16 A. For -- for a minor you're asking, or adult? 17 Q. I'm asking for both, so let me rephrase my 18 question. 19 So for the letters that you have written for 20 adults -- sorry. 21 For the letters you've been asked to write for 22 adults or minors for reconstructive chest surgery, how many 23 of those letters have you declined to write? 24 MS. HAMBURGER: Object as to form; asked and 25 answered.	Page 68 1 that he presented with depression? 2 A. Well, it's difficult because dysphoria is a form of 3 depression, so that's why I said "other" to be more specific 4 that it was for dysphoria as far as the kind of depression. 5 Q. But you diagnosed him as presenting with symptoms 6 of depression. This was a -- your diagnosis, in other 7 words, right? 8 A. No, I did not diagnose him with depression. You 9 can see by the diagnosis, I did not. I checkmarked that 10 there was some symptoms of depression, but they are more 11 accounted for by dysphoria. Did not -- did not diagnose him 12 with depression, did not meet that -- those criteria. 13 Q. Okay. So just so I'm understanding, this -- the 14 checkboxes here do not indicate a diagnosis? 15 A. Right. 16 Q. They indicate present -- that the client -- that 17 your client is presenting with certain symptoms? 18 A. Symptoms or problems -- 19 Q. Symptoms or problems? 20 A. -- has them. 21 Q. Okay. Thank you. 22 A. Issues -- 23 Q. For C.P. -- 24 A. It could be issues -- sorry. 25 Q. Thank you.
Page 67 1 Q. (By Ms. Bedard) You can answer. 2 A. I need to answer this is in a very specific way. 3 Please don't interrupt me. 4 So basically, I haven't done that many not [sic] 5 letters for top surgery in general. I think I've told you 6 that. And most of -- if it -- if it's a secondary letter, 7 I've done very few of those. But generally, I had very well 8 trained people doing the first letter and, you know, with 9 a -- and -- and the first letter was very thorough, so -- 10 but on none of these did I have the need to say no based on 11 what I, you know, assessed. 12 Q. How many primary letters have you written for top 13 surgery? 14 A. Ten, 12. Something in that range. 15 Q. How many secondary letters have you written for top 16 surgery? 17 A. I don't know. Five and under. Five or under. 18 Again, we're talking about -- I've been doing this for 14 19 years. 20 Q. Turning back to Exhibit 11, Ms. Booker, on 21 Page 2 -- I'm scrolling down -- there's a section of this 22 form titled "Presenting Problem or Symptom." 23 A. Mm-hm. 24 Q. And one of the checkmarks is for depression. 25 Did you conduct an assessment of C.P. and determine	Page 69 1 For C.P., you checked the boxes that he was 2 presenting with problems or symptoms of depression, poor 3 concentration and focus and gender dysphoria; is that right? 4 A. I've already specified about the depression. It's 5 not the way you said it. 6 Q. And moving on down to "Treatment Goals," under 7 Treatment Goals, it says: "Provide an assessment and letter 8 for gender-affirming reconstructive surgery." Right? 9 A. Well, that was the purpose that was presented to 10 me. It's -- 11 Q. Are there any -- 12 A. I don't really have a good place to put that, you 13 know, about the letter. You know, these forms are made for 14 other things and ongoing therapy. They're not necessarily 15 made for this, for doing an assessment. 16 Q. Are there any other treatment goals listed for C.P. 17 other than the letter? 18 A. No. 19 Q. Because writing a letter is not a treatment goal, 20 right? 21 A. As I say, this form is a -- we don't really have a 22 form for those individuals coming in just asking for an 23 assessment letter, so that's when I put that. I didn't have 24 another place to put it on that form. 25 You have to understand, those forms are made for

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5/6/2022

Page 62 1 A. It could have been February. I'd have to look. 2 Q. Okay. Thank you. 3 A. Yeah. For this -- 4 Q. The parent -- Ms. Booker, we've got to be really 5 careful not to talk over each other, okay? 6 A. I know. 7 Q. Thank you. 8 So for this first entry in the medical notes for 9 parent intake, regardless of the date, symptoms addressed, 10 it states: "History of gender dysphoria." Right? 11 A. Right. 12 Q. And can you read us what it says for your notes and 13 observations there? 14 A. It says: "Met with mother to discuss doing -- it's 15 covered up, but -- "assessment letter for C.P. for top 16 surgery." I can't read that because there's covered ups. 17 "Reconstructive surgery. Went over history of symptoms." 18 Q. Now let's look at the second entry on the page for 19 June 20th of 2019. 20 A. Mm-hm. 21 Q. This indicates that you met with C.P. himself from 22 4 p.m. to 5 p.m., for one hour, right? 23 A. Correct. 24 Q. And under "Notes and Observations," it says: "Met 25 with C.P. alone to go over history, treatment and what to	Page 64 1 MS. HAMBURGER: Object as to form; asked and 2 answered. 3 Q. (By Ms. Bedard) Ms. Booker, I'm going through some 4 more of the documents that you provided us prior to your 5 deposition today. 6 I'm showing you what's been marked as Defendant's 7 Exhibit 11. 8 A. Mm-hm. 9 (Exhibit 11 marked.) 10 Q. (By Ms. Bedard) And what is this document? 11 A. This is that just initial intake. It's a kind of 12 cursory one; it's not a -- it's not in depth, just where we 13 kind of record what initially is discussed. 14 Q. So you filled out the form? 15 A. Yes. But -- but I filled this out actually after 16 also meeting with, you know, C.P. You know, I -- it took 17 a -- you know, because I wanted -- I needed to talk -- 18 I'm -- it was kind of after those -- the meeting with C.P., 19 after meeting with the mom, you know, to get, you know, 20 intake, you know, get a feel for what's going on. 21 Again, it's not like a huge, in-depth evaluation; 22 it's just mainly for our information. 23 Q. And scrolling down on the first page, under "Reason 24 for Referral," it says that the reason was "assessment 25 letter for reconstructive chest surgery." Right?
Page 63 1 expect with reconstructive surgery." Right? 2 A. As part of it. That's a -- that's not necessarily 3 the whole thing. I mean, that's just something -- a part of 4 what we discussed. I didn't put down everything we 5 discussed. 6 Q. And then on July 23rd, '2019, it says you met with 7 client and mother, right? 8 A. Correct. 9 Q. And then under Notes and Observations, it says you 10 "went over the plan for recovery from surgery during break. 11 Client and mother were well educated in what to expect," 12 right? 13 A. Yeah. Those are all part of the assessment 14 process, required, guidelines and criteria. 15 Q. And going back up to the top, for your initial 16 intake session, under Notes and Observations, it says: "Met 17 with mother to discuss doing an assessment letter." Right? 18 A. Correct. 19 Q. So just to summarize, based on what we see here 20 today, you met with C.P. himself twice on two occasions for 21 an hour each time, correct? 22 A. Yes. 23 Q. So the total time that you have spent with C.P. was 24 two hours? 25 A. Yes.	Page 65 1 A. Correct. 2 Q. So the letter -- assessment letter for 3 reconstructive chest surgery was the purpose of the visit, 4 right? 5 MS. HAMBURGER: Object as to form. 6 THE WITNESS: Purpose of the visit? 7 MS. HAMBURGER: Ms. Booker, you can answer -- 8 Q. (By Ms. Bedard) You can answer. 9 MS. HAMBURGER: -- if you're able. 10 THE WITNESS: Well, from the initial 11 assessment with the mother, you know, meeting with the 12 mom -- the meeting with the mother, she was straightforward 13 about what she -- what was -- what they were needing. 14 Q. (By Ms. Bedard) If you had found, based on your 15 assessment of C.P., that C.P. was not a good candidate for 16 reconstructive chest surgery -- 17 A. Yeah. 18 Q. -- would you have declined to write a letter? 19 A. Yes. 20 Q. And have you ever been asked to write a letter for 21 reconstructive chest surgery and declined to write a letter? 22 A. I have -- no, I have not. Not had to. 23 Q. How many letters in support of reconstructive chest 24 surgery have you been asked to write? 25 A. Are you talking about adults? You're talking

EXHIBIT Q

NCA - Gender Dysphoria and Gender Reassignment Surgery (CAG-00446N) - Decision Memo

Links in PDF documents are not guaranteed to work. To follow a web link, please use the MCD Website.

Decision Summary

Currently, the local Medicare Administrative Contractors (MACs) determine coverage of gender reassignment surgery on a case-by-case basis. We received a complete, formal request to make a national coverage determination on surgical remedies for gender identity disorder (GID), now known as gender dysphoria. The Centers for Medicare & Medicaid Services (CMS) is not issuing a National Coverage Determination (NCD) at this time on gender reassignment surgery for Medicare beneficiaries with gender dysphoria because the clinical evidence is inconclusive for the Medicare population.

In the absence of a NCD, coverage determinations for gender reassignment surgery, under section 1862(a)(1)(A) of the Social Security Act (the Act) and any other relevant statutory requirements, will continue to be made by the local MACs on a case-by-case basis. To clarify further, the result of this decision is not national non-coverage rather it is that no national policy will be put in place for the Medicare program. In the absence of a national policy, MACs will make the determination of whether or not to cover gender reassignment surgery based on whether gender reassignment surgery is reasonable and necessary for the individual beneficiary after considering the individual's specific circumstances. For Medicare beneficiaries enrolled in Medicare Advantage (MA) plans, the initial determination of whether or not surgery is reasonable and necessary will be made by the MA plans.

Consistent with the request CMS received, the focus of this National Coverage Analysis (NCA) was gender reassignment surgery. Specific types of surgeries were not individually assessed. We did not analyze the clinical evidence for counseling or hormone therapy treatments for gender dysphoria. As requested by several public commenters, we have modified our final decision memorandum to remove language that was beyond the scope of the specific request. We are not making a national coverage determination related to counseling, hormone therapy treatments, or any other potential treatment for gender dysphoria.

While we are not issuing a NCD, CMS encourages robust clinical studies that will fill the evidence gaps and help inform which patients are most likely to achieve improved health outcomes with gender reassignment surgery, which types of surgery are most appropriate, and what types of physician criteria and care setting(s) are needed to ensure that patients achieve improved health outcomes.

Decision Memo

To: Administrative File: CAG #00446N

From: Tamara Syrek Jensen, JD
Director, Coverage and Analysis Group

Joseph Chin, MD, MS
Deputy Director, Coverage and Analysis Group

James Rollins, MD, PhD
Director, Division of Items and Devices

Elizabeth Koller, MD
Lead Medical Officer

Linda Gousis, JD
Lead Analyst

Katherine Szarama, PhD
Analyst

Subject: Final Decision Memorandum on Gender Reassignment Surgery for Medicare Beneficiaries with Gender Dysphoria

Date: August 30, 2016

I. Decision

Currently, the local Medicare Administrative Contractors (MACs) determine coverage of gender reassignment surgery on a case-by-case basis. We received a complete, formal request to make a national coverage determination on surgical remedies for gender identity disorder (GID), now known as gender dysphoria. The Centers for Medicare & Medicaid Services (CMS) is not issuing a National Coverage Determination (NCD) at this time on gender reassignment surgery for Medicare beneficiaries with gender dysphoria because the clinical evidence is inconclusive for the Medicare population.

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II. Background

Below is a list of acronyms used throughout this document.

AHRQ - Agency for Healthcare Research and Quality
AIDS - Acquired Immune Deficiency Syndrome
ANOVA - Analysis of Variance

APA - American Psychiatric Association
 APGAR - Adaptability, Partnership Growth, Affection, and Resolve test
 BIQ - Body Image Questionnaire
 BSRI - Bem Sex Role Inventory
 CCEI - Crown Craps Experimental Index
 CDC – Centers for Disease Control
 CHIS - California Health Interview Survey
 CI - Confidence Interval
 CMS - Centers for Medicare & Medicaid Services
 DAB - Departmental Appeals Board
 DSM - Diagnostic and Statistical Manual of Mental Disorders
 EMBASE - Exerpta Medica dataBASE
 FBeK - Fragebogen zur Beurteilung des eigenen Körpers
 FDA - Food and Drug Administration
 FPI-R - Freiburg Personality Inventory
 FSFI - Female Sexual Function Index
 GAF - Global Assessment of Functioning
 GID - Gender Identity Disorder
 GIS - Gender Identity Trait Scale
 GRS - Gender Reassignment Surgery
 GSI - Global Severity Indices
 HADS - Hospital Anxiety Depression Scale
 HHS - U.S. Department of Health and Human Services
 HIV - Human Immunodeficiency Virus
 IIP - Inventory of Interpersonal Problems
 IOM - Institute of Medicine
 KHQ - King’s Health Questionnaire
 LGB - Lesbian, Gay, and Bisexual
 LGBT - Lesbian, Gay, Bisexual, and Transgender
 MAC - Medicare Administrative Contractor
 MMPI - Minnesota Multiphasic Personality Inventory
 NCA - National Coverage Analysis
 NCD - National Coverage Determination
 NICE - National Institute for Health Care Excellence
 NIH - National Institutes of Health
 NZHTA - New Zealand Health Technology Assessment
 PIT - Psychological Integration of Trans-sexuals
 QOL - Quality of Life
 S.D. - Standard Deviation
 SADS - Social Anxiety Depression Scale
 SCL-90R - Symptom Check List 90-Revised
 SDPE - Scale for Depersonalization Experiences
 SES - Self Esteem Scale
 SF - Short Form
 SMR - Standardized Mortality Ratio
 SOC – Standards of Care
 STAI-X1 - Spielberger State and Trait Anxiety Questionnaire
 STAI-X2 - Spielberger State and Trait Anxiety Questionnaire
 TSCS - Tennessee Self-Concept Scale
 U.S. - United States
 VAS - Visual Analog Scale
 WHOQOL-BREF - World Health Organization Quality of Life - Abbreviated version of the WHOQOL-100
 WPATH - World Professional Association for Transgender Health

A. Diagnostic Criteria

The criteria for gender dysphoria or spectrum of related conditions as defined by the American Psychiatric Association (APA) in the Diagnostic and Statistical Manual of Mental Disorders (DSM) has changed over time (See Appendix A).

Gender dysphoria (previously known as gender identity disorder) is a classification used to describe persons who experience significant discontent with their biological sex and/or gender assigned at birth. Although there are other therapeutic options for gender dysphoria, consistent with the NCA request, this decision only focuses on gender reassignment surgery.

B. Prevalence of Transgender Individuals

For estimates of transgender individuals in the U.S., we looked at several studies.

The Massachusetts Behavior Risk Factor Surveillance Survey (via telephone) (2007 and 2009) identified 0.5% individuals as transgender (Conron et al., 2012).

Derivative data obtained from the 2004 California Lesbian Gay Bisexual and Transgender (LGBT) Tobacco Survey (via telephone) and the 2009 California Health Interview Survey (CHIS) (via telephone) suggested the LGB population constitutes 3.2% of the California population and that transgender subjects constitute approximately 2% of the California LGBT population and 0.06% of the overall California population (Bye et al., 2005; CHIS 2009; Gates, 2011).

Most recently, the Williams Institute published a report that utilized data from the Centers for Disease Control's (CDC) Behavioral Risk Factor Surveillance System (BRFSS). Overall, they found that 0.6% or 1.4 million U.S. adults identify as transgender. The report further estimated 0.7% of adults between the ages of 18-25 identify as transgender, 0.6% of adults between the ages of 25-65 identify as transgender, and 0.5% of adults age 65 or older identify as transgender (Flores et al., 2016).

In a recent review of Medicare claims data, CMS estimated that in calendar year 2013 there were at least 4,098 transgender beneficiaries (less than 1% of the Medicare population) who utilized services paid for by Medicare, of which 90% had confirmatory diagnosis, billing codes, or evidence of a hormone therapy prescription. The Medicare transgender population is racially and ethnically diverse (e.g., 74% White, 15% African American) and spans the entire country. Nearly 80% of transgender beneficiaries are under age 65, including approximately 23% ages 45-54. (CMS Office of Minority Health 2015).

For international comparison purposes, recent estimates of transgender populations in other countries are similar to those in the United States. New Zealand researchers, using passport data, reported a prevalence of 0.0275% for male-to-female adults and 0.0044% female-to-male adults (6:1 ratio) (Veale, 2008). Researchers from a centers of transgender treatment and reassignment surgery in Belgium conducted a survey of regional plastic surgeons and reported a prevalence of 0.008% male-to-female and 0.003% female-to-male (ratio 2.7:1) surgically reassigned transsexuals in Belgium (De Cuyper et al., 2007). Swedish researchers, using national mandatory reporting data on those requesting reassignment surgery, reported secular changes over time in that the number of completed reassignment surgeries per application increased markedly in the 1990s; the male-to-female/female-to-male sex ratio changed from 1:1 to 2:1; the age of male-to-female and female-to-male applicants was initially similar, but increased by eight years for male-to-female applicants; and the proportion of foreign born applicants increased (Olsson and Moller 2003).

III. History of Medicare Coverage

Date	Action
August 1, 1989	CMS published the initial NCD, titled "140.3, Transsexual Surgery" in the Federal Register. (54 Fed. Reg. 34,555, 34,572)
May 30, 2014	The HHS Departmental Appeals Board (DAB) determined that the NCD denying coverage for all transsexual surgery was not valid. As a result, MACs determined coverage on a case-by-case basis.

CMS does not currently have a NCD on gender reassignment surgery.

A. Current Request

On December 3, 2015, CMS accepted a formal complete request from a beneficiary to initiate a NCA for gender reassignment surgery.

CMS opened this National Coverage Analysis (NCA) to thoroughly review the evidence to determine whether or not gender reassignment surgery may be covered nationally under the Medicare program.

B. Benefit Category

Medicare is a defined benefit program. For an item or service to be covered by the Medicare program, it must fall within one of the statutorily defined benefit categories as outlined in the Act. For gender reassignment surgery, the following are statutes are applicable to coverage:

Under §1812 (Scope of Part A) Under §1832 (Scope of Part B)
 Under §1861(s) (Definition of Medical and Other Health Services)
 Under §1861(s)(1) (Physicians' Services)

This may not be an exhaustive list of all applicable Medicare benefit categories for this item or service.

IV. Timeline of Recent Activities**Timeline of Medicare Coverage Policy Actions for Gender Reassignment Surgery**

Date	Action
December 3, 2015	CMS accepts an external request to open a NCD. A tracking sheet was posted on the web site and the initial 30 day public comment period commenced.
January 2, 2016	Initial comment period closed. CMS received 103 comments.
June 2, 2016	Proposed Decision Memorandum posted on the web site and the final 30 day public comment period commenced.
July 2, 2016	Final comment period closed. CMS received 45 comments.

V. FDA Status

Surgical procedures per se are not subject to the Food and Drug Administration's (FDA) approval.

Inflatable penile prosthetic devices, rigid penile implants, testicular prosthetic implants, and breast implants have been approved and/or cleared by the FDA.

VI. General Methodological Principles

In general, when making national coverage determinations, CMS evaluates relevant clinical evidence to determine whether or not the evidence is of sufficient quality to support a finding that an item or service is reasonable and necessary for the diagnosis or treatment of illness or injury or to improve the functioning of a malformed body member. (§ 1862 (a)(1)(A)). The evidence may consist of external technology assessments, internal review of published and unpublished studies, recommendations from the Medicare Evidence Development & Coverage Advisory Committee (MEDCAC), evidence-based guidelines, professional society position statements, expert opinion, and public comments.

The overall objective for the critical appraisal of the evidence is to determine to what degree we are confident that: 1) specific clinical question relevant to the coverage request can be answered conclusively; and 2) the extent to which we are confident that the intervention will improve health outcomes for patients.

A detailed account of the methodological principles of study design the agency staff utilizes to assess the relevant literature on a therapeutic or diagnostic item or service for specific conditions can be found in Appendix B. In general, features of clinical studies that improve quality and decrease bias include the selection of a clinically relevant cohort, the consistent use of a single good reference standard, blinding of readers of the index test, and reference test results.

VII. Evidence

A. Introduction

Below is a summary of the evidence we considered during our review, primarily articles about clinical trials published in peer-reviewed medical journals. We also considered articles cited by the requestor, articles identified in public comments, as well as those found by a CMS literature review. Citations are detailed below.

B. Literature Search Methods

CMS staff extensively searched for primary studies for gender dysphoria. The emphasis focused less on specific surgical techniques and more on functional outcomes unless specific techniques altered those types of outcomes.

The reviewed evidence included articles obtained by searching literature databases and technology review databases from PubMed (1965 to current date), EMBASE, the Agency for Healthcare Research and Quality (AHRQ), the Blue Cross/Blue Shield Technology Evaluation Center, the Cochrane Collection, the Institute of Medicine, and the National Institute for Health and Care Excellence (NICE) as well as the source material for commentary, guidelines, and formal evidence-based documents published by professional societies. Systematic reviews were used to help locate some of the more obscure publications and abstracts.

Keywords used in the search included: Trans-sexual, transgender, gender identity disorder (syndrome), gender dysphoria and/or hormone therapy, gender surgery, genital surgery, gender reassignment (surgery), sex reassignment (surgery) and/or quality of life, satisfaction-regret, psychological function (diagnosis of mood disorders, psychopathology, personality disorders), suicide (attempts), mortality, and adverse events-reoperations. After the identification of germane publications, CMS also conducted searches on the specific psychometric instruments used by investigators.

Psychometric instruments are scientific tools used to measure individuals' mental capabilities and behavioral style. They are usually in the form of questionnaires that numerically capture responses. These tools are used to create a psychological profile that can address questions about a person's knowledge, abilities, attitudes and personality traits. In the evaluation of patients with gender dysphoria, it is important that both validity and reliability be assured in the construction of the tool (validity refers to how well the tool actually measures what it was designed to measure, or how well it reflects the reality it claims to represent, while reliability refers to how accurately results of the tool would be replicated in a second identical piece of research). Reliability and validity are important because when evaluating patients with gender dysphoria most of the variables of interest (e.g., satisfaction, anxiety, depression) are latent in nature (not directly observed but are rather inferred) and difficult to quantify objectively.

Studies with robust study designs and larger, defined patient populations assessed with objective endpoints or validated test instruments were given greater weight than small, pilot studies. Reduced consideration was given to studies that were underpowered for the assessment of differences or changes known to be clinically important. Studies with fewer than 30 patients were reviewed and delineated, but excluded from the major analytic framework. Oral presentations, unpublished white papers, and case reports were excluded. Publications in languages other than English were excluded. The CMS initial internal search for the proposed decision memorandum was limited to articles published prior to March 21, 2016. The CMS internal search for the final decision memorandum continued through articles published prior to July 22, 2016.

Included studies were limited to those with adult subjects. Review and discussion of the management of children and adolescents with the additional considerations of induced pubertal delay are outside the scope of this NCD. In cases where the same population was studied for multiple reasons or where the patient population was expanded over time, the latest and/or most germane sections of the publications were analyzed. The excluded duplicative publications are delineated.

CMS also searched Clinicaltrials.gov to identify relevant clinical trials. CMS looked at trial status including early termination, completed, ongoing with sponsor update, and ongoing with estimated date of completion. Publications on completed trials were sought. For this final decision, CMS also reviewed all evidence submitted via public comment.

C. Discussion of Evidence

The development of an assessment in support of Medicare coverage determinations is based on the same general question for almost all national coverage analyses (NCAs): "Is the evidence sufficient to conclude that the application of the item or service under study will improve health outcomes for Medicare patients?" For this specific NCA, CMS is interested in answering the following question:

Is there sufficient evidence to conclude that gender reassignment surgery improves health outcomes for Medicare beneficiaries with gender dysphoria?

The evidence reviewed is directed towards answering this question.

1. Internal Technology Assessment

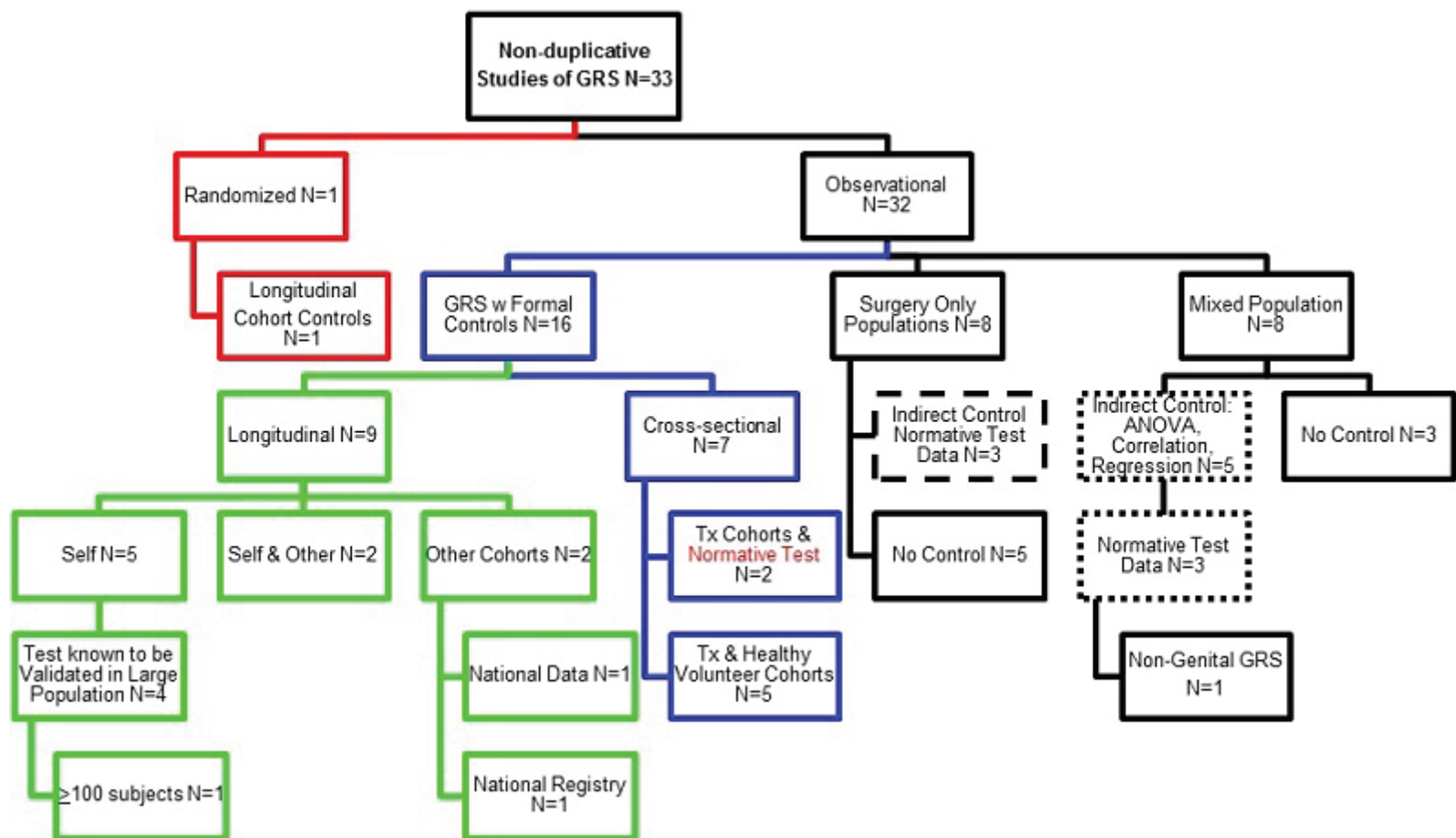
CMS conducted an extensive literature search on gender reassignment related surgical procedures and on facets of gender dysphoria that provide context for this analysis. The latter includes medical and environmental conditions.

CMS identified numerous publications related to gender reassignment surgery. A large number of these were case reports, case series with or without descriptive statistics, or studies with population sizes too small to conduct standard parametric statistical analyses. Others addressed issues of surgical technique.

CMS identified and described 36 publications on gender reassignment surgery that included health outcomes. Because the various investigators at a site sometimes conducted serial studies on ever-enlarging cohort populations, studied sub-populations, studied different outcomes, or used different tools to study the same outcomes, not all study populations were unique. To reduce bias from over-lapping populations, only the latest or most germane publication(s) were described. Subsumed publications were delineated.

Of these 36 publications, two publications used different assessment tools on the same population, and, so for the purposes of evaluation, were classified as one study (Udeze et al., 2008; Megeri and Khoosal, 2007). A total of 33 studies were reviewed (See Figure 1). Appendices C, D, and F include more detail of each study. The publications covered a time span from 1979 to 2015. Over half of the studies were published after 2005.

Figure 1. Studies of Gender Reassignment Surgery (GRS)



ANOVA=Analysis of Variance Normative=Psychometric Tests with known normative for large populations

Figure 1 Legend: The studies in Figure 1 are categorized into three groups. The first group, depicted by the colored

boxes (red, blue, and green), had explicit controls. There was a single randomized study. The remainder in the first group were observational studies. These were subdivided into longitudinal studies and cross-sectional studies. The second group, depicted by black boxes (starting with the surgery only population box) consisted of surgical series. The third group, depicted by black boxes (starting with mixed population), was composed of patients whose treatment could involve a variety of therapeutic interventions, but who were not stratified by that treatment.

When looking at the totality of studies, the 33 studies could be characterized by the following research design groups:

a. Observational, mixed population of surgical and non-surgical patients without stratification

Asscheman H, Giltay EJ, Megens JA, de Ronde WP, van Trotsenburg MA, Gooren LJ. A long-term follow-up study of mortality in transsexuals receiving treatment with cross-sex hormones. Eur J Endocrinol. 2011 Apr;164(4):635-42. Epub 2011 Jan 25.

Asscheman et al. conducted a retrospective, non-blinded, observational study of mortality using a longitudinal design to assess a mixed population treated with hormones, as well as, reassignment surgery in comparison to a population-based cohort. The study was not designed to assess the specific impact of gender reassignment surgery on clinical outcomes.

The investigators assessed mortality in patients who (a) were from a single-center, unspecified, Dutch university specialty clinic, (b) had initiated cross-sex hormone treatment prior to July 1, 1997, and (c) had been followed (with or without continued hormone treatment) by the clinic for at least one year or had expired during the first year of treatment. The National Civil Record Registry (Gemeentelijke Basis Administratie) was used to identify/confirm deaths of clinic patients. Information on the types or hormones used was extracted from clinic records, and information on the causation of death was extracted from medical records or obtained from family physicians. Mortality data for the general population were obtained through the Central Bureau of Statistics of the Netherlands (Centraal Bureau voor Statistiek). Mortality data from Acquired Immune Deficiency Syndrome (AIDS) and substance abuse were extracted from selected Statistics Netherlands reports. The gender of the general Dutch population comparator group was the natal sex of the respective gender dysphoric patient groups.

A total of 1,331 patients who met the hormone treatment requirements were identified (365 female-to-male [27.4%]; 966 male- to-female [72.6%]; ratio 1:2.6). Of these, 1,177 (88.4%) underwent reassignment surgery (343 [94.0% of female-to-male entrants]; 834 [86.3% of male-to-female entrants]; ratio difference 1:2.4 with a p-value $p < 0.0001$). Later calculations did not distinguish between those with hormone therapy alone versus those with hormone therapy plus reassignment surgery. The mean age at the time of hormone initiation in female-to-male and male-to-female patients was 26.1 ± 7.6 (range 16–56) years and 31.4 ± 11.4 (range 16–76) years respectively, although the male-to-female subjects were relatively older ($p < 0.001$). The mean duration of hormone therapy in female-to-male and male-to-female patients was 18.8 ± 6.3 and 19.4 ± 7.7 years respectively.

There were a total of 134 deaths in the clinic population using hormone therapy with or without surgical reassignment. Of these patients, 12 (3.3%) of the 365 female-to-male patients and 122 (12.6%) of the 966 male-to-female patients died. All-cause mortality for this mixed population was 51% higher and statistically significant (Standardized Mortality Ratio [SMR] 95% confidence interval [CI] 1.47-1.55) for males-to-females when compared to males in the general Dutch population. The increase in all-cause mortality (12%) for females-to-males when compared to females in the general Dutch population was not statistically significant (95% CI 0.87-1.42).

Ischemic heart disease was a major disparate contributor to excess mortality in male-to-female patients but only in older patients ($n = 18$, SMR 1.64 [95% CI 1.43-1.87]), mean age [range]: 59.7 [42-79] years. Current use of a

particular type of estrogen, ethinyl estradiol, was found to contribute to death from myocardial infarction or stroke (Adjusted Hazard Ratio 3.12 [95% CI 1.28-7.63], $p=0.01$). There was a small, but statistically significant increase in lung cancer that was thought to possibly be related to higher rates of smoking in this cohort.

Other contributors to the mortality difference between male-to-female patients and the Dutch population at large were completed suicide ($n=17$, SMR 5.70 [95% CI 4.93-6.54]), AIDS ($n=16$, SMR 30.20 [95% CI 26.0-34.7]), and illicit drug use ($n=5$, SMR 13.20 [95% CI 9.70-17.6]). An additional major contributor was "unknown cause" ($n=21$, SMR 4.00 [95% CI 3.52-4.51]). Of the 17 male-to-female hormone treated patients who committed suicide, 13 (76.5%) had received prior psychiatric treatment and six (35.3%) had not undergone reassignment surgery because of concerns about mental health stability.

Overall mortality, and specifically breast cancer and cardiovascular disease, were not increased in the hormone-treated female-to-male patients. Asscheman et al. reported an elevated SMR for illicit drug use ($n=1$, SMR 25 [6.00-32.5]). This was the cause of one of the 12 deaths in the cohort.

This study subsumes earlier publications on mortality (Asscheman et al. 1989 [$n=425$]; Van Kesteren et al. 1997 [$n=816$]).

Gómez-Gil E, Zubiaurre-Elorza L, Esteva I, Guillamon A, Godás T, Cruz Almaraz M, Halperin I, Salamero M. Hormone-treated transsexuals report less social distress, anxiety and depression. Psychoneuroendocrinology. 2012 May;37(5):662-70. Epub 2011 Sep 19.

Gómez-Gil et al. conducted a prospective, non-blinded observational study using a cross-sectional design and non-specific psychiatric distress tools in Spain. The investigators assessed anxiety and depression in patients with gender dysphoria who attended a single-center specialty clinic with comprehensive endocrine, psychological, psychiatric, and surgical care. The clinic employed World Professional Association for Transgender Health (WPATH) guidelines. Patients were required to have met diagnostic criteria during evaluations by 2 experts. Investigators used the Hospital Anxiety and Depression Scale (HADS) and the Social Anxiety and Distress Scale (SADS) instruments. The SADS total score ranges from 0 to 28, with higher scores indicative of more anxiety. English language normative values are 9.1 ± 8.0 . HAD-anxiety and HAD-depression total score ranges from 0 to 21, with higher scores indicative of more pathology. Scores less than 8 are normal. ANOVA was used to explore effects of hormone and surgical treatment.

Of the 200 consecutively selected patients recruited, 187 (93.5% of recruited) were included in the final study population. Of the final study population, 74 (39.6%) were female-to-male patients; 113 (60.4%) were male-to-female patients (ratio 1:1.5); and 120 (64.2%) were using hormones. Of those using hormones, 36 (30.0%) were female-to-male; 84 (70.0%) were male-to-female (ratio 1:2.3). The mean age was 29.87 ± 9.15 years (range 15-61). The current age of patients using hormones was 33.6 ± 9.1 years ($n=120$) and older than the age of patients without hormone treatment (25.9 ± 7.5) ($p=0.001$). The age at hormone initiation, however, was 24.6 ± 8.1 years.

Of those who had undergone reassignment surgery, 29 (36.7%) were female-to-male; 50 (63.3%) were male-to-female (ratio 1:1.7). The number of patients not on hormones and who had undergone at least one gender-related surgical procedure (genital or non-genital) was small ($n=2$). The number of female-to-male patients on hormones who had undergone such surgery (mastectomy, hysterectomy, and/or phalloplasty) was 28 (77.8%). The number of male-to-female patients on hormones who had undergone such surgery (mammoplasty, facial feminization, buttock feminization, vaginoplasty, orchiectomy, and/or vocal feminization (thyroid chondroplasty) was 49 (58.3%).

Analysis of the data revealed that although the mean scores HAD-Anxiety, HAD-Depression, and SADS were statistically lower (better) in those on hormone therapy than in those not on hormone therapy, the mean scores for

HAD-Depression and SADS were in the normal range for gender dysphoric patients not using hormones. The HAD-Anxiety score was 9 in transsexuals without hormone treatment and 6.4 in transsexuals with hormone treatment. The mean scores for HAD-Anxiety, HAD-Depression, and SADS were in the normal range for gender dysphoric patients using hormones. ANOVA revealed that results did not differ by whether the patient had undergone a gender related surgical procedure or not.

Gómez-Gil E, Zubiaurre-Elorza L, de Antonio I, Guillamon A, Salamero M. Determinants of quality of life in Spanish transsexuals attending a gender unit before genital sex reassignment surgery. Qual Life Res. 2014 Mar;23(2):669-76. Epub 2013 Aug 13.

Gómez-Gil et al. conducted a prospective, non-blinded observational study using a non-specific quality of life tool. There were no formal controls for this mixed population ± non-genital reassignment surgery undergoing various stages of treatment.

The investigators assessed quality of life in the context of culture in patients with gender dysphoria who were from a single-center (Barcelona, Spain), specialty and gender identity clinic. The clinic used WPATH guidelines. Patients were required to have met diagnostic criteria during evaluations by both a psychologist and psychiatrist. Patients could have undergone non-genital surgeries, but not genital reassignment surgeries (e.g., orchiectomy, vaginoplasty, or phalloplasty). The Spanish version of the World Health Organization Quality of Life-Abbreviated version of the WHOQOL-100 (WHOQOL-BREF) was used to evaluate quality of life, which has 4 domains (environmental, physical, psychological, and social) and 2 general questions. Family dynamics were assessed with the Spanish version of the Family Adaptability, Partnership Growth, Affection, and Resolve (APGAR) test. Regression analysis was used to explore effects of surgical treatment.

All consecutive patients presenting at the clinic (277) were recruited and, 260 (93.9%) agreed to participate. Of this number, 59 of these were excluded for incomplete questionnaires, 8 were excluded for prior genital reassignment surgery, and 193 were included in the study (the mean age of this group was 31.2±9.9 years (range 16-67)). Of these, 74 (38.3%) were female-to-male patients; 119 (61.7%) were male-to-female patients (ratio1:1.6). Of these, 120 (62.2%) were on hormone therapy; 29 (39.2%) of female-to-male patients had undergone at least 1 non-genital, surgical procedure (hysterectomy n=19 (25.7%); mastectomy n=29 (39.2%)); 51 (42.9%) of male-to-female patients had undergone at least one non-genital surgical procedure with mammoplasty augmentation being the most common procedure, n=47 (39.5%), followed by facial feminization, n=11 (9.2%), buttocks feminization, n=9 (7.6%), and vocal feminization (thyroid chondroplasty), n=2 (1.7%).

WHOQOL-BREF domain scores for gender dysphoric patients with and without non-genital surgery were: "Environmental" 58.81±14.89 (range 12.50-96.88), "Physical" 63.51±17.79 (range 14.29-100), "Psychological" 56.09±16.27 (range 16.67- 56.09), "Social" 60.35±21.88 (range 8.33-100), and "Global QOL and Health" 55.44±27.18 (range 0-100 with higher score representing better QOL). The mean APGAR family score was 7.23±2.86 (range 0-10 with a score of 7 or greater indicative of family functionality).

Regression analysis, which was used to assess the relative importance of various factors to WHOQOL-BREF domains and general questions, revealed that family support was an important element for all four domains and the general health and quality-of-life questions. Hormone therapy was an important element for the general questions and for all of the domains except "Environmental." Having undergone non-genital reassignment surgery, age, educational levels, and partnership status, did not impact domain and general question results related to quality of life.

Hepp U, Kraemer B, Schnyder U, Miller N, Delsignore A. Psychiatric comorbidity in gender identity disorder. J Psychosom Res. 2005 Mar;58(3):259-61.

Hepp et al. conducted a single-site (Zurich, Switzerland) prospective, non-blinded, observational study using a cross-sectional design. There was some acquisition of retrospective data. The investigators assessed current and lifetime psychiatry co-morbidity using structured interviews for diagnosis of Axis 1 disorders (clinical syndromes) and Axis 2 disorders (developmental or personality disorders) and HADS for dimensional evaluation of anxiety and depression. Statistical description of the cohort and intra-group comparisons was performed. Continuous variables were compared using t-tests and ANOVA.

A total of 31 patients with gender dysphoria participated in the study: 11 (35.5%) female-to-male; 20 (64.5%) male-to-female (ratio 1:1.8). The overall mean age was 32.2 ± 10.3 years. Of the participants, seven had undergone reassignment surgery, 10 pre-surgical patients had been prescribed hormone therapy, and 14 pre-surgical patients had not been prescribed hormone therapy. Forty five and one half percent of female-to-male and 20% of male-to-female patients did not carry a lifetime diagnosis of an Axis 1 condition. Sixty three and six tenths percent of female-to-male and 60% of male-to-female patients did not carry a current diagnosis of an Axis 1 condition. Lifetime diagnosis of substance abuse and mood disorder were more common in male-to-female patients (50% and 55% respectively) than female-to-male patients (36.4% and 27.3% respectively). Current diagnosis of substance abuse and mood disorder were present in male-to-female patients (15% and 20% respectively) and absent in female-to-male patients. One or more personality disorders were identified 41.9%, but whether this was a current or lifetime condition was not specified. Of the patients, five (16.1%) had a Cluster A personality disorder (paranoid-schizoid), seven (22.6%) had a Cluster B personality disorder (borderline, anti-social, histrionic, narcissistic), six (19.4%) had a Cluster C personality disorder (avoidant, dependent, obsessive-compulsive), and two (6.5%) were not otherwise classified.

HADS scores were missing for at least one person. The HADS test revealed non-pathologic results for depression (female-to-male: 6.64 ± 5.03 ; male-to-female: 6.58 ± 4.21) and borderline results for anxiety (female-to-male: 7.09 ± 5.11 ; male-to-female: 7.74 ± 6.13 , where a result of 7-10 = possible disorder). There were no differences by natal gender. The investigators reported a trend for less anxiety and depression as measured by HADS in the patients who had undergone surgery.

Johansson A, Sundbom E, Höjerback T, Bodlund O. A five-year follow-up study of Swedish adults with gender identity disorder. Arch Sex Behav. 2010 Dec;39(6):1429-37. Epub 2009 Oct 9.

Johansson et al. conducted a two center (Lund and Umeå, Sweden) non-blinded, observational study using a semi-cross-sectional design (albeit over an extended time interval) using a self-designed tool and Axis V assessment. The study was prospective except for the acquisition of baseline Axis V data. There were no formal controls in this mixed population with and without surgery.

The investigators assessed satisfaction with the reassignment process, employment, partnership, sexual function, mental health, and global satisfaction in gender-reassigned persons from two disparate geographic regions. Surgical candidates were required to have met National Board of Health and Welfare criteria including initial and periodic psychiatric assessment, ≥ 1 year of real-life experience in preferred gender, and ≥ 1 year of subsequent hormone treatment. In addition, participants were required to have been approved for reassignment five or more years prior and/or to have completed surgical reassignment (e.g., sterilization, genital surgery) two or more years prior. The investigators employed semi-structured interviews covering a self-designed list of 55 pre-formulated questions with a three or five point ordinal scale. Clinician assessment of Global Assessment of Functioning (GAF; Axis V) was also conducted and compared to initial finding during the study. Changes or differences considered to be biologically significant were not pre-specified except for GAF, which pre-specified a difference to mean change ≥ 5 points. Statistical corrections for multiple comparisons were not included. There was no stratification by treatment.

Of the pool of 60 eligible patients, 42 (70.0% of eligible) (17 [40.5 %] female-to-male; 25 [59.5%] male-to-female;

ratio 1:1.5) were available for follow-up. Of these, 32 (53.3% of eligible) (14 [43.8%] female-to-male; 18 [56.2%] male-to-female [ratio 1:1.3]) had completed genital gender reassignment surgery (not including one post mastectomy), five were still in the process of completing surgery, and five (one female-to-male; four male-to-female; ratio 1:4) had discontinued the surgical process prior to castration and genital surgery.

The age (ranges) of the patients at entry into the program, reassignment surgery, and follow-up were 27.8 (18-46), 31.4 (22- 49), and 38.9 (28-53) years in the female-to-male group respectively and 37.3 (21-60), 38.2 (22-57), and 46.0 (25.0-69.0) years in the male-to-female group respectively. The differences in age by cohort group were statistically significant. Of participants, 88.2% of all enrolled female-to-male versus 44.0% of all enrolled female-to-male patients had cross-gender identification in childhood (versus during or after puberty) ($p < 0.01$).

Although 95.2% of all enrolled patients self-reported improvement in GAF, in contrast, clinicians determined GAF improved in 61.9% of patients. Clinicians observed improvement in 47% of female-to-male patients and 72% of male-to-female patients. A ≥ 5 point improvement in the GAF score was present in 18 (42.9%). Of note, three of the five patients who were in the process of reassignment and five of the five who had discontinued the process were rated by clinicians as having improved.

Of all enrolled 95.2% (with and without surgery) reported satisfaction with the reassignment process. Of these 42 patients, 33 (79%) identified themselves by their preferred gender and nine (21%) identified themselves as transgender. None of these nine (eight male-to-female) had completed reassignment surgery because of ambivalence secondary to lack of acceptance by others and dissatisfaction with their appearance. Of the patients who underwent genital surgery ($n=32$) and mastectomy only ($n=one$), 22 (66.7%) were satisfied while four (three female-to-male) were dissatisfied with the surgical treatment.

Regarding relationships after surgery, 16 (38.1%) (41.2% of female-to-male; 36.0% of male-to-female patients) were reported to have a partner. Yet more than that number commented on partner relationships: (a) 62.2 % of the 37 who answered (50.0% of female-to-male; 69.6% of male-to-female patients) reported improved partner relationships (five [11.9%] declined to answer.); (b) 70.0% of the 40 who answered (75.0% of female-to-male; 66.7% of male-to-female patients) reported an improved sex life. Investigators observed that reported post-operative satisfaction with sex life was statistically more likely in those with early rather than late cross-gender identification. In addition 55.4% self-reported improved general health; 16.1% reported impaired general health; 11.9% were currently being treated with anti-depressants or tranquilizers.

