

**IN THE UNITED STATES DISTRICT COURT
FOR THE WESTERN DISTRICT OF NORTH CAROLINA**

KANAUTICA ZAYRE-BROWN,
Plaintiff,

v.

THE NORTH CAROLINA
DEPARTMENT OF ADULT
CORRECTION, *et al.*,

Defendants.

No. 3:22-cv-00191-MOC-DCK

**PLAINTIFF'S DAUBERT MOTION TO EXCLUDE
THE TESTIMONY OF DR. FAN LI**

Pursuant to Local Civil Rule 7.1, Federal Rule of Civil Procedure 7(b), Federal Rules of Evidence 702 and 703, and *Daubert v. Merrell Dow Pharmaceuticals, Inc.*, 509 U.S. 579 (1993), Plaintiff Kanautica Zayre-Brown hereby moves this Court to exclude the report and testimony of Defendants' expert Dr. Fan Li (Doc. 65-15) filed in support of Defendants' opposition to Plaintiff's motion for partial summary judgment. For the reasons stated in Plaintiff's brief filed in support of this motion, Dr. Li is not qualified to opine on the matters at issue, and her opinions lack a reliable basis and are ultimately irrelevant to the Court's consideration.

Respectfully submitted this 26th day of October 2023.

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CERTIFICATE OF SERVICE

I hereby certify that on October 26, 2023, I electronically filed the foregoing Plaintiff's *Daubert* Motion to Exclude the Testimony of Dr. Fan Li using the ECF system which will send notification of such filing to all counsel of record.

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UNITED STATES DISTRICT COURT
FOR THE WESTERN DISTRICT OF NORTH CAROLINA

CHARLOTTE DIVISION

Case No. 3:22-cv-0191

KANAUTICA ZAYRE-BROWN,)

)

Plaintiff,)

)

v.)

)

THE NORTH CAROLINA)

DEPARTMENT OF PUBLIC)

SAFETY, et al.,)

)

Defendants.)

Deposition of FAN LI, Ph.D.

(Taken by the Plaintiff)

Raleigh, North Carolina

Friday, August 11, 2023

Reported by: Marisa Munoz-Vourakis -
RMR, CRR and Notary Public

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Deposition of FAN LI, taken by the
Plaintiff, at North Carolina Department of Justice, 114 W.
Edenton Street, Raleigh, North Carolina, on the 11th day
of August, 2023 at 10:12 a.m., before Marisa
Munoz-Vourakis, Registered Merit Reporter, Certified
Realtime Reporter and Notary Public.

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I N D E X

Examination of: Page

FAN LI, Ph.D.

EXAMINATION BY MS. NOWLIN-SOHL 5

DEPOSITION EXHIBITS

EXHIBIT NUMBER	DESCRIPTION	PAGE
Exhibit 1	Expert Report	10
Exhibit 2	Dr. Antommara's Rebuttal Report	48
Exhibit 3	GRADE Guidelines Article	89
Exhibit 4	Pediatric Obesity Article	94
Exhibit 5	Lindqvist study	111

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P R O C E E D I N G S

Whereupon, FAN LI, having
been first duly sworn, was examined
and testified as follows:

EXAMINATION BY COUNSEL FOR PLAINTIFF
BY MS. NOWLIN-SOHL:

Q. Hi, good morning, Dr. Li. My name is Li
Nowlin-Sohl. I use she/her pronouns. I am an attorney
with the ALCU.

Would you mind stating your full name for
the record, please?

A. My full name is Fan Li.

Q. Can you spell that?

A. F-A-N, that's first name. Last name is
L-I, Li, happen to be your first name.

Q. Yes. Have you been deposed before, Dr. Li?

A. Ten years ago. So I think by the record is
like five years. No, I haven't been deposed in five
years, but I was deposed ten years ago once.

Q. Okay. And what was that in relation to?

A. Sorry?

Q. What was that deposition for?

A. Oh, that was for litigation, litigation for
Monsanto vs. a school. It's so long time ago, I forgot
the details.

1 Q. Okay. Were you an expert witness in that
2 case?

3 A. Yes, I was.

4 Q. Okay. And what were you providing
5 testimony about?

6 A. Some statistical methods, statistics and
7 using the data that they provided.

8 Q. Okay. And did that case have anything to
9 do with transgender people or gender dysphoria?

10 A. No.

11 Q. So I'm going to go over some of the ground
12 rules about depositions, just because it's been a while
13 since you had one of these.

14 As the court reporter said, you are under
15 oath, and it's much better if you can answer my
16 questions verbally. And it's important that we don't
17 talk over each other, and I don't anticipate any
18 issues, just to let everyone know about that.

19 Is there any reason why you are not able to
20 testify truthfully today?

21 A. No.

22 Q. Okay. How did you prepare for this
23 deposition?

24 A. Oh, I talked to Orlando, talked to him for
25 like one hour before yesterday, and we talked last

1 week. And then I read through my report and, yeah,
2 that's how I, how I prepared.

3 Q. Okay. Did you discuss anything about this
4 deposition with anyone else?

5 A. No.

6 Q. And you mentioned reviewing your report.
7 Did you review any other documents?

8 A. Oh, I also reviewed the rebuttal report,
9 the rebuttal that was sent to me on Monday, and what
10 else? I think -- oh, yeah, of course in preparing my
11 documents, my report, I reviewed 80-some papers, that's
12 the bulk, of course, of my work, the bulk of the report
13 is about. So I reviewed those documents. And, of
14 course, Dr. Aetna's report and also WPATH, but not all
15 of it, because I focus on the, you know, the assertions
16 that Orlando pointed out to me.

17 So that's all the documents I have
18 reviewed.

19 Q. And you mentioned the rebuttal report. Do
20 you know whose rebuttal report that was?

21 A. Oh, the name is long Dr. Antommara.

22 Q. Okay. Did you also review Dr. Ettner's
23 rebuttal report?

24 A. I reviewed very quickly, but it seems that
25 she didn't like that report, didn't really directly

1 counter my arguments. So I just very quickly went
2 through that.

3 Q. Any other documents that you reviewed to
4 prepare for this deposition?

5 A. No.

6 Q. Okay. Did you conduct any additional
7 research to prepare for this?

8 A. No.

9 Q. Since you submitted your expert report?

10 A. No.

11 Q. So you mentioned that Monsanto case that
12 you were an expert in. Have you been retained as an
13 expert in any other cases?

14 A. Yes. Currently there's another case at
15 NCDOJ, but that is, again, I mean, I'm still preparing
16 my report.

17 Q. Who is the case for? I missed that, I'm
18 sorry.

19 A. I think it is -- I don't even know much
20 about the exact name. It's about NC -- NJA, it's North
21 Carolina. It's basically a prisoner talking about the
22 race versus the -- whether race is a part of the
23 division in the division of the legal procedure, and
24 then I would need to determine that whether race or use
25 data to determine that whether race is used as a

1 factor, whether it's a causal factor or whatever factor
2 in the legal decision.

3 Q. Did that case have anything to do with
4 transgender people or gender dysphoria?

5 A. No.

6 Q. Are you currently serving as an expert in
7 any other matters?

8 A. No.

9 Q. And so other than the Monsanto case, this
10 case and that other one you just mentioned, are you --
11 have you ever served as an expert in another case?

12 A. No. Oh, I think I did. That was long time
13 ago. I wasn't even deposed. That was over ten years
14 ago in another case. It's technology. It's about,
15 yeah, talking about -- it's a tech. I don't even know
16 the exact name of the case, but that was a tech, yeah,
17 it's very -- that was very, all about numbers and
18 substantive methods.

19 Q. Okay. Any other?

20 A. No.

21 Q. Have you ever served as an expert in a
22 case, other than this one, that relates to medical
23 care?

24 A. No.

25 Q. Have you ever served as an expert in a

1 case, other than this one, that relates to gender
2 dysphoria or transgender people?

3 A. No.

4 Q. And you've never published on the topics of
5 gender dysphoria or transgender people, correct?

6 A. Correct.

7 Q. And you've never published on the topic of
8 gender affirming surgery?

9 A. Correct, I never.

10 Q. Okay. I'm going to mark as Exhibit 1 your
11 expert report in this case.

12 (The document referred to was marked
13 Deposition Exhibit Number 1 for
14 identification.)

15 MS. MAFFETORE: I am marking, just
16 because of awkward room setup, so here's the
17 one for the witness.

18 MR. RODRIGUEZ: This would be for you.

19 Q. Dr. Li, did you submit an expert report in
20 this case in Brown v. North Carolina DPS?

21 A. Yeah, I submitted report. So what is the
22 question? Sorry, yeah, I submitted report, but is that
23 the question?

24 Q. That was the question, yes.

25 A. Oh, okay.

1 Q. And my next question is, is this your
2 expert report?

3 A. Yes, this is.

4 Q. Okay. And how did you come to be retained
5 as an expert in this matter?

6 A. Oh, well, I was just one day I got a call
7 from -- well, actually Orlando emailed me and somehow
8 it went into spam and then took a while, and then he
9 called me, and then we talk about the case, and I
10 realized after I heard what he -- the background and
11 what he wanted, the opinion about, and I realized this
12 is my expertise. So I said yes.

13 Q. Okay. And what did you do to prepare this
14 report?

15 A. Oh, again, so Orlando gave me WPATH and
16 Dr. Ettner's, the report, and then he also gave me the
17 specific, the assertions that he picked out from the
18 WPATH and Dr. Ettner's report, and then asked me to
19 review the body of literature that was cited on
20 those -- by WPATH and Dr. Ettner, so asked me to review
21 that.

22 So that's how I -- and then I went to
23 review the documents and that's how I prepared this, my
24 report.

25 Q. Had you reviewed the WPATH, and by WPATH

1 are you referring to the WPATH standards of care needs?

2 A. I believe so.

3 Q. Have you reviewed that document before
4 Orlando gave it to you?

5 A. No, I wasn't even aware of that document.

6 Q. Okay. And did anyone help you prepare this
7 report?

8 A. No.

9 Q. Did you discuss it with anyone, other than
10 counsel, in this case?

11 A. No.

12 Q. So you mentioned that Orlando gave you
13 these documents and kind of pointed you to the specific
14 assertions that are included in your report. You
15 looked at those studies. Is there anything else that
16 you did to prepare this report? Did you look at any
17 other studies? Any other literature?

18 A. No, I didn't.

19 Q. Okay. Are you aware of any inaccuracies in
20 your report?

21 A. Oh, I actually yesterday found two typos,
22 so I don't know whether that's called an inaccuracy,
23 but that's typos.

24 So let me -- one I think is page 5, page 5
25 on top, so B. And so the first paragraph it say: The

1 statistical methodology for quality of life belongs to
2 the, blah, blah. So it's not for quality of life.
3 What I meant is for comparative effectiveness research.
4 So that was a typo, probably copy, paste wrong there.

5 So that was the first I noticed yesterday
6 when I reviewed.

7 The second one was on page 6, the bullet 2,
8 it say: Types of biases in causal -- it should be
9 causal inference, not causal interference. So that's a
10 typo. That's probably Microsoft, maybe Word, just auto
11 corrected or whatever. But that's a typo, yeah, yeah.

12 So other than that, I'm pretty sure there
13 are typos somewhere, but in terms of my opinion, the
14 bulk of my opinion, it's all accurate. It's an
15 accurate reflection of my opinion.

16 Q. Okay. And then other than the typos that
17 you just flagged, is there anything about your report
18 that you'd like to amend or correct?

19 A. Not at this point.

20 Q. Okay. Would you like to change any of your
21 opinions expressed in the report?

22 A. No.

23 Q. And are there any documents and materials
24 that you relied on that are not cited in the report?

25 A. No.

1 Q. Okay. And does this report contain a
2 complete statement of the opinions you intend to
3 provide in this litigation?

4 A. Yes.

5 Q. Do you know what gender dysphoria is?

6 A. Well, I think from the papers, I'm not
7 expert on that, from the papers, I reviewed it, yeah,
8 it's like someone has -- feel that his or her gender is
9 disaligned with his sex at born -- I guess, I mean,
10 that's how I understand it. Again, I didn't do any
11 research on that. And to me that is just one type of
12 outcome that we're dealing with. I'm using the
13 terminology in my field. It's just the one type of
14 symptom or outcome. It's a variable to me. Variable,
15 again, it's a statistical terminology.

16 So, yeah, that's all I know about gender
17 dysphoria.

18 Q. Okay. And so are you familiar with what
19 the DSM is?

20 A. DSM? Oh, yeah, DSM, I say again before
21 when I was a research assistant, it's a type of, I
22 believe it's a mental health or, you know,
23 psychological disease. It's a code for that.

24 Q. The Diagnostic and Statistical Manual, and
25 you said it's to diagnose certain conditions?

1 A. Yes.

2 Q. Are you aware that gender dysphoria is a
3 condition in the DSM?

4 A. I didn't know until now you tell me.

5 Q. Okay. And so it's defined as the
6 psychological distress that results from an
7 incongruence between one's sex assigned at birth and
8 one's gender identity.

9 Is that consistent with your understanding
10 of what gender dysphoria is?

11 A. Yes.

12 Q. Now, I'd like to look at the CV that's
13 included as Appendix A in your report. It's roughly
14 around page 27, I think.

15 A. Page 27?

16 Q. It's not numbered, but it's about a third
17 of the way through.

18 A. Oh, I see. I see. Oh, yes, my CV, yes. I
19 know my CV. Go ahead.

20 Q. And so I just want to walk through this a
21 little bit.

22 So it looks like you got a bachelor's in
23 science in 2001, is that accurate?

24 A. Yes.

25 Q. Okay. And then you got a Ph.D. in 2006.

1 What is your Ph.D. in?

2 A. Biostatistics.

3 Q. And what is Biostatistics?

4 A. So that's basically a branch of statistics,
5 kind of use statistics as a methodology or a theory to
6 solve problems, particularly in bioscience or health
7 studies, you know, medicine. But it is, can also be
8 theoretical, but it's just a branch of statistics.

9 Q. It is not a medical degree?

10 A. It's not.

11 Q. Okay. Do you have a medical degree?

12 A. I don't.

13 Q. Okay. Do you have any other degree that
14 would qualify you to provide healthcare to patients?

15 A. No.

16 Q. Do you have any degrees related to mental
17 health?

18 A. No.

19 Q. And I see that you had a post doc between
20 2006 and 2008. What was that post doc?

21 A. Oh, it was in the department of healthcare
22 policy, but it's really in statistics, because my
23 mentor, he was -- he is a statistician, but he works at
24 the healthcare policy. So I just work there, and yeah.

25 Q. Okay. And so as part of that post doc, you

1 were doing statistics?

2 A. Yes.

3 Q. And not any sort of medical care?

4 A. Yeah, I mean, most of the data from medical
5 care, yeah. Sometimes we also work on like social
6 science, but, yeah, but the department was healthcare
7 policy, but I was doing statistics.

8 Q. Were you involved in creating healthcare
9 policy?

10 A. No. I'm not important enough. I was not
11 important enough.

12 Q. Okay. And so as part of your formal
13 education, have you ever taken any courses regarding
14 transgender people or gender dysphoria?

15 A. No.

16 Q. Have you ever taken any continuing
17 education classes regarding transgender people or
18 gender dysphoria?

19 A. No.

20 Q. Have you ever attended any presentations
21 about transgender people or gender dysphoria?

22 A. No.

23 Q. Have you ever conducted any research
24 concerning transgender people or gender dysphoria?

25 A. No.

1 Q. And do you have any other educational
2 training that I may be missing related to transgender
3 people or gender dysphoria?

4 A. No.

5 Q. And have you ever been a reviewer for any
6 academic journals with regard to issues relating to
7 transgender people or gender dysphoria?

8 A. No.

9 Q. So after your post doc, it looks like you
10 became an assistant professor at Duke, is that correct?

11 A. Yes.

12 Q. Okay. And so -- and you've been at Duke
13 since then?

14 A. Yes.

15 Q. And so in layperson's terms, what do you do
16 for work?

17 A. Oh, okay. So I teach, and I also do
18 research. That's kind of -- well, supposedly 50/50,
19 but I spend more time on research, and I also advise
20 Ph.D. students.

21 And thus -- oh, and also in my research, I
22 do statistical theory, but I also collaborate with
23 medical doctors, sometimes social scientists or
24 economists, again, on statistics or substantive field,
25 and, yeah, that's more or less what I do; teaching,

1 research, mentoring and, of course, service to the
2 community, again, to the academic community. Like I
3 have been the editor, associate editor and editor for
4 multiple journals, including, for example, JAMA, like
5 also review papers for my own field statistics but also
6 for like medical field. Like so I review for JAMA,
7 JAMA Cardiology, that kind of thing.

8 Q. You mentioned you reviewed for JAMA. What
9 does that entail?

10 A. Oh, Journal of American -- Journal for
11 Medical Association of America, JAMA, Journal of
12 Association --

13 Q. You don't have to define the acronym.

14 A. No, it just a top medical journal. It's a
15 top medical journal. The other one is New England
16 Journal of Medicine. I assume people know JAMA. It's
17 just a top medical journal.

18 Q. I'm familiar with JAMA. I'm just curious
19 what your role is as a reviewer. What do you do?

20 A. So I usually serve as a statistical
21 reviewer. So sometimes they have papers, so that they
22 want the editor or the AE want a statistical expert to
23 review the statistical method, the rigor of statistical
24 methodology analysis in the paper. I'm not like in
25 charge of judging the clinical side of things, but

1 purely judging the rigor of the statistical
2 methodology. So that's what I do.

3 Q. And so looking at your CV, what's the
4 difference between an assistant professor, an associate
5 professor and a professor?

6 A. Oh, just get more senior. Paid more I
7 guess. So -- and most universities when you assist --
8 this is the so-called tenure track position.

9 So when I assistant professor, you are on
10 the tenured track but you don't get tenured.

11 So at associate level you get tenured.
12 Basically they cannot fire you for, without reason, and
13 then full professor you get more senior. Yeah, you get
14 paid more, and you are more senior.

15 Q. And so in all of those roles, were you
16 teaching, doing research and advising Ph.D. students?

17 A. Yes. Yeah.

18 Q. And what do you teach?

19 A. Oh, I teach -- so I teach -- so a range of
20 classes, but like statistics, and, well, they are all
21 statistics, but they are different.

22 If you go to the -- further down my CV, I
23 list the classes I teach. So I don't want to bother
24 you with this jargon. So I teach probabilities,
25 statistical engineering, design and analysis of causal

1 studies, but because my research expertise is causal
2 inference, so I teach a lot of -- many classes in
3 causal interference, like specialized. For example,
4 causal inference, I've been teaching almost every year
5 different versions of that.

6 So yeah, it's generally statistics.

7 Q. And you say generally, are there any
8 classes that you teach that are not statistics?

9 A. Oh, no, because I only know statistics. I
10 don't have the expertise to teach topics not
11 statistics.

12 Q. Okay. And what is your role with the Duke
13 Clinical Research Institute?

14 A. Oh, so it's, yeah, so it's like I am
15 affiliated. So it's like when they have -- so how it
16 works is so they have projects or trials or studies,
17 observational study or clinical trials, and then
18 basically all of those studies they need statistics.
19 So they always need statistics experts. So, of course,
20 they, you know, because I'm Duke faculty, so I have
21 natural connection at the people at the Duke Clinical
22 Research Institute. And so they come to me, so when
23 they have projects, and I am on their projects, and I
24 provide statistical analysis or methodology guidance
25 for them. So that's how I work with them.

1 Q. And so are you involved at all in the
2 stages of a study from kind of in the preplanning, in
3 the post analysis and also the execution of the study?

4 A. It depends. So sometimes they come to me
5 when the study is already, like the data collection is
6 already done. Then the data is messy. Then they come
7 to me. So that's -- sometimes it's like that.

8 And sometimes, sometimes it's like at the
9 beginning of the, even at the early planning stage,
10 like they want to write a grant to get money to get
11 funded for that study, so they need a priority
12 analysis, and they come to me.

13 So it highly depends on the specific
14 project or study, so I --

15 Q. Okay.

16 A. Yeah.

17 Q. And you mentioned that you -- well, sorry
18 let me rephrase that.

19 So the institute conducts randomized
20 control studies and observational studies?

21 A. Yes. Well, again, it depends on the
22 specific project. Yes, sometimes it's randomized
23 study. Sometimes it's observational study. Yeah, it's
24 individual investigators. They write proposals and get
25 funded. Once you get funded, you do the study. So

1 it's a wider range of things.

