

**IN THE UNITED STATES DISTRICT COURT
FOR THE NORTHERN DISTRICT OF FLORIDA
Tallahassee Division**

AUGUST DEKKER *et al.*,

Plaintiffs,

v.

JASON WEIDA, *et al.*,

Defendants.

Case No. 4:22-cv-00325-RH MAF

**PLAINTIFFS' MEMORANDUM OF LAW IN SUPPORT OF MOTION TO
EXCLUDE EXPERT TESTIMONY OF STEPHEN B. LEVINE, M.D.**

TABLE OF CONTENTS

I. INTRODUCTION	1
II. LEGAL STANDARD	2
III. ARGUMENT.....	6
A. Many Of Dr. Levine’s Opinions Will Not Help the Trier of Fact Because They Support Plaintiffs’ Position.	8
B. Dr. Levine’s Opinions That Do Not Support Plaintiffs’ Position Are Methodologically Unreliable and Scientifically Unsupported.	12
1. Dr. Levine’s Assertion that the WPATH SOC Version 8 Is Not the Widely Accepted and Authoritative Protocol for the Treatment of Gender Dysphoria Is Misleading and Unreliable Because It Is Demonstrably False.....	13
2. Dr. Levine’s Opinions That Gender-Affirming Medical Care Is Experimental, Is Provided Without Mental Health Assessments or Sufficiently Informed Consent, and Is Without Lasting Benefit are Inaccurate and Unsupported.....	17
3. Dr. Levine’s Opinions About Gender Dysphoria “Naturally Resolving” in Children and Adolescents Are Not Based In Fact.....	22
4. Dr. Levine’s Assertion that “Rapid Onset Gender Dysphoria,” as a Cause of Gender Dysphoria or the Concept of “Detransition” Justifies Denying Treatment to Florida Medicaid Beneficiaries Is Unsupported By Scientific Evidence.....	24
C. Dr. Levine Is Not Qualified To Offer Opinions About Puberty-Delaying Treatment or the Treatment of Prepubertal Children Generally.	27
D. Dr. Levine’s Report, Opinions, and Testimony Lack Probative Value and Are Thus Inadmissible Under Federal Rule Of Evidence 403.....	29
IV. CONCLUSION.....	30

I. INTRODUCTION

Plaintiffs are transgender Medicaid beneficiaries who have been diagnosed with gender dysphoria. In August 2022, Defendants adopted a rule, Florida Administrative Code 59G-1.050(7) (the “Challenged Exclusion”), prohibiting Medicaid coverage of services for the treatment of gender dysphoria. Defendants adopted the Challenged Exclusion after undergoing a process with a predetermined outcome that concluded that the provision of medical treatment for the treatment of gender dysphoria, including puberty blockers, hormone therapy, and surgery, “do not conform to GAPMS [(“generally accepted professional medical standards”)] and are experimental and investigational.” Defendants thus deny equal treatment to Plaintiffs based on sex because they are transgender.

In response, Defendants have put forward an expert, Dr. Stephen Levine, a psychiatrist, whose opinions other federal courts have significantly narrowed, excluded in part, and in one case, dismissed altogether. The same is true here. Dr. Levine’s opinions should be excluded because (1) many are unhelpful because they are not opposed to the relief Plaintiffs seek and (2) the remaining opinions are unreliable because they are not based on scientifically valid principles, reasoning, and methodology. The Court should therefore, with narrow exception, exclude Dr.

Levine's opinions.¹

II. LEGAL STANDARD

The admission of expert testimony is governed by Federal Rule of Evidence 702, as explained by *Daubert* [v. *Merrell Dow Pharm., Inc.*, 509 U.S. 579, 597 (1993)] and its progeny.” *Rink v. Cheminova, Inc.*, 400 F.3d 1286, 1291 (11th Cir. 2005). “District courts are [thus] charged with [a] gatekeeping function.” *Id.*; see also *United States v. Frazier*, 387 F.3d 1244, 1260 (11th Cir. 2004) (“The importance of *Daubert*’s gatekeeping requirement cannot be overstated.”). In conducting their gatekeeping function, courts must “engage in a rigorous three-part inquiry and determine whether:

(1) the expert is qualified to testify competently regarding the matters he intends to address; (2) the methodology by which the expert reaches his conclusions is sufficiently reliable as determined by the sort of inquiry mandated in *Daubert*; and (3) the testimony assists the trier of fact, through the application of scientific, technical, or specialized expertise, to understand the evidence or to determine a fact in issue.

Frazier, at 1260; see also *City of Tuscaloosa v. Harcross Chems., Inc.*, 158 F.3d 548, 562 (11th Cir. 1998), *cert. denied*, 528 U.S. 812 (1999). The Eleventh Circuit refers to these three considerations separately as “qualification,” “reliability,” and “helpfulness” and has emphasized that they are “distinct concepts that courts and

¹ Excerpts of the Expert Disclosure of Stephen B. Levine, M.D., signed February 16, 2023, is attached as Exhibit A to the concurrently filed Declaration of Carl S. Charles (“Charles Decl.”)

litigants must take care not to conflate.” *Quiet Tech. DC-8, Inc. v. Hurel-Dubois UK Ltd.*, 326 F.3d 1333, 1341 (11th Cir. 2003). “The party offering the expert has the burden of satisfying each of these three elements by a preponderance of the evidence.” *Rink*, 400 F.3d at 1292.

To be sure, “[i]mplementing Rule 702, *Daubert* requires district courts to ensure that any and all scientific testimony or evidence admitted is both relevant and reliable.” *Claire v. Fla. Dep’t of Mgmt. Servs.*, 2021 WL 5982330, at *1 (N.D. Fla. Oct. 20, 2021). “[T]he trial judge must determine [this] **at the outset**.” *Daubert*, 509 U.S. at 592 (emphasis added). The court’s gatekeeping role and the test for admissibility of expert testimony are applicable even at a bench trial or at the summary judgment stage. *See, e.g., Rink v. Cheminova*, 400 F.3d 1286 (11th Cir.) (granting motions to exclude in the context of summary judgment); *Kadel v. Folwell*, 2022 WL 3226731, at **5-17 (M.D.N.C. Aug. 10, 2022) (same); *Lo v. United States*, 2022 WL 1014902, at *12 (W.D. Wash. Apr. 5, 2022) (excluding unqualified expert evidence in the context of a bench trial); *cf. UGI Sunbury*, 949 F.3d at 833 (holding the district court abused its discretion in a bench trial when it “ignored rule [702]’s clear mandate” by “sidestepping Rule 702 altogether and declining to perform any assessment of [expert]’s testimony before trial”).

It is axiomatic that “[a] witness may be qualified as an expert by virtue of his ‘knowledge, skill, experience, training, or education.’” *Quiet Technology DC-8, Inc.*,

326 F.3d at 1342. However, credentials are not dispositive when determining qualification. In conducting the *Daubert* inquiry, each of the three analytical prongs is assessed in reference to the matter to which the expert seeks to testify—i.e., “to the task at hand.” *Daubert*, 509 U.S. at 597. It is for that reason that “expertise in one field does not qualify a witness to testify about others.” *Lebron v. Sec’y of Fla. Dep’t of Children & Families*, 772 F.3d 1352, 1368 (11th Cir. 2014) (holding that a psychiatrist was properly prevented from opining on rates of drug use in an economically vulnerable population because he had never conducted research on the subject, and instead relied on studies to form his opinion). If a proposed expert witness does not “propose to testify about matters growing naturally and directly out of research he had conducted independent of the litigation,” such an expert should be disqualified. *Lebron*, 772 F.3d at 1369 (quoting Fed. R. Evid. 702 (cleaned up)).

An expert’s testimony should only be admitted if it is sufficiently reliable. “To meet the reliability requirement, an expert's opinion must be based on scientifically valid principles, reasoning, and methodology that are properly applied to the facts at issue.” *In re 3M Combat Arms Earplug Products Liab. Litig.*, 3:19MD2885, 2022 WL 1262203, at *1 (N.D. Fla. Apr. 28, 2022). The requirement of reliability found in Rule 702 is “the centerpiece of any determination of admissibility.” *Rider v. Sandoz Pharm. Corp.*, 295 F.3d 1194, 1197 (11th Cir. 2002). In making this determination the court can consider a variety of factors, including whether the

purported expert's theory has been tested, whether it has been subjected to peer review and publication, and whether the theory has been generally accepted in the scientific community. *See Daubert*, 509 U.S. at 593-94; *Rink*, 400 F.3d at 1291-92.² To be reliable the expert's testimony must always be based on "good grounds." *Daubert*, 509 U.S. at 590. Moreover, *Daubert* requires that reliable expert testimony be more than scientifically unsupported "leaps of faith." *Rider v. Sandoz Pharm. Corp.*, 295 F.3d 1194, 1202 (11th Cir. 2002).

To satisfy the helpfulness requirement, the testimony must have a justified scientific relationship to the facts at issue. *Daubert*, 509 U.S. at 591. Thus, helpfulness, "goes primarily to relevance." *Id.* at 580. Relevant expert testimony "logically advances a material aspect of the proposing party's case" and "fits" the disputed facts. *McDowell v. Brown*, 392 F.3d 1283, 1298-99 (11th Cir. 2004). "The relationship must be an appropriate 'fit' with respect to the offered opinion and the facts of the case." *Id.* Expert testimony does not "fit" when there is "too great an analytical gap" between the facts and the opinion offered. *Gen. Elec. Co. v. Joiner*, 522 U.S. 136, 147 (1997) (offering animal studies showing one type of cancer in mice to establish causation of another type of cancer in humans is "simply too great

² Other factors that may be relevant include (1) the nature of the field of claimed expertise, (2) the source of the expert's knowledge, (3) the expert's level of care in using the knowledge, and (4) the expert's consideration of alternative hypotheses. *Hendrix*, 255 F.R.D. at 578-79.

an analytical gap between the data and the opinion offered”); *Boca Raton Cmty. Hosp., Inc. v. Tenet Health Care Corp.*, 582 F.3d 1227, 1232 (11th Cir.2009) (“if an expert opinion does not have a ‘valid scientific connection to the pertinent inquiry’ it should be excluded because there is no ‘fit.’”).

Finally, because of the potentially misleading effect of expert evidence, *see Daubert*, 509 U.S. at 595, expert opinions that otherwise meet admissibility requirements may still be excluded under Fed. R. Evid. 403. Exclusion under Rule 403 is appropriate if the testimony is cumulative or needlessly time consuming. *See, e.g., Hull v. Merck & Co., Inc.*, 758 F.2d 1474, 1477 (11th Cir.1985) (admission of speculative and “potentially confusing testimony is at odds with the purposes of expert testimony as envisioned in Fed. R. Evid. 702”); *Tran v. Toyota Motor Corp.*, 420 F.3d 1310, 1316 (11th Cir. 2005) (affirming exclusion of expert testimony as cumulative). Consequently, because “[e]xpert evidence can be both powerful and quite misleading because of the difficulty in evaluating it...[T]he judge in weighing possible prejudice against probative force under Rule 403...exercises *more* control over experts than over lay witnesses.” *Daubert*, 509 U.S. at 595 (cleaned up) (emphasis added).

III. ARGUMENT

As noted above, other federal courts have narrowed, excluded, and in one case, entirely dismissed Dr. Levine’s opinions about transgender people and the

treatment of gender dysphoria.³ This began several years ago with district court’s holding in *Norsworthy v. Beard*, that “the Court gives very little weight to the opinions of Levine, whose report misrepresents the Standards of Care; overwhelmingly relies on generalizations about gender dysphoric prisoners, rather than an individualized assessment of Norsworthy; contains illogical inferences; and admittedly includes references to a fabricated anecdote.” 87 F. Supp. 3d 1164, 1188 (N.D. Cal. 2015). This holding was echoed in *Edmo v. Idaho Dep’t of Corr.*, 358 F. Supp. 3d 1103, 1125-1126 (D. Idaho 2018) (holding that Dr. Levine “is considered an outlier in the field of gender dysphoria” and gave “virtually no weight” to his opinions), *vacated in part on other grounds sub nom. in Edmo v. Corizon, Inc.*, 935 F.3d 757 (9th Cir. 2019). Dr. Levine’s opinions were likewise excluded in *Hecox v. Little*, where the Court dismissed his opinion that “gender-affirming policies ... are ... harmful to transgender individuals,” and instead “accept[ed] Plaintiffs’ evidence regarding the harm forcing transgender individuals to deny their gender identity can cause.” 479 F. Supp. 3d 930, 977 n.33 (D. Idaho 2020).

Of most relevance to this case, several of Dr. Levine’s proposed opinions were

³ Because of the numerical limitation on the parties depositions, Plaintiffs opted not to depose Dr. Levine and instead rely on his prior deposition and trial testimony in cases similar to this one, where his expert reports and proffered opinions have been nearly identical to his report submitted here. *See Brandt et al., v. Rutledge et al.* No. 4:21-cv-00450-JM (E.D. Ark., 2022); *Fain et al., v. Crouch et al.*, No. CV 3:20-0740, 2022 WL 3051015 (S.D.W. Va. Aug. 2, 2022); *Kadel et al., v. Folwell et al.*, No. 1:19CV272, 2022 WL 3226731 (M.D.N.C. Aug. 10, 2022).

excluded based on irrelevance and unreliable methodology by the U.S. District Court for the Middle District of North Carolina in *Kadel v. Folwell*, No. 1:19CV272, 2022 WL 3226731 (M.D.N.C. Aug. 10, 2022). Judge Loretta C. Biggs granted in part a motion to exclude Dr. Levine’s testimony, noting that he would be limited to offering opinions primarily to the following matters: (1) identifying risks associated with prescribing medication and surgery to adolescents, (2) and criticizing the quality of the research on treatments for gender dysphoria.⁴ At a minimum, Dr. Levine’s proposed opinions in this matter should be so limited as well, with his remaining testimony, opinions and content of reports otherwise excluded.