This study subsumes earlier work by Bodlund et al. (1994, 1996). The nationwide mortality studies by Dhejne et al. (2011) may include all or part of this patient population.

Leinung M, Urizar M, Patel N, Sood S. Endocrine treatment of transsexual persons: extensive personal experience. Endocr Pract. 2013 Jul-Aug;19(4):644-50. (United States study)

Leinung et al. conducted a single-center (Albany, New York) a partially prospective, non-blinded, observational study using a cross-sectional design and descriptive statistics. There were no formal controls. The investigators assessed employment, substance abuse, psychiatric disease, mood disorders, Human Immunodeficiency Virus (HIV) status in patients who had met WPATH guidelines for therapy, and who had initiated cross-sex hormone treatment.

A total of 242 patients treated for gender identity disorder in the clinic from 1992 through 2009 inclusive were identified. The number of those presenting for therapy almost tripled over time. Of these patients, 50 (20.7%) were female-to-male; 192 (79.3%) male-to-female (ratio 1:3.8).

The age of female-to-male and male-to-female patients with gender dysphoria at the time of clinic presentation was 29.0 and 38.0 years respectively.

The female-to-male and male-to-female patients with gender dysphoria at the time of hormone initiation were young: 27.5 and 35.5 years old respectively ($p < 0.5$). Of the male-to-female cohort, 19 (7.8%) had received hormone therapy in the absence of physician supervision; Of the patient population, 91 (37.6%) had undergone gender-reassignment surgery (32 female-to-male [64.0% of all female-to-male; 35.2% of all surgical patients]; 59 male-to-female [30.7% of all male-to-female; 64.8% of all surgical patients]; ratio 1:1.8).

Psychiatric disease was more common in those who initiated hormone therapy at an older age (>32 years) 63.9% versus 48.9% at a younger age and by natal gender (48.0% of female-to-male; 58.3% male-to-female). Mood disorders were more common in those who initiated hormone therapy at an older age (>32 years) 52.1% versus 36.0% at a younger age and this finding did not differ by natal gender (40.0% of female-to-male; 44.8% male-to-female). The presence of mood disorders increased the time to reassignment surgery in male-to-female patients.

Motmans J, Meier P, Ponnet K, T'Sjoen G. Female and male transgender quality of life: socioeconomic and medical differences. J Sex Med. 2012 Mar;9(3):743-50. Epub 2011 Dec 21.

Motmans et al., conducted a prospective, non-blinded, observational study using a cross-sectional design and a non-specific quality of life tool. No concurrent controls were used in this study. Quality of life in this Dutch-speaking population was assessed using the Dutch version of a SF-36 (normative data was used). Participants included subjects who were living in accordance with the preferred gender and who were from a single Belgian university specialty clinic at Ghent. The Dutch version of the SF-36 questionnaire along with its normative data were used. Variables explored included employment, pension status, ability to work, being involved in a relationship. Also explored, was surgical reassignment surgery and the types of surgical interventions. Intragroup comparisons by transgender category were conducted, and the relationships between variables were assessed by analysis of variance (ANOVA) and correlations.

The age of the entire cohort ($n=140$) was 39.89 ± 10.21 years (female-to-male: 37.03 ± 8.51 ; male-to-female: 42.26 ± 10.39). Results of the analysis revealed that not all female-to-male patients underwent surgical reassignment surgery and, of those who did, not all underwent complete surgical reassignment. The numbers of female-to-male surgical interventions were: mastectomy 55, hysterectomy 55, metaoidplasty eight (with five of these later having phalloplasty), phalloplasty 40, and implantation of a prosthetic erectile device 20. The frequencies of various male-to-female surgical interventions were: vaginoplasty 48, breast augmentation 39, thyroid cartilage reduction 17, facial feminization 14, and hair transplantation three.

The final number of subjects with SF-36 scores was 103 (49 [47.6%] female-to-male; 54 [52.4%] male-to-female; ratio 1:1.1). For this measure, the scores for the vitality and mental health domains for the final female-to-male cohort ($n=49$ and not limited to those having undergone some element of reassignment surgery) were statistically lower: 60.61 ± 18.16 versus 71.9 ± 18.31 and 71.51 ± 16.40 versus 79.3 ± 16.4 respectively. Scores were not different from the normative data for Dutch women: vitality: 64.3 ± 19.7 or mental health 73.7 ± 18.2 . None of the domains of the SF-36 for the final male-to-female cohort ($n=54$ and not limited to those having undergone some element of reassignment surgery) were statistically different from the normative data for Dutch women.

Analysis of variance indicated that quality of life as measured by the SF-36 did not differ by whether female-to-male patients had undergone genital surgery (metaoidplasty or phalloplasty) or not. Also, ANOVA indicated that quality of life as measured by the SF-36 did not differ by whether male-to-female patients had undergone either breast augmentation or genital surgery (vaginoplasty) or not.

Whether there is overlap with the Ghent populations studied by Heylens et al. or Weyers et al. is unknown.

Newfield E, Hart S, Dibble S, Kohler L. Female-to-male transgender quality of life. Qual Life Res. 2006 Nov;15(9):1447-57. Epub 2006 Jun 7. (United States study)

Newfield et al. conducted a prospective, observational internet self-report survey of unknown blinding status using a cross-sectional design and a non-specific quality of life tool in a mixed population with and without hormone therapy and/or reassignment surgery. There were no formal controls.

The investigators recruited natal female participants identifying as male using email, internet bulletin boards, and flyers/postcards distributed in the San Francisco Bay Area. Reduction of duplicate entries by the same participant was limited to the use of a unique user name and password.

The investigators employed the Short-Form 36 (SF-36) Version 2 using U.S. normative data. They reported using both male and female normative data for the comparator SF-36 cohort. Data for the eight domains were expressed as normative scoring. The Bonferroni correction was used to adjust for the risk of a Type 1 error with analyses using multiple comparisons.

A total of 379 U.S. respondents classified themselves as males-or-females to males with or without therapeutic intervention. The mean age of the respondents who classified themselves as male or female-to-male was 32.6 ± 10.8 years. Of these 89% were Caucasian, 3.6% Latino, 1.8% African American, 1.8% Asian, and 3.8% other. Of these, 254 (67.0%) reported prior or current testosterone use while 242 (63.8%) reported current testosterone use. In addition, 136 (36.7%) reported having had "top" surgery and 11 (2.9%) reported having "bottom" surgery.

Complete SF-36 data were available for 376 U.S. respondents. For the complete, non-stratified U.S. cohort the Physical Summary Score (53.45 ± 9.42) was statistically higher (better) than the natal gender unspecified SF-36 normative score (50 ± 10) ($p < 0.001$), but was within one standard deviation of the normative mean. The Mental Summary Score (39.63 ± 12.2) was statistically lower (worse) than the natal gender unspecified SF-36 normative score (50 ± 10) ($p < 0.001$), but was well within two standard deviations of the normative mean. Subcomponents of this score: Mental Health (42.12 ± 10.2), Role Emotional (42.42 ± 11.6), Social Functioning (43.14 ± 10.9), and Vitality (46.22 ± 9.9) were statistically lower (worse) than the SF-36 normative sub-scores, but well within one standard deviation of the normative sub-score means. Interpretive information for these small biologic differences in a proprietary assessment tool was not provided.

Additional intragroup analyses were conducted, although the data were not stratified by type of therapeutic intervention (hormonal, as well as, surgical). Outcomes of hormone therapy were considered separately and dichotomously from reassignment surgery. The Mental Summary Score was statistically higher (better) in those who had "Ever Received Testosterone" (41.22 ± 11.9) than those with "No Testosterone Usage" (36.08 ± 12.6) ($p = 0.001$). The Mental Summary Scores showed a trend towards statistical difference between those who "Ever Received Top Surgery" (41.21 ± 11.6) and those without "Top Surgery" (38.01 ± 12.5) ($p = 0.067$). These differences were well within one standard deviation of the normative mean. Interpretive information for these small biologic differences in a proprietary assessment tool was not provided.

b. Observational, surgical series, without concurrent controls

Blanchard R, Steiner BW, Clemmensen LH. Gender dysphoria, gender reorientation, and the clinical management of transsexualism. J Consult Clin Psychol. 1985 Jun; 53(3):295-304.

Blanchard et al. conducted a single-center (Ontario, Canada), prospective, non-blinded, cross-sectional study using a self-designed questionnaire and a non-specific psychological symptom assessment with normative data. The investigators assessed social adjustment and psychopathology in patients with gender dysphoria and who were at least one year post gender reassignment surgery. Reassignment surgery was defined as either vaginoplasty or mastectomy/construction of male chest contour with or without nipple transplants, but did not preclude additional procedures. Partner preference was determined using Blanchard's Modified Androphilia-Gynephilia Index, and the nature and extent of any psychopathology was determined with the Symptom Check List 90-Revised (SCL-90R). Differences in test scores considered to be biologically significant were not pre-specified in the methods.

Of the 294 patients (111 natal females and 183 natal males, ratio: 1:1.65) initially evaluated, 263 were diagnosed with gender dysphoria. Of these 79 patients participated in the study (38 female-to-male; 32 male-to-female with male partner preference; 9 male-to-female with female partner preference). The respective mean ages for these 3 groups were 32.6, 33.2, and 47.7 years with the last group being older statistically ($p=0.01$).

Additional surgical procedures in female-to-male patients included: oophorectomy/hysterectomy (92.1%) and phalloplasty (7.9%). Additional surgical procedures in male-to-female patients with male partner preference included facial hair electrolysis 62.5% and breast implantation (53.1%). Additional procedures in male-to-female patients with female partner preference included facial hair electrolysis (100%) and breast implantation (33.3%). The time between reassignment surgery and questionnaire completion did not differ by group.

Psychopathology as measured by the Global Severity Index of the SCL-90R was absent in all three patient groups. Interpretation did not differ by the sex of the normative cohort.

Of participants, 63.2% of female-to-male patients cohabitated with partners of their natal gender; 46.9% of male-to-female patients with male partner preference cohabitated with partners of their natal gender; and no male-to-female patients with female partner preference cohabitated with partners of their natal gender.

Of participants, 93.7% reported that they would definitely undergo reassignment surgery again. The remaining 6.3% (one female-to-male; one male-to-female with male partner preference; three male-to-female with female partner preference) indicated that they probably would undertake the surgery again. Post hoc analysis suggested that the more ambivalent responders had more recently undergone surgery. Of responders, 98.7% indicated that they preferred life in the reassigned gender. The one ambivalent subject was a skilled and well compensated tradesperson who was unable to return to work in her male dominated occupation.

Eldh J, Berg A, Gustafsson M. Long-term follow up after sex reassignment surgery. Scand J Plast Reconstr Surg Hand Surg. 1997 Mar;31(1):39-45.

Eldh et al. conducted a non-blinded, observational study using a prospective cross-sectional design with an investigator designed questionnaire and retrospective acquisition of pre-operative data. The investigators assessed economic circumstances, family status, satisfaction with surgical results, and sexual function in patients who had undergone gender reassignment surgery.

Of the 175 patients who underwent reassignment surgery in Sweden, 90 responded. Of this number, 50 were female-to-male and 40 were male-to-female (ratio: 1:0.8). Patients reportedly were generally satisfied with the appearance of the reconstructed genitalia (no numbers provided). Of the patients who had undergone surgery prior to 1986, seven (14%) were dissatisfied with shape or size of the neo-phallus; eight (16%) declined comment. There were 14 (35%), with 12 having surgery prior to 1986 and two between 1986 and 1995 inclusive, were moderately satisfied because of insufficient vaginal volume; 8 (20%) declined comment. A neo-clitoris was not constructed until the later surgical cohort. Three of 33 reported no sensation or no sexual sensation. Eight had difficulties

comprehending the question and did not respond.

A total of nine (18%) patients had doubts about their sexual orientation; 13 (26%) declined to answer the question. The study found that two female-to-male patients and two male-to-female patients regretted their reassignment surgery and continued to live as the natal gender, and two patients attempted suicide.

Hess J, Rossi Neto R, Panic L, Rübber H, Senf W. Satisfaction with male-to-female gender reassignment surgery. Dtsch Arztebl Int. 2014 Nov 21;111(47):795-801.

Hess et al. conducted a prospective, blinded, observational study using a cross-sectional design and a self-designed anonymous questionnaire. The investigators assessed post-operative satisfaction in male-to-female patients with gender dysphoria who were followed in a urology specialty clinic (Essen, Germany). Patients had met the ICD-10 diagnostic criteria, undergone gender reassignment surgeries including penile inversion vaginoplasty, and a Likert-style questionnaire with 11 elements. Descriptive statistics were provided.

There were 254 consecutive eligible patients who had undergone surgery between 2004 and 2010 identified and sent surveys, of whom 119 (46.9%) responded anonymously. Of the participants, 13 (10.9%) reported dissatisfaction with outward appearance and 16 (13.4%) did not respond; three (2.5%) reported dissatisfaction with surgical aesthetics and 25 (21.0%) did not respond; eight (6.7%) reported dissatisfaction with functional outcomes of the surgery and 26 (21.8%) did not respond; 16 (13.4%) reported they could not achieve orgasm and 28 (23.5%) did not respond; four (3.4%) reported feeling completely male/more male than female and 28 (23.5%) did not respond; six (5.0%) reported not feeling accepted as a woman, two (1.7%) did not understand the question, and 17 (14.3%) did not respond; and 16 (13.4%) reported that life was harder and 24 (20.2%) did not respond.

Lawrence A. Patient-reported complications and functional outcomes of male-to-female sex reassignment surgery. Arch Sex Behav. 2006 Dec;35(6):717-27. Epub 2006 Nov 16. (United States study)

Lawrence conducted a prospective, blinded observational study using a cross-sectional design and a partially self-designed quality of life tool using yes/no questions or Likert scales. The investigator assessed sexual function, urinary function, and other pre/post-operative complications in patients who underwent male-to-female gender reassignment surgery. Questions addressed core reassignment surgery (neo-vagina and sensate neo-clitoris) and related reassignment surgery (labiaplasty, urethral meatus revision, vaginal deepening/widening, and other procedures), use of electrolysis, and use of hormones.

Questionnaires were designed to be completed anonymously and mailed to 727 eligible patients. Of those eligible, 232 (32%) returned valid questionnaires. The age at the time reassignment surgery was 44 ± 9 (range 18-70) years and mean duration after surgery was 3 ± 1 (range 1-7) years.

Happiness with sexual function and the reassignment surgery was reported to be lower when permanent vaginal stenosis, clitoral necrosis, pain in the vagina or genitals, or other complications such as infection, bleeding, poor healing, other tissue loss, other tissue necrosis, urinary incontinence, and genital numbness were present. Quality of life was impaired when pain in the vagina or genitals was present.

Satisfaction with sexual function, gender reassignment surgery, and overall QOL was lower when genital sensation was impaired and when vaginal architecture and lubrication were perceived to be unsatisfactory. Intermittent regret regarding reassignment surgery was associated with vaginal hair and clitoral pain. Vaginal stenosis was associated with surgeries performed in the more distant past; whereas, more satisfaction with vaginal depth and width was present in more recent surgical treatment.

Salvador J, Massuda R, Andreazza T, Koff WJ, Silveira E, Kreische F, de Souza L, de Oliveira MH, Rosito T, Fernandes BS, Lobato MI. Minimum 2-year follow up of sex reassignment surgery in Brazilian male-to-female transsexuals. *Psychiatry Clin Neurosci*. 2012 Jun; 66(4):371-2. PMID: 22624747.

Salvador et al. conducted a single center (Port Alegre, Brazil) prospective, non-blinded, observational study using a cross-sectional design (albeit over an extended time interval) and a self-designed quality of life tool. The investigators assessed regret, sexual function, partnerships, and family relationships in patients who had undergone gender reassignment surgery at least 24 months prior.

Out of the 243 enrolled in the clinic over a 10 year interval, 82 underwent sex reassignment surgery. There were 69 participants with a minimum 2-year follow up, of whom 52 patients agreed to participate in the study. The age at follow-up was 36.3 ± 8.9 (range 15-58) years with the time to follow-up being 3.8 ± 1.7 (2-7) years. A total of 46 participants reported pleasurable neo-vaginal sex and post-surgical improvement in the quality of their sexual experience. The quality of sexual intercourse was rated as satisfactory to excellent, average, unsatisfactory, or not applicable in the absence of sexual contact by 84.6%, 9.6%, 1.9%, and 3.8% respectively. Of the participants, 78.8% reported greater ease in initiating and maintaining relationships; 65.4% reported having a partner; 67.3% reported increased frequency of intercourse; 36.8% reported improved familial relationships. No patient reported regret over reassignment surgery. The authors did not provide information about incomplete questionnaires.

Tsoi WF. Follow-up study of transsexuals after sex-reassignment surgery. *Singapore Med J*. 1993 Dec; 34(6):515-7.

Tsoi conducted a single-center (Singapore) prospective, non-blinded, observational study using a cross-sectional design and a self-designed quality of life tool. The investigator assessed overall life satisfaction, employment, partner status, and sexual function in gender-reassigned persons who had undergone gender reassignment surgery between 1972 and 1988 inclusive and who were approximately 2 to 5 years post-surgery. Acceptance criteria for surgery included good physical health, good mental health, absence of heterosexual tendencies, willingness to undergo hormonal therapy for ≥ 6 months, and willingness to function in the life of the desired gender for ≥ 6 months. Tsoi also undertook retrospective identification of variables that could predict outcomes.

The size of the pool of available patients was not identified. Of the 81 participants, 36 (44.4%) were female-to-male and 45 (55.6%) were male-to-female (ratio 1:1.25).

The mean ages at the time of the initial visit and operation were: female-to-male 25.4 ± 4.4 (range 14-36) and 27.4 ± 4.0 ; (range 14-36); male-to-female 22.9 ± 4.6 (range 14-36) and 24.7 ± 4.3 (14-36) years respectively. Of all participants, 14.8% were under age 20 at the time of the initial visit. All were at least 20 at the time of gender reassignment surgery. The reported age of onset was 8.6 years for female-to-male patients and 8.7 years for male-to-female patients.

All participants reported dressing without difficulty in the reassigned gender; 95% of patients reported good or satisfactory adjustment in employment and income status; 72% reported good or satisfactory adjustment in relationships with partners. Although the quality of life tool was self-designed, 81% reported good or satisfactory adjustment to their new gender, and 63% reported good or acceptable satisfaction with sexual activity. Of the female-to-male patients, 39% reported good or acceptable satisfaction with sex organ function in comparison to 91% of male-to-female patients ($p < 0.001$). (The author reported that a fully functioning neo-phallus could not be constructed at the time.) The age of non-intercourse sexual activity was the only predictor of an improved outcome.

Weyers S, Elaut E, De Sutter P, Gerris J, T'Sjoen G, Heylens G, De Cuypere G, Verstraelen H. Long-term assessment of the physical, mental, and sexual health among transsexual women. *J Sex Med*. 2009 Mar;6(3):752-60. Epub 2008 Nov 17.

Weyers et al. (2009) conducted a prospective, non-blinded, observational study using a cross-sectional design and several measurement instruments including a non-specific quality of life tool and a semi-specific quality of life tool (using normative data) along with two self-designed tools.

The investigators assessed general quality of life, sexual function, and body image from the prior four weeks in Dutch-speaking male-to-female patients with gender dysphoria who attended a single-center (Ghent, Belgium), specialized, comprehensive care university clinic. Investigators used the Dutch version of the SF-36 and results were compared to normative data from Dutch women and U.S. women. The 19 items of the Dutch version of the Female Sexual Function Index (FSFI) were used to measure sexual desire, function, and satisfaction. A self-designed seven question visual analog scale (VAS) was used to measure satisfaction with gender related body traits and appearance perception by self and others. A self-designed survey measured a broad variety of questions regarding personal medical history, familial medical history, relationships, importance of sex, sexual orientation, gynecologic care, level of regret, and other health concerns. For this study, hormone levels were also obtained.

The study consisted of 50 (71.5% of the eligible recruits) participants. Analysis of the data revealed that the patient's average age was 43.1 ± 10.4 years, and all of the patients had vaginoplasty. This same population also had undergone additional feminization surgical procedures (breast augmentation 96.0%, facial feminization 36.0%, vocal cord surgery 40.0%, and cricoid cartilage reduction 30.0%). A total of two (4.0%) participants reported "sometimes" regretting reassignment surgery and 23 (46.0%) were not in a relationship. For the cohort, estradiol, testosterone, and sex hormone binding globulin levels were in the expected range for the reassigned gender. The SF-36 survey revealed that the subscale scores of the participants did not differ substantively from those of Dutch and U.S. women. VAS scores of body image were highest for self-image, appearance to others, breasts, and vulva/vagina (approximately 7 to 8 of 10). Scores were lowest for body hair, facial hair, and voice characteristics (approximately 6 to 7 of 10).

The total FSFI score was 16.95 ± 10.04 out of a maximal 36. The FSFI scores averaged 2.8 (6 point maximum): satisfaction 3.46 ± 1.57 , desire 3.12 ± 1.47 , arousal 2.95 ± 2.17 , lubrication 2.39 ± 2.29 , orgasm 2.82 ± 2.29 , and pain 2.21 ± 2.46 . Though these numbers were reported in the study, data on test population controls were not provided.

A post hoc exploration of the data suggested the following: perceived improvement in general health status was greater in the subset that had undergone reassignment surgery within the last year; sexual orientation impacted the likelihood of being in a relationship; SF-36 scores for vitality, social functioning, and mental health were nominally better for those in relationships, but that overall SF-36 scores did not differ by relationship status; sexual orientation and being in a relationship impacted FSFI scores; and reported sexual function was higher in those with higher satisfaction with regards to their appearance.

Wierckx K, Van Caenegem E, Elaut E, Dedeker D, Van de Peer F, Toye K, Weyers S, Hoebeke P, Monstrey S, De Cuypere G, T'Sjoen G. Quality of life and sexual health after sex reassignment surgery in transsexual men. J Sex Med. 2011 Dec;8 (12):3379-88. Epub 2011 Jun 23.

Wierckx et al. conducted a prospective, non-blinded, observational study using a cross-sectional design and several measurement instruments (a non-specific quality of life tool with reported normative data along with three self-designed tools). The investigators assessed general quality of life, sexual relationships, and surgical complications in Dutch-speaking female-to-male patients with gender dysphoria who attended a single-center, specialized, comprehensive care, university clinic (Ghent, Belgium). Investigators used the Dutch version of the SF-36 with 36 questions, eight subscales, and two domains evaluating physical and mental health. Results were compared to normative data from Dutch women and Dutch men. Self-designed questionnaires to evaluate aspects of medical history, sexual functioning (there were separate versions for those with and without partners), and surgical results were also used. The Likert-style format was used for many of the questions.

A total of 79 female-to-male patients with gender dysphoria had undergone reassignment surgery were recruited; ultimately, 47 (59.5%) chose to participate. Three additional patients were recruited by other patients. One of the 50 participants was later excluded for undergoing reassignment surgery within the one year window. The age of patients was: 30 ± 8.2 years (range 16 to 49) at the time of reassignment surgery and 37.1 ± 8.2 years (range 22 to 54) at the time of follow-up. The time since hysterectomy, oophorectomy, and mastectomy was 8 years (range 2 to 22). The patient population had undergone additional surgical procedures: metoidioplasty ($n=9$; 18.4%), phalloplasty ($n=8$ after metoidioplasty, 38 directly; 93.9% total), and implantation of erectile prosthetic device ($n=32$; 65.3%). All had started hormonal therapy at least two years prior to surgery and continued to use androgens.

The SF-36 survey was completed by 47 (95.9%) participants. The "Vitality" and the "Mental Health" scales were lower than the Dutch male population: 62.1 ± 20.7 versus 71.9 ± 18.3 and 72.6 ± 19.2 versus 79.3 ± 16.4 respectively. These subscale scores were equivalent to the mean scores of the Dutch women.

None of the participants were dissatisfied with their hysterectomy-oophorectomy procedures; 4.1% were dissatisfied with their mastectomies because of extensive scarring; and 2.2% were dissatisfied with their phalloplasties. Of the participants, 17.9% were dissatisfied with the implantation of an erectile prosthetic device; 25 (51.0%) reported at least one post-operative complication associated with phalloplasty (e.g., infection, urethrostenosis, or fistula formation); 16 (50.0% of the 32 with an erectile prosthetic device) reported at least one post-operative complication associated with implantation of an erectile prosthetic (e.g., infection, leakage, incorrect positioning, or lack of function).

A total of 18 (36.7%) participants were not in a relationship; 12.2% reported the inability to achieve orgasm with self-stimulation less than half the time; 12.2% did not respond to the question. Of those participants with partners, 28.5% reported the inability to achieve orgasm with intercourse less than half the time and 9.7% did not respond to this question. Also, 61.3% of those with partners reported (a) no sexual activities (19.4%) or (b) activities once or twice monthly (41.9%), and there were 12.9% who declined to answer.

c. Observational, surgical patients, cross-sectional, with controls

Ainsworth TA, Spiegel JH. Quality of life of individuals with and without facial feminization surgery or gender reassignment surgery. Qual Life Res. 2010 Sep;19(7):1019-24.

Ainsworth and Spiegel conducted a prospective, observational study using a cross-sectional design and a partially self-designed survey tool. The blind status is unknown. Treatment types served as the basis for controls.

The investigators, head and neck surgeons who provided facial feminization services, assessed perception of appearance and quality of life in male-to-female subjects with self-reported gender dysphoria. Patients could have received no therapeutic intervention, hormone therapy, reassignment surgery, and/or facial feminization surgery and an unrestricted length of transition. (Transition refers to the time when a transgender person begins to live as the gender with which they identify rather than the gender assigned at birth.) Criteria for the various types of interventions were not available because of the survey design of the study. Patients were recruited via website or at a 2007 health conference. Pre-specified controls to eliminate duplicate responders were not provided. The investigators employed a self-designed Likert-style facial feminization outcomes evaluation questionnaire and a "San Francisco 36" health questionnaire. No citations were provided for the latter. It appears to be the Short-form (SF) 36-version 2. Changes or differences considered to be biologically significant were not pre-specified. Power corrections for multiple comparisons were not provided.

The investigators reported that there were 247 participants. (The numbers of incomplete questionnaires was not reported.) Of the 247 participants, 25 (10.1%) received only primary sex trait reassignment surgery, 28 (11.3%)

received facial surgery without primary sex trait reassignment surgery, 47 (19.0%) received both facial and primary sex trait reassignment surgery, and 147 (59.5%) received neither facial nor reassignment surgery.

The mean age for each of these cohorts was: 50 years (no standard deviation [S.D.]) only reassignment surgery, 51 years (no S.D.) only facial surgery, 49 years (no S.D.) both types of surgery, and 46 years (no S.D.) (neither surgery). Of the surgical cohorts: 100% of those who had undergone primary sex trait reassignment surgery alone used hormone therapy, 86% of those who had undergone facial feminization used hormone therapy, and 98% of those who had undergone both primary sex trait reassignment surgery and facial feminization used hormone therapy. In contrast to the surgical cohorts, 66% of the "no surgery" cohort used hormonal therapy, and a large proportion (27%) had been in transition for less than one year.

The investigators reported higher scores on the facial outcomes evaluation in those who had undergone facial feminization. Scores of the surgical cohorts for the presumptive SF-36 comprehensive mental health domain did not differ from the general U.S. female population. Scores of the "no surgery" cohort for the comprehensive mental health domain were statistically lower than those of the general U.S. female population, but within one standard deviation of the normative mean. Mean scores of all the gender dysphoric cohorts for the comprehensive physical domain were statistically higher than those of the general female U.S. population, but were well within one standard deviation of the normative mean. Analyses of inter-cohort differences for the SF-36 results were not conducted. Although the investigators commented on the potential disproportionate impact of hormone therapy on outcomes and differences in the time in "transition", they did not conduct any statistical analyses to correct for putative confounding variables.

Kraemer B, Delsignore A, Schnyder U, Hepp U. Body image and transsexualism. Psychopathology. 2008;41(2):96-100. Epub 2007 Nov 23.

Kraemer et al. conducted a single center (Zurich, Switzerland) prospective, non-blinded, observational study using a cross-sectional design comparing pre-and post- surgical cohorts. Patients were required to meet DSM III or DSM IV criteria as applicable to the time of entry into the clinic. Post-surgical patients were from a long-term study group (Hepp et al., 2002). Pre-surgical patients were recent consecutive referrals. The assessment tool was the Fragebogen zur Beurteilung des eigenen Körpers (FBek) which contained three domains.

There were 23 pre-operative patients: 7 (30.4%) female-to-male and 16 (69.6%) male-to-female (ratio 1:2.3). There were 22 post-operative patients: 8 (36.4 %) female-to-male and 14 (63.6%) male-to-female (ratio 1:1.8). The mean ages of the cohorts were as follows: pre-operative 33.0 ± 11.3 years; post-operative 38.2 ± 9.0 years. The mean duration after reassignment surgery was 51 ± 25 months (range 5-96).

The pre-operative groups had statistically higher insecurity scores compared to normative data for the natal sex: female-to-male 9.0 ± 3.8 versus 5.1 ± 3.7 ; male-to-female 8.1 ± 4.5 versus 4.7 ± 3.1 as well as statistically lower self-confidence in one's attractiveness: female-to-male 3.1 ± 2.9 versus 8.9 ± 3.1 ; male-to-female 7.0 ± 2.9 vs 9.5 ± 2.6 .

Mate-Kole C, Freschi M, Robin A. Aspects of psychiatric symptoms at different stages in the treatment of transsexualism. Br J Psychiatry. 1988 Apr;152: 550-3.

Mate-Kole et al. conducted a single site (London, United Kingdom) prospective non-blinded, observational study using a cross-sectional design and two psychological tests (one with some normative data). Concurrent controls were used in this study design. The investigators assessed neuroticism and sex role in natal males with gender dysphoria. Patients at various stages of management, (i.e., under evaluation, using cross-sex hormones, or post reassignment surgery [6 months to 2 years]) were matched by age of cross-dressing onset, childhood neuroticism, personal psychiatric history, and family psychiatric history. Both a psychologist and psychiatrist conducted assessments. The

instruments used were the Crown Crisp Experiential Index (CCEI) for psychoneurotic symptoms and the Bem Sex Role Inventory. ANOVA was used to identify differences between the three treatment cohorts.

For each cohort, investigators recruited 50 male-to-female patients from Charing Cross Hospital. The mean ages of the three cohorts were as follows: 34 years for patients undergoing evaluation; 35 years for wait-listed patients; and 37 years for post-operative patients. For the cohorts, 22% of those under evaluation, 24% of those on hormone treatment only, and 30% of those post-surgery had prior psychiatric histories, and 24%, 24%, while 14% in each cohort, respectively, had a history of attempted suicide. More than 30% of patients in each cohort had a first degree relative with a history of psychiatric disease.

The scores for the individual CCEI domains for depression and somatic anxiety were statistically higher (worse) for patients under evaluation than those on hormone treatment alone. The scores for all of the individual CCEI domains (free floating anxiety, phobic anxiety, somatic anxiety, depression, hysteria, and obsessionality) were statistically lower in the post-operative cohort than in the other two cohorts.

The Bem Sex Role Inventory masculinity score for the combined cohorts was lower than for North American norms for either men or women. The Bem Sex Role Inventory femininity score for the combined cohorts was higher than for North American norms for either men or women. Those who were undergoing evaluation had the most divergent scores from North American norms and from the other treatment cohorts. Absolute differences were small. All scores of gender dysphoric patients averaged between 3.95 and 5.33 on a 7 point scale while the normative scores averaged between 4.59 and 5.12.

Wolfradt U, Neumann K. Depersonalization, self-esteem and body image in male-to-female transsexuals compared to male and female controls. Arch Sex Behav. 2001 Jun;30(3):301-10.

Wolfradt and Neumann conducted a controlled, prospective, non-blinded, observational study using a cross-sectional design. The investigators assessed aspects of personality in male-to-female patients who had undergone vocal cord surgery for voice feminization and in healthy non-transgender volunteers from the region. The patients had undergone gender reassignment surgery 1 to 5 years prior to voice surgery. The volunteers were matched by age and occupation.

The primary hypothesis was that depersonalization, with the sense of being detached from one's body or mental processes, would be more common in male-to-female patients with gender dysphoria. German versions of the Scale for Depersonalization Experiences (SDPE), the Body Image Questionnaire (BIQ), a Gender Identity Trait Scale (GIS), and the Self-Esteem Scale (SES) were used in addition to a question regarding global satisfaction. Three of the assessments used a 5 point scale (BIQ, GIS, and SDPE) for questions. One used a 4 point scale (SES). Another used a 7 point scale (global satisfaction). The study consisted of 30 male-to-female patients, 30 healthy female volunteers, and 30 healthy male volunteers. The mean age of study participants was 43 years (range 29- 67).

Results of the study revealed that there were no differences between the three groups for the mean scores of measures assessing depersonalization, global satisfaction, the integration of masculine traits, and body-image-rejected (subset). Also, the sense of femininity was equivalent for male-to-female patients and female controls and higher than that in male controls. The levels of self-esteem and body image-dynamic (subset) were equivalent for male-to-female patients and male controls and higher than that in female controls, and none of the numeric differences between means exceeded 0.61 units.

Kuhn A, Bodmer C, Stadlmayr W, Kuhn P, Mueller M, Birkhäuser M. Quality of life 15 years after sex reassignment surgery for transsexualism. Fertil Steril. 2009 Nov;92(5):1685-1689.e3. Epub 2008 Nov 6.

Kuhn et al. conducted a prospective, non-blinded, observational study using a cross-sectional design and semi-matched control cohort. The investigators assessed global satisfaction in patients who were from gynecology and endocrinology clinic (Bern, Switzerland), and who had undergone some aspect of gender reassignment surgery in the distant past, but were still receiving cross-sex hormones from the clinic. The quality of life assessment tools included a VAS and the King's Health Questionnaire (KHQ), which consists of eight domains with scores between zero and five or one and five, with lower scores indicating higher preference. The KHQ and the numerical change/difference required for clinical significance (≥ 5 points in a given domain, with higher scores being more pathologic) were included in the publication. Twenty healthy female controls from the medical staff who had previously undergone an abdominal or pelvic surgery were partially matched by age and body mass index (BMI), but not sex. No corroborative gynecologic or urologic evaluations were undertaken.

Of the 55 participants, three (5.4%) were female-to-male and 52 (94.5%) were male-to-female (ratio 1:17.3). Reassignment surgery had been conducted 8 to 23 years earlier (median 15 years). The median age of the patients at the time of this study was 51 years (range 39-62 years). The patients had undergone a median of nine surgical procedures in comparison to the two undergone by controls. Reassignment patients were less likely to be married (23.6% versus 65%; $p=0.002$); partnership status was unknown in five patients. The scores of VAS global satisfaction (maximal score eight) were lower for surgically reassigned patients (4.49 ± 0.1 SEM) than controls (7.35 ± 0.26 SEM) ($p < 0.0001$).

The abstract stated that quality of life was lower in reassignment patients 15 years after surgery relative to controls. One table in the study, Table 2, delineated statistically and biologically significant differences for four of the eight KHQ domains between the patients and controls: physical limitation: 37.6 ± 2.3 versus 20.9 ± 1.9 ($p < 0.0001$), personal limitation: 20.9 ± 1.9 versus 11.6 ± 0.4 ($p < 0.001$), role limitation: 27.8 ± 2.4 versus 34.6 ± 1.7 ($p = 0.046$), and general health: 31.7 ± 2.2 versus 41.0 ± 2.3 ($p < 0.02$). There is a related paper by Kuhn et al. 2006.

Haraldsen IR, Dahl AA. Symptom profiles of gender dysphoric patients of transsexual type compared to patients with personality disorders and healthy adults. Acta Psychiatr Scand. 2000 Oct;102(4):276-81.

Haraldsen and Dahl conducted a single-center (Oslo, Norway) partially prospective, non-blinded, observational study using a cross-sectional design and a non-specific psychometric test. There was a control group, but it was not concurrent.

In the germane sub-study, the investigator assessed psychopathology in patients with gender dysphoria. Patients, who were independently evaluated by two senior psychiatrists, were required to meet DSM III-R or DSM IV diagnostic criteria and the Swedish criteria for reassignment surgery. The Norwegian version of the SCL-90 was used. The testing was conducted from 1987 to 1989 for those who had undergone reassignment surgery between 1963 and 1987 and from 1996 to 1998 for pre-surgical patients who had applied for reassignment surgery between 1996 and 1998. In addition, Axis I, Axis II, and Axis V (Global Functioning) was assessed.

Of 65 post-surgical and 34 pre-surgical patients, 59 post-surgical and 27 pre-surgical patients ultimately entered the study. The combined cohorts consisted of 35 (40.7%) female-to-male patients and 51 (59.3%) male-to-female patients (ratio 1:1.5). The ages were female-to-male 34 ± 9.5 years and male-to-female 33.3 ± 10.0 years. The other control group consisted of patients with personality disorder. Of these, 101 (27 men (33.9 ± 7.3 years) and 74 women (31.6 ± 8.2)) were tested during a treatment program. One year later, 98% were evaluated. A total of 28 (32.5%) of the pre- and post-reassignment surgery patients had an Axis I diagnosis compared to 100 (99.0%) of those with personality disorders. Depression and anxiety were the most common diagnoses in both groups, but were approximately three to four times more common in the personality disorder cohort. Seventeen (19.8%) of the pre- and post-reassignment surgery patients had an Axis II diagnosis whereas the mean number of personality disorders in the personality disorder cohort was 1.7 ± 1 . The Global Assessment of Function was higher (better) in the gender

dysphoric groups (78.0 ± 8.9) than in the personality disorder cohort (53.0 ± 9.0).

Global Severity Indices (GSI) were highest for those with personality disorder regardless of gender and exceeded the cut-point score of 1.0. The GSI scores for females-to-males and males-to-females were 0.67 ± 0.57 and 0.56 ± 0.45 . Although they were nominally higher than the healthy normative controls (males: 0.32 ± 0.36 and females 0.41 ± 0.43), they were well within the non-pathologic range. The same was true for the subscales.

SCL-90 GSI scores did not differ substantively between pre- and post-surgical patients, nor did the SCI subscale scores differ substantively between pre- and post-surgical patients. Any small non-significant differences tracked with the age and sex differences.

Beatrice J. A psychological comparison of heterosexuals, transvestites, preoperative transsexuals, and postoperative transsexuals. J Nerv Ment Dis. 1985 Jun;173(6):358-65. (United States study)

Beatrice conducted a prospective, non-blinded, observational study using a cross-sectional design and control cohorts in the U.S. The investigator assessed psychological adjustment and functioning (self-acceptance) in male-to-female patients with gender dysphoria (with and without GRS), transvestites from two university specialty clinics, and self-identified heterosexual males recruited from the same two universities. The criteria to qualify for the study included being known to the clinic for at least one year, cross-dressing for at least one year without arrest, attendance at 10 or more therapy sessions, emotionally self-supporting, and financially capable of payment for reassignment surgery, and all of these criteria were met by the pre-operative cohort as well as the post-operative cohort. The cohorts were matched to the post-operative cohort (age, educational level, income, ethnicity, and prior heterosexual object choice). The post-operative cohort was selected not on the basis of population representation, but on the basis of demographic feasibility for a small study. The instruments used were the Minnesota Multiphasic Personality Inventory (MMPI) and the Tennessee Self-Concept Scale (TSCS). Changes or differences considered to be biologically significant were not pre-specified.

Of the initial 54 recruits, ten subjects were left in each of the cohorts because of exclusions identified due to demographic factors. The mean age of each cohort were as follows: pre-operative gender dysphoric patients 32.5 (range 27-42) years, postoperative patients 35.1 (30-43) years old, transvestite 32.5 (29-37) years old, and heterosexual male 32.9 (28-38) years old. All were Caucasian. The mean age for cross-dressing in pre-operative patients (6.4 years) and post-operative patients (5.8 years) was significantly lower than for transvestites (11.8 years).

The scores for self-acceptance did not differ by diagnostic category or surgical status as measured by the TSCS instrument. As measured by the T-scored MMPI instrument (50 ± 10), levels of paranoia and schizophrenia were higher for post-operative (GRS) patients (63.0 and 68.8) than transvestites (55.6 and 59.6) and heterosexual males (56.2 and 51.6). Levels of schizophrenia were higher for pre-operative patients (65.1) than heterosexual males (51.6). There were no differences between patients with gender dysphoria. Scores for the Masculine-Feminine domain were equivalent in those with transvestitism and gender dysphoria with or without surgery, but higher than in heterosexual males. The analysis revealed that despite the high level of socio-economic functioning in these highly selected subjects, the MMPI profiles based on the categories with the highest scores were notable for antisocial personality, emotionally unstable personality, and possible manic psychosis in the pre-operative GRS patients and for paranoid personality, paranoid schizophrenia, and schizoid personality in the post-operative GRS patients. By contrast, the same MMPI profiling in heterosexual males and transvestites was notable for the absence of psychological dysfunction.

d. Observational, surgical patients, longitudinal, with controls

Dhejne C, Lichtenstein P, Boman M, Johansson A, Långström N, Landén M. Long-term follow-up of transsexual persons undergoing sex reassignment surgery: cohort study in Sweden. *PLoS One*. 2011;6(2):e16885. Epub 2011 Feb 22.

Dhejne et al. conducted a retrospective, non-blinded, observational study of nation-wide mortality using a longitudinal and a population-based matched cohort. The investigators assessed conditions such as, but not limited to, mortality, suicide attempts, psychiatric hospitalization, and substance abuse in gender-reassigned persons and randomly selected unexposed controls matched by birth year and natal sex (1:10) as well as by birth year and the reassigned gender (1:10). Data were extracted from national databases including the Total Population Register (Statistics Sweden), the Medical Birth Register, the Cause of Death Register (Statistics Sweden), the Hospital Discharge Register (National Board of Health and Welfare), the Crime Register (National Council of Crime), and those from the Register of Education for highest educational level. The criteria required to obtain the initial certificate for reassignment surgery and change in legal status from the National Board of Health and Welfare were the 2002 WPATH criteria and included evaluation and treatment by one of six specialized teams, name change, a new national identity number indicative of gender, continued use of hormones, and sterilization/castration. Descriptive statistics with hazard ratios were provided.

Investigators identified 804 patients with gender identity disorder (or some other disorder) in Sweden during the period from 1973 to 2003 inclusive. Of these patients, 324 (40.3%) underwent gender-reassignment surgery (133 female-to-male [41.0%]; 191 male-to-female [59.0%]; ratio 1:1.4). The average follow-up time for all-cause mortality was 11.4 years (median 9.1). The average follow-up time for psychiatric hospitalization was 10.4 years (median 8.1).

The mean ages in female-to-male and male-to-female reassigned patients were: 33.3 ± 8.7 (range 20–62) and 36.3 ± 10.1 (range 21–69) years, respectively. Immigrant status was two times higher in reassigned patients ($n=70$, 21.6%) than in either type of control (birth [natal] sex matched $n=294$ [9.1%] or reassigned gender matched $n=264$ [8.1%]). Educational attainment (10 or more years) was somewhat lower for reassigned patients ($n=151$ [57.8%]) than in either type of control (birth sex matched $n=1,725$ [61.5%] or reassigned gender matched $n=1804$ [64.3%]) (cohort data were incomplete). The biggest discordance in educational attainment was for female-to-male reassigned patients regardless of the control used. Prior psychiatric morbidity (which did not include hospitalization for gender dysphoria) was more than four times higher in reassigned patients ($n=58$, 17.9%) than in either type of control (birth sex matched $n=123$ [3.8%] or reassigned gender matched $n=114$ [3.5%]).

All-cause mortality was higher for patients who underwent gender reassignment surgery ($n=27$ [8.3%]) than in controls (hazard ratio 2.8 [CI 1.8–4.3]) even after adjustment for covariants (prior psychiatric morbidity and immigration status). Divergence in the survival curves began at 10 years. Survival rates at 20 year follow-up (as derived from figure 1) were: female control 97%, male controls 94%, female-to-male patients 88%, and male-to-female patients 82%. The major contributor to this mortality difference was completed suicide ($n=10$ [3.1%]; adjusted hazard ratio 19.1 [CI 5.8–62.9]). Mortality due to cardiovascular disease was modestly higher for reassigned patients ($n=9$ [2.8%]) than in controls (hazard ratio 2.5 [CI 1.2–5.3]).

Suicide attempts were more common in patients who underwent gender reassignment surgery ($n=29$ [9.0%]) than in controls (adjusted hazard ratio 4.9 [CI 2.9–8.5]). Male-to-female patients were at higher adjusted risk for attempted suicide than either control whereas female-to-male patients were at higher adjusted risk compared to only male controls and maintained the female pattern of higher attempted suicide risk. Hospitalizations for psychiatric conditions (not related to gender dysphoria) were more common in reassigned persons $n=64$ [20.0%] than in controls (hazard ratio 2.8 [CI 2.0–3.9]) even after adjusting for prior psychiatric morbidity. Hospitalization for substance abuse was not greater than either type of control.

The nationwide mortality studies by Dhejne et al. (2011) includes much, if not all, of the Landén (1998) patient population and much of the Dhejne et al. (2014) population.

Dhejne C, Öberg K, Arver S, Landén M. An analysis of all applications for sex reassignment surgery in Sweden, 1960-2010: prevalence, incidence, and regrets. Arch Sex Behav. 2014 Nov;43(8):1535-45. Epub 2014 May 29 and Landén M, Wålinder J, Lambert G, Lundström B. Factors predictive of regret in sex reassignment. Acta Psychiatr Scand. 1998 Apr;97(4):284 (Dhejne et al., 2014; Landén et al., 1998) Sweden-All

Dhejne et al. conducted a non-blinded, observational study that was longitudinal for the capture of patients with "regret" in a national database. This same group (Landén et al., 1998) conducted a similar study along with retrospective acquisition of clinical data to explore the differences between the cohorts with and without regret. There were no external controls; only intra- group comparisons for this surgical series.