2 Q. And have you assisted with both types of
3 those studies?

4 A. Yes.

5 Q. Okay. And I think we covered this a little
6 bit, but just to be clear, do you practice medicine?

7 A. No.

8 Q. Do you see patients?

9 A. No.

10 Q. Okay. Do you know what a clinical practice
11 guideline is?

12 A. No.

13 Q. No, okay. Have you ever been involved in
14 the development of one?

15 A. No.

16 Q. So going back to your CV on page 8 of the
17 CV, there are same grants listed. Can you tell me just
18 a little bit about that first grant?

19 A. Oh, the Innovative Biostatistical Methods
20 for Analysis and Assessment of Clinical Trials
21 Augmented by Real World Data, yeah, so this is funded
22 by the Burroughs Wellcome Fund Innovation. So it's
23 a -- so it's funded by a private foundation, and this
24 is to study, again, to develop statistical methods for
25 clinical trials. Well, it's basically --

1 Okay. So what this study is proposed to do
2 is try to use real world data, real world data means
3 like observational study or the historical data,
4 historical clinical trial or current like electronic
5 health record, use that data to combine that data, this
6 clinical trial data, and that is, yeah, so there are a
7 lot of challenges, methodology challenges there, and
8 then that's what this grant is supposed to do to
9 develop those methods.

10 Q. Okay. So it's about finding methods to be
11 able to use that real world data?

12 A. Well, combination, basically clinical
13 trials. Like you can have clinical trials. You can
14 also have external data. How do you properly combine
15 them?

16 Q. Okay. And can you tell me about the second
17 grant that is listed?

18 A. Oh, the second one, that's a funny one. So
19 the second one is this Covid-19 Enhancement. So this
20 actually is better to read it. So second and fourth
21 actually kind of connected.

22 So the fourth one is my, again, I'm just --
23 I'm not the primary investigator there. So if you look
24 at that it's called Co-I, it's a coinvestigator.

25 So the number four, that was the kind of

1 the mother grant with my collaborator Laine Thomas got
2 the grant from PCORI. PCORI stand for Patient Centered
3 Outcome Reference Institute.

4 So that was the primary grant, and then
5 when Covid-19 hit, the agency had more money, and so
6 then we asked, like we basically ask for supplement to
7 do additional methodology work. So that's why you have
8 this number two. So that's actually just, again, a
9 supplement of the grant number four.

10 Q. Okay. And at a very high level, what was
11 grant number four?

12 A. Oh, again --

13 Q. What was the goal?

14 A. The goal is try to develop statistical
15 methods to improve the design and the conduct of the
16 observational study, particularly this type of subgroup
17 analysis. So high level is the observational study, so
18 the methodology and the design and the methodology.
19 There are challenges, and we propose new methods to
20 solve those challenges.

21 Q. Okay. So going back to the substance of
22 your report, can you summarize your conclusion in your
23 report for me?

24 A. Absolutely. Give me a minute.

25 So I will just read it.

1 Q. Actually, I don't want you to read it. Can
2 you summarize it for me?

3 A. Yeah, I know. So I think I should -- okay,
4 I should start with what my assignment was. So I was
5 asked to assess whether the assertions made by
6 Dr. Ettner and WPATH, the specific assertions made by
7 them are supported by the reference they cited. And my
8 conclusion is I do not believe that their assertion,
9 specific assertions point by point are supported by
10 those -- well, supported by the body of literature they
11 cited.

12 In other words, I will say that the
13 evidence cited by Dr. Ettner and WPATH do not provide
14 reasonable or sufficient support for the assertions,
15 specific assertions.

16 Q. Okay. And what do you mean by reasonable?

17 A. What do I mean by reasonable is reasonable
18 judged by me, my expertise as an expert in the
19 so-called comparative effectiveness research.

20 Like I'm an expert, so as a statistician,
21 my expert is actually called inference. Well, the
22 inference is essentially to determine what kind of
23 evidence needed to establish the effectiveness,
24 effectiveness or safety of a treatment, and that's my
25 expertise. And based on my expertise, after I review,

1 the references cited by them and look at the specific
2 assertion, I don't think that they provide support,
3 provide -- it's just not enough.

4 Like if I'm a medical -- if I'm a reviewer
5 of a medical journal, if you submit a paper with those
6 assertions and those references, I would reject it on
7 the ground that the evidence is not enough.

8 Q. Okay. And so how much is enough?

9 MR. RODRIGUEZ: Objection, vague. You
10 can answer.

11 A. Yeah, I think your question is very vague,
12 and it's beyond more than being vague, it's also this
13 is all very case by case.

14 So I read a paper, for example, if it says
15 if you want to establish the effectiveness of say a
16 vaccine, and then I would expect to see evidence,
17 clinical evidence from a randomized trial or
18 well-designed observational study, and if it does not
19 provide that, or the study does not have good quality,
20 for example, those retrospective study assay, then I
21 will judge it's not enough. So it's highly case by
22 case.

23 So, again, that's why I was very specific.
24 So in my report, I provide not a blanket statement. I
25 went case -- point-by-point the assertion and exam

1 one-by-one and say why I believe that is not enough.

2 So in order to answer that question, I
3 think it's better for you to actually go through the
4 details.

5 Q. So at the bottom of page four in your
6 report, so at the end of the second line, you said: I
7 conclude, to a reasonable degree of statistical
8 certainty, that these studies failed to provide
9 rigorous and consistent statistical evidence on the
10 benefits and quality of life and well-being of sex
11 reassignment surgery. Do you see that?

12 A. Yes.

13 Q. What do you mean by statistical certainty
14 there?

15 A. Oh, statistical certainty, again, because
16 I'm a statistician, right, I look at the papers, those
17 papers and the papers, that actually a big quantity of
18 papers, 80-some studies, and the statistical certainty
19 means that my statement is based on the kind of data,
20 the data of those 80-some papers I reviewed.

21 So that's what I meant by statistical
22 certainty. It means that I -- my judgment or my
23 opinion is based on data, again, data in this case,
24 those papers.

25 Q. And how did you calculate that statistical

1 certainty?

2 A. I don't calculate that statistical
3 certainty. That is a phrase, and, yeah, you cannot
4 calculate. But I based on my expertise as a
5 statistician, my expertise in this field.

6 Q. Okay. So the phrase is not that there is
7 certainty supported by numbers, but rather that you are
8 confident and you relied on statistics?

9 A. Yes.

10 Q. Okay. And what do you mean by rigorous and
11 consistent statistical evidence?

12 A. Oh, rigorous and consistent, okay, so
13 rigorous is, again, rigorous is based on the strengths
14 of the study. So my judgment of the strengths of the
15 design quality, the quality of the study, that means
16 rigorous.

17 So in science, we always say whether this
18 study is conducted with vigor. So things with more
19 vagueness, or like with a lot of authenticity and
20 noise, we call that that's not rigorous.

21 And consistent, that is consistent means if
22 you read through my report, you will see that I review
23 this 80-some documents and I divided the papers into
24 different categories by design. So they are -- one of
25 my studies, they are prospective studies, and they are

1 retrospective studies, and the prospective studies, I
2 cited many of them, there are not too many, there are
3 five of them. They provide mixed results, mixed
4 results about the benefit of the sex reassignment
5 surgery on quality of life and well-being of the --
6 well, quality of life.

7 So they are mixed results.

8 And so, yeah, by consistent, I mean all the
9 studies suggest, point to the same thing, and I don't
10 see it here.

11 So that's what I meant by rigorous and
12 consistent, and the documents, the papers that I
13 reviewed do not provide rigorous or consistent
14 evidence.

15 Q. Okay. And only randomized control trials
16 qualified as rigorous?

17 A. No, I didn't say that. I never say that in
18 my opinion. I mentioned in my opinion randomized study
19 is to establish the treatment -- effectiveness of a
20 treatment. They are hierarchy of study designs. The
21 gold standard is randomized study, but I didn't say
22 that's the only one or that it must. I said is the
23 gold standard is randomized study, and then the second
24 one, when that is not available, you can resort to
25 observational study, but it need to be well designed.

1 The best quality of observational study
2 design is prospective study, this before and after
3 comparison, and that is doable, that is visible, and
4 that is reported in some of this 5 of these 80-some
5 studies.

6 And the last, the worst quality of all of
7 this is the retrospective study results, before/after
8 comparison, and that was the bulk of the study that was
9 cited.

10 So that was my argument. I never said RCT,
11 randomized trial is the only -- is the only one that is
12 rigorous.

13 Q. Okay. And you mentioned kind of the mixed
14 results. How many or what percentage of studies have
15 to show the same results for them to be considered
16 consistent?

17 A. You cannot make that judgment. That's not
18 a good question, because you can have a bunch of very
19 low quality ones, one hundred -- and all of them are
20 very deeply flawed methodology wise, and one hundred
21 percent of them point to -- point to one direction.

22 And then if you have a small bunch of high
23 quality study, they all point to the other one, other
24 direction. In that case, I would take that small bunch
25 of quality over the large bunch of low quality studies.

1 So you can never say -- you can never say
2 that oh, how much, what the percentage has to be,
3 what's the percentage of the signals has to be in the
4 studies, then it can be regarded as enough. You don't
5 do that. You judge by the first, so their order in the
6 judgment, so their order in the criterion. Well, the
7 first order of business or the criterion would be the
8 quality of the design.

9 So, yes, if there are two randomized study,
10 if there are only one of two randomized study, show me
11 one direction. And then I have one hundred very
12 methodologically flawed low quality retrospect study
13 shows the treatment from the other direction, I
14 probably will trust -- well, not probably, I will
15 trust, and FDA will trust a randomized study, take the
16 randomized study result, which is much more -- consider
17 that is much more reliable or valid evidence.

18 Q. Okay. So stepping away from the quality of
19 the design, we're talking about consistency. You've
20 concluded here that they are not consistent?

21 A. Yes.

22 Q. So I guess I'm trying to understand where
23 that line is? What makes it consistent versus what
24 makes it not consistent? And how do you know here to
25 conclude that it is not consistent?

1 A. Yes. If you go to my expert report,
2 consistent -- it's hard to find this, let me see. I
3 think for the assertion -- let me see, the WPATH
4 assertion one. So it's on page 12.

5 Q. Okay.

6 A. So I state very carefully, so first of all,
7 there's no RCT, but that is not end of the world,
8 because they are -- actually they do have five
9 prospective studies. And so I wrote this very clear.
10 I don't need to read it, but I cited to see that, you
11 know, they have mixed results for them to Lindqvist --
12 if you read page 12, the second to the last paragraph:
13 Lindqvist, et al, found mixed results on the effects of
14 SRS on quality of life. Specifically, they found that
15 comparing to before treatment, quality of life is
16 better one year after operation but worse three and
17 five years after operation.

18 So that is -- so that's one. And also if
19 you flip to the next --

20 Q. So is that finding sufficient for you to
21 find that there's not consistent statistical evidence?

22 MR. RODRIGUEZ: Li, she's still
23 answering your question.

24 A. Yeah, I'm not done yet.

25 Q. Okay.

1 A. Because that is several -- so there are
2 actually five prospective studies cited here, and those
3 are of higher quality than the retrospect study.

4 And then here, one-by-one I actually
5 specific tell what their findings. And not -- the
6 Lindqvist one I read. I don't know whether I should
7 read all of it, but you can read, you can read it
8 yourself to say that the other one, so let me see, like
9 the --

10 Q. I don't need you to read the actual citing.
11 That's not my question. So maybe I can rephrase.
12 Would that be helpful?

13 A. Yeah, again, before you rephrase, I just
14 answer that you say not consistent, yes.

15 So what I wrote here is the five higher
16 quality of higher quality observational study, they
17 find mixed results. They don't find all that it's
18 helpful for quality of life, and this is every paper is
19 like, and, yes, that's my answer.

20 Q. Okay. So stepping away from this report, I
21 guess I'm trying to understand how you determine when
22 it's consistent or when it's not.

23 And so is it that, you know, one study out
24 of five, is it -- you know, I don't need an exact
25 percentage, but is the expectation that all of the

1 studies are consistent?

2 MR. RODRIGUEZ: I'm going to object to
3 form. You can answer.

4 A. Oh, again, this is same kind of problems I
5 have with your previous question is vague. It's --
6 well, let me say this: So consistent, again, so I
7 have -- so, again, you have -- so this is already you
8 cannot just take the consistent out of context.

9 So here there's five prospective studies,
10 right. And I think at least three of them, the results
11 are saying that the result is not beneficial or some of
12 the result are beneficial, some of the outcomes are not
13 beneficial. And so that is just -- that's
14 inconsistent. I mean, there because you have five
15 different -- you have five studies, and the five
16 studies say -- have very different conclusions. And
17 that is inconsistency. I cannot name whether there's
18 one out of five or three out of five because that is
19 inconsistent. Like here, at least three out of five
20 they are showing mixed result. And also this is just
21 mixed result, and those result are different from the
22 direction that from the large body of low quality
23 retrospective studies.

24 So that's what I meant by not consistent,
25 because you have both retrospective study and

1 prospective study and observational studies, and they
2 are of different results.

3 Q. Okay. Going to page 25 of your report, to
4 the conclusion.

5 A. Yes.

6 Q. At the end, you state your opinion to a
7 reasonable degree of statistical certainty that the
8 studies cited by Ettner and/or WPATH and reviewed in
9 this report simply do not provide reasonable support
10 for the assertions made, and then it continues.

11 A. Yes.

12 Q. What do you mean by reasonable support?

13 MR. RODRIGUEZ: Asked and answered.

14 You can answer.

15 A. I think I answered your question before.

16 A reasonable -- I already said a formal
17 reviewer of a medical journal, and you submit things,
18 you make assertions of this, and then you submit
19 your -- and your paper or your report, you submit
20 evidences. And based on like those -- the reference
21 they cited, I would reject it, because I don't -- I
22 already explain many times why I think that's -- the
23 quality is low. The better quality of study that is
24 available show mixed results. The lower quality ones,
25 they are subject to a lot of methodology flaws. And

1 even their own expert, like even their own -- many of
2 the papers they cited, I reviewed, call for better
3 design studies. In that instance, I would not think --
4 I would not regard the evidence that they showed or in
5 this case it's the reference they cited, provide
6 reasonable or provide support, sufficient support for
7 their argument.

8 Q. Okay. And this -- so the standard of
9 reasonable support that you're using is sufficiently
10 supported for you to accept it for publication in a
11 medical journal?

12 MR. RODRIGUEZ: Objection,
13 mischaracterization of testimony.

14 You can answer.

15 A. No, I use that as analogy, but I'm just
16 saying as a scientist, how do you establish evidence
17 for something? Okay. You actually go to the, like in
18 this case, you want to establish the effectiveness of
19 medical intervention. And there are ways of study --
20 there are different ways, study designs you can do.
21 You can conduct those studies. And then you can
22 analyze the data.

23 And, again, as an expert, I am involved in
24 many of like this type of study, not about gender
25 dysphoria, but just to kind of establish the

1 effectiveness of treatment. And my expertise, my
2 experience tell me, based on that, I judge that what
3 they cited here do not support their assertions. So
4 it's overstretched.

5 Q. Okay. Can prospective observational
6 studies provide reasonable support?

7 A. So the answer to that is not black and
8 white.

9 So the best one, if possible, there would
10 be a randomized study that's gold standard, but that
11 is -- when that is not available, if you --

12 Q. Okay. Continue.

13 A. So that's the gold standard. I'm just
14 stating a consensus in the field. When that is not
15 available, then you have, yes, then you try to do the
16 best quality observational study.

17 So, yeah, prospective study can be used,
18 prospective study can be used as part of the evidence,
19 but whether that can be viewed towards -- can be taken
20 as the foundation for treatment recommendation, that's
21 not a question that I can answer, because I'm not a
22 medical doctor. But I can just tell you that the
23 prospective study, yes, it is well conducted. If it's
24 repeated many times with consistent result, then, yes,
25 I believe that that would -- some medical doctors can

1 take that as a strong evidence. But whether that
2 can -- again, who made that decision, I don't know, and
3 I'm not going to -- like that's not the question I'm
4 going to answer, like I'm supposed to answer, because
5 that's not my expertise.

6 Q. Okay. Just to clarify on that, you said
7 you're not opining on whether treatment recommendations
8 can be made from this?

9 A. Well, yeah, so treatment recommendations,
10 so evidence needed to make treatment recommendation is
11 a different point, it's a different question from how
12 do you establish the effectiveness of a treatment?
13 Those two are different things.

14 So my assignment as a statistician, I can
15 answer the first. I can answer the later question. I
16 can answer the question of how do you establish the
17 effectiveness of a treatment, but that is not
18 equivalent to how do you make a treatment
19 recommendation, because making a treatment
20 recommendation, from my understanding, involves a lot
21 of, you know, other considerations.

22 So -- but my, again, my scope is on whether
23 the treatment, it's not treatment effectiveness.
24 Arguably, that's one of the most important point
25 consideration in making treatment recommendation.

1 Arguably that's the most important one, but that might
2 not be the only one.

3 But, again, my scope is to answer the
4 question, the more focused, specific question about
5 whether you can establish the treatment -- the
6 effectiveness of a treatment.

7 Q. Okay. So what is the significance of your
8 conclusion that the studies failed to provide
9 reasonable support for the assertions made by
10 Dr. Ettner and WPATH?

11 MR. RODRIGUEZ: Objection, vague and
12 form. You can answer.

13 A. Yeah, what do you mean by what is the
14 significance? The significance in what aspect? In
15 terms of what?

16 Q. So, okay. So you're talking about -- your
17 question is about establishing the effectiveness of the
18 treatment. So is your conclusion that the
19 effectiveness of the treatment has not been established
20 to a degree of statistical certainty?

21 MR. RODRIGUEZ: Objection,
22 mischaracterization of the report, and her
23 previous testimony as to what her
24 conclusions are. You can answer.

25 A. So, again, I don't quite understand what

1 you are trying to ask here.

2 So my conclusion is, yes, based on my
3 expertise and the document I reviewed, I conclude that
4 the body of literature they cited do not support their
5 assertions.

6 And you asked me is that significant?
7 Again, sorry, I don't understand. What do you mean?
8 What do you want me to say? I mean, what do you mean?
9 Can you phrase this again?

10 Q. Yeah. Well, let me ask a follow-up
11 question on that, because you're saying that the
12 evidence does not support the assertion. And in
13 layman's terms, I'm wondering if support has a
14 different meaning, right, because is it that they don't
15 support it with vigor, or that they don't support it at
16 all?

17 A. Oh, okay. Oh, it's just they make
18 assertion -- if you look at the assertions, some are
19 very -- okay, let's go to specifics.

20 So, for example, some of the assertions
21 I -- yeah, what do you mean by support? You want me to
22 elaborate on that. I can do that.

23 So, for example, page 11 on my report,
24 WPATH assertion one: There is strong evidence
25 demonstrate the benefit of the quality of life. And so

1 I focused on this strong evidence.

2 So they claim this is strong evidence. I
3 don't think that has strong evidence, okay, so that's
4 what I meant by no support.

5 And the second, to give you another
6 example, I should probably go to Dr. Ettner's
7 assertion, let me see.

8 Q. And we will go through these one-by-one
9 later, so you know.

10 A. Okay. That's even more fun. But, yeah,
11 that's what I meant. Like I was very specific in this
12 specific point-to-point discussion.

13 So when I say do not support, I meant,
14 yeah, point-by-point, yeah, it's better point-by-point,
15 then you go and see the problems. I mean, they do not
16 support. It's often exaggeration or overstatement or
17 sometimes just factually mistake, factual mistake.
18 Sorry, go ahead.

19 Q. Are you saying that the WPATH standards of
20 care are wrong?

21 MR. RODRIGUEZ: Objection,
22 mischaracterization of the report and the
23 testimony. You can answer.

24 A. No. It's a long document with many
25 different opinions. I cannot just say it's wrong, no

1 it's not. I was talking about the assertions they made
2 are not supported by -- well, again, as I just
3 described not -- yeah, supported by their -- well, in
4 other words, that it's often an overstretch,
5 exaggeration, over characterization of the -- of
6 things, of opinions. I didn't say it's strong.

7 Q. Are you saying that the WPATH standards of
8 care should not be followed?

9 MR. RODRIGUEZ: Objection,
10 mischaracterizes testimony. You can answer.

11 A. No, I didn't say that. I don't have the
12 expertise to say things like that.

13 Again, my opinion is very focused on
14 specific -- the assertions to counter or to exam the
15 specific assertions, and I didn't make any statement
16 about whether they should follow WPATH.