A. Many Of Dr. Levine’s Opinions Will Not Help the Trier of Fact Because They Support Plaintiffs’ Position.

Many of Dr. Levine’s opinions do not “logically advance a material aspect of *the proposing party’s case*” and do not “fit” the disputed facts because his proposed opinions do not oppose the relief Plaintiffs seek. *McDowell v. Brown*, 392 F.3d 1283, 1298-99 (11th Cir. 2004) (emphasis added). For that reason, Dr. Levine’s opinions “fit” with the facts relevant to resolving this matter in favor of Plaintiffs’ claims, not those of Defendants. *Id.* And even though several of Dr. Levine’s opinions, and the clinical experience upon which they are based, do not stand in opposition to the relief

⁴ The court in *Kadel* also found that Dr. Levine was permitted to testify as to his opinions of WPATH but for the reasons stated herein, *infra*, this Court should not so permit.

Plaintiffs seek, many do, and admitting this unreliable and unhelpful testimony wholesale would not meet the standard set forth by *Daubert* and its progeny.

Significantly, several of Dr. Levine’s proposed opinions regarding gender-affirming medical care, and his clinical experience upon which those opinions are based, are not contrary to the relief Plaintiffs seek in this case: that Florida Medicaid beneficiaries diagnosed with gender dysphoria receive appropriate medical care. Charles Decl., Ex. A at ¶6. On November 28, 2022, Dr. Levine testified at length about his proposed opinions regarding gender-affirming care at the bench trial in *Brandt v. Rutledge*, No. 4:21-cv-00450-JM (E.D. Ark., 2022).⁵ There, as here, Dr. Levine was Defendants’ only expert witness to have ever treated patients for gender dysphoria, and he testified that removing gender affirming medical care from patients currently receiving it would have “shocking and devastating” psychological consequences. Charles Decl. Ex. B at 912:3-19. Dr. Levine testified there, as he does in his report in this matter, that “there is no evidence beyond anecdotal reports that psychotherapy can enable a return to male identification for genetically male boys, adolescents, and men, or return to female identification for genetically female girls, adolescents, and women.” Charles Decl., Ex. A at ¶49; Charles Decl., Ex. B at 920:18-24. And to be sure, “broad opinions [that] are based solely on ... anecdotal accounts, and speculation ... are not reliable.” *In re 3M Combat Arms Earplug Prod.*

⁵ The Plaintiffs in *Brandt* did move to exclude or limit Dr. Levine’s testimony.

Liab. Litig., 2021 WL 684183, at *3. Dr. Levine also testified that reliance on self-report from the patients and information from parents is not unique to the diagnosis of gender dysphoria and is “ideally” how psychiatry works. Charles Decl. Ex. B at 894:24-895:6. He also testified that the use of medications to treat gender dysphoria is off-label—meaning not FDA approved for this specific indication—does not mean the drugs are experimental. Charles Decl. Ex B. at 930:14-17. And while Dr. Levine agreed that the “overwhelming majority” of his patients have been adults, he testified that he has written letters of authorization for hormone therapy for some patients under 18 and, going forward, would consider doing so on a case-by-case basis. Charles Decl. Ex. B at 886:13-18, 897:1-898:18, 900:21-902:15, 902:25-903:6.

Similarly, in *Fain v. Crouch*, No. CV 3:20-0740, 2022 WL 3051015 (S.D.W. Va. Aug. 2, 2022), where plaintiffs challenged a Medicaid coverage restriction of gender-affirming care in West Virginia, similar to the one at issue in this case, Dr. Levine testified at deposition that in the previous seven months he had provided several letters of approval for gender-affirming surgeries for transgender people incarcerated at Framingham, a correctional institution in Massachusetts. Charles Decl. Ex. C at 84:4-85:4. Dr. Levine has also previously testified that he has written similar letters for gender-affirming hormones and surgery in accordance with the medical community’s widely accepted and authoritative guidance for transgender care, World Professional Association of Transgender Health (“WPATH”) Standards

of Care (“SOC”). Charles Decl., Ex. C. at 139:14-19; Ex. D at 55:13-17; 56:2-5; 112:16-21; 176:8-16; Ex. E at 1-90:15-22. He also testified that he does not provide such letters unless he has sufficiently informed his patients of possible risks and received a reasonable assurance that they understand. Charles Decl., Ex. D at 176:8-16; 225:24-226:17. For almost 50 years, Dr. Levine’s clinical practice has generally adhered to the WPATH SOC. Charles Decl. Ex. C at 136:8-11. And, as WPATH’s former Chairman of the SOC Committee, Dr. Levine helped to write Version 5 of the SOC, recognized his own writing in Version 7, and asked if he could help draft the recently published Version 8. Charles Decl., Ex. A at ¶5; Ex. C at 147:12-149:18. He testified at deposition in *Fain*, and under oath previously, that he “is not advocating denying endocrine treatment or surgical treatment” to transgender people, a position he described as “draconian.”⁶

Finally, Dr. Levine testified at deposition in *Fain* and that he was not offering

⁶ Charles Decl., Ex. C at 88:10-13; Ex. D at 73:4-7 (“Q: Is the worrisomeness about a patient’s future health, is that a reason to ban all medical care for gender dysphoria? A: Absolutely not.”); 84:21-85:1 (“Q: Given all those concerns you have, is that a reason to deny all medical interventions to people with gender dysphoria? A: No”); 85:4-11 (“Q: Are those concerns you raised justifications in your mind for denying medical interventions to people who have gender dysphoria? A: You know, I’m not advocating denying endocrine treatment or surgical treatment.”); 152:1-6 (“Q: Do you think because that study showed that some people committed suicide after gender affirming surgery that no patient should be able to access gender affirming surgery? A: That would be illogical”); 154:3-5 (“Q: But you’re not recommending total bans on gender affirming surgery? A: I’m not recommending total bans.”); 160:23-25 (“I did not say that gender affirming treatment in general should be stopped. I’ve never said that.”).

any opinions about whether Defendants should have an exclusion in their Medicaid program for coverage of gender-affirming medical care. Charles Decl. Ex. C at 86:25-87:19. He also testified that he does not feel his “expertise extends to how the insurance industry works and how governments and legislatures work,” nor “does he consider himself an expert” on whether the West Virginia Medicaid exclusion should exist. Charles Decl., Ex. C at 87:14-22. Nevertheless, Dr. Levine has testified that he is “an agent of the patient, I want what’s best for the patient, and especially if the patient couldn’t otherwise afford it, I would wish for my patient to have it, yes.” Charles Decl., Ex. F at 157:7.

At bottom, Dr. Levine has repeatedly and consistently testified in federal court that he does not support banning the provision or coverage of gender-affirming medical care, that for 50 years he has and continues to provide letters of authorization for gender affirming medical treatments for adult and minor patients, and that he is not an expert about insurance coverage of gender-affirming medical care. *See e.g.* Charles Decl., Ex. D at 86:1-8. Many of his opinions do not “logically advance a material aspect *of the proposing party’s case*,” do not “fit” the disputed facts, and will ultimately not assist the trier of fact because his proposed opinions do not oppose the relief Plaintiffs seek. *McDowell*, 392 F.3d at 1298-99 (emphasis added).

B. Dr. Levine’s Opinions That Do Not Support Plaintiffs’ Position Are Methodologically Unreliable and Scientifically Unsupported.

An expert’s opinion should only be admitted if it is based on scientifically

valid methodology that is properly applied to the facts. *In re 3M*, 2022 WL 1262203, at *1. Dr. Levine’s opinions fall far short of the reliability standard, a reality he has admitted to as recently as November 2022. Dr. Levine admits in his report submitted here, at trial in *Brandt*, and at deposition in *Fain* and other recent cases, that theories upon which he relies lack *any* scientific support and have not been tested or subjected to peer review or publication. Charles Decl., Ex. A at ¶49; Ex. B 797:8-19, 887:19-888:25, 921:21-922:7, 924:12-25, 949:24-954:22; Ex. C at 140:12-143:2, 145:19-25; Ex. D at 109:20-25; 116:4-7, 122:8-124:22, 200:11-201:25.

Even putting that aside, although Dr. Levine claims many times that his “experience” is sufficient foundation for his opinions, he fails to address how this purported experience leads to his conclusions and how such experience is reliably applied to the facts here. Afterall, “At this stage, the court must undertake an independent analysis of each step in the logic leading to the expert's conclusions; if the analysis is deemed unreliable at any step the expert's entire opinion must be excluded.” *Hendrix v. Evenflo Co., Inc.*, 255 F.R.D. 568, 578 (N.D. Fla. 2009), *aff’d sub nom. Hendrix ex rel. G.P. v. Evenflo Co., Inc.*, 609 F.3d 1183 (11th Cir. 2010).

1. Dr. Levine’s Assertion that the WPATH SOC Version 8 Is Not the Widely Accepted and Authoritative Protocol for the Treatment of Gender Dysphoria Is Misleading and Unreliable Because It Is Demonstrably False.

Chief among Dr. Levine’s many unreliable opinions is his assertion that the

widely-accepted and utilized WPATH SOC are not widely-accepted and considered to be authoritative treatment protocols for gender dysphoria. Contradicting himself, Dr. Levine has repeatedly testified that he generally adheres to the WPATH SOC in his own clinical practice. Charles Decl., Ex. C at 136:8-11; Ex. D at 55:13-17; 56:2-5; 112:16-21; 176:8-16; 225:24-226:17; Ex. F at 29:10-18; 37:2-13; 47:22-49:3; 103:11-19. Nevertheless, Dr. Levine’s attempt to undermine the WPATH SOC fail because he lacks evidence to support his assertions, contradicts his assertions with other binding testimony, misrepresents sources in his report, and fails to include relevant information that is contrary to his assertion—ultimately undermining the reliability and overall admissibility of his opinions.

First, Dr. Levine alleges that “reviews” of the 7th Version of the SOC (“SOC 7”) “published in 2021 by Dahlen et al [sic] and Sapir in 2022 have clarified the low reliability and bias inherent in its recommendations. (Dahlen et al 2022).” The Dahlen et al. 2021 article does not characterize the SOC 7 as having “low reliability” or “inherent bias.” Charles Decl., Ex. A at ¶69; Ex. G. The article does state that the SOC 7 are due for an update and acknowledges that evaluations of clinical practice guidelines in other medical areas including cancer, diabetes, pregnancy, and depression “tend to show room for improvement,” and that “finding poor quality CPGs is not confined to this area of healthcare.” Charles Decl., Ex. G at 8. Again, without evidence, Dr. Levine claims the 8th Version of the SOC (“SOC 8”) has “not

gained additional confidence in its scientific merit.” Charles Decl., Ex. A ¶¶69. He also claims that the presence of transgender participants at WPATH meetings “makes it difficult for professionals to raise their concerns.” Charles Decl., Ex. A ¶¶69. But Dr. Levine admits he has not been a member of WPATH for more than 20 years and does not provide evidence to support these claims. *Id.* at ¶¶66.⁷ The reality is that no one, not transgender people or other health professionals (whether transgender or cisgender), are preventing Dr. Levine from “raising his concerns.” As Dr. Levine testified, he presented alongside other panelists with dissenting views, without interruption, at an American Psychiatric Association conference in 2022. Charles Decl., Ex. B at 925:16-926:23, 927:10-17.

Second, Dr. Levine makes inaccurate statements about other countries’ treatment protocols for gender dysphoria in youth to support his claim that “opinions

⁷ Dr. Levine claims in his report that “Two groups of individuals that I regularly work with have attended recent and separate WPATH continuing education sessions. There, questions about alternative approaches were quickly dismissed with ‘There are none. This is how it is done.’” Charles Decl. Ex. A at ¶¶68. But Dr. Levine fails to name these groups he works with, the people who attended the WPATH sessions, the dates, times and other identifying information about the alleged sessions, or the people who supposedly “quickly dismissed” questions. This assertion is mere conjecture, and methodologically unreliable. Not only is such “reliance on anecdotal evidence” a “red flag[] that caution[s] against certifying an expert,” *Newell Rubbermaid, Inc. v. Raymond Corp.*, 676 F.3d 521, 527 (6th Cir. 2012), but the Court should not countenance Dr. Levine testifying “based on limited personal accounts and information relayed to [him] by an unspecified number of third parties,” as doing so “would be to sanction [his] use as a vehicle for introducing hearsay testimony.” *In re 3M Combat Arms Earplug Prod. Liab. Litig.*, 2021 WL 684183, at *2.

and practices vary widely with respect to puberty blockers and hormones” and as evidence that the WPATH SOC 8 are not authoritative. Charles Decl., Ex. A at ¶82. However, Dr. Levine admitted in his *Brandt* trial testimony that in Finland, gender affirming medical care is provided to adolescents with gender dysphoria when indicated under their guidelines. Charles Decl., Ex. B at 938:16-939:3. He also testified that France does not have a prohibition on minors receiving gender affirming medical care, nor does Canada. Charles Decl., Ex. B at 939:23-940:9, 944:2-5. And Dr. Levine conceded he does not know how the provision of gender affirming care for minors works in Sweden but agreed that the Swedish National Board of Health stated puberty blockers and cross sex hormones may be given in exceptional cases in accordance with their guidelines criteria. Charles Decl., Ex. B at 960:1-17, 961:11-962:1. Dr. Levine has admitted these facts when asked at deposition in *Fain*. Ex. C at 106:4-108:8. Dr. Levine also acknowledged that the United Kingdom’s Cass Review, which is still underway and not final, begins from the premise that some youth experience gender dysphoria and will need clinical support and medical interventions and that such care is not prohibited in their health system. Charles Decl., Ex H; Ex. C at 191:20-192:16.