The investigators assessed the frequency of regret for gender reassignment surgery. Data were extracted from registries at the National Board of Health and Welfare to which patients seeking reassignment surgery or reversal of reassignment surgery make a formal application and which has maintained such records since a 1972 law regulating surgical and legal sex reassignment. The investigators reviewed application files from 1960 through 2010. The specific criteria to qualify for gender surgery were not delineated. Patients typically underwent diagnostic evaluation for at least one year. Diagnostic evaluation was typically followed by the initiation of gender confirmation treatment including hormonal therapy and real-life experience. After two years of evaluation and treatment, patients could make applications to the national board. Until recently sterilization or castration were the required minimal surgical procedures (Dhejne et al., 2011). Secular changes in this program included consolidation of care to limited sites, changes in accepted diagnostic criteria, and provision of non-genital surgery, e.g., mastectomy during the real- life experience phase, and family support.

There were 767 applicants for legal and surgical reassignment (289 [37.7%] female-to-male and 478 [62.3%] male-to-female; ratio 1:1.6). The number of applicants doubled each ten year interval starting in 1981.

Of the applicants, 88.8% or 681 (252 [37.0%] female-to-male and 429 [63.0%] male-to-female; ratio 1:1.7) had undergone surgery and changed legal status by June 30, 2011. This number included eight (four [50.0%] female-to-male and four [50.0%] male to female; ratio 1:1) people who underwent surgery prior to the 1972 law. This number appears to include 41 (two [4.9%] female-to-male and 39 [95.1%] male-to-female; ratio 1:19.5) people who underwent surgery abroad at their own expense (usually in Thailand or the U.S.). This cohort (6% of 681) includes one person who was denied reassignment surgery by Sweden.

Twenty-five (3.3%) of the applications were denied with the two most common reasons being an incomplete application or not meeting the diagnostic criteria. An additional 61(8.0%) withdrew their application, were wait-listed for surgery, postponed surgery (perhaps in hopes of the later revocation of the sterilization requirement), or were granted partial treatment.

The formal application for reversal of the legal gender status, the "regret rate", was 2.2%. No one who underwent sex- reassignment surgery outside of Sweden (36 of these 41 had surgery after 1991) has requested reversal. The authors noted, however, that this preliminary number may be low because the median time interval to reversal request was eight years-only three of which had elapsed by publication submission- and because it was the largest serial cohort. This number did not include other possible expressions of regret including suicide (Dhejne et al., 2011).

Dhejne et al. in 2014 reported that the female-to-male (n=5): male-to-female (n=10) ratio among those who made formal applications for reversal was 1:2. The investigators also reported that the female-to-male applicants for reversal were younger at the time of initial surgical application (median age 22 years) than the complete female-to-

male cohort at the time of surgical application (median age 27 years). By contrast the male-to-female applicants for reversal were older at the time of initial surgical application (median age 35 years) than the complete male-to-female cohort at the time of initial surgical application (median age 32 years). Other clinical data to explore the differences between the cohorts with and without regret were not presented in this update publication.

In their earlier publication, in addition to determining a regret rate (3.8%), Landén et al. extracted data from medical records and government verdicts. Pearson Chi-square testing with Yates' correction for small sample sizes was used to identify candidate variables predictive of regret. They observed that: (a) 25.0% of the cohort with regrets and 11.4% of the cohort without regrets were unemployed, (b) 16.7% of the cohort with regrets and 15.4% of the cohort without regrets were on "sick benefit", (c) 15.4% of the cohort with regrets and 13.9% of the cohort without regrets had problems with substance abuse, (d) 69.2% of the cohort with regrets and 34.6% of the cohort without regrets had undergone psychiatric treatment, (e) 15.4% of the cohort with regrets and 8.8% of the cohort without regrets had a mood disorder, and (f) 15.4% of the cohort with regrets and 1.5% of the cohort without regrets had a psychotic disorder.

The putative prognostic factors that were statistically different between the cohorts with and without regret included prior psychiatric treatment, a history of psychotic disorder, atypical features of gender identity, and poor family support. Factors that trended towards statistical difference included having an unstable personality, sexual orientation and transvestitism. Univariate regression analyses further clarified the most important variables. These variables were tested with logistic regression. Initial modeling included the variable "history of psychotic disorder". Although this variable was predictive, it was excluded from future analyses because it was already a contraindication to reassignment surgery. Additional multivariate regression analyses identified poor family support as the most predictive variable and atypical features of gender identity as the second most important variable. Presence of both variables had a more than additive effect.

The nationwide mortality studies by Dhejne et al. (2011) includes much, if not all, of the Landén (1998) patient population and most of the Dhejne (2014) population. There is a related paper by Landén et al. 1998b that included the criteria to qualify for surgical intervention at that time.

Heylens G, Verroken C, De Cock S, T'Sjoen G, De Cuypere G. Effects of different steps in gender reassignment therapy on psychopathology: a prospective study of persons with a gender identity disorder. J Sex Med. 2014 Jan;11(1):119-26. Epub 2013 Oct 28.

Heylens et al. conducted a prospective, non-blinded observational study using a longitudinal design in which patients served as their own controls. They used a non-specific psychiatric test with normative data along with two self-designed questionnaires. The investigators assessed psychosocial adjustment and psychopathology in patients with gender identity disorders. Patients were to be sequentially evaluated prior to institution of hormonal therapy, then 3 to 6 months after the start of cross-sex hormone treatment, and then again one to 12 months after reassignment surgery. The Dutch version of the SCL-90R with eight subscales (agoraphobia, anxiety, depression, hostility, interpersonal sensitivity, paranoid ideation/psychoticism, and sleeping problems) and a global score (psycho-neuroticism) was used serially. A seven parameter questionnaire was used serially to assess changes in social function. Another cross-sectional survey assessed emotional state. The cohorts at each time point consisted of patients who were in the treatment cohort at the time and who had submitted survey responses.

Ninety of the patients who applied for reassignment surgery between June 2005 and March 2009 were recruited. Fifty seven entered the study. Forty-six (51.1% of the recruited population) underwent reassignment surgery. Baseline questionnaire information was missing for 3 patients. Baseline SCL-90 scores were missing for 1 patient but included SCL-90 scores from some of the 11 recruits who had not yet undergone reassignment surgery. Time point 2 (after hormone therapy) SCL-90 information was missing for 10, but included SCL-90 scores from some of the 11

recruits who had not yet undergone reassignment surgery. At time point 3, 42 (91.3% of those who underwent reassignment surgery) patients completed some part of the SCL-90 survey and the psychosocial questionnaires. Some questionnaires were incomplete. The investigators reported response rates of 73.7% for the psychosocial questionnaires and 82.5% for the SCL-90.

Of those who responded at follow-up after surgery, 88.1% reported having good friends; 52.4% reported the absence of a relationship; 47.6% had no sexual contacts; 42.9% lived alone; 40.5% were unemployed, retired, students, or otherwise not working; 2.4% reported alcohol abuse; and 9.3% had attempted suicide. The frequency of these parameters reportedly did not change statistically during the study interval, but there was no adjustment for the inclusion of patients who did not undergo surgery.

In a cross-sectional, self-report mood survey, of the 42 study entrants who completed the entire treatment regimen including reassignment surgery and the final assessment (refers to the initial 57) reported improved body-related experience (97.6%), happiness (92.9%), mood (95.2%), and self-confidence (78.6%) and reduced anxiety (81.0%). Of participants, 16.7% reported thoughts of suicide. Patients also reported on the intervention phase that they believed was most helpful: hormone initiation (57.9%), reassignment surgery (31.6%), and diagnostic-psychotherapy phase (10.5%).

The global "psycho-neuroticism" SCL-90R score, along with scores of 7 of the 8 subscales, at baseline were statistically more pathologic than the general population. After hormone therapy, the score for global "psycho-neuroticism" normalized and remained normal after reassignment surgery. More specifically the range for the global score is 90 to 450 with higher scores being more pathologic. The score for the general population was 118.3 ± 32.4 . The respective scores for the various gender dysphoric cohorts were 157.7 ± 49.8 at initial presentation, 119.7 ± 32.1 after hormone therapy, and 127.9 ± 37.2 after surgery. The scores for the general population and the scores after either hormone treatment or surgical treatment did not differ.

Kockott G, Fahrner EM. Transsexuals who have not undergone surgery: a follow-up study. Arch Sex Behav. 1987 Dec;16 (6):511-22.

Kockott and Fahrner conducted a single center (Munich, Germany) prospective, observational study using a longitudinal design. Treatment cohorts were used as controls, and patients served as their own controls. The investigators assessed psychosocial adjustment in patients with gender identity issues. Patients were to have met DSM III criteria. Trans-sexuality, transvestitism, and homosexuality were differentiated. The criteria required for patients to receive hormone therapy and/or reassignment surgery were not delineated. After receiving hormone therapy, patients were later classified by surgical reassignment status (pre-operative and post-operative) and desire for surgery (unchanged desire, hesitant, and no longer desired).

The first investigative tool was a semi-structured in-person interview consisting of 125 questions. The second investigative tool was a scale that organized the clinical material into nine domains which were then scored on a scale. The Psychological Integration of Trans-sexuals (PIT) instrument developed according to the scale used by Hunt and Hampson (1980) for assessment of 17 post-operative patients. There were 15 interviews and two separate interviewers. There were 80 patients identified, but 58 (72.5%) patients (26 pre-operative; 32 post-operative) were ultimately included in the analysis. The duration of follow-up was longer for post-operative patients (6.5 years) than for pre-operative patients (4.6 years) (including time for one patient subsequently excluded). The mean age of the post-operative patients was 35.5 ± 13.1 years, and the age of the patients who maintained a continued desire for surgery was 31.7 ± 10.2 years. The age of the patients who hesitated about surgery was somewhat older, 40.3 ± 9.4 years. The age of the patients who were no longer interested in surgery was 31.8 ± 6.5 years. All were employed or in school at baseline. Patients with hesitation were financially better-off, had longer-standing relationships even if unhappy, and had a statistical tendency to place less value on sex than those with an unchanged wish for surgery.

Post-operative patients more frequently reported contentment with the desired gender and the success of adaption to the gender role than the pre-operative patients with a persistent desire for surgery. Post-operative patients more frequently reported sexual satisfaction than pre-operative patients with a continuing desire for surgery. Post-operative patients also more frequently reported financial sufficiency and employment than pre-operative patients with a persistent desire for surgery. Suicide attempts were stated to be statistically less frequent in the post-surgical cohort.

Psychosocial adjustment scores were in the low end of the range with "distinct difficulties" (19-27) at the initial evaluation for the post-operative patients (19.7), the pre-operative patients with a persistent wish for surgery (20.2), and the hesitant patients (19.7). At initial evaluation, psychosocial adjustment scores for patients no longer wanting surgery were at the high end of the range with "few difficulties" (10-18). At the final evaluation, Psychosocial adjustment scores were at the high end of the range "few difficulties" (10-18) for the post-operative patients (13.2) and the patients no longer wanting surgery (16.5). Psychosocial adjustment scores at the final evaluation were in the borderline range between "few difficulties" (10-18) and "distinct difficulties" (19-27) for both the pre-operative patients with a persistent desire for surgery (18.7), and the hesitant patients (19.1).

The changes in the initial score and the final follow-up score within each group were tracked and reported to be statistically significant for the post-operative group, but not for the other groups. Statistical differences between groups were not presented. Moreover, the post-operative patients had an additional test immediately prior to surgery. The first baseline score (19.7) would have characterized the patients as having "distinct difficulties" in psychosocial adjustment while the second baseline score (16.7) would have categorized the patients as having "few difficulties" in psychosocial adjustment despite the absence of any intervention except the prospect of having imminent reassignment surgery. No statistics reporting on the change between scores of the initial test and the test immediately prior to surgery and the change between scores of the test immediately prior to surgery and the final follow-up were provided.

Meyer JK, Reter DJ. Sex reassignment. Follow-up. Arch Gen Psychiatry. 1979 Aug;36(9):1010-5. (United States study)

Meyer and Reter conducted a single-center (Baltimore, Maryland, U.S.) prospective, non-blinded, observational study using a longitudinal design and retrospective baseline data. Interview data were scored with a self-designed tool. There were treatment control cohorts, and patients served as their own controls. The investigators assessed patients with gender dysphoria. The 1971 criteria for surgery required documented cross-sex hormone use as well as living and working in the desired gender for at least one year in patients subsequently applying for surgery. Clinical data including initial interviews were used for baseline data. In follow-up, the investigators used extensive two to four hour interviews to collect information on (a) objective criteria of adaptation, (b) familial relationships and coping with life milestones, and (c) sexual activities and fantasies. The objective criteria, which were the subject of the publication, included employment status (Hollingshead job level), cohabitation patterns, and need for psychiatric intervention. The investigators designed a scoring mechanism for these criteria and used it to determine a global adjustment score. The score value or the change score that was considered to be biologically significant was not pre-specified in the methods.

The clinic opened with 100 patients, but when the follow-up was completed, 52 patients were interviewed and 50 gave consent for publication. Of these, 15 (four female-to-male, 11 male-to-female; ratio 1:2.8) were part of the initial operative cohort, 14 (one female-to-male; 13 male-to-female; ratio 1:13) later underwent reassignment surgery at the institution or elsewhere, and 21 (five female-to-male; 16 male-to-female; ratio 1:3.2) did not undergo surgery. The mean ages of these cohorts were 30.1, 30.9, and 26.7 years respectively. The mean follow-up time was 62 months (range 19-142) for those who underwent surgery and 25 months (range 15-48) for those who did not. Socioeconomic status was lowest in those who subsequently underwent reassignment surgery.

Of patients initially receiving surgery, 33% had some type of psychiatric contact prior to the initial clinic evaluation and 8% had psychiatric contact during the follow-up. Of the patients who had not undergone surgery or who had done so later, 72% had some type of psychiatric contact prior to the initial clinic evaluation and 28% had psychiatric contact during follow-up. There was a single female-to-male patient with multiple surgical complications who sought partial reassignment surgery reversal.

The adjustment scores improved over time with borderline statistical significance for the initial operative group and with statistical significance for the never operated group. The absolute score value at follow-up was the same for both groups (1.07 ± 1.53 and 1.10 ± 1.97 respectively). By contrast, the adjustment scores did not improve for those who were not in the cohort initially approved for surgery, but who subsequently underwent surgery later. This was particularly true if the surgery was performed elsewhere. The absolute score value at follow-up was 0.21 ± 1.89 .

Related papers include Meyer et al. (1971), Meyer et al. (1974a-d), and Derogatis et al. (1978) along with commentary response by Fleming et al. (1980).

Rakic Z, Starcevic V, Maric J, Kelin K. The outcome of sex reassignment surgery in Belgrade: 32 patients of both sexes. Arch Sex Behav. 1996 Oct;25(5):515-25.

Rakic et al. single-center (Belgrade, Yugoslavia) conducted a prospective, non-blinded, observational study using a cross-sectional design and an investigator-designed quality of life tool that asked longitudinal (pre- and post-treatment) questions. Patients served as their own controls. The authors state that the study was not designed to assess the predictors of poor outcomes.

The investigators assessed global satisfaction, body image, relationships, employment status, and sexual function in patients with gender dysphoria who underwent reassignment surgery between 1989 and 1993 and were at least six months post-operative. The criteria to qualify for gender surgery were delineated (1985 standards from the Harry Benjamin International Gender Dysphoria Association) and included cross-gender behavior for at least one year and sexual orientation to non-natal sex. The questionnaire consisted of 10 questions using yes/no answers or Likert-type scales. Findings were descriptive without statistical analysis. As such, changes or differences considered to be biologically significant were not pre-specified, and there were no adjustments for multiple comparisons.

Of the 38 patients who had undergone reassignment surgery, 34 were eligible for the study and 32 participated in the study (two were lost to follow-up and four were in the peri-operative period) - 10 (31.2%) female-to-male and 22 (68.8%) male-to-female (ratio 1:2.2). The duration of follow-up was 21.8 ± 13.4 months (range 6 months to 4 years). The age was female-to-male 27.8 ± 5.2 (range 23-37) and male-to-female 26.4 ± 7.8 (range 19-47).

Using an investigator-designed quality of life tool, all patients reported satisfaction with having undergone the surgery. Of the total participants, four (12.5%) (all male-to-female) and eight (25%) (87.5% male-to-female) reported complete dissatisfaction or partial satisfaction with their appearance. Regarding relationships, 80% of female-to-male and 100% of male-to-female patients were dissatisfied with their relationships with others prior to surgery; whereas, no female-to-male patients and 18.1% of male-to-female patients were dissatisfied with relationships after surgery. Regarding sexual partners, 60% of female-to-male and 72.7% of male-to-female patients reported not having a sexual partner prior to surgery; whereas, 20% of female-to-male patients and 27.3% of male-to-female patients did not have a sexual partner after surgery. Of those with partners at each time interval, 100% of female-to-male and 50% of male-to-female patients reported not experiencing orgasm prior to surgery; whereas, 75% of female-to-male and 37.5% of male-to-female patients reported not experiencing orgasm after surgery.

Ruppin U, Pfäfflin F. Long-term follow-up of adults with gender identity disorder. Arch Sex Behav. 2015 Jul;44(5):1321-9. Epub 2015 Feb 18.

Rupp and Pfafflin conducted a single-center (Ulm, Germany) partially prospective, non-blinded, observational study using a longitudinal design and non-specific psychometric tests and a self-designed interview tool and questionnaire. Patients served as their own controls.

The investigators assessed psychological symptoms, interpersonal difficulties, gender role stereotypes, personality characteristics, societal function, sexual function, and satisfaction with new gender role in patients with gender dysphoria. Patients were required to have met the ICD-10 criteria for trans-sexualism, been seen by the clinic by prior to 2001, and completed an official change in gender including name change prior to 2001. Assessment tools included German versions of standardized surveys with normative data: the SCL 90R, the Inventory of Interpersonal Problems (IIP), Bem Sex Role Inventory (BSRI), and the Freiburg Personality Inventory (FPI-R), along with semi-structured interviews with self-designed questionnaires. The prospective survey results were compared to retrospective survey results. Changes or inter-group differences considered to be biologically significant were not pre-specified. Diagnostic cut points were not provided. Statistical corrections for multiple comparisons were not included.

Overall, 140 patients received recruitment letters and then 71 (50.7%) agreed to participate. Of these participants, 36 (50.7%) were female-to-male; 35 (49.3%) were male-to-female (ratio 1:0.97). The ages of the patients were: 41.2 ± 5.78 years (female-to-male) and 52.9 ± 10.82 years (male-to-female). The intervals for follow-up were 14.1 ± 1.97 years and 13.7 ± 2.17 years, respectively.

All female-to-male patients had undergone mastectomy; 91.7% had undergone oophorectomy and/or hysterectomy; 61.1% had undergone radial forearm flap phalloplasty or metaoidioplasty. Of male-to-female patients, 94.3% had undergone vaginoplasty and perhaps an additional procedure (breast augmentation, larynx surgery, or vocal cord surgery). Two male-to-female patients had not undergone any reassignment surgery, but were still included in the analyses.

A total of 68 patients ranked their well-being as 4.35 ± 0.86 out of five (three patients did not respond to this question). Of respondents, 40% reported not being in a steady relationship. Regular sexual relationships were reported by 57.1% of 35 female-to-male respondents and 39.4% of 33 male-to-female respondents (three patients did not respond to this question). A total of 11 patients reported receiving out-patient psychotherapy; 69 did not express a desire for gender role reversal (two did not respond to this question). The response rate was less than 100% for most of the self-designed survey questions.

Changes from the initial visit to the follow-up visit were assessed for the SCL-90R in 62 of 71 patients. The effect size was statistically significant and large only for the "Interpersonal Sensitivity" scale (one of 10 parameters). The absolute magnitude of mean change was small: from 0.70 ± 0.67 to 0.26 ± 0.34 (scale range 0-4). The duration of follow-up did not correlate with the magnitude of change on the various scales. Differences in baseline SCL-90R scores of 62 participants were compared with the score of 63 of the 69 eligible recruits who declined to enter the study and were notable for higher "Depression" scores for the latter.

Changes from the initial visit to the follow-up visit were assessed for the IIP in 55 of 71 patients. The effect size was statistically significant and large only for the "Overly Accommodating" scale (one of eight parameters). The absolute magnitude of mean change was small: from 11.64 ± 5.99 to 7.04 ± 4.73 (scale range 0-32). The duration of follow-up did not correlate with the magnitude of change on the various scales.

Changes from the initial visit to the follow-up visit were assessed for the FPI-R in 58 of 71 patients. The effect size was statistically significant and large only for the "Life Satisfaction" scale (one of 12 parameters). The absolute magnitude of mean change was substantive: from 4.43 ± 2.99 to 8.31 ± 2.63 (scale range 0-12). The duration of follow-up did not correlate with the magnitude of change on the various scales.

Changes from the initial visit to the follow-up visit were assessed for the BSRI in 16 of 36 female to male patients and 19 of 35 male to female patients. The "Social Desirability" score increased for the female-to-male respondents. At endpoint, both categories of respondents reported androgynous self-images.

This current report is an update of prior publications by Pfafflin including work with Junge which was published in a variety of formats and initially in German.

Smith YL, Van Goozen SH, Kuiper AJ, Cohen-Kettenis PT. Sex reassignment: outcomes and predictors of treatment for adolescent and adult transsexuals. Psychol Med. 2005 Jan;35(1):89-99.

Smith et al. conducted a single-center (Amsterdam, Netherlands) prospective, non-blinded, observational study using a longitudinal design and psychological function tools. Patients served as their own control prior to and after reassignment surgery. The investigators assessed gender dysphoria, body dissatisfaction, physical appearance, psychopathology, personality traits, and post-operative function in patients with gender dysphoria. Patients underwent some aspect of reassignment surgery. The test instruments included the Utrecht Gender Dysphoria Scale (12 items), the Body Image Scale adapted for a Dutch population (30 items), Appraisal of Appearance Inventory (3 observers, 14 items), the Dutch Short MMPI (83 items), the Dutch version of the Symptom Checklist (SCL)(90 items), and clinic-developed or modified questionnaires. Pre-treatment data was obtained shortly after the initial interview. Post- surgery data were acquired at least one year post reassignment surgery.

Three hundred twenty five consecutive adolescents and adults were screened for the study. One-hundred three (29 [28.2%] female-to-male patients and 74 [71.8%] male-to-female patients [ratio 1:2.6]) never started hormone therapy; 222 (76 [34.2%] female-to-male patients and 146 [65.8%] male-to-female patients [ratio 1:1.9]) initiated hormone therapy. Of the patients who started hormone therapy, 34 (5 [14.7%] female-to-male patients and 29 [85.3%] male-to-female patients [ratio 1:5.8]) discontinued hormone therapy.

Subsequently, the study analysis was limited to adults. One hundred sixty-two (58 [35.8%] female-to-male and 104 [64.2%] male-to-female [ratio 1:1.8]) were eligible and provided pre-surgical test data, and 126 (77.8% of eligible adults) (49 [38.9%] female-to-male and 77 [61.1%] male-to-female [ratio 1:1.6]) provided post-surgical data. For those patients who completed reassignment, the mean age at the time of surgical request was 30.9 years (range 17.7-68.1) and 35.2 years (range 21.3-71.9) years at the time of follow-up. The intervals between hormone treatment initiation and surgery and surgery and follow-up were 20.4 months (range 12 to 73) and 21.3 months (range 12 to 47) respectively.

Of the 126 adults who provided post-surgical data, 50 (40.0%) reported having a steady sexual partner, three (2.3%) were retired, and 58 (46.0%) were unemployed. Regarding regret, six patients expressed some regret regarding surgery, but did not want to resume their natal gender role, and one male-to-female had significant regret and would not make the same decision.

Post-surgery Utrecht dysphoria scores dropped substantially and approached reportedly normal values. The patients' appearance better matched their new gender. No one was dissatisfied with his/her overall appearance at follow-up. Satisfaction with primary sexual, secondary sexual, and non-sexual body traits improved over time. Male-to-female patients, however, were more dissatisfied with the appearance of primary sex traits than female-to-male patients. Regarding mastectomy, 27 of 38 (71.1%) female-to-male respondents (not including 11 non-respondents) reported incomplete satisfaction with their mastectomy procedure. For five of these patients, the incomplete satisfaction was because of scarring. Regarding vaginoplasty, 20 of 67 (29.8%) male-to-female respondents (not including 10 non-respondents) reported incomplete satisfaction with their vaginoplasty.

Most of the MMPI scales were already in the normal range at the time of initial testing and remained in the normal

range after surgery. SCL global scores for psycho- neuroticism were minimally elevated before surgery 143.0 ± 40.7 (scoring range 90 to 450) and normalized after surgery 120.3 ± 31.4 . (An analysis using patient level data for only the completers was not conducted.)

Udeze B, Abdelmawla N, Khoosal D, Terry T. Psychological functions in male-to- female people before and after surgery. Sexual and Relationship Therapy. 2008 May; 23(2):141-5. (Not in PubMed) and Megeri D, Khoosal D. Anxiety and depression in males experiencing gender dysphoria. Sexual and Relationship Therapy. 2007 Feb; 22(1):77-81. (Not in PubMed)

Udeze et al. conducted a single-center (Leicester, United Kingdom) prospective, non-blinded, longitudinal study assessing a randomized subset of patients who had completed a non-specific psychological function tool prior to and after male-to-female reassignment surgery. Patients served as their own controls. The investigators used the WPATH criteria for patient selection. Psychiatric evaluations were routine. All patients selected for treatment were routinely asked to complete the self-administered SCL-90R voluntarily on admission to the program and post-operatively. A post-operative evaluations (psychiatric and SCL-90R assessment) were conducted within six months to minimize previously determined loss rates. The patient pool was domestic and international. There were 546 gender dysphoric patients from all over the United Kingdom and abroad, of whom 318 (58.2%) progressed to surgery. Of these, 127 were from the local Leicester area in the United Kingdom and 38 (29.9%) progressed to surgery. The mean age for the selected male-to-female patients at the time of study was 47.33 ± 13.26 years (range 25 to 80) and reflected an average wait time for surgery of 14 months (range 2 months to 6 years). For this investigation, 40 male-to-female subjects were prospectively selected.

The raw SCL-90 global scores for psycho-neuroticism were unchanged over time: 48.33 prior to surgery and 49.15 after surgery. If the scale was consistent with T-scoring, the results were non-pathologic. No psychiatric disorders were otherwise identified prior to or after surgery.

Investigators from the same clinical group (Megeri, Khoosal, 2007) conducted additional testing to specifically address anxiety and depression with the Beck Depression Inventory, General Health Questionnaire (with 4 subscales), HADS, and Spielberger State and Trait Anxiety Questionnaire (STAI-X1 and STA-X2). The test population and study design appear to be the same. No absolute data were presented. Only changes in scores were presented. There were no statistically significant changes.

e. Randomized, surgical patients, longitudinal, with controls

Mate-Kole C, Freschi M, Robin A. A controlled study of psychological and social change after surgical gender reassignment in selected male transsexuals. Br J Psychiatry. 1990 Aug;157:261-4.

Mate-Kole et al. conducted a prospective, non-blinded, controlled, randomized, longitudinal study using investigator-designed patient self-report questionnaires and non-specific psychological tests with some normative data. The investigators assessed neuroticism and sex role in natal males with gender dysphoria who had qualified for male-to-female reassignment surgery at a single-center specialty clinic (London, United Kingdom). Forty sequential patients were alternately assigned to early reassignment surgery or to standard wait times for reassignment surgery. Patients were evaluated after acceptance and 2 years later. The criteria used to qualify for gender surgery were the 1985 standards from the Harry Benjamin International Gender Dysphoria Association. These included a ≥ 2 year desire to change gender, a ≥ 1 year demonstrable ability to live and be self-supporting in the chosen gender, and psychiatric assessment for diagnosis and reassessment at six months for diagnostic confirmation and exclusion of psychosis.

Reassignment surgery was defined as orchidectomy, penectomy, and construction of a neo-vagina. The instruments used were the CCEI for psychoneurotic symptoms and the Bem Sex Role Inventory along with an incompletely

described investigator- designed survey with questions about social life and sexual activity.

The mean age and range of the entire cohort was 32.5 years (21-53). Members of the early surgery cohort had a history of attempted suicide (one patient), psychiatric treatment for non-gender issues (six patients), and first degree relatives with psychiatric histories (four patients). Members of the standard surgery cohort were similar, with a history of attempted suicide (two patients), psychiatric treatment for non-gender issues (five patients), and first degree relatives with psychiatric histories (six patients). The early surgery group had surgery approximately 1.75 years prior to the follow-up evaluation. In both groups, cross-dressing began at about age 6.

At baseline, the Bem Sex Role Inventory femininity scores were slightly higher than masculinity scores for both cohorts and were similar to Bem North American female normative scores. The scores did not change in either group over time.

At baseline, the scores for the CCEI individual domains (free floating anxiety, phobic anxiety, somatic anxiety, depression, hysteria, and obsessionality) were similar for the cohorts. The total CCEI scores for the two cohorts were consistent with moderate symptoms (Birchnell et al. 1988). Over the two year interval, total CCEI scores increased for standard wait group and approached the relatively severe symptom category. During the same interval, scores dropped into the asymptomatic range for the post-operative patients.

The investigator-designed survey assessed changes in social and sexual activity of the prior two years, but the authors only compared patients in a given cohort to themselves. Though the researchers did not conduct statistical studies to compare the differences between the two cohorts, they did report increased participation in some, but not all, types of social activities such as sports (solo or group), dancing, dining out, visiting pubs, and visiting others. Sexual interest also increased. By contrast, pre-operative patients did not increase their participation in these activities.

2. External Technology Assessments

- a. CMS did not request an external technology assessment (TA) on this issue.
- b. There were no AHRQ reviews on this topic.
- c. There are no Blue Cross/Blue Shield Health Technology Assessments written on this topic within the last three years.
- d. There were two publications in the COCHRANE database, and both were tangentially related. Both noted that there are gaps in the clinical evidence base for gender reassignment surgery.
Twenty Years of Public Health Research: Inclusion of Lesbian, Gay, Bisexual, and Transgender Populations
Boehmer U. Am J Public Health. 2002; 92: 1125–30.

“Findings supported that LGBT issues have been neglected by public health research and that research unrelated to sexually transmitted diseases is lacking.”

A systematic review of lesbian, gay, bisexual and transgender health in the West Midlands region of the UK compared to published UK research. West Midlands Health Technology Assessment Collaboration. Health Technology Assessment Database. Meads, et al., 2009. No.3.

“Further research is needed but must use more sophisticated designs with comparison groups. This systematic review demonstrated that there are so many gaps in knowledge around LGBT health that a wide variety of studies are needed.”

- e. There were no National Institute for Health and Care Excellence (NICE) reviews/guidance documents on this

topic.

- f. There was a technology assessment commissioned by the New Zealand Ministry of Health and conducted by New Zealand Health Technology Assessment (NZHTA) (Christchurch School of Medicine and the University of Otago).

Tech Brief Series: Transgender Re-assignment Surgery Day P. NZHTA Report. February 2002;1(1).
http://nzhta.chmeds.ac.nz/publications/trans_gender.pdf

The research questions included the following:

1. Are there particular subgroups of people with transsexualism who have met eligibility criteria for gender reassignment surgery (GRS) where evidence of effectiveness of that surgery exists?
2. If there is evidence of effectiveness, what subgroups would benefit from GRS?"

The authors concluded that there was not enough evidence to answer either of the research questions.

3. Medicare Evidence Development & Coverage Advisory Committee (MEDCAC) Meeting

CMS did not convene a MEDCAC meeting.

4. Evidence-Based Guidelines

- a. American College of Obstetricians and Gynecologists (ACOG)

Though ACOG did not have any evidence-based guidelines on this topic, they did have the following document:

Health Care for Transgender Individuals: Committee Opinion

Committee on Health Care for Underserved Women; The American College of Obstetricians and Gynecologists. Dec 2011, No. 512. *Obstet Gynecol.* 2011;118:1454-8.

"Questions [on patient visit records] should be framed in ways that do not make assumptions about gender identity, sexual orientation, or behavior. It is more appropriate for clinicians to ask their patients which terms they prefer. Language should be inclusive, allowing the patient to decide when and what to disclose. The adoption and posting of a nondiscrimination policy can also signal health care providers and patients alike that all persons will be treated with dignity and respect. Assurance of confidentiality can allow for a more open discussion, and confidentiality must be ensured if a patient is being referred to a different health care provider. Training staff to increase their knowledge and sensitivity toward transgender patients will also help facilitate a positive experience for the patient."

- b. American Psychiatric Association

Report of the American Psychiatric Association Task Force on Treatment of Gender Identity Disorder. Byne, W, Bradley SJ, Coleman E, Eyler AE, Green R, Menvielle EJ, Meyer-Bahlburg HFL, Richard R. Pleak RR, Tompkins DA. Arch Sex Behav. 2012; 41:759-96.

The American Psychiatric Association (APA) was unable to identify any Randomized Controlled Trials (RCTs) regarding mental health issues for transgender individuals.

"There are some level B studies examining satisfaction/regret following sex reassignment (longitudinal follow-up after an intervention, without a control group); however, many of these studies obtained data retrospectively and without a control group (APA level G). Overall, the evidence suggests that sex reassignment is associated with an

improved sense of well-being in the majority of cases, and also indicates correlates of satisfaction and regret. No studies have directly compared various levels of mental health screening prior to hormonal and surgical treatments on outcome variables; however, existing studies suggest that comprehensive mental health screening may be successful in identifying those individuals most likely to experience regrets."

Relevant Descriptions of APA Evidence Coding System/Levels:

[B] Clinical trial. A prospective study in which an intervention is made and the results of that intervention are tracked longitudinally. Does not meet standards for a randomized clinical trial."

[G] Other. Opinion-like essays, case reports, and other reports not categorized above."

c. Endocrine Society

Endocrine Treatment of Transsexual Persons: an Endocrine Society Clinical Practice Guideline.

Hembree WC, Cohen-Kettenis P, Delemarre-van de Waal HA, Gooren LJ, Meyer WJ 3rd, Spack NP, Tangpricha V, Montori VM; Endocrine Society. J Clin Endocrinol Metab. 2009; 94:3132-54.

This guideline primarily addressed hormone management and surveillance for complications of that management. A small section addressed surgery and found the quality of evidence to be low.

"This evidence-based guideline was developed using the Grading of Recommendations, Assessment, Development, and Evaluation (GRADE) system to describe the strength of recommendations and the quality of evidence, which was low or very low."

d. World Professional Association for Transgender Health (WPATH)

Standards of Care for the Health of Transsexual, Transgender, and Gender-Nonconforming People (Version 7). Coleman E, Bockting W, Botzer M, Cohen-Kettenis P, DeCuypere G, Feldman J, Fraser L, Green J, Knudson G, Meyer WJ, Monstrey S, Adler RK, Brown GR, Devor AH, Ehrbar R, Ettner R, Eyler E, Garofalo R, Karasic DH, Lev AI, Mayer G, Meyer-Bahlburg H, Hall BP, Pfäfflin F, Rachlin K, Robinson B, Schechter LS, Tangpricha V, van Trotsenburg M, Vitale A, Winter S, Whittle S, Kevan R, Wylie KR, Zucker K. www.wpath.org/_files/140/files/Standards%20of%20Care,%20V7%20Full%20Book.pdf Int J Transgend. 2011;13:165-232.

The WPATH is "an international, multidisciplinary, professional association whose mission is to promote evidence-based care, education, research, advocacy, public policy, and respect in transsexual and transgender health."

WPATH reported, "The standards of care are intended to be flexible in order to meet the diverse health care needs of transsexual, transgender, and gender-nonconforming people. While flexible, they offer standards for promoting optimal health care and guiding the treatment of people experiencing gender dysphoria—broadly defined as discomfort or distress that is caused by a discrepancy between a person's gender identity and that person's sex assigned at birth (and the associated gender role and/or primary and secondary sex characteristics) (Fisk, 1974; Knudson, De Cuypere, & Bockting, 2010b)."

The WPATH standards of care (SOC) "acknowledge the role of making informed choices and the value of harm-

reduction approaches.”

The SOC noted, “For individuals seeking care for gender dysphoria, a variety of therapeutic options can be considered. The number and type of interventions applied and the order in which these take place may differ from person to person (e.g., Bockting, Knudson, & Goldberg, 2006; Bolin, 1994; Rachlin, 1999; Rachlin, Green, & Lombardi, 2008; Rachlin, Hansbury, & Pardo, 2010). Treatment options include the following:

- Changes in gender expression and role (which may involve living part time or full time in another gender role, consistent with one’s gender identity);
- Hormone therapy to feminize or masculinize the body;
- Surgery to change primary and/or secondary sex characteristics (e.g., breasts/chest, external and/or internal genitalia, facial features, body contouring);
- Psychotherapy (individual, couple, family, or group) for purposes such as exploring gender identity, role, and expression; addressing the negative impact of gender dysphoria and stigma on mental health; alleviating internalized transphobia; enhancing social and peer support; improving body image; or promoting resilience.”

e. American Psychological Association

Suggested citation until formally published in the American Psychologist: American Psychological Association. (2015): *Guidelines for Psychological Practice with Transgender and Gender Nonconforming People Adopted by the Council of Representatives, August 5 & 7, 2015*. www.apa.org/practice/guidelines/transgender.pdf

“The purpose of the Guidelines for Psychological Practice with Transgender and Gender Nonconforming People (hereafter Guidelines) is to assist psychologists in the provision of culturally competent, developmentally appropriate, and trans-affirmative psychological practice with TGNC people.”

“These Guidelines refer to psychological practice (e.g., clinical work, consultation, education, research, training) rather than treatment.”

5. Other Reviews

a. Institute of Medicine (IOM)

The Health of Lesbian, Gay, Bisexual, and Transgender People: Building a Foundation for Better Understanding. Robert Graham (Chair); Committee on Lesbian, Gay, Bisexual, and Transgender Health Issues and Research Gaps and Opportunities. (Study Sponsor: The National Institutes of Health). Issued March 31, 2011. <http://www.nationalacademies.org/hmd/Reports/2011/The-Health-of-Lesbian-Gay-Bisexual-and-Transgender-People.aspx>

“To advance understanding of the health needs of all LGBT individuals, researchers need more data about the demographics of these populations, improved methods for collecting and analyzing data, and an increased participation of sexual and gender minorities in research. Building a more solid evidence base for LGBT health concerns will not only benefit LGBT individuals, but also add to the repository of health information we have that pertains to all people.”

“Best practices for research on the health status of LGBT populations include scientific rigor and respectful involvement of individuals who represent the target population. Scientific rigor includes incorporating and monitoring culturally competent study designs, such as the use of appropriate measures to identify participants and

implementation processes adapted to the unique characteristics of the target population. Respectful involvement refers to the involvement of LGBT individuals and those who represent the larger LGBT community in the research process, from design through data collection to dissemination.”

b. National Institutes of Health (NIH)

National Institutes of Health Lesbian, Gay, Bisexual, and Transgender (LGBT) Research Coordinating Committee. Consideration of the Institute of Medicine (IOM) report on the health of lesbian, gay, bisexual, and transgender (LGBT) individuals. Bethesda, MD: National Institutes of Health; 2013.

http://report.nih.gov/UploadDocs/LGBT%20Health%20Report_FINAL_2013-01-03-508%20compliant.pdf

In response to the IOM report, the NIH LGBT research Coordinating Committee noted that most of the health research for this set of populations is “focused in the areas of Behavioral and Social Sciences, HIV (human immunodeficiency virus)/AIDS, Mental Health, and Substance Abuse. Relatively little research has been done in several key health areas for LGBT populations including the impact of smoking on health, depression, suicide, cancer, aging, obesity, and alcoholism.”

6. Pending Clinical Trials

ClinicalTrials.gov

There is one currently listed and recently active trial directed at assessment of the clinical outcomes pertaining to individuals who have had gender reassignment surgery. The study appears to be a continuation of work conducted by investigators cited in the internal technology assessment.

NCT01072825 (Ghent, Belgium sponsor) European Network for the Investigation of Gender Incongruence (ENIGI) is assessing the physical and psychological effects of the hormonal treatment of transgender subjects in two years prior to reassignment surgery and subsequent to surgery. This observational cohort study started in 2010 and is still in progress.

7. Consultation with Outside Experts

Consistent with the authority at 1862(I)(4) of the Act, CMS consulted with outside experts on the topic of treatment for gender dysphoria and gender reassignment surgery.

Given that the majority of the clinical research was conducted outside of the United States, and some studies either took place in or a suggested continuity-of-care and coordination-of-care were beneficial to health outcomes, we conducted expert interviews with centers across the U.S. that provided some form of specialty-focused or coordinated care for transgender patients. These interviews informed our knowledge about the current healthcare options for transgender people, the qualifications of the professionals involved, and the uniqueness of treatment options. We are very grateful to the organizations that made time to discuss treatment for gender dysphoria with us.

From our discussions with the all of the experts we spoke with, we noted the following practices in some centers: (1) specialized training for all staff about transgender healthcare and transgender cultural issues; (2) use of an intake assessment by either a social worker or health care provider that addressed physical health, mental health, and other life factors such as housing, relationship, and employment status; (3) offering primary care services for transgender people in addition to services related to gender-affirming therapy/treatments; (4) navigators who connected patients with name-change information or other legal needs related to gender; (5) counseling for individuals, groups, and families; (6) an informed-consent model whereby individuals were often referred to as

"clients" instead of "patients," and (7) an awareness of depression among transgender people (often measured with tools such as the Adult Outcomes Questionnaire and the Patient Health Questionnaire).

8. Public Comments

We appreciate the thoughtful public comments we received on the proposed decision memorandum. In CMS' experience, public comments sometimes cite the published clinical evidence and give CMS useful information. Public comments that give information on unpublished evidence such as the results of individual practitioners or patients are less rigorous and therefore less useful for making a coverage determination. CMS uses the initial public comments to inform its proposed decision. CMS responds in detail to the public comments on a proposed decision when issuing the final decision memorandum. All comments that were submitted without personal health information may be viewed in their entirety by using the following link: <https://www.cms.gov/medicare-coverage-database/details/nca-view-public-comments.aspx?NCAId=282&ExpandComments=n#Results>

a. Initial Comment Period: December 3, 2015 – January 2, 2016

During the initial comment period, we received 103 comments. Of those, 78% supported coverage of gender reassignment surgery, 15% opposed, and 7% were neutral. The majority of comments supporting coverage were from individuals and advocacy groups.

b. Second Comment Period: June 2, 2016 – July 2, 2016

During the second 30-day public comment period, we received a total of 45 public comments, 7 of which were not posted on the web due to personal health information content. Overall, 82% supported coverage of gender reassignment surgery, 11% opposed, and 7% were neutral or silent in their comment whether they supported or opposed coverage. Half of the comments were submitted by individuals who expressed support for coverage of gender reassignment surgery (51%). We also received comments from physicians, providers, and other health professionals who specialize in healthcare for transgender individuals (17%). We received one comment from a municipality, the San Francisco Department of Public Health. Associations (American Medical Association, American College of Physicians, American Academy of Nursing, American Psychological Association, and LGBT PA Caucus) and advocates (Center for American Progress with many other signatories, Jamison Green & Associates) also submitted comments.

Below is a summary of the comments CMS received. In some instances, commenters identified typographical errors, context missed, and opportunities for CMS to clarify wording and classify articles for ease of reading in the memorandum. As noted earlier, when appropriate and to the extent possible, we updated the decision memorandum to reflect those corrections, improved the context, and clarified the language. In light of public comments, we re-evaluated the evidence and our summaries. We updated our summaries of the studies and clarified the language when appropriate.

1. Contractor Discretion and National Coverage Determination

Comment: Some commenters, including advocates, associations, and providers, supported CMS' decision for MAC contractor discretion/case-by-case determination for gender reassignment surgery. One stakeholder stated, "We agree with the conclusion that a NCD is not warranted at this time."

Response: We appreciate the support and understanding among stakeholders for our proposed decision to have the MACs determine coverage on a case-by-case basis. We have clarified in this final decision memorandum that

coverage is available for gender reassignment surgery when determined reasonable and necessary and not otherwise excluded by any other relevant statutory requirements by the MAC on a case-by-case basis. "The case-by-case model affords more flexibility to consider a particular individual's medical condition than is possible when the agency establishes a generally applicable rule." (78 Fed. Reg. 48165 (August 7, 2013)).

Comment: Some commenters cautioned that CMS' choice to not issue a NCD at this time must not be interpreted as a national non-coverage determination or used in any way to inappropriately restrict access to coverage for transgender Medicare beneficiaries or other transgender individuals. Multiple commenters indicated their disappointment that CMS did not propose a National Coverage Determination (NCD) and, instead, chose to continue to have local MACs make the coverage decisions on a case-by-case basis. Commenters stated this could result in variability in coverage.

Response: We appreciate the comments. We are not issuing a NCD at this time because the available evidence for gender reassignment surgery provides limited data on specific health outcomes and the characteristics of specific patient populations that might benefit from surgery. In the absence of a NCD, the MAC's use the same statutory authority as NCDs, section 1862(a)(1)(A) of the Social Security Act (the Act). Under section 1862(a)(1)(A) an item or service must be reasonable and necessary for the diagnosis or treatment of illness or injury or to improve the functioning of a malformed body member. While CMS did not have enough evidence to issue a NCD, we believe the MACs will be able to make appropriate coverage decisions on a case-by-case basis taking into account individual characteristics of the Medicare beneficiary.

Comment: Some commenters sought a NCD that would establish guidelines for coverage and include elements such as a prescribed set of surgeries and a shared decision making element.