17 Q. Are you saying that WPATH should not rely
18 on the studies that are cited in your report?

19 MR. RODRIGUEZ: Same objection,
20 mischaracterization of the evidence and the
21 report. You can answer.

22 A. I didn't say. Again, WPATH, what kind of
23 document they want to decide on is they decide. It's
24 not my opinion about. My opinion is about they cite,
25 they decide, they cite a bunch of papers, references.

1 And, again, I try to judge that, whether the reference
2 they cited support their assertions. So that's a
3 different concept.

4 Q. Okay. Dr. Ettner stated in her report that
5 the standards of care for treatment of gender dysphoria
6 are currently set forth in the WPATH standards of care.

7 Do you disagree with that statement?

8 MR. RODRIGUEZ: Objection, outside of
9 the scope of this witness' opinion. You can
10 answer.

11 A. Yeah, yes, I agree with Orlando that is
12 outside my scope.

13 Again, my job is to exam the specific
14 assertions of Dr. Ettner and WPATH, and what you just
15 asked is not part of the assertions I was asked to
16 provide opinions on.

17 Q. Okay. So you are not providing an opinion
18 on whether the standards of care for the treatment of
19 gender dysphoria, or you are not providing an expert
20 opinion on the standards of care for treatment of
21 gender dysphoria?

22 MR. RODRIGUEZ: You can answer.

23 A. No, I was not -- I'm not providing opinions
24 on that.

25 Q. Okay. And Dr. Ettner also stated that the

1 WPATH standards of care are the internationally
2 recognized guidelines for the treatment of persons with
3 gender dysphoria and informed medical treatment
4 throughout the world.

5 Do you disagree with that statement?

6 MR. RODRIGUEZ: Objection, outside of
7 the scope of the witness' opinions.

8 You can answer.

9 A. Yeah, that's outside -- that's not what I'm
10 asked to write opinion on. It's outside the scope of
11 my expert opinion.

12 Q. Okay. Dr. Ettner also stated that the
13 American Medical Association, the Endocrine Society,
14 the American Psychological Association, the American
15 Psychiatric Association and a host of other entities
16 all endorse treatment protocols in accordance with the
17 standards of care.

18 Do you disagree with that statement?

19 MR. RODRIGUEZ: Same objection,
20 outside the scope of the witness' opinions.

21 You can answer.

22 A. Same answer. It's outside my opinion, my
23 report.

24 Q. Do you think that all of those medical
25 associations should not endorse treatment protocols in

1 accordance with the standards of care by WPATH?

2 MR. RODRIGUEZ: Objection, outside the
3 scope of the witness' opinions.

4 You can answer.

5 A. Same answer as before. That is outside of
6 my -- the scope of my report.

7 MS. NOWLIN-SOHL: So we've been going
8 for about an hour now. I'm at a good pause
9 place, if you'd like a break?

10 THE WITNESS: Yes.

11 MS. NOWLIN-SOHL: So we'll take five,
12 ten minutes Orlando?

13 MR. RODRIGUEZ: Let's do ten, because
14 we have to walk across the other side of the
15 building, so let's do ten.

16 MS. NOWLIN-SOHL: We'll be back at
17 11:20.

18 THE WITNESS: Sounds good.

19 (Off the record at 11:10 a.m.)

20 (On the record at 11:22 a.m.)

21 BY MS. NOWLIN-SOHL:

22 Q. Welcome back, Dr. Li. You are aware that
23 you are still under oath?

24 A. Yes.

25 Q. Okay. And okay, so I want to go to page

1 four of your expert report.

2 A. Yes.

3 Q. And in the middle of that last large
4 paragraph, you state that: Most of the studies cited
5 in support of those assertions are of low quality in
6 terms of study design and statistical methodology.

7 What do you mean by low quality?

8 A. Well, by low quality, again, I explained,
9 explain a lot in the later part of the report, but I
10 list a bunch of commonly known problems of study or
11 like biases in study can happen, like confronting bias,
12 selection bias, nonresponse bias, recall bias.

13 So by low quality, I meant that those
14 studies are very prone to those kind of biases of
15 deficiency in the -- or flaws, design flaws.

16 Q. Okay. Are you familiar with the GRADE
17 system?

18 A. The GRADE system? No.

19 Q. Yes. No, okay.

20 So when you say low quality, is that a term
21 that's used in statistics, or is that your own
22 phrasing?

23 A. So of course it's my own phrasing, but I
24 actually borrow that from -- I reviewed those studies,
25 and quite a few of those studies, like a dozen or so,

1 they are literature review of the papers. And this is
2 a phrase they repeatedly use themselves, low quality.

3 So I kind of borrow that phrase and, of
4 course, that's also known in English what low quality
5 means.

6 Q. You say it's not the English of what low
7 quality means?

8 A. No, I'm saying that it's first of all, they
9 themselves call it low quality, and also to me that is
10 layman can understand low quality in English. So
11 that's why I adopt that.

12 Q. Okay. And you said that you reviewed
13 Dr. Antommara's rebuttal report in this matter
14 correct?

15 A. Yes, quickly reviewed, yes, I reviewed it.

16 Q. Okay. I'd like to mark as Exhibit 2
17 Dr. Antommara's rebuttal.

18 (The document referred to was marked
19 Deposition Exhibit Number 2 for
20 identification.)

21 A. Yes, I have it.

22 Q. Okay. And is this the rebuttal report that
23 you reviewed?

24 A. Yes.

25 Q. Okay. And I'd like to direct you to page

1 9.

2 A. Yes.

3 Q. Okay. And so there he talks about the
4 GRADE system as distinguishing four levels of evidence.
5 Do you see that?

6 A. Yes, I see that.

7 Q. Okay. And those levels are high, moderate,
8 low and very low?

9 A. Yes.

10 Q. Have you encountered those ratings before?

11 A. Again, I'm not familiar with the GRADE
12 system. I don't know who decide the GRADE system, but
13 I look at high, moderate, low and very low, that sounds
14 like a reasonable, reasonable, you know, GRADE, yes,
15 and, yeah.

16 Q. Okay. And you said that you used the word
17 low because that was what was used in several of the
18 studies that you reviewed?

19 A. Yes.

20 Q. Okay. And so Dr. Antommaria says these
21 levels are relative to one another, and low does not
22 necessarily mean poor or inadequate.

23 Do you have any reason to disagree with
24 that statement?

25 A. Per se, no. Yes, right, low or very low

1 does not necessarily mean that it's complete garbage.
2 But on the other hand, who decide this study is low?
3 Like the papers I reviewed, there's no GRADE system
4 GRADE them as low or very low.

5 So, again, I just use their expert's own
6 terminology. Per se, this sentence that Dr. Antommara
7 said I have nothing to disagree.

8 Q. Okay. And so the GRADE system is used to
9 evaluate the evidence often in clinical practice
10 guidelines. Do you have any reason to disagree with
11 that?

12 MR. RODRIGUEZ: Objection, lacks
13 foundation. You can answer.

14 A. Again, I'm not familiar with that, so I'm
15 not familiar with the system. Then I'm not going to --
16 so I don't have opinion to say that I agree or disagree
17 with that.

18 Q. Okay. Going down to page 10, paragraph 23.

19 A. 23, sorry, yeah, I got it.

20 Q. Okay. Dr. Antommara said that
21 observational studies are additionally assigned to the
22 low category.

23 A. Yes.

24 Q. And so under the GRADE system, is it true
25 that observational studies are always, almost always

1 going to be considered low quality evidence?

2 MR. RODRIGUEZ: Objection, lacks

3 foundation. You can answer.

4 A. As I said I don't -- I'm not familiar with
5 the GRADE system. So I don't know whether that is what
6 you just asked, whether observational study always
7 considered low or high. I repeatedly said that my
8 expertise, my experience with observational study, even
9 with -- observational study is a very vast, a range of
10 studies. Some designs are of higher quality. Some are
11 lower quality. But, again, where do they fall into the
12 GRADE system, now who decide that? I don't know.

13 Q. Give me one minute.

14 (Pause.)

15 Q. Okay. Do you always consider observational
16 studies as low quality evidence?

17 A. No. I said clearly in the world of
18 comparative effectiveness research, there's a
19 hierarchy, RCT randomized study is the best.
20 Observational study, there are good ones. There are
21 bad ones. There are high quality ones. There are low
22 quality ones. I don't blankedly(sic) say observational
23 study are all of low quality. I never said that.

24 Q. Okay. Does a study being low quality, in
25 your opinion, mean that it does not have value?

1 MR. RODRIGUEZ: Objection, vague and
2 ambiguous. You can answer.

3 A. That's not my opinion is about. I don't
4 stretch anything. I just purely say that when I say
5 low quality, I meant there are flaws. There are
6 serious flaws in the study design, that has rendered
7 the conclusion be unreliable or subject to noise. And
8 so more studies are needed.

9 So I didn't say that whether they have
10 value or not. That's not up to me to judge.

11 Q. Do you have an opinion on whether low
12 quality studies should be used in treatment
13 recommendations?

14 MR. RODRIGUEZ: Objection, outside the
15 scope of the witness' testimony. You can
16 answer.

17 A. I don't have opinion on that.

18 Q. Okay. So going back to your report --

19 A. My report?

20 Q. Yes.

21 A. Okay.

22 Q. On page 9.

23 A. Yes.

24 Q. You discuss prospective studies and
25 retrospective studies. Those are both types of

1 observational studies, correct?

2 A. Oh, caveat, yes. So observational study
3 can -- so randomized experiment also belong to the
4 broad spectrum of prospective study. But -- well,
5 because prospect and retrospect means the time, the
6 timing of when you collect the data, yes.

7 But to answer your question so
8 observational study indeed can have both retrospective
9 study and prospective study. They are just two
10 different designs.

11 Q. Okay. So you see the prospective
12 observational study is generally considered superior to
13 retrospective observational study, correct?

14 A. Correct.

15 Q. Okay. And then on page 10, you also say
16 that the design of the lowest quality is a
17 retrospective observational study?

18 A. Yes.

19 Q. Do you see that?

20 A. Did I say --

21 Q. It's kind of at the bottom of page 10.

22 A. Yes. Okay. So to be clear, here I say the
23 lowest quality that is of course I have a scope. I
24 meant among, you know, if you have like three
25 categories, you can, of course, further define them,

1 refine them into more categories. But I'm saying that
2 randomized study, prospective observational study and
3 retrospective observational study, this is -- among the
4 three, this is of the lowest quality.

5 Q. Okay. And does that mean that
6 retrospective observational studies do not have value?

7 MR. RODRIGUEZ: Objection, vague and
8 outside the scope of the witness' opinions.

9 You can answer.

10 A. Yeah, well, I think you asked a similar
11 question before saying whether this has value. Again,
12 I don't provide opinion on that. They are studies.
13 Those studies have, I call them low quality, because
14 they have flaws in the designs, renders the conclusion
15 to subject to be -- subject to all different biases.
16 So they might not be reliable. But whether they have
17 value or not, that's not what I'm -- I'm not providing
18 opinion on that.

19 Q. When you say unreliable, you mean that they
20 should not be relied upon?

21 A. I think that's an English word, unreliable
22 has its obvious English meaning. It means that -- when
23 I say unreliable, I mean that the conclusion is subject
24 to a lot of biases.

25 So if you want to interpret that as

1 something strong or interpret that, interpret that
2 those results -- you have to interpret the results with
3 much caution and caveats. That's what I meant
4 reliable, and they are -- those caveats or like those
5 assumptions, if those are violated to any degree, then
6 the result invalid.

7 So that's what I meant unreliable. They
8 are just more subject to all sorts of challenges and,
9 you know, biases.

10 Q. Okay. But you are not stating that they
11 should not be relied upon?

12 A. I did not say that. But, of course, from
13 common sense, if you have high quality, you want to
14 make your decisions on high quality studies rather than
15 low quality studies.

16 Q. Okay. So go to page 5 of your report.

17 A. Yes, I'm there.

18 Q. So in the second line under section 1, you
19 say that: The main barrier to interpreting the
20 association between the treatment and the outcome as a
21 causal effect is the presence of factors that are
22 associated with both the treatment and the outcome.
23 These factors are commonly referred to as confounders
24 or confounding variables or confounding factors.

25 A. Correct.

1 Q. Is the presence of confounders called
2 confounding bias?

3 A. Yes. That's precisely why, again, as I
4 later said, that's precisely the presence of
5 confounding factors, that's precisely why retrospective
6 study resolved before/after this data is viewed as low
7 quality, because they cannot control at all the
8 confounding factors.

9 Q. Okay. And that inability to control the
10 confounding factors is inherent to a retrospective
11 observational study?

12 A. It's inherent to -- so confounding bias is
13 inherent to all observational study, whether it's
14 prospective or retrospective. But prospective study do
15 a better job in controlling those confounding bias by
16 providing the before and after comparison.

17 Q. Okay. In going to page 6, you have a
18 subsection called confounding bias. You state that
19 randomized controlled trials eliminates all confounding
20 bias.

21 Are there situations where that would not
22 be true?

23 A. Again, that's -- we can get to too
24 technical academic.

25 So, again, per se, if you have a study --

1 so raising the scope, if you do a randomized study that
2 is because you flip a coin, so that is -- so for that
3 specific study population, you're operating on the
4 randomized study, yes, it does take into account,
5 eliminate all the observed and unobserved confounding
6 bias. So any confounding bias. So that's true. But
7 then, of course, there are other things, if you want to
8 put them a stretch, that a randomized study to a
9 different population, then that's a different matter.

10 So, yes, so for the study per se, if you do
11 a randomized study, operating on the population, the
12 target population that you are operating the randomized
13 study, yes, it eliminates all the confounding bias, and
14 that's why it is regarded as gold standard.

15 Q. What if there's a very small sample size in
16 a randomized control trial? Is it possible that would
17 not eliminate all confounding factors?

18 A. Technically that's a different problem. So
19 it still eliminate confounding bias just by design.

20 Small sample size is a different problem.
21 Small sample size will give you larger extended error,
22 or, in other words, the procedure, it will not be that
23 precise. There is a statistical concept called
24 standard error or variance. So that's a different one,
25 like that's a second other problem.

1 So in confounding bias, the study design,
2 randomized study design will admit no matter how small
3 the sample size is. The small sample size, the key
4 question is it will erode the procession of the study.
5 So, again, statistically, it's like first order problem
6 second order problem.

7 Q. Are there types of bias that can be present
8 in randomized controlled trials?

9 A. Again, this is highly depend on the
10 specifics, what do you mean? Like what type of bias?

11 As I mentioned, that if you want to
12 stretch -- so the -- so confounding bias -- no, so the
13 answer is so randomized study is subject to other type
14 of bias, but not for the treatment effect for this
15 population you study on. It's subject to other type of
16 bias. For example, the randomized study, the
17 population does not representing the general
18 population, but that's a whole different matter.

19 And -- but always your first, again, like
20 in FDA, if you want to have a new drug or treatment or
21 medical device, you always first -- first order you do
22 a randomized study. But that is understandable that
23 it's not always feasible, but I won't go into that.

24 So your question, yeah, there are all sorts
25 of different biases, but that is, again, we're talking

1 about first order problem and second order problem.

2 So why randomized study is prized is
3 because the biggest problem to interpret the barrier
4 from association to causation is confounding bias, and
5 this randomized study is the most -- I mean, it's the
6 single most effective design to admit that.

7 So that's a first order problem. Yeah,
8 there are all sorts of other type of bias, but the
9 second order problem and all the other observational
10 study also subject too.

11 Q. Okay. So on page 6 and 7 of your report,
12 you talk about different types of biases, and so
13 selection bias, is that -- can that be present in a
14 randomized controlled trial?

15 A. Oh, yes, that can be presented in
16 randomized study or retrospect or prospective, but
17 that's a different -- again, I say that's a second
18 order problem, but yes.

19 Q. What about nonresponse bias?

20 A. Nonresponse bias, again, in randomized,
21 yes, all of this study can be subject to that. But in
22 randomized study, usually the way it's conducted,
23 usually the nonresponse rate is controlled, because the
24 study is controlled. So it's controlled by the --
25 highly controlled by investigated.

1 So it's usually subject to less of that
2 kind of bias than the observational studies.

3 Q. Can recall bias be present in a randomized
4 control trial?

5 A. Yeah, again, recall bias can present in all
6 of these studies. But, again, because of the way that
7 the randomized study is conducted, is well controlled
8 by -- highly controlled by investigators, the
9 occurrence of that is, the chance of that is much less
10 than observational study, particularly for
11 retrospective study. Because retrospective study
12 often, like you don't design, because at the time you
13 do the study, all these things already happened. So
14 then that's a time lag.

15 That make it -- so in randomized study, you
16 conduct the study. It's a prospective -- randomized
17 study is prospective study. So you follow them. So,
18 of course, there's much less chance of recall bias.

19 Q. Okay. What does it mean to mask or double
20 mask a study?

21 A. Sorry, say it again, match?

22 Q. Mask or double mask, also known as blinding
23 or double blinding?

24 A. Oh, I didn't say it here, yeah, double
25 blinding, yeah, that is just a -- so that is you flip a

1 coin. Yeah, double blind, that means you don't -- so
2 basically the treatment assignment, whether you get the
3 true, the control or treatment is not known -- it's not
4 revealed to the patient, and in some cases also not
5 revealed to the people who conduct the study.

6 Q. So double masking means neither the
7 participant or the conductors know who --

8 A. Correct.

9 Q. So if a randomized control study is not
10 masked or double masked, can that induce bias?

11 A. Well, that can. I mean, I can give you a
12 statistical lesson. Yes, it always -- like none of the
13 study is perfect. Some are more imperfect. Others are
14 less perfect. Yeah, so you're talking about double
15 blindness. Yeah, the studies are not double blind.
16 It's not always. So the problem of a double -- okay,
17 so why do we want to do double blind study is try to
18 reduce the chance of the so-called placebo effect. The
19 placebo effect, like the psychological placebo effect,
20 and, again, that is a possibility, like if you don't do
21 double blind, there's a possibility that there's a
22 placebo effect that will bias your result. But, again,
23 comparing to other sorts of unmeasured confounding,
24 there's a bigger problem. This is minor concern.

25 Q. On page 6, when you're talking about

1 confounding bias, you say: Therefore, in order to
2 interpret the association between treatments and
3 outcomes as causal effects in observational studies,
4 one must assume that there's no unmeasured confounding
5 factor. Such an assumption is untestable and is almost
6 always untenable.

7 What do you mean by untenable here?

8 A. That means just almost always violated.
9 There's always presence, in observational study, there
10 almost always unmeasured confounded. And why I say
11 it's untestable, because there's no unmeasured
12 confounding. So it's unmeasured. How do you know
13 whether there is or not? So, I mean, that's just
14 common sense. That is like a standard in the
15 literature.

16 Q. I'm not sure I followed. Can you explain
17 it a little differently by what you mean? I get the
18 untestable part, but can you tell me a little bit by
19 what you mean untenable?

20 A. Untenable means, again, it's always
21 violated to a certain degree, because you are basically
22 saying -- so I'll give you an example.

23 If people say there's association between
24 smoking and lung cancer, and then you calculate the
25 association, so it's strongly correlated. But then if

1 you say smoking indeed caused lung cancer from
2 observational study. If you want to make that
3 statement, you basically say that well, then in my
4 analysis, all the confounding factors, all the
5 confounding factors that can affect both smoking and
6 lung cancer has been collected and controlled in my
7 analysis. And that is almost always weighted, because
8 we can collect as much information about smoking and
9 lung cancer, but there's always something missing, for
10 example, like whether there might be genetic reasons,
11 like your parents' -- like your parents' genes, or your
12 parents' health, behavior, that kind of thing, you
13 don't collect it.

14 So that's why I say it's always -- almost
15 always they are -- you don't collect the whole universe
16 of data.

17 So that's always -- this all matching
18 confounding assumption in observational studies almost
19 always violated. That's a consensus in the field, and
20 that's actually the whole point like why people like
21 me, a methodologist try to deal with this problem.

22 Q. Okay. So are you saying that observational
23 studies can never be used to support treatment
24 recommendations because there is a risk of confounding
25 bias?