Dr. Levine’s own testimony at trial and at deposition contradict the opinions offered by his expert report here, which underscores serious flaws in his methodology and demonstrates that his opinions about the WPATH SOC do not

meet the reliability burden under *Daubert* or related standards for admissibility of expert testimony.

2. Dr. Levine’s Opinions That Gender-Affirming Medical Care Is Experimental, Is Provided Without Mental Health Assessments or Sufficiently Informed Consent and Is Without Lasting Benefit are Inaccurate and Unsupported.

Dr. Levine opines that gender-affirming medical care is experimental, is provided without mental health assessments or sufficiently informed consent and is without lasting benefit. Charles Decl., Ex. A at VIII, X, ¶73, ¶176. But Dr. Levine has, and continues to, write letters authorizing gender affirming medical care for his patients, including for hormone therapy for some patients under 18 and, going forward, would consider doing so on a case-by-case basis. Charles Decl., Ex. B at 897:1-898:18, 900:21-902:15, 902:25-903:6. The *Kadel* court cites to an opinion that Dr. Levine has identically asserted here: that it is impossible “to make a single, categorical statement about the proper treatment of children presenting with gender dysphoria or other gender-related issues.” Charles Decl., Ex. A at ¶61. As a result, the *Kadel* court observed, “Notably, Levine does not testify that medical or surgical care for gender dysphoria is categorically inappropriate.” *Kadel*, 2022 WL 322673, at *15. And when asked if based on his publication from March 2022 “Reconsidering Informed Consent for Trans-Identified Children, Adolescents, and Young Adults,” he claimed that “gender affirming medical care, specifically hormone therapy or

blockers or surgeries, should be categorically prohibited for minors,” he replied “No, I don’t.” Charles Decl., Ex. B at 905:11-16. Dr. Levine is “not motivated to prohibit care.” *Id.* at 906:11-14.

Dr. Levine asserts repeatedly that gender-affirming medical care is provided by doctors who encourage patients to identify as transgender and provide hormones without assessing patients and addressing other mental health conditions or without informing patients and their parents of the risks and limitations of the evidence regarding treatments. Charles Decl. Ex. A at ¶¶50, 64, 74, 83. As an initial matter, Dr. Levine admits in his report that he cannot confirm if any practitioners engage in this “affirmation care/therapy model” he describes. Charles Decl. Ex. A at ¶53. And he confirmed his lack of support for this assertion during his testimony in *Brandt*, when on cross-examination, he admitted that he does not know how common it is for doctors to provide care the way he described, which is contrary to WPATH SOC 8 and Endocrine Society clinical guideline, both of which require comprehensive psychological assessments prior to initiation of any medical treatment for adolescents. Charles Decl., Ex. B at 887:19-888:21, 890:24, 933:2-7; Charles Decl. Ex. I at 3870, 3876-3878; Charles Decl., Ex. J at S48-51.

Finally, the *Kadel* court also recognized that Dr. Levine’s assertions that healthcare providers are prescribing treatment without due caution or informed consent were not admissible:

Fourth, as discussed, it does not appear that he offers any categorical opinion as to the medical necessity of medical and surgical treatments of gender dysphoria, nor does he testify that healthcare providers are prescribing such treatment without due caution and informed consent beyond his anecdotal “experience.” To the extent that Defendants seek to introduce testimony from Levine to that effect, he has not provided the Court with any data or methodology from which such claims could be made. Levine has conducted no research to identify which physicians are proceeding as he does, and which do not, rendering any broader opinion about the practice of such healthcare providers pure speculation.

Kadel, 2022 WL 322673, at *17. This is no less true here.

Dr. Levine’s opinions that gender-affirming medical care is without lasting benefit also fail the reliability test because he ignores studies contrary to his personal belief or distorts studies’ findings beyond the authors’ explicit intentions, conclusion, or study design. Significantly, he omits recent studies demonstrating that medical treatments for transgender adolescents and adults have favorable outcomes across many measures. Charles Decl., Ex. K at ¶55. A plethora of studies show that transgender people experience pervasive stigma and discrimination, resulting in health disparities. But Dr. Levine omits any reference to that evidence and instead suggests that “long-term life in a transgender identity, however, correlates with very high rates of completed suicide,” and goes on to discuss four studies that reviewed the rate of suicide among transgender adults who received gender-affirming medical care. Charles Decl., Ex. A at ¶¶166-171. While Dr. Levine admits, as he must, that “None of the studies demonstrated the hormonal or surgical intervention *caused* [sic]

suicide,” he goes on in the same paragraph to assert a different unsupported conclusion, that “what these studies demonstrate” is that transgender people “are in need of extensive psychological care they don’t receive,” and that “neither hormonal nor surgical transition and ‘affirmation’ resolve their underlying problems and put them on the path to a stable and healthy life.” *Id.* at ¶172. This is unreliable methodology at its finest. First, none of the four studies purport to analyze the efficacy of “hormonal or surgical transition,” or whether gender-affirming medical care “resolves underlying problems” or “puts [people] on a path to a stable and healthy life.” As least one of the studies’ authors, Cecilia Dhejne, has explicitly said as much, both in the study itself (it is not designed to “address whether sex reassignment is an effective treatment or not.”) and in direct response to Dr. Levine’s misuse of her work. Charles Decl., Ex. L at 2; Charles Decl., Ex. M at 65. Another major flaw in Dr. Levine’s methodology is that three of the studies’ control groups were comprised of the general Dutch population, not of other transgender people with gender dysphoria who did not receiving any gender-affirming medical care. In other words, it is comparing apples to oranges. But Dr. Levine has acknowledged that the Dhejne study does not lend the study to be used to draw any conclusions about the efficacy of gender-affirming care. Charles Decl., Ex. D at 156:7-11. Finally, Dr. Levine’s description of the Hall et al. 2021 study obscures the study’s actual rate of suicide for the cohort by, without explanation but presumably to

support his description of a “rather shocking result,” focusing on the number of transgender women in the group who died by suicide, rather than the total number of deaths by suicide for the entire cohort—which was 3 out of 175 participants, or 1.7%. Charles Decl., Ex. A at ¶171.

Furthermore, as the *Kadel* court observed, Dr. Levine himself has conceded that:

he does not know how often medical or surgical care helps alleviate symptoms of gender dysphoria and does not offer an opinion as to the portion of these procedures that are necessary and unnecessary. (*Id.* at 67:24–68:3 (“It is not our [clinic's] knowledge base to know who's going to do better and who's going to do worse and who is not going to have any difference at all with hormones or with surgery.”).)

Kadel, 2022 WL 322673, at *15.

Ultimately, Dr. Levine fails to cite any literature or clinical experience of his own to support this opinion, and regardless, he has testified that studies like these should not prevent youth and adults with gender dysphoria from receiving gender affirming care. When asked recently if he believes that because a study showed that some people committed suicide *no patient* should be able to access gender-affirming surgery, Dr. Levine responded, “that would be illogical.” Charles Decl., Ex. D at 151:25-152:6. And when asked if his concerns justify denying medical interventions to all people with gender dysphoria, he responded “I’m not advocating denying endocrine treatment or surgical treatment.” *Id.* at 85:4-11.

At bottom, Dr. Levine’s report and the opinions contained therein are wildly

inconsistent with his oral testimony, making both unreliable.

3. Dr. Levine’s Opinions About Gender Dysphoria “Naturally Resolving” in Children and Adolescents Are Not Based In Fact.

Another unreliable opinion presented by Dr. Levine is that “the large majority” of *prepubertal* children diagnosed with gender dysphoria will, absent intervention, cease to be transgender (or “desist”) through puberty. Charles Decl., Ex. A at ¶¶109-111, 113-114. Putting aside that Dr. Levine has almost no clinical experience with children during his 50-year career treating patients with gender dysphoria to support this opinion, it is unreliable and methodologically unsound for other reasons.

First, Dr. Levine has conceded that some children are and will continue to be transgender and that as they progress into adolescence and adulthood, they would need medical care that he has, and would, authorize. Charles Decl., Ex. D. at 173:7-15, 137:14-23, 173:22-174:5, 53:2-10. Second, as the scholarly basis for this opinion, Dr. Levine cites three articles that share the same core characteristic that reveals the methodological flaw in Dr. Levine’s analysis: they rely on previous studies whose underlying data included gender non-conforming children who never identified as a sex different from their birth-assigned sex in the first place. In other words, they included children who were never transgender. That is because the diagnosis at the time these studies were conducted— “Gender Identity Disorder in

Children” —did not include a cross-gender identification or clinically significant distress requirement for the diagnosis. *See, e.g.*, Diagnostic Statistical Manuals (“DSM”) III, III-R, IV, and IV-R. Under these outdated diagnostic criteria, most of the children diagnosed with “Gender Identity Disorder in Children” were not actually transgender but were gender non-conforming boys who grew up to be gay or bisexual. Because the years of initial visits in the study samples were from 1952-2008, none of these children were diagnosed under the current, and relevant to the case at hand, diagnostic criteria for “Gender Dysphoria in Children,” in the DSM 5, published in 2013, which requires for diagnosis “a strong desire to be of the other gender or an insistence that one is the other sex” and “clinically significant distress or impairment in social, school, or other important areas of functioning.”⁸ Charles Decl., Ex. N at 452. Dr. Levine confirmed this fact as to these and others of the “11 studies,” at his deposition in *Fain*. Charles Decl., Ex. C at 221:2-229:14. Therefore, the “desistance rates” from the studies upon which Dr. Levine bases his opinion reflect children who, while they exhibited gender non-conforming behaviors, were

⁸ Based on Dr. Levine’s failure to identify at deposition in *Kadel* any of the underlying “11 studies” upon which this opinion is based, the court found his methodology to be unreliable and therefore inadmissible: “Levine’s testimony regarding desistance rates does not appear to be based on reliable methodology. During deposition, Levine was unable to recall many of the studies that purportedly support his conclusion. (ECF No. 213-3 at 191:20-192:14.)” *Kadel*, 2022 WL 322673, at *16.

not transgender, or suffering from gender dysphoria.

4. Dr. Levine’s Assertion that “Rapid Onset Gender Dysphoria,” as a Cause of Gender Dysphoria or the Concept of “Detransition” Justifies Denying Treatment to Florida Medicaid Beneficiaries Is Unsupported By Scientific Evidence.

A stark example of one of Dr. Levine’s opinions failing to meet methodological reliability is the assertion that “rapid onset gender dysphoria” is a credible phenomenon caused by “social influences through friend groups or through the internet.” Charles Decl., Ex. A at II(1)(f), ¶38, ¶96, ¶114. Dr. Levine admitted at the *Brandt* trial, just six months ago, that such a conclusion is based on speculation, not science. Ex. B at 797:8-19. Furthermore, “rapid onset gender dysphoria” (“ROGD”) is a scientifically unsupported hypothesis and the only article Dr. Levine routinely cites or discusses regarding ROGD was withdrawn and republished with a significant correction. Dr. Levine testified at deposition in *Kadel* he had not read the correction. Charles Decl., Ex. D at 116:22-117:9. Had he done so, Dr. Levine would be forced to acknowledge the correction’s explicit disclaimers that “rapid onset gender dysphoria is not a formal mental health diagnosis,” “the report did not collect data from adolescents and young adults or clinicians and therefore does not validate the phenomenon,” and “the use of the term, ‘rapid onset gender dysphoria’ should be used cautiously by clinicians and parents to describe youth.” Charles Decl., Ex. O at 1. Despite this, at deposition in *Fain*, Dr. Levine attempted to conflate an

increased number of transgender young people presenting to clinics for care with the theory of “rapid onset gender dysphoria” and asserted, without evidence, it is not a hypothesis but “a fact,” that he “assumes everyone understands [this] is true.” Charles Decl. Ex. C at 151:18-152:6, 152:22-153:5. When pressed to provide peer-reviewed articles, sources, or studies as scientific support he referenced presentations without title or date, admitted he could not remember the names of “authors from Europe” but asserted it had been documented by “DiAngelo and Clayton in Australia.” To date, the only peer-reviewed study that interrogates this hypothesis using adolescent clinical data “did not support the ROGD hypothesis.” Charles Decl., Ex. P at 1.

Similarly, Dr. Levine’s opinions that there is “a growing number of detransitioners [sic],” or that the number of detransitioners is “accelerating,” are also methodologically unreliable, largely because he lacks any evidence to support this belief. Charles Decl., Ex. A at ¶120. The three papers he cites for support of this assertion, “Entwistle 2020, Littman 2021, and Vandenbussche 2021,” are purely descriptive, not statistical, or quantitative studies. These, respectively, include a description of anecdotal experiences of “detransitioners,” describe the results of “a survey of 100 detransitioners,” and report on responses from an online survey about the needs and support for people who detransition. None of the three articles purports to establish that the rate of detransition is growing or accelerating, a fact

Dr. Levine admitted as to two of the studies at deposition in *Fain*. Charles Decl., Ex. C at 155:8-163:24. Indeed, Dr. Levine’s own clinical experience is contrary to this assertion—in 50 years of seeing patients with gender dysphoria, he is aware of only two patients who detransitioned. Charles Decl., Ex. B at 920:25-921:5. Nevertheless, Dr. Levine doubles down in his expert rebuttal report, relying on a reference to a “detransition subreddit” with 16,000 members as evidence that “the assumption that [detransition] was a rare occurrence began to lose traction.” Ex. Q at ¶30. When confronted about this so-called evidence at deposition in *Kadel*, Dr. Levine admitted he had no evidence that *even one* of the 16,000 members of the subreddit had actually “detransitioned.” Charles Decl., Ex. D at 200:6-201:25. Unsurprisingly, the *Kadel* court found such testimony lacking:

His anecdotal testimony concerning adults and adolescents who regret their transitions appears to be based on a misreading of an article that reviewed entries on the website Reddit. (See ECF No. 215-1 ¶¶ 35, 56, 98.) He admitted during deposition that the article referred to 16,000 entries—not 60,000, as he repeatedly stated in his report—and that he had no knowledge of the content of those entries or whether any of the authors actually de-transitioned or regret their transitions. (Id. at 196:3-7, 201:12-25).