Response: For the reasons stated above, we are not issuing a NCD at this time and, therefore, are not establishing specific gender reassignment surgery coverage guidelines for the Medicare program. We generally agree that shared decision-making is a fundamental approach to patient-centered health care decisions and strongly encourage providers to use these types of evidence based decision aids. We have not found a shared decision aid on GRS and encourage the development of this necessary element to conduct formal shared-decision making.

Comment: Some commenters expressed concern that there is a misunderstanding of transgender individuals as having a disorder or being abnormal. Some commenters indicated a history of bias and discrimination within society as a whole that has occurred when transgender individuals have sought health care services from the medical community. Some commenters are concerned that the decision not to make a NCD will subject individuals seeking these services to corporate bias by Medicare contractors.

Response: We acknowledge the public comments and that there has been a transformation in the treatment of individuals with gender dysphoria over time. In this NCA, we acknowledge that gender dysphoria is a recognized Diagnostic and Statistical Manual of Mental Disorders (DSM) condition. With respect to the concern about potential bias by Medicare contractors, we have no reason to expect that the judgments made on specific claims will be influenced by an overriding bias, hostility to patients with gender dysphoria, or discrimination. Moreover, the Medicare statute and our regulations provide a mechanism to appeal an adverse initial decision if a claim is denied and those rights may include the opportunity for judicial review. We believe the Medicare appeals process would provide an opportunity to correct any adverse decision that was perceived to have been influenced by bias.

Comment: Commenters mentioned the cost of gender reassignment surgery could influence MAC decision making.

Response: The decisions on whether to cover gender reassignment surgery in a particular case are made on the basis of the statutory language in section 1862 of the Social Security Act that establish exclusions from coverage and

would not depend on the cost of the procedure.

2. Coverage with Evidence Development and Research

Comment: In our proposed decision memorandum, we specifically invited comments on whether a study could be developed that would support coverage with evidence development (CED). One organization commented, “We strongly caution against instituting a CED protocol.” Commenters were opposed to coverage limited in clinical trials, suggesting that such coverage would restrict access to care. Several commenters provided suggested topics for clinical research studies for the transgender population. For example, one commenter suggested a study of non-surgical treatment for transgender children prior to puberty.

Response: While we appreciate the comments supporting further research, in general, for gender reassignment surgery, we agree that CED is not the appropriate coverage pathway at this time. While CED is an important mechanism to support research and has the potential to be used to help address gaps in the current evidence, we are not aware of any available, appropriate studies, ongoing or in development, on gender reassignment surgery for individuals with gender dysphoria that could be used to support a CED decision.

3. Gender Reassignment Surgery as Treatment

Comment: One group of commenters requested that CMS consider that, “The established medical consensus is that GRS is a safe, effective, and medically necessary treatment for many individuals with gender dysphoria, and for some individuals with severe dysphoria, it is the only effective treatment.”

Response: We acknowledge that GRS may be a reasonable and necessary service for certain beneficiaries with gender dysphoria. The current scientific information is not complete for CMS to make a NCD that identifies the precise patient population for whom the service would be reasonable and necessary.

4. Physician Recommendations

Comment: Several commenters stated that gender reassignment surgery should be covered as long as it was determined to be necessary, or medically necessary by a beneficiary’s physician.

Response: Physician recommendation is one of many potential factors that the local MAC may consider when determining whether the documentation is sufficient to pay a claim.

5. WPATH Standards of Care

Comment: Several commenters suggested that CMS should recommend the WPATH Standards of Care (WPATH) as the controlling guideline for gender reassignment surgery. They asserted it could satisfy Medicare's reasonable and necessary criteria for determining coverage on a case-by-case basis.

Response: Based on our review of the evidence and conversations with the experts and patient advocates, we are aware some providers consult the WPATH Standards of Care, while others have created their own criteria and requirements for surgery, which they think best suit the needs of their patients. As such, and given that WPATH acknowledges the guidelines should be flexible, we are not in the position to endorse exclusive use of WPATH for coverage. The MACs, Medicare Advantage plans, and Medicare providers can use clinical guidelines they determine useful to inform their determination of whether an item or service is reasonable and necessary. When making this

determination, local MACs may take into account physician's recommendations, the individual's clinical characteristics, and available clinical evidence relevant to that individual.

6. Scope of the NCA Request

Comment: One commenter stated that CMS did not address the full scope of the NCA request.

Response: The formal request for a NCD is publicly available on our tracking sheet. (<https://www.cms.gov/Medicare/Coverage/DeterminationProcess/downloads/id282.pdf>) The letter did not explicitly seek a national coverage determination related to counseling or hormone therapies, but focused on surgical remedies. CMS is aware that beneficiaries with gender dysphoria use a variety of therapies.

Comment: Other commenters stated the scope of the proposed decision is unnecessarily broad because it discussed therapies other than surgery. They suggested this discussion could lead to the unintended consequence of restricting access to those services for transgender Medicare beneficiaries and other transgender individuals.

Response: As we noted in our proposed decision, our decision focused only on gender reassignment surgery. In the course of reviewing studies related to those surgeries, occasionally authors discussed other therapies that were mentioned in our summaries of the evidence. To the extent possible, we have modified our decision to eliminate the discussion of other therapies which were not fully evaluated in this NCA.

7. NCA Question

Comment: Some commenters expressed concern about the phrasing of the question in this NCA.

Response: The phrasing of the research question is consistent with most NCAs and we believe it is appropriate.

8. Evidence Summary and Analysis

Comment: Several commenters disagreed with our summary of the clinical evidence and analysis. A few commenters contended that the overall tone of the review was not neutral and seemed biased or flawed. One commenter noted that the Barrett publication was available on the Internet.

Response: We appreciate the comments that identified technical errors, and we made the necessary revisions to this document. However, we disagree with the contention that our evidence review was not neutral and seemed biased or flawed. We believe that the summary and analysis of the clinical evidence are objective. As with previous NCAs, our review of the evidence was rigorous and methodical. Additionally, we reviewed the Barrett publication, but it did not meet our inclusion criteria to be included in the Evidence section.

9. Evidence Review with Transgender Experts

Comment: Several commenters requested that CMS re-review the clinical evidence discussed in the proposed decision memorandum with outside experts in the field of transgender health and transition/gender reassignment-related surgeries. Several offered the expertise within their organization to assist in this effort.

Response: We appreciate these comments and the transgender health community's willingness to participate. For

this NCA we discussed gender reassignment surgery protocols with experts, primarily in coordinated care settings. Additionally, the public comment periods provide opportunities for expert stakeholder input. According to our process for all NCAs, we do not jointly review evidence with external stakeholders but have carefully reviewed the very detailed comments submitted by a number of outside experts in transgender health care.

10. Previous Non-Coverage NCD

Comment: One commenter noted that they thought research studies for gender reassignment surgery could not take place when the old NCD that prohibited coverage for gender reassignment surgery was in effect.

Response: CMS does not directly conduct clinical studies or pay for research grants. Some medical services are non-covered by Medicare; however, national non-coverage does not preclude research via a number of avenues and other funding entities such as the National Institutes of Health. In this instance, the previous NCD did not preclude interested parties from funding research for gender reassignment surgery that could have been generalizable to the Medicare population.

11. How the Medicare Population Differs from the General Population

Comment: One commenter questioned how the Medicare population differed from the general population, and why any differences would be important in our decision-making.

Response: The Medicare population is different from the general population in age (65 years and older) and/or disability as defined by the Social Security Administration. Due to the biology of aging, older adults may respond to health care treatments differently than younger adults. These differences can be due to, for example, multiple health conditions or co-morbidities, longer duration needed for healing, metabolic variances, and impact of reduced mobility. All of these factors can impact health outcomes. The disabled Medicare population, who are younger than age 65, is different from the general population and typical study populations due to the presence of the causes of disability such as psychiatric disorders, musculoskeletal health issues, and cardiovascular issues.

12. Medicare Evidence Development & Coverage Advisory Committee (MEDCAC)

Comment: One commenter suggested CMS should have convened a MEDCAC for this topic.

Response: We appreciate the comment. Given the limited evidence, we did not believe a MEDCAC was warranted according to our guidance document entitled "Factors CMS Considers in Referring Topics to the Medicare Evidence Development & Coverage Advisory Committee" (<https://www.cms.gov/Regulations-and-Guidance/Guidance/FACA/MEDCAC.html>).

13. §1557 of the Affordable Care Act (ACA)

Comment: Some commenters asserted that by not explicitly covering gender reassignment surgery at the national level, CMS was discriminating against transgender beneficiaries in conflict with Section 1557 of the Accountable Care Act (ACA).

Response: This decision does not affect the independent obligation of covered entities, including the Medicare program and MACs, to comply with Section 1557 in making individual coverage decisions. In accordance with Section 1557, MACs will apply neutral nondiscriminatory criteria when making case-by-case coverage determinations related

to gender reassignment surgery.

14. Medicaid

Comment: Some commenters observed that some states cover gender reassignment surgery through Medicaid or require commercial insurers operating in the state to cover the surgery.

Response: We appreciate the information about Medicaid and state requirements; however, State decisions are separate from Medicare coverage determinations. We make evidence-based determinations based on our statutory standards and processes.

15. Commercial Insurers

Comment: In several instances, commenters told us that the healthcare industry looks to CMS coverage determinations to guide commercial policy coverage.

Response: CMS makes evidence-based national coverage determinations based on our statutory standards and processes as defined in the Social Security Act, which may not be the same standards that are used in commercial insurance policies or by other health care programs. In addition as noted above, the Medicare population is different (e.g., Medicare covers 95% of adults 65 and older) than the typical population under commercial insurers. We do not issue coverage decisions to drive policy for other health organizations' coverage in one way or the other.

16. Healthcare for Transgender Individuals

Comment: Numerous professional associations wrote to CMS to explain their support for access to healthcare for transgender individuals.

Response: CMS recognizes that transgender beneficiaries have specific healthcare needs. Many health care treatments are available. We encourage all beneficiaries to utilize their Medicare benefits to help them achieve their best health.

17. Intended Use of the Decision Memorandum

Comment: Several commenters expressed concern that the analysis provided in the proposed and final decision memorandums may be used by individuals, entities, or payers for purposes unrelated to Medicare such as denial of coverage for transgender-related surgeries.

Response: The purpose of the decision memoranda is to memorialize CMS' analysis of the evidence, provide responses to the public comments received, and to make available the clinical evidence and other data used in making our decision consistent with our obligations under the § 1862 of the Act. The NCD process is open and transparent and our decisions are publicly available. Congress requires that we provide a clear statement of the basis for our determinations. The decision memoranda are an important part of the record of the NCD. Our focus is the Medicare population which, as noted above, is different than the general population in a number of ways. Other entities may conduct separate evidence reviews and analyses that are suited for their specific populations.

18. Cost Barriers to Care and Effects

Comment: A few commenters stated that without Medicare coverage, surgery is difficult to afford and there may be a risk of negative consequences for the individual. One commenter suggested that CMS should consider prior-authorization for these surgeries.

Response: CMS is aware that paying out-of-pocket for medical care is a strain on a beneficiary's finances. We are also aware of beneficiaries' hesitancy to undergo surgery prior to knowing whether or not Medicare will pay the claim. Gender reassignment surgeries are not the only procedures whereby payment is not determined until after the provider submits the claim to Medicare. Importantly, documentation for the claims need to be explicit about what procedures were performed and include the appropriate information in the documentation to justify using the code or codes for surgery. Of note, CMS has claims data that indicate Medicare has paid for gender reassignment surgeries in the recent past. Determining which services are designated for prior-authorization is outside of the scope of the NCA process.

19. Surgical Risks and Benefits

Comment: A number of commenters conveyed the benefits of gender reassignment surgery, while other commenters expressed concern that gender reassignment surgery was harmful.

Response: We appreciate these comments.

20. Expenditure of Federal Funds

Comment: Some commenters opposed spending Medicare program funds on gender reassignment surgery for a variety of reasons. For example, some commenters believe it is an "elective" procedure. Other commenters suggested that funds should first be spent on other priorities such as durable medical equipment (DME) or mobility items such as power chairs; increasing reimbursement to providers; or that spending should be limited to the proportion to the transgender adult population in the Medicare program.

Response: The purpose of this NCA is to determine whether or not CMS should issue a NCD to cover surgery for patients who have gender dysphoria. NCAs do not establish payment amounts or spending priorities and, therefore, these comments are outside the scope of this consideration.

VIII. CMS Analysis

National coverage determinations are determinations by the Secretary with respect to whether or not a particular item or service is covered nationally under § 1862(l)(6) of the Act. In general, in order to be covered by Medicare, an item or service must fall within one or more benefit categories contained within Part A or Part B and must not be otherwise excluded from coverage.

Moreover, in most circumstances, the item or service must be reasonable and necessary for the diagnosis or treatment of illness or injury or to improve the functioning of a malformed body member (§1862(a)(1)(A)). The Supreme Court has recognized that "[t]he Secretary's decision as to whether a particular medical service is 'reasonable and necessary' and the means by which she implements her decision, whether by promulgating a generally applicable rule or by allowing individual adjudication, are clearly discretionary decisions." *Heckler v. Ringer*, 466 U.S. 602, 617 (1984). See also, 78 Fed. Reg. 48,164, 48,165 (August 7, 2013)

When making national coverage determinations, we consider whether the evidence is relevant to the Medicare

beneficiary population. In considering the generalizability of the results of the body of evidence to the Medicare population, we carefully consider the demographic characteristics and comorbidities of study participants as well as the provider training and experience. This section provides an analysis of the evidence, which included the published medical literature and guidelines pertaining to gender dysphoria, that we considered during our review to answer the question:

Is there sufficient evidence to conclude that gender reassignment surgery improves health outcomes for Medicare beneficiaries with gender dysphoria?

CMS carefully considered all the studies listed in this decision memorandum to determine whether they answered the question posed in this NCA. While there appears to be many publications regarding gender reassignment surgery, it became clear that many of the publications did not meet our inclusion/exclusion criteria as explained earlier in the decision memorandum.

Thirty-three papers were eligible based on our inclusion/exclusion criteria for the subsequent review (Figure 1). All studies reviewed had potential methodological flaws which we describe below.

A. Quality of the Studies Reviewed

Overall, the quality and strength of evidence were low due to mostly observational study designs with no comparison groups, subjective endpoints, potential confounding (a situation where the association between the intervention and outcome is influenced by another factor such as a co-intervention), small sample sizes, lack of validated assessment tools, and considerable lost to follow-up (Appendices C and F). The impact of a specific therapeutic intervention can be difficult to determine when there are multiple serial treatments such as psychotherapy, hormone treatment and surgery. To reduce confounding, outcome assessment just prior to and after surgery such as in a longitudinal study would be helpful. The objective endpoints included psychiatric treatment, attempted suicide, requests for surgical reversal, morbidity (direct and indirect adverse events), and mortality (Appendix F). CMS agrees with the utility of these objective endpoints. Quality of life, while important, is more difficult to measure objectively (Appendix E).

Of the 33 studies reviewed, published results were conflicting – some were positive; others were negative. Collectively, the evidence is inconclusive for the Medicare population. The majority of studies were non-longitudinal, exploratory type studies (i.e., in a preliminary state of investigation or hypothesis generating), or did not include concurrent controls or testing prior to and after surgery. Several reported positive results but the potential issues noted above reduced strength and confidence. After careful assessment, we identified six studies that could provide useful information (Figure 1). Of these, the four best designed and conducted studies that assessed quality of life before and after surgery using validated (albeit non-specific) psychometric studies did not demonstrate clinically significant changes or differences in psychometric test results after GRS. (Heylens et al., 2014; Ruppin, Pfafflin, 2015; Smith et al., 2005; Udeze et al., 2008) (Appendix C Panel A and Appendix G.)

Two studies (three articles) assessed functional endpoints (request for surgical reassignment reversal and morbidity/mortality) (Dhejne et al., 2011; Dhejne et al., 2014 along with Landén et al., 1998) (Figure 1 and Appendix C, Panel A and Appendix G). Although the data are observational, they are robust because the Swedish national database is comprehensive (including all patients for which the government had paid for surgical services) and is notable for uniform criteria to qualify for treatment and financial coverage by the government. Dhejne et al. (2014) and Landén et al. (1998) reported cumulative rates of requests for surgical reassignment reversal or change in legal status of 3.3% while Dhejne et al. (2014) reported 2.2%. The authors indicated that the later updated calculation had the potential to be an underestimate because the most recent surgical cohorts were larger in size and had shorter periods of follow-up.

Dhejne et al., (2011) tracked all patients who had undergone reassignment surgery (mean age 35.1 years) over a 30 year interval and compared them to 6,480 matched controls. The study identified increased mortality and psychiatric hospitalization compared to the matched controls. The mortality was primarily due to completed suicides (19.1-fold greater than in control Swedes), but death due to neoplasm and cardiovascular disease was increased 2 to 2.5 times as well. We note, mortality from this patient population did not become apparent until after 10 years. The risk for psychiatric hospitalization was 2.8 times greater than in controls even after adjustment for prior psychiatric disease (18%). The risk for attempted suicide was greater in male-to-female patients regardless of the gender of the control. Further, we cannot exclude therapeutic interventions as a cause of the observed excess morbidity and mortality. The study, however, was not constructed to assess the impact of gender reassignment surgery *per se*.

We believe at minimum study designs should have a pre-test/post-test longitudinal design accompanied by characterization of all patients lost to follow-up over the entire treatment series as well as those patients who did not complete questionnaires, and the use of psychometric quality-of-life tools which are well validated with linkage to “hard” (objective) patient outcomes in this particular patient population (Trentacosti 2007, PRO 2009) (Appendices C and D).

Patient Care

Clinical evidentiary questions regarding the care of patients with gender dysphoria remain. Many of the publications focused on aspects of surgical technique as opposed to long-term patient outcomes. The specific type(s) of gender/sex reassignment surgery (e.g., genital, non-genital) that could improve health outcomes in adults remain(s) uncertain because most studies included patients who had undertaken one or more of a spectrum of surgical procedures or did not define the specific types of surgical procedures under study. Furthermore, surgical techniques have changed significantly over the last 60 years and may not reflect current practice (Bjerrome Ahlin et al., 2014; Doornaert, 2011; Green, 1998; Pauly, 1968; Selvaggi et al., 2007; Selvaggi, Bellringer, 2011; Tugnet et al., 2007; Doornaert, 2011).

The WPATH care recommendations present a general framework and guidance on the care of the transgender individual. The standards of care are often cited by entities that perform gender reassignment surgery. WPATH notes, “More studies are needed that focus on the outcomes of current assessment and treatment approaches for gender dysphoria.” Appendix D in the WPATH Standards of Care briefly describes their evidence base and acknowledges the historical problems with evidentiary standards, the preponderance of retrospective data, and the confounding impact of multiple interventions, specifically distinguishing the impact of hormone therapy from surgical intervention.

Additionally, CMS met with several stakeholders and conducted several interviews with centers that focus on healthcare for transgender individuals in the U.S. Primary care rather than gender reassignment surgery was often the main focus. Few of the U.S.-based reassignment surgeons we could identify work as part of an integrated practice, and few provide the most complex procedures.

Psychometric Tools

CMS reviewed psychometric endpoints because gender dysphoria (inclusive of prior nomenclature) describes an incongruence between the gender assigned at birth and the gender(s) with which the person identifies.

The psychometric tools used to assess outcomes have limitations. Most instruments that were specific for gender dysphoria were designed by the investigators themselves or by other investigators within the field using limited populations and lacked well documented test characterization. (Appendices E and F) By contrast, test instruments with validation in large populations were non-specific and lacked validation in the gender dysphoric patient populations. (Appendices E and F). In addition, the presentation of psychometric results must be accompanied by

enough information about the test itself to permit adequate interpretation of test results. The relevant diagnostic cut-points for scores and changes in scores that are clinically significant should also be scientifically delineated for interpretation.

Generalizability

It is difficult to generalize these study results to the current Medicare population. Many of the studies are old given they were conducted more than 10 years ago. Most of these studies were conducted outside of the U.S. in very different medical systems for treatment and follow-up. Many of the programs were single-site centers without replication elsewhere. The study populations were young and without significant physical or psychiatric co-morbidity (Appendix D). As noted earlier, psychiatric co-morbidity may portend poor outcomes (Asscherman et al., 2011; Landén et al., 1998).

Knowledge Gaps

This patient population faces complex and unique challenges. The medical science in this area is evolving. This review has identified gaps in the evidentiary base as well as recommendations for good study designs. The Institute of Medicine, the National Institutes of Health, and others also identified many of the gaps in the data. (Boehmer, 2002; HHS-HP, 2011; IOM, 2011; Kreukels-ENIGI, 2012; Lancet, 2011; Murad et al., 2010; NIH-LGBT, 2013) The current or completed studies listed in ClinicalTrials.gov are not structured to assess these gaps. These gaps have been delineated as they represent areas in which patient care can be optimized and are opportunities for much needed research.

B. Health Disparities

Four studies included information on racial or ethnic background. The participants in the three U.S. based studies were predominantly Caucasian (Beatrice, 1985; Meyer, Reter, 1979; Newfield et al., 2006). All of the participants in the single Asian study were Chinese (Tsoi, 1993). Additional research is needed in this area.

C. Summary

Based on an extensive assessment of the clinical evidence as described above, there is not enough high quality evidence to determine whether gender reassignment surgery improves health outcomes for Medicare beneficiaries with gender dysphoria and whether patients most likely to benefit from these types of surgical intervention can be identified prospectively.

The knowledge on gender reassignment surgery for individuals with gender dysphoria is evolving. Much of the available research has been conducted in highly vetted patients at select care programs integrating psychotherapy, endocrinology, and various surgical disciplines. Additional research of contemporary practice is needed. To assess long-term quality of life and other psychometric outcomes, it will be necessary to develop and validate standardized psychometric tools in patients with gender dysphoria. Further, patient preference is an important aspect of any treatment. As study designs are completed, it is important to include patient-centered outcomes.

Because CMS is mindful of the unique and complex needs of this patient population and because CMS seeks sound data to guide proper care of the Medicare subset of this patient population, CMS strongly encourages robust clinical studies with adequate patient protections that will fill the evidence gaps delineated in this decision memorandum. As the Institute of Medicine (IOM, 2011) importantly noted: "Best practices for research on the health status of LGBT populations include scientific rigor and respectful involvement of individuals who represent the target population.

Scientific rigor includes incorporating and monitoring culturally competent study designs, such as the use of appropriate measures to identify participants and implementation processes adapted to the unique characteristics of the target population. Respectful involvement refers to the involvement of LGBT individuals and those who represent the larger LGBT community in the research process, from design through data collection to dissemination.”

IX. Decision

Currently, the local Medicare Administrative Contractors (MACs) determine coverage of gender reassignment surgery on a case-by-case basis. We have received a complete, formal request to make a national coverage determination on surgical remedies for gender identity disorder (GID), now known as gender dysphoria. The Centers for Medicare & Medicaid Services (CMS) is not issuing a National Coverage Determination (NCD) at this time on gender reassignment surgery for Medicare beneficiaries with gender dysphoria because the clinical evidence is inconclusive for the Medicare population.

In the absence of a NCD, coverage determinations for gender reassignment surgery, under section 1862(a)(1)(A) of the Social Security Act (the Act) and any other relevant statutory requirements, will continue to be made by the local MACs on a case-by-case basis. To clarify further, the result of this decision is not national non-coverage rather it is that no national policy will be put in place for the Medicare program. In the absence of a national policy, MACs will make the determination on whether or not to cover gender reassignment surgery based on whether gender reassignment surgery is reasonable and necessary for the individual beneficiary after considering the individual's specific circumstances. For Medicare beneficiaries enrolled in Medicare Advantage (MA) plans, the initial determination of whether or not surgery would be reasonable and necessary will be made by the MA plans.

Consistent with the request CMS received, the focus of this National Coverage Analysis (NCA) was gender reassignment surgery. Specific types of surgeries were not individually assessed. We did not analyze the clinical evidence for counseling or hormone therapy treatments for gender dysphoria. As requested by several public commenters, we have modified our final decision memorandum to remove language that was beyond the scope of the specific request. We are not making a national coverage determination relating to counseling, hormone therapy treatments, or any other potential treatment for gender dysphoria.

While we are not issuing a NCD, CMS encourages robust clinical studies that will fill the evidence gaps and help inform which patients are most likely to achieve improved health outcomes with gender reassignment surgery, which types of surgery are most appropriate, and what types of physician criteria and care setting(s) are needed to ensure that patients achieve improved health outcomes.

A. Appendix A

Diagnostic & Statistical Manual of Mental Disorders (DSM) Criteria for Disorders of Gender Identity since 1980

DSM Version	Condition Name	Criteria	Criteria	Comments
DSM III 1980 <i>Chapter: Psychosexual Disorders</i>	Trans-sexualism 302.5x [Gender Identity]	Required A (cross-gender identification) and B (aversion to	Sense of discomfort and inappropriateness about one's anatomic sex. Wish to be rid of one's own genitals and	Further characterization by sexual orientation Distinguished

	Disorder of Child-hood (302.6)]	one's natal gender) criteria Dx excluded by physical intersex condition Dx excluded by another mental disorder, e.g., schizophrenia	to live as a member of the other sex. The disturbance has been continuous (not limited to periods of stress) for at least 2 years.	from Atypical Gender Identity Disorder 302.85
DSM III-Revised 1987 <i>TS classified as an Axis II dx (personality disorders and mental retardation) in a different chapter. GID included under Disorders Usually First Evident in Infancy, Childhood, Adolescence</i>	Trans- sexualism (TS) (302.50) [GID of C]	Required A and B criteria	Persistent discomfort and sense of inappropriateness about one's assigned sex. Persistent preoccupation for at least 2 years with getting rid of one's 1 ^o and 2 ^o sex characteristics and acquiring the sex characteristics of the other sex. Has reached puberty	Further characterization by sexual orientation Distinguished from Gender Identity Disorder of Adolescence or Adulthood, Non-trans- sexual Type - e.g., cross- dressing not for the purposes of sexual excitement Gender Identity Disorder Not Otherwise Specified 302.6 - e.g., intersex conditions Gender Identity Disorder Not Otherwise Specified 302.85 - e.g., persistent preoccupation with castration or penectomy w/o desire to acquire the sex traits of the other sex
	GID of adulthood,			

	non-trans-sexual type, added			
DSM IV 1994 <i>Chapter: Sexual & Gender Identity Disorders</i>	Gender Identity Disorder in Adolescents and Adults (302.85) (Separate criteria & code for children, but same name)	Required A and B criteria Dx excluded by physical intersex condition	Cross-gender identification - e.g., Stated desire to be another sex - e.g., Desire to live or be treated as a member of the other sex - e.g., conviction that he/she has the typical feelings and reactions of the other sex - e.g., frequent passing as the other sex Persistent discomfort with his/her sex or sense of inappropriateness in the gender role of that sex. - e.g., belief the he/she was born the wrong sex - e.g., preoccupation with getting rid of 1^o and 2^o sex characteristics &/or acquiring sexual traits of the other sex - Clinically significant distress or impairment in social, occupational, or other important areas of functioning	Further characterization by sexual orientation Distinguished from Gender Identity Disorder Not Otherwise Specified 302.6 - e.g., intersex conditions - e.g., stress related cross-dressing - e.g., persistent preoccupation with castration or penectomy w/o desire to acquire the sex traits of the other sex
DSM IV-Revised 2000 <i>Chapter: Sexual & Gender Identity Disorders</i>	Gender Identity Disorder (Term trans-sexual-ism eliminated)	Required A & B criteria Dx excluded by physical intersex condition	Cross-gender identification - e.g., stated desire to be the other sex - e.g., desire to live or be treated as the other sex - e.g., conviction that he/she has the typical feelings & reactions of the other sex	Outcome may depend on time of onset Further characterization by sexual orientation Distinguished from Gender Identity Disorder Not Otherwise

			• e.g., frequent passing as the other sex - Persistent discomfort with his or her sex OR sense of inappropriateness in the gender role of that sex • e.g., belief the he/she was born the wrong sex • e.g., preoccupation with getting rid of 1⁰ and 2⁰ sex characteristics &/or acquiring sexual traits of the other sex - Clinically significant distress or impairment in social, occupational, or other important areas of functioning	Specified 302.6 • e.g., intersex conditions • e.g., stress related cross-dressing • e.g., persistent preoccupation with castration or penectomy w/o desire to acquire the sex traits of the other sex
DSM V 2013 <i>Separate Chapter from Sexual Dysfunctions & Paraphilic Disorders</i>	Gender Dysphoria (302.85)	Gender nonconformity itself not considered to be a mental disorder The dysphoria associated with the gender incongruence is Eliminates A & B criteria Considers gender incongruence to be a spectrum Considers intersex/ "disorders of sex development" to be a	• Marked discordance between natal 1⁰ and 2⁰ sex characteristics* and experienced/expressed gender • Conviction that he/she has the typical feelings & reactions of the other sex (or some alternative gender) • Marked desire to be the other sex (or some alternative gender) • Marked desire to desire be treated as the other sex (or some alternative gender) • Marked desire to be rid of natal 1⁰ and 2⁰ sex characteristics** • Marked desire to acquire 1⁰ and 2⁰ sex characteristics of the other sex (or some alternative gender) - Clinically significant	Includes diagnosis for post transition state to permit continued treatment access Includes disorders of sexual development such as congenital hyperplasia and androgen insensitivity syndromes

		subsidiary and not exclusionary to dx of GD	distress or impairment in social, occupational, or other important areas of functioning * or in young adolescents, the anticipated 2^o sex characteristics ** or in young adolescents, prevent the development of the anticipated 2^o sex characteristics ≥ 6 month marked discordance between natal gender & experienced/expressed gender as demonstrated by ≥ 6 criteria: • Strong desire to be of the other gender or an insistence that one is of another gender. • Strong preference for cross-gender roles in make-believe play. • Strong preference for the toys, games, or activities of the other gender. • Strong preference for playmates of the other gender. • In boys, strong preference for cross-dressing; in girls, strong preference for wearing masculine clothing • In boys, rejection of masculine toys, games, activities, avoidance of rough and tumble play; in girls, rejection of feminine toys, games, and activities.	
	Unspecified Gender Dysphoria		This category applies to presentations in which sx c/w gender	

	(302.6) (F64.9)		dysphoria that cause clinically significant distress or impairment, but do not meet the full criteria for gender dysphoria & the reason for not meeting the criteria is not provided.	
	Specified Gender Dysphoria 302.6 (F64.8)		If the reason that the presentation does not meet the full criteria is provided then this dx should be used	

C/W=consistent with Dx=diagnosis GD=gender dysphoria Sx=symptoms TS=transsexual 1⁰=primary 2⁰=secondary

B. Appendix B

1. General Methodological Principles of Study Design

When making national coverage determinations, CMS evaluates relevant clinical evidence to determine whether or not the evidence is of sufficient quality to support a finding that an item or service is reasonable and necessary. The overall objective for the critical appraisal of the evidence is to determine to what degree we are confident that: 1) the specific assessment questions can be answered conclusively; and 2) the intervention will improve health outcomes for patients.

We divide the assessment of clinical evidence into three stages: 1) the quality of the individual studies; 2) the generalizability of findings from individual studies to the Medicare population; and 3) overarching conclusions that can be drawn from the body of the evidence on the direction and magnitude of the intervention's potential risks and benefits.

The methodological principles described below represent a broad discussion of the issues we consider when reviewing clinical evidence. However, it should be noted that each coverage determination has its unique methodological aspects.

Assessing Individual Studies

Methodologists have developed criteria to determine weaknesses and strengths of clinical research. Strength of evidence generally refers to: 1) the scientific validity underlying study findings regarding causal relationships between health care interventions and health outcomes; and 2) the reduction of bias. In general, some of the methodological attributes associated with stronger evidence include those listed below:

- Use of randomization (allocation of patients to either intervention or control group) in order to minimize bias.
- Use of contemporaneous control groups (rather than historical controls) in order to ensure comparability between the intervention and control groups.
- Prospective (rather than retrospective) studies to ensure a more thorough and systematic assessment of factors related to outcomes.
- Larger sample sizes in studies to demonstrate both statistically significant as well as clinically significant

outcomes that can be extrapolated to the Medicare population. Sample size should be large enough to make chance an unlikely explanation for what was found.

- Masking (blinding) to ensure patients and investigators do not know to which group patients were assigned (intervention or control). This is important especially in subjective outcomes, such as pain or quality of life, where enthusiasm and psychological factors may lead to an improved perceived outcome by either the patient or assessor.

Regardless of whether the design of a study is a randomized controlled trial, a non-randomized controlled trial, a cohort study or a case-control study, the primary criterion for methodological strength or quality is the extent to which differences between intervention and control groups can be attributed to the intervention studied. This is known as internal validity. Various types of bias can undermine internal validity. These include:

- Different characteristics between patients participating and those theoretically eligible for study but not participating (selection bias).
- Co-interventions or provision of care apart from the intervention under evaluation (performance bias).
- Differential assessment of outcome (detection bias).
- Occurrence and reporting of patients who do not complete the study (attrition bias).

In principle, rankings of research design have been based on the ability of each study design category to minimize these biases. A randomized controlled trial minimizes systematic bias (in theory) by selecting a sample of participants from a particular population and allocating them randomly to the intervention and control groups. Thus, in general, randomized controlled studies have been typically assigned the greatest strength, followed by non-randomized clinical trials and controlled observational studies. The design, conduct and analysis of trials are important factors as well. For example, a well-designed and conducted observational study with a large sample size may provide stronger evidence than a poorly designed and conducted randomized controlled trial with a small sample size. The following is a representative list of study designs (some of which have alternative names) ranked from most to least methodologically rigorous in their potential ability to minimize systematic bias:

Randomized controlled trials
 Non-randomized controlled trials
 Prospective cohort studies
 Retrospective case control studies
 Cross-sectional studies
 Surveillance studies (e.g., using registries or surveys)
 Consecutive case series
 Single case reports

When there are merely associations but not causal relationships between a study's variables and outcomes, it is important not to draw causal inferences. Confounding refers to independent variables that systematically vary with the causal variable. This distorts measurement of the outcome of interest because its effect size is mixed with the effects of other extraneous factors. For observational, and in some cases randomized controlled trials, the method in which confounding factors are handled (either through stratification or appropriate statistical modeling) are of particular concern. For example, in order to interpret and generalize conclusions to our population of Medicare patients, it may be necessary for studies to match or stratify their intervention and control groups by patient age or co-morbidities.

Methodological strength is, therefore, a multidimensional concept that relates to the design, implementation and analysis of a clinical study. In addition, thorough documentation of the conduct of the research, particularly study selection criteria, rate of attrition and process for data collection, is essential for CMS to adequately assess and

consider the evidence.

Generalizability of Clinical Evidence to the Medicare Population

The applicability of the results of a study to other populations, settings, treatment regimens and outcomes assessed is known as external validity. Even well-designed and well-conducted trials may not supply the evidence needed if the results of a study are not applicable to the Medicare population. Evidence that provides accurate information about a population or setting not well represented in the Medicare program would be considered but would suffer from limited generalizability.

The extent to which the results of a trial are applicable to other circumstances is often a matter of judgment that depends on specific study characteristics, primarily the patient population studied (age, sex, severity of disease and presence of co-morbidities) and the care setting (primary to tertiary level of care, as well as the experience and specialization of the care provider). Additional relevant variables are treatment regimens (dosage, timing and route of administration), co-interventions or concomitant therapies, and type of outcome and length of follow-up.

The level of care and the experience of the providers in the study are other crucial elements in assessing a study's external validity. Trial participants in an academic medical center may receive more or different attention than is typically available in non-tertiary settings. For example, an investigator's lengthy and detailed explanations of the potential benefits of the intervention and/or the use of new equipment provided to the academic center by the study sponsor may raise doubts about the applicability of study findings to community practice.

Given the evidence available in the research literature, some degree of generalization about an intervention's potential benefits and harms is invariably required in making coverage determinations for the Medicare population. Conditions that assist us in making reasonable generalizations are biologic plausibility, similarities between the populations studied and Medicare patients (age, sex, ethnicity and clinical presentation) and similarities of the intervention studied to those that would be routinely available in community practice.

A study's selected outcomes are an important consideration in generalizing available clinical evidence to Medicare coverage determinations. One of the goals of our determination process is to assess health outcomes. These outcomes include resultant risks and benefits such as increased or decreased morbidity and mortality. In order to make this determination, it is often necessary to evaluate whether the strength of the evidence is adequate to draw conclusions about the direction and magnitude of each individual outcome relevant to the intervention under study. In addition, it is important that an intervention's benefits are clinically significant and durable, rather than marginal or short-lived. Generally, an intervention is not reasonable and necessary if its risks outweigh its benefits.

If key health outcomes have not been studied or the direction of clinical effect is inconclusive, we may also evaluate the strength and adequacy of indirect evidence linking intermediate or surrogate outcomes to our outcomes of interest.

Assessing the Relative Magnitude of Risks and Benefits

Generally, an intervention is not reasonable and necessary if its risks outweigh its benefits. Health outcomes are one of several considerations in determining whether an item or service is reasonable and necessary. CMS places greater emphasis on health outcomes actually experienced by patients, such as quality of life, functional status, duration of disability, morbidity and mortality, and less emphasis on outcomes that patients do not directly experience, such as intermediate outcomes, surrogate outcomes, and laboratory or radiographic responses. The direction, magnitude, and consistency of the risks and benefits across studies are also important considerations. Based on the analysis of

the strength of the evidence, CMS assesses the relative magnitude of an intervention or technology's benefits and risk of harm to Medicare beneficiaries.

Appendix C

Patient Population: Enrolled & Treated with Sex Reassignment Surgery Loss of Patients & Missing Data

Panel A (Controlled Studies)

Author	Study Type	Recruitment Pool	Enrolled	% GRS	Completion
Dhejne 2011	Longitudinal Controlled	804 w GD	324	324 (100%)	-
Dhejne 2014 Landén	Longitudinal for test variable Controlled	767 applied for SRS 25 applications denied. 61 not granted full legal status 15 formal applications for surgical reversal	681	681 (100%)	NA: Clinical data extracted retrospectively in earlier paper
Heylens	Longitudinal Controlled	90 applicants for SRS 33 excluded 11 later excluded had not yet received SRS by study close.	57 (→46)	46 (80.7%) Only those w SRS evaluated	Psycho-social survey missing data for 3 at baseline & 4 after SRS. SCL90 not completed by 1 at baseline, 10 after hormone tx, & 4 after SRS →missing data for another 1.1% to 11.1%.
Kockott	Longitudinal Controlled	80 applicants for SRS 21 excluded	59	32 (54.2%) went to surgery	1 preoperative patient was later excluded b/c lived completely in aspired gender w/o SRS. Questions on financial sufficiency not answered by 1 surgical pt. Questions on sexual satisfaction & gender contentment not answered by 1 & 2 patients awaiting surgery respectively.
Mate-Kole 1990	Longitudinal Controlled	40 sequential patients of accepted patients. The number in the available patient pool was not specified.	40	20 (50%) went to surgery	-
Meyer	Longitudinal Controlled	Recruitment pool: 100 50 were excluded.	50	15 (30%) had undergone surgery 14 (28%) underwent surgery later	The assessments of all were complete

Rakic	Longitudinal Controlled	92 were evaluated 54 were excluded from surgery 2 post SRS were lost to follow-up 2 post SRS were excluded for being in the peri-operative period	32	32 (100%)	Questionnaire completed by all.
Ruppin	Longitudinal Controlled	The number in the available patient pool was not specified. 140 received recruitment letters. 69 were excluded	71	69 (97.2%)	The SCL-90, BSRI, FPI-R, & IPP tests were not completed by 9, 34, 13, & 16 respectively. Questions about romantic relationships, sexual relationships, friendships, & family relationships were not answered by 1, 3, 2, & 23 respectively. Questions regarding gender security & regret & were not answered by 1 & 2 respectively.
Smith	Longitudinal Controlled	The number in the available adult patient pool was not specified. 325 adult & adolescent applicants for SRS were recruited. 103 were excluded from additional tx	162	162 (100%)	36 to 61 (22.2%-37.6% of those adults w pre-SRS data) did not complete various post-SRS tests.
Udeze Megeri	Longitudinal Controlled	International patient w GD 546 & post SRS 318. 40 M to F subjects were prospectively selected.	40	40 (100%)	-
Ainsworth	Internet/convention Survey Cross-sectional Controlled	Number of incomplete questionnaires not reported	247	72 (29.1%) 75 (30.6%) facial 147 (59.5%) had received neither facial nor reassignment surgery	-
Beatrice	Cross-sectional Controlled	14 excluded for demographic matching reasons	40	10 (25%)	The assessments were completed by all
Haraldsen	Cross-sectional Controlled	Recruitment pool: 99	86	59 (68.6%)	-
Kraemer	Cross-sectional	The number in the	45	22 (48.9%)	-

	Controlled	available patient pool was not specified.			
Kuhn	Cross-sectional Controlled	The number in the available patient pool was not specified.	75	55 (73.3%)	-
Mate-Kole 1988	Cross-sectional Controlled	150 in 3 cohorts. Matched on select traits. The number in the available patient pool was not specified.	150	50 (66.7%)	-
Wolfradt	Cross-sectional Controlled	The number in the available patient pool was not specified.	90	30 (33.3%)	-

Panel B (Surgical Series: No Concurrent Controls)

Author	Study Type	Recruitment Pool	Enrolled	% GRS	Completion
Blanchard et al.	Cross-sectional Control: Normative test data	294 clinic patients w GD had completed study questionnaire 116 authorized for GRS. 103 completed GRS & 1 yr post-operative. 24 excluded	79	79(100%)	-
Weyers et al.	Cross-sectional Control: Normative test data	>300 M to F patients had undergone GRS 70 eligible patients recruited 20 excluded	50	50 (100%)	SF-26 not completed by 1
Wierckx et al.	Cross-sectional except for recall questions Control: Normative test data	79 F to M patients had undergone GRS & were recruited. 3 additional non-clinic patients were recruited by other patients. 32 excluded initially; 1 later.	49	49 (100%)	SF-36 test not completed by 2. Questions regarding sexual relationship, sex function, & surgical satisfaction were answered by as few as 27, 28, 32 respectively.
Eldh et al.	Cross-sectional except for 1 variable Control: Self for 1 variable-employment	136 were identified. 46 excluded	90	90 (100%)	Questions regarding gender identity, sex life, acceptance, & overall satisfaction were not answered by 13, 14, 14 & 16 respectively. Employment data missing for 11.
Hess et al.	Cross-sectional No control	254 consecutive eligible patients post GRS identified & sent surveys. 135 excluded.	119	119 (100%)	Questions regarding the esthetics, functional, and social outcomes of GRS were not answered by 16 to 28 patients.
Lawrence	Cross-sectional	727 eligible patients	232	232	-

	No control	were recruited. 495 were excluded		(100%)	
Salvador et al.	Cross-sectional No control	243 had enrolled in the clinic 82 completed GRS 69 eligible patients were identified. 17 excluded.	52	52 (100%)	-
Tsoi	Cross-sectional No control	The number in the available patient pool was not specified.	81	81 (100%)	-

Panel C (Mixed Treatment Series: No Direct Control Groups)

Author	Study Type	Recruitment Pool	Enrolled	% GRS	Completion
Gómez-Gil et al. 2012	Cross-sectional No direct control: Analysis of variance	200 consecutive patients were recruited. 13 declined participation or were excluded for incomplete questionnaires.	187	79 (42.2%)	See prior box.
Hepp et al.	Cross-sectional No direct control: Analysis of variance	The number in the available patient pool was not specified.	31	7 (22.6%)	HADS test not completed by 1
Motmans et al.	Cross-sectional No direct control: Analysis of variance & regression	255 with GD were identified. 77 were excluded.	148 (→140)	Not clearly stated. At least 103 underwent some form of GRS.	8 later excluded for incomplete SF-36 tests. 37 w recent GRS or hormone initiation were excluded from analysis of SF-36 results→103.
Newfield et al.	Internet survey Cross-sectional No direct control: Analysis of variance	Number of incomplete questionnaires not reported 446 respondents; 384 U.S. respondents 62 non-U.S. respondents excluded from SF-36 test results 8 U.S. respondents excluded	376 (U.S.)	139 to 150 (37.0-39.9%) in U.S.	-
Gomez-Gil et al. 2014	Cross-sectional No direct control: Analysis w regression	The number in the available patient pool was not specified. 277 were recruited. 25 excluded	252(→193)	80 (41.4%) non-genital surgery	59 were excluded for incomplete questionnaires. See prior box.
Asscherman	Longitudinal No analysis by tx	The number in the available patient pool	1331	1177 (88.4%)	-

	status	was not specified.			
Johansson et al.	Cross-sectional except for 1 variable No analysis by tx status except for 1 question	60 eligible patients 18 excluded.	42	32 (76.2% of enrolled & 53.3% of eligible) (genital surgery)	-
Leinung et al.	Cross-sectional No analysis by tx status	242 total clinic patients	242	91 (37.6%)	Employment status data missing for 81 of all patients

*Data obtained via a survey on a website and distributed at a conference

B/C=because

BSRI=Bem Sex Role Inventory

F=Female

FP-R=Freiberg Personality Inventory

GD=Gender dysphoria

GID=Gender identity disorder

HADS=Hospital Anxiety & Depression Scale

IPP=Inventory of Interpersonal Problems

M=Male

NA=Not applicable

SCL-90=Symptom Checklist-90

SF-36=Short Form 36

GRS=Sex reassignment surgery

Tx=Treatment

W/o=without

Appendix D

Demographic Features of Study Populations

Panel A (Controlled Studies)