1 MR. RODRIGUEZ: Objection, asked and
2 answered. Mischaracterization of testimony
3 and report. And you can answer.

4 A. I think you asked this question or similar
5 question many times. So I'll answer again.

6 I didn't make -- I didn't -- I don't come
7 here or write my report to say that whether you can --
8 I didn't make the blanket statement to say that you
9 cannot use observational study as the evidence for
10 treatment recommendation. I purely said that they are
11 different methods, different studies that can provide
12 -- establish the treatment effectiveness of a
13 treatment, and there are some better designs, some of
14 worse design, and there's a reason I clearly describe
15 here why there's a reason the confounding bias is the
16 reason.

17 But, again, the answer has always been the
18 same. I didn't say that because they are -- I didn't
19 say that whether you should use it or not for your
20 treatment recommendation, and that's not my scope. And
21 I say again, I hope you don't ask this again, because
22 my answer will always be the same.

23 Q. Is the concern that an outcome is the
24 result of a confounding factor, rather than the
25 treatment, mitigated by the number of studies

1 evaluating the treatment?

2 A. Can you say that again?

3 Q. So is the concern that an outcome is the
4 result of a confounding factor, rather than the
5 treatment being validated, is that concern mitigated by
6 the number of studies evaluating the treatment?

7 A. I think your question mixed a lot of -- why
8 I didn't first get it is I think you mixed a lot of
9 statistical concepts.

10 So a confounding factor, a confounder is,
11 by definition, is associated with both the treatment
12 and the outcome, okay.

13 So I vaguely understand your question
14 you're asking that whether this problem, this -- the
15 problems of the existence of confounding bias or
16 confounder is mitigated by the -- like the more study
17 you do, like you are less concerned about that. Again,
18 the answer of that is it depends on the quality of the
19 study.

20 So if you give me one hundred studies, and
21 one hundred studies are all very low quality, don't do
22 a good job in controlling for confounders, if you give
23 me 101, it doesn't matter, because they are all subject
24 to the same problem. But if you give me a few high
25 quality studies that did it good job in conjoining for

1 confounding bias then, yeah, it would be mitigated.

2 But the sheer number, the number of study does not have
3 nothing to do. The quality trumps quantity -- the
4 quality trumps quantity here in terms of the studies.

5 Q. Okay. So you just gave the example it
6 doesn't matter if it's a hundred or a thousand, so if
7 you had a thousand observational studies with similar
8 outcomes, you're saying that's still not as useful as
9 having a few high quality studies?

10 A. Well, to answer your question, let's just
11 look at the study I reviewed, right. Here I reviewed
12 80-some studies. So my -- based on my count, I think
13 probably like 50 or, I don't know, 50 of them, I mean,
14 not solvent. There's no solvent studies, but 50 of
15 them are basically retrospective study resolved
16 before/after comparison, and there are five prospective
17 study that has the before/after comparison. And I
18 explain why before after is important, because the
19 before/after study provide you the most important
20 confounder, which is the baseline measure of the
21 outcome. So that's why it's regarded as better.

22 So I already said that, you know, you have
23 50, those 50 studies, even their own expert, even the
24 own literature review say that they are low quality,
25 and I'm calling for better prospective study, yeah, but

1 there are 50 of them providing the result. I would
2 not, because they all have the same problem, they all
3 subject to the confounding bias of, in this particular
4 case, the confounding bias, particularly they're
5 lacking the baseline. The most important confounder is
6 that's the baseline outcome. They are basing that.

7 So they are all subject to that. Then, of
8 course, you can do 50, you can do 100, you can do
9 1,000. That is just all subject to the same problem.
10 Why do you repeat the mistake?

11 So that's why I don't -- I view that the
12 evidence provide by a few high quality studies is
13 better than 100 repeated, the studies low quality study
14 repeat the same problem.

15 That being said, I do believe that it's
16 better to have even -- the best would be to have both
17 quality and quantity, means the best would be I have a
18 high number of prospective studies. If you cannot do
19 RCTs, that's fine. But if you can have a high number
20 of high quality prospective study that all show
21 consistent result, that's the best. But we don't have
22 that, and actually the only ones they have have mixed
23 results.

24 Q. When you say high quality studies, are you
25 referring to randomized control trials?

1 A. No. I said that that's the best, but it's
2 not always available. High quality, I meant that well
3 designed, before/after retrospective study, if it's
4 done nicely, done properly, yes, it can be viewed as
5 high quality.

6 But, again, this is not the -- what is high
7 quality or low quality is for any single study, of
8 course, it's a subjective concept.

9 But here when I'm using the high quality
10 and low quality I'm mostly talking about the, you know,
11 from the perspective of whether it control for
12 confounding bias. And why I say that is because
13 confounding bias is the single most important barrier
14 between the association and the causation, or that's
15 the single most important barrier before you can
16 establish the effectiveness of the treatment.

17 Q. So when you talk about high quality/low
18 quality, you are not using those terms as they are used
19 in the GRADE system?

20 A. Again, I'm not very familiar with the GRADE
21 system. I don't know who decide that, and I don't know
22 who decide that, and I'm not referring to GRADE system.

23 I already explained earlier in my case, I
24 said there's at least three broad class of designs; one
25 is randomized study, the other is prospective

1 observational study, and the last is retrospective
2 observational study. And I say higher quality, low
3 quality and lower quality is missing that. I have a
4 hierarchy, one, two three, and I don't need to repeat
5 that.

6 Q. And your hierarchy is yours and is not the
7 GRADE system?

8 MR. RODRIGUEZ: Asked and answered.

9 You can answer.

10 A. Well, it's mine, but remember, I'm a
11 national leading expert in inference, in study designs.
12 So yes, it's mine. So I -- it's mine, but also I can
13 tell you with confidence that is also the consensus in
14 the field in terms --

15 Q. In terms of statistics?

16 A. In the field of causal inference
17 comparative effectiveness research. That also include
18 epidemiologist.

19 If you go out to any statistic,
20 statistician, epidemiologist, ask them rank these three
21 type of studies, they will give you exactly the same
22 order as I just gave you. Randomized study is the top,
23 and prospect is the second, and the retrospective
24 third. So that's what I meant.

25 Q. I'm not trying to dispute that ranking. I

1 think I'm trying to understand, make sure that we're
2 using the same language here.

3 And so my understanding from what you just
4 said is you consider high quality studies to be
5 randomized control trials or well designed prospective
6 before and after observational studies, is that
7 accurate?

8 A. Yes. Again, even there, yeah, randomized
9 is still better than the other, yes, higher quality.
10 But, again, even prospective before/after, you can
11 still mess it up.

12 But, yeah, if it's like well, well studied,
13 like it's well designed, yes, it can be considered as a
14 high quality. But I didn't say every single
15 prospective study is high quality, but it's still
16 better than retrospective study.

17 Q. Are there ever reasons why a randomized
18 control trial might not be ethical?

19 MR. RODRIGUEZ: Objection, outside the
20 scope of this witness' opinions.

21 You can answer.

22 A. Yeah, I -- I don't think that whether a
23 randomized study is ethical or not has anything to do
24 with my opinions.

25 My opinion is about like whether the

1 references cited supported the assertions.

2 So it has nothing -- didn't touch anything
3 about whether it's ethical or not.

4 Q. Okay. You've come into this case as an
5 expert, and I don't want to go beyond your expertise,
6 but I am permitted to ask questions that are related to
7 this report, even if they are not discussed in the
8 report.

9 A. I understand.

10 Q. Okay. And so do you have any knowledge as
11 to whether there are situations where randomized
12 control trials might not be ethical?

13 MR. RODRIGUEZ: Same objection,
14 outside the scope of the witness' report.
15 You can answer.

16 A. I mean, we can -- offline, I can tell you a
17 lot of things. But, again, this has nothing to do with
18 my opinion, and I don't think it's relevant. So I'm
19 not going to answer.

20 Q. Okay. I'm still allowed to ask the
21 question, so you're not necessarily allowed to make a
22 determination on relevance, and so if you don't know or
23 if there are situations, then you can say that.

24 A. I am fully aware of the situations that,
25 again, particularly in history, they are randomized

1 studies that were conducted that are unethical.

2 And so in modern -- if you ask me, that's
3 why in modern medicine or in health studies, like
4 especially when you conduct randomized study, it's very
5 important to have ethical -- like to be -- to be
6 ethical. And then that's about the conduct ethical
7 part of the randomized study, has always been important
8 consideration.

9 And to answer your question, I'm aware in
10 the history, yes, they okayed this. It was not well
11 regulated. It was not ethical, yes, but that has
12 nothing to do with my opinion here.

13 Q. And so to clarify, I think there are
14 situations where studies can be conducted unethically,
15 and I guess my question is: Are there situations where
16 the actual act of conducting the study will be
17 unethical, and specifically maybe -- let me scratch
18 that.

19 Do you know what clinical equipoise is?

20 A. Yes, I'm expert, and actually my signature
21 work is providing some, yeah, some methods actually
22 related to that. So I know that very well.

23 Q. Okay. And so what is clinical equipoise?

24 A. Well, clinical equipoise is means that you
25 have to -- so the subject of the patient population has

1 to be about the treatment benefit, has to be ambiguous.
2 Basically you don't know, a priority you don't know
3 whether this treatment is beneficial or not. So only
4 in this situation you can conduct it on the patient,
5 because if you indeed know a treatment is beneficial or
6 harmful, then you shouldn't do randomized study. You
7 shouldn't randomize on those patients. That's clinical
8 equipoise.

9 Q. And so if there is not clinical equipoise,
10 it would be unethical to conduct a randomized control
11 trial?

12 MR. RODRIGUEZ: Objection, beyond the
13 scope of this witness' testimony.

14 You can answer.

15 A. Again, I know the concept. I don't know
16 whether that's a clean cut, whether if it's not a
17 clinical equipoise, you cannot conduct, because that
18 might be, again, I don't know that. I just know that
19 this is -- clinical equipoise is important criterion
20 principal in the conduct of randomized trial, but
21 whether that is always the -- always the clean cut
22 position, I don't know.

23 Q. Okay. Are there ever reasons why a
24 randomized control trial might not be feasible?

25 MR. RODRIGUEZ: Objection to

1 vagueness, and outside the scope of this
2 witness' testimony, but you can answer.

3 A. Oh, yeah, yes, that's so many examples of
4 that. I mean, yes the randomized study is not always
5 feasible.

6 For example, you cannot randomize people
7 with smoking and nonsmoking, because that's like, yeah,
8 because that break the clinical equipoise, because
9 nowadays we know that smoking is harmful. So you
10 cannot randomize people to smoking and nonsmoking.
11 That's one of the examples. There are many of that
12 kind of examples.

13 Q. And so you just said now nowadays we know
14 smoking is harmful, so we can't do a randomized control
15 trial. Is that an example of a lack of clinical
16 equipoise?

17 A. I would say it's lack of clinical
18 equipoise.

19 Q. What are some other reasons that it might
20 not be feasible to conduct a randomized control trial?

21 MR. RODRIGUEZ: Objection, beyond the
22 scope of this witness' report and ambiguous.
23 You can answer.

24 A. Yeah, I do think that this is going too
25 far. It's really beyond the scope of my witness -- my

1 expert, my report.

2 My report is about the study, the quality
3 of study needed, the type of study needed to establish
4 the treatment effect. It's not about whether, how you
5 conduct a randomized study. That's not what I'm -- I
6 can tell you offline, give you a whole class, but
7 that's not what I'm assigned to, and I'm not willing to
8 waste my time on that.

9 Q. Okay. Well, I get to ask the questions and
10 determine how we spend your time. And you just said
11 your opinion is about the need for randomized control
12 studies, and so my question --

13 A. Go ahead.

14 Q. My questions are potential barriers to
15 randomized control studies, and so I think they are
16 directly to the scope, and if you don't know, you can
17 say that. And so are you aware of barriers to
18 conducting randomized control trials?

19 MR. RODRIGUEZ: I'm going object to
20 the form and beyond the scope and asked and
21 answered. You can answer.

22 A. Yes. First of all, in your statement, you
23 mischaracterized what I said.

24 I didn't -- so I didn't, again, in my
25 report, I didn't say that randomized study is required.

1 So you mischaracterized that.

2 And second, yeah, okay, so I guess I --
3 maybe I'm hungry or whatever, but, yeah, so you can ask
4 me a question. I can answer. I just don't think it's
5 the best use of our time. But you can say that, that's
6 your judgment, that's fine.

7 But now back to your question. So your
8 question say that I am aware of any barriers to conduct
9 randomized study, of course, I do, of course, I'm
10 aware, and, of course, I understand what your next and
11 predict what your next question in this case, but I'm
12 not going to say that. I'm aware of that, yes.

13 Q. Okay. And you probably predicted my next
14 question correctly. What are some of those barriers?

15 A. Yes. Well, actually your third question.

16 But, yeah, the barriers, again, you already
17 talked about the lack of clinical equipoise, and
18 second, sometimes it's like a rare disease, and there
19 are a very small sample size. Like there are very few,
20 basically there are very few patients available, and
21 another case it's like if it's an advanced disease,
22 then it's also from a practical perspective, doctors
23 are not waiting to randomize the very advanced, like
24 advanced cancer. Because you don't want to randomize
25 patients. They are all desperate to get the new

1 treatment. It's very difficult to randomize patients
2 with advanced cancer into a control arm, for example.

3 So there are many of those kinds of things,
4 yeah.

5 Q. Why is it difficult to randomize the
6 advanced care patients into a control arm?

7 MR. RODRIGUEZ: Object, outside the
8 scope of the witness's witness.

9 She can answer.

10 A. I'm not a doctor, but just to use your
11 common sense. If those people drive -- like if you
12 have advanced pancreatic cancer, you have six months to
13 live, and then you drive three hours to Duke Clinic to
14 get, to attend the randomized trial, your hope is you
15 will get the treatment. You will get the new
16 treatment. So that's why doctors feel also it's not
17 ethical, or feel like it's very hard for them, just
18 psychologically to give that to the randomized patient
19 into control arm. But I don't see -- that's all.

20 Q. To make sure I'm understanding that
21 correctly, it would be challenging because patients
22 would be unlikely to sign up for a trial where they
23 might not get any treatment?

24 A. No, it's not like unlikely. The problem is
25 precisely they are likely, because they are

1 50/50 percent of chance being assigned to a control.

2 And then the doctors, just from, you know, from purely
3 just compassion perspective, the doctors don't want to
4 do that.

5 Q. Okay. And I heard another barrier that you
6 mentioned was kind of difficulty in recruiting a
7 sufficient number of patients, is that accurate?

8 A. Yes.

9 Q. Okay. And the high cost of randomized
10 control trials is also a barrier?

11 A. It can it cannot. It depends on the -- it
12 can or cannot. Its cost is one consideration, but
13 often I think a bigger -- the bigger barriers are the
14 ethical, clinical equipoise.

15 So yes, it can be, but it's not the only
16 one or it's not the most important one. Maybe in some
17 cases it is, but I cannot give a blanket statement of
18 that.

19 Q. Okay. I'm aware that it's lunchtime on the
20 east coast. I have just a few more questions, and then
21 maybe we can take a break for lunch. Does that work
22 for people?

23 A. Go ahead, yeah. Again, I was just -- I
24 just used -- I'm probably more actually drinking too
25 much water, that's a bigger problem. But go ahead.

1 Q. What are some of the challenges that you
2 would anticipate in conducting a randomized control
3 trial on gender affirming surgery?

4 MR. RODRIGUEZ: Objection, outside the
5 scope of the witness' knowledge and
6 testimony. You can answer.

7 A. Yeah, that's the third question I predict
8 you're going to ask, and I will not answer that
9 question, because this is really beyond the scope of my
10 opinions, because I'm not -- so that one I can talk
11 about statistical methodology, but I am not a medical
12 doctor. And I don't conduct, I don't conduct,
13 physically conduct randomized study.

14 I can tell them about oh, when you collect
15 the data, what kind of consideration, what kind of
16 methodology considering you have to do. I'm not in
17 charge of, or actually I'm not responsible, or I'm
18 never asked to consider this kind of practical issues,
19 clinical practical issues. So it's for that reason I
20 will not -- like I will not provide an opinion. I will
21 not answer your question. And I have a reason. That's
22 because that's beyond my expertise.

23 Q. Okay. So it's beyond your expertise to
24 know whether there are any barriers to conducting
25 randomized control trials for gender affirming surgery,

1 is that correct?

2 A. From clinical aspect. I do with the
3 barriers from statistical methodology perspective, from
4 clinical perspective, yes, it's beyond my knowledge,
5 beyond my expertise.

6 Q. Can you tell me the barriers that you're
7 aware of from the statistical perspective?

8 A. Statistical perspective, again, there's no
9 barrier. If you can do it, like this should be the way
10 you do it. You should do a randomized study. And
11 that's like, I mean, then I will tell them pay
12 attention to like missing data, you know, that kind of
13 thing, whether you have missing data, or that is all
14 like in this case anticipating you might have small
15 sample size, and then how do you correct for that, and
16 how do you use corollary adjustment or regression that
17 kind of legal method to improve procedure, those kind
18 of things. There's no barrier. I mean, use barrier, I
19 would just say not barrier. More means that the
20 methodology aspect of -- anticipate the type of data
21 you are going to get, and then like the challenges in
22 statistical analysis. But that being said, randomized
23 study probably is the easiest to analyze, because,
24 again, the design is the best. So that's why the
25 analysis is also easier.

1 Q. So we were talking about barriers to
2 randomized control trials. We talked about a
3 population sample size. Do you think that that is a
4 barrier for conducting randomized control trials on
5 gender affirming surgery?

6 MR. RODRIGUEZ: Objection, beyond the
7 scope of this witness' report and testimony.
8 You can answer.

9 A. I don't know. Because, again, some even
10 rare -- I don't know. I mean, in this gender dysphoria
11 or like in advanced cancer, whatever, to me it's no
12 difference. To me they are all like one condition that
13 you conduct a randomized experiment on.

14 So I don't know whether it would be a
15 barrier or not. It depends on this specific study.

16 I suspect that you will have a small sample
17 size, yes, particularly for small, like for one single
18 medical center, that will be, I expect that you will
19 have small sample size.

20 But, again, that is a separate question
21 from whether this is the best design or not.

22 Q. Could a randomized control trial on gender
23 affirming surgery be masked?

24 MR. RODRIGUEZ: Objection, beyond the
25 scope of this witness' testimony and report.

1 You can answer.

2 A. That's beyond my expertise. I don't --
3 well, that's beyond my expertise. But obviously not.
4 This is a surgery. If it's a surgery, then, of course,
5 you know, how can you double blind that? No, you
6 cannot.

7 MS. NOWLIN-SOHL: Orlando, I'm going
8 to ask you to maybe limit the speaking
9 objections, just note the objections, but
10 it's almost guiding the witness.

11 MR. RODRIGUEZ: So it's not guiding
12 the witness, and actually I'm obligated to
13 state the basis of my objection. I'm doing
14 so as concisely as possible, and I'm
15 repeating the same phrase that I've been
16 repeating all morning. So we are allowed to
17 agree to disagree on that point.

18 MS. NOWLIN-SOHL: Okay.

19 Q. So, okay. You said it is not possible to
20 mask a randomized control trial for gender affirming
21 surgery?

22 A. Yes.

23 Q. Okay. And do you know if there's clinical
24 equipoise for a randomized control study for gender
25 affirming surgery?

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MR. RODRIGUEZ: Same objection, beyond this witness' testimony and report.

You can answer.

A. I already answered no clinical equipoise on a higher level, like a statistical level. But whether it's to a specific disease or specific -- to a specific disease, whether it's a cancer or gender dysphoria, I don't make the judgment. I don't know, because I'm not a medical doctor in that field.

Q. So you do not know if there's clinical equipoise for randomized control trials on gender affirming surgery?

A. I don't.

MS. NOWLIN-SOHL: Okay. I think that this is a good place to take a break. How long do you all need for lunch?

MR. RODRIGUEZ: Forty-five minutes.

MS. NOWLIN-SOHL: We will come back at 1 p.m. eastern.

(Off the record at 12:14 p.m.)

(Luncheon recess.)

(Continued on next page.)

1 A F T E R N O O N S E S S I O N

2 (On the record at 1:03 p.m.)

3 BY MS. NOWLIN-SOHL:

4 Q. And Dr. Li, you're aware that you're still
5 under oath, correct?

6 A. Yes.

7 Q. Okay. Earlier I had mentioned clinical
8 practice guidelines. Do you know what a clinical
9 practice guideline is?

10 A. Well, I know, I think I know from a lay
11 perspective, layperson perspective, yeah, they are sort
12 of these guidelines, but I don't know specific ones,
13 because that's not my expertise.