Kadel, 2022 WL 3226731, at *16.

Similarly, when asked in *Fain* about his opinion that there is “evidence that a growing number of young people regret transition and wish to reverse it,” Dr. Levine admitted he lacked any scientific support for such an opinion. Charles Decl., Ex. C at 158:8-159:2; 160:25-161:9; 163:9-24. Dr. Levine did not point to his own

experience as a basis for this opinion and conceded three times that the sources he cited in his report did not provide relevant evidence. *Id.*

Given that these hypotheses about “rapid onset gender dysphoria” and ideas about “detransition” are unverified or unsupported, Dr. Levine cannot claim the use of reliable methodology. His reliance on his own *ipse dixit* fails to establish a basis upon which to assert these opinions. Indeed, case law establishes that “broad opinions [that] are based solely on ... generalized views, anecdotal accounts, and speculation ... are not reliable.” *In re 3M Combat Arms Earplug Prod. Liab. Litig.*, 2021 WL 684183, at *3 (N.D. Fla. Feb. 11, 2021). And that opinions “based on mere conjecture, assumption, credibility calls, and amounting to no more than ipse dixit” are “neither reliable nor helpful.” *Day v. Edenfield*, 2022 WL 972430, at *10 (N.D. Fla. Mar. 31, 2022).

C. Dr. Levine Is Not Qualified To Offer Opinions About Puberty-Delaying Treatment or the Treatment of Prepubertal Children Generally.

Dr. Levine has repeatedly admitted, most recently at the *Brandt* trial six months ago, and at depositions for the last several years, that he has virtually no experience administering psychiatric treatment to prepubertal children and no experience performing research or publishing studies about them. Charles Decl., Ex. A at ¶5; Ex. B at 887:5-8; Ex. C at 26:10-13; Ex. D at 23:1-8. When asked whether he has treated any children with gender dysphoria, he admitted, “I have only on rare

occasion personally treated or directly or indirectly treated a child.” Charles Decl. Ex. C at 28:23-29:6; 62:6-14. Dr. Levine also confirmed his testimony from March 30, 2022, that over the course of his nearly 50-year career, he had only seen an estimated six prepubertal children, and not for more than one visit. Charles Decl., Ex. B at 887:5-8; Ex. R at 87:1-7. When asked if he had helped to develop guidelines for the treatment of prepubertal children or adolescents with gender identity issues he responded “the answer is no.” Charles Decl., Ex. C at 51:10-16. Dr. Levine is not recognized as an expert in providing treatment to prepubertal children by his private employer who by his own admission does not refer children to him as patients, nor by the University Hospitals’ LGBTQ and Gender Care Program--the Cleveland hospital affiliated with Case Western Reserve University Medical School where Dr. Levine is a clinical professor—which he previously admitted did not consult with him as part of its formation or their ongoing work. Charles Decl., Ex. R at 113:19-114:4. Nor does he write or research about providing treatment to prepubertal children or deliver any psychiatric care to them in his day-to-day practice.⁹

While lacking a reliable methodology for his proposed opinions about the

⁹ Notably, the *Kadel* court held that “Levine's opinions on mental health approaches to social transition are irrelevant as well, as Defendants maintain that the Plan's exclusion of coverage for mental health treatments of gender dysphoria has never been given effect and is no longer part of the Plan. (See ECF Nos. 137 n.2; 137-4 ¶ 27.)” *Kadel*, 2022 WL 3226731, at *16. Dr. Levine has also testified that he has counseled some parents to support their minor child’s social transition. Charles Decl., Ex. B at 896:23-25.

treatment of prepubertal children, Dr. Levine does not hesitate to offer his personal beliefs about their care. Dr. Levine would “consider banning puberty blocking hormones even for children who have been cross-gender identified for four years to give them a chance to desist.” Charles Decl., Ex. D at 186:20-25. But Dr. Levine acknowledges the unscientific nature of this opinion, admitting he does not know where it comes from or “to what extent it’s from my politics, or from my being a parent or a doctor, I don’t know.” Charles Decl., Ex. D at 187:20-24.

In short, given his proposed testimony and experience, Dr. Levine is not qualified under the *Daubert* standards to offer opinions on matters relating to the care of prepubertal children, and he cannot use his personal beliefs as reliable evidence. Nor is any of this testimony relevant. This case concerns coverage of gender-affirming medical care, and no clinical practice guideline recommends the provision of medical treatments, like puberty delaying medications or hormones, until after the onset of puberty.¹⁰

D. Dr. Levine’s Report, Opinions, and Testimony Lack Probative Value and Are Thus Inadmissible Under Federal Rule Of Evidence 403.

Finally, the Court should exclude Dr. Levine’s opinions because their

¹⁰ The *Kadel* court also found that Dr. Levine’s criticism of medical or surgical treatment of gender dysphoria in prepubescent children was not relevant because “Plaintiffs conceded that such treatments are not medically necessary until the onset of puberty. *See* Section II.B, *supra*.” *Kadel*, 2022 WL 322673, at *16.

introduction will result in unfair prejudice, confusion of the issues, or in misleading testimony. Fed. R. Evid. 403. Most of Dr. Levine's opinions are unreliable and unhelpful. The testimony would also result in prejudice, as the testimony seeks to sow confusion about the veracity of Plaintiffs' gender identity, gender dysphoria diagnosis, and treatment they have been undergoing for years—issues unrelated to whether the Florida Medicaid Program can deny coverage of the same kinds of treatments to transgender people that it provides cisgender people.

IV. CONCLUSION

For the foregoing reasons, Plaintiffs respectfully request the Court grant the instant motion and limit Dr. Levine's opinions and testimony, at a minimum, to his opinions (1) identifying risks associated with prescribing medication and surgery to adolescents, and (2) criticizing the quality of the research on treatments for gender dysphoria and that Dr. Levine's report, opinions, and his testimony be otherwise excluded in full.

Dated this 7th day of April 2023.

Respectfully Submitted,

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CERTIFICATE OF SERVICE

I hereby certify that on this 7th day of April 2023, a true copy of the foregoing has been filed with the Court utilizing its CM/ECF system, which will transmit a notice of electronic filing to counsel of record for all parties in this matter registered with the Court for this purpose.

/s/ Carl S. Charles
Carl S. Charles
Counsel for Plaintiffs

CERTIFICATE OF WORD COUNT

As required by Local Rule 7.1(F), I certify that this Memorandum contains 7,636 words.

/s/ Carl S. Charles
Carl S. Charles
Counsel for Plaintiffs

**IN THE UNITED STATES DISTRICT COURT
FOR THE NORTHERN DISTRICT OF FLORIDA
Tallahassee Division**

AUGUST DEKKER *et al.*,

Plaintiffs,

v.

JASON WEIDA, *et al.*,

Defendants.

Case No. 4:22-cv-00325-RH MAF

DECLARATION OF CARL S. CHARLES

Pursuant to 28 U.S.C. § 1746, I, Carl S. Charles, do hereby declare as follows:

1. I am over 18 years of age.
2. I am a Senior Attorney at Lambda Legal Defense and Education Fund, Inc. and serve as counsel of record for the plaintiffs in the above-captioned matter.
3. I have personal knowledge of the facts stated herein and if called upon, could and would testify competently to them.
4. I submit this declaration in support of Plaintiffs' Motion to Exclude Expert Testimony of Stephen B. Levine, M.D. ("Dr. Levine.").
5. Attached as **Exhibit A** is a true and correct copy of excerpts of the expert declaration of Dr. Levine in the above-captioned matter,

which is dated and was served on Plaintiffs on February 16, 2023.

6. Attached as **Exhibit B** is a true and correct copy of excerpts of the transcript of the bench trial in *Brandt v. Rutledge* No. 4:21-cv-00450-JM (E.D. Ark., 2022), where Dr. Levine testified on November 28, 2022.

7. Attached as **Exhibit D** is a true and correct copy of excerpts from the transcript of the deposition of Dr. Levine taken on September 10, 2021, in relation to *Kadel v. N. C. State Health Plan for Tchrs. and State Emps.*, 12 F.4th 422, 427 (4th Cir. 2021).

8. Attached as **Exhibit E** is a true and correct copy of excerpts from the transcript of the bench trial in *Soneeya v. Turco*, No. 07-12325-DPW (D. Mass 2019) where Dr. Levine testified on April 4, 2019.

9. Attached as **Exhibit F** is a true and correct copy of excerpts of the zoomed deposition of Dr. Levine taken December 21, 2020, in relation to *Claire v. Florida Dept. of Management Services*, 504 F. Supp. 3d 1328 (N.D. Fla. 2020).

10. Attached as **Exhibit G** is a true and correct copy of the article “International Clinical Practice Guidelines For Gender Minority/Trans People: Systematic Review And Quality Assessment,” published in April 2021.

11. Attached as **Exhibit H** is a true and correct copy of a printout from the Cass Review website “About The Review” page, which was last accessed on April 7, 2023.

12. Attached as **Exhibit I** is a true and correct copy of excerpts of the Endocrine Society Clinical Practice Guideline for Endocrine Treatment of Gender-Dysphoric/Gender-Incongruent Persons, published in November 2017.

13. Attached as **Exhibit J** is a true and correct copy of excerpts of the WPATH Standards of Care Version 8, published on September 15, 2022.

14. Attached as **Exhibit K** is a true and correct copy of excerpts of the expert report of Joanna Olson-Kennedy, M.D., signed and served on Defendants on February 16, 2023, in the above captioned matter.

15. Attached as **Exhibit L** is a true and correct copy of the article “Long-Term Follow-Up of Transsexual Persons Undergoing Sex Reassignment Surgery: Cohort Study in Sweden,” published in February 2011.

16. Attached as **Exhibit M** is a true and correct copy of an excerpt from the published Ph.D. Thesis, “On Gender Dysphoria,” written by Cecilia Dhejne, Ph.D., in 2017.

17. Attached as **Exhibit N** is a true and correct copy of an excerpt from the Diagnostic and Statistical Manual of Mental Disorders, Version 5 published in 2013.

18. Attached as **Exhibit O** is a true and correct copy of the article “Correction: Parent reports of adolescents and young adults perceived to show signs of a rapid onset of gender dysphoria,” published March 19, 2019.

19. Attached as **Exhibit P** is a true and correct copy of the article “Do Clinical Data From Transgender Adolescents Support the Phenomenon of ‘Rapid-Onset Gender Dysphoria’?,” published in The Journal of Pediatrics in April 2022.

20. Attached as **Exhibit Q** is a true and correct copy of an excerpt from the expert rebuttal report of Dr. Levine, which is dated and was served on Plaintiffs on March 10, 2023.

21. Attached as **Exhibit R** is a true and correct copy of an excerpt from the transcript of the deposition of Stephen Levine, M.D., taken on March 31, 2022, in relation to *B. P. J. v. W. Va. State Bd. of Educ.*, 550 F. Supp. 3d 347 (S.D.W. Va. 2021).

I declare under the penalty of perjury that the foregoing is true and correct.

Dated this 7th day of April 2023.

/s/Carl S. Charles
Carl S. Charles
Counsel for Plaintiffs

**IN THE UNITED STATES DISTRICT COURT
FOR THE NORTHERN DISTRICT OF FLORIDA
TALLAHASSEE DIVISION**

AUGUST DEKKER, et al.,

Plaintiffs,

v.

JASON WEIDA, et al.,

Defendants.

Case No. 4:22-cv-00325-RH-MAF

EXPERT REPORT OF STEPHEN B. LEVINE, M.D.