Author	Age (years; mean, S.D., range)	Gender	Race
Ainsworth	Only reassignment surgery: 50 (no S.D.) Only facial surgery: 51 (no S.D.) Both types of surgery: 49 (no S.D.) Neither surgery: 46 (no S.D.)	247 M to F	-
Beatrice	Pre-SRS M to F: 32.5 (27-42), Post-SRS: 35.1 (30-43)	20 M to F plus 20 M controls	100% Caucasian
Dehjne 2011	Post-SRS: all 35.1±9.7 (20-69), F to M 33.3+8.7 (20-62), M to F 36.3+ 10.1(21-69)	133 (41.0%) F to M, 191 (59.0%) M to F; ratio 1:1.4	-
Dhejne 2014 Landén	F to M SRS cohort: median age 27 M to F SRS cohort: median age 32 F to M applicants for reversal: median age 22 M to F applicants for reversal: median age 35	767 applicants for legal/surgical reassignment 289 (37.7%) F to M, 478 (62.3%) M to F; ratio 1:1.6 681 post SRS & legal change 252 (37.0%) F to M, 429 (63.0%) M to F; ratio 1:1.7	-

		15 applicants for reversal 5 (33.3%) F to M, 10 (66.7%) M to F; ratio 1:2	
Haraldsen	Pre-SRS & Post-SRS: F to M 34±9.5, F to M 33.3±10.0 Post-SRS cohort reportedly older. No direct data provided.	Pre & Post SRS 35 (40.7%) F to M, 51 (59.3%) M to F; ratio 1:1.5	-
Heylens	-	11 (19.3% of 57) F to M, 46 (80.7%); ratio 1:4.2 (80.7% underwent surgery)	-
Kockott	Pre-SRS (continued wish for surgery): 31.7±10.2 Post-SRS: 35.5±13.1	Pre-SRS (continued wish for surgery) 3 (25%) F to M, 9 (75%) M to F; ratio 1:3 Post SRS: 14 (43.8%) F to M, 18 (56.2%) M to F; ratio 1:1.3	-
Kraemer	Pre-SRS: 33.0±11.3, Post-SRS: 38.2±9.0	Pre-SRS 7 F to M (30.4%), 16 M to F (69.6%); ratio 1:2.3 Post-SRS 8 F to M (36.4%), 14 M to F (63.6%); ratio 1:1.8	-
Kuhn	All post SRS: median (range): 51 (39-62) (long-term follow-up)	3 (5.4%) F to M, 52 (94.5%) M to F; ratio 1:17.3.	-
Mate-Kole 1988	Initial evaluation: 34, Pre-SRS: 35, Post-SRS: 37	150 M to F	-
Mate-Kole 1990	Early & Usual wait SRS: 32.5 years (21-53)	40 M to F	-
Meyer	Pre-SRS: 26.7 Delayed, but completed SRS: 30.9 Post-SRS: 30.1	Pre-SRS: 5 (23.8%) F to M, 16 (76.2%) M to F; ratio 1:3.2 Delayed, but completed SRS: 1 (7.1%) F to M, 13 (92.9%) M to F; ratio 1:13 Post-SRS: 4 (26.7%) F to M, 11 (73.3%) M to F; ratio 1:2.8	86% Caucasian
Rakic	All: 26.8±6.9 (median 25.5, range 19-47), F to M: 27.8±5.2 (median 27, range 23-37), M to F: 26.4±7.8 (median 24, range 19-47).	10 (31.2%) F to M, 22 (68.8%) M to F; ratio 1:2.2	-
Ruppin	All: 47.0±10.42 (but 2 w/o SRS) (13.8±2.8 yrs post legal name change) (long-term follow-up) F to M: 41.2±5.78, M to F 52.9±10.82	36 (50.7%) F to M, 35 (49.3%) M to F; ratio 1:0.97	-
Smith	Time of surgical request for post-SRS: 30.9 (range 17.7-68.1) Time of follow-up for post-SRS: 35.2 (range 21.3-71.9)	Pre-SRS: 162: 58 (35.8%) F to M, 104 [64.2%] M to F; ratio 1:1.8 Post-SRS: 126: 49 (38.9%) F to M, 77 (61.1%) M to F; ratio 1:1.6	-
Udeze Megeri	M to F: 47.33±13.26 (range 25-80).	40 M to F	-
Wolfradt	Patients & controls: 43 (range 29-67).	30 M to F plus 30 F controls plus 30 M controls.	-

*Data obtained via a survey on a website and distributed at a conference SD=Standard deviation

Panel B (Surgical Series: No Concurrent Controls)

Author	Age (years; mean, S.D., range)	Gender	Caucasian
Blanchard et al.	F to M: 32.6, M to F w M partner preference: 33.2, F to M w F partner preference: 47.7 years	Post-GRS: 47 (45.6%) F to M, 56 (54.4%) M to F; ratio 1:1.19. In study: 38 (48.1%) F to M, 32 (40.5%) M to F w M partner preference, 9 (11.4%) M to F w F partner preference; ratio 1:0.8:0.2	-
Weyers et al.	Post-GRS M to F: 43.1 ±10.4 (long-term follow-up)	50 M to F	-
Wierckx et al.	Time of GRS: 30±8.2 years (range 16 to 49) Time of follow-up: 37.1 ±8.2.4 years (range 22 to 54)	49 M to F	-
Eldh et al.	-	50 (55.6%) F to M, 40 (44.4%) M to F; ratio 1:0.8 There is 1 inconsistency in the text suggesting that these should be reversed.	-
Hess et al.	-	119 M to F	-
Lawrence	Time of GRS: 44±9 (range 18-70)	232 M to F	-
Salvador et al.	Time of follow-up for post-GRS: 36.28±8.94 (range 18-58) (Duration of follow-up: 3.8±1.7 [2-7])	52 M to F	-
Tsoi	Time of initial visit: All: 24.0±4.5, F to M: 25.4±4.4 (14-36), M to F: 22.9±4.6 (14-36). Time of GRS: All: 25.9±4.14, F to M: 27.4±4.0 (20-36), M to F: 24.7±4.3 (20-36).	36 (44.4%) F to M, 45 (55.6%) M to F; ratio 1:1.25	0% 100% Asian

Panel C (Mixed Treatment Series: No Direct Control Groups)

Author	Age (years; mean, S.D., range)	Gender	Caucasian
Gómez-Gil et al. 2012	W & W/O GRS: All: 29.87±9.15 (range 15-61), W/O hormone tx: 25.9±7.5, W current hormone tx: 33.6±9.1. (At hormone initiation: 24.6±8.1).	W/O hormone tx: 38 (56.7%) F to M, 29 (43.3%) M to F; ratio 1:0.8. W hormone tx: 36 (30.0%) F to M, 84 (70.0%) M to F; ratio 1:2.3. Post-GRS: 29 (36.7%) F to M, 50 (63.3%) M to F; ratio 1:1.7.	-
Hepp et al.	W & W/O GRS: 32.2±10.3	W & W/O GRS: 11 (35.5%) F to M; 20 (64.5%) M to F; ratio 1:1.8.	-
Motmans et al.	W & W/O GRS: All (n=140) : 39.9±10.2, F to M: 37.0±8.5, M to F: 42.3±10.4	W & W/O GRS: N=140 63(45.0%) F to M, 77 (55.0%) M to F; ratio 1:1.2 N=103 49 (47.6%) F to M; 54 (52.4%) M to F; ratio 1:1.1	-
Newfield et al.	W & W/O GRS: U.S.+ non-U.S. : 32.8±11.2, U.S. 32.6±10.8	W & W/O GRS: U.S.+ non-U.S.: F to M, 438, U.S.: F to M: 376	89% of 336 respondents Caucasian
Gomez-Gil, et al. 2014	W & W/O Non-genital GRS: 31.2±9.9 (range 16-67).	W & W/O Non-genital GRS: 74 (38.3%) F to M, 119 (61.7%) M to	-

		F; ratio 1:1.6.	
Asscherman	Time of hormone tx: F to M: 26.1±7.6 (16–56), M to F: 31.4±11.4 (16–76)	Met hormone tx requirements: 365 (27.4%) F to M, 966 (72.6%) M to F; ratio 1:2.6. Post-GRS: 343 (29.1%) F to M, 834 (70.9%) M to F; ratio 1:2.4.	-
Johanssen	Time of initial evaluation: F to M: 27.8 (18–46), M to F 37.3 (21–60). Time of GRS: F to M: 31.4 (22–49), M to F 38.2 (22–57). Time of follow-up for post-GRS: F to M: 38.9 (28–53), M to F 46.0 (25–69) (Long-term follow-up)	Approved for GRS: 21 (35%) F to M, 39 (65%) M to F; ratio 1:1.9 Post GRS: 14 (43.8%) F to M; 18 (56.2%) M to F; ratio 1:1.3	-
Leinung et al.	Time of hormone initiation : F to M: 27.5, M to F 35.5	W & W/O GRS: 50 (20.7%) F to M, 192 M to F (79.3%); ratio 1:3.8. Post-GRS: 32 F to M (35.2%); 59 (64.8%) M to F; ratio 1:1.8.	-

Appendix E

Psychometric and Satisfaction Survey Instruments

Instrument Name and Developer	Development and Validation Information
APGAR Family Adaptability, Partner-ship Growth, Affection, and Resolve <i>Smilkstein</i>	Published in 1978 Initial data: 152 families in the U.S. A “friends” component was added in 1983. Utility has challenged by many including Gardner 2001
Beck Depression Inventory <i>Beck, Ward, Mendelson, Mock, & Erbaugh</i>	Published initially in 1961 with subsequent revisions It was initially evaluated in psychiatric patients in the U.S.A. Salkind (1969) evaluated its use in 80 general outpatients in the UK. It is copyrighted and requires a fee for use
Bem Sex Role Inventory <i>Bem</i>	Published 1974 Initial data: 100 Stanford Undergraduates 1973 update: male 444; female 279 1978 update: 470; female 340
Body Image Questionnaire <i>Clement & Lowe</i>	Validity study published 1996 (German) Population: 405 psychosomatic patients, 141 medical students, 208 sports students
Body Image Scale <i>Lindgren & Pauly</i> (<i>Kuiper, Dutch adaptation 1991</i>)	1975 Initial data: 16 male and 16 female transsexual patients in Oregon
Crown Crisp Experiential Index (formerly Middlesex Hospital Questionnaire)	Developed circa 1966 Manual published 1970 Initial data: 52 nursing students while in class in the UK

<i>Crown & Crisp</i>	
(2nd) European Quality of Life Survey <i>Anderson, Mikulić, Vermeylen, Lyly-Yrjanainen, & Zigante,</i>	Published in 2007 The pilot survey was tested in the UK and Holland with 200 interviews. The survey was revised especially for non-response questions. Another version was tested in 25 persons of each of the 31 countries to be surveyed. Sampling methods were devised. 35,634 Europeans were ultimately surveyed. Additional updates
Female Sexual Function Index <i>Rosen, Brown, Heiman, Leiblum, Meston, Shabsigh, Ferguson, D'Agostino Wiegel, Meston, & Rosen</i>	Published in 2000 Initial data: 131 normal controls & 128 age-matched subjects with female sexual arousal disorder from 5 U.S. research centers. Updated 2005: the addition of those with hypoactive sexual desire disorder, female sexual orgasm disorder, dyspareunia/vaginismus, & multiple sexual dysfunctions (n=568), plus more controls (n=261).
Fragebogen zur Beurteilung des eigenen Körpers <i>Strauss</i>	Published 1996 (German)
Freiberg Personality Inventory <i>Fahrenberg, Hampel, & Selg</i>	7 th edition published 2001, 8 th edition in 2009 (Not in PubMed) German equivalent of MMPI
"gender identity disorder in childhood" <i>Smith, van Goozen, Kuiper, & Cohen-Kettenis</i>	11 items derived from the Biographical Questionnaire for Trans-sexuals (Verschoor Poortinga 1988) (Modified by authors of the Smith study)
Gender Identity Trait Scale <i>Altstotter-Gleich</i>	Published 1989 (German)
General Health Questionnaire <i>Goldberg & Blackwell (initial study)</i> <i>Goldberg & Williams (manual)</i>	Initial publication 1970 Manual published ?1978, 1988 (Not in PubMed) Initial data: 553 consecutive adult patients in a single UK primary care practice were assessed. Sample of 200 underwent standardized psychiatric interview. Developed to screen for hidden psychological morbidity. Proprietary test. Now 4 versions.
Hospital Anxiety & Depression Scale <i>Zigmond & Snaith</i>	Published in 1983 Initial data: Patients between 16 & 65 in outpatient clinics in the UK >100 patients; 2 refusals. 1 st 50 compared to 2 nd 50.
Inventory of Interpersonal Problems <i>Horowitz</i>	Published 1988 Initial data: 103 patients about to undergo psychotherapy; some patients post psycho-therapy (Kaiser Permanente-San Francisco) Proprietary test
King's Health Questionnaire	1997 Initial data: 293 consecutive women referred for urinary

<i>Kelleher, Cardozo, Khullar, & Salvatore</i>	incontinence evaluation in London Comparison to SF-36
Minnesota Multi-phasic Personality Inventory <i>Hathaway & McKinley</i> <i>Butcher, Dahlstrom, Graham, & Tellegen</i>	Published in 1941 Updated in 1989 with new, larger, more diverse sample. MMPI-2: 1,138 men & 462 women from diverse communities & several geographic regions in the U.S.A. The test is copyrighted.
Modified Androphilia-Gynephilia Index	Neither the underlying version or the Blanchard modified version could be located in PubMed (Designed by the author of the Blanchard et al. study)
"post-operative functioning 13 items" <i>Doorn, Kuiper, Verschoor, Cohen-Kettenis</i>	Published 1996 (Dutch) (Not in PubMed) (Designed by 1 of the authors of the Smith study)
"post-operative functioning 21 items" <i>Doorn, Kuiper, Verschoor, Cohen-Kettenis</i>	Published 1996 (Dutch) (Not in PubMed) (Designed by 1 of the authors of the Smith study)
Scale for Depersonalization Experiences <i>Wolfradt</i>	Unpublished manuscript 1998 (University of Halle) (Designed by 1 of the authors of the Wolfradt study)
"sex trait function" <i>Cohen-Kettenis & van Goozen</i>	Published 1997 Assessed in 22 adolescents (Designed by 1 of the authors of the Smith Study)
Self-Esteem Scale <i>Rosenberg</i>	Published 1965 (Not in PubMed) Initial data: 5,024 high-school juniors & seniors from 10 randomly selected New York schools
Short-Form 36 <i>RAND</i> <i>Ware & Sherbourne</i> 1992 <i>McHorney, Ware, & Raczek</i> 1993	Originally derived from the Rand Medical Outcomes Study (n=2471 in version 1; 6742 in version 2 1989). The earliest test version is free. Alternative scoring has been developed. There is a commercial version with a manual.
Social Anxiety & Distress Scale <i>Watson & Friend</i>	Initial publication in 1969 Requires permission for use
Social Support Scale <i>Van Tilburg</i> 1988	Published 1988 (Dutch) (Not in PubMed)
Spielberger State & Trait Anxiety Questionnaire <i>Spielberger, Gorsuch, Lushene, Vagg, & Jacobs</i>	Current format published in 1983 Proprietary test
Symptom Checklist-90 <i>Derogatis, Lipman, Covi</i> <i>Derogatis & Cleary</i>	Published in 1973 & 1977 Reportedly with normative data for psychiatric patients (in- & out-patient) & normal subjects in the U.S. Has undergone a revision Requires qualification for use
Tennessee Self-Concept	In use prior to 1988 publication.

Scale <i>Fitts & Warren</i>	Initial data: 131 psychiatric day care patients. Updated manual published 1996. Update population >3000 with age stratification. No other information available. Requires qualification for use
Utrecht Gender Dysphoria Scale <i>Cohen-Kettenis & van Goozen</i>	Published in 1997 Initial population: 22 transgender adolescents who underwent reassignment surgery. (Designed by 1 of the authors of the Smith study)
WHO-Quality of Life (abbreviated version) <i>Harper for WHO group</i>	Field trial version released 1996 Tested in multiple countries. The Seattle site consisted of 192 of the 8294 subjects tested). Population not otherwise described. The minimal clinically important difference has not been determined. Permission required

Althof et al., 1983; Greenberg, Frank, 1965; Gurtman, 1996; Lang, Vernon, 1977; Paap et al., 2012; Salkind et al., 1969; Vacchiano, Strauss, 1968.

Appendix F

Endpoint Data Types and Sources

Panel A (Controlled Studies)

Author	National Data	Instrument w Substantive Normative Data	Instrument w/o Substantive &/or Accessible Normative Data	Investigator-designed	Other	Other
Dhejne 2011	Yes	-	-	-	-	Mortality (Suicide, Cardiovascular Disease [possible adverse events from Hormone Tx], Cancer), Psych hx & hospitalization, Suicide attempts
Dhejne Landén	Yes	-	-	-	Includes demographics*	Education, Employment, Formal application for reversal of status, Psych dx & tx, Substance abuse** More elements in earlier paper
Beatrice	-	MMPI form R, TSCS	-	-	Demographic	Education, Income, Relationships

Haraldsen	-	SCL-90/90R	-	-	Demographic	DSM Axis 1, II, V (GAF), Substance abuse
Heylens	-	SCL-90	-	Yes-2	Demographic	Employment, Relationships, Substance abuse, Suicide attempts
Ainsworth	-	Likely SF-36v2*	-	Yes-1	Demographic	-
Rupp	-	SCL-90R	BSRI, FPI-R, IIP	Yes-2	Demographic	Adverse events from surgery, Employment, Psych tx, Relationships, Substance abuse
Smith	-	MMPI-short, SCL-90?R	BIS, UGDS, ? Cohen-Kettenis', Doorn's x2, (Gid-c, SSS)	Yes-1 or 2	Demographic	Adverse events from surgery, Employment, Relationships
Udeze Megeri	-	SCL-90R	BDI, GHQ, HADS, STAI-X1, STAI-X2	-	-	Psych eval & ICD-10 dx
Kuhn	-	-	KHQ	Yes-1	Demographic	Relationships
Mate-Kole 1990	-	-	BSRI, CCEI	Yes-1	Demographic	Employment (relative change), Psych hx, Suicide hx
Wolfradt	-	-	BIQ, GITS, SDE, SES	Yes-1	-	-
Kraemer	-	-	FBeK	-	Demographic	-
Mate-Kole 1988	-	-	BSRI, CCEI	-	Demographic	Employment, Psych hx, Suicide hx,
Kockott	-	-	-	Yes-1	Demographic	Employment, Income, Relationships, Suicide attempts
Meyer	-	-	-	Yes-1	Demographic	Education, Employment, Income, Psych tx, Phallus removal request
Rakic	-	-	-	Yes-1	Demographic	Employment, Relationships

Panel B (Surgical Series: No Concurrent Controls)

Author	National Data	Instrument w Substantive Normative Data	Instrument w/o Sub-stative &/or Accessible Normative Data	Investigator-designed	Other	Other
Weyers	-	SF-36	FSFI	Yes-2	Demographic	Hormone levels, Adverse events from surgery, Relationships
Blanchard	-	SCL-90R	(AG)	Yes-1	Demographic	Education, Employment, Income,

						Relationships, Suicide (Incidental finding)
Wierckx	-	SF-36	-	Yes-3	Demographic	Hormone levels, Adverse events from surgery, Relationships
Eldh	-	-	-	Yes-1	-	Adverse events from surgery, Employment, Relationships, Suicide attempts
Hess	-	-	-	Yes-1	-	-
Lawrence	-	-	-	Yes-4	Demographic	Adverse events from surgery
Salvador	-	-	-	Yes-1	Demographic	Relationships
Tsoi	-	-	-	Yes-1	Demographic	Education, Employment, Relationships (relative change)

Panel C (Mixed Treatment Series: No Direct Control Groups)

Author	National Data	Instrument w Substantive Normative Data	Instrument w/o Sub-stantive &/or Accessible Normative Data	Investigator-designed	Other	Other
Asscheman et al.	Yes	-	-	-	Demographic	Mortality (HIV, Possible adverse events from Hormone Tx, Substance abuse, Suicide)
Motmans et al.	-	SF36 EQOLS (2 nd)	-	-	Demographic	Education, Employment, Income, Relationships
Newfield et al.	-	SF-36v2	-	-	Demographic	Income
Gómez-Gil et al. 2014	-	WHOQOL-BREF	APGAR	Yes-1	Demographic	Education, Employment, Relationships
Gómez-Gil et al. 2012	-	-	HADS, SADS	-	Demographic	Education, Employment, Living arrangements
Hepp et al.	-	-	HADS	-	Demographic	DSM Axis I & II Psych dx
Johansson et al.	-	-	-	Yes-1	Demographic	Axis V change (Pt & Clinician) Employment (relative change) Relationship (relative change)

Leinung et al.	-	-	-	-	Demographic	Employment, Disability, DVT, HIV status, Psych dx

*Listed as San Francisco-36 in manuscript

** From medical charts & verdicts ?=Possibly self-designed

AG=Androphilia-Gynephilia Index (investigator designed 1985) (used more for classification)

APGAR=Family Adaptability, Partnership growth, Affection, and Resolve

BDI=Beck Depression Inventory

BIQ=Body Image Questionnaire

BIS=Body Image Scale

BSRI=Bem Sex Role Inventory

CCEI=Crown Crisp Experiential Index

Cohen-Kettenis'= Sex trait function (An author helped design)

Dorn's x2= Post-operative functioning 13 items (An author helped design)

Post-operative functioning 21 items (An author helped design)

EQOLS (2nd)=2nd European Quality of Life Survey

FBeK=Fragebogen zur Beurteilung des eigenen Körpers

FPI-R=A version of the Freiberg Personality Inventory

FSFI+Female Sexual Function Index

GHQ=General Health Questionnaire

Gid-c=Gender identity disorder in childhood (used more for predictors) (An author helped design)

GITS=Gender Identity Trait Scale

HADS=Hospital Anxiety Depression Scale

IIP=Inventory of Interpersonal Problems

KHQ=King's Health Questionnaire

MMPI=Minnesota Multi-phasic Personality Inventory

SADS=Social Anxiety & Distress Scale

SCL-90 (±R)=A version of the Symptom Checklist 90

SDE=Scale for Depersonalized Experiences (An author designed)

SES=Self-Esteem Scale

SF-36 (v2)=Short Form-36(version2)

SSS=Social Support Scale (used more for predictors)

STAI-X1, STAI-X2=Spielberger State and Trait Anxiety Questionnaire

TSCS=Tennessee Self-Concept Scale

UGDS=Utrecht Gender Dysphoria Scale (An author helped design)

WHOQOL-BREF=World Health Organization-Quality of Life (abbreviated version)

Appendix G.

Longitudinal Studies Which Used Patients as Their Own Controls and Which Used Psychometric Tests with Extensive Normative Data or Longitudinal Studies Which Used National Data Sets

Author	Test	Patient and Data Loss	Results
	Psychometric Test		
Heylens et al. Belgium 2014	SCL-90R	90 applicants for SRS were recruited. • 8 (8.9%) declined participation.	At t=0, the mean global "psychoneuroticism" SCL-90R score, along with scores of 7 of 8 subscales, were statistically

		• 12 (13.3%) excluded b/c GID-NOS dx. • 12 (13.3%) did not complete the treatment sequence b/c of psychiatric/physical co-morbidity, personal decision for no tx, or personal decision for only hormone tx. • 1 (1.1%) committed suicide during follow-up. 57 (63.3% of recruited) entered the study. • 1 (12.2% of initial recruits) had not yet received SRS by study close. →46 (51.1% of recruited) underwent serial evaluation • The test was not completed by 1 at t=0, 10 at t=1 (after hormone tx), & 4 at t=2 (after SRS) →missing data for another 1.1% to 11.1%.	more pathologic than the general population. After hormone tx, the mean score for global "psychoneuroticism" normalized & remained normal after reassignment surgery.
Rupp, Pfafflin, Germany 2015	SCL-90R	The number in the available patient pool was not specified. 140 received recruitment letters. • 2 (1.4% of those with recruitment letters) had died. • 1 (0.7%) was institutionalized. • 5 (3.6%) were ill. • 8 (5.7%) did not have time. • 8 (5.7%) stated that GD was no longer an issue. • 8 (5.7%) provided no reason. • 28 (20.0%) declined further contact. • 9 (6.4%) were lost to follow-up. →71 (50.7%) agreed	At t=0, the "global severity index "SCL-90R score was 0.53 ± 0.49. At post-SRS follow-up the score had decreased to 0.28 ± 0.36. The scores were statistically different from one another, but are of limited biologic significance given the range of the score for this scale: 0-4. In the same way, all of the subscale scores were statistically different, but the effect size was reported as large only for "interpersonal sensitivity": 0.70 ± 0.67 at t=0 and 0.26 ± 0.34 post-SRS.

		to participate. • 2 (1.4%) had not undergone SRS • The test was not completed by 9. →missing data for another 6.4%.	
Smith et al. Holland 2005	MMPI SCL-90	The number in the available adult patient pool was not specified. 325 adult & adolescent applicants for SRS were recruited. • 103 (31.7%) were not eligible to start hormone tx & real-life experience. • 34 (10.7%) discontinued hormone tx 162 (an unknown percentage of the initial recruitment) provided pre-SRS test data. • 36 to 61 (22.2%-37.6% of those adults w pre-SRS data) did not complete post-SRS testing.	Most of the MMPI scales were already in the normal range at the time of initial testing. At t=0, the global "psychoneuroticism" SCL-90 score, which included the drop-outs, was 143.0±40.7. At post SRS-follow-up, the score had decreased to 120.3±31.4. The scores were statistically different from one another, but are of limited biologic significance given the range of the score for this scale: 90 to 450, with higher scores consistent with more psychological instability.
Udeze, et al. 2008 Megeri, Khoosal 2007 UK	SCL-90R	The number in the available patient pool was not specified. 40 subjects were prospectively selected. • Post-operative testing was conducted within 6 months to minimize previously determined loss rates.	At t=0, the mean raw global score was 48.33. At post-SRS follow-up, the mean score was 49.15. There were no statistically significant changes in the global score or for any of the subscales.
National Databases			
Dehjne Sweden 2011	Swedish National Records	804 with GID in Sweden 1973 to 2003 were identified. • 480 (59.7%) did not apply or were not approved for SRS • 324 (40.3%) underwent SRS. • All were followed. 3240 controls of the natal sex and 3240 controls of the reassigned gender	All cause mortality was higher (n=27[8%]) than in controls (H.R 2.8 [1.8-4.3]) even after adjustment for covariants. Divergence in survival curves was observed after 10 years. The major contributor was completed suicide (n=10 [3%]; adjusted H.R. 19.1 [5.8-62.9]). Suicide attempts were more

		were randomly selected from national records	common (n= 29 [9%]) than in controls (adjusted H.R. 4.9 [2.9–8.5]). Hospitalizations for psychiatric conditions (not related to gender dysphoria) were more common n= 64 [20%] than in controls (H.R. 2.8 [2.0–3.9]) even after adjusting for prior psychiatric morbidity.
Dhejne et al. 2014 Landén et al. 1998 Sweden	Swedish National Registry	767 applied for SRS/legal status (1960-2010) • 25 (3.3%) applications denied. • 61 (8.0%) not granted full legal status 681 (88.7%) underwent SRS. • All were followed.	15 formal applications for reversal to natal/original gender (2.2% of the SRS population) were identified thus far (preliminary number). (Does not reflect other manifestations of regret such as suicide.)

GID=NOS=Gender Identity Disorder-Not Otherwise Specified HR=Hazard Ratio SRS=Sex reassignment surgery
Tx=Treatment

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EXHIBIT R

HONORABLE JUDGE ROBERT J. BRYAN

**IN THE UNITED STATES DISTRICT COURT
FOR THE WESTERN DISTRICT OF WASHINGTON
AT TACOMA**

C. P., by and through his parents,
Patricia Pritchard and Nolle Pritchard;
and PATRICIA PRITCHARD,

Plaintiff,

vs.

BLUE CROSS BLUE SHIELD OF
ILLINOIS,

Defendants.

Case No. 3:20-cv-06145-RJB

**EXPERT DECLARATION OF
MICHAEL K. LAIDLAW, M.D.**

I, Michael K. Laidlaw, M.D., hereby declare as follows:

I. Expert Witness Background & Qualifications

1. My name is Michael K. Laidlaw. I am over the age of eighteen and submit this expert declaration based on my personal knowledge and experience.

2. I am a board-certified endocrinologist. I received my medical degree from the University of Southern California in 2001. I completed my residency in internal medicine at Los Angeles County/University of Southern California Medical Center in 2004. I also completed a fellowship in endocrinology, diabetes, and metabolism at Los Angeles County/University of Southern California Medical Center in 2006.

EXPERT DECLARATION OF
MICHAEL K. LAIDLAW, M.D. - 1

KILPATRICK TOWNSEND 76350748 2

KILPATRICK TOWNSEND & STOCKTON
LLP 1420 FIFTH AVENUE, SUITE 3700
SEATTLE, WA 98101
(206) 626-7713 FAX: (206) 260-8946

1 3. I have been board certified by (1) the National Board of Physicians and Surgeons
2 for Endocrinology, Diabetes & Metabolism, (2) the National Board of Physicians and Surgeons
3 for Internal Medicine, and (3) the American Board of Internal Medicine for Endocrinology,
4 Diabetes and Metabolism.

5 4. The information provided regarding my professional background are detailed in
6 my curriculum vitae. A true and correct copy of my curriculum vitae is attached as Exhibit A.

7 5. In my clinical practice as an endocrinologist, I evaluate and treat patients with
8 hormonal and/or gland issues. Hormone and gland disorders can cause or be associated with
9 psychiatric symptoms, such as depression, anxiety, and other psychiatric symptoms. Therefore,
10 I frequently assess and treat patients demonstrating psychiatric symptoms and determine whether
11 their psychiatric symptoms are being caused by a hormonal issue, gland issue, or a different
12 cause. The reason that endocrinologists become involved in treatment of gender dysphoria is
13 that gender dysphoria, a psychiatric issue, may be interrelated with hormone and gland disorders.
14 Indeed, the expert witnesses retained by Plaintiffs in this case treat gender dysphoria as
15 presumptively a hormone and gland disorder. The Endocrine Society has issued guidelines for
16 the diagnosis and treatment of gender dysphoria.

17 **II. Summary of Work Performed**

18 6. I have been retained by Blue Cross Blue Shield of Illinois (“BCBSIL”) to provide
19 a rebuttal expert opinion in response to the declarations of the expert declarations of Dr. Randi
20 C. Ettner, Ph.D.; Dr. Dan H. Karasic, M.D.; and Dr. Loren S. Schechter, M.D.

21 7. If called to testify in this matter, I would testify truthfully and based on my expert
22 opinion. The opinions and conclusions I express herein are based on a reasonable degree of
23 scientific certainty.

24 8. I am being compensated at an hourly rate of \$450 per hour plus expenses for my
25 time spent preparing this declaration and \$650 per hour for providing testimony in this matter.
26 My compensation does not depend on the outcome of this litigation, the opinions I express, or
27 the testimony I may provide.

EXPERT DECLARATION OF
MICHAEL K. LAIDLAW, M.D. - 2

KILPATRICK TOWNSEND 76350748 2

KILPATRICK TOWNSEND & STOCKTON
LLP 1420 FIFTH AVENUE, SUITE 3700
SEATTLE, WA 98101
(206) 626-7713 FAX: (206) 260-8946

1 9. My opinions contained in this report are based on: (1) my clinical experience as
2 an endocrinologist; (2) my clinical experience evaluating individuals who have or have had
3 gender incongruence and/or gender dysphoria; (3) my knowledge of research and studies
4 regarding the treatment of gender dysphoria, including for minors; and (4) my review of the
5 various declarations submitted by Plaintiffs in the present lawsuit, *C.P. et al. v. Blue Cross Blue*
6 *Shield of Illinois*, Case No. 3:20-cv-06145-RJB (W.D. Wash).

7 10. I was provided with and reviewed the following case-specific materials: (1) C.P.'s
8 medical records from the Polyclinic; (2) the deposition of Plaintiff Patricia Pritchard; (3) the
9 depositions of C.P.'s treating providers, Kevin Hatfield, M.D.; Jeffrey Kylo, M.D.; and Sharon
10 Booker, MA, LHMC; and (4) the expert declarations of Dr. Randi C. Ettner, Ph.D.; Dr. Dan H.
11 Karasic, M.D.; and Dr. Loren S. Schechter, M.D., and (5) the deposition of Blue Cross Blue
12 Shield of Illinois Medical Director, Kim Reed, M.D..

13 **III. Summary of Opinions**

14 11. In my professional opinion, treatment interventions on behalf of individuals
15 diagnosed with gender dysphoria must be held to the same scientific standards as other medical
16 treatments. These interventions must be optimal, efficacious, and safe. Any treatment which
17 alters biological development in children should be used with extreme caution and regarded as a
18 last resort.

19 12. The Plaintiffs' experts' opinions are substantively the same. They each opine that
20 for patients with gender dysphoria, the only acceptable path forward that meets the standard of
21 care is the approach endorsed by the World Professional Association for Transgender Health
22 ("WPATH").

23 13. The implication is that if an employer excludes gender affirmative care from
24 coverage, it must be because the employer is prejudiced against transgender individuals. This is
25 demonstrably false.

26 14. In my opinion, these opinions are too absolute and the product of political
27 advocacy. There is ongoing debate and study in the medical community regarding gender

1 affirmative treatment. The medical community is divided on many issues related to the
 2 appropriate medical care for gender identity and the necessity or value of gender affirmative care.
 3 This is especially true for minors.

4 15. For example, Plaintiffs' experts opine that gender dysphoria is an immutable,
 5 permanent condition. That is not the consensus in the relevant community and there is much
 6 debate and disagreement about whether gender dysphoria is always permanent.

7 16. A recurring problem is the quality of medical care received by minors who
 8 undergo irreversible gender-affirming treatments. This appears to result at least in part because
 9 gender dysphoria treatments are so entangled with advocacy. WPATH itself recognizes that it
 10 is not only a scientific organization but also as an advocacy organization, and these two objectives
 11 are not compatible.

12 17. Based on the materials I have reviewed and in my professional opinion, the
 13 treatment of C.P. is indicative of these quality-of-care problems that I have observed.

14 **IV. Analysis.**

15 **A. Background**

16 **1. The WPATH and The Endocrine Society**

17 18. I have read the reports of expert witnesses retained by Plaintiffs in this case, Randi
 18 C. Ettner, Ph.D., Dan H. Karasic, M.D., and Loren S. Schechter, M.D. Drs. Ettner, Karasic, and
 19 Schechter all rely almost exclusively on the WPATH *Standards of Care for the Health of*
 20 *Transsexual, Transgender and Gender-nonconforming People* (7th version) (WPATH *Standards*
 21 *of Care*). See Ettner Report, ¶¶ 33-34; Karasic Report, ¶¶ 25-34, 43-44; Schechter Report, ¶¶
 22 24-27. These experts also briefly cite the Endocrine Society guidelines for support. See Ettner
 23 Report, ¶ 54; Karasic Report, ¶¶ 35-36; Schechter Report, ¶ 26.

24 19. Dr. Ettner is the immediate past Secretary of the World Professional Association
 25 for WPATH and has been a member of the Board of Directors for 12 years. Dr. Ettner is an
 26 author of the WPATH *Standards of Care*.

1 20. Dr. Karasic previously sat on the Board of Directors of WPATH. Dr. Karasic
2 Ettner is also an author of the WPATH *Standards of Care*. Dr. Karasic is also a member of the
3 WPATH Global Education Initiative.

4 21. Dr. Schechter is also a contributing author to the WPATH *Standards of Care*. Dr.
5 Schechter has taught a number of courses through WPATH's Gender Education Institute.

6 22. The WPATH *Standards of Care* were produced over a decade ago, in 2011. They
7 were prepared within their advocacy organization and are purported to be a "professional
8 consensus about the psychiatric, psychological, medical, and surgical management of gender
9 dysphoria" (WPATH, 2022). However, there is no "professional consensus" on these issues in
10 the medical community at this time. Furthermore, WPATH's "Standards of Care," unlike the
11 Endocrine Society's guidelines, do not have a grading system for either the strength of their
12 recommendations or the quality of the evidence presented.

13 23. There is widespread agreement among relevant health care providers that
14 WPATH is not merely a scientific organization but also as an advocacy organization that supports
15 gender affirmative surgery. WPATH explicitly regards itself as such. WPATH has advocated
16 positions on issues that have drawn varying opinions and views in the relevant medical
17 community.

18 24. WPATH's *Standards of Care*, in contrast to, for example, the Endocrine Society's
19 guidelines, do not follow recognized procedures for establishing the guidelines as the fruit of
20 genuine scientific method. For example, the *Standards of Care* lack a grading system for the
21 strength of its recommendations or the quality of the evidence presented to support its
22 recommendations. WPATH claims to be a scientific organization while explicitly acting as an
23 advocacy group. These are incompatible goals.

24 25. WPATH no longer considers preoperative psychotherapy to be a requirement
25 before gender affirmative surgery. This follows many years in which the role of WPATH
26 downgraded the role of psychotherapy. Many facilities that follow WPATH standards permit
27

1 patients to receive counseling from individuals with masters rather than medical or PhD degrees
2 or clinical psychology qualifications.

3 26. While the Endocrine Society has issued “Endocrine Treatment of Gender-
4 Dysphoric / Gender-Incongruent Persons: An Endocrine Society Clinical Practice Guideline,”
5 these are only “guidelines.” The Endocrine Society’s guidelines specifically state that their
6 “guidelines cannot guarantee any specific outcome, nor do they establish a standard of care”
7 (Hombre *at al.*, 2017, p. 3895).

8 27. In the Endocrine Society’s guidelines, the quality of evidence for the treatment of
9 adolescents is rated “very low-quality evidence” and “low quality evidence.” “The quality of
10 evidence for [puberty blocking agents] is noted to be low. In fact, all of the evidence in the
11 guidelines with regard to treating children/adolescents by [gender affirmative therapy] is low to
12 very low because of the absence of proper studies” (Laidlaw et al., 2019).

13 28. Unlike some other recommendations for adolescent Gender Affirmative Therapy
14 (“GAT”), the Endocrine Society’s guidelines do not include any grading of the quality of
15 evidence specifically for their justification of laboratory ranges of testosterone or estrogen or for
16 adolescent mastectomy or other surgeries.

17 29. Endocrinologists W. Malone and P. Hruz and colleagues have written discussing
18 the limitations of the Endocrine Society’s guidelines as well: “Unlike standards of care, which
19 should be authoritative, unbiased consensus positions designed to produce optimal outcomes,
20 practice guidelines are suggestions or recommendations to improve care that, depending on their
21 sponsor, may be biased. In addition, the ES claim of effectiveness of GAT interventions is at
22 odds with several systematic reviews, including a recent Cochrane review of evidence and a now
23 corrected population-based study that found no evidence that hormones or surgery improve long-
24 term psychological well-being. Lastly, the claim of relative safety of these interventions ignores
25 the growing body of evidence of adverse effects on bone growth, cardiovascular health, and
26 fertility, as well as transition regret” (Malone et al., 2021).

1 **2. Gender Dysphoria as a Subjective, Psychological Condition with**
2 **Unknown Causes**

3 30. *According to Dr. Ettner, “A growing assemblage of research documents that*
4 *gender identity is immutable and biologically based.”* Ettner Report, ¶ 25.

5 31. This assertion lacks scientific support and therefore impairs the credibility of Dr.
6 Ettner’s opinions. There is no objective physical measure to identify either gender identity or
7 gender dysphoria. One cannot do imaging of the human brain to find the gender identity.
8 Likewise, there is no other imaging, laboratory tests, biopsy of tissue, autopsy of the brain, or
9 genetic testing that can identify the gender identity. There is no known gene that maps to gender
10 identity or to gender dysphoria.

11 32. Gender dysphoria is a psychological diagnosis. It is diagnosed purely by
12 psychological methods of behavioral observation and questioning.

13 33. Likewise, what is termed gender identity is a psychological concept. It has no
14 correlate in the human body. “There are no laboratory, imaging, or other objective tests to
15 diagnose a ‘true transgender’ child” (Laidlaw et al., 2019).

16 34. This is in contrast to all other endocrine disorders which have a measurable
17 physical change in either hormone levels or gland structure which can be confirmed by physical
18 testing. Endocrinology is the study of glands and hormones. Endocrine disorders can be divided
19 into three main types: those that involve hormone excess, those that involve hormone deficiency,
20 and those that involve structural abnormalities of the glands such as cancers.

21 35. Notably, Noteworthy in these three types is that all three disease conditions are
22 diagnosed by physical observations. In other words, a laboratory test of a hormone, an imaging
23 test of an organ, an examination of cells under a microscope, or all three may be employed in the
24 diagnosis of endocrine disease.

25 **3. There is Evidence of Substantial Desistance Among Those Who Have**
26 **Received Gender Affirming Care.**

27 36. *According to dr. Ettner, “[e]fforts to change an individual’s gender identity are*
 therefore both futile and unethical” because [t]he evidence demonstrating that gender identity

1 *cannot be altered, either for transgender or for non-transgender individuals,” and is therefore*
 2 *“innate and immutable.”* Ettner Report, ¶ 25. *According to Dr. Karasic, “[r]egret among those*
 3 *who are treated with gender-affirming medical care is rare.”* Karasic Report, ¶ 51.

4 37. There is substantial evidence to the contrary.

5 38. These assertions are not supported by the scientific evidence. Gender dysphoria
 6 is a persistent state of distress that stems from the feeling that one’s gender identity does not align
 7 with their physical sex (American Psychiatric Association, 2013).

8 39. Desistance is a term indicating that the child, adolescent, or adult who initially
 9 presented with gender incongruence has come to experience a realignment of their internal sense
 10 of gender and their physical body.

11 40. “There is currently no way to predict who will desist and who will remain
 12 dysphoric.” “Children with [gender dysphoria] will outgrow this condition in 61% to 98% of
 13 cases by adulthood. (Laidlaw et al., 2019).

14 41. Because the rate of desistance is so high, gender affirmative therapy will
 15 necessarily cause serious and irreversible harm to many children and adolescents who would
 16 naturally outgrow the condition if not affirmed.

17 42. With respect to minors, because there is no physical marker to diagnose gender
 18 identity, and because it is not possible to predict which child or adolescent will desist, it is not
 19 possible to know which young person will still identify as transgender as an adult.

20 43. Concern for desistance has increased as, in recent years, there have been very
 21 significant increases in referrals for this condition noted around the globe. For example, in the
 22 UK, “[t]he number of referrals to GIDS [Gender Identity Development Service] has increased
 23 very significantly in recent years. In 2009, 97 children and young people were referred. In 2018
 24 that number was 2519” (Bell v. Tavistock Judgment, 2020). (Littman, 2018).

25 44. The likelihood of desistance may be greater if there are social causes of gender
 26 dysphoria, because those are transient. The French National Academy of Medicine, the premier
 27 such academy in the country and founded in 1820 by Louis XVIII, wrote recently: “Parents

1 addressing their children's questions about transgender identity or associated distress should
 2 remain vigilant regarding the addictive role of excessive engagement with social media" (SEGM,
 3 2022).

4 45. The large percentage of individuals suffering from diagnosed mental illnesses also
 5 is reason for concern about dissidence. In "a study of the Finnish gender identity service, '75%
 6 of adolescents [assessed] had been or were currently undergoing child and adolescent psychiatric
 7 treatment for reasons other than gender dysphoria' (Kaltiala-Heino, 2015). In fact, '68% had
 8 their first contact with psychiatric services due to other reasons than gender identity issues.' The
 9 same study also showed that 26% percent had an autistic spectrum disorder and that a
 10 disproportionate number of females (87%) were presenting to the gender clinics compared to the
 11 past" (Laidlaw in gdworkinggroup.org, 2018).

12 4. Biological Sex in Contrast to Gender Identity

13 46. *According to Dr. Ettner, "a number of factors go into the determination of a*
 14 *person's sex." Dr. Ettner then lists a number of physical factors and then adds "gender*
 15 *identity."* Ettner, ¶ 21.

16 a. Human Sexual Development

17 (1) Embryologic development

18 47. Another confirmation that there are only two biological sexes comes from what is
 19 known about embryologic development and fertilization. The biologic development of the
 20 human person begins with a gamete from a female termed an ovum or egg and a gamete from a
 21 biological male which is termed sperm. The fertilization of the egg by the sperm begins the
 22 process of human biological development. The cells of the fertilized ovum then multiply and the
 23 person undergoes the incredible changes of embryologic development.

24 48. It is noteworthy that the male sperm comes from the biological male and the
 25 female egg comes from the biological female. There is no other third or fourth or fifth type of
 26 gamete that exists to begin the development of the human person. This is consistent with the
 27 binary nature of human sex (Alberts et al., 2002).

1 will develop sperm under the influence of testosterone and become capable of ejaculation.
2 Because of these changes, the male will become capable of fertilizing an egg. The inability to
3 produce sperm sufficient to fertilize an egg is termed infertility.

4 55. For the female, pubertal development includes changes such as breast
5 development, widening of the pelvis, and menstruation. The female will also begin the process
6 of ovulation which is a part of the menstrual cycle and involves the release of an egg or eggs
7 from the ovary. Once the eggs are released in a manner in which they can become fertilized by
8 human sperm, then the female is termed fertile. The inability to release ovum that can be
9 fertilized is termed infertility (Kuohong and Hornstein, 2021).

10 (3) Tanner stages of development

11 56. From a medical perspective it is important to know the stage of pubertal
12 development of the developing adolescent. This can be determined through a physical
13 examination of the body. The female will have changes in breast characteristics and pubic hair
14 development. Similarly, the male will have changes in testicular size and pubic hair
15 development. These findings can be compared to the Tanner staging system which will allow
16 the stage of puberty to be known.

17 57. Tanner stages are divided into five stages. Stage 1 is the pre-pubertal state before
18 pubertal development of the child begins. Stage 5 is full adult sexual maturity. Stages 2 through
19 4 are various phases of pubertal development (Greenspan and Gardner, 2004).