14 Q. What is your lay understanding of them?

15 A. Well, it's -- yeah, it's a document. I
16 don't know whether it's binding or not, but it's a
17 document, usually kind of composed by the medical
18 society or, you know, a group of expert in one field,
19 and then talking about, you know, some guidelines of
20 what normal -- I don't know whether it's
21 recommendation, or just guideline about the clinical
22 practice of a certain condition, medical condition.

23 Q. Okay. And so they kind of provide
24 treatment and diagnosis recommendations?

25 A. I don't know -- again, the details, it

1 depends on the -- you know, I don't know what it is
2 about treatment, diagnosis, but I would expect, I would
3 expect that that would be like, what I know a little
4 bit more about breast cancer, or like breast cancer,
5 that kind of thing, or you need to do mammogram like
6 every, every year at 40 or things like that.

7 So I think it's a general, kind of, yeah,
8 recommendations of what general practice, but I don't
9 know whether that's binding, yeah.

10 Q. Okay. And in his rebuttal report
11 Dr. Antommara described or said medical
12 professionals -- sorry, Dr. Antommara said in his
13 rebuttal report that medical professional organizations
14 develop clinical practice guidelines that provide
15 clinicians with helpful evidence-based recommendations
16 and improve patient care and outcomes.

17 Is that consistent with what your
18 understanding is of clinical practice guidelines?

19 MR. RODRIGUEZ: I'm going to object to
20 scope and foundation. You can answer.

21 A. Well, I don't have an expert opinion,
22 because I'm not an expert. But my understanding is,
23 yes, the existence of those recommendations, obviously
24 they try to improve the clinical practice.

25 But the one thing, at least I know is that

1 those kind of guidelines also keep changing according
2 to the emergence of new evidence. And they like,
3 again, if you now look at the breast cancer management
4 from 40 years ago, the guidelines, I believe, have
5 changed quite a bit, yeah.

6 Q. Okay. Do you know who develops those
7 guidelines?

8 A. I don't know. Again, it's case -- I think
9 it's condition specific. So I don't know. It's
10 usually -- I know that it will be a big, like a group,
11 consortium, or something like that. But it's not one
12 person comes up with that. It's usually organization.

13 Q. Like a medical association?

14 A. Sometimes the CDC or sometimes -- I don't
15 know the details of this.

16 Q. Okay. Have you ever been involved in the
17 development of clinical practice guidelines?

18 A. Not so far, no.

19 Q. Okay. And do you know how they're
20 developed?

21 A. I don't. I don't, but, again, because I
22 work a lot with the, you know, in clinical research, so
23 I know that like I work a bit with cardiologists and
24 people like, yeah, expert in cardiologist, and I know
25 that they, again, as new studies, they do new studies

1 or trials, clinical trials and new observational study.
2 As new information come in, they revise their
3 guideline, their clinical guideline, and they always --
4 yeah, they usually have a bunch of lay expert in that
5 field, and then they all have clinical research
6 background, know the research in that field, and then
7 they develop guideline. And then, as I said, they keep
8 changing, according to the new evidence emerge.

9 Q. I want to go back to Dr. Antommaria's
10 rebuttal report and specifically page 8:

11 A. Yes. Yes.

12 Q. Okay. And so in paragraph 20, he says
13 that, the first line I already read to you. The second
14 line or the second sentence says: Clinical practice
15 guidelines are developed using systematic reviews of
16 the literature-systematic processes to collect and
17 review relevant scientific evidence. Do you see that?

18 A. Yes, I see that.

19 Q. Okay. And then he says: Systematic
20 reviews evaluate the evidence but do not make treatment
21 recommendations. Clinical practice guidelines both
22 evaluate the evidence and make recommendations.

23 Do you see that?

24 A. Yes, I see that.

25 Q. Okay. And your expert opinion here is

1 solely about the evaluation of the evidence and not
2 about treatment recommendations, correct?

3 A. Correct.

4 Q. Okay. And are you providing any expert
5 opinion on the recommendations that are made by WPATH
6 in their standards of care?

7 A. No, I don't.

8 Q. Okay. Do you know what quality levels of
9 evidence clinical practice guidelines can rely on?

10 A. I don't, but I expect it's also case by
11 case, but I don't.

12 Q. What do you mean that you expect it case by
13 case?

14 A. Well, it's like -- for like for cardiology
15 it's probably different from cancer. And like also for
16 like an advanced disease, a severe disease is probably
17 different from behavioral signs. Like, again, there
18 are many different type of medical conditions.

19 So I -- just from a scientific perspective,
20 I expect that they not always follow exactly the same.
21 You know, the way they come up with the recommendation
22 is different, but, again, I'm not an expert on that, so
23 I guess my opinion will stop here.

24 Q. You mentioned cardiology might be different
25 from another practice of medicine that I missed?

1 A. Like cancer.

2 Q. What do you mean?

3 A. Well, I mean it's different conditions. I
4 mean, they treat -- people are treated different, and
5 also like the severity and the consequence of the
6 disease, if remain untreated is different. I mean,
7 that's, again, from my layperson's understanding, I
8 imagine it's different.

9 Q. Okay. Let's go ahead and mark as Exhibit 3
10 an article with the GRADE guidelines.

11 (The document referred to was marked
12 Deposition Exhibit Number 3 for
13 identification.)

14 A. Yes, I have it.

15 Q. This is an article in the Journal of
16 Clinical Epidemiological. Are you familiar with that
17 journal?

18 A. I know this journal. I never published on
19 it, but I know this journal.

20 Q. Okay. And can you read me the title of
21 this article?

22 A. GRADE 3 guidelines: 3 Rating of the
23 Quality of Evidence.

24 Q. And have you seen this article before?

25 A. No.

1 Q. Okay. And so if you look at the abstract
2 it talks about the GRADE system, right, and that it
3 specifies four categories for rating the quality of
4 evidence: High, moderate, low and very low. And
5 earlier, I know you mentioned you are not familiar with
6 the GRADE system, but I just wanted to ask about that.

7 So on the second page, there's a section 4.
8 Do you see that?

9 A. Yes, I do.

10 Q. Okay. And the first paragraph, the last
11 sentence it says that: Sometimes low or very low
12 quality evidence can lead to a strong recommendation,
13 and this is in the context of clinical practice
14 guidelines.

15 Do you have any concerns about clinical
16 practice guidelines making recommendations on low or
17 very low quality evidence?

18 MR. RODRIGUEZ: I'm going to object to
19 the scope and form. You can answer.

20 A. I don't have an opinion on that without
21 reviewing the -- well, first of all, this is -- this is
22 the first time I have seen this document, and I think I
23 would have a better opinion if I read through this
24 whole document.

25 For this single -- I actually haven't find

1 that, but I hear what you said for that argument, for
2 that sentence per se, yes, it is -- that sentence I
3 don't -- I don't disagree that might be a valid
4 sentence. But, again, that is, in my view, it's
5 irrelevant from my expert opinion.

6 Q. Okay. So your expert opinion does not
7 include an opinion on what quality of evidence clinical
8 practice guidelines and recommendations can be made
9 upon?

10 MR. RODRIGUEZ: Asked and answered.

11 You can answer.

12 A. Correct. My opinion is about whether the
13 assertions made there are made in Dr. Antommaria's
14 report is supported by the reference they cited. My
15 opinion is not about what kind of evidence you have to
16 have in order to make treatment recommendation. Again,
17 my opinion has nothing to do with whether you can make
18 treatment recommendation or not.

19 Q. Okay. Are you aware that it is very common
20 in medicine for clinical practice guidelines to make
21 recommendations based on solely on observational
22 studies?

23 MR. RODRIGUEZ: Object to the scope.

24 You can answer.

25 A. That I don't know. I don't know. I

1 would -- yeah, I don't know. But I would expect that
2 the higher quality probably the better, but, yeah, I
3 don't know. I cannot answer to that question.

4 Q. Okay. Is it your view that medical care
5 should not be provided to patients if the only evidence
6 available supporting recommendations in a clinical
7 practice guideline is low quality?

8 MR. RODRIGUEZ: Objection, form and
9 scope. You can answer.

10 A. So I think your question is, again, is too
11 broad. So you're saying medical care, should medical
12 care be provided? But what kind of medical care?

13 So, again, it depends on what kind of
14 medical care. It's very case specific.

15 So I don't have an answer to your general
16 question, because that's clearly that's case by case.

17 So your question is well should medical
18 care be provided to people based on, you know, like
19 when there's a lack of evidence of -- again, that's
20 case by case. And, I mean, again, as a layperson or as
21 just a scientist, you would hope that, you know, or the
22 treatment recommendations based on high quality
23 studies, but, again, that's case by case, so.

24 Q. Why is it case by case?

25 A. Well, let's say -- okay, I will give you an

1 example. Let's say pancreatic cancer, so advanced
2 pancreatic cancer, so that is a lethal, very severe
3 disease, right. So let's say you have a new drug
4 developed, and at that time you still don't know like,
5 let's say, phase two trials. You don't know whether
6 this drug is helpful, but there's no alternative,
7 because this patient, if they don't get, they don't get
8 it, they will die. Because all the current available
9 things out there available, you know, will not -- the
10 patient will die.

11 So then they would, in that case, you know,
12 that's -- I think that -- I believe that an
13 extraordinary condition like this is that kind of cases
14 then(sic) the patient wanted. And also there's no
15 alternative.

16 So this is like give you maybe 50 percent
17 of chance of improving, so people will take that, so
18 that's the case, yeah. You don't have evidence, yeah,
19 you get it, but in other cases, like if you have flu,
20 and if you have flu, for example, that's not a lethal
21 disease. And in that case, you know, if you want to
22 use some alternative medical care and then probably
23 unresolved evidence, that's probably not a good idea,
24 or that's probably likely your doctor can decline that.

25 So, again, that's what I'm saying. Just in

1 this case, I give you two examples of flu, which is
2 like a -- it's not a too-sever disease, versus advanced
3 pancreatic cancer.

4 Q. Okay. And those opinions you just
5 provided, are those your expert opinions or
6 layperson's?

7 A. Lay opinions. Lay opinions.

8 Q. Okay. I'm going to mark as Exhibit 4 an
9 article on pediatric obesity.

10 (The document referred to was marked
11 Deposition Exhibit Number 4 for
12 identification.)

13 A. Yes, I have it.

14 Q. Okay. What is this?

15 A. This is a clinical practice guideline.

16 Q. For pediatric obesity?

17 A. Yes.

18 Q. I'm assuming you had not seen this before,
19 but have you seen this before?

20 A. No.

21 Q. Okay. And do you know who published this
22 guideline?

23 A. I don't.

24 Q. At the top of the title, it says:
25 Endocrine Society Clinical Practice Guideline.

1 Are you familiar with the Endocrine
2 Society?

3 A. No.

4 Q. Have you ever heard of it?

5 A. No, I have not heard of it, but I'm not
6 surprised the existence of it. Every field has a
7 society.

8 Q. Okay. On the page, the conclusion says:
9 Pediatric obesity remains an ongoing serious
10 international health concern.

11 Do you agree that pediatric obesity is a
12 serious health concern?

13 MR. RODRIGUEZ: Objection, scope.

14 You can answer.

15 A. I'm not an expert in obesity, and I hear
16 from news, but, yeah, but I don't -- again, I can give
17 you a layperson view on this, but I don't know how that
18 is related to what we're talking here.

19 Q. Okay. But in your lay opinion, would you
20 agree that pediatric obesity is a serious health
21 condition?

22 MR. RODRIGUEZ: Scope. You can
23 answer.

24 A. So you asked me whether pediatric obesity
25 is a serious condition. Well, again, I don't know what

1 do you define as serious? And I guess it's not good,
2 but I don't know how serious that is. And also I don't
3 know how the -- like here, the epidemic, like how
4 widespread it's got. So again, it's just I lack
5 expertise in answering that.

6 Q. Okay. And if we go to page two, do you see
7 that there's a summary of recommendations?

8 A. Yes, I do.

9 Q. And each one is numbered?

10 A. Yes, I do see that.

11 Q. Okay. So going to the end of this section,
12 which is, I think, on the page titled 712?

13 A. Sorry, page what? 712. Oh, okay, 712.

14 Q. In the upper right paragraph in the middle
15 it says that the number one is for a strong
16 recommendation, and then number two is for a weak
17 recommendation. Do you see that?

18 A. Yeah, the number one, yes. Yes, I see
19 that.

20 Q. Okay. And then it continues where it says:
21 Cross-filled circles indicate the quality of evidence.

22 A. Yes.

23 Q. So one filled circle is very low quality,
24 two is low quality, three is moderate, and four is high
25 quality?

1 A. Yes.

2 Q. Okay. And I know you're not familiar with
3 the GRADE recommendations, but do you recall reading in
4 Dr. Antommaria's report that randomized controlled
5 trials are generally assigned high quality, and
6 observational studies are generally signs of low
7 quality?

8 A. Yeah, I -- yes, I think I remember.

9 Q. Okay. But in the summary of
10 recommendations, do you see any recommendations that
11 are based on high quality evidence, which would be four
12 cross-filled circles?

13 MR. RODRIGUEZ: Object to foundation.

14 You can answer.

15 A. It goes through that. I guess if you ask
16 my question like that, obviously, the answer is no, I
17 don't see any. But I can go through that, right. It's
18 like what they are doing here is high quality plus plus
19 plus. No, I don't, but they do have a few -- three
20 process, and that I will call prospective study.

21 Yeah, well, to answer your question, no, I
22 don't see any. I don't see any of this high plus plus
23 plus, a high quality one. But I do see -- yeah, well,
24 I will stop there.

25 Q. You mentioned three pluses suggests a

1 prospective study, is that what you said?

2 A. No, I didn't. I'm just saying that, again,
3 I don't know -- because I'm not familiar with the GRADE
4 system. I don't know how that is equivalent to the --
5 how you would characterize or classify the prospective
6 study. But I do relative like quality of the relative
7 or the order in terms of their quality. Yeah, that's
8 what I want to say.

9 Q. Okay. So none of these recommendations do
10 they characterize as relying on high quality evidence,
11 correct?

12 A. Well, again, I see where you're going, but
13 maybe I should -- so high quality, yeah, so it's a high
14 quality. High quality in the GRADE system, yes. I
15 don't see any of that. But I do see a few of them
16 based on moderate quality. And, again, I don't know
17 what do they -- what kind of study they call moderate
18 quality, but I do see they have moderate quality in
19 this, yeah, in this guideline.

20 Q. Okay. But there's no high quality?

21 MR. RODRIGUEZ: Asked and answered.

22 You can answer.

23 A. Yeah, there's no high quality.

24 Q. Okay. And does that mean that the studies
25 relied upon by these guidelines do not provide

1 meaningful support for the assertions and
2 recommendations made?

3 MR. RODRIGUEZ: Object to the form and
4 foundation and scope. You can answer.

5 A. I don't think that that is -- again, that's
6 a different -- you're asking a different question,
7 because I -- so what you are showing me here is those
8 guidelines, and then they have -- they label the
9 evidence. They label the evidence they rely upon, but
10 it didn't say -- I didn't inspect the evidence they
11 cited to decide whether that's supported. They decide
12 to use those evidence and use it in their guideline to
13 support -- use those to basically to cite the support.

14 But I didn't, again, that's a different
15 question from what my assignment was, right, or my
16 argument.

17 My argument was whether you can establish
18 the treatment effectiveness, whether this -- about
19 treatment effectiveness, whether that can be supported
20 by the reference they cited. But, again, this is here
21 your question, I think, it's a separate question. It's
22 yeah, I mean, I don't know whether the things they
23 cited support their recommendation, because I didn't
24 review that. So I don't have opinion on that.

25 Q. Okay. So the question of establishing

1 treatment effectiveness is separate from the question
2 of clinical recommendations?

3 A. Correct.

4 Q. Turning back to your report, how would you
5 decide which WPATH assertions to evaluate?

6 A. How do I decide?

7 Q. Yes.

8 A. Oh, Orlando come to me and then he already,
9 he gave me this numbers of assertions, asked me to
10 examine that, and that's how I decide. I examined them
11 one by one.

12 Q. Okay. Did you consider evaluating the
13 assertions by the Endocrine Society and its clinical
14 practice guidelines on the treatment of gender
15 dysphoria?

16 A. Sorry. Can you ask that again?

17 Q. So the Endocrine Society also have clinical
18 practice guidelines on treatment for gender dysphoria.
19 Did you consider evaluating the assertions by the
20 Endocrine Society in that guideline?

21 A. No, I didn't review. I'm not aware of that
22 document, and I didn't review that.

23 Q. Okay. And in WPATH, in terms of care, are
24 there recommendations made in that document?

25 A. I don't know. I don't remember. Again, I

1 focused on my opinion, or my expert report was focused
2 on the specific assertions that was presented by
3 Orlando to me, ask me to take a look.

4 So I didn't -- yeah, I glanced through that
5 document, but I didn't remember everything that was
6 said there or anything beyond that.

7 Q. Did you read the sections of the assertions
8 that you were evaluating were in?

9 A. Oh, yes, I read, but, I mean, that's --
10 basically that's bullet points. Yes, I read those
11 sections very quickly, but I think I actually did a
12 good job in picking those assertions out is a good
13 summary of the -- yeah, I mean that's paragraph.

14 Q. When you reviewed it, do you recall that
15 there were recommendations numbered similar to what we
16 just saw in the Pediatric Obesity Guideline?

17 A. I don't.

18 Q. Okay. And so you were not providing an
19 opinion on the recommendations themselves?

20 A. No.

21 Q. Your chart at the end of your report lists
22 Assertions 1 through 11. Are they numbered that way in
23 the standards of care?

24 A. I don't know. I guess not. I mean, I
25 don't know, because I didn't pay attention to the

1 standard of care.

2 Q. Okay. Were they numbered that way when
3 Orlando gave them to you?

4 MR. RODRIGUEZ: Object, borderline on
5 getting into communications between counsel
6 and the retained expert.

7 A. I don't remember clearly. I believe that
8 was the order he gave me, because I just then take it,
9 and then it's like dealing with, paper -- I mean, it's
10 dealing with one by one. So I didn't change the order
11 or anything.

12 Q. Okay. In your report, you only include
13 your evaluation of Assertions 1, 2, 6, 10 and 11. Why
14 only those ones?

15 A. Say it again? So I only -- I believe that
16 everything Orlando asked me to -- the assertion I
17 indeed reply. Oh, 1 through 6? Why the -- okay. I
18 need to look at the -- let me take a look.

19 Oh, did I say -- again, I don't remember
20 clearly. I think the -- again, this I need --
21 actually, if I have a computer, I can see what is the
22 original Assertion 7 to -- 7 to 9. I need to look. I
23 don't know.

24 So if I didn't respond to that, it's -- oh,
25 it's because --

1 THE WITNESS: Do you have the charge?

2 MR. RODRIGUEZ: Keep on looking
3 through the rest of that.

4 THE WITNESS: Oh, okay.

5 A. Just give me some time. I look through the
6 charge, then I know. Almost there.

7 So Assertion 7, so let me see, Assertion 7
8 says: Too often the agency's structure and personnel
9 provide care are lacking in knowledge, training and
10 capacity of care for gender diverse people.

11 So the paper -- well, oh, I see. So why I
12 didn't, because this has nothing to do with my
13 expertise, because my expertise was talking about -- it
14 established the effectiveness or the safety of a
15 medical intervention.

16 So for this assertion, I don't have opinion
17 to provide, because I don't have expertise on this. So
18 that's why I didn't provide.

19 So I think the same thing for the 8 and 9.
20 So I provide the -- so there are a bunch of assertions,
21 but I provide the opinions on the assertion that I feel
22 that I have expertise on to judge.

23 Q. Okay. So you were not providing an opinion
24 on Assertions 3 through 5 or 7 through 9?

25 A. I think -- yes. Yes.

1 Q. Okay. Well, let's go to Assertion 1 in the
2 body of the report, not the chart.

3 A. Let me get there.

4 Q. I think that's page 11.

5 A. Yes, I found it.

6 Q. Okay.

7 A. Yes.

8 Q. Okay. So what do you mean when you
9 conclude that studies failed to provide rigorous and
10 statistical evidence on the benefits of quality of life
11 and well-being of gender-affirming treatments? And
12 apologies, I should have directed you to where that
13 quote is. It's at the very end of your discussion of
14 Assertion 1.