TABLE OF CONTENTS

I. CREDENTIALS	5
II. SUMMARY	8
III. BACKGROUND ON THE FIELD.....	12
A. The biological baseline of the binary sexes	12
B. Definition and diagnosis of gender dysphoria	17
C. Impact of gender dysphoria on minority and vulnerable groups	18
D. Three competing conceptual models of gender dysphoria and transgender identity	19
E. Four competing models of therapy	22
(1) The “watchful waiting” therapy model	23
(2) The psychotherapy model: Alleviate distress by identifying and addressing causes (model #3)	24
(3) The affirmation therapy model (model #4).....	27
IV. THERE IS NO CONSENSUS OR AGREED “STANDARD OF CARE” CONCERNING THERAPEUTIC APPROACHES TO CHILD OR ADOLESCENT GENDER DYSPHORIA.....	30
A. Experts and organizations disagree as to whether “distress” is a necessary element for diagnoses that justifies treatment for gender identity issues.....	31
B. Opinions and practices vary widely about the utilization of social transition for children and adolescents.	33
C. The WPATH “Standards of Care” is not an impartial or evidence-based document.....	34
D. Opinions and practices differ widely with respect to the proper role of psychological counseling before, as part of, or after a diagnosis of gender dysphoria.....	39
E. Opinions and practices vary widely with respect to the administration of puberty blockers and cross-sex hormones.....	40
V. TRANSGENDER IDENTITY IS NOT BIOLOGICALLY BASED.....	45
A. No theory of biological basis has been scientifically validated.....	46
B. Large changes across time and geography in the epidemiology of transgender identification are inconsistent with the hypothesis of a biological basis for transgender identity.	47

C. Disorders of sexual development (or DSDs) and gender identity are very different phenomena, and it is an error to conflate the two.....	51
D. Studies of individuals born with DSDs suggest that there may be a biological predisposition towards <i>typical</i> gender identifications, but provide no support for a biological basis for <i>transgender</i> identification.	53
VI. GENDER IDENTITY IS EMPIRICALLY NOT FIXED FOR MANY INDIVIDUALS.....	54
A. Most children who experience gender dysphoria ultimately “desist” and resolve to cisgender identification.....	54
B. Desistance is increasingly observed among teens and young adults who first manifest GD during or after adolescence.	56
VII. TRANSITION AND AFFIRMATION ARE IMPORTANT PSYCHOLOGICAL AND MEDICAL INTERVENTIONS THAT CHANGE GENDER IDENTITY OUTCOMES.....	60
A. If both a typical gender or a transgender long-term gender identity outcome are possible for a particular patient, the alternatives are not medically neutral. 60	
B. Social transition of young children is a powerful psychotherapeutic intervention that radically changes outcomes, almost eliminating desistance. 61	
C. Administration of puberty blockers is a powerful medical and psychotherapeutic intervention that radically changes outcomes, almost eliminating desistance on the historically observed timeline.....	63
VIII. TRANSITION AND AFFIRMATION ARE EXPERIMENTAL THERAPIES THAT HAVE NOT BEEN SHOWN TO IMPROVE MENTAL OR PHYSICAL HEALTH OUTCOMES BY YOUNG ADULTHOOD.	65
B. Youth who adopt a transgender identity show no durable improvement in mental health after social, hormonal, or surgical transition and affirmation..	69
C. Long-term mental health outcomes for individuals who persist in a transgender identity are poor.	72
IX. TRANSITION AND AFFIRMATION DO NOT DECREASE, AND MAY INCREASE, THE RISK OF SUICIDE.	74
A. The risk of suicide among transgender youth is confused and exaggerated in the public mind.	74
B. Transition of any sort has not been shown to reduce levels of suicide.	76

X. HORMONAL INTERVENTIONS ARE EXPERIMENTAL PROCEDURES THAT HAVE NOT BEEN PROVEN SAFE.....	81
A. Use of puberty blockers has not been shown to be safe or reversible for gender dysphoria.....	82
B. Use of cross-sex hormones in adolescents for gender dysphoria has not been shown to be medically safe except in the short term.....	88
C. The timing of harms.....	93
Bibliography	97
Curriculum Vita.....	2
Brief Introduction.....	2
Personal Information	2
Education	2
Appointments at Case Western Reserve University School of Medicine	2
Honors	3
Professional Societies.....	3
Community Boards	4
Editorial Boards	4
Manuscript Reviewer for:.....	4
Prospectus Reviewer	5
Administrative Responsibilities.....	5
Expert testimony at trial or by deposition within the last 4 years	5
Consultancies	5
Grant Support/Research Studies	5
Publications.....	7
B) Research and Invited Papers	7
C) Book Chapters.....	17
D) Book Reviews	20

I. CREDENTIALS

1. I am Clinical Professor of Psychiatry at Case Western Reserve University School of Medicine, and maintain an active private clinical practice. I received my MD from Case Western Reserve University in 1967, and completed a psychiatric residency at the University Hospitals of Cleveland in 1973. I became an Assistant Professor of Psychiatry at Case Western in 1973, became a Full Professor in 1985, and in 2021 was honored to be inducted into the Department of Psychiatry's "Hall of Fame."

2. Since July 1973, my specialties have included psychological problems and conditions relating to individuals' sexuality and sexual relations, therapies for sexual problems, and the relationship between love, intimate relationships, and wider mental health. In 2005, I received the Masters' and Johnson Lifetime Achievement Award from the Society of Sex Therapy and Research. I am a Distinguished Life Fellow of the American Psychiatric Association.

3. I have served as a book and manuscript reviewer for numerous professional publications. I have been the Senior Editor of the first (2003), second (2010), and third (2016) editions of the *Handbook of Clinical Sexuality for Mental Health Professionals*. In addition to five previously solo-authored books for professionals, I have published *Psychotherapeutic Approaches to*

Sexual Problems (2020). The book has a chapter titled “The Gender Revolution.”

4. In total I have authored or co-authored over 180 journal articles and book chapters, 27 of which deal with the issue of gender dysphoria. I was an invited member of a Cochrane Collaboration subcommittee that sought to publish a review of the scientific literature on the effectiveness of puberty blocking hormones and of cross-sex hormones for gender dysphoria for adolescents. Cochrane Reviews are a well-respected cornerstone of evidence-based practice, comprising a systematic review that aims to identify, appraise, and synthesize all the empirical evidence that meets pre-specified eligibility criteria in response to a particular research question.

5. I first encountered a patient suffering what we would now call gender dysphoria in July 1973. In 1974, I founded the Case Western Reserve University Gender Identity Clinic, and have served as Co-Director of that clinic since that time. Across the years, our Clinic treated hundreds of patients who were experiencing a transgender identity. An occasional child was seen during this era. I was the primary psychiatric caregiver for several dozen of our patients and supervisor of the work of other therapists. I was an early member of the Harry Benjamin International Gender Dysphoria Association (later known as WPATH) and served as the Chairman of the committee that developed the 5th version of its Standards of Care. In 1993 the Gender Identity Clinic was renamed, moved to a

new location, and became independent of Case Western Reserve University. I continue to serve as Co-Director.

6. In the course of my five decades of practice treating patients who suffered from gender dysphoria, I have at one time or another recommended or supported social transition, cross-sex hormones, and surgery for particular patients, but only after extensive diagnostic and psychotherapeutic work.

7. In 2006, Judge Mark Wolf of the Eastern District of Massachusetts asked me to serve as an independent, court-appointed expert in a litigation involving the treatment of a transgender inmate within the Massachusetts prison system. In that litigation, the U.S. Court of Appeals for the First Circuit in a 2014 (En Banc) opinion cited and relied on my expert testimony. I have been retained by the Massachusetts Department of Corrections as a consultant on the treatment of transgender inmates since 2007.

8. In 2019, I was qualified as an expert and testified concerning the diagnosis, understanding, developmental paths and outcomes, and therapeutic treatment of transgenderism and gender dysphoria, particularly as it relates to children, in the matter of *In the Interest of J.A.D.Y. and J.U.D.Y.*, Case No. DF-15-09887-S, 255th Judicial District, Dallas County, TX (the “*Younger* litigation”).

9. In 2019, I provided written expert testimony in the landmark case in the United Kingdom in the case of *Bell v. The Tavistock and Portman NHS Foundation Trust*. I have provided expert testimony in other litigation as listed in

my curriculum vitae, which is attached as Exhibit “A”.

10. I am regularly requested to speak on the topic of gender dysphoria and have given countless presentations to academic conferences and Departments of Psychiatry around the country. In May 2022, I organized and co-presented a symposium on the management of adolescent-onset transgender identity at American Psychiatric Association’s Annual Meeting.

11. A fuller review of my professional experience, publications, and awards is provided in my curriculum vitae, a copy of which is attached hereto as Exhibit “A”.

12. I am being compensated for my time spent in connection with this case at a rate of \$400.00 per hour. My compensation is not dependent upon the outcome of this litigation or the substance of my opinions.

II. SUMMARY

1. A summary of the key points that I explain in this report is as follows:

a. Sex as defined by biology and reproductive function is clear, binary, and cannot be changed. While hormonal and surgical procedures may enable some individuals to “pass” as the opposite gender during some or all of their lives, such procedures carry with them physical, psychological, and social risks, and no procedures can enable an individual to perform the reproductive role of the opposite sex. (Section III.A.)

b. The diagnosis of “gender dysphoria” encompasses a diverse array of conditions, with widely differing pathways and characteristics depending on age of onset, biological sex, mental health, intelligence, motivations for gender transition, socioeconomic status, country of origin, etc. Data from one population (e.g., adults) cannot be assumed to be applicable to others (e.g., children). (Section III.B.)

c. Among practitioners in the field, there are currently widely varying views concerning both the causes of and appropriate therapeutic response to gender dysphoria in children or adolescents. There are no generally accepted “standards of care” and existing studies do not provide a basis for a scientific conclusion as to which therapeutic response results in the best long-term outcomes for affected individuals. The scientific basis for affirmative care is uncertain. (Section III.)

d. Transgender identity is not biologically based. Rather, gender dysphoria is a psychiatric condition that cannot be identified by any biological test or measurement. (Sections V.A, IV.B.)

e. Disorders of sexual development (“DSDs”) are biological phenomena. It is an error to conflate and/or scientifically link DSDs with incidents of gender dysphoria. (Sections V.C, V.D.)

f. The large majority of children who are diagnosed with gender dysphoria “desist”—that is, their gender dysphoria does not persist—by

puberty or adulthood. Desistance is also increasingly observed among teens and young adults who have experienced “rapid onset gender dysphoria” — first manifesting gender dysphoria during or shortly after adolescence. (Section VI.A., VI.B.)

g. “Social transition” —the active affirmation of transgender identity—in young children is a powerful psychotherapeutic intervention that will substantially reduce the number of children “desisting” from transgender identity. Therefore, the profound implications of “affirmative” treatment—which include taking puberty blockers and cross-sex hormones—must be taken into account where social transition is being considered. (Section VII.A., VII.B.)

h. Administration of puberty blockers is not a benign “pause” of puberty, but rather a powerful medical and psychotherapeutic intervention that almost invariably leads to persistence in a transgender identity and, ultimately, to the administration of cross-sex hormones. (Section VII.C.)

i. The knowledge base concerning the “affirmative” treatment of gender dysphoria available today has very low scientific quality with many relevant long-term implications remaining unknown. (Section VIII.A)

j. There are no studies that show that affirmation of transgender identity in young children reduces suicide or suicidal ideation, or improves

long-term outcomes, as compared to other therapeutic approaches. Meanwhile, multiple studies show that adult individuals living transgender lives suffer much higher rates of suicidal ideation, completed suicide, and negative physical and mental health conditions than does the general population. This is true before and after transition, hormones, and surgery. (Section VIII.B., VIII.C.)

k. In light of what is known and not known about the impact of affirmation on the incidence of suicide, suicidal ideation, and other indicators of mental and physical health, it is scientifically baseless, and therefore unethical, to assert that a child or adolescent who express an interest in a transgender identity will kill him- or herself unless adults and peers affirm that child in a transgender identity. (Section IX.)

l. Hormonal interventions to treat gender dysphoria are experimental in nature and have not been shown to be safe, but rather put an individual at risk of a wide range of long-term and even life-long harms including: physical health risks; sterilization and the associated emotional response; impaired sexual response; surgical complications and life- long after-care; alienation of family and romantic relationships; elevated mental health risks of depression, anxiety, and substance abuse. (Section X.)

III. BACKGROUND ON THE FIELD

A. The biological baseline of the binary sexes

19. Biological sex is very well defined in all biological sciences including medicine. It is pervasively important in human development throughout the lifecycle.

20. Sex is not “assigned at birth” by humans visualizing the genitals of a newborn; it is not imprecise. Rather, it is clear, binary, and determined at conception. The sex of a human individual at its core structures the individual’s biological reproductive capabilities—to produce ova and bear children as a mother, or to produce semen and beget children as a father. As physicians know, sex determination occurs at the instant of conception, depending on whether a sperm’s X or Y chromosome fertilizes the egg. A publication of the federal government’s National Institute of Health accurately summarizes the scientific facts:

“Sex is a biological classification, encoded in our DNA. Males have XY chromosomes, and females have XX chromosomes. Sex makes us male or female. Every cell in your body has a sex— making up tissues and organs, like your skin, brain, heart, and stomach. Each cell is either male or female depending on whether you are a man or a woman.” (NIH 2022.)

21. The binary of biological sex is so fundamental and wide-ranging in its effects on human (and mammal) development and physiology that since 2014 the NIH has required all funded research on humans or vertebrate animals to include

“sex as a biological variable” and give “adequate consideration of both sexes in experiments.” (NIH 2015). In 2021, the Endocrine Society issued a position paper elaborating on the application of the NIH requirement. The Endocrine Society correctly stated that “Sex is a biological concept . . . all mammals have 2 distinct sexes;” that “biological sex is . . . a fundamental source of intraspecific variation in anatomy and physiology;” and that “In mammals, numerous sexual traits (gonads, genitalia, etc.) that typically differ in males and females are tightly linked to each other because one characteristic leads to sex differences in other traits.” (Bhargava et al. 2021 at 221, 229.)

22. The Endocrine Society emphasized that “The terms sex and gender should not be used interchangeably,” and noted that even in the case of those “rare” individuals who suffer from some defect such that they “possess a combination of male- and female-typical characteristics, those clusters of traits are sufficient to classify most individuals as either biologically male or female.” They concluded, “Sex is an essential part of vertebrate biology, but gender is a human phenomenon. Sex often influences gender, but gender cannot influence sex.” (Bhargava et al. 2021 at 220-221, 228.)