20 58. Awareness of the Tanner stage of the developing adolescent is also useful to
21 assess for maturation of sex organ development leading to fertility. For girls, the first
22 menstruation (menarche) occurs about two years after Tanner stage 2 and will typically be at
23 Tanner stage 4 or possibly 3 (Emmanuel and Boker, 2022). The first appearance of sperm
24 (spermarche) will typically be Tanner stages 4 (*Id.*). If puberty is blocked or disrupted before
25 reaching these critical stages, the sex glands will be locked in a premature state and incapable of
26 fertility.
27

(4) **Biological Sex Cannot Be Changed**

59. It is not possible for a person to change from one biological sex to the other, and there is no technology that allows a biological male to become a biological female or vice-versa. It is not technologically possible at this time to change sex chromosomes; these will remain in every cell throughout life. It is not technologically possible to transform sex glands from one to the other. In other words, there are no hormones or other means currently known to change an ovary into a testicle or a testicle into an ovary.

60. Furthermore, as noted earlier, several of the sex specific structures (such as the epidymis of the male or uterus of the female) are produced early in embryological development from around weeks 8 to 12. The primitive ducts which lead to these organs of the opposite sex are obliterated. There is no known way to resuscitate these ducts and continue development of opposite sex structures.

61. It is also not possible to produce gametes of the opposite sex. In other words, there is not any known way to induce the testicles to produce eggs. Nor is there any known way to induce the ovaries to produce sperm. Therefore, creating conditions for a biological female to create sperm capable of fertilizing another ovum is impossible. The induction of opposite sex fertility is impossible.

62. In fact, some gender affirming therapy actually leads to infertility and potential sterilization.

B. Effectiveness and Safety of Gender Affirmative Therapies Recommended by WPATH

63. According to Dr. Ettner, “[t]here is a large and growing body of evidence that demonstrates that the provision of gender affirming medical and surgical treatment to treat gender dysphoria are both safe and effective.” Ettner, Report, ¶ 49. According to Dr. Karasic, “gender dysphoria is a condition that is highly amenable to treatment, and the prevailing treatment for it is highly effective. . . . Gender-affirming medical and surgical interventions in accordance with the WPATH SOC 7 and Endocrine Society Guidelines are widely recognized

1 *in the medical community as safe, effective, and medically necessary for many transgender*
 2 *people with gender dysphoria...risks do decline when transgender individuals are supported*
 3 *and live according to their gender identity.”* Karasic Report, ¶¶ 24, 43. Dr. Schechter’s
 4 testimony is the same. Schechter Report, ¶¶ 37-41.

5 64. The scientific evidence does not support these unequivocal assertions. Gender
 6 affirmative therapy suffers from a lack of a quality evidence base and from poorly-performed
 7 studies.

8 65. The approaches to gender dysphoria may be divided into three main types.
 9 (Zucker, 2020). One is psychosocial treatment that helps the young person align their internal
 10 sense of gender with their physical sex. Another would be to “watch and wait” and allow time
 11 and maturity to help the young person align sex and gender through natural desistance. The third
 12 option is referred to as gender affirmative therapy or GAT and is the approach recommended by
 13 WPATH.

14 66. GAT consists of psychosocial, medical, and surgical interventions that attempt to
 15 psychologically and medically alter the patient so that they come to believe they may become
 16 similar to the physical sex which aligns with their gender identity (but not their biological sex)
 17 and thereby reduce gender dysphoria. GAT consists of four main parts: 1) social transition, 2)
 18 blocking normal puberty or menstruation, 3) high dose opposite sex hormones, and 4) surgery of
 19 the genitalia and breasts.

20 67. I will describe each stage of GAT and then address scientific evidence regarding
 21 the efficacy of GAT to treat gender dysphoria and the safety of these treatments.

22 **1. Gender Affirmative Therapies Recommended by WPATH**

23 **a. Social Transition**

24 68. The first stage of gender affirmative therapy is termed social transition. Social
 25 transition is a psychological intervention. The child may be encouraged to adopt the type of
 26 clothing and mannerisms or behaviors which are stereotypical of the opposite sex within a
 27 culture. For example, in the United States a boy might wear his hair long and wear dresses in

1 order to socially transition. A girl may cut her hair short and wear clothes from the boys' section
2 of a department store.

3 **b. Medications which Block Pubertal Development**

4 **(1) Background**

5 69. A second stage of gender affirmative therapy may involve blocking normal
6 pubertal development. This may be done with puberty blocking medications that act directly on
7 the pituitary.

8 70. In order to understand what is occurring in this process, it is helpful to be aware
9 of normal hormone function during pubertal development.

10 71. There is a small pea-sized gland in the brain called the pituitary. It is sometimes
11 referred to as the "master gland," as it controls the function of several other glands. One key
12 function for our purposes is the control of the sex glands. There are two specific hormones
13 produced by the pituitary referred to as luteinizing hormone ("LH") and follicle stimulating
14 hormone ("FSH"). These hormones are responsible for sex hormone production and fertility.
15 The LH and FSH act as signals to tell the sex glands begin or continue their function.

16 72. In the adult male, the production of LH will cause adult levels of testosterone to
17 be produced by the testicles. In the adult female, the production of LH will cause adult levels of
18 estrogen to be produced by the ovaries.

19 73. In early childhood, prior to the beginning of puberty, the pituitary function with
20 respect to the sex glands is quiescent. However, during pubertal development, for the female,
21 the interaction of LH with the ovaries increases estrogen production and carries the girl through
22 the stages of development into womanhood. For boys, LH will signal the testicle to increase
23 testosterone production, which carries the boy through the stages of pubertal development into
24 manhood. Likewise for the female, the interaction of LH with the ovaries increases estrogen
25 production, which carries the girl through the stages of development into womanhood.

26 74. There are conditions diagnosed by endocrinologists which involve a disruption of
27 this normal communication between the pituitary and the sex glands. There is a medical

1 condition called hypogonadotropic hypogonadism. The meaning of this term is that the pituitary
2 is not sending the hormonal signals (LH and FSH) to the sex glands and therefore the sex glands
3 are unable to make their sex hormones. The result is hormonal deficiencies of LH, FSH, and
4 either testosterone or estrogen.

5 75. If this condition occurs during puberty, the effect will be to stop pubertal
6 development. This is a disease state which is diagnosed and treated by the endocrinologist.

7 76. Medications such as GnRH agonists act on the pituitary gland to lower the
8 pituitary release of LH and FSH levels dramatically. The result is a blockage of the signaling of
9 the pituitary to the ovaries or the testicles and therefore underproduction of the sex hormones.
10 This will stop normal menstrual function for the female and halt further pubertal development.
11 For the male this will halt further pubertal development. If the male had already reached
12 spermatarche, then production of new sperm will stop.

13 (2) GnRH Agonist Medication Effects

14 77. There are a variety of uses for GnRH agonists. The use and outcome can be very
15 different for different applications.

16 78. For example, the initial development of the medication called Lupron was for the
17 treatment of prostate cancer. The idea being that blocking pituitary hormones will block the adult
18 male's release of testosterone from the testicles. Since testosterone will promote the growth of
19 prostate cancer, the idea is to lower testosterone levels to a very low amount and therefore prevent
20 the growth and spread of prostate cancer. This is a labeled use of the medication. In other words,
21 there is FDA approval for this use.

22 79. Another labeled use of GnRH agonist medication is for the treatment of central
23 precocious puberty. In the disease state of central precocious puberty, pituitary signaling is
24 activated at an abnormally young age, say age four, to begin pubertal development. In order to
25 halt puberty which has begun at an abnormally early time, a GnRH agonist may be used. Here
26 the action of the medication on the pituitary will disrupt the signaling to the sex glands, stop early
27 sex hormone production, and therefore stop abnormal pubertal development.

1 80. Then, at a more normal time of pubertal development, say age 11, the medication
2 is stopped and puberty is allowed to proceed. The end result is to restore normal sex gland
3 function and timing of puberty. This is a labeled use for a GnRH agonist medication.

4 81. What about the use of puberty blockers such as Lupron in gender affirmative
5 therapy? In these cases, we have physiologically normal children who are just beginning puberty
6 or are somewhere in the process of pubertal development. They have healthy pituitary glands
7 and sex organs. However, a puberty blocking medication is administered to stop normal pubertal
8 development.

9 82. In this case, the condition of hypogonadotropic hypogonadism described above (a
10 medical disease) is induced by medication and is an iatrogenic effect of treating the psychological
11 condition of gender dysphoria. GnRH agonist medications have not been FDA approved for this
12 use.

13 c. **Opposite Sex Hormones**

14 83. The third stage of gender affirmative therapy involves using hormones of the
15 opposite sex at high doses to attempt to create secondary sex characteristics in the person's body.

16 (1) **Testosterone**

17 84. Testosterone is an anabolic steroid of high potency. It is classified as a Schedule
18 3 controlled substance by the DEA: "Substances in this schedule have a potential for abuse less
19 than substances in Schedules I or II and abuse may lead to moderate or low physical dependence
20 or high psychological dependence" (DEA, 2022). A licensed physician with a valid DEA
21 registration is required to prescribe testosterone.

22 85. I prescribe testosterone to men for testosterone deficiency. The state of
23 testosterone deficiency can cause various problems, including problems of mood, sexual
24 function, libido, and bone density. Prescription testosterone is given to correct the abnormally
25 low levels and bring them back into balance. The dose of testosterone must be carefully
26 considered and monitored to avoid excess levels in the male as there are a number of serious
27 concerns when prescribing testosterone.

(2) Estrogen

86. Estrogen is the primary sex hormone of the female. Prescription estrogen may be used if a woman has low estrogen levels due to premature failure of her ovaries. Estrogen is prescribed to bring these levels back into a normal range for the patient's age. Another labeled use of estrogen is to treat menopausal symptoms.

87. For the male, estrogen is being used at supraphysiologic doses. The high doses are used in an attempt to primarily affect an increase of male breast tissue development known as gynecomastia. Gynecomastia is the abnormal growth of breast tissue in the male. The occurrence of gynecomastia in the male is sometimes corrected by medication or more commonly by surgery if needed. Other changes of secondary sex characteristics may develop such as softening of the skin and changes in fat deposition and muscle development.

d. Surgeries as Gender Affirmative Therapy

88. Surgical alterations of the body of various kinds attempt to somehow mimic features of the opposite sex.

89. Individual surgical procedures can be a complex topic. It is helpful to first step back and consider conceptually what any surgery can and cannot accomplish.

90. In its basic form surgery is subtractive. In other words, a portion of tissue, an organ or organs are removed in order to restore health. For example, a diseased gallbladder may be surgically removed to help the patient get back to wellness. An infected appendix may be surgically removed to prevent worsening infection or even death. In both of these cases, an unhealthy body part is surgically removed in order to restore health.

91. In some cases, a diseased tissue or organ is removed so that a foreign replacement part may be substituted for an unhealthy organ or tissue. For example, a diseased heart valve may be replaced with a pig valve or a prosthetic heart valve. Another example is a failed liver may be replaced by liver transplant.

92. Though modern surgical techniques and procedures are astounding, there are very noteworthy limitations. Importantly, surgery cannot *de novo* create new organs. If a person's

1 kidneys fail, the surgeon has no scientific method for creating a new set of kidneys that can be
 2 implanted or grown within the patient. This conceptual background is helpful when considering
 3 various gender affirming surgeries.

4 93. There are a variety of gender affirming surgeries for females. These may include
 5 mastectomies, metoidioplasty, and phalloplasty.

6 **2. The Lack of Evidence of Effectiveness of GAT**

7 94. There is much evidence that questions the long-term benefits of opposite sex
 8 hormones and gender reassignment surgery and in fact suggests serious harms.

9 **a. Sweden's Long-term study of 30 years of data by Dhejne**

10 95. The most comprehensive study of its kind is from Sweden in 2011. The authors
 11 examined data over a 30-year time period (Dhejne, 2011). The Dhejne team made extensive use
 12 of numerous Swedish database registries and examined data from 324 patients in Sweden over
 13 30 years who had taken opposite sex hormones and had undergone sex reassignment surgery.
 14 They used population controls matched by birth year, birth sex, and reassigned sex. When
 15 followed out beyond ten years, the sex-reassigned group had nineteen times the rate of completed
 16 suicides and nearly three times the rate of all-cause mortality and inpatient psychiatric care
 17 compared to the general population of Sweden.

18 **b. The Bränström and Panchankis Retraction**

19 96. Other published studies of GAT have been shown to have serious errors. For
 20 example, a major correction was issued by the American Journal of Psychiatry. The authors and
 21 editors of a 2020 study, titled "Reduction in mental health treatment utilization among
 22 transgender individuals after gender-affirming surgeries: a total population study" (Bränström
 23 study, 2020) retracted their original primary conclusion. Letters to the editor by twelve authors,
 24 including myself, led to a reanalysis of the data and a corrected conclusion stating that, in fact,
 25 the data showed no improvement in mental health for transgender identified individuals after
 26 surgical treatment, nor was there improvement with opposite sex hormones ("Correction", 2020;
 27 Van Mol et al., 2020).

1 97. The initial reports of this study claimed that the authors found treatment benefits
2 with surgery, and this was shared widely in the media. For example, ABC News posted an article
3 titled “Transgender surgery linked with better long-term mental health, study shows” (Weitzer,
4 2019). An NBC news/Reuters headline reads “Sex-reassignment surgery yields long-term
5 mental health benefits, study finds” (Reuters, 2019).

6 98. However, after twelve authors from around the world, including our team,
7 investigated the study in detail, a number of serious errors were exposed, leading to a retraction
8 (Kalin, 2020; Anckarsäter et al., 2020).

9 99. In our letter to the editor, which I co-wrote with former Chairman of Psychiatry
10 at Johns Hopkins Medical School, Paul McHugh, MD, we noted key missing evidence in the
11 original Branstrom report when compared to the previous body of knowledge yielded from the
12 Swedish Dhejne study. We wrote that “[t]he study supports only weak conclusions about
13 psychiatric medication usage and nothing decisive about suicidality. In overlooking so much
14 available data, this study lacks the evidence to support its pro gender-affirmation surgery
15 conclusion” (Van Mol, Laidlaw, et al., 2020).

16 100. In another letter, Professor Mikael Landen writes that “the authors miss the one
17 conclusion that can be drawn: that the perioperative transition period seems to be associated with
18 high risk for suicide attempt. Future research should use properly designed observational studies
19 to answer the important question as to whether gender-affirming treatment affects psychiatric
20 outcomes” (Landen, 2020).

21 101. In another letter to the editor, psychiatrist David Curtis noted that “[t]he study
22 confirms the strong association between psychiatric morbidity and the experience of incongruity
23 between gender identity and biological sex. However, the Branstrom study does not demonstrate
24 that either hormonal treatment or surgery has any effect on this morbidity. It seems that the main
25 message of this article is that the incidence of mental health problems and suicide attempts is
26 especially high in the year after the completion of gender-affirming surgery” (Curtis, 2020).

102. In yet another critical letter, Dr. Agnes Wold states that “[w]hether these factors involve a causal relationship (*i.e.*, that surgery actually worsens the poor mental health in individuals with gender dysphoria) cannot be determined from such a study. Nevertheless, the data presented in the article do not support the conclusion that such surgery is beneficial to mental health in individuals with gender dysphoria” (Wold, 2020).

c. Flawed studies based on the problematic 2015 US Transgender Survey

103. A 2021 study by Almazan and Keurghlian attempted to address mental health outcomes in relation to surgery as a part of GAT (Almazan & Keurghlian, 2021). This was not a randomized controlled study nor a prospective observational study. Rather, the study relied upon the 2015 US Transgender Survey (“USTS”), which has been severely criticized for its serious limitations and weaknesses.

104. D’Angelo *et al.* have written about the 2015 USTS survey as part of the criticism of another flawed study in the journal Pediatrics by Jack Turban in 2020 titled “Pubertal Suppression for Transgender Youth and Risk of Suicidal Ideation” (Turban, 2020). They write in their critique of the USTS that it is “a convenience sampling, a methodology which generates low-quality, unreliable data.” (Bornstein, Jager, & Putnick, 2013). Specifically, the participants were recruited through transgender advocacy organizations and subjects were asked to “pledge” to promote the survey among friends and family. This recruiting method yielded a large but highly skewed sample. Their analysis is compromised by serious methodological flaws, including the use of a biased data sample, reliance on survey questions with poor validity, and the omission of a key control variable, namely subjects’ baseline mental health status.” They also state that “[s]igmatizing non-‘affirmative’ psychotherapy for GD [gender dysphoria] as ‘conversion’ will reduce access to treatment alternatives for patients seeking non-biomedical solutions to their distress” (D’Angelo et al., 2021).

d. Centers for Medicare and Medicaid Services Findings

105. The Centers for Medicare and Medicaid Services (“CMS”) has found “inconclusive” clinical evidence regarding gender reassignment surgery. Specifically, the CMS Decision Memo for Gender Dysphoria and Gender Reassignment Surgery (CAG-00446N) (June 19, 2019) states: “The Centers for Medicare & Medicaid Services (CMS) is not issuing a National Coverage Determination (NCD) at this time on gender reassignment surgery for Medicare beneficiaries with gender dysphoria because the clinical evidence is inconclusive for the Medicare population.”

e. Nations and States Question and Reverse Course on GAT

106. Also noteworthy is that other nations are questioning and reversing course regarding gender affirmative therapy. For example, in the *Bell v. Tavistock* judgment in the UK, regarding puberty blockers in GAT, they concluded that “there is real uncertainty over the short and long-term consequences of the treatment with very limited evidence as to its efficacy, or indeed quite what it is seeking to achieve. This means it is, in our view, properly described as experimental treatment” (*Bell v. Tavistock* Judgment, 2020).

107. The case was appealed, and although the medical decision making was returned to clinicians (rather than the courts), it was noted that great pains should be taken to ensure that the child and parents are properly informed before embarking on such treatments. In its conclusion the appeals court stated that “[c]linicians will inevitably take great care before recommending treatment to a child and be astute to ensure that the consent obtained from both child and parents is properly informed by the advantages and disadvantages of the proposed course of treatment and in the light of evolving research and understanding of the implications and long-term consequences of such treatment. Great care is needed to ensure that the necessary consents are properly obtained” (*Bell v. Tavistock* Appeal, Judgment, 2021).

108. In the bulletin of the Royal College of Psychiatrists in 2021, in a reevaluation of the evidence, Griffin and co-authors write as follows: “As there is evidence that many psychiatric disorders persist despite positive affirmation and medical transition, it is puzzling why transition

1 would come to be seen as a key goal rather than other outcomes, such as improved quality of life
2 and reduced morbidity. When the phenomena related to identity disorders and the evidence base
3 are uncertain, it might be wiser for the profession to admit the uncertainties. Taking a supportive,
4 exploratory approach with gender-questioning patients should not be considered conversion
5 therapy” (Griffin et al., 2021).

6 109. In 2020, Finland recognized that “[r]esearch data on the treatment of dysphoria
7 due to gender identity conflicts in minors is limited” and recommended prioritizing
8 psychotherapy for gender dysphoria and mental health comorbidities over medical gender
9 affirmation (Council for Choices in Healthcare in Finland, 2020). Additionally, “[s]urgical
10 treatments are not part of the treatment methods for dysphoria caused by gender-related conflicts
11 in minors.”

12 110. In 2021, Sweden’s largest adolescent gender clinic announced that it would no
13 longer prescribe puberty blockers or cross-sex hormones to youth under 18 years outside clinical
14 trials (SEGM, 2021). “In December 2019, the SBU (Swedish Agency for Health Technology
15 Assessment and Assessment of Social Services) published an overview of the knowledge base
16 which showed a lack of evidence for both the long-term consequences of the treatments, and the
17 reasons for the large influx of patients in recent years. These treatments are potentially fraught
18 with extensive and irreversible adverse consequences such as cardiovascular disease,
19 osteoporosis, infertility, increased cancer risk, and thrombosis. This makes it challenging to
20 assess the risk / benefit for the individual patient, and even more challenging for the minors or
21 their guardians to be in a position of an informed stance regarding these treatments” (Gauffen
22 and Norgren, 2021).

23 111. Dr Hilary Cass “was appointed by NHS England and NHS Improvement to chair
24 the Independent Review of Gender Identity Services for children and young people in late 2020”
25 (The Cass Review website, 2022). In her interim report dated February 2022, it states that
26 “[e]vidence on the appropriate management of children and young people with gender
27 incongruence and dysphoria is inconclusive both nationally and internationally” (Cass, 2022).

1 112. In April of 2022, the Florida Secretary of the Agency for Health Care
2 Administration requested that Florida Medicaid program review “whether treatments are
3 consistent with widely accepted professional medical standards.”

4 113. On June 2, 2022, the report was completed and concluded: “Following a review
5 of available literature, clinical guidelines, and coverage by other insurers and nations, Florida
6 Medicaid has determined that the research supporting sex reassignment treatment is insufficient
7 to demonstrate efficacy and safety. In addition, numerous studies, including the reports provided
8 by the clinical and technical experts listed above, identify poor methods and the certainty of
9 irreversible physical changes. Considering the weak evidence supporting the use of puberty
10 suppression, cross-sex hormones, and surgical procedures when compared to the stronger
11 research demonstrating the permanent effects they cause, these treatments do not conform to
12 GAPMS and are experimental and investigational” (Florida Medicaid, 2022)

13 **f. Mastectomy Surgery for Minors**

14 114. Any serious look at the long-term effects at surgical treatment would follow
15 subjects out at least ten years. For example, an article was published recently examining patients
16 who had mild calcium disorders due to a gland called the parathyroid. They compared a group
17 of patients who had surgical removal of the parathyroid to a control group who had not. They
18 examined data ten years after surgery was completed and concluded that parathyroid surgery in
19 this group “did not appear to reduce morbidity or mortality” in that patient group (Pretorius,
20 2022).

21 115. To my knowledge, there exists no comparable studies of minors with gender
22 dysphoria comparing those who had mastectomy surgery to a control group who had not. There
23 are also no known studies of minors followed for 10 years or more to determine the long-term
24 risks and benefits of mastectomy for gender dysphoria.

25 116. Good quality studies specifically showing that mastectomy surgery is safe,
26 effective, and optimal for treating minors with gender dysphoria do not exist. For example, there
27 is a study titled “Chest Reconstruction and Chest Dysphoria in Transmasculine Minors and

1 Young Adults Comparisons of Nonsurgical and Postsurgical Cohorts” (Olson-Kennedy, 2018).
2 The study authors conclude that “[c]hest dysphoria was high among presurgical transmasculine
3 youth, and surgical intervention positively affected both minors and young adults.” However,
4 there are a number of problems with this study. First, the term “chest dysphoria” is not found as
5 a diagnosis or even referenced in the DSM-5. Second the “chest dysphoria scale” is a measuring
6 tool created by the authors, but which the authors state “is not yet validated.” (*Id.*, p. 435) Third,
7 the mastectomies were performed on girls as young as 13 and 14 years old and who thereby
8 lacked the maturity and capacity of good judgment for truly informed consent for this life altering
9 procedure. For this reason, in my professional opinion, the research and surgeries performed
10 were flawed and unethical.

11 117. There exists another poorly designed study which suffers from similar
12 methodological and ethical problems as the Olson-Kennedy study. A 2021 study published in
13 Pediatrics examined females aged 13-21 recruited from a gender clinic. Thirty young females
14 had mastectomy procedures and sixteen had not. The average age at surgery was 16.4 years
15 (Mehring, 2021). The follow up time after surgery was only 19 months and no data is provided
16 or analyzed about key psychiatric information such as comorbid psychological illnesses, self-
17 harming behaviors, psychiatric hospitalizations, psychiatric medication use, or suicide attempts.

18 118. Information returned from the study surveys were all qualitative and included
19 responses such as “[My chest dysphoria] made me feel like shit, honestly. It made me suicidal.
20 I would have breakdowns.” Another respondent stated, “I’ve been suicidal quite a few times
21 over just looking at myself in the mirror and seeing [my chest]. That’s not something that I
22 should have been born with” (Mehring, 2021). The omission of psychiatric data is a major
23 flaw in the study and also irresponsible given the obviously dangerous psychological states that
24 some of these young people were in.

25 119. Since such a high proportion of subjects were using testosterone (83%), some of
26 the responses could be attributed to adverse effects of testosterone. For example, as related
27 earlier, high dose testosterone can manifest in irritability and aggressiveness. One study subject

1 responded, “I get tingly and stuff and it kind of makes me want to punch something” (Mehringer,
2 2022).

3 120. The testosterone labeling also indicates nausea and depression as adverse
4 reactions which are described by another study subject “There’s a feeling of hopelessness, of
5 desperation, of—almost makes me feel physically sick” (Actavis Pharma, Inc., 2018; Mehninger,
6 2022).

7 121. The study appears to have been designed, at least in part, to justify insurance
8 companies paying for mastectomy procedure for minors with gender dysphoria, even though they
9 have provided no long-term statistical evidence of benefit: “These findings...underscore the
10 importance of insurance coverage not being restricted by age” (Mehrniger, 2021). This also
11 appears to be part of the aim of the flawed Olson-Kennedy study, which stated, “changes in
12 clinical practice and in insurance plans’ requirements for youth with gender dysphoria who are
13 seeking surgery seem essential” (Olson-Kennedy, 2018). So these two studies, rather than being
14 a thorough examination of the psychological and physical risks and benefits of mastectomy
15 surgery over the long-term, appear instead to exist, at least in part, to validate the need for
16 insurance companies to insure the costs of these dubious procedures for minors.

17 3. Iatrogenic Harms of GAT

18 122. The term iatrogenic is used in medicine to describe harms or newly created
19 medical conditions that are the result of medications, surgeries, or even psychological treatments.
20 Each of the four interventions for gender affirmative surgery (social transition, blocking normal
21 puberty, opposite sex hormones, and surgery) lead to iatrogenic harms to the patient. These
22 harms will be described in detail below. GAT interrupts the natural desistence process and
23 instead places the patient on a lifetime regimen of hormonal and surgical care. A good
24 understanding of these harms is also critical to my practice as an endocrinologist, because if I did
25 not understand these harms, I could not advise patients of the risks associated with GAT.

1 **a. Adverse Health Consequences of Blocking Normal Puberty**

2 123. There are a number of serious health consequences that occur as the result of
3 blocking normal puberty. The first problem is infertility. The Endocrine Society Guidelines
4 recommend beginning puberty blockers as early as Tanner stage 2. As discussed earlier, this is
5 the very beginning of puberty. Fertility development happens later generally in Tanner stage 4.
6 One can see that if the developing person is blocked at Tanner stage 2 or 3 as advocated by the
7 guidelines, this is prior to becoming fertile. The gonads will remain in an immature, undeveloped
8 state.

9 124. Although procedures to preserve fertility are available, studies show that less than
10 5% of adolescents receiving GAT even attempt fertility preservation (FP) (Nahata, 2017).
11 Moreover, “ovarian tissue cryopreservation is still considered experimental in most centers and
12 testicular tissue cryopreservation remains entirely experimental. These experimental forms of
13 FP would be the only options in children [with puberty] blocked prior to spermatarche and
14 menarche and are high in cost and limited to specialized centers. Even with FP there is no
15 guarantee of having a child” (Laidlaw, Cretella, et al., 2019).

16 125. Naturally, these children are at a developmental age where they are not thinking
17 about adult related concepts such as having children as they are children themselves. This is only
18 natural and to be expected. The medical problem imposed on them is that if they remain blocked
19 in an early pubertal stage then even the addition of opposite sex hormones will not allow for the
20 development of fertility. In fact, high dose opposite sex hormones may permanently damage the
21 immature sex organs leading to sterilization. Certainly the removal of the gonads, which will be
22 discussed later, will ensure sterilization.

23 126. Another problem with blocking puberty at an early stage is sexual dysfunction.
24 The child will continue their chronological age progression toward adulthood and yet remain
25 with undeveloped genitalia. This will lead to sexual dysfunction including potential erectile
26 dysfunction and inability to ejaculate and orgasm for of the male. For the female with
27

1 undeveloped genitalia potential sexual dysfunction may include painful intercourse and
2 impairment of orgasm.

3 127. In addition to direct effects on the developing genitalia and fertility, there are other
4 important aspects of puberty that are negatively affected. For example, puberty is a time of rapid
5 bone development. This time of development is critical in attaining what we call peak bone
6 density or the maximum bone density that one will acquire in their lifetime (Elhakeem, 2019).

7 128. Any abnormal lowering of sex hormones occurring during this critical time will
8 stop the rapid accumulation of bone and therefore lower ultimate adult bone density. If a person
9 does not achieve peak bone density, they would be expected to be at future risk for osteoporosis
10 and the potential for debilitating spine and hip fractures as adults. Hip fractures for the older
11 patient very significantly increase the risk of major morbidity and death (Bentler, 2009).
12 Allowing a “pause” in puberty for any period of time leads to an inability to attain peak bone
13 density.

14 129. Another consideration is maturation of the human brain. Much of what happens
15 is actually unknown. However, “sex hormones including estrogen, progesterone, and
16 testosterone can influence the development and maturation of the adolescent brain” (Araín,
17 2013). Therefore there are unknown, but likely negative consequences to blocking normal
18 puberty with respect to brain development.

19 130. A third potential problem with blocking normal puberty involves psychosocial
20 development. Adolescence is a critical time of physical, mental, and emotional changes for the
21 adolescent. It is important that they develop socially in conjunction with their peers. This is well
22 recognized in the psychological literature: “For decades, scholars have pointed to peer
23 relationships as one of the most important features of adolescence.” (Brown, 2009). If one is left
24 behind for several years under the impression that they are awaiting opposite sex puberty, they
25 will miss important opportunities for socialization and psychological development. Psychosocial
26 development will be necessarily stunted as they are not developing with their peers. This is a
27 permanent harm as the time cannot be regained.

131. Aside from the multiple serious problems that are iatrogenically acquired by blocking normal puberty, there appear to be independent risks of the puberty blocking medication themselves. For example, one can read the labeling of a common puberty blocking medication called Lupron Depot-Ped and find under psychiatric disorders: “emotional lability, such as crying, irritability, impatience, anger, and aggression. Depression, including rare reports of suicidal ideation and attempt. Many, but not all, of these patients had a history of psychiatric illness or other comorbidities with an increased risk of depression” (Lupron, 2022). This is particularly concerning given the high rate of psychiatric comorbidity with gender dysphoria discussed previously.

b. The Effect of Puberty Blockers on Desistance

132. As stated earlier, a very high proportion of minors diagnosed with gender dysphoria will eventually desist or come to accept their physical sex. Puberty blockers have been shown to dramatically alter natural desistance.

133. In a Dutch study that included seventy adolescents who took puberty blockers, all seventy decided to go on to hormones of the opposite sex (de Vries, et al. 2011). In a follow-up study, the overwhelming majority went on to have sex reassignment surgery by either vaginoplasty for males or hysterectomy with ovariectomy for females (de Vries, et al. 2014). These surgeries resulted in sterilization. This is why puberty blockers, rather than being a “pause” to consider aspects of mental health, are instead a pathway towards future sterilizing surgeries.

c. Infertility as a result of Puberty Blockers in GAT

134. Giving puberty blockers to a four-year-old with central precocious puberty will obviously not impair fertility, as the four-year-old has not yet become fertile. The child will at a later time have the puberty blocker discontinued and then normal pubertal development can proceed. Therefore, when they are no longer taking the medication, they will gain natural fertility.

135. In contrast, puberty blocking medication given in GAT occurs at precisely the time that the child will gain reproductive function. This will stop sperm production in the male and ovulation in the female (if these have already occurred, otherwise the functions will not even begin) which produces the infertile condition. Importantly, so long as the minor continues puberty blockers they will remain infertile. Should they continue on to opposite sex hormones as part of GAT then they will remain infertile. There is the additional possibility that cytotoxic effects of high dose opposite sex hormones will damage the immature gonads leading to permanent sterility. This is yet to be discovered.

d. Adverse Health Effects of Supraphysiologic Doses of Testosterone for Females in GAT

136. Regarding the potential for abuse, the labeling reads “Testosterone has been subject to abuse, typically at doses higher than recommended for the approved indication . . . Anabolic androgenic steroid abuse can lead to serious cardiovascular and psychiatric adverse reactions . . . Abuse and misuse of testosterone are seen in male and female adults and adolescents . . . There have been reports of misuse by men taking higher doses of legally obtained testosterone than prescribed and continuing testosterone despite adverse events or against medical advice.” (Actavis Pharma, 2018)

137. Adverse events with respect to the nervous system include: “Increased or decreased libido, headache, anxiety, depression, and generalized paresthesia.” (Actavis Pharm, 2018)

138. With regard to ultimate height, “[t]he following adverse reactions have been reported in male and female adolescents: premature closure of bony epiphyses with termination of growth” (Actavis Pharma, Inc., 2018). What this means is that testosterone applied to the adolescent will cause premature closure of the growth plates, stopping further gains in height in the growing individual and ultimately making the person shorter than they otherwise would have been.

1 139. With respect to the cardiovascular system of men using ordinary doses, “Long-
2 term clinical safety trials have not been conducted to assess the cardiovascular outcomes of
3 testosterone replacement therapy in men” (Actavis Pharma, 2018). No clinical safety trials have
4 been performed for women or adolescent girls to my knowledge.

5 140. “There have been postmarketing reports of venous thromboembolic events [blood
6 clots], including deep vein thrombosis (DVT) [blood clot of the extremity such as the leg] and
7 pulmonary embolism (PE) [blood clot of the lung which may be deadly], in patients using
8 testosterone products, such as testosterone cypionate” (Actavis Pharma, 2018).

9 141. A recently published study of adverse drug reactions (ADRs) as part of gender
10 affirming hormone therapies in France states that “[o]ur data show a previously unreported, non-
11 negligible proportion of cases indicating cardiovascular ADRs in transgender men younger than
12 40 years... In transgender men taking testosterone enanthate, all reported ADRs were
13 cardiovascular events, with pulmonary embolism in 50% of cases” (Yelehe et al., 2022).

14 142. There are also serious concerns regarding liver dysfunction: “Prolonged use of
15 high doses of androgens ... has been associated with development of hepatic adenomas [benign
16 tumors], hepatocellular carcinoma [cancer], and peliosis hepatis [generation of blood-filled
17 cavities in the liver that may rupture] —all potentially life-threatening complications” (Actavis
18 Pharma, 2018).

19 143. In GAT, what is termed “cross sex hormones” is the use of hormones of the
20 opposite sex to attempt to create secondary sex characteristics. To do so, very high doses of these
21 hormones are administered. When hormone levels climb above normal levels they are termed
22 supraphysiologic.

23 144. The female person does produce some smaller amount of testosterone relative to
24 the male. The normal reference range for adult females depending on the lab is about 10 to 50
25 ng/dL. However, in female disease conditions these levels can be much higher. For example, in
26 polycystic ovarian syndrome levels may range from 50 to 150 ng/dL. PCOS has been associated
27

1 with insulin resistance (Dunaif, 1989), metabolic syndrome (Apridonidze, 2005) and diabetes
2 (Joham, 2014).

3 145. In certain endocrine tumors such as adrenal carcinoma these levels may be
4 substantially higher in the 300 to 1000 ng/dl range. Adrenal carcinoma is a serious medical
5 condition and may be treated by surgery and potent endocrine medications.

6 146. Recommendations from the Endocrine Society's clinical guidelines related to
7 GAT are to ultimately raise female levels of testosterone to 320 to 1000 ng/dL², which is on the
8 same order as dangerous endocrine tumors for women as described above (Hembree, 2017). A
9 simple calculation shows this level for the adult may be anywhere from 6 to 100 times higher
10 than native female testosterone levels. In doing so they are creating a hormone imbalance known
11 as hyperandrogenism. These extraordinarily high levels of testosterone are associated with
12 multiple risks to the physical and mental health of the patient.

13 147. "Studies of transgender males taking testosterone have shown up to a nearly 5-
14 fold increased risk of myocardial infarction relative to females not receiving testosterone"
15 (Laidlaw et al., 2021; Alzahrani et al., 2019). A female can also develop unhealthy, high levels
16 of red blood cells referred to as erythrocytosis. These high red blood cell counts in young women
17 have been shown to be an independent risk factor for cardiovascular disease, coronary heart
18 disease and death due to both (Gagnon, 1994).

19 148. Other permanent effects of testosterone therapy involve irreversible changes to
20 the vocal cords. Abnormal amounts of hair growth which may occur on the face, chest, abdomen,
21 back and other areas is known as hirsutism. Should the female eventually change her decision
22 to take testosterone, this body hair can be very difficult to remove. Male pattern balding of the
23 scalp may also occur.

24 149. Changes to the genitourinary system include polycystic ovaries and atrophy of the
25 lining of the uterus. The breasts have been shown to have an increase in fibrous breast tissue and
26 a decrease in normal glandular tissue (Grynberg et al., 2010). Potential cancer risks from high
27 dose testosterone include ovarian and breast cancer (Hembree, 2017).

150. According to research regarding testosterone abuse, high doses of testosterone have been shown to predispose individuals towards mood disorders, psychosis, and psychiatric disorders. The “most prominent psychiatric features associated with AAS [anabolic androgenic steroids, *i.e.* testosterone] abuse are manic-like presentations defined by irritability, aggressiveness, euphoria, grandiose beliefs, hyperactivity, and reckless or dangerous behavior.

151. Other psychiatric presentations include the development of acute psychoses, exacerbation of tics and depression, and the development of acute confusional/delirious states (Hall, 2005). Moreover, “[s]tudies... of medium steroid use (between 300 and 1000 mg/week of any AAS) and high use (more than 1000 mg/week of any AAS) have demonstrated that 23% of subjects using these doses of steroids met the DSM-III-R criteria for a major mood syndrome (mania, hypomania, and major depression) and that 3.4% — 12% developed psychotic symptoms” (Hall, 2005).

e. Adverse Health Effects of Supraphysiologic Estrogen for Males in GAT

152. The doses of estrogen given to males for GAT are high and may vary from two to eight or more times higher than normal adult male levels. This produces the endocrine condition called hyperestrogenemia. Long-term consequences include increased risk of myocardial infarction and death due to cardiovascular disease (Irwig, 2018). Also “[t]here is strong evidence that estrogen therapy for trans women increases their risk for venous thromboembolism¹ over 5 fold” (Irwig, 2018).

153. Breast cancer is a relatively uncommon problem of the male. However, the risk of a male developing breast cancer has been shown to be 46 times higher with high dose estrogen (Christel *et al.*, 2019).

154. It is clear that supraphysiologic doses of either testosterone for the female or estrogen for the male can have detrimental health consequences. This is only now being borne out in the literature for adults. However, as more children and adolescents are put on these

¹ Venous thromboembolism is a blood clot that develops in a deep vein and “can cause serious illness, disability, and in some cases, death” (CDC, 2022).

1 medications one would expect these consequences to become more frequent and to occur earlier
2 in their lives.

3 **f. Adverse Effects of Mastectomy GAT**

4 155. Mastectomies are the surgical removal of the breasts. The procedure is used in
5 GAT in an attempt to make the chest appear more masculine. The surgery results in a permanent
6 loss of the ability to breastfeed and significant scarring of 7 to 10 inches. The scars are prone to
7 widening and thickening due to the stresses of breathing and arm movement. Other potential
8 complications include the loss of normal nipple sensation and difficulties with wound healing
9 (American Cancer Society, 2022).

10 156. It is important to note that this operation cannot be reversed. The person will
11 never regain healthy breasts capable of producing milk to feed a child (Mayo Clinic, Top Surgery,
12 2022).

13 157. Another important consideration is that compared to the removal of an unhealthy
14 gallbladder or appendix, in the case of gender dysphoria the breasts are perfectly healthy and
15 there is no organic disease process such as a cancer warranting their removal. The future person
16 who later desists is left with regret about what happened to her at an age before she could provide
17 true informed consent. Functioning breasts cannot be created by a surgeon and restored to a
18 patient in case of regret. She is left with permanent injury and loss of function with respect to
19 her breasts.

20 **g. Adverse Effects of GAT Surgeries of the Female Pelvis and**
21 **Genitalia**

22 158. Other types of surgery for females include those of the genitalia and reproductive
23 tract. For example, the ovaries, uterus, fallopian tubes, cervix, and vagina may be surgically
24 removed. Removal of the ovaries results in sterilization.

25 159. Importantly, removing female body parts does not produce a male. Rather, the
26 female has had sex specific organs permanently destroyed with no hope of replacement.
27

160. There have also been attempts to create a pseudo-penis. This procedure is known as phalloplasty. It is not possible to de novo create a new human penis. Instead, a roll of skin and subcutaneous tissue is removed from one area of the body, say the thigh or the forearm, and transplanted to the pelvis. An attempt is made to extend the urethra or urinary tract for urination through the structure. This transplanted tissue lacks the structures inherent in the male penis which allow for erection; therefore, erectile devices such as rods or inflatable devices are placed within the tube of transplanted tissue in order to simulate erection (Hembree, 2017). The labia may also be expanded to create a simulated scrotum containing prosthetic objects to provide the appearance of testicles.

161. Complications may include urinary stricture, problems with blood supply to the transplanted roll of tissue, large scarring to the forearm or thigh, infections including peritonitis, and possible injury to the sensory nerve of the clitoris (Mayo Clinic, Masculinizing Surgery, 2022).

h. Adverse Effects of GAT Surgeries on the Male

162. GAT surgeries for the male include removal of the testicles alone to permanently lower testosterone levels. This is by nature a sterilizing procedure. Further surgeries may be done in an attempt to create a pseudo-vagina which is called vaginoplasty. In this procedure, the penis is surgically opened and the erectile tissue is removed. The skin is then closed and inverted into a newly created cavity in order to simulate a vagina. A dilator must be placed in the new cavity for some time so that it does not naturally close.

163. Potential surgical complications may include urethral strictures, infection, prolapse, fistulas, and injury to the sensory nerves with partial or complete loss of erotic sensation (Mayo Clinic, Feminizing Surgery, 2022).

C. Life Threatening Physical Medical Conditions Versus Suicidal Ideation

164. *According to both Dr. Ettner and Dr. Karasic, the denial of gender affirmative care to transgender people results in the prolonging of their gender dysphoria, and causes*

1 *additional distress and other health risks, such as depression, posttraumatic stress disorder,*
2 *and suicidality.* Karasic Report, ¶ 57; Ettner Report, ¶ 65-66.

3 165. It is important to contextualize gender dysphoria and the need to balance the
4 potential advantages and disadvantages of GAT.

5 166. Any child or adolescent who has suicidal ideation or has attempted suicide should
6 receive immediate, appropriate psychiatric care. Psychologists and psychiatrists are trained in
7 the recognition and treatment of suicidal ideation and prevention of suicide.

8 167. A child or adolescent with gender dysphoria who also has suicidal ideation should
9 not be treated any differently. They require compassionate care and a full psychological
10 evaluation of comorbidities such as depression, anxiety, and self-harming behaviors.

11 168. However, suicidal ideation or attempts are categorically different than other life-
12 threatening situations, such as a rapidly expanding brain tumor or a severe infection. In these
13 situations, a medication or a surgery is used to stop the progression of an organic physical
14 condition. In contrast, the danger to the self with suicidal ideation relates to a condition of the
15 mind.

16 169. Gender affirmative therapy does not treat any life-threatening physical condition.
17 In fact, it creates a number of new medical conditions as described above. It is also not an
18 appropriate treatment for suicidal ideation. Neither puberty blocking medications, nor
19 testosterone, nor estrogen have been FDA approved for suicide prevention. Moreover, the
20 hormone imbalances generated by the medications used in GAT may actually increase
21 psychological conditions that lead to suicidal ideation and completed suicide.

22 **D. Informed Consent**

23 170. According to Dr. Karasic, *“[a]s part of the treatment process for gender*
24 *dysphoria, patients provide informed consent to their care. In addition, a treating doctor will*
25 *not offer gender-affirming medical treatments unless they have concluded after weighing the*
26 *risks and benefits of care that treatment is appropriate. The risks and benefits of care are*
27 *discussed with the transgender patient, who must assent.”* Karasic Report, ¶ 50.

171. Any person who is to take a medication, undergo a surgical procedure, or have a psychological intervention should understand the risks and benefits before proceeding. A discussion of these risks and benefits should be provided by medical professionals and then the person of sufficient intellectual capacity and maturity can consent to the treatment.

172. However, difficulties arise when a minor is involved in the process of medical decision-making. Their intellect, emotions, and judgment are not fully developed and they are not capable of fully appreciating permanent, life altering changes such as described above. Therefore, they cannot provide informed consent. Naturally, they may sometimes “assent” to a procedure or medication with a parent or guardian making the final decision.

173. With respect to GAT, in my opinion, it is not possible for the parent or guardian to make a true informed consent decision for the child because of the poor quality of evidence of benefit, the known risks of harm, and the many unknown long-term risks of harm which could only truly be known after years and decades of gender affirmative therapy. A parent or guardian cannot consent to dubious treatments which result in irreversible changes to their child’s body, infertility, sexual dysfunction, and in many cases eventual sterilization.

174. Because this age group is still undergoing brain development and they are immature with respect to intellect, emotion, judgment, and self-control, in my professional opinion there is a significant chance a young person may later regret the irreversible bodily changes that result from hormones or from removing an organ or organs that will no longer function and cannot be replaced.

175. Adolescents are more prone to high-risk behavior and less likely to fathom the risks and consequences of these decisions (Steinberg, 2008).

E. Assessment of the Patient with Gender Dysphoria

176. According to Dr. Ettner, *“[o]nce a diagnosis of gender dysphoria is established, individualized treatment should be initiated. Without treatment, individuals with gender dysphoria experience anxiety, depression, suicidality, and other attendant mental health issues*

1 *and are often unable to adequately function in occupational, social, or other areas of life.”*

2 Ettner Report, ¶ 32.

3 177. Unfortunately, too often there is a rush to GAT before essential criteria are applied
4 to determine a course of treatment based on a complete understanding of the patient’s diagnosis
5 and needs. In light of the very serious medical concerns and potential harms of gender
6 affirmative therapy, there are several criteria that are important to fulfill before applying the GAT
7 model to a patient:

- 8 • Patients should be evaluated to determine if they will follow the natural pattern of
9 desistance which 50 to 98% of pediatric age children will follow.
- 10 • Patients, parents, and guardians should be made aware of other options for treatment of
11 gender dysphoria including active psychosocial treatment or watching and waiting with
12 support in order to accommodate natural desistance.
- 13 • The patient should be provided an assessment by a qualified psychologist or psychiatrist
14 who does not follow the WPATH GAT model. If underlying psychological conditions are
15 diagnosed then these should be adequately evaluated and treated before proceeding to
16 hormones and surgery.
- 17 • If a medicalized approach with hormones such as testosterone or medications to stop
18 menstruation is being considered then a clear description of the risks and benefits needs to
19 be conveyed to the minor and the parent or guardian. It needs to be verified that they fully
20 understand these risks.
- 21 • If surgical procedures such as mastectomy, hysterectomy, ovariectomy, orchiectomy, or
22 vaginoplasty are being considered then clear descriptions of the risks and benefits need to
23 be conveyed to the minor and the parent or guardian.