15 A. Okay.

16 Q. Page 15.

17 A. Yes. Yeah, so the end I said: I conclude,
18 yeah, contrary to the statement in the assertion, these
19 studies failed to provide rigorous and statistical
20 evidence on the benefit of life and quality and
21 well-being of gender-affirming treatments. Yes.

22 So your question? Can you repeat your
23 question, please?

24 Q. Okay. Yeah. So I know earlier we talked
25 about rigorous, and in this context, what do you mean

1 by rigorous?

2 A. Well, I explain that, okay. So if you look
3 at the assertion, it says: There is strong evidence
4 demonstrating the benefit, okay. So what do I mean by
5 strong evidence? Okay. So I focused on that strong
6 evidence. So as I go through my assertion, so I --
7 strong evidence, I show that they cited 21 studies, and
8 so there are five prospective studies, which, again, in
9 my GRADE, that is higher quality ones, and those have
10 mixed results. And then they are now retrospective
11 studies and others of lower qualities, and they have
12 their lower qualities, and they are -- I describe all
13 sorts of flaws in the design. And also I have, I said,
14 there are also seven literature reviews.

15 So the literature reviews point out
16 themselves that, you know, acknowledge the current
17 available research based mostly on cross-sectional
18 studies and call for -- so they acknowledge it's low
19 quality studies.

20 So, I mean, rigorous, again, it's not
21 rigorous. So they have this retrospective studies, and
22 you would not cite those as rigorous, and the
23 consistency part I already mentioned, because the
24 higher quality prospective studies, actually the
25 results show mixed. It's not always provide benefits

1 for that.

2 And 7, actually quite a sizable number of
3 literature reviews point out, acknowledge the
4 shortcomings and flaws in the current state of the
5 research.

6 So that's what I meant it's not rigorous or
7 consistent.

8 Q. Would there have needed to be a randomized
9 control study here for you to find that there was
10 rigorous and consistent statistical evidence to support
11 this assertion?

12 A. If there's one that will add to the
13 reader -- that will definitely add to the reader,
14 there's none, which, again, that's not the end of the
15 world, but they do have some higher quality ones,
16 prospective ones. Unfortunately, they show the result
17 of the benefit on quality of life is mixed. They find
18 some positive, some are negative.

19 So, again, I don't -- I mean, I don't have
20 an opinion. Like, again, it would be great if they
21 have randomized study, but they don't have that, but I
22 don't think that's the end of the world.

23 So I judge, I judge this, because they say
24 that the assertions say there's a strong evidence. By
25 my knowledge -- but by my examination of the literature

1 they reviewed, I find that's really a stretch, because
2 the higher quality ones states actually mixed results.

3 I'm not going to repeat, but, yeah, that's
4 what I meant.

5 Q. So if there are no randomized control
6 studies, and the observational studies did not have
7 mixed results, would you find that their assertion was
8 supported by rigorous and consistent statistical
9 evidence?

10 A. Can you say that again? Can you say --
11 sorry, I didn't hear clearly.

12 Q. Okay. So my last question was, you know,
13 if there was a randomized control study, would you find
14 that there was rigorous and consistent statistical
15 evidence? And you said the lack of a randomized
16 control study was not the end of the world. And so my
17 next question is, you know, if there are no randomized
18 control studies, and the prospective observational
19 study has consistent results or not mixed results,
20 would you find that there was rigorous and consistent
21 statistical evidence to support this assertion?

22 MR. RODRIGUEZ: Object to speculation.
23 You can answer.

24 A. Yeah, this is speculation. So this is
25 speculation. So I can only speak to the five, like the

1 studies they cited.

2 But to answer your question, yes, if they
3 have like -- they have other prospective studies and
4 well done, and they described nicely, it described very
5 clearly the methodology and the result not mixed, I
6 would feel a bit more confidence in -- like then, yeah,
7 that definitely is some more strong evidence than what
8 is currently presented here.

9 Q. And is there a set number of additional
10 prospected numbers that would be needed?

11 A. No, I don't. Again, the better, the higher
12 number, the better quality, it's better. But there's
13 no number I can say well, you need five studies, you
14 need ten studies. We don't have that.

15 Q. Okay. So I guess I'm trying to find where
16 the line is for you, right. You've concluded that this
17 is not rigorous and consistent. And so you must have
18 some sense of what is, and like how do you make that
19 determination? And it sounds like there's some gray
20 areas. There's a lot of factors. How do you make that
21 determination?

22 A. So the key thing, actually, I made my -- I
23 made my opinion or my opinion, not like what you're
24 saying that I don't need to make a line. I examine
25 what is cited there, and what is cited there -- what

1 was cited there, the high quality ones already show you
2 a mixed result. I don't think that I need to go
3 further and say how much evidence I need to make this
4 recommendation? Because I examine what is presented to
5 me, what is cited by them. They cite it for a reason.
6 They cite it for -- I assume they cite those papers to
7 support the opinion. But what is cited there, if you
8 close exam, provide mixed result that I think is
9 enough. I don't need to -- for your question, it's
10 beyond my scope to say oh, where should I draw that
11 line? I judge -- I examine what is presented, what is
12 cited by them, and thus result is not consistent, and I
13 don't think that constitute a strong evidence for
14 the -- strong evidence for treatment effectiveness, and
15 that's what my opinion is about.

16 Q. And you know that this is not enough
17 evidence to be considered rigorous and consistent, but
18 you don't know how much would be needed to be rigorous
19 and consistent?

20 A. Correct.

21 Q. Okay. So in here, you're talking about
22 mixed results in the prospect area. Are you talking
23 about is it the Lindqvist study?

24 A. That's one of the studies. I mention many.
25 I also -- not many. I mean, there are just five,

1 right.

2 So Lindqvist is one. So, again, I went one
3 by one. The other is before -- after.

4 Okay, so the other one, that is the Cardosa
5 da Silva paper also find mixed results. Specifically
6 they found that psychological side -- help and social
7 relationship was significantly improved after SRS, but
8 physical health and level of independence was
9 significantly worse.

10 So that's another one. And another one
11 is -- so another one, again, I don't know whether I
12 need to read through, I mean, this says very clearly
13 that the other one is a prospective study. So they
14 focused on specific type of surgery, and they, the
15 study does not provide no information about the fact of
16 the surgery on general quality of life or well-being.

17 So then the other one, again, the five
18 specific, the other one, the 2014 one, is focused on
19 the safety and side effects of intervention, not
20 quality of life. And the other one is prospective
21 study, but that did not provide before/after comparison
22 of the same patients.

23 So you can see that I list carefully there
24 are five studies. There are five studies, and I
25 mention that some of them do result mix. Some of them

1 simply do not provide information about quality of
2 life, which is -- in the assertion, they say assertions
3 about strong evidence of the quality of life or
4 well-being.

5 So I'm saying that, okay, so there are two
6 studies talk about that, the result is mixed. And then
7 there are other studies that do not provide information
8 for quality of life. So you cannot use that for
9 evidence.

10 And the other one, the last one did not
11 provide a before and after comparison of the same
12 patient.

13 So that's why I clearly examined them one
14 by one in five study, and then why I tell you that, you
15 know, they're essentially among the five studies, there
16 are two studies actually specifically talking about
17 quality of life, and they are of high quality and the
18 results are mixed.

19 Q. Okay. I'm trying to look at the document
20 quickly. All right. So let's mark Exhibit 5, the
21 Lindqvist study.

22 (The document referred to was marked
23 Deposition Exhibit Number 5 for
24 identification.)

25 A. Yes, I have it.

1 Q. And is this the study that you reviewed as
2 part of your expert report?

3 A. Let me look at it. I believe so. It must
4 be this, yes. Yes.

5 Q. Okay. And in the abstract, can you read
6 the last sentence or the second to last sentence that
7 starts with GRS?

8 A. The last sentence says: GRS -- so no, the
9 abstract, they have background, they have methods, they
10 have results, which one are you talking about?

11 Q. On the very first page where it says
12 abstract, the last sentence of that section on the
13 upper right side it says GRS.

14 A. Oh, GRS.

15 Q. Gender --

16 A. Yes, I read that: GRS lead to an
17 improvement in general well-being as a trend, but over
18 the long term, quality of life decreased slightly in
19 line with that of comparison group.

20 Q. Does GRS refer to gender reassignment
21 surgery?

22 A. Yes.

23 Q. Okay. And so this study, the people who
24 conducted this study, did they conclude that gender
25 reassignment surgery leads to an improvement in general

1 well-being?

2 A. Well, it said it proved as a trend but, but
3 the key thing is but over long term, quality of life
4 decreased slightly.

5 Q. Right. And what does it mean to decrease
6 in line with that of the comparison group?

7 A. Well, he said that the comparison group
8 also decreased, and the quality of life, yeah, it's --
9 I need to read more carefully what the comparison
10 group, so who they compared to. I mean, it's one of
11 the many papers. But the comparison group, I don't
12 know what the comparison group is, without looking
13 carefully. Is the comparison group -- I mean, they
14 have a comparison group. I don't know that the
15 comparison group is -- actually, I don't know here.

16 Oh, okay. So -- okay. So I'm now on page
17 225, and so the last sentence: Our findings on lower
18 quality of life in transgender woman compared to the
19 general population of women is in line with the same
20 previous studies, and in contrast to others. However,
21 one of those were performed on transgender men only.

22 So, again, they have a comparison. So I
23 guess it's a comparison compared to the general
24 population of women? I assume. Like that's my
25 understanding, just quickly reading through this.

1 Q. Okay. And so you've described this study
2 as having mixed results, why?

3 A. Well, because the first -- again, by mixed,
4 I mean the initial, there's the increase, and then what
5 I describe here then over the years at three years and
6 five years, it's decreased. So that's mixed. It's not
7 like by mixed I mean the trend of direction, the
8 direction of the outcome is not one-sided, like
9 maintain the same over years. That's what I meant,
10 mixed.

11 Q. Okay. And you conclude that even though
12 the comparison group had a similar decline with the
13 same timing?

14 A. Again, that's their conclusion. They say
15 it's similar. But if you look at the numbers, I don't
16 know how similar that is, whether that's significant.
17 What they say is yes, that is in line,
18 basically the comparison group, like, it's the general
19 population, I assume, yes.

20 Q. So is it possible to interpret this as not
21 mixed, because everyone is going to have a slight
22 decline in quality of life at that time?

23 A. No, this is -- no, this is -- I cannot
24 interpret that way, because this is about -- because
25 the treatment in fact is on the population, on the

1 patient who received the treatment.

2 So you're talking about for this person,
3 for those patients who receive the treatment, so then
4 it's going up and then going down. You cannot stretch
5 that to well, then there's -- like the fact is that
6 there's indeed decrease. And what happened about the
7 general population, I don't know, and that's not
8 because they don't provide data for that. They are
9 just saying oh, that is acknowledged by other, other
10 studies.

11 Q. Okay. So do you disagree with the
12 conclusion of this paper that gender reassignment
13 surgery needs improvement in general well-being as a
14 trend, but over the long term, the quality of life
15 decreases slightly in line with that of the comparison
16 group?

17 A. Not the conclusion. I take it at face
18 value. I don't disagree. I mean, that's what they
19 said, and then I just use that as one of the many
20 papers. I mean, I don't know whether I agree. I take
21 that at face value, this is what they said.

22 Q. But do you agree with it?

23 MR. RODRIGUEZ: Asked and answered.

24 You can answer.

25 A. Well, according to their study, according

1 to what they described, I agree with the conclusion.
2 Again, they clearly try to spin it, make it sound more
3 positive than it is. But that's what we all do when
4 you write papers, because you get published that way.

5 But, yes, I mean, I think what their
6 conclusion is supported by their data.

7 Q. You said they clearly tried to spin it.
8 Where is that clear?

9 A. Where is that clear? So let's look at the
10 numbers. Again, this is getting too details, but I can
11 try.

12 So there's a decrease of general health.
13 I'm looking at page 225. Again, this is one of the
14 many studies. So I'm now doing on cite examine the
15 paper for you. Where I say the main clinical -- so
16 okay. So this is what I -- let me see, this is year
17 one, okay. So that's year one.

18 Let's look at table two. So you have year
19 two, table two that's individuals in this study. Okay,
20 all of that year 0, 1, 3, 5, okay, then let's look at
21 the general -- I see. I see what -- okay. Because
22 they didn't provide data actually about the general
23 population, so if you look at this study, is table two
24 is providing information about all individuals in the
25 study. They are on this through, you know, the

1 treatment. They didn't provide any information about
2 the general population. There's nothing qualitative
3 about their decrease. They purely just say oh, there
4 are other papers. There's general decrease of the
5 quality of life, and I don't, at least as far as I can
6 see here, they don't provide information, quality of
7 information, don't provide data to talk about the
8 comparison group. So that's why I say that it's really
9 a stretch, because they just say oh, there are other
10 studies, but this paper did not provide that data, and
11 they just say that it's inline, but there's no data
12 supporting their argument, so, but, yeah.

13 Q. Do they --

14 A. Sorry, keep going.

15 Q. Go ahead.

16 A. No, I was just saying, it was very clear
17 that -- but the trend talking about the patients in
18 this particular study, as far as increase then
19 decrease, that is clear. That is supported by the data
20 by table 2. But then saying that is in line with the
21 other general populations, that aspect, I don't see
22 data supporting them. So that's why I see clear.

23 Q. Did you read this paper in your entirety in
24 preparation for your expert report?

25 A. Yes, I read through that question quickly.

1 I focused more on the design and the data points. Yes,
2 I read through that.

3 Q. Did you read fully all of the studies cited
4 in your expert report?

5 A. Again, how do I define fully, right? I
6 mean, I skim through them, and I focus -- I know the
7 abstract, the conclusion. I skim through the -- very
8 quickly the paper, but I focus mostly on the
9 statistical methodology and the results and the
10 numbers, that aspect. But, again, I guess that is
11 entirety, but there's no -- I didn't check all the
12 references and stuff, because that's -- that will take
13 an infinite of time.

14 Q. So going back to WPATH Assertion 1 on page
15 11 of your report.

16 A. Okay. Yes, I'm there.

17 Q. Okay. So do you disagree that there are
18 benefits in quality of life and well-being of
19 gender-affirming treatment, including endocrine and
20 surgical procedures?

21 MR. RODRIGUEZ: Objection, scope.

22 You can answer.

23 A. So, I mean, again, my opinion is about
24 whether the references cited provide strong evidence
25 for, as they claimed, for the benefit of quality of

1 life, and that's all my opinion is about.

2 So sorry, what are you asking?

3 Q. I was asking if you disagree that there are
4 benefits in quality of life and well-being of
5 gender-affirming treatment, including endocrine and
6 surgical procedures, properly indicated and performed,
7 and outlined by the standards of care?

8 A. As I said, they are papers that they cite
9 that shows that -- again, those papers show, yeah,
10 there is benefit in quality of life, but unfortunately,
11 those studies are of low quality, and they are subject
12 to all sorts of biases and the design flaws. So then
13 how reliable that evidence is, that's questionable.

14 And so that's why I disagree with these
15 assertions that say there's strong evidence, because
16 this is at best pretty flimsy evidence.

17 Q. Okay. So the scope of your opinion is just
18 as to whether or not there is strong evidence?

19 A. Yes.

20 Q. Okay. And you are not providing an expert
21 opinion on whether there are benefits in quality of
22 life and well-being of gender-affirming treatment?

23 A. No.

24 Q. Okay. Going to page 15, still in Assertion
25 1.

1 A. Yes, I'm there.

2 Q. On the fourth line down, oh, sorry, a
3 little bit further down, I think roughly the sixth
4 line, you said: None of the studies compare sexual
5 assignment surgery with alternative treatment.

6 So what alternative treatment are you
7 thinking of?

8 A. Oh, any. Like, so -- there so, again, this
9 is also kind of academic in the sense that you compare.

10 So I say this it's because -- so they might
11 be, again, gender dysphoria, I'm not an expert on that,
12 but I'm saying that, for example, heart disease. There
13 might be assorted different medications, right. So
14 often we study -- in comparative effectiveness
15 research, often we kind of do studies or trials,
16 observational study, to see that among these different
17 alternative, like four different medications, which one
18 is the best? So that's what I meant by alternative
19 treatments.

20 So here I say that, you know, this is --
21 they're not talking about, they're just talking about
22 one particular type of treatment. And then I don't
23 know whether there are other alternative treatments,
24 but I'm just saying that in the statement, that here,
25 they don't talk about -- like maybe their hormone

1 therapy. I don't know. But they don't compare like
2 the surgery versus hormone therapy. Because, again, I
3 over here, because later, in the later assertion there,
4 the reason I'm thinking Dr. Ettner's point she made
5 that, she made the one statement something like this is
6 the only effective treatment.

7 So I think that is -- when I wrote that
8 part, I was having that in mind. It's like well, all
9 of these studies, particularly about having this
10 treatment versus, I guess, not having this treatment,
11 but not versus alternative treatment, for example,
12 hormone therapy, things like that. So that's what I
13 meant.

14 Q. But you're not aware of any alternative
15 treatments?

16 MR. RODRIGUEZ: Object to the scope.

17 You can answer.

18 A. Again, this is -- this depends on like,
19 yeah, I'm not an expert of that. I don't know. I
20 cannot say, have a blanket statement say that there's
21 no alternative treatments or I am aware of that,
22 because it obviously depends, there's different type of
23 surgeries out there. I know that there's surgery
24 versus hormone therapy. That's probably more or
25 less -- and I also know there's different types of

1 surgeries.

2 So that's what I have in mind when I wrote
3 that alternative treatment. I'm just saying that they
4 are all -- all the studies here is comparing having
5 this versus not, but not different treatment. You
6 know, that's what I meant.

7 Q. So let's move on to WPATH Assertion 2 and
8 looking at the bottom of page 16.

9 A. Yes.

10 Q. So you summarize that because the studies
11 are all of low quality and they're subject to selection
12 bias, nonresponse bias and recall bias, that they fail
13 to provide rigorous and statistical evidence for the
14 assertion, is that correct?

15 MR. RODRIGUEZ: Objection,
16 incomplete -- incomplete recitation of the
17 opinion. You can answer.

18 A. Yes, correct. I mean, you were basically
19 reading out the rigorous and statistical sentence of
20 mine. I reported on that point, yes. Yes, that's my
21 opinion.

22 Q. Okay. And earlier we talked about
23 nonresponse bias and recall bias, both being present in
24 randomized control trials as well as observational
25 studies, correct?

1 A. Correct.

2 Q. Okay. And so is it your opinion here that
3 because there are no high quality randomized control
4 trials, there could not be rigorous statistical
5 evidence to support the assertions?

6 A. That's not my opinion. My opinion, as I
7 said, that there are different -- there are different
8 classes of study. Randomized control study is the
9 best. If it's not available and not always available,
10 then you resort to observational study. But even in
11 observational study, there are good quality and poorer
12 quality ones, higher quality or lower quality ones.
13 And that I didn't say, I didn't say like there's no
14 randomized study then -- like I didn't make my
15 statements or opinion based on, entirely based on the
16 lack of randomized study. Yeah, it is one of the
17 weakness, but that is not the end of the world. I am
18 more focused on actually the higher quality ones that
19 are there. You know, there are very few high quality
20 ones, and the results are mixed, and most of them are
21 low quality ones. And I explain that, why they are low
22 quality, what kind of bias they are subject to.

23 Q. And is it your assertion that the studies
24 are subject to selection bias based on the fact that
25 they are not randomized control trials?

1 A. No, that's not -- no, it's a different,
2 it's a different aspect. So randomized, again, as I
3 explain earlier, so why do you want to randomize study?
4 All the classification of the quality of the study
5 including inference.

6 The big -- like there are all sorts of
7 considerations, but the biggest hurdle is confounding.

8 So randomized trial is good in dealing with
9 that, okay. And so that was my point. And then as I
10 said, the other type of bias, selection bias or
11 nonresponse bias, yeah, those are all the studies
12 subject to, but they are more of the second order
13 issue. And also randomized subject is subject to
14 those, but because of the ways randomized study is
15 highly controlled by the investigators, the chance of
16 those biases are much smaller than the observational
17 studies.

18 So that's why randomized studies always
19 prized, but I repeatedly said that without that, it's
20 not the end of the world. There's still plenty of good
21 well-designed observational study that, you know, can
22 be valuable.