23. As these statements and the NIH requirement suggest, biological sex pervasively influences human anatomy, its development and physiology. This includes, of course, the development of the human brain, in which many sexually dimorphic characteristics have now been identified. In particular, the Endocrine

Society and countless other researchers have determined that human brains undergo particular sex-specific developmental stages during puberty. This predictable developmental process is a genetically controlled coordinated endocrine response that begins with pituitary influences leading to increases in circulating sex hormones. (Bhargava et al. 2021 at 225, 229; Blakemore et al. 2010 at 926-927, 929; NIH 2001.).

24. Humans have viewed themselves in terms of binary sexes since the earliest historical records. Recognizing a concept of “gender identity” as something distinct from sex is a rather recent innovation whose earliest manifestations likely began in the late 1940s. Its usage became common in medicine in the 1980s and subsequently in the larger culture. Definitions of gender have been evolving and remain individual-centric and subjective. In a statement on “Gender and Health,” the World Health Organization defines “gender” as “the characteristics of women, men, girls and boys that are socially constructed” and that “var[y] from society to society and can change over time,” and “gender identity” as referring to “a person’s deeply felt, internal and individual experience of gender.” (WHO Gender and Health.) As these definitions indicate, a person’s “felt” “experience of gender” is inextricably bound up with and affected by societal gender roles and stereotypes—or, more precisely, by the affected individual’s *perception* of societal gender roles and stereotypes and their personal idiosyncratic meanings. Typically,

gendered persons also have subtly different, often idiosyncratic, reactions to societal gender roles and stereotypes without preoccupation with changing their anatomy.

25. Thus, the self-perceived gender of a child begins to develop along with the early stages of identity formation generally, influenced in part from how others label the infant: “I love you, son (daughter).” This designation occurs thousands of times in the first two years of life when a child begins to show awareness of the two possibilities. As acceptance of the designated gender corresponding to the child’s sex is the outcome in >99% of children everywhere, anomalous gender identity formation begs for understanding. Is it biologically shaped? Is it biologically determined? Is it the product of how the child was privately regarded and treated? Is it a product of the quality of early life caregiver attachments? Does it stem from trauma-based rejection of maleness or femaleness, and if so, flowing from what trauma? Does it derive from a tense, chaotic interpersonal parental relationship without physical or sexual abuse? Is it a symptom of another, as of yet, unrevealed, emotional disturbance or neuropsychiatric condition (autism)? The answers to these relevant questions are not scientifically known but are not likely to be the same for every trans-identified child, adolescent, or adult.

26. Under the influence of hormones secreted by the testes or ovaries, numerous additional sex-specific differences between male and female bodies

continuously develop postnatally, culminating in the dramatic maturation of the primary and secondary sex characteristics with puberty. These include differences in hormone levels, height, weight, bone mass, shape, musculature, internal organ size, body fat levels and distribution, and hair patterns, as well as physiological differences such as menstruation and ejaculation. These are genetically programmed biological consequences of sex—the actual meaning of sex over time. Among the consequences of sex is the evolution and consolidation of gender identity during childhood, adolescence, and adulthood.

27. Despite the increasing ability of hormones and various surgical procedures to reconfigure some male bodies to visually pass as female, or vice versa, the biology of the person remains as defined by his (XY) or her (XX) chromosomes, including cellular, anatomic, and physiologic characteristics and the particular disease vulnerabilities associated with that chromosomally defined sex. For instance, the XX (genetically female) individual who takes testosterone to stimulate certain male secondary sex characteristics will nevertheless remain unable to produce sperm and father children. Contrary to assertions and hopes that medicine and society can fulfill the aspiration of the trans individual to become “a complete man” or “a complete woman,” this is not biologically attainable. (Levine 2018 at 6; Levine 2016 at 238.) It is possible for some adolescents and adults to pass unnoticed—that is, to be perceived by most individuals as a member of the gender that they aspire to be—but with limitations, costs, and risks, as I detail

later.

B. Definition and diagnosis of gender dysphoria

28. Specialists have used a variety of terms over time, with somewhat shifting definitions, to identify and speak about a distressing incongruence between an individual's genetically determined sex and the gender with which they identify or to which they aspire. Today's American Psychiatric Association *Diagnostic and Statistical Manual of Mental Disorders* ("DSM-5-TR") employs the term Gender Dysphoria and defines it with separate sets of criteria for adolescents and adults on the one hand, and children on the other.

29. There are at least five distinct pathways to gender dysphoria: early childhood onset; onset near or after puberty with no prior cross gender patterns; onset after defining oneself as gay for several or more years and participating in a homosexual lifestyle; adult onset after years of heterosexual transvestism; and onset in later adulthood with few or no prior indications of cross-gender tendencies or identity. (Levine 2021.)

30. Gender dysphoria has very different characteristics depending on age and sex at onset. Young children who are living a transgender identity commonly suffer materially fewer symptoms of concurrent mental distress than do older patients. (Zucker 2018 at 10.) The developmental and mental health patterns for each of these groups are sufficiently different that data developed in connection with one of these populations cannot be assumed to be applicable to

another.

31. The criteria used in DSM-5-TR to identify Gender Dysphoria include a number of signs of discomfort with one’s natal sex and vary somewhat depending on the age of the patient, but in all cases require “clinically significant distress or impairment in . . . important areas of functioning” such as social, school, or occupational settings. The symptoms must persist for at least six months.

32. Children who conclude that they are transgender are often unaware of a vast array of adaptive possibilities for how to live life as a man or a woman—possibilities that become increasingly apparent over time to both males and females. A boy or a girl who claims or expresses interest in pursuing a transgender identity often does so based on stereotypical notions of femaleness and maleness that reflect constrictive notions of what men and women can be. (Levine 2017 at 7.) A young child’s—or even an adolescent’s—understanding of this topic is quite limited. Nor can they grasp what it may mean for their future to be sterile (Levine et al, 2022). These children and adolescents consider themselves to be relatively unique; they do not realize that discomfort with the body and perceived social role is neither rare nor new to civilization. What is new is that such discomfort is thought to indicate that they must be a trans person.

C. Impact of gender dysphoria on minority and vulnerable groups

33. Given that, as I discuss later, a diagnosis of gender dysphoria is now

frequently putting even young children on a pathway that leads to irreversible physical changes and sterilization by young adulthood, it should be of serious concern to all practitioners that minority and vulnerable groups are receiving this diagnosis at disproportionately high rates. These include: children of color (Rider et al. 2018), children with mental developmental disabilities (Reisner et al. 2015), children on the autistic spectrum (at a rate more than 7x the general population) (Shumer et al. 2016; van der Miesen et al. 2018), children with ADHD (Becerra-Culqui et al. 2018), children residing in foster care homes, adopted children (at a rate more than 3x the general population) (Shumer et al. 2017), victims of childhood sexual or physical abuse or other “adverse childhood events” (Thoma 2021 et al.; Newcomb et al. 2020; Kozłowska et al., 2021), children with a prior history of psychiatric illness (Edwards-Leeper et al. 2017; Kaltiala-Heino et al. 2015; Littman 2018), and more recently adolescent girls (in a large recent study, at a rate more than 2x that of boys) (Rider et al. 2018 at 4).

D. Three competing conceptual models of gender dysphoria and transgender identity

34. Discussions about appropriate responses by mental health professionals (“MHPs”) to actual or sub-threshold gender dysphoria are complicated by the fact that various speakers and advocates (or a single speaker at different times) view transgenderism through at least three very different paradigms, often without being aware of, or at least without acknowledging, the

distinctions.

35. Gender dysphoria is **conceptualized and described by some professionals and laypersons as though it were a serious, physical medical illness that causes suffering**, comparable to diseases that are curable before it spreads, such as melanoma or sepsis. Within this paradigm, whatever is causing distress associated with gender dysphoria—whether secondary sex characteristics such as facial hair, nose and jaw shape, presence or absence of breasts, or the primary anatomical sex organs of testes, ovaries, penis, or vagina—should be removed to alleviate the illness. The promise of these interventions is the cure of the gender dysphoria.

36. Gender dysphoria is a psychiatric, not a medical, diagnosis. Since its inception in DSM-III in 1983, it has always been specified in the psychiatric DSM manuals and has not been specified in medical diagnostic manuals. Notably, gender dysphoria is the only psychiatric condition to be treated by surgery, even though no endocrine or surgical intervention package corrects any identified biological abnormality. (Levine 2016 at 240.)

37. Gender dysphoria is alternatively **conceptualized in developmental terms**, as an adaptation to a psychological problem that may have been first manifested as a failure to establish a comfortable conventional sense of self in early childhood. This paradigm starts from the premise that all human lives are influenced by past processes and events. Trans lives are not exceptions to this

axiom. (Levine 2016 at 238.) MHPs who think of gender dysphoria through this paradigm may work both to identify and address causes of the basic problem of the deeply uncomfortable self or a sense of self impaired by later adversity or abuse. The purpose is to ameliorate suffering when the underlying problem cannot be solved. MHPs first work with the patient and (ideally) family to learn about the events and processes that may have led to the trans person repudiating the gender associated with his sex. The developmental paradigm is mindful of temperamental, parental bonding, psychological, sexual, and physical trauma influences, and the fact that young children work out their psychological issues through fantasy and play and adolescents work out their issues by adopting various interests and identity labels.

38. There is evidence among adolescents that peer social influences through “friend groups” (Littman 2018) or through the internet can increase the incidence of gender dysphoria or claims of transgender identity. Responsible MHPs will want to probe these potential influences to better understand what is truly deeply tied to the psychology of the patient, and what may instead be being “tried on” by the youth as part of the adolescent process of self-exploration and self-definition.

39. In addition, the developmental paradigm recognizes that, with the important exception of genetic sex, essentially all aspects of an individual’s identity evolve—often markedly—across the individual’s lifetime. This includes

gender. Some advocates assert that a transgender identity is biologically caused, fixed from early life, and eternally present in an unchanging manner. As I review later, however, this assertion is not supported by science.¹

40. The third paradigm through which gender dysphoria is alternatively conceptualized is from **a sexual minority rights perspective**. Under this paradigm, any response other than medical and societal affirmation and implementation of a patient's claim to "be" the opposite gender is a violation of the individual's civil right to self-expression. Any effort to ask "why" questions about the patient's condition, or to address underlying causes, is viewed as a violation of autonomy and civil rights. In the last few years, this paradigm has been successful in influencing public policy and the education of pediatricians, endocrinologists, and many mental health professionals. Obviously, however, this is not a medical or psychiatric perspective. Unfortunately, it appears to be the most powerful perspective that exists in the public, non- scientific debate.

E. Four competing models of therapy

41. Few would disagree that the human psyche is complex. Few would disagree that children's and adolescents' developmental pathways typically have surprising twists and turns. The complexity and unpredictability of childhood and adolescent development equally applies to

¹ Even the advocacy organization The Human Rights Campaign asserts that a person can have "a fluid or unfixed gender identity." <https://www.hrc.org/resources/glossary-of-terms>.

trans-identifying youth. Because of past difficulties of running placebo-controlled clinical trials in the transgender treatment arena, substantial disagreements among professionals about the causes of trans identities and their ideal treatments exist. These current disagreements might have been minimized if trans treated persons were carefully followed up to determine long term outcomes. They have not been. When we add to this to the very different current paradigms for understanding transgender phenomena, it is not scientifically surprising that disagreements are sharply drawn. It is with this in mind that I summarize below the leading approaches, and offer certain observations and opinions concerning them.

(1) The “watchful waiting” therapy model

42. In Section V.A below I review the uniform finding of eleven follow-up studies that the large majority of children who present with gender dysphoria will desist from desiring a transgender identity by adulthood if left untreated by social transition approaches.

43. When a pre-adolescent child presents with gender dysphoria, a “watchful waiting” approach seeks to allow for the fluid nature of gender identity in children to naturally evolve— that is, take its course from forces within and surrounding the child. Watchful waiting has two versions:

- a. Treating any other psychological co-morbidities—that is, other mental illnesses as defined by DSM-5-TR (separation anxiety disorder, attention deficit hyperactivity disorder, autism spectrum disorder, obsessive

compulsive disorder, etc), or subthreshold for diagnosis but behavioral problems that the child may exhibit (school avoidance, bedwetting, inability to make friends, aggression/defiance) without a focus on gender (**model #1**); and

b. No treatment at all for anything but a regular follow-up appointment. This might be labeled a “hands off” approach (**model #2**).

(2) The psychotherapy model: Alleviate distress by identifying and addressing causes (model #3)

44. One of the foundational principles of psychotherapy has long been to work with a patient to identify the causes of observed psychological distress and then to address those causes as a means of alleviating the distress. The National Institute of Mental Health has promulgated the idea that 75% of adult psychopathology has its origins in childhood experience.

45. Many experienced practitioners in the field of gender dysphoria, including myself, have believed that it makes sense to employ these long-standing tools of psychotherapy for patients suffering gender dysphoria, asking the question as to what factors in the patient’s life are the determinants of the patient’s repudiation of his or her natal sex. (Levine 2017 at 8; Spiliatis 2019; Levine 2021. Levine et al, 2022) I and others have reported success in alleviating distress in this way for at least some patients, whether the patient’s sense of discomfort or incongruence with his or her natal sex entirely disappeared or not. Relieving

accompanying psychological co-morbidities leaves the patient freer to consider the pros and cons of transition as he or she matures.