24 178. However, even if a minor and their parents or guardian are made fully aware of
25 the risks and benefits of hormones and surgeries, in my opinion, the minor does not have adequate
26 maturity and judgment to make permanent changes to their body that may result in
27

1 infertility/sterility and the permanent loss of organs such as breasts whose functions will not be
2 fully utilized (such as breastfeeding) until adulthood.

3 **F. C.P.'s Medical Care**

4 179. According to Dr. Ettner, *“with the support of parents and extended family, C.P.*
5 *was able obtain the medically necessary care he required, thereby avoiding the negative*
6 *sequelae of female puberty and attendant menses and unwanted secondary sex*
7 *characteristics.”* Ettner Report, ¶ 77. According to Dr. Karasic, *“the 2019 BlueCross*
8 *BlueShield Medical Policies Gender Reassignment Surgery and Related Services for Children*
9 *and Adolescents . . . states that puberty-suppressing hormones or masculinizing hormones, as*
10 *well as chest surgery for transmasculine individuals, may be considered medically necessary,”*
11 *and in his opinion, “[t]hese treatments were medically necessary for C.P.”* Karasic Report at
12 ¶ 76.

13 180. In my professional opinion, it is not possible to make a single, categorical
14 statement about the proper treatment of minors presenting with gender dysphoria. A provider
15 cannot reasonably opine on the proper treatment of a particular minor presenting with gender
16 dysphoria unless he or she has had more than one working sessions with the minor and has taken
17 a thorough developmental history of the minor's gender-related issues before attempting to
18 decide on a course of therapy for that individual.

19 181. For these reasons, in my professional opinion, an irreversible chest reconstruction
20 surgery should not have been performed on minor C.P. Based on the studies and research cited
21 above, in my professional opinion there is insufficient quality of evidence at this time
22 demonstrating the benefit of bilateral mastectomy with chest wall recontouring surgery on
23 individuals diagnosed with gender dysphoria in any age group. For those under 21, there is an
24 additional reason to avoid irreversible procedures: there are no laboratory, imaging, or other
25 objective tests to predict whether a young person with gender dysphoria will outgrow this
26 condition. Because this age group is still undergoing brain development and as such, they are
27 immature with respect to intellect, emotion, judgment, and self-control, in my professional

1 opinion this means there is a significant chance that a young person may later regret removing
 2 an organ that cannot be replaced. Thus, in my professional opinion, it is never appropriate to
 3 provide bilateral mastectomy with chest wall recontouring surgery on individuals diagnosed with
 4 gender dysphoria, particularly those under the age of 21. In my opinion, a substantial percentage
 5 of physicians would agree. The following summarizes my specific concerns.

6 182. None of the reports offered by Plaintiffs' experts address whether any of the steps
 7 I have identified above were undertaken before a course of GAT was started. There is no mention
 8 of any psychiatric evaluation. *See* Ettner Report, ¶ 77; Karasic Report at ¶¶ 66-77.

9 183. Based on the declarations, depositions, and medical records I reviewed, there is
 10 insufficient evidence to establish that C.P.'s psychiatric issues have been thoroughly evaluated
 11 and adequately treated by a qualified psychiatrist or clinical psychologist.

12 184. Depression, if not properly treated before surgery, may result in an increase in
 13 morbidity and mortality post-surgery: "Several studies reported increased rate of postoperative
 14 infections in patients suffering from depression." With respect to depression treatment for
 15 patients before major surgery, where it is "[n]on-alleviated, it may predict increased morbidity
 16 and mortality after the operation. It may be associated with greater postoperative pain, higher
 17 incidence of postoperative infections, progression of malignant tumors, poor health-related
 18 quality of life as well as other complications." Ghoneim & O'Hara, "Depression and
 19 Postoperative complications: an overview," *BMC Surg.* 2016; 16:5 (Feb. 2, 2016).

20 **Medical course and complications**

21 185. All three expert reports refer to Endocrine Society's 2017 guidelines (ESG) as an
 22 exemplary model for gender affirmative therapy. **"A clinical practice guideline from the
 23 Endocrine Society (the Endocrine Society Guideline) provides similar protocols for the
 24 medically necessary treatment of gender dysphoria. (Hembree et al., 2017)." Karasic
 25 Expert Report ¶ 27. "The Endocrine Society—the leading professional organization devoted
 26 to research on hormones and the clinical practice of endocrinology—has also issued clinical
 27**

1 **guidelines for the treatment of transgender individuals.”** Schechter Expert Report, ¶ 26. Dr.
2 Ettner also references the same guidelines. Ettner Expert Report 2022, ¶ 34.

3 186. However, Dr. Hatfield’s consult and progress notes from the medical records
4 provided do not refer to the Endocrine Society’s guidelines at all. He notes that he had been a
5 member of WPATH and does refer to a “standard of care”—apparently WPATH’s—in several
6 places in his deposition (Hatfield Deposition, p. 20, 54, 57). However, there is no reference to
7 the Endocrine Society’s 2009 or 2017 guidelines.

8 187. This is very unfortunate because the 2017 ESG emphasize the critical importance
9 of a mental health evaluation, particularly for children and adolescents: “Because of the
10 psychological vulnerability of many individuals with GD/gender incongruence, it is important
11 that mental health care is available before, during, and sometimes also after transitioning. For
12 children and adolescents, a mental health provider (“MHP”) who has training/experience in child
13 and adolescent gender development (as well as child and adolescent psychopathology) should
14 make the diagnosis, because assessing GD/gender incongruence in children and adolescents is
15 often extremely complex.” (Hembree et al., 2017)

16 188. Indeed, the 2009 ESG guidelines (which were available when Dr. Hatfield first
17 started C.P. on puberty blockers) specifically state that a qualified mental health professional
18 (MHP) should make the diagnosis of gender dysphoria (at that time referred to as gender identity
19 disorder, or GID): “Because GID may be accompanied with psychological or psychiatric
20 problems, it is necessary that the clinician making the GID diagnosis be able 1) to make a
21 distinction between GID and conditions that have similar features; 2) to diagnose accurately
22 psychiatric conditions; and 3) to undertake appropriate treatment thereof. Therefore, the SOC
23 guidelines of the WPATH recommend that the diagnosis be made by an MHP. For children and
24 adolescents, the MHP should also have training in child and adolescent developmental
25 psychopathology” (Hembree et al., 2009). Note that the ESG refers directly to WPATH’s
26 guidelines recommending that “the diagnosis be made by a MHP” and also that “the MHP should
27 also have training in child and adolescent developmental psychopathology.”

1 189. From the available records, there is no evidence that Dr. Hatfield consulted with
2 a qualified psychiatrist or psychologist prior to initiating puberty blocking medications or
3 testosterone. Although Dr. Hatfield's initial note of 9/27/16 states, "Ongoing recommendations
4 for continued counseling strongly reinforced today," there is no evidence that C.P. was being
5 seen by a qualified psychiatrist or psychologist.

6 190. With regards to future fertility, the guideline states, "We recommend that all
7 transsexual individuals be informed and counseled regarding options for fertility prior to
8 initiation of puberty suppression in adolescents and prior to treatment with sex hormones of the
9 desired sex in both adolescents and adults" (*Id.*) However, in the medical records, prior to
10 initiating puberty-blocking medication, there is only a single reference to a discussion of fertility
11 during the patient's initial visit. It is unclear what a child of age 11 would be able to comprehend
12 during this single first visit with respect to the complex issues of attempting to preserve fertility
13 and had not yet undergone puberty.

14 191. Regarding follow up after initiating blocking of normal pubertal development, the
15 ESG state: "[T]his protocol [of suppression of pubertal development] requires a MHP skilled in
16 child and adolescent psychology to evaluate the response of the adolescent with GID after
17 pubertal suppression" (*Id.*, p 3140). There is no evidence in the medical records that a qualified
18 MHP evaluated C.P. after pubertal suppression was initiated and continued.

19 192. The ESG very explicitly state that puberty blocking medications should not be
20 started before puberty has begun (Tanner stage 2): "We recommend that suppression of pubertal
21 hormones start when girls and boys first exhibit physical changes of puberty, but no earlier than
22 Tanner stages 2–3." *Id.* at 3133.

23 193. This is consistent also with WPATH's recommendation: "Adolescents may be
24 eligible for puberty suppressing hormones as soon as pubertal changes have begun. In order for
25 adolescents and their parents to make an informed decision about pubertal delay, it is
26 recommended that adolescents experience the onset of puberty to at least Tanner Stage 2."
27 (WPATH SOC, 2011, p. 18).

1 194. The Tanner stage of pubertal development is assessed by physical exam of the
2 body. A description of the physical findings would be found in the physical exam description of
3 the clinical notes. For the female this would involve a description of the breasts and genitalia.
4 From these findings an assessment of the Tanner stage is made. For example, a Tanner stage 2
5 description would describe “breast buds palpable beneath the areola” (Emmanuel and Boker,
6 2022).

7 195. However, in the initial consult visit, Dr. Hatfield did not describe the breasts at
8 all, nor a description of the genitals. He jumped to an assessment which states: “Phenotype
9 Tanner 2.” Therefore, it is not clearly stated to what degree the C.P. had breast development, if
10 at all, at that time, because there is no physical exam description. However, on a subsequent visit
11 dated 05/22/17, the physical exam states “no breast budding noted,” which would indicate that
12 there had been no breast development at all up to that point. This is consistent with Tanner 1
13 staging, which is prepubertal. Therefore, it appears that Dr. Hatfield had begun pubertal
14 suppression at Tanner stage 1, which was not advised by either the ESG or even the WPATH’s
15 SOC.

16 **Testosterone**

17 196. As for starting hormones of the opposite sex, the ESG also have a number of
18 criteria to be fulfilled. The first is that a qualified MHP has confirmed (a) “the persistence of
19 gender dysphoria”; (b) that “any coexisting psychological, medical, or social problems that could
20 interfere with treatment ... have been addressed, such that the adolescent’s situation and
21 functioning are stable enough to start sex hormone treatment”; (c) “the adolescent has sufficient
22 mental capacity (which most adolescents have by age 16 years) to estimate the consequences of
23 this (partly) irreversible treatment, weigh the benefits and risks, and give informed consent to
24 this (partly) irreversible treatment” (Hembree et al., 2017). The medical records do not show
25 that C.P. had seen a qualified MHP who had ensured that any of these criteria were met prior to
26 initiating testosterone treatment.

197. The ESG also recommend that “a pediatric endocrinologist or other clinician experienced in pubertal induction: agrees with the indication for sex hormone treatment, has confirmed that there are no medical contraindications to sex hormone treatment” (*Id.*) This does not appear to have happened either.

Absence of a proper diagnosis of gender dysphoria

198. Gender dysphoria was not diagnosed by a MHP and was also not entered into the medical record as a diagnosis by Dr. Hatfield in his initial consult. Instead, the consult visit of 9/27/16 states “No diagnosis found” in the assessment section. The 5/22/17 visit has a diagnosis of “Hormone deficiency - Testosterone?” It is not clear on what basis he has diagnosed a testosterone deficiency. The diagnosis in the assessment of 02/28/18 is “Hormone deficiency.”

199. It seems that the only time that Dr. Hatfield has used the diagnosis of gender dysphoria is in conjunction with procedures requiring approval for coverage such as the Vantas implant. In Dr. Hatfield's deposition he states: “We simply include the code of gender dysphoria on the . . . prior authorization request and that is actually what allows it to be covered” (Hatfield Depo, p. 32).

200. Therefore, the procedure note for the Vantas implant on 11/18/16 has the diagnosis of gender dysphoria, but the preceding and following progress notes do not. Also, Dr. Hatfield’s letter for surgery on 05/29/19 states that there has been a “long-standing medical diagnosis of gender dysphoria/transgender identity (F64.0)”;

however, the preceding date of service 02/18/19, and date of service following the letter 07/11/19, do not have gender dysphoria as a diagnosis in the assessment and plan.

Estradiol promotes breast tissue growth

201. On 6/9/18, Dr. Hatfield prescribed estradiol “to improve bone growth.” But what is significant for C.P. is that estradiol will cause breast tissue growth. Testosterone can also cause breast tissue growth by conversion to estrogen. There is no further record of a breast exam by Dr. Hatfield leading up to the time of his 05/29/19 letter to the surgeon Dr. Kylo. Given that

1 the patient was receiving estrogen and testosterone, it would have been important to monitor
2 development of the patient's chest and breast development.

3 202. As noted previously, Dr. Hatfield's 05/22/17 physical exam of C.P. states "no
4 breast budding noted" indicating there had been no breast development. But by the time C.P. had
5 seen the surgeon Dr. Kylo for consult on 04/30/2019, Dr. Kylo's physical exam describes:
6 "Very small breasts with minimal development." In my opinion, Dr. Hatfield's prescription of
7 estradiol in addition to testosterone led C.P. to progress from having no breast budding at all to
8 small minimally, developed breasts.

9 **Major discrepancy in breast size description**

10 203. On 5/29/19, Dr. Hatfield wrote a letter to Dr. Kylo regarding C.P. In the letter,
11 Dr. Hatfield describes a "severe case of gynecomastia" and "extremely large
12 breasts/gynecomastia." Again, in contrast to Dr. Hatfield's description, Dr. Kylo in his initial
13 consult note describes "[v]ery small breasts with minimal development."

14 204. It appears to me that Dr. Hatfield grossly exaggerated the size of the patient's
15 breasts. Further supporting evidence for this is found in the pathology report of 12/19/19
16 (Pritchard POL, 56). The right breast tissue was described as "8 x 4 x 2 cm" which equates to a
17 volume of 64 cubic cm (64 ml). The left breast tissue was described as "9.5 x 5 x 2 cm which
18 equates to a volume of 95 cubic cm (95 ml)".

19 205. However, the average volume of breast tissue after mastectomy has been shown
20 to be 623.5 ml with a range of 150-1490 ml (Kayar et al., 2011). Therefore, C.P.'s breast size
21 has been confirmed by pathology exam to be very considerably below average and even below
22 the lowest reference range for adult females, which contradicts Dr. Hatfield's description.

23 **Informed Consent**

24 206. Dr. Hatfield has been a member of WPATH and follows the WPATH model.
25 According to WPATH, before initiating medical treatment it is important that "[t]he adolescent
26 has given informed consent and, particularly when the adolescent has not reached the age of
27 medical consent, the parents or other caretakers or guardians have consented to the treatment and

1 are involved in supporting the adolescent throughout the treatment process.” SOC WPATH p
2 25.

3 207. As to informed consent for puberty blockers, there is no signed documentation
4 regarding benefits, adverse effects or alternatives, and so it is not clear as to exactly what C.P.
5 and parents were informed of regarding the numerous side effects of PB. There also does not
6 appear to be any alternative presented to C.P. such as watching and waiting with support to see
7 if the patient desists or active psychotherapy with a non-biased, non-WPATH psychologist or
8 psychiatrist.

9 208. With respect to testosterone, the ESG state that it is essential that “the adolescent
10 has sufficient mental capacity (which most adolescents have by age 16 years) to estimate the
11 consequences of this (partly) irreversible treatment, weigh the benefits and risks, and give
12 informed consent to this (partly) irreversible treatment” (Hembree et al., 2017).

13 209. There is no indication that C.P. had been assessed by a qualified MHP to assess
14 for sufficient mental capacity to estimate the consequences and weigh the benefits and risks of
15 testosterone.

16 210. The patient’s mother signed the testosterone consent form on 2/28/18, two days
17 after the patient turned 13. Although Mrs. Pritchard initialed next to the statement “My medical
18 provider has discussed my questions and concerns with me” and signed that day, the provider’s
19 signature is dated 18 days later, and calls into question the provider’s availability to answer any
20 questions and concerns on 2/28/18.

21 211. The ESG also recommends that the adolescent “has been informed of the
22 (irreversible) effects and side effects of treatment (including potential loss of fertility and options
23 to preserve fertility)” (Hembree et al., 2017, p. 3878).

24 212. The consent form for testosterone from The Polyclinic states under risks and side
25 effects: “Possible loss of fertility; you may not be able to get pregnant after being on testosterone
26 therapy for some time; how long this might take to be a permanent effect is unknown. Some
27 persons choose to harvest and bank eggs before starting on testosterone therapy” (Pritchard POL,

1 117). It goes to say that “[o]ther effects of testosterone on the ovaries and on developing eggs
2 are not fully known.” *Id.*

3 213. Infertility or permanent sterilization are drastic long-term consequences that are
4 difficult for a person just turning 13 to comprehend. C.P. had not had enough time and maturity
5 to grasp this complication. Thirteen-year-old girls are generally not thinking about their future
6 family planning as they are still children themselves under the care of another. It is known that
7 fertility preservation is very low in this age group, being less than 5%. It would also be difficult
8 to understand the complex, physically and emotionally difficult procedure of egg preservation.
9 Also, because C.P. appeared to have been pre-pubertal at the initiation of puberty blockers, C.P.
10 by definition had immature eggs which would require advanced and expensive fertility
11 techniques of uncertain outcome for ovum preservation (Laidlaw, Cretella, et al., 2019 AJOB).

12 214. With respect to cardiovascular disease, the consent form states: “Possible changes
13 in cholesterol, higher blood pressure and other changes to the body that might lead to an increased
14 risk of cardiovascular disease (heart attacks, strokes and blockages in the arteries” (Pritchard
15 POL, 117). These risks are important as they were amplified in C.P.’s cases by combining
16 testosterone with estrogen and by an increase in C.P.’s red blood cell count which will be
17 discussed further below.

18 215. Other portions of the consent form point to the still experimental nature of using
19 high dose testosterone on young females. For example, “all of the long-term consequences and
20 effects of hormone therapy may not be fully understood.” *Id.* “The effects of hormones on the
21 brain are not fully understood” *Id.* “Some trans men, after being on testosterone for a number of
22 months, may develop pelvic pain; often this will go away after some time, but it may persist; the
23 cause of this is not known.” *Id.*

24 216. There is no discussion of alternatives such as watching and waiting to follow a
25 natural course of desistance or active psychotherapy to help with potential mental health issues
26 such as ADHD or family or school issues that may be affecting C.P.’s mental health. There is a
27 statement, “Hormone therapy is not the only way that a person may appear more masculine and

1 live as a male, your medical provider and/or a mental health provide can help you think about
2 these other options.” *Id.* at 118. However, there is no discussion of what these other options
3 are.

4 217. The consent form states that “[t]he effect on the risk of breast, uterine and ovarian
5 cancer is not any higher than the background occurrence for people with these body organs.” *Id.*
6 at 117. However, the ESG state that the patient should be prepared for a potential total
7 hysterectomy for cancer prevention: “Although there is limited evidence for increased risk of
8 reproductive tract cancers in transgender males, health care providers should determine the
9 medical necessity of a laparoscopic total hysterectomy as part of a gender affirming surgery to
10 prevent reproductive tract cancer,” including ovariectomy “after the completion of hormone
11 transition” (Hembree et al., 2017, p. 3892, 3890).

12 218. This drastic, sterilizing procedure for a young person is not mentioned in the
13 consent form. This is particularly concerning given the fact that Dr. Hatfield commented in his
14 progress note that C.P.’s “mom has a strong history of ovarian cancer on her side of the family .
15 . . His mom is wondering if there is anything [C.P.] needs to do for testing/prevention” (Pritchard
16 POL, 15). The ESG adds that “Studies have reported cases of ovarian cancer” (Hembree, 2017).
17 But no particular guidance from Dr. Hatfield regarding these serious issues are found in the
18 medical record.

19 **Mastectomy**

20 219. In contrast to the many criteria listed prior to initiating PB or opposite sex
21 hormones in the ESG, there is little guidance and no evidence presented as to the benefits of
22 mastectomy specifically for the minor.

23 220. However, analogously, the ESG advise that before initiating testosterone for the
24 minor, it is necessary that “a multidisciplinary team of medical and MHPs has confirmed the
25 persistence of GD/gender incongruence and sufficient mental capacity to give informed consent.”
26 It follows that for something as permanently altering as surgical removal of organs, such as the
27

1 breasts, a patient should be seen by a psychiatrist or psychologist to assess for “sufficient mental
2 capacity to give informed consent.”

3 221. This did not happen here. Instead, C.P. saw Sharon Booker who is a licensed
4 mental health counselor for a one-hour evaluation and who produced an assessment letter dated
5 07/24/19 (Pritchard CFT, 3-4). There is no mention in the letter that C.P. had sufficient mental
6 capacity to provide informed consent. There is also no discussion of the fact that C.P. was 14
7 and had not reached the age of majority.

8 222. In Dr. Schechter’s declaration, he states that “[f]or individuals seeking male chest
9 reconstruction, the criteria are: The patient has the capacity to make fully informed decisions and
10 to consent for treatment.” (Schechter depo, p. 11). Again, from the records it does not appear that
11 C.P. had an adequate assessment by a qualified psychiatrist or psychologist prior to signing a
12 consent form for the mastectomy procedure.

13 223. C.P. was only 14 years old when C.P. signed the consent form for a bilateral
14 mastectomy surgery on 12/10/19 (Pritchard POL, 139). Nolle Pritchard signed as a witness. The
15 surgeon, Dr. Kylo, did not sign the form. It is not clear to what degree he was involved (if at
16 all) in the informed consent process. As part of the consent for surgery there is a listing of
17 “Surgical Risks and Advisories.” There is no listing of the complication that the patient would
18 be unable to breastfeed. Nor is there evidence of a discussion with the patient by the involved
19 clinicians of this problem, nor could C.P. have had sufficient capacity at that age to fully
20 appreciate the future ramifications of such a complication.

21 **Difficulty in assessing C.P.’s complete hormonal and medical condition given**
22 **absence of labwork provided in the record**

23 224. Although Dr. Hatfield’s medical records refer to labwork on multiple occasions,
24 these have not been provided and therefore cannot be assessed.

25 225. The following are quotes from the medical record by visit date and for which
26 corresponding labwork was not provided as part of the record:

- 27
 - 09/27/16 “Baseline blood work ... have been discussed and ordered today.”

- 1 • 11/08/16 “First blood work to be repeated in 6 months. This checks the efficacy of the
- 2 implant.”
- 3 • 05/22/17 “Return to clinic sometime in the Fall (Oct 31-Jan 1) for repeat blood work.”
- 4 • 02/28/18 “Please have blood work done in 3 to 3.5 months (early June).”
- 5 • 06/09/18 “Please call the family and inform the testosterone values very good at 76.
- 6 • 08/14/18 “return around November 2018 for his next set of blood work.”
- 7 • 02/18/19 “We will send you the results of your labs from today. - We may increase your
- 8 dose based on these results.”
- 9 • 07/11/19 “I will contact you with your lab results from today.”

10 226. The absence of laboratory records makes assessing C.P.’s complete hormonal and
11 medical condition difficult.

12 **Side effects of puberty blocking medication**

13 227. In my opinion, the patient developed side effects of puberty blocking medication
14 as evidenced in Dr. Hatfield’s medical records. “He is getting headaches almost every day and
15 this is new since the hormone blocker was placed.” DOS 02/28/18. “His mother notes he is a
16 lot less active than he was when he was younger. She is wondering if this is related to low
17 hormone levels.” DOS 02/28/18. The Vantas implant labeling describes both headaches and
18 fatigue as side effects (Vantas implant labeling, table 1). Rather than stopping puberty blockers
19 because of headaches and fatigue, C.P. was given a prescription for testosterone cream.

20 **Side effects of estrogen and the conversion of testosterone to estrogen**

21 228. Another side effect of estrogen is vaginal spotting which is found as a diagnosis
22 in the consult note of Dr. Kylo on 4/30/19. This indicates development of the endometrial lining
23 of the uterus. Typically, this would be prevented by the addition of progesterone. The
24 administration of progesterone is also important for the long term prevention of endometrial
25 cancer. Dr. Hatfield does not appear to have prescribed progesterone at any time.

26 229. Testosterone was prescribed to be taken simultaneously with the estradiol
27 medication. As an endocrinologist I am concerned that both hormonal medications were being

1 used off label and in combination. This combined use has not been studied to my knowledge
2 and would be considered high risk. As discussed previously, warnings for both estradiol and
3 testosterone included thrombosis (blood clots which may be deadly such as clots of the lungs).

4 **Chronic high dose testosterone**

5 230. The progress notes indicate the initiation of a testosterone cream, later followed
6 by testosterone injections. Again, the Endocrine Society Guidelines provide no evidence for why
7 any particular dose should be given to females. However, one can see from the limited labwork
8 provided that the dose was exceedingly high.

9 231. The normal reference range for testosterone for adult females depending on the
10 lab is about 10 to 50 ng/dL. For adolescents, the range is lower. On 12/16/20 C.P.'s testosterone
11 level was 227 ng/dL. A simple calculation shows that this was 4.5 to 23 times higher than an
12 adult female level. On 6/24/21, C.P.'s testosterone level was 443. This was approximately 9 to
13 44 times higher than an adult female level. This is evidence that C.P. had been receiving
14 chronically high levels of testosterone leading to hyperandrogenism. High testosterone levels
15 can result in erythrocytosis.

16 232. Erythrocytosis is a condition in which the blood contains abnormally high
17 amounts of red blood cells. This can be detected by doing blood tests of hematocrit.

18 233. "Current guidelines on the management of secondary erythrocytosis in trans men
19 on testosterone therapy refer to the guideline for testosterone-treated hypogonadal cis men and
20 consider hematocrit levels > 0.509 [50%] L/L as potentially dangerous, as it has a very high risk
21 of adverse outcome " (Madsen, 2021). This was written by a team in favor of transitioning and
22 in their estimation a hematocrit level above 50% is potentially dangerous. We have written a
23 response letter to this study in JCEM. In our letter we state that for females who identify as trans
24 males, physicians should use the normal female range of hematocrit as levels above the female
25 range have been shown to be an independent risk factor for heart disease and death due to heart
26 disease (Laidlaw et al, 2021).

1 234. For adult women, the normal hematocrit range is 35.5 to 44.9 percent. On
2 12/16/2020, the hematocrit level was elevated above the adult female reference range at 45.5 as
3 a result of very high dose testosterone. This is consistent with the development of erythrocytosis.

4 235. We can see from this that over time the patient had developed erythrocytosis,
5 meaning harmful high red blood cell levels due to chronic high dose testosterone. This exposes
6 C.P. to increased long-term cardiovascular risk and other possible unknown harms. This serious
7 problem does not appear to have been assessed or addressed adequately by Dr. Hatfield.

8 236. Erythrocytosis was not written as a diagnosis in any problem list. There is no
9 differential diagnosis to determine if there are other causes or factors such as breathing
10 difficulties could have contributed to this problem. There is no discussion of either stopping
11 testosterone injections or lowering the dose to help treat the condition. There are also no follow
12 up labs available to track this problem.

13 **Mental Health**

14 237. C.P. had undergone a psychological evaluation at age 16 years and 7 months by
15 the psychologist Steve Tutty, MA, PhD. This was after having been on puberty blockers followed
16 by high dose testosterone for nearly five years. C.P. has developed serious issues with anger as a
17 result of chronic high dose testosterone. “‘Sometimes I will be angry for no reason.’. . . This
18 agitation typically manifests in [C.P.] yelling at his mom and dad. ‘I also burst out on my
19 friends.’ [C.P.’s] mother stated they are ‘walking on eggshells at home.’” (PLA, 3066).

20 238. C.P.’s mood was assessed using the Beck Youth Inventories. Dr. Tutty states that
21 C.P.’s “endorsements resulted in a mildly elevated indication of anger problems.” However, this
22 is likely to be an underestimation of C.P.’s actual level of anger, because the diagnostic scales
23 are gendered, and Dr. Tutty refers to C.P. as a male rather than a natal female.

24 239. C.P. also experiences significant problems with inattention “with more inattention
25 related symptoms present than for 97 percent” of C.P.’s same aged peers (PLA, 3074). C.P. was
26 diagnosed by Dr. Tutty with attention deficit disorder.

240. Rather than seeing an improvement in the patient's mental health by gender affirmative therapy, it seems to be worsening. In my opinion, this is consistent with adverse psychological effects of puberty blockers followed by chronic high dose testosterone use.

Sterilization

241. C.P. started receiving puberty blockers before puberty had started. C.P.'s ovaries and eggs were by definition in an immature state. C.P. was later placed on high dose testosterone which has the effect of inhibiting the normal communication between the pituitary ovaries, thus "freezing" C.P.'s ovaries in an immature state. Additionally high dose testosterone has unknown, but likely cytotoxic effects on the immature ovaries.

242. There is a very high probability that C.P. has been or will be permanently sterilized by these treatments. The potential reasons are several. 1) The ovaries are locked in an immature state while C.P. takes testosterone; 2) the cytotoxic effects of testosterone on the ovaries; 3) the pituitary is inhibited from communicating with the ovaries from allowing for a normal menstrual cycle and release of an ovum; 4) and, as mentioned above, the ESG have a recommendation for a total abdominal hysterectomy for cancer prevention and ovariectomy after hormone transition which necessarily eliminates any chance of pregnancy (Hembree et al., 2017, p. 3890, p. 3892).

Abnormal sexual function

243. There is a high probability that C.P. will have permanent abnormal sexual function due to the fact that C.P.'s pelvic genitalia were not allowed to develop fully under the influence of the pituitary directing proper estrogenization of the genitalia. Furthermore, high dose testosterone leads to abnormal enlargement of the clitoris and also vaginal atrophy (Hembree et al., 2017).

V. Conclusion.

244. As explained above, there is ongoing debate and study in the medical community regarding gender affirmative treatment. The opinions of Plaintiffs' experts in this matter do not

1 represent the medical consensus. The medical community is divided on many issues related to
2 gender identity and the necessity or value of gender affirmative care.

3 245. The Plaintiffs' experts' opinions, which are substantively the same, do not
4 represent the diversity of opinions in the medical community, nor account for the fact-based
5 inquiry that must occur, in my opinion. Their opinions that the only acceptable path forward
6 that meets the standard of care is the approach endorsed by the WPATH is inconsistent with
7 scientific standards, and diverges from the standard of care for other medical treatments.

8 246. The implication is that if an employer excludes gender affirmative care from
9 coverage, it must be because the employer is prejudiced against transgender individuals is
10 therefore not correct.

11 247. C.P.'s case illustrates the recurring problem that quality of medical care received
12 by minors who undergo irreversible gender-affirming treatments results at least in part because
13 gender dysphoria treatments are so entangled with advocacy. Much of this advocacy comes
14 from WPATH, which not only attempts to do scientific work, but is also as an advocacy
15 organization, and these two objectives are not compatible.

16 248. Based on the materials I have reviewed and in my professional opinion, the
17 treatment of C.P. is indicative of these quality-of-care problems that I have observed.

18 I declare under penalty of perjury under the laws of the State of Washington that the
19 foregoing is true and correct to the best of my knowledge and belief.

20 August 3, 2022, at Brockway, CA.

21
22 By 
23 Michael K. Laidlaw, M.D.

CERTIFICATE OF SERVICE

I certify that on the date indicated below I caused a copy of the foregoing document, EXPERT DECLARATION OF MICHAEL K. LAIDLAW, M.D. to be served on the following attorneys of record:

Eleanor Hamburger
Daniel S. Gross
SIRIANNI YOUTZ SPOONEMORE HAMBURGER
3101 WESTERN AVENUE STE 350
SEATTLE, WA 98121
206-223-0303
Fax: 206-223-0246
Email: ehamburger@sylaw.com
Email: dgross@sylaw.com

Jennifer C Pizer
LAMBDA LEGAL DEFENSE AND EDUCATION FUND, INC
4221 WILSHIRE BLVD., STE 280
LOS ANGELES, CA 90010
213-382-7600
Email: jpizer@lambdalegal.org

Omar Gonzalez-Pagan
LAMBDA LEGAL DEFENSE AND EDUCATION FUND, INC. (NY)
120 WALL STREET
19TH FLOOR
NEW YORK, NY 10005
212-809-8585
Email: ogonzalez-pagan@lambdalegal.org

DATED this 4th day of August, 2022.

Kilpatrick, Townsend & Stockton LLP

By: /s/ Gwendolyn C. Payton
Gwendolyn C. Payton, WSBA #26752
gpayton@kilpatricktownsend.com

Counsel for Defendant Blue Cross and
Blue Shield of Illinois

EXPERT DECLARATION OF
MICHAEL K. LAIDLAW, M.D. - 54

KILPATRICK TOWNSEND 76350748 2

KILPATRICK TOWNSEND & STOCKTON
LLP 1420 FIFTH AVENUE, SUITE 3700
SEATTLE, WA 98101
(206) 626-7713 FAX: (206) 260-8946

EXHIBIT S

**UNITED STATES DISTRICT COURT
WESTERN DISTRICT OF WASHINGTON
AT TACOMA**

Case Number: 3:20-cv-06145-RJB

**C.P., by and through his parents, Patricia Pritchard and Nolle Pritchard;
and PATRICIA PRITCHARD (Plaintiffs)**

v.

BLUE CROSS BLUE SHIELD OF ILLINOIS (Defendant)

EXPERT REBUTTAL REPORT OF SCOTT CARR, PH.D.

October 21, 2022

EXPERT REBUTTAL REPORT OF SCOTT CARR, PH.D.

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EXPERT REBUTTAL REPORT OF SCOTT CARR, PH.D.

I. Introduction and Summary of Opinions

A. Overview of Credentials

I am Scott Carr, Ph.D., a Senior Managing Director and leader of the Competition and Class Actions Practice at Ankura Consulting Group (“Ankura”). I was engaged by the Defendant, Blue Cross Blue Shield of Illinois (“BCBSIL”) to respond to materials prepared by Dr. Frank Fox on behalf of Plaintiffs, C.P., by and through his parents, Patricia Pritchard and Nolle Pritchard; and Patricia Pritchard. Dr. Fox submitted a report (“Fox Report”) on August 19, 2022. He subsequently submitted a short addendum (“Fox Addendum”) on September 29, 2022, in which he updated portions of his data and numerical results.¹ Thus, throughout this report, I primarily refer to Dr. Fox’s report, but I refer to his addendum when discussing the data and results that he updated.

I hold a Ph.D. in Business Administration and in Industrial and Operations Engineering, an M.S.E. in Industrial and Operations Engineering, an M.S.E. in Construction Management and Engineering, and a B.S.E. in Mechanical Engineering. These degrees are from the University of Michigan. In my current position at Ankura, I provide consulting and expert services on a variety

¹ The Fox Addendum contains two tables. The first table, labeled “Updated Table 1,” updates the data and results in Table 4 (not Table 1) of his original report. The second table, labeled “Updated Table 5,” updates the data and results in Table 5 of his original report. Dr. Fox states, “These updates do not affect or change the conclusions set forth in paragraph 17 of my original report.” (Fox Addendum, p. 3)

of economic and engineering topics, including in the context of litigation. To perform these services, I regularly perform complex economic analyses, often using sophisticated computer and analytical tools. Prior to joining Ankura, I was a Director at Navigant Consulting, Inc., a Senior Managing Director at ARPC, a Principal at LECG, and a professor at the UCLA Anderson School of Management in the Department of Decisions, Operations, and Technology Management. As a professor, I taught courses in the areas of Operations Management and Quantitative Analysis to M.B.A. and Ph.D. students and to business executives. I also performed and published research related to Operations Management and Industrial Economics.

I have extensive experience in the analysis and modeling of complex business, financial, and health-related circumstances and events. For example, my prior projects included forecasting the future incidence of diseases and cognitive impairments due to concussions in National Football League players; developing a machine-learning algorithm to predict outcomes of asbestos-related litigation; testimony regarding accommodations for people with physical disabilities; and forecasting of future personal injury liabilities due to environmental contamination. My areas of expertise include probability and statistics, data analytics, and predictive modeling. Exhibit 1 contains my current *curriculum vitae*.

B. Terminology Used in This Report

Dr. Fox uses the terms “transgender” and “transgender and gender diverse,” abbreviated “TGD”, throughout his report. However, the materials on which he relies, as well as the Amended Complaint and Plaintiff C.P.’s Motion for Class Certification (“Motion for Class

Certification”), use the term “transgender” exclusively and appear to disregard gender-diverse people that are not transgender. Thus, I use the term “transgender” exclusively in this report.

I understand that this proceeding relates to ERISA self-funded health plans administered by BCBSIL during the class period that contain some form of exclusion for transgender-related services.² For brevity, I refer to these plans as the “relevant plans” or “relevant Group Plans.” Further, my references to “Group Members” or “enrollees” exclusively refer to people enrolled in the relevant plans.

I use the term “relevant period” to refer to the six-year period from 2016 through 2021 because that is the period covered in Dr. Fox’s analysis.

Dr. Fox and the Plaintiffs are inconsistent in how they refer to the Group Members who sought transgender-related services or who would have sought such services but for exclusions in the relevant Group Plans. For example: (1) in paragraph 3 of his report, Dr. Fox states that these are “TGD persons seeking care”; (2) in paragraph 16 of his report, he refers to them as “insureds who are estimated to have sought gender-affirming care”; (3) in paragraph 17, he refers to them as persons who “would have been expected to seek gender-affirming care”; and (4) the Motion for Class Certification at page 14 refers to them as individuals “likely to seek care” (with no characterization of the type or timing of the care involved). For brevity and consistency, I refer to all such people as Group Members or enrollees who “sought transgender-related services.”

² Motion for Class Certification, p. 4, which defines the class period as “November 23, 2016, through the termination of the litigation.”

Dr. Fox occasionally refers to “medically necessary” transgender-related services (as opposed to all transgender-related services or non-medically necessary transgender-related services). For example, he refers to enrollees “who would be expected to utilize *medically necessary* treatment for gender dysphoria.”³ (italics added) However: (1) Dr. Fox’s report and analyses make no distinction between care that is medically necessary and care that is not; (2) the Quinn Study relied upon by Dr. Fox makes no characterization of whether the transgender-related services studied were medically necessary; (3) Dr. Fox did not review the relevant plans to determine whether or not the exclusions are specifically for medically necessary transgender-related services;⁴ and (4) Dr. Fox is not a medical doctor and did not perform the “extensive literature review” that would be needed for him to opine on which transgender-related services are medically necessary and which are not.⁵ Thus, Dr. Fox’s references to medically necessary transgender-related services are baseless and gratuitous.

C. Summary of Opinions

This report sets forth the conclusions I have reached to date in this proceeding. To summarize, I have reached the following primary conclusions based on my review of Dr. Fox’s report, the documents he cites, other data and documents I reviewed, and factors discussed herein:

³ Fox Report, ¶10. *See also* Fox Report, ¶5 and ¶11.

⁴ Deposition of Dr. Frank Fox, September 12, 2022, pp. 31-35, (hereafter “Fox Deposition”).

⁵ Fox Deposition, pp. 22-23.

1. Dr. Fox's estimates of the number of transgender people enrolled in the relevant Group Plans is misleading and unreliable because Dr. Fox fails to account for the marked uncertainty in the published data upon which he relies, assumes that the prevalence of transgender people in the relevant Group Plans is identical to the prevalence of transgender people in the general population, assumes that all Group Members in these plans reside in Illinois, and failed to exclude duplicate data entries in the data on which he relies.
2. Dr. Fox's estimates of the number of transgender Group Members who sought transgender-related services is methodologically incorrect because Dr. Fox misinterprets, misuses, and overstates the published data upon which he relies. Thus, Dr. Fox's estimate of the number of transgender enrollees who sought transgender-related services is misleading and unreliable.

II. Dr. Fox's Estimated Number of Transgender Enrollees in the Relevant Group Plans

In Updated Table 1 of his addendum,⁶ Dr. Fox estimates the number of transgender enrollees in the relevant plans using a three-step process for each year in the relevant period.⁷ First, he estimates the number of enrollees in the relevant Group Plans using data produced by

⁶ As discussed above, the Fox Addendum contains two tables. The first table, labeled "Updated Table 1," updates the data and results in Table 4 (not Table 1) of his original report. The second table, labeled "Updated Table 5," updates the data and results in Table 5 of his original report.

⁷ Fox Report, ¶¶ 2-15; Fox Addendum, Updated Table 1.

BCBSIL.⁸ Second, he estimates the percentage of individuals who identify as transgender.⁹

Third, he multiplies together the estimates from the first two steps to get his final estimates of the number of transgender enrollees in the relevant plans. Dr. Fox summarizes his estimates as “about 1,740 TGD persons per year were enrolled in one of the BCBSIL affected plans.”¹⁰

Dr. Fox does not address the assumptions and uncertainties underlying his analysis, yet these assumptions and uncertainties call into question the reliability of his estimates. I describe four significant deficiencies in Dr. Fox’s estimates of transgender enrollees below.

A. Uncertainty in the Percentage of Individuals Who Identify as Transgender

Dr. Fox estimates the number of transgender enrollees from the relevant Group Plans enrollment counts by adopting “age-specific population estimates of the proportion of persons who identify as [transgender] to population by age” from a 2022 study conducted by The Williams Institute (“Williams Study”).¹¹ Table 1 below shows the percentage of individuals who identify as transgender by age in Illinois as reported in the Williams Study. Dr. Fox assumes that

⁸ Fox Report, ¶¶ 10-14, Table 3.

⁹ Fox Report, ¶ 15; Fox Addendum, Updated Table 1.

¹⁰ Fox Report, ¶ 16. In the second sentence of paragraph 16 of his report, Dr. Fox erroneously describes this number as “the number of BCBSIL insureds who *met the definition of gender-affirming care* and were included in such plans that had plan exclusions for such care.” (italics added)

¹¹ Fox Report, ¶ 15; Fox Addendum, Updated Table 1; Jody L. Herman et. al, “How Many Adults and Youth Identify as Transgender in the United States?” The Williams Institute, UCLA School of Law, June 2022 (hereafter “Williams Study”).

these percentages reflect the percentage of transgender individuals within the relevant Group Plans in each year of the relevant period.

Table 1
Percentage of Individuals who Identify as Transgender in Illinois, by Age

Age	13 to 17	18 to 24	25 to 64	65 and older
Dr. Fox's Assumption	1.66%	1.94%	0.24%	0.24%

Source: Fox Addendum, Updated Table 1, Rows 7 through 11, citing Williams Study, Table 4.

The Williams Study from which Dr. Fox took these values indicates that they are merely estimates, with substantial uncertainty remaining about the actual percentage of persons in Illinois, and elsewhere, who identify as transgender. Dr. Fox fails to even mention this uncertainty despite it being quantified within the study and despite the fact that the actual percentages of persons identifying as transgender may be very different than Dr. Fox assumes.

The Williams Study quantifies this uncertainty using “credible intervals.” In particular, it uses a 95 percent credibility interval which, a previous version of the study explains, “represents the upper and lower bounds [for the reported value] where there is a 0.95 probability an estimate falls between them.”¹² Table 2 below gives the Williams Study’s credible intervals for the number of people identifying as transgender in Illinois (*i.e.*, the percentages

¹² Jody L. Herman et. al, "Age of Individuals Who Identify as Transgender in the United States," The Williams Institute, UCLA School of Law, January 2017., p.9 and Table A1. The study also explains, “A credible interval is a Bayesian equivalent of a confidence interval.” For additional information about credible intervals, see American Association for Public Opinion Research (AAPOR), “Understanding a ‘credibility interval’”, October 7, 2012, <https://www.aapor.org/Publications-Media/Public-Statements/Understanding-a-credibility-interval%E2%80%9D.aspx>.

shown in Table 1 above and assumed by Dr. Fox). For example, the table indicates that the true percentage of individuals who identify as transgender in the 13 to 17 age bracket is between 0.46 percent and 5.85 percent (based on a 95 percent confidence threshold).

Table 2
Credible Interval For Percentage of Individuals who Identify as Transgender in Illinois, by Age

Age	13 to 17	18 to 24	25 to 64	65 and older
Lower Bound	0.46%	0.42%	0.11%	0.07%
Upper Bound	5.85%	3.46%	0.38%	0.40%
(Upper Bound) ÷ (Lower Bound)	12.72	8.24	3.45	5.71

Source: Williams Study, Table A4

These credible intervals are very wide – with the upper bounds more than 3 times as large as the lower bounds for every age bracket – and are sufficiently large to undermine the reliability of Dr. Fox’s estimates. Had Dr. Fox considered the large credible intervals in his analysis, his estimate of transgender enrollees would be as low as 555 or as high as 3,885 on average across the relevant period – compared to Dr. Fox’s estimate of 1,740.¹³

B. Dr. Fox’s Use of General Population Proportions

As discussed above, Dr. Fox relies on the Williams Study, which uses “state-level, population-based surveys to estimate the proportion of the population that identifies as

¹³ In his addendum, Dr. Fox does not update his estimate from his original report that “about 1,740 TGD persons per year were enrolled in one of the BCBSIL affected plans.” When updated using the data from the 2022 version of the Williams Study, his estimate is 1,817 vs 1,740.

transgender by age group.”¹⁴ As a result of Dr. Fox’s reliance on this study, his analysis inherently assumes that the prevalence of transgender persons in the relevant Group Plans is identical to the prevalence of transgender persons in the general population.

Multiple factors indicate that this is not the case. First, transgender adults are twice as likely as cisgender adults to be unemployed.¹⁵ Second, transgender adults are more likely to be uninsured than cisgender adults.¹⁶ Third, many of the Group Members have a choice of health insurance plans,¹⁷ and, if given the choice between two healthcare plans, one that contains some form of exclusion for transgender-related services and one without such an exclusion,

¹⁴ This quotation is from a previous version of the study: Jody L. Herman et. al, "Age of Individuals Who Identify as Transgender in the United States," The Williams Institute, UCLA School of Law, January 2017, p.1.