23 Q. You say that most of these studies are
24 subject to selection bias. Why do you say that?

25 A. Well, because that's just the way it is.

1 Okay. I can go into details.

2 So one thing I can think of is many of the
3 studies are from like a single, like a patient -- like
4 a doctor from all the patients he has treated, or like
5 they are locally in one hospital, one medical center
6 over the years have done.

7 So again, in that case, then the patient,
8 the patient population they consider might not be
9 representative of the general population.

10 So that's what I meant. I mean, that's
11 just a general, like if you read through the studies
12 and I found that most of them have that kind of issue.

13 But I do note that they are studies,
14 like -- I don't know whether it's here -- somewhere
15 there's a study of like the Danish study of all the
16 national registry over 20 years of the whole
17 population. Yeah, that one I think, as I said, the
18 quality is higher, because it's a more general
19 population. But even that, it's still like focused on
20 the Danish population. Whether that is representing
21 the whole universe of transgender people, I don't know,
22 and most likely it's not.

23 Q. Okay. And is your assertion that most of
24 these studies are subject to recall bias based on the
25 fact that some of the studies are retrospective?

1 A. Not some of them, yes. If they're
2 retrospective, they are more likely subject to recall
3 bias.

4 Q. Okay. So retrospective studies inherently
5 have a degree of recall bias?

6 A. Yes, because, again, because this happened.
7 You usually collect the data once things already
8 happened. So that is -- you don't like collect the
9 data -- the happening of the thing. Yes, it's
10 inherent.

11 Q. And why do you conclude that these studies
12 are subject to nonresponse bias?

13 A. Oh, well, nonresponse bias, as I mentioned,
14 that when you have -- there's some patients who just do
15 not provide data. And it's pretty well-known
16 methodology that, you know, the people who do not
17 respond to -- there's a reason they don't respond.
18 They don't provide information.

19 So most likely they are different from the
20 people who respond, who provide information.

21 So, again, or if you want to make them --
22 if you -- like only if you make the assumption that
23 these two people, the people who respond versus people
24 who don't respond are exactly the same, like if you
25 want to say there's no nonresponse bias, basically you

1 are saying that the people who respond versus people
2 who don't respond, they are the same. But that
3 assumption most likely is, you know, not plausible.

4 So that is why I say that they're all
5 subject to nonresponse bias. And I read in many of the
6 studies, actually the nonresponse rate is pretty high,
7 like they send out the surveys to the patients, and
8 often the response rate is like 30 percent. That's
9 really low.

10 Q. Okay. And are all types of study designs
11 subject to nonresponse bias?

12 A. Yes, that's correct. But as I said, that
13 some of the studies, like a randomized study, because
14 you are -- you closely monitor them. Like you sign
15 agreement, I think. So there are ways of improving
16 that, but among all of the -- like the retrospective
17 study, again, has the highest -- like is most
18 vulnerable to that, because you have very little
19 control over the response.

20 Q. Looking at the assertion itself, do you
21 disagree with the statement that gender-affirming
22 interventions are not considered experimental, cosmetic
23 or for the mere inconvenience of a patient?

24 MR. RODRIGUEZ: Object to incomplete
25 statement of the actual text.

1 You can answer.

2 A. This is not -- again, my opinion is -- so
3 if you see that in what I wrote, I focused on the last
4 sentence: They are safe and effective in reducing the
5 gender, the gender dysphoria.

6 So my statement was not about like whether
7 they are considered experimental, cosmetic for the
8 convenience of patients, because, again, I'm not an
9 expert in the medical practice of transgender people.
10 So I cannot make -- I don't think I have the expertise
11 to make a statement on that. But my statement is more
12 about the second sentence, is they are safe and
13 effective in reducing gender dysphoria, because that
14 is -- fall into my expertise in comparative
15 effectiveness research.

16 Q. And you are not providing an expert opinion
17 on whether gender-affirming interventions are safe and
18 effective at reducing gender incongruence and gender
19 dysphoria, correct?

20 A. Well, I'm actually providing an opinion on
21 whether this statement is supported by the references
22 they cited, because they make this statement obviously
23 based on, based on those references. And I want to
24 examine that. And I find that statement is I disagree
25 with that statement. Well, it's not I disagree with

1 the statement. My opinion is about that statement is
2 not supported by the reference they cited.

3 Q. Okay. And so you are not providing an
4 opinion on the safety and efficacy of gender-affirming
5 interventions?

6 A. I don't, but if you read the sentence, they
7 say they are safe and effective. And I say that this
8 is not supported by the reference they cited.

9 So if you -- if you just not even stretch,
10 if you continue on that argument, I don't think there's
11 enough evidence to support that statement.

12 But, again, yeah, I'm not saying that
13 whether this is -- whether those are safe and
14 effective. I can only say those papers they cite do
15 not provide evidence for this statement.

16 Myself don't have opinion on whether they
17 are safe and effective, because I don't have enough
18 evidence. At least all the evidence they provided, I
19 would not make this kind of statement based on the
20 references they cited. That's -- yeah. That is my
21 opinion.

22 So based on the documents or the papers
23 they cited, I would not make this kind of statement.

24 MS. NOWLIN-SOHL: Okay. We've been
25 going for about an hour. Are you good to

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keep going? Would you like a break?

THE WITNESS: Maybe five-minute break.

Again, I drink too much water.

MS. NOWLIN-SOHL: Five-minute break.

Sounds good.

(Off the record at 2:11 p.m.)

(On the record at 2:16 p.m.)

BY MS. NOWLIN-SOHL:

Q. We're back on the record. I'd like to move on with the WPATH number 10, which is on page 17.

A. Yes, I am there.

Q. Okay. So on page 18 in the middle paragraph at the end, you see the last point: Most studies do not discuss quality of life outcomes?

What is the significance of the fact that most studies do not discuss quality of life outcomes?

A. Okay. Let me look at the assertion first, just to refresh my mind.

So it says: Although different assessments result from -- okay. So the assertion says: Although different assessment measurements were used, the results from all studies consistently reported both a high level of patient satisfaction as well as satisfaction with sexual function. Although different measures -- assessment measurements were used, the

1 results from all studies consistently reported both
2 high level -- oh, did I repeat? I think this is --

3 MR. RODRIGUEZ: Yes.

4 A. It's a typo.

5 So this was especially evident when used
6 more recent surgical gender techniques.

7 Gender-affirming, this surgery was also associated with
8 low level -- low rate of complication and a low
9 incidence of regret.

10 So then I wrote -- so you mentioned that I
11 say most of the study is not -- which one -- did not
12 provide -- which sentence -- did not provide quality of
13 life. Did I -- sorry, I was just trying to -- can you
14 re-point out like which sentence you are referring to?

15 Q. Yes, it's on page 18, the bottom of the
16 middle paragraph.

17 A. Oh, bottom of the middle paragraph. Okay.
18 Okay. Oh, most of the -- most studies use
19 self-reported outcomes, instead of standardized
20 instrument. And lastly, most study do not discuss
21 quality of life.

22 Oh, so if you ask about the last sentence,
23 most of the studies do not discuss quality of life
24 specific to this assertion. They -- so, yeah, they
25 talk about patient satisfaction and the satisfaction

1 with sexual functions.

2 So in that regard, yeah, they don't discuss
3 quality of life. It's not a problem for this
4 assertion. But also -- but I'm still reviewing the
5 whole thing in the context of also the general forming
6 my opinions. My general, like my overall opinion then
7 in that case those studies that cited here don't talk
8 about quality of life, then that is a concern, because
9 my opinion was it was a part of that. It was about
10 quality of life. Specific to this, to this assertion,
11 this is not a concern.

12 Q. Okay. And then the bottom of page 18, the
13 last full sentence you say: This body of literature
14 supports the high self-reported satisfaction rate among
15 the patients who underwent gender affirming
16 vaginoplasty.

17 And how do you conclude that it supports
18 that?

19 A. Oh, so are you referring to my sentence
20 that says: But does not provide any evidence for the
21 necessity or advantage of GAV comparing to alternative
22 treatments? Are you asking me how I make that
23 conclusion?

24 Q. It's that sentence, but I'm just asking
25 about the first half of it right now.

1 A. Okay. So the body supports high
2 self-reported among the patients who underwent -- yes,
3 that is a fact, yes. That is a fact, yeah. This body
4 of literature indeed support that, because that's a
5 fact. And -- but the emphasis here is the
6 self-reported, as I earlier discuss, self-reported also
7 acknowledged by many of the expert in this field, in
8 these papers.

9 So the self-reported outcomes often have --
10 it's also subject to some methodology flaw.

11 So in terms of this sentence, yes, that's
12 just a state of fact, that's correct.

13 Q. You said that's a fact?

14 A. I mean, that's a fact that taking their
15 numbers and their numbers says that consistent report,
16 both a high level -- I'm saying the assertion, if you
17 go back to the assertion, page 17, it said that results
18 from all the studies consistently reported both a high
19 level of patient satisfaction, so 78 percent to
20 100 percent, yeah, I mean, if you take that at face
21 value, take that, then that is indeed a high
22 satisfaction rate. I mean, that is a fact. A fact in
23 the sense that the number stated there, and I trust
24 that they didn't make up that number.

25 Q. Okay. And so you find that that body of

1 literature can support the high satisfaction rate even
2 though there's no randomized control trial?

3 MR. RODRIGUEZ: Object to the
4 mischaracterization of the actual text.

5 You can answer.

6 A. Yeah, here the English, I probably
7 shouldn't say support. The body of literature
8 basically just reports. I would say the body of
9 literature report a high self-reported satisfaction.

10 So you can cross this supports, but I would
11 use it as a reports, and that's what I meant the
12 literature indeed reports that number.

13 Q. All right. And then the second half of
14 your sentence says: But does not provide any evidence
15 for the necessity or advantage of gender-affirming
16 vaginoplasty comparing to alternative treatments.

17 Can you explain to me what you mean by that
18 conclusion?

19 A. Yes. So as I earlier discussed to you,
20 that -- so all of these studies is talking about this
21 one particular surgery, GAV. So the study subjects are
22 all the people who underwent GAV, and then they go to,
23 as far as I remembered, the researchers surveyed those
24 patients and asked whether they are satisfied, and, you
25 know, their satisfaction and things like that. But it

1 didn't compare to people who could take alternative
2 treatment, for example, hormone therapy or, you know,
3 other -- I don't know. I only know hormone therapy.

4 So it did not compare GAV with anyone who
5 takes say hormone therapy. Also, it didn't compare
6 people who take GAV versus people who didn't take GAV.

7 So that's what I meant.

8 So you are just saying the statement, the
9 study decided is focused on the people who indeed take
10 this surgery, right, and then ask them whether you are
11 satisfied. But there's nothing comparing there,
12 because they didn't compare in the comparative world
13 that had this person not take the treatment or had the
14 person taken another treatment, like hormone therapy,
15 what it would be.

16 So in that regard, that's like you can say
17 oh, we've satisfied this, but there's no comparative
18 statement. That's what I meant.

19 If there's no comparative statement, then
20 you cannot say oh, this is the only one, that you must
21 take this, because you don't know what will happen to
22 those people that had they taken different treatment.

23 So the key thing is what I -- to summarize
24 what I just said, it definitely means that these
25 studies does not -- did not provide like any

1 information about comparisons, comparisons of this
2 treatment versus control versus no treatment or other
3 treatment, so that's what I meant.

4 Q. You mentioned hormone therapy as an
5 alternative. Are you aware that the WPATH standards of
6 care and the Endocrine Society recommend that people
7 have at least 6 to 12 months of hormone therapy prior
8 to undergoing gender-affirming surgery?

9 A. I'm not aware of that. Again, that's not
10 my expertise. I say hormone therapy, it's just because
11 when I review the literature, and I see people mention
12 hormone therapy. I can -- I say hormone therapy, but
13 when I put my sinus hat on, it would be treatment A
14 versus treatment B. So hormone therapy would be
15 treatment B.

16 Q. And do you know if anyone undergoes
17 gender-affirming vaginoplasty or vulvoplasty without
18 having hormone therapy?

19 A. I don't know. That sounds like a medical
20 question that I cannot answer. I don't know.

21 Q. And your other conclusion does not provide
22 any evidence for the necessity of gender-affirming
23 vaginoplasty. Where does it say that that is what it
24 is attempting to do?

25 A. Oh, it didn't. It's just, again, I just

1 rolled it. Probably when I rolled that, again, I was
2 thinking -- well, okay.

3 So, yeah, it didn't, but I just make the
4 statement because based on the fact -- based on the
5 fact that none of this study comparing the treatment to
6 alternative or to no treatment. So then once you don't
7 have that, you know, you cannot say anything about this
8 is necessary. Yes, this is not on the assertion. So
9 this is -- I just roll that as if you don't have
10 comparison, then you cannot, like there are a bunch of
11 possibles, then you cannot say this is must, this is
12 next.

13 I guess when I wrote that, I probably
14 crossed -- was still thinking about some point of like
15 this is the only effective thing or something like
16 that.

17 So yes, you are right. In terms of in
18 this -- specific to this assertion, they didn't, in
19 this assertion, didn't say anywhere that it's
20 necessary, okay. And I made -- yeah, I didn't -- well,
21 this assertion actually is, yeah, I didn't make that
22 statement. But, again, I was just based on the -- on
23 the review I did, I add this -- I mean, I add this
24 phrase there. That is accurate. The phrase is
25 accurate. But, yeah, it is not, it's not stated in the

1 assertion, that is correct.

2 Q. Okay. And for the women who have been
3 receiving hormone therapy and continue to have
4 significant gender dysphoria, are you aware of any
5 alternative treatments besides gender affirming
6 surgery?

7 MR. RODRIGUEZ: Object to the scope.

8 You can answer.

9 A. No, that's, again, that's not my expertise.
10 So I don't have answer to that. I don't have enough
11 information about that.

12 Q. But you don't know if there are alternative
13 treatments?

14 A. I don't know.

15 Q. Okay. Let's go to page 19, which has
16 Ettner Assertion 1.

17 A. Yes, I'm there.

18 Q. Okay. And so in that -- your first
19 paragraph after the assertion, about the fourth line
20 down you say: As elaborated in my assessment of WPATH
21 Assertion 1, the statistical methodology in the field
22 of comparative effectiveness of SRS is not up to the
23 long-established standard in comparative effectiveness
24 research in medicine.

25 A. Correct.

1 Q. What is comparative effectiveness research?

2 A. Oh, comparative effective research, as I
3 wrote in page 5 of my report, I said in medicine, the
4 type of research used to evaluate the effects and
5 safety of an intervention, it's broadly referred to as
6 comparative effectiveness research. The statistical
7 methodology for, again, here's a typo, for the
8 comparative effectiveness research is generally --
9 belongs to the general statistics field of causal
10 inference, which I am an expert on.

11 So basically in medicine and health
12 studies, like the whole type of study I tried to
13 establish the effectiveness, the safety, or efficacy of
14 treatment is broadly referred to as comparative
15 effectiveness research.

16 Again, you can see that there's emphasis,
17 the two things: One is effectiveness, the other is
18 comparative. So it's a comparison, yeah. That's what
19 I meant.

20 Q. Okay. And did you mention there was a
21 typo?

22 A. Yeah, the typo was -- so the last sentence
23 says: The statistical methodology for quality of life,
24 it shouldn't be quality of life. It's statistical
25 methodology for comparative effectiveness research

1 belongs to the general statistical field called
2 inference.

3 Q. Got it. That's the one we identified
4 earlier?

5 A. Yes.

6 Q. Okay. So going back to page 19, what is
7 the long-established standard that you're referring to
8 in comparative effectiveness research in medicine?

9 A. Oh, well, as I said, that is -- that would
10 be in the best case scenario, when available, you do a
11 randomized experiment or maybe multiple randomized
12 experiment. And when that is not available, you resort
13 to observational study but well-designed observational
14 study, and, for example, prospective before/after
15 studies, and this like a more represent -- like a large
16 study sample, things like that. And then like the
17 other would be considered good or like acceptable. And
18 then long-established, that, as I said, the consensus
19 is then this kind of retrospect study resolved
20 before/after measurement those -- and why you have also
21 a lot of nonresponse as more sample size those of low
22 quality.

23 So, again, that's what I meant by
24 long-established standard and comparative effectiveness
25 research in medicine.

1 Yeah, so like when you try to publish
2 something, like about comparative effectiveness of
3 treatment, then you expect to provide either randomized
4 study or high quality observational study. So that's
5 what I meant.

6 Q. And must that standard be met before a
7 treatment can be provided to a patient?

8 MR. RODRIGUEZ: Objection to scope.

9 You can answer.

10 A. Not necessarily, because there's a lot
11 of -- so, okay, different, different medical conditions
12 like FDA. For example, if we are talking about new
13 drugs and new medical devices, FDA would almost
14 always -- well, most of the time would require a
15 randomized study, right, but that's not the end of it,
16 because they would do phase one, phase two, phase three
17 randomized study, and then after approval, they will
18 actually also do the post marketing, they call post
19 marketing analysis.

20 Like, for example, we now all use Covid
21 vaccine, right? We use Covid vaccine. So after Covid
22 vaccine is proved, then actually there will be
23 continuous study, actually to like in real world
24 scenario. When Covid-19 vaccine is used, and then
25 what's the population? So you go to continue. In that

1 case, you cannot do an online study, right. But you do
2 an observational study for a large population, and then
3 you calculate -- you study the effect in real life.

4 So, again, I think your question is like
5 whether you should have kind of treatment provided
6 before the -- sorry, can you rephrase? I cannot -- can
7 you rephrase your question?

8 A. Yes. So you're talking about the
9 methodology in the field of comparative effectiveness
10 of sex reassignment surgery is not up to the
11 long-established standard in medicine. And so I'm
12 asking if that standard must be met before treatment
13 can be provided?

14 MR. RODRIGUEZ: Objection, scope.

15 You can answer.

16 A. I think that's a different question from
17 what I tried to -- from what my opinion is about,
18 because I don't have -- I mean, I don't have answer to
19 that.

20 What I can just say is the current state on
21 the research on the sex reassignment surgery, at least
22 based on the document they cited that I reviewed, do
23 not -- because most of them are low quality, and the
24 better quality ones have mixed results. Based on that,
25 I would not -- I don't think that would meet the high

1 standards -- the high standard that people expect in,
2 you know, he recommend -- I'm not going to recommend,
3 just in reporting the effectiveness of those surgeries.

4 Q. So you are not providing an opinion on
5 whether the evidence meets the standard in comparative
6 effectiveness research, impacts whether treatment can
7 be provided?

8 MR. RODRIGUEZ: Objection, scope.

9 You can answer.

10 A. Correct. I'm not providing opinion on
11 that. I focused on Ettner's assertion. I focused on
12 her assertion saying that studies show that
13 gender-affirming surgery as safe and effective, safe
14 and effective. And also she said that indeed for many
15 people, this is the only effective treatment.

16 So my assertion is about whether she has
17 enough evidence from those references she cited to
18 support this two statement: One is whether they are
19 safe and effective; the other is this is the only
20 effective.

21 As I mentioned earlier, the only effective,
22 that's kind of the necessity my understanding is. But
23 when you say only effective, you have to compare, you
24 have to can see that there's a possibility of
25 alternatives. And that's one thing. And the first

1 sentence about safe and effective, I already said many
2 times why, why the studies they decided do not meet the
3 standard in providing rigorous and consistent evidence
4 for that statement.

5 Q. Okay. And you're also not providing an
6 opinion on what degree of statistical methodology is
7 needed for a treatment to be included in a clinical
8 practice guideline, correct?

9 MR. RODRIGUEZ: Asked and answered and
10 scope. You can answer.

11 A. Correct. I'm not providing opinion on
12 that. Again, I provided opinion on whether those
13 assertions are supported or, yeah, by the documents
14 they cited.

15 As I said, I would not, based on -- if I'm
16 an expert in this field, which I am not in gender
17 dysphoria, and if I'm an expert, and if I read this
18 document -- no.

19 I'm a statistician, and I read those
20 documents. I should say I'm a statistician. I read
21 all the documents they cited, and then I would not make
22 the statement as they make it. That's a better summary
23 of what I want to say. Because I would say that there
24 would not be enough evidence. I don't think there's
25 evidence strong enough for me to make this kind of

1 statement.

2 Q. You disagree with Dr. Ettner's assertion
3 describing the research as methodologically sound?

4 A. I disagree with that statement, and I think
5 I said I don't think it's methodologically sound, and I
6 already clarify why I think that many of the studies
7 are fraud. And, again, that opinion has been -- that
8 statement has been made in multiple, in large
9 literature review in that field. So it's not -- yeah.