46. Among other things, the psychotherapist who is applying traditional methods of psychotherapy may help—for example—the male patient appreciate the wide range of masculine emotional and behavioral patterns as he grows older. He may discuss with his patient, for example, that one does not have to become a “woman” to be kind, compassionate, caring, noncompetitive, to love the arts, and to be devoted to others’ feelings and needs. (Levine 2017 at 7.) Many biologically male trans individuals, from childhood to older ages, speak of their perceptions of femaleness as enabling them to discuss their feelings openly, whereas they perceive boys and men to be constrained from emotional expression within the family and larger culture, and to be aggressive. Men, of course, can be emotionally expressive, just as they can wear pink. Converse examples can be given for girls and women. These types of ideas regularly arise during psychotherapies.

47. As I note above, many gender-nonconforming children and adolescents in recent years derive from minority and vulnerable groups who have reasons to feel isolated and have an uncomfortable sense of self. A trans identity may be a hopeful attempt to redefine the self in a manner that increases their comfort and decreases their anxiety. The clinician who uses traditional methods of psychotherapy may not focus on their gender identity, but instead work to help them to address the actual sources of their discomfort. They may enable the patient

to understand the commonality of discomfort with the body's physiology, the growth process, and the struggle to accept oneself during the pubertal developmental process. Patients need to understand that this discomfort with one's body, per se, and one's attractiveness relative to others, typically lasts for several years. Success in this effort may remove or reduce the desire for a redefined identity. This often involves a focus on disruptions in their attachment to parents in vulnerable children, for instance, those in the foster care system.

48. Because "watchful waiting" can include treatment of accompanying psychological co-morbidities, and the psychotherapist who hopes to relieve gender dysphoria may focus on potentially causal sources of psychological distress rather than on the gender dysphoria itself, there is no sharp line between "watchful waiting" and the psychotherapy model in the case of prepubescent children.

49. To my knowledge, there is no evidence beyond anecdotal reports that psychotherapy can enable a return to male identification for genetically male boys, adolescents, and men, or return to female identification for genetically female girls, adolescents, and women. On the other hand, anecdotal evidence of such outcomes does exist; I and other clinicians have witnessed reinvestment in the patient's biological sex in some individual patients who are undergoing psychotherapy. The Internet contains many such reports, and I have published a paper on a patient who sought my therapeutic assistance to reclaim his male

gender identity after 30 years living as a woman and is in fact living as a man today. (Levine 2019.) I have seen children desist even before puberty in response to thoughtful parental interactions and a few meetings of the child with a therapist.

There are now a series of articles and at least one major book on the psychological treatment of adolescents. (D'Angelo et al. 2021 at 7-16; Evans & Evans 2021.)

Among detransitioners, a large percentage express regret that their affirmative therapists did not recommend psychotherapy before encouraging hormonal treatment (Littman, (2021). *Individuals treated for gender dysphoria with medical and/or surgical transition who subsequently detransitioned: A survey of 100 detransitioners. Archives of Sexual Behavior*, 50(8)3353-3369). Exposito-Campos pointed out the large amount reports on detransition and the far greater traffic on various nonprofessional websites (Exposito-Campos, 2021)

(3) The affirmation therapy model (model #4)

50. While it is widely agreed that the therapist should not directly challenge a claimed transgender identity in a child, some advocates and practitioners go much further, and promote and recommend that any expression of transgender identity should be immediately accepted as decisive, and thoroughly affirmed by means of consistent use of clothing, toys, pronouns, etc., associated with transgender identity. They argue that the child should be comprehensively re-socialized in grade school in their aspired-to gender. As I understand it, this is asserted as a reason why male students who assert a female gender identity must

be permitted to compete in girls' or women's athletic events. These advocates treat any question about the causes of the child's transgender identification as inappropriate. They may not recognize the child's ambivalence. They assume that observed psychological co-morbidities in the children or their families are unrelated or will get better with transition, and need not be addressed by the MHP who is providing supportive guidance concerning the child's gender identity.

51. Some advocates, indeed, assert that unquestioning affirmation of any claim of transgender identity in children is essential, and that the child will otherwise face a high risk of suicide or severe psychological damage. This claim is simply not supported by the clinical data we have available to us. Indeed, available long-term data contradicts this claim. I address physical and mental health outcomes in Section VII below, and suicide in Section VIII below.

52. The commonly referenced scientific basis for affirmative care of both early life onset and adolescent onset gender dysphoria are two reports from deVries et al (2011, 2014) that seemingly demonstrated the resolution of gender dysphoria after a sequence of puberty blocking hormones, cross-sex hormones, and breast removal or vaginoplasty. However, recently three articles describing the distinct limitations of the "Dutch Protocol have been widely circulating throughout the world (Levine et al, 2022; Biggs, 2022, Abbruzzese et al, 2023) It is now apparent that the basis for such affirmative care is not scientifically solid. Rapid diffusion of the innovative Dutch Protocol occurred without the scientifically

required confirmatory more rigorous studies. The one attempt to repeat their protocol in the UK failed to demonstrate psychological benefits claimed by the Dutch studies. (Carmichael et al 2021).

53. I do not know what proportion of practitioners are using which model.

However, in my opinion, in the case of young children, prompt and thorough affirmation of a transgender identity disregards the principles of child development and family dynamics and is not supported by science. Instead of science, this approach is currently being reinforced by an echo-chamber of approval from other like-minded child-oriented professionals who do not sufficiently consider the known negative medical and psychiatric outcomes of trans adults. Rather than recommend social transition in grade school, the MHP must focus attention on the child's underlying internal and familial issues. Ongoing relationships between the MHP and the parents, and the MHP and the child, are vital to help the parents, child, other family members, and the MHP to understand over time the issues that need to be dealt with by each of them.

54. Likewise, since the child's sense of gender develops in interaction with his parents and their own gender roles and relationships, the responsible MHP will almost certainly need to delve into family and marital dynamics. This, however, requires time and effort and for many parents, a challenge to find a therapist to do such work with them.

IV. THERE IS NO CONSENSUS OR AGREED “STANDARD OF CARE” CONCERNING THERAPEUTIC APPROACHES TO CHILD OR ADOLESCENT GENDER DYSPHORIA.

55. There is far too little firm clinical evidence in this field to permit any evidence-based standard of care. Given the lack of scientific evidence, it is neither surprising nor improper that—as I detailed in Section II—there is a diversity of views among practitioners as to as to the best therapeutic response for the child, adolescent, or young adult who suffers from gender dysphoria.

56. Reviewing the state of opinion and practice in 2021, the Royal Australian and New Zealand College of Psychiatrists observed that “There are polarised views and mixed evidence regarding treatment options for people presenting with gender identity concerns, especially children and young people.” (RANZCP, 2021.) Similarly, a few years earlier prominent Dutch researchers noted: “[T]here is currently no general consensus about the best approach to dealing with the (uncertain) future development of children with GD, and making decisions that may influence the function and/or development of the child — such as social transition.” (Ristori & Steensma 2016 at 18.)² In this Section, I comment on some of the more important areas of disagreement within the field.

² See also Zucker 2020 which questions the merit of social transition as a first-line treatment.

A. Experts and organizations disagree as to whether “distress” is a necessary element for diagnoses that justifies treatment for gender identity issues.

57. As outlined in Section II.B above, “clinically significant distress” is one of the criteria used in DSM-5 to identify gender dysphoria. This indicates a heightened level of distress that rises beyond a threshold level of social awkwardness or discomfort with the changing body. It is known that many trans-identified youth with incongruence between their sexed bodies and their gender identity choose not to take hormones; their incongruence is quite tolerable as they further clarify their sexual identity elements. This population raises the questions of what distress is being measured when DSM-5-TR criteria are met and what else might be done about it.

58. I note that there is no “clinically significant distress” requirement in World Health Organization’s International Classification of Diseases (ICD-11) criteria for gender incongruence, which rather indicates “a marked and persistent incongruence between an individual’s experienced gender and the assigned sex.” (World Health Organization 2019.)

59. Therefore, even between these two committee-based authorities, there is a significant disagreement as to what constitutes a gender condition justifying life-changing interventions. To my knowledge, some American gender clinics and practitioners are essentially operating under the ICD-11 criteria rather than the DSM-5-TR criteria, prescribing transition for children, hormonal

interventions for slightly older children, and different hormones for adolescents who assert a desire for a transgender identity whether or not they are exhibiting “clinically significant distress.” Others adhere to the DSM-5 diagnostic standard.

60. It is ironic that affirmative care is said by advocates to be life enhancing and often to be lifesaving because of the risk of suicide. Based on the DSM-5-TR criterion, distress is required for the diagnosis and its subsequent hormonal and surgical treatments. Gender incongruence is often referred to as a unique form of suffering. Yet, ICD-11 the criteria for the diagnosis of Gender Incongruence do not require distress, just the wish to have the characteristics of the other sex and to change their own sex demarcating features. It seems that as the field moves on in time, the emphasis is on desire rather than distress, pain, or suffering.

61. I will add that even from within one “school of thought,” it is not responsible to make a single, categorical statement about the proper treatment of children or adolescents presenting with gender dysphoria or other gender-related issues. There is no single pathway to the development of a trans identity and no reasonably uniform short- or long-term outcome of medically treating it. As individuals grow physically, mature psychologically, and experience or fail to experience satisfying romantic relationships, their life course depends on their differing psychological, social, familial, and life experiences. There should be no trust in assertions that trans identified youth must be treated in a particular manner

to avoid harm for two reasons: first, there is no systematic data on the nature of, and the rate of harms of either affirmative treatment, no treatment, or psychological only treatment. Second, as in other youthful psychiatric and other challenges, outcomes vary.

B. Opinions and practices vary widely about the utilization of social transition for children and adolescents.

62. The World Professional Association for Transgender Health (WPATH) has published a guidance document under the title of “standards of care.” Below, I will provide some explanation of WPATH and its “Standards of Care,” which are not the product of a strictly scientific organization, and are by no means accepted by all or even most practitioners as setting out best practices.

63. Here, however, I will note that WPATH does not take a position concerning whether or when social transition may be appropriate for pre-pubertal children. Instead, the WPATH “Standards of Care version 7” states that the question of social transition for children is a “controversial issue” and calls for mental health professionals to support families in what it describes as “difficult decisions” concerning social transition. Its version 8, however, no longer uses the word “controversial” even though it extensively discusses the dangers of harms versus the possibility of benefits of early transition (Coleman et al, 2022).

64. Dr. Erica Anderson is a prominent practitioner in this area who

identifies as a transgender woman, who was the first transgender president of USPATH, and who is a former board member of WPATH. Dr. Anderson recently resigned from those organizations and has condemned automatic approval of transition upon the request of a child or adolescent, noting that “adolescents . . . are notoriously susceptible to peer influence,” that transition “doesn’t cure depression, doesn’t cure anxiety disorders, doesn’t cure autism-spectrum disorder, doesn’t cure ADHD,” and instead that “a comprehensive biopsychosocial evaluation” should proceed allowing a child to transition. (Davis 2022.) And as I have explained previously, my own view based on 50 years of experience in this area favors strong caution before approving life-altering interventions such as social transition, puberty blockers, or cross-sex hormones.

C. The WPATH “Standards of Care” is not an impartial or evidence-based document.

65. Because WPATH is frequently cited by advocates of social, hormonal, and surgical transition, I provide some context concerning that private organization and its “Standards of Care.”

66. I was a member of the Harry Benjamin International Gender Dysphoria Association from 1974 until 2001. From 1997 through 1998, I served as the Chairman of the eight-person International Standards of Care Committee that issued the fifth version of the Standards of Care. I resigned my membership in 2002 due to my regretful conclusion that the organization and its

recommendations had become dominated by politics and ideology, rather than by scientific process, as it was years earlier. In approximately 2007, the Harry Benjamin International Gender Dysphoria Association changed its name to the World Professional Association for Transgender Health (WPATH).

67. WPATH is a voluntary membership organization. Since at least 2002, attendance at its biennial meetings has been open to trans individuals who are not licensed professionals. While this ensures taking patients' needs into consideration, it limits the ability for honest and scientific debate, and means that WPATH can no longer be considered a purely professional organization.

68. WPATH takes a decided view on issues as to which there is a wide range of opinion among professionals. WPATH explicitly views itself as not merely a scientific organization, but also as an advocacy organization. (Levine 2016 at 240.) WPATH is supportive to those who want sex reassignment surgery ("SRS"). Skepticism as to the benefits of SRS to patients, and strong alternate views, are not well tolerated in discussions within the organization or their educational outreach programs. Such views have been known to be shouted down and effectively silenced by the large numbers of nonprofessional adults who attend the organization's biennial meetings. Two groups of individuals that I regularly work with have attended recent and separate WPATH continuing education sessions. There, questions about alternative approaches were quickly dismissed with "There are none. This is how it is done." Such a response does not accurately

reflect what is known, what is unknown, and the diversity of clinical approaches in this complex field.

69. The reviews of WPATH's 7th edition of standards of care published in 2021 by Dahlen et al and Sapir in 2022 have clarified the low quality, low reliability, and bias inherent in its recommendations. (Dahlen et al 2022) Its 8th edition, which is three times the length of the 7th, has not gained additional confidence in its scientific merit. The Standards of Care ("SOC") document is the product of an effort to be balanced, but it is not politically neutral. WPATH aspires to be both a scientific organization and an advocacy group for the transgendered. It articulates policy. These aspirations sometimes conflict. The limitations of the Standards of Care, however, are not primarily political. They are caused by the lack of rigorous research in the field, which allows room for passionate convictions on how to care for the transgendered. And, of course, once individuals have socially, medically, and surgically transitioned, WPATH members and the trans people themselves at the meetings are committed to supporting others in their transitions. Not only have some trans participants been distrustful or hostile to those who question the wisdom of these interventions, their presence makes it difficult for professionals to raise their concerns. Vocal trans rights advocates have a worrisome track record of attacking those who have alternative views. (Dreger 2015. McNamarra et al 2022) .