¹⁵ McKinsey & Company, "Being transgender at work," *McKinsey Quarterly*, November 10, 2021, <https://www.mckinsey.com/featured-insights/diversity-and-inclusion/being-transgender-at-work>. See also, Kaiser Family Foundation, "Demographics, Insurance Coverage, and Access to Care Among Transgender Adults," October 21, 2020, <https://www.kff.org/health-reform/issue-brief/demographics-insurance-coverage-and-access-to-care-among-transgender-adults/>. "Among adults still in the labor force, a higher share of cisgender adults report being employed compared to transgender adults (56% vs. 48% respectively). Nearly one in ten (9%) of transgender adults reports they were unemployed from 2017-2018, a share much higher than that of cisgender adults (5%)."

¹⁶ Kaiser Family Foundation, "Demographics, Insurance Coverage, and Access to Care Among Transgender Adults," October 21, 2020, <https://www.kff.org/health-reform/issue-brief/demographics-insurance-coverage-and-access-to-care-among-transgender-adults/>. "A larger share of transgender than cisgender adults (19% vs. 12% respectively) report that they were uninsured over the 2017-2018 period."

¹⁷ Third Supplemental Answer to Interrogatory No. 6. "BCBSIL further states that of the 398 ERISA self-funded group health plans for which BCBSIL administers a gender-affirming care exclusion, some employers who offer a plan containing a gender-affirming care exclusion offer one or more plans in the same year that do not contain a gender-affirming care exclusion." Additionally, married Group Members may have an option of enrolling in their spouse’s healthcare plan.

transgender persons will tend to choose the option without the exclusion. These factors all indicate, contrary to Dr. Fox's assumption, that the prevalence of transgender people is smaller within the relevant Group Plans than in the general population.

The following example illustrates the importance of Dr. Fox's failure to account for disparities in employment and insurance experienced by transgender persons. A recent study using data from the U.S. Centers for Disease Control and Prevention concluded that "transgender adults are more likely to be uninsured [than cisgender adults] (19% vs. 12%)."¹⁸ Adjusting Dr. Fox's analysis to account for this disparity in insurance rates (but not correcting any other infirmities in his analysis) causes his estimate of the number of transgender enrollees in the relevant plans to fall by 8.6 percent, or approximately 150 people.

C. Dr. Fox's Use of Population Proportions for the State of Illinois

In estimating the number of transgender persons enrolled in the relevant Group Plans, Dr. Fox uses population proportions for the state of Illinois only. He states, "I do not know

¹⁸ Kaiser Family Foundation, "Demographics, Insurance Coverage, and Access to Care Among Transgender Adults," October 21, 2020, <https://www.kff.org/health-reform/issue-brief/demographics-insurance-coverage-and-access-to-care-among-transgender-adults/>. "Our analysis finds that transgender adults are more likely to be uninsured (19% vs. 12%) and report cost-related barriers to care (19% vs. 13%) than cisgender adults"; also, "A larger share of transgender than cisgender adults (19% vs. 12% respectively) report that they were uninsured over the 2017-2018 period." This study used data from the 2017 and 2018 Behavioral Risk Factor Surveillance System (BRFSS) administered by the U.S. Centers for Disease Control and Prevention.

where BSBCIL [*sic*] insureds in these plans reside so have assumed, for purposes of modeling, the majority live in the state of Illinois.”¹⁹

Dr. Fox does not assume the *majority* of Group Members live in the state of Illinois, he assumes that *all* Group Members live in the state of Illinois. Dr. Fox is aware that his assumption is wrong, or at least baseless.²⁰ I understand from counsel for BCBSIL that BCBSIL administers healthcare plans for companies domiciled in Illinois. However, I further understand from counsel for BCBSIL that employees of companies domiciled in Illinois may work and reside in other states, and many do.

These facts are exemplified by the named plaintiffs in this matter. Plaintiff Patricia Pritchard receives health coverage through her employer, St. Michael Medical Center in the state of Washington.²¹ Plaintiff C.P. receives health coverage as a dependent of Ms. Pritchard.²² Ms. Pritchard’s employer is part of the Catholic Health Initiatives Franciscan Health System, now known as CommonSpirit Health, whose national office is located in Chicago, Illinois.²³ Despite working and residing in the state of Washington,²⁴ Ms. Pritchard’s healthcare plan is administered by BCBSIL because CommonSpirit Health is domiciled in Illinois. Because Dr. Fox’s

¹⁹ Fox Report, fn. 17.

²⁰ Fox Report, fn. 17, quoted above.

²¹ Amended Complaint, ¶ 13.

²² Amended Complaint, ¶ 13.

²³ Amended Complaint, ¶ 13; CommonSpirit, Contact Us, <https://www.commonspirit.org/contact-us>.

²⁴ Amended Complaint, ¶ 13.

analysis assumes that all Group Members live in the state of Illinois, Ms. Pritchard, and her dependent C.P., would not be accounted for in Dr. Fox's estimates of transgender enrollees in the relevant Group Plans.

Additionally, Plaintiff C.P.'s Motion for Class Certification states that the "putative class members are geographically dispersed across the country."²⁵ Dr. Fox's estimates of transgender enrollees in the relevant Group Plans is unreliable because his estimates depend solely on population proportions for Illinois which do not reflect the wide geographic spread of the Group Members. The Williams Study, which Dr. Fox relies upon, includes percentages of individuals who identify as transgender by age for all 50 states and the District of Columbia, as well as regionally and nationally.²⁶ These percentages vary considerably on a state-by-state basis. For example, in the 13 to 17 age bracket, the percentage of individuals who identify as transgender is highest for New York (3.00 percent) and lowest for Wyoming (0.56 percent).²⁷ Dr. Fox did not evaluate where Group Members reside or how their geographic dispersion impacts his estimates of transgender enrollees in the relevant Group Plans. Instead, Dr. Fox assumes that all Group Members live in Illinois and provides no justification for why this

²⁵ Motion for Class Certification, p. 15.

²⁶ Williams Study, Table 4.

²⁷ Williams Study, Table 4. In the three remaining age brackets, the percentages of individuals who identify as transgender are highest for Arkansas (3.59 percent) for the 18 to 24 age bracket, the District of Columbia (0.77 percent) for the 25 to 64 age bracket, and New Mexico (0.73 percent) for the 65 and older age bracket. The lowest percentages are for Iowa (0.45 percent) for the 18 to 24 age bracket, Missouri (0.07 percent) for the 25 to 64 age bracket, and Nevada (0.04 percent) for the 65 and older age bracket.

demonstrably incorrect assumption should be accepted in his analysis when his assumption fails to reflect the facts in this matter.

D. Duplicate Observations in Dr. Fox's "Enrollment Counts"

As discussed above, one of the inputs into Dr. Fox's analysis is the total number of enrollees in the relevant Group Plans during each year in the relevant period; Dr. Fox refers to these values as "Enrollment Counts."²⁸ Dr. Fox compiled his Enrollment Counts from data provided by BCBSIL. However, when processing this data, he double- or triple-counted some entries because he failed to remove duplicate entries from the data. Specifically, he failed to remove some entries that had the same "group number" and the same number of enrollees as other entries. I note that these duplicate entries have different group names within the data (often, only slightly different), but I understand from Counsel for BCBSIL that the group number, not the group name, is the more accurate data field for identifying unique Group Plans in a given year. Thus, Dr. Fox should have removed these duplicate entries from the data before compiling his Enrollment Counts.

Table 3 below shows the effect of removing the duplicate entries. This table shows Dr. Fox's Enrollment Counts, the number of enrollees in the duplicate entries ("Duplicate Enrollments"), and the Enrollment Counts that remain after removing the duplicate entries

²⁸ Fox Addendum, Updated Table 1.

(“Enrollment Counts with Duplicate Enrollments Removed”). As the table shows, Dr. Fox overstates his Enrollment Counts by 8,299 to 13,461 per year, or 2.0 to 3.6 percent per year.

Table 3
Dr. Fox’s Duplicate Enrollment Counts

Year	2016	2017	2018	2019	2020	2021
Dr. Fox's Enrollment Counts (Table 3)	391,117	405,278	426,996	417,615	400,842	384,711
Duplicate Enrollments	8,299	8,478	8,572	8,713	9,284	13,461
Enrollment Counts With Duplicate Enrollments Removed	382,818	396,800	418,424	408,902	391,558	371,250
Overstatement % by Dr. Fox	2.2%	2.1%	2.0%	2.1%	2.4%	3.6%

III. Dr. Fox’s Estimated Number of Transgender Enrollees Who Sought Transgender-Related Services

For each year of the relevant period, Dr. Fox presents an estimate of the number of transgender enrollees in the relevant Group Plans who sought transgender-related services, and he summarizes that this number is “about 300.”²⁹ The table below shows these estimates.

²⁹ Fox Report, ¶¶ 16-17, cited in the Motion for Class Certification, p. 14. Dr. Fox and the Plaintiffs are inconsistent in how they refer to these estimates. For example: (1) in paragraph 3 of his report, Dr. Fox states that these are “TGD persons seeking care”; (2) in paragraph 16 of his report, he refers to them as “insureds who are estimated to have sought gender-affirming care”; (3) in paragraph 17, he refers to them as persons that “would have been expected to seek gender-affirming care”; and (4) the Motion for Class Certification at page 14 refers to them as individuals “likely to seek care” (with no characterization of the type or timing of the care involved).

Table 4
Dr. Fox's Estimated Number of Transgender Enrollees
Seeking Transgender-Related Services

	2016	2017	2018	2019	2020	2021
Fox Row 16:						
Enrollees That Sought Gender-Affirming Care	293	304	320	313	301	289

Source: Fox Addendum, Updated Table 5, Row 16. Dr. Fox labels the values "Numerosity, Health Care Users Only"

This section of my report discusses these estimates in more detail. Subsection A below demonstrates that Dr. Fox includes meaningless variables in his calculations of these estimates. Subsection B shows that these estimates are fatally flawed because Dr. Fox misinterprets and misuses the published data on which he relies, and Subsection C shows that these estimates are additionally flawed because they are inappropriately biased upwards for other reasons.

A. Dr. Fox's Inclusion of Meaningless Variables in Calculations

In Updated Table 1 and Updated Table 5 of his addendum, Dr. Fox sets forth his revised estimation of the number of transgender enrollees in the relevant Group Plans who sought transgender-related services. Dr. Fox describes his estimation as a "two-stage model," where the first stage "estimate[d] the prevalence of transgender persons" and the second stage estimated "which proportion of them utilized some sort of medically necessary care."³⁰ However, in effect, Dr. Fox's analysis is not a two-stage model. As discussed below, his

³⁰ Fox Deposition, p. 75.

estimation of the number of transgender enrollees who sought transgender-related services is just a simple multiplication, not a two-stage model.

In his text, tables, notes, and deposition testimony, Dr. Fox appears to indicate that his estimates mathematically depend on all the variables appearing in his Updated Tables 1 and 5 (*i.e.*, Rows 1 through 15 of his tables). For example, Dr. Fox appears to indicate that his estimates depend on “Population Proportions by Age” (Rows 2 through 6), “Proportion [of the Illinois Population that identifies as transgender] by Age” (Rows 7 through 11), “Numerosity” (*i.e.*, Dr. Fox’s estimated number of transgender enrollees in Row 12), and the “Average Proportion” of transgender individuals within the relevant plans (Row 13).

However, despite the appearance of a complicated mathematical analysis, Dr. Fox’s calculations do not depend on these variables at all. As a matter of basic mathematics, Dr. Fox’s estimates of transgender enrollees who sought transgender-related services is a simple multiplication of just two variables:

1. Dr. Fox’s Row 1, “Enrollment Counts,” which is Dr. Fox’s estimate of the number of enrollees in the relevant plans.
2. Dr. Fox’s Row 14, “Population Proportion,”³¹ which equals 0.075 percent for every year. Dr. Fox does not describe or discuss this value which, as discussed below, he takes from a published research article and misuses.

³¹ Dr. Fox’s full heading for Row 14 is “Population Proportion From Study of Health Care Users Only”, but I truncate this heading to just “Population Proportion” for brevity.

Table 5 below, which I created from values in Dr. Fox's addendum,³² demonstrates this observation. Rows (A) and (B) of the table are the two variables listed just above (Dr. Fox's Enrollment Counts and Population Proportions). Row (C) is these two variables multiplied together, and this row is the same as Dr. Fox's final estimates.³³ This equivalence means that Dr. Fox's estimates of the number of transgender enrollees who sought transgender-related services depend solely on his Enrollment Counts and Population Proportion variables. In other words, Dr. Fox's estimate of the number of transgender enrollees who sought transgender-related services is mathematically independent of all the other variables (Rows 2 through 13) in Updated Table 1 of his analysis, and his inclusion of those variables in his calculations is meaningless.

³² Dr. Fox's report contains identical values.

³³ *I.e.*, the same as Row 16 in Dr. Fox's analysis and Table 4 above.

Table 5
Simplified Computation of Dr. Fox's Estimated Number of
Transgender Enrollees Seeking Transgender-Related Services

		2016	2017	2018	2019	2020	2021
Fox Row 1: Enrollment Counts	(A)	391,117	405,278	426,996	417,615	400,842	384,711
Fox Row 14: Population Proportion	(B)	0.075%	0.075%	0.075%	0.075%	0.075%	0.075%
Fox Row 16: Enrollees Who Sought Gender-Affirming Care	(C) = (A) x (B)	293	304	320	313	301	289

Source: Fox Addendum: (A) Updated Table 1, Row 1; (B) Updated Table 5, Row 14; (C) is identical to Updated Table 5, Row 16.

B. Dr. Fox's Invalid "Population Proportion" Assumption

In Section III.A of this report (immediately above), I showed that Dr. Fox's estimates of the number of transgender enrollees in the relevant plans who sought transgender-related services³⁴ actually depend on just two variables, Rows (A) and (B) in the table above. In Section II, I discussed the flaws in the first of these two variables, which is Dr. Fox's estimate of the total number of enrollees in the relevant Group Plans.³⁵ In particular, Dr. Fox failed to delete duplicate entries in the data on which he relied. Below, I discuss the second of these variables which is Dr. Fox's assumption that 0.075 percent³⁶ of enrollees sought transgender-related services in each year. In this discussion, I show that this assumption is a misinterpretation and

³⁴ Row 16 of Dr. Fox's analysis and Row (C) in Table 5.

³⁵ Row 1 of Dr. Fox's analysis, and Row (A) in Table 5.

³⁶ Row 14 of Dr. Fox's analysis, and Row (B) in Table 5.

misuse of the published research on which Dr. Fox relies. As a result, Dr. Fox's assumption is invalid, his analysis is incorrect, and his results are unreliable.

1. The "Quinn Study" on Which Dr. Fox Relies

The source of Dr. Fox's assumption that 0.075 percent of enrollees in the relevant Group Plans sought transgender-related services annually is a research article published by Virginia P. Quinn, PhD, and other researchers that is titled "Cohort profile: Study of Transition, Outcomes and Gender (STRONG) to assess health status of transgender people" (henceforth, the "Quinn Study").³⁷ The objectives of the study were to develop methods for using computerized searches of electronic medical records to identify transgender people and assess their health status.³⁸

The Quinn Study identified 6,456 transgender people across three different Kaiser Permanente health plans in Northern California, Southern California, and Georgia based on medical health record information from 2006 through 2014, a nine-year period. The study describes the methodology used to identify transgender people, and it reports numerous

³⁷ Virginia P Quinn et al., "Cohort profile: Study of Transition, Outcomes and Gender (STRONG) to assess health status of transgender people," *BMJ Open*, 2017;7:e018121. doi:10.1136/bmjopen-2017-018121, ("Quinn Study") cited in Fox Report at p. 4, note 13; p. 8, note 18; pp. 8-9, 12; and Fox Addendum, Updated Table 5 notes. I use the term "Quinn Study" to refer to both the published research article and the underlying research.

³⁸ Quinn Study, p. 1 ("Purpose [: the study] was initiated to assess the health status of transgender people in general and following gender-affirming treatments at Kaiser Permanente health plans in Georgia, Northern California and Southern California. The objectives of this communication are to describe methods of cohort ascertainment and data collection and to characterise the study population".)

demographic and health-related statistics. For example, the Quinn Study reports the following estimated percentages of transgender enrollees in the Kaiser Permanente health plans studied, as of 2014:³⁹ (1) 0.075 percent in Northern California,⁴⁰ (2) 0.044 percent in Southern California, and (3) 0.038 percent in Georgia. The Quinn Study defines these values as the “proportions of transgender enrollees” as of 2014.⁴¹

2. Dr. Fox’s Misinterpretation and Misuse of the Quinn Study

The precise source of Dr. Fox’s assumption about the annual rate at which enrollees in the relevant Group Plans sought transgender-related services is the Quinn Study’s 0.075 percent estimate for the prevalence of transgender people in the Northern California Kaiser Permanente health plan.⁴² In his analysis, Dr. Fox assumes that this value is the *annual rate* at which these Kaiser Permanente enrollees sought transgender-related services. It is not. The Quinn Study’s 0.075 percent value is the “proportion of transgender enrollees”⁴³ in the Kaiser plan; *i.e.*, it is a measure of the number of transgender enrollees. It is not a measure of the

³⁹ Quinn Study, p. 9 and Figure 3 (where the values appear graphically). In the Quinn Study, these percentages are expressed as the number of transgender people per 100,000 enrollees.

⁴⁰ As discussed in detail below, this 0.075 percent value for the Northern California Kaiser Permanente health plan is the source of Dr. Fox’s assumption.

⁴¹ Quinn Study, p. 9. *Also*, Quinn Study, p. 6, Figure 3, showing these values graphically for 2014 with heading “Prevalence of transgender status by site and year of health plan enrolment.”

⁴² Fox Addendum, Updated Table 5, citing the Quinn Study and stating, “This 0.075% estimate is for Northern California Kaiser enrollees.”

⁴³ Quinn Study, p. 9.

amount or frequency of transgender-related services that these enrollees sought, which is how Dr. Fox uses the percentage.

In fact, the Quinn Study does not present any conclusion about the rate at which Kaiser Permanente enrollees sought transgender-related services. While the study does report evidence of “gender-affirming treatment” for 63 percent of the transgender people and no evidence of “gender-affirming treatment” for the remaining 37 percent,⁴⁴ it does not indicate the year in which these treatments were provided or the number of treatments provided, and it does not provide sufficient information to derive annual treatment rates.

In sum, Dr. Fox assumes the 0.075 percent value from the Quinn Study is something that it is not, and he then misuses the 0.075 percent value in the analysis. Consequently, the analysis in Dr. Fox’s Updated Table 5 is incorrect, and his conclusions, which he summarizes as “about 300 persons would have been expected to seek [transgender-related services] each year,” are unreliable.

C. Dr. Fox’s Estimates are Biased Upwards

As discussed above, Dr. Fox’s estimates are irrecoverably flawed due to his misuse of the 0.075 percent value from the Quinn Study. Additionally, his estimates are unreliable even if we disregard that flaw, *arguendo*. Specifically, they are inappropriately biased upwards for three reasons discussed below.

⁴⁴ Quinn Study, p. 8, Table 4.

1. No Evidence of Transgender-Related Services

Dr. Fox fails to account for the study's finding that there was no evidence of "gender-affirming treatment" for 37 percent of transgender Kaiser Permanente enrollees. That is, he incorrectly assumes that every transgender Kaiser Permanente enrollee had received transgender-related services despite the fact that the study explicitly states that there was "no evidence" of "gender-affirming treatments" for 37 percent of them.

2. Dr. Fox Disregards Results for Southern California and Georgia

Dr. Fox relies solely on Kaiser Permanente data in the Quinn Study for Northern California, and he ignores analogous data in that same study for Southern California and Georgia. In other words, he uses the higher value for the Northern California Kaiser Permanente plan (0.075 percent) while ignoring the values for the Southern California plan (0.044 percent) and the Georgia plan (0.038 percent), which are much lower.⁴⁵ Dr. Fox stated in deposition that he used the value for Northern California because "[i]t had the largest sample size," and therefore, he claims, the "highest level of confidence."⁴⁶ This rationale is both incorrect and irrelevant.

Dr. Fox's rationale is incorrect because the sample size for the Northern California data is actually smaller than for the Southern California data. While the Quinn Study does not explicitly state the sample sizes, they can be inferred as follows: for each region, the sample

⁴⁵ Quinn Study, p. 9.

⁴⁶ Fox Deposition, p. 93.

size is the number of transgender enrollees identified in the study divided by the fraction of the total sample that these enrollees represent. For Northern California, the study identified 3,842 transgender enrollees which amounts to 0.075 percent of the total sample, so the sample size is 5.12 million.⁴⁷ For Southern California, the study identified 2,440 transgender enrollees which amounts to 0.044 percent of the total sample, so the sample size is 5.54 million⁴⁸ -- which is larger than the sample size for Northern California. Moreover, the Quinn Study reports confidence intervals associated with its prevalence estimates – and the confidence interval for Northern California is wider than for Southern California.⁴⁹ Mathematically, *wider* confidence intervals indicate *lower* levels of confidence, so Northern California provides a lower level of confidence than Southern California, contrary to Dr. Fox’s claim. Therefore, based on Dr. Fox’s stated criteria of using the region with the “largest sample size” and “highest level of confidence,” he should have used the transgender prevalence value for Southern California (0.044 percent), not Northern California (0.075 percent).

Dr. Fox’s rationale for using the transgender percentage value for Northern California is not only incorrect, but also irrelevant. It is irrelevant because the appropriate criterion for selecting among the three regions discussed in the Quinn Study is the extent to which the

⁴⁷ $3,842 \div 0.075\% = 5.12$ million. The number of transgender enrollees identified is shown in Table 3 of the study, and the percentages these enrollees represent is shown in Figure 3 and p. 9 of the study.

⁴⁸ $2,440 \div 0.044\% = 5.54$ million.

⁴⁹ Quinn Study, p. 9. The 95 percent confidence interval for the Southern California estimate is 0.042 percent to 0.046 percent. For the Northern California estimate, the 95 percent confidence interval is 0.072 to 0.078.

enrollee populations studied by Dr. Quinn and her co-authors is representative of the enrollee population within the relevant plans. Dr. Fox did not consider this criterion,⁵⁰ so his decision to use the Northern California data and exclude the Southern California and Georgia data is baseless.

3. Bias Due to Duplicate Observations

As discussed in Section II.D of this report, Dr. Fox overestimates the number of enrollees in the relevant Group Plans because he failed to account for duplicate entries in the data he processed.

4. Quantifying Dr. Fox's Bias

Table 6 below illustrates the degree to which Dr. Fox's estimates are overstated due to the three factors discussed immediately above. The first row of this table is Dr. Fox's estimated number of transgender enrollees in the relevant Group Plans who sought transgender-related services. The remaining rows indicate how these estimates change when Dr. Fox's analysis is adjusted to remove the sources of bias discussed above. First, I reduced Dr. Fox's estimates by 37 percent to account for the 37 percent of transgender patients in the Quinn Study for which there was no evidence of "gender-affirming treatments." Second, I reduced Dr. Fox's estimates by 2.0 to 3.6 percent, depending on the year, to reflect the duplicate observations in the BCBSIL data that Dr. Fox used. Third, I show how Dr. Fox's estimates change (with these other

⁵⁰ Fox Deposition, p. 93, stating that "largest sample size" and "highest level of confidence" were the only reasons he chose to use the Northern California data and exclude the Southern California and Georgia data.

adjustments also in place) depending on whether the analysis is based on the Quinn Study's conclusions for Northern California, Southern California, or Georgia. As the table indicates, these adjustments result in markedly lower estimates than Dr. Fox reports, especially for the Southern California and Georgia analyses, when the analysis is adjusted to remove Dr. Fox's bias.

Table 6
Dr. Fox's Estimated Number of Transgender Enrollees
Who Sought Transgender-Related Services:
Corrected to Remove Bias,⁵¹ by Kaiser Permanente Plan

	Kaiser Permanente Plan	2016	2017	2018	2019	2020	2021
Dr. Fox's Estimate: Northern California		293	304	320	313	301	289
Dr. Fox's Estimate, Corrected:							
Northern California		180	186	196	192	184	174
Southern California		105	109	115	113	108	102
Georgia		91	94	99	97	93	88

IV. Conclusions

Dr. Frank Fox, on behalf of the plaintiffs in this litigation, provides estimates of both the number of transgender people enrolled in the relevant Group Plans and the number of these enrollees who sought transgender-related services annually during the relevant period. As discussed herein, Dr. Fox's analysis is deficient in numerous ways including: (1) he failed to

⁵¹ As discussed above, Dr. Fox's misuse of the Quinn Study cannot be corrected because the study does not provide annual treatment rates. Thus, while this table demonstrates the bias in Dr. Fox's estimates, the values shown are not reliable annual estimates of the number of transgender enrollees who sought transgender-related services.

account for the marked uncertainty in the published data upon which he relies; (2) he incorrectly assumes that the prevalence of transgender people in the relevant Group Plans is identical to the prevalence of transgender people in the general population and that all Group Members in these plans reside in Illinois; (3) he failed to exclude duplicate data entries in the data on which he relies; and (4) he misinterprets, misuses, and overstates published data upon which he relies. Consequently, Dr. Fox's estimates are misleading and unreliable.

October 21, 2022, at 2000 K Street NW, Washington, DC.

By  _____

Scott Carr, Ph.D.

Scott M. Carr, Ph.D.

Senior Managing Director

2000 K Street, NW, 12th Floor | Washington, DC 20006



Contact

Main +1.202.797.1111
Direct +1.202.481.7546
Mobile +1.202.656.6407
scott.carr@ankura.com

Education

PhD Business Administration and Industrial & Operations Engineering, University of Michigan

MS Engineering, Industrial & Operations Engineering, University of Michigan

MS Engineering, Construction Management and Engineering (Civil and Environmental Engineering), University of Michigan

BS Engineering, Mechanical Engineering, University of Michigan

Affiliations

American Bar Association

Scott Carr, Ph.D., is a Senior Managing Director and leader of the Competition and Class Actions Practice at Ankura Consulting Group. His areas of expertise include data analytics, statistics, and predictive modeling; manufacturing, supply chain and distribution systems; energy economics; and financial modeling.

Dr. Carr has extensive experience in the analysis and modeling of complex business, financial, and health-related circumstances and events. His projects include forecasting the future incidence of diseases and cognitive impairments due to concussions in National Football League players, developing a machine-learning algorithm to predict outcomes of asbestos-related litigation, testimony regarding accommodations for people with physical disabilities, forecasting of future personal injury liabilities due to environmental contamination, expert testimony in contractual disputes within manufacturing supply chains, and economic analysis of crude oil, gasoline, and ethanol distribution systems.

Dr. Carr was formerly a professor at the UCLA Anderson School of Management in the Department of Decisions, Operations, and Technology Management. As a professor, he taught courses on operations management, supply chain management, and quantitative analysis to MBA and Ph.D. students and to executives, and he performed and published research on industrial economics and supply chain and distribution systems. Prior to joining academia, Dr. Carr traded and managed portfolios of foreign exchange and Treasury bond options as a member of both the Chicago Board of Trade and the Chicago Mercantile Exchange.

Dr. Carr has provided expert testimony to state and federal courts and regulatory bodies and to arbitration panels.



AREAS OF EXPERTISE

- Supply chain management, logistics, production and operations management
- Energy economics, competition economics, environmental economics
- Process design and analysis
- Financial modelling
- Risk modeling, analysis, and management
- Probability and statistics
- Optimization, modeling, simulation, pricing, forecasting, and data analytics

PROFESSIONAL EXPERIENCE

Faculty and Expert Services Experience

Ankura Consulting Group, August 2018 – Present

Senior Managing Director and Competition and Class Actions Practice Leader, April 2019 – Present

Managing Director, August 2018 – March 2019

Navigant Economics, Director, 2014 – August 2018

ARPC, 2011 – 2013

Senior Managing Director, 2012 – 2013

Managing Director, 2011

LECG, 2006-2010

Principal, 2009 – 2010

Senior Managing Economist, 2006 – 2009

UCLA Anderson School of Management, Faculty, 1999 – 2007

Professional Activities – representative examples

Economic modeling and analysis including:

- Testimony in a supply chain dispute on behalf of a major consumer goods packaging manufacturer
- Testimony in a supply chain dispute related to the distribution of rum in Puerto Rico



- Testimony for Saddlehorn Pipeline Company regarding competition in crude oil transportation as part of a market-based rates application for its pipeline running between Rocky Mountain crude oil production regions and Cushing, Oklahoma.
- Testimony regarding gasoline and ethanol distribution on behalf of Joint Defendants in environmental litigation
- Testimony for the New York State Department of Health regarding the availability of accessible housing for people with mobility disabilities in New York City
- Analysis of the pricing and profitability of the United States Postal Service's (USPS's) ten largest Negotiated Service Agreements on behalf of the USPS Board of Governors
- Testimony for BridgeTex Pipeline Co. involving disputed rates and capacity allocation procedures for the transportation of crude oil
- Testimony in a supply chain dispute involving the manufacture and distribution of women's shoes in Australia and New Zealand
- Engaged as Testifying Expert regarding supply chain management and manufacturing issues involved in an \$800 million light rail project in Canada
- Testimony for Wells Fargo regarding the valuation of oil-producing properties
- Testimony for Scotiabank regarding financial modeling practices in the investment banking industry and damages in a failed Build-Operate-Transfer construction project in Chile
- Testimony for Rayonier Advanced Materials regarding the pricing and supply of raw materials in the chemicals industry
- Testimony for the Tennessee Fuel and Convenience Store Association to the Tennessee Regulatory Authority regarding competition in the market for compressed natural gas as a transportation fuel
- Testimony for TransCanada regarding competition in crude oil transportation as part of a market-based rates application for its Marketlink Pipeline running between Cushing, Oklahoma, and Houston, Texas
- Testimony for Buckeye Pipe Line Company to the Federal Energy Regulatory Commission regarding competition in wholesale gasoline markets as part of a market-based rates protest of a refined products pipeline running from Delaware City, Delaware, to Pittsburgh and Harrisburg, Pennsylvania
- Testimony for Tyson Foods regarding production and supply chain practices in U.S. Dept. of Agriculture litigation brought under the Packers and Stockyards act
- Testimony to Federal District Court regarding a new business valuation in a breach of contract matter
- Testimony to the Federal Energy Regulatory Commission regarding credit issues in the New England ISO on behalf of Constellation Energy and other electricity generators

- Arbitration testimony in support of a Tier-1 automotive supplier's claim that its profits were negatively impacted by a partner firm's inability to reliably supply raw materials to their joint venture manufacturing plant
- Damages analysis (submitted in arbitration) for a delayed Guatemalan hydroelectric construction project
- Preparation of market-based rate applications for
 - Saddlehorn Pipeline Company, LLC (crude oil pipeline running from Fort Laramie, Wyoming, and Denver, Colorado, to Cushing, Oklahoma)
 - Marketlink, LLC (crude oil pipeline running from Cushing, Oklahoma, to the U.S. Gulf Coast)
 - Osage Pipeline Company (crude oil pipeline running from Cushing, Oklahoma, to El Dorado, Kansas)
 - Buckeye Pipe Line Company, Long Island System (refined products pipeline running from Linden, New Jersey, to Long Island, New York)
 - Seaway Crude Pipeline Company (crude oil pipeline running from Cushing, Oklahoma, to the U.S. Gulf Coast)
 - Enterprise TEPPCO (refined products pipeline running from the U.S. Gulf Coast to Louisiana and Arkansas)
 - Magellan Pipeline Mountain System (refined products pipeline running from Kansas to Colorado)
- Testimony to the California Air Resources Board regarding the financial impact of automotive emissions control regulations for the Alliance of Automobile Manufacturers
- Forecasting of the future incidence of diseases and cognitive impairments due to concussions for the National Football League players
- Analysis of fuel costs for an electric generation firm in bankruptcy litigation
- Analysis of gasoline and ethanol supply chain economics for Tesoro Corporation in several cases involving MTBE groundwater contamination
- Creation of a machine-learning algorithm to predict outcomes of asbestos-related litigation
- Estimation of lost income and other financial damages due to the BP oil spill in the Gulf of Mexico for the \$20 billion Gulf Coast Claims Facility
- Probabilistic modeling of future mass tort litigation at environmental contamination sites for Anadarko Petroleum Corporation
- Analysis of large data sets in class action litigation related to labor disputes, antitrust claims, and insurance litigation.
- Analysis of the cost-of-capital implications of subsidies provided to Persian Gulf airlines by their respective governments on behalf of several major U.S. airlines

- Financial analysis of natural gas pipeline leases for the U.S. Department of Justice and the Internal Revenue Service
- Estimation of the likelihood of injury from home electrical devices for Underwriter Laboratories
- Probabilistic modeling and simulation of private equity funds' performance
- Analysis of demand variability within the automobile supply network for Brembo Brakes
- Valuation and depreciation analysis of crude oil pipelines for Imperial Oil
- Bond, stock, and derivative analyses for bankruptcy litigation in the electricity industry
- Valuation of supply contracts for a new mining venture
- Analysis for class-certification and merits stages of antitrust litigation for Dow Chemical
- Analysis of alleged monopolization of industrial chemicals for Honeywell
- Managed, advised, or performed strategic projects for firms/organizations including:
 - Rio Tinto Energy America (coal mining)
 - TRW Aerospace (semiconductor manufacturing technology and equipment)
 - Broadcom (Bluetooth chipsets)
 - Meade Instruments (night vision technology)
 - Macy's (retail clothing)
 - Los Angeles Community Redevelopment Agency
 - Los Angeles County Metropolitan Transportation Authority
 - Pilkington (glass manufacturing)
 - Deutsch Advertising
 - Six Flags (amusement parks)

Numerous Speeches/presentations delivered at academic conferences

Principal investigator in a project and grant to improve small enterprises' access to business expansion capital

Member of editorial board for *Decision Sciences Journal* and frequent reviewer for *Management Science*, *Operations Research*, and other academic journals

Professional Affiliations

- American Bar Association – Infrastructure and Regulated Industries Section; Section of Litigation and its Environmental & Energy Litigation Committee
- LECG, Los Angeles (Affiliate) – Professional services for antitrust litigation and competition policy, 2005–2006

Graduate-Level Courses Taught at the UCLA Anderson School of Management

Competition and Industrial Organization [Ph.D.] – Game theoretic models of inter-firm interaction. Classic and seminal oligopoly models. Pricing theory. Advanced game theory. Models of strategic interaction within complex production networks. Antitrust. Analysis and proof techniques, 2006

Managerial Model Building [MBA] – Mathematical modeling, analysis, and optimization. Linear, non-linear, and integer programming/optimization. Monte-Carlo simulation. Forecasting methods. Project Management models and tools. Application of optimization models in business settings, 2005-2006

Simulation Theory and Applications [Ph.D.] – Monte-Carlo, discrete event, and agent-based simulation for finance, marketing, and operations. The use of simulation in empirical research. Simulation of stochastic processes. Option valuation (both financial and real) using simulation. Applications (e.g., simulation of intellectual property piracy over the Internet), 2004-2006

Management in the Information Economy [MBA] – Internet and telecommunication technology. Internet business models and strategy. Economics of information products and processes, 2003

Fundamentals of Operations Management [MBA] – Analysis of business processes. Formulating and executing business strategy. Service and performance measurement and metrics. Managing risk, variability, and uncertainty. Management of supply chains and production processes. 1999-2003, 2006

Dynamic Programming and Sequential Optimization [Ph.D.] – Dynamic programming, Markov chains and decision processes, solution and proof techniques, and structural results and proofs, 2000

Other Teaching

Ph.D. Dissertation Committees (including Dissertation Advisor) – topic areas including: competition economics, operations management, information technology, international business, simulation

Executive Education at UCLA Anderson – Various topics in the following programs (1999 to 2007):

- Managing the Information Resource
- Creating and Leading the Project-Centered Organization (faculty director)
- Supply Chain Management
- Head Start – Johnson & Johnson Management Fellows Program
- UCLA Strategic Leadership Institute
- California HealthCare Foundation's Health Care Leadership Program
- Johnson & Johnson Healthcare Leadership Program

University of Michigan, Ross School of Business [BBA] – Operations Management, 1997

University of Michigan, College of Engineering [BSE] – Computer Programming, 1995

Research

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Scott Carr and Izak Duenyas, "Optimal Admission Control and Sequencing in a Make-to-Stock/Make-to-Order Production System," *Operations Research*, vol. 48, Sept.-Oct. 2000, 709-719

Scott Carr, *Essays on the Allocation of Scarce Capacity Among Multiple Market Segments*, Ph.D. dissertation

Other Relevant Experience

Automotive Supply Chain and Manufacturing – Libbey-Owens-Ford (1995–1998)

- Consulting and research related to contracting and demand management, information systems, data-mining, production planning and scheduling, demand forecasting, and materials management
- Analysis to determine which of the firm's products to manufacture using a joint venture manufacturing plant instead of the client firm's own fully-owned facilities

Legal – Case management and expert-witness preparation (1995–1998)

- Researched case and administrative law on employers' and owners' safety responsibilities in multi-employer construction jobsites
- Developed case theories and strategies, wrote briefing materials, and engaged in trial preparation

Finance – Traded and managed portfolios of foreign exchange and Treasury bond options (1986–1991)

- Member of Chicago Board of Trade
- Member of Chicago Mercantile Exchange

Information Technology – Computer Associates, Chicago Illinois (1991–1992)

- Mainframe software systems (datacenter management, security, database management, finance and production applications)



EXPERT TESTIMONY AND SUBMISSIONS

Arbitration testimony of Scott Carr, Ph.D. on behalf of Ball Corporation and Rexam Beverage Can Company; Arizona Beverages USA LLC v. Ball Corporation and Rexam Beverage Can Company; American Arbitration Association, Case Number 01-21-0017-2481; June 2, 2022.

Deposition Testimony of Scott Carr, Ph.D. on behalf of Brugal & CO., S.A.; Ballester Hermanos, Inc. v. Brugal & CO., S.A.; United States District Court, District of Puerto Rico, Docket No. 3:19-cv-02100; May 11, 2022.

Deposition Testimony of Scott Carr, Ph.D. on behalf of Joint Defense Group; Commonwealth of Pennsylvania, etc. v. Exxon Mobil Corporation, et al, Docket No. 1:14-cv-06228-SAS, MDL No. 1358, May 20, 2022.

Prepared Direct Testimony of Scott Carr, PhD, on behalf of Saddlehorn Pipeline Company, LLC, in support of the Application of Saddlehorn Pipeline Company, LLC for Authorization to Charge Market-Based Rates; April 12, 2022.

Expert Report of Scott Carr, Ph.D. on behalf of Brugal & CO., S.A.; Ballester Hermanos, Inc. v. Brugal & CO., S.A.; United States District Court, District of Puerto Rico, Docket No. 3:19-cv-02100; March 29, 2022.

Rebuttal Expert Report of Scott Carr, Ph.D. on behalf of Ball Corporation and Rexam Beverage Can Company; Arizona Beverages USA LLC v. Ball Corporation and Rexam Beverage Can Company; American Arbitration Association, Case Number 01-21-0017-2481; March 7, 2022.

Expert Report of Scott Carr, Ph.D. on behalf of Ball Corporation and Rexam Beverage Can Company; Arizona Beverages USA LLC v. Ball Corporation and Rexam Beverage Can Company; American Arbitration Association, Case Number 01-21-0017-2481; February 25, 2022.

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Expert Report of Scott Carr, Ph.D.; Michelle Bagley et al. against The New York State Department of Health et al.; United States District Court, Eastern District of New York; Case No. 15-cv-4845 (FB) (CLP); December 16, 2020.

United States Postal Service, Negotiated Service Agreement Review, Solicitation 2A-20-A-0029; October 2020.

Prepared Direct Testimony of Dr. Scott M. Carr on behalf of Marketlink, LLC, in support of the Application of Marketlink, LLC, for Authorization to Charge Market Based Rates. F.E.R.C. Docket No. OR19-30; July 24, 2019.

Expert Report of Scott Carr, PhD, and Michal Malkiewicz Regarding the 2019 Roland Garros Code Violation Against Anna Tatishvili; Grand Slam Board (for tennis); June 20, 2019.

Prepared Rebuttal Testimony of Dr. Scott M. Carr on behalf of BridgeTex Pipeline Company, LLC; Occidental Energy Marketing, Inc. v. BridgeTex Pipeline Company, LLC; Railroad Commission of Texas GUD No.10675; December 21, 2018.



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Engaged as Testifying Expert on behalf of Metrolinx; Bombardier Transportation Canada Inc. v. Metrolinx; November 2017.

Financial analysis by Scott Carr, Ph.D., and Cliff Hamal on behalf of OHL Industrial; OHL Industrial S.L. and OHL Industrial Delegacion Guatemala, Sociedad Anonima disclosed in Claimants' Rejoinder to Counterclaim; OHL Industrial S.L. and OHL Industrial Delegacion Guatemala, Sociedad Anonima, v. Energia Limpia De Guatemala, S.A.; International Chamber of Commerce International Court of Arbitration, September 19, 2017.

Expert Report of Scott Carr, Ph.D., on behalf of Wells Fargo Bank, N.A.; Extex Energy Partners, Ltd., v. Wells Fargo, N.A.; American Arbitration Association, Case No. 01-16-0003-7384; August 25, 2017.

Deposition Testimony of Scott Carr, Ph.D., on behalf of The Bank of Nova Scotia, Scotiabank Global Banking and Markets, and Scotia Capital; S.A. de Obras y Servicios, COPASA v. The Bank of Nova Scotia, and Scotiabank Global Banking and Markets f/k/a Scotia Capital Inc.; Supreme Court of the State of New York, County of New York; IAS Part 49, Index No. 651649/2013; December 20, 2016.

Expert Report of Scott Carr, Ph.D., on behalf of The Bank of Nova Scotia, Scotiabank Global Banking and Markets, and Scotia Capital; S.A. de Obras y Servicios, COPASA v. The Bank of Nova Scotia, and Scotiabank Global Banking and Markets f/k/a Scotia Capital Inc.; Supreme Court of the State of New York, County of New York; IAS Part 49, Index No. 651649/2013; September 28, 2016.

Expert Disclosure of Scott M. Carr, Ph.D., on behalf of Rayonier Advanced Materials, Inc.; Eastman Chemical Company v. Rayonier Advanced Materials Inc., Rayonier Performance Fibers, LLC, and Rayonier A.M. Sales and Technology Inc.; Chancery Court for Sullivan County, Tennessee, Case No. 15-ck-40024(C); October 22, 2015.



Live Testimony of Dr. Scott M. Carr on Behalf of Buckeye Pipe Line Company; Guttman Energy v. Buckeye Pipe Line Company, L.P. and Laurel Pipe Line Company, L.P.; F.E.R.C. Docket No. OR14-4-000 and -001; October 13, 2015.

Answering Testimony to Commission Trial Staff of Dr. Scott M. Carr on Behalf of Buckeye Pipe Line Company; Guttman Energy v. Buckeye Pipe Line Company, L.P. and Laurel Pipe Line Company, L.P.; F.E.R.C. Docket No. OR14-4-000 and -001; June 26, 2015.

Answering Testimony of Dr. Scott M. Carr on Behalf of Buckeye Pipe Line Company; Guttman Energy v. Buckeye Pipe Line Company, L.P. and Laurel Pipe Line Company, L.P.; F.E.R.C. Docket No. OR14-4-000 and -001; January 20, 2015.

Live Testimony of Scott M. Carr, Ph.D. on behalf of the Tennessee Fuel and Convenience Store Association; Petition of Piedmont Natural Gas Company, Inc. for Approval of a CNG Infrastructure Rider to its Approved Rate Schedules and Service Regulations; Tennessee Regulatory Authority, Docket No. 14-00086; January 12, 2014.

Direct Written Testimony of Scott M. Carr, Ph.D. on behalf of the Tennessee Fuel and Convenience Store Association; Petition of Piedmont Natural Gas Company, Inc. for Approval of a CNG Infrastructure Rider to its Approved Rate Schedules and Service Regulations; Tennessee Regulatory Authority, Docket No. 14-00086; December 11, 2014.

Live Testimony of Scott M. Carr, Ph.D. on behalf of Tyson Farm's Inc. before the U.S. Department of Agriculture, P&S Docket No. D-12-0123, December 10, 2012.

Written Testimony of Scott Carr, Ph.D., on behalf of Summit Point Automotive Research Center and William Scott Inter Vivos Trust. Homeland Training Center LLC v. Summit Point Automotive Research Center and William Scott Inter Vivos Trust. U.S. District Court for the Northern District of West Virginia, Case No. 3:07-cv-00160-JPB, September 15, 2010.

Affidavit of Scott Carr, Ph.D., in support of the New England Credit Policy Coalition; U.S. Federal Energy Regulatory Commission, Docket No. ER10-942-000; April 16, 2010.

Prepared Testimony of Scott M. Carr, Ph.D. on behalf of Brembo North America and Affiliated Companies; Sanluis Rassini S.A. de C.V. and Rassini Frenos S.A. de C.V. vs. Brembo North America, Brembo Participations S.A. and Brembo S.p.A., Brembo International S.A., and Brembo-Rassini, S.A. de C.V.; International Centre for Dispute Resolution, Case No. 50 154 T 00450 07; July 2008.

Comments by Scott Carr, Ph.D., to the California Air Resource Board Regarding California's Emission Warranty Information Reporting and Recall Regulations and Emission Test Procedures on behalf of the Alliance of Automobile Manufacturers, March 20, 2007.

Exhibit 2
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Virginia P Quinn et al., "Cohort profile: Study of Transition, Outcomes and Gender (STRONG) to assess health status of transgender people," <i>BMJ Open</i> , 2017;7:e018121. doi:10.1136/bmjopen-2017-018121

Data
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