10 Q. Okay. And your first sort of comment after
11 the sentence we were just talking about, comparative
12 effectiveness research is that: There has not been a
13 single randomized control trial. Is that the primary
14 reason that you view the research is not
15 methodologically sound?

16 A. No. As I said many times, that's not the
17 end of the world, but it's one thing you can easily
18 point out.

19 So my statement is -- my argument of --
20 basically my opinion consists of four things: First is
21 there's no randomized study. Second is that's not the
22 end of the world. You can still do good quality
23 observational study, that is prospective before/after
24 study. And then they don't -- and in the study they
25 cited, they indeed have a few of them and the result

1 are mixed. And the third part of the argument is that
2 in the vast majority of the study they cite are low
3 quality retrospect study that subject to a lot of
4 confounding bias and all sorts of biases. And the
5 fourth component of my argument is that even in
6 their -- many of their own large scale systematic
7 review, literature review, they -- the expert are
8 calling for better methodology or more prospective
9 studies and call the current state of many of the
10 studies of low quality.

11 So that's my -- like my statement has four
12 components, and they are all integral.

13 So the lack of randomized study, that's the
14 first component, but that's not the only component, and
15 also that's not the only reason I made my statement.

16 So I think it's -- those four components
17 are equally important.

18 Q. Are all cross-sectional retrospective
19 studies methodologically unsound?

20 A. Well, all retrospect -- again, as a
21 scientist, you don't make this kind of blanket
22 statement. But what I can say, as I already repeatedly
23 said, that you can have a prospective study if it's
24 before/after data, that is far superior than
25 retrospective study without before/after data. And the

1 reason of that is the confounding. The reason of that
2 is the baseline measure of the outcome is often the
3 most important predictive, the most important
4 confounder out there. But retrospect studies do not
5 control for that. So that's why it's low quality.

6 But I would not say that, you know, I would
7 not blankedly(sic) say that every single retrospect
8 study is garbage. No, that's not my point.

9 Q. Okay. But here, for this assertion, you're
10 saying that the cross-sectional retrospective studies
11 are not methodologically sound?

12 A. Yes, correct. In the studies they cite, I
13 look at their methodology. They are, yeah, they're all
14 lacking the baseline -- they're all lacking baseline
15 measure of the outcomes, and they are subject to very
16 severe confounding bias and they are not
17 methodologically sound.

18 Yes, I stand by that statement in the
19 context of what I reviewed.

20 Q. And are all retrospective studies subject
21 to severe confounding bias?

22 A. Again, it depends on how much. So the
23 answer is it depends on how many things you control
24 for, how many confounders you control for, right. And
25 as I said, that if in retrospective study, that if they

1 could get the baseline measure, baseline outcome, then
2 they will have high quality, higher quality than those
3 ones without.

4 But -- so I'm not saying that they are all
5 bad, but I'm just saying all the studies they cited
6 here none of them provide that. So because of that
7 this is of low quality, and I don't think that quality
8 is sound in that aspect, because they are missing the
9 single most -- often the most important confounders
10 there.

11 Q. Okay. Do you agree that the FDA approves
12 some treatment and medical devices without having
13 randomized control trials?

14 MR. RODRIGUEZ: Objection, scope.
15 You can answer.

16 A. Well, there must be some, but I cannot
17 think of off the top of my head, yeah. I mean, as I
18 said, I think extraordinary cases they approve, but I
19 don't know. I cannot give you a specific example. But
20 I won't be surprised in some studies -- in some
21 conditions they do. But I really don't know.

22 Q. Okay. Go to page 8 of your report.

23 A. Which page?

24 Q. 8.

25 A. 8?

1 Q. Yes.

2 A. Yes, I'm there.

3 Q. Do you see the header that says randomized
4 control trials versus observational studies?

5 A. Correct.

6 Q. Okay. And the second sentence of that you
7 say that: The FDA requires evidence of efficacy and
8 safety of a new product based on randomized controlled
9 trials in the approval of the vast majority of new
10 drugs and medical devices.

11 A. Correct.

12 Q. Did I read that correctly?

13 A. Correct.

14 Q. Okay. And so the vast majority means that
15 it was not followed then, correct?

16 A. Correct.

17 Q. So would you agree that the FDA does
18 approve new products despite not having randomized
19 trials?

20 A. Again, I cannot say -- give you example,
21 but I believe so, yeah. I believe so. So that's why I
22 say vast majority rather than all, because I didn't go
23 to do research about what the FDA, all of the scope.
24 It's just my experience with the FDA is, yeah, the vast
25 majority of new drugs and medical devices that's what

1 they use.

2 Q. Let's go back to the Ettner assertion,
3 which is number 2 on page 20.

4 A. Yes, correct.

5 Q. In your report, you do not disagree with
6 this assertion, correct?

7 A. Let me see. I need to read the conclusion.
8 So I'm just reading it. The conclusion that is the
9 gender-affirming surgery is the most appropriate
10 treatment to alleviate suffering of extreme gender
11 dysphoria individuals still stands. 96 percent of
12 patients who underwent that surgery were satisfied, and
13 the regret was rare.

14 So what did I say? I said that:
15 Immediately after the quote contained in this
16 assertion, the authors themselves acknowledged.
17 However, even today, this conclusion is based on
18 methodologically less than perfect design studies.
19 Okay. I guess I don't need to read it. But this is --
20 said very well what I think, right. And then this
21 says, that this paper actually wrote that none of the
22 study was a controlled one. So basically this paper
23 described what are the -- why they say this
24 methodologically less than perfectly -- less than
25 perfect, right.

1 So the authors also acknowledge a few other
2 methodological shortcomings, like attrition, or
3 selection bias of the patient sample, which echo my
4 critiques with respect to the WPATH Assertion 1. Yes.

5 Again, mine was based on -- so this
6 particular assertion, so they analyzed that. So
7 Ettner's assertion is -- yeah, so Ettner's assertion
8 say that those -- they conclude that, and then I say
9 that even as authors themselves that acknowledge the
10 methodology is not perfect or is less than perfect.

11 Q. Okay. But you're not disagreeing with the
12 statement?

13 A. I didn't provide opinion on this. Well, I
14 didn't assess, because, again, as an expert, I'm a
15 statistic expert, right. So then I can judge on the,
16 again, from statistical aspect, whether this statement
17 is based on like what kind of statistical strengths --
18 statistical evidence they have. And then I go to
19 say -- well, I go to acknowledge, I go to find that the
20 authors themselves acknowledge that those studies, you
21 know, it's not -- the foundation is not most perfect,
22 and I didn't direct -- in this assertion, I didn't
23 directly say that -- yeah, I didn't provide opinion on
24 whether that this is what I feel about this statement.
25 Again, that's not what my opinion is about. My opinion

1 is about whether this is supported by the references,
2 yeah.

3 Q. So looking at the Assertion 5 through 9,
4 which is on page 21.

5 A. Correct.

6 Q. In your conclusion at the end of that
7 section, does your use of the phrase rigorous and
8 consistent scientific evidence, does that have the same
9 meaning that we've discussed previously?

10 A. Correct.

11 Q. So if I were to tell you that 1 in 20 high
12 schoolers in America die by suicide, would you say that
13 America's high schoolers often die by suicide?

14 MR. RODRIGUEZ: Objection,
15 speculation. You can answer.

16 A. That's how do we define often? Like my
17 training is in mathematics, and you always say you need
18 to give me a definition.

19 So if my definition is below -- is
20 10 percent -- if often is 10 percent, then it's not.
21 If it's 5 percent, yes. So it depends on how you
22 define often.

23 So my answer of this would be by definition
24 tied to the definition of often, so I'm not going to
25 speculate that.

1 Q. Okay. And how does one define often? How
2 does one go about defining that?

3 A. Does that have anything to do with what we
4 are talking about here?

5 Q. Yes.

6 A. So you're talking about a hypothetical
7 about the high school, this like 1 out of 20. And as I
8 said -- so as I said that if, I mean, I don't know,
9 there's an English word, also if you want to go jargon,
10 you can define this 5 percent or 10 percent. So --

11 Q. Does the context matter whether something
12 is often or not?

13 A. Again, the definition matters. The
14 definition matters, not the context. It's the
15 definition.

16 Q. Okay. So if we say 10 percent is often,
17 that would be often in every scenario that we can think
18 of?

19 A. Again, you need to first define things.
20 Like as a mathematician, we always first define a
21 thing, especially if you want to attach, if you talk
22 about numbers, you talk about often, yeah, the
23 frequency. So the frequency, if I define -- if I say
24 that by often I mean more than 10 percent, then that is
25 often. But -- yeah, I really don't know how to further

1 elaborate this.

2 Q. Okay. How do you define often?

3 A. As I said -- well, as I said, that it's --
4 okay. So now I get to a point you say that depends on
5 the context. I mean, I use this English word, and
6 usually when I say often, it probably means something
7 like over 50 percent.

8 So now I see your point. So, okay, so
9 maybe it depend on the context.

10 So, again, this plain language or common
11 sense often versus if you're talking about
12 scientifically. So that's why in papers we don't write
13 often, because this is like vague, non-defined terms,
14 yeah.

15 Q. Okay. So let's move forward to page 23 and
16 Assertion 11.

17 A. Yes.

18 Q. So midway through your paragraph, you
19 comment on the Brown study, which reports that
20 5 percent of transgender inmates report that they had
21 attempted or completed autocastration while
22 incarcerated. And then you continue: This percentage
23 supports the occurrence is relatively rare rather than
24 often.

25 How did you define often and rare in that

1 assertion?

2 A. Well, okay, as I said, as common sense, I
3 think often is probably 2 percent or 1 percent is not
4 often, because that's 100 incidents. Then 100 times 2
5 or 3 times happen. I don't -- again, I don't -- I went
6 from a layperson just a common sense. I would not say
7 that's often.

8 Often, I would feel that is, if you say
9 10 percent or 20 percent, that sounds often.

10 So now I see your point. So you're going
11 through this one, okay.

12 But as I said, I would not -- I mean, from
13 a common sense perspective, regard 2 percent or
14 3 percent as often.

15 Q. Okay. Just a few minutes ago you said you
16 would consider often as generally more than 50 percent?

17 A. No. As I said -- as I said, that is --
18 there's like if you want to go statistically, that I
19 can say probably what you should write is probably
20 Dr. Ettner or whatever should say by often, I mean
21 this. And she didn't provide any of the numbers there.
22 She just said often. I don't know what she mean by
23 often. I'm just using the numbers I see at 2 percent
24 or 3 percent, and I say that common sense, this is not
25 often.

1 Q. But that assumes often is objective or
2 consistent, doesn't it?

3 A. What do you mean by often is objective and
4 consistent? Again, if you go to grab anyone on the
5 street and ask them something happened 2 percent of the
6 time, is it often? I bet you'd probably 99 percent of
7 people tell you that's not often. That count as not
8 often.

9 Q. Okay. We're talking about 5 percent here.
10 So if I told you that 1 in 20 high schoolers, which is
11 5 percent, die by suicide in America, would you think
12 that was often?

13 MR. RODRIGUEZ: Objection, scope.

14 You can answer.

15 A. Would I consider that often? So that's
16 5 percent, so that's another thing, okay. So high
17 schoolers is a large population. So if you have say 10
18 million, let's say 1 million high schoolers, so
19 5 percent of that is, what, that would be 5,000, right?
20 That would be 5,000. And then from that, yeah, that
21 is -- so that quantity that is often.

22 Q. I think it would be 50,000.

23 A. 50,000 anyway, so that would be often in
24 terms of the number, okay. But in rate wise, again,
25 5 percent, I don't know where to cut the line. But I

1 can tell you 2 percent or 3 percent is just not by any
2 common sense would be viewed as common -- as often.

3 Q. Do you know what the rate of attempted or
4 completed surgical treatment or autocastration is among
5 non-transgender adults?

6 A. I do not, no.

7 Q. All right. Looking at Assertion 12, on the
8 fourth line you say that: The WPATH study only
9 provided qualitative studies, not any formal
10 statistical meta-analysis.

11 Can qualitative evidence be useful in
12 medicine?

13 MR. RODRIGUEZ: Objection, scope.

14 You can answer.

15 A. Of course it can. Of course they can be
16 useful. But, again, this is -- what I wrote here is
17 just a pure statement. It's -- of course qualitative
18 would be better, because they provide -- they quantify
19 things. I didn't say this -- their qualitative is not
20 valuable. I'm not saying that.

21 Q. Okay. And then moving forward to the top
22 of page 24, you are talking about other 9 studies. You
23 say: The methodological problems include retrospective
24 cross-sectional studies.

25 Is a retrospective cross-sectional study a

1 methodological problem?

2 A. Yes, I mean, again, as I said,
3 retrospective cross-sectional means that there's no
4 baseline measure of the outcome of the low quality,
5 because it cannot control -- because it's subject to
6 severe confounding bias, yes. So that is a problem.
7 That is of low quality. And so the methodology did
8 include that.

9 So it's one of the many weaknesses those
10 studies are subject to.

11 Q. Do you disagree that researchers -- in
12 looking at Ettner's assertion, do you disagree that
13 researchers concluded that gender-affirming surgery
14 positively affects well being, sexuality and quality of
15 life in general?

16 A. As I said, that's not my opinion.

17 My opinion is that based on what they
18 cited, the reference they cited, that those references
19 they cited do not provide consistent or rigorous
20 support for their statement.

21 In other words, if I'm a researcher, I look
22 at those references. I would not make this statement,
23 because I feel that the evidence is not strong enough.

24 Q. But you're not providing an opinion on
25 whether the researchers conclude -- made that

1 conclusion?

2 A. Well, some of the researchers themselves
3 said that they have called for -- again, they've called
4 for this literature review. They called for better
5 studies, better designs, and acknowledge the low
6 quality of the current studies. So I stop there.

7 Q. So are you providing an opinion on whether
8 the researchers concluded that gender-affirming surgery
9 positively affects well-being, sexuality and quality of
10 life in general?

11 MR. RODRIGUEZ: Asked and answered and
12 scope. You can answer.

13 A. No, I didn't provide an opinion on that. I
14 provided opinion on the quality of the study decided,
15 and whether those studies that -- those studies would
16 support the assertions they make.

17 Q. And so you are also not providing an
18 opinion on whether gender affirming surgery does
19 positively affect well-being, sexuality and quality of
20 life in general?

21 MR. RODRIGUEZ: Scope, asked and
22 answered. Go ahead.

23 A. Again, it's all of my scope, but as I
24 repeated saying that, if I'm a researcher, and if I'm a
25 researcher, and then I look at those studies, look at

1 those studies and decided I would not go to make that
2 statement or those caveats, okay. Or I would
3 acknowledge those assertions, or I would acknowledge
4 the current state of the studies in this field do not
5 provide consistent or rigorous conclusions and whether
6 that equivalent to what you just said. That's not
7 my -- that's a different question.

8 Q. Are you aware that the American Medical
9 Association, the Endocrine Society and the American
10 Psychological Association also put surgery in
11 accordance with the WPATH standards of care as
12 medically necessary treatments for individuals with
13 severe gender dysphoria?

14 MR. RODRIGUEZ: Objection, scope,
15 medical opinion. You can answer.

16 A. I'm not aware of that, because that's not
17 my expertise.

18 Q. Okay. Do you think that they are wrong to
19 do so, given your view that there is no rigorous and
20 consistent statistical evidence on the benefits of
21 sexual reassignment surgery?

22 MR. RODRIGUEZ: Objection,
23 mischaracterization of testimony, scope and
24 medical opinion. You can answer.

25 A. As I said, the treatment recommendations

1 goes -- there's a lot of things go into that, and
2 arguably the treatment, the effectiveness of a
3 treatment, and the safety of a treatment is one of the
4 important considerations. And, yeah, my opinion is
5 focused on that part, the effectiveness, whether the
6 effectiveness has been established by the studies they
7 cited. I don't have opinion on whether, you know,
8 they're wrong, any medical society whether it's wrong
9 or right for them to suggest, you know, to make their
10 recommendations.

11 Q. Are you aware that the appellate division
12 of the Departmental Appeals Board of the United States
13 Department of Health and Human Services concluded in
14 2014 that transsexual surgery is an effective treatment
15 option of transsexualism in appropriate cases?

16 MR. RODRIGUEZ: Objection, medical
17 opinion, scope. You can answer.

18 A. I don't know. Again, that's not my
19 expertise, so I don't know. I don't know.

20 Q. Do you think that they were wrong to make
21 that conclusion, given your view that there is no
22 rigorous and consistent statistical evidence on the
23 benefits of sexual reassignment surgery?

24 MR. RODRIGUEZ: Objection,
25 mischaracterization of testimony and report,

1 scope and medical opinion. You can answer.

2 A. Again, as I said before, that, yeah, I
3 don't have an opinion whether they are right or wrong.

4 As I said, that medical recommendations is
5 not my expertise, and many things go into that
6 decision, and treatment and effectiveness is one of the
7 important consideration, but it's not the only one.
8 And my scope, what my opinion is solely about whether
9 the statement or the statement about the treatment is
10 effective, is supported by the references as cited, and
11 the answer to that is no.

12 Q. Have you looked at any studies on the
13 effects of not providing gender-affirming care to
14 people with gender dysphoria?

15 A. No, I don't -- I didn't.

16 Q. Why not?

17 A. Oh, it's just because, again, the scope of
18 my study is to exam that those assertions and the
19 references cited, and if they don't cite it, then I
20 didn't review.

21 Q. Do you know if such studies exist?

22 A. I don't know. I don't know whether they
23 exist or not.

24 Q. Okay. I'm just looking at some notes.

25 So -- and part of your expert report and

1 opinions are you providing an opinion on whether
2 gender-affirming surgery can be ethically provided to
3 treat gender dysphoria by a physician given the
4 existing body of evidence?

5 MR. RODRIGUEZ: Objection, scope and
6 medical opinion you can answer.

7 A. No, I don't provide opinion on that. That
8 is beyond my expertise.

9 Q. And are you providing an opinion on whether
10 gender-affirming surgery can be medically necessary to
11 treat gender dysphoria?

12 MR. RODRIGUEZ: Objection, scope and
13 medical opinion. You can answer.

14 A. No, I don't have -- I don't provide opinion
15 on that.

16 Q. And are you providing an opinion on whether
17 gender-affirming surgery is medically necessary for
18 Ms. Zayre-Brown, the plaintiff in this case?

19 MR. RODRIGUEZ: Objection, scope and
20 medical opinion. You can answer.

21 A. No, I don't provide opinion on that.

22 Q. Okay. And are you providing an opinion
23 on -- let me rephrase that.

24 Are you providing an opinion on the
25 recommendations contained in the WPATH standards of

1 care?

2 MR. RODRIGUEZ: Objection, scope.

3 You can answer.

4 A. No, I don't provide opinion on that.

5 MS. NOWLIN-SOHL: Okay. Orlando,
6 maybe we can take a short break. I think
7 that might be everything I have. I just
8 want to take a look at my notes.

9 MR. RODRIGUEZ: Yeah, we'll step out.
10 Five minutes good?

11 MS. NOWLIN-SOHL: That sounds good.
12 Thank you.

13 (Off the record at 3:06 p.m.)

14 (On the record at 3:12 p.m.)

15 MS. NOWLIN-SOHL: Dr. Li, we are back
16 on the record, and I have no further
17 questions.

18 MR. RODRIGUEZ: No questions from us.

19 MS. NOWLIN-SOHL: Thank you for your
20 time.

21 THE WITNESS: Thank you for being
22 respectful.

23 (Whereupon the deposition was
24 concluded at 3:13 p.m.)

25 (Signature reserved.)

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C E R T I F I C A T E

I, Marisa Munoz-Vourakis, Stenographic Reporter, RMR, CRR and Notary Public, the officer before whom the foregoing proceeding was conducted, do hereby certify that the witness whose testimony appears in the foregoing proceeding, were duly sworn by me; that the testimony of said witness were taken by me to the best of my ability and thereafter transcribed under my supervision; and that the foregoing pages, inclusive, constitute a true and accurate transcription of the testimony of the witness.

I do further certify that I am neither counsel for, related to, nor employed by any of the parties to this action in which this proceeding was conducted, and further, that I am not a relative or employee of any attorney or counsel employed by the parties thereof, nor financially or otherwise interested in the outcome of the action.

IN WITNESS WHEREOF, I have hereunto subscribed my name this of , 2023.

MARISA MUNOZ-VOURAKIS

Notary #20032900127