70. In recent years, WPATH has fully adopted some mix of the medical

and civil rights paradigms. It has downgraded the role of counseling or psychotherapy as a requirement for these life-changing processes. WPATH no longer considers preoperative psychotherapy to be a requirement. It is important to WPATH that the person has gender dysphoria; the pathway to the development of this state is not. (Levine 2016 at 240.) The trans person is assumed to have thoughtfully considered his or her options before seeking hormones, for instance. In actual practice, that thoughtful person may be as young as age 11!

71. Most psychiatrists and psychologists who treat patients suffering sufficiently severe distress from gender dysphoria to seek inpatient psychiatric care are not members of WPATH. Many psychiatrists, psychologists, and pediatricians who treat some patients suffering gender dysphoria on an outpatient basis are not members of WPATH. WPATH represents a self-selected subset of the profession along with its many non-professional members; it does not capture the clinical experiences of others. WPATH claims to speak for the medical profession; however, it does not welcome skepticism and therefore, deviates from the philosophical core of medical science. There are pediatricians, psychiatrists, endocrinologists, and surgeons who object strongly, on professional grounds, to transitioning children and providing affirmation in a transgender identity as the first treatment option. WPATH does not speak for all of the medical profession.

72. In 2010 the WPATH Board of Directors issued a statement advocating that incongruence between sex and felt gender identity should cease to be

identified in the DSM as a pathology.³ This position was debated but not adopted by the (much larger) American Psychiatric Association, which maintained the definitions and diagnoses of gender dysphoria as a pathology in the DSM-5 manual issued in 2013.

73. In my experience some current members of WPATH have little ongoing experience with the mentally ill, and many trans care facilities are staffed by MHPs who are not deeply experienced with recognizing and treating frequently associated psychiatric co-morbidities. Further, being a mental health professional, per se, does not guarantee experience and skill in recognizing and effectively intervening in serious or subtle patterns. Because the 7th version of the WPATH SOC deleted the requirement for therapy, trans care facilities that consider these Standards sufficient are permitting patients to be counseled to transition by means of social presentation, hormones, and surgery by individuals with masters rather than medical degrees. The 8th version of the SOC continues this tradition. When this document recommends a comprehensive psychiatric evaluation, it fails to elaborate its duration, the topics to be covered, and necessary treatment results of the commonly found previous and co-current psychiatric conditions.

³ WPATH *De-Psychopathologisation Statement* (May 26, 2010), available at wpath.org/policies (last accessed January 21, 2020).

D. Opinions and practices differ widely with respect to the proper role of psychological counseling before, as part of, or after a diagnosis of gender dysphoria.

74. In Version 7 of its Standards of Care, released in 2012, WPATH downgraded the role of counseling or psychotherapy, and the organization no longer sees psychotherapy without transition and hormonal interventions as a potential path to eliminate gender dysphoria by enabling a patient to return to or achieve comfort with the gender identity aligned with his or her biology. Around the world, many prominent voices and practitioners disagree. For example, renowned gender therapists Dr. Laura Edwards-Leeper and Dr. Erica Anderson (who, as mentioned above, identifies as a transgender woman) have recently spoken out arguing that children and adolescents are being subjected to puberty blockers and hormonal intervention far too quickly, when careful and extended psychotherapy and investigation for potential causes of feelings of dysphoria (such as prior sexual abuse) should be the first port of call and might resolve the dysphoria. (Edwards-Leeper & Anderson 2021; Davis 2022.)

75. In a recently published position statement on gender dysphoria, the Royal Australian and New Zealand College of Psychiatrists emphasized the critical nature of mental health treatment for gender dysphoric minors, stressing “the importance of the psychiatrist’s role to undertake thorough assessment and evidence-based treatment ideally as part of a multidisciplinary team, especially highlighting co-existing issues which may need addressing and treating.” The

Royal College also emphasized the importance of assessing the “psychological state and context in which Gender Dysphoria has arisen,” before any treatment decisions are made. (RANZCP, 2021.)

76. Dr. Paul Hruz of the University of Washington St. Louis Medical School has noted, “The WPATH has rejected psychological counseling as a viable means to address sex– gender discordance with the claim that this approach has been proven to be unsuccessful and is harmful (Coleman et al. 2012). Yet the evidence cited to support this assertion, mostly from case reports published over forty years ago, includes data showing patients who benefited from this approach (Cohen-Kettenis and Kuiper 1984).” (Hruz 2020.)

77. In several recent publications, my colleagues and I have demonstrated that both the Endocrine Society’s and WPATH’s citations for the scientific basis of affirmative care of adolescents reference the same two Dutch studies. We have demonstrated in considerable details the limitations of these studies, their lack of applicability to today’s transgendered youth, and the dangers of following therapeutic fashion rather than evidence-based medicine (Levine et al, 2022; Abbruzzese et al, 2023).

E. Opinions and practices vary widely with respect to the administration of puberty blockers and cross-sex hormones.

78. There is likewise no broadly accepted standard of care with respect to use of puberty blockers. The WPATH Standards of Care explicitly recognize the

lack of any consensus on this important point, stating: “Among adolescents who are referred to gender identity clinics, the number considered eligible for early medical treatment—starting with GnRH analogues to suppress puberty in the first Tanner stages—differs among countries and centers. Not all clinics offer puberty suppression. . . The percentages of treated adolescents are likely influenced by the organization of health care, insurance aspects, cultural differences, opinions of health professionals, and diagnostic procedures offered in different settings.”

79. The use of puberty blockers as a therapeutic intervention for gender dysphoria is often justified by reference to the seminal work of a respected Dutch research team that developed a protocol that administered puberty blockers to children no younger than age 14. However, it is well known that many clinics in North America now administer puberty blockers to children at much younger ages than the “Dutch Protocol” allows. (Zucker 2019.) The Dutch protocol only treated children with these characteristics: a stable cross gender identity from early childhood; dysphoria that worsened with the onset of puberty; were otherwise psychologically healthy; had healthy families; the patient and family agreed to individual and family counselling throughout the protocol. But the experience and results of the Dutch model is being used as a justification for giving puberty blockers to children who differ considerably from these criteria. Its authors have also recently noted this fact (de Vries 2020).

80. However, Zucker notes that “it is well known” that clinicians are administering cross-sex hormones, and approving surgery, at ages lower than the minimum age thresholds set by that “Dutch Protocol.” (Zucker 2019 at 5.)

81. Similarly, at least one prominent clinic—that of Dr. Safer at Columbia’s Mt. Sinai Medical Center—is quite openly admitting patients for even *surgical* transition who are not eligible under the criteria set out in WPATH’s Standards of Care. A recent study published by Dr. Safer and colleagues revealed that of a sample of 139 individuals, 45% were eligible for surgery “immediately” under the center’s own criteria, while only 15% were eligible under WPATH’s criteria. That is, *three times* as many patients immediately qualified for surgery under the center’s loose standards than would have qualified under WPATH criteria. (Lichenstein et al. 2020.)

82. Internationally, there has been a recent marked trend *against* use of puberty blockers, as a result of extensive evidence reviews by national medical bodies, which I discuss later. The main gender clinic in Sweden has declared that it will no longer authorize use of puberty blockers for minors below the age of 16. Finland has similarly reversed its course, issuing new guidelines that allow puberty blockers only on a case-by-case basis after an extensive psychiatric assessment. A landmark legal challenge against the UK’s National Health Service in 2020 by “detransitioner” Keira Bell led to the suspension of the use of puberty blockers and new procedures to ensure better psychological care, as well as

prompting a thorough evidence review by the National Institute for Health and Care Excellence (NICE 2021a; NICE 2021b).⁴ That review in 2022 reorganized trans adolescent care throughout the UK and emphasized the need to focus on the patients' psychological state rather than treat first the gender incongruence. Puberty blockers are not to be initially employed.

83. In this country, some voices in the field are now publicly arguing that *no* comprehensive mental health assessment at all should be required before putting teens on puberty blockers or cross-sex hormones (Ghorayshi 2022), while Dr. Anderson and Dr. Edwards-Leeper argue that U.S. practitioners are already moving too quickly to hormonal interventions. (Edwards-Leeper & Anderson 2021; Davis 2022.) It is evident that opinions and practices are all over the map.

1. In 2018, committee of the American Academy of Pediatrics issued a policy statement supporting administration of puberty blockers to children diagnosed with gender dysphoria. No other American medical association has endorsed the use of puberty blockers. Pediatricians are neither endocrinologists nor psychiatrists. Many pediatricians were horrified by the recommendation. Dr. James Cantor published a peer-reviewed paper detailing that the Academy's statement was not

⁴ The decision requiring court approval for administration of hormones to any person younger than age 16 was later reversed on procedural grounds by the Court of Appeal and is currently under consideration by the UK Supreme Court.

evidence- based and misdescribed the few scientific sources it did reference. (Cantor 2019.) It has been well noted in the field that the AAP has declined invitations to publish any rebuttal to Dr. Cantor’s analysis. But this is all part of ongoing debate, simply highlighting the absence of any generally agreed standard of care. In 2022, the same committee of the AAP modified their recommendation supporting alternative treatments but still held out that affirmative care is still a viable option. Evidence after all is required for policy decisions and the 2018 evidence base is now widely appreciated as insubstantial.

84. The 2017 Endocrine Society Guidelines themselves expressly state that they are *not* “standards of care.” The document states: “The guidelines cannot guarantee any specific outcome, *nor do they establish a standard of care*. The guidelines are not intended to dictate the treatment of a particular patient.” (Hembree et al. 2017 at 3895 (emphasis added).) Nor do the Guidelines claim to be the result of a rigorous scientific process. Rather, they expressly advise that their recommendations concerning use of puberty blockers are based only on “low quality” evidence.

85. The 2017 Guidelines assert that patients with gender dysphoria often must be treated with “a safe and effective hormone regimen. . .” Notably, however, the Guidelines do not make any firm statement that use of puberty blockers for this purpose *is* safe, and the Guidelines go no further than “suggest[ing]” use of puberty blockers—language the Guidelines warn represents

only a “weak recommendation.” (Hembree 2017 at 3872.) Several authors have pointed out that not only were the Endocrine Society suggestions regarding use of puberty blockers reached on the basis of “low quality” evidence, but its not-quite claims of ‘safety’ and ‘efficacy’ are starkly contradicted by several in-depth evidence reviews. (Laidlaw et al., 2019; Malone et al. 2021.) The most recent systematic independent review of hormonal treatment of adolescents reaffirmed the poor quality of evidence making their use questionable (Brignardello-Peterson, & Wiercioch 2022). I detail these contradictory findings in more detail in Section VII below.

86. While there is too little meaningful clinical data and no consensus concerning best practices or a “standard of care” in this area, there are long-standing ethical principles that do or should bind all medical and mental health professionals as they work with, counsel, and prescribe for these individuals.

87. One of the oldest and most fundamental principles guiding medical and psychological care—part of the Hippocratic Oath—is that the physician must “do no harm.” This states an ethical responsibility that cannot be delegated to the patient. Physicians themselves must weigh the risks of treatment against the harm of not treating. If the risks of treatment outweigh the benefits, principles of medical ethics prohibit the treatment.

V. TRANSGENDER IDENTITY IS NOT BIOLOGICALLY BASED.

88. There is no medical consensus that transgender identity has any biological basis. Furthermore, there is considerable well-documented evidence that is inconsistent with the hypothesis of a biological basis for gender identity—at least in the large majority of currently-presenting patients.

A. No theory of biological basis has been scientifically validated.

89. At the outset, the attempt to identify a single, biological cause for psychiatric conditions (including gender dysphoria) has been strongly criticized as “out of step with the rest of medicine” and as a lingering “ghost” of an understanding of the nature of psychiatric conditions that is now broadly disproven. (Kendler 2019 at 1088-1089.) Gender dysphoria is defined and diagnosed only as a psychiatric, not a medical, condition. Courts need to have clarified that just because some physicians use medication and surgery to treat gender dysphoria does not make it a “medical condition” or that the psychological identity has been determined by a biological mechanism.

90. While some have pointed to very small brain scan studies as evidence of a biological basis, no studies of brain structure of individuals identifying as transgender have found any statistically significant correlation between any distinct structure or pattern and transgender identification, after controlling for sexual orientation and exposure to exogenous hormones. (Sarawat et al. 2015 at 202; Frigerio et al. 2021.)

91. Indeed, the Endocrine Society 2017 Guidelines recognizes: “With

current knowledge, we cannot predict the psychosexual outcome for any specific child” and “there are currently no criteria to identify the GD/gender-incongruent children to whom this applies. At the present time, clinical experience suggests that persistence of GD/gender incongruence can only be reliably assessed after the first signs of puberty.” (Hembree et al. 2017 at 3876.)

92. In short, no biological test or measurement has been identified that provides any ability to predict which children will exhibit, and which children will persist in, gender dysphoria or a transgender identification. Unless and until such a test is identified, the theory of a biological basis is a hypothesis still searching for support. A hypothesis is not a fact, and responsible scientists will not confuse the two.

B. Large changes across time and geography in the epidemiology of transgender identification are inconsistent with the hypothesis of a biological basis for transgender identity.

93. In fact, there is substantial evidence that the “biological basis” theory is incorrect, at least with respect to the large majority of patients presenting with gender dysphoria today.

94. **Vast changes in incidence:** Historically, there were very low reported rates of gender dysphoria or transgender identification. In 2013, the DSM-5 estimated the incidence of gender dysphoria in adults to be at 2-14 per 100,000, or between 0.002% and 0.014%. (APA 2013 at 454.) Recently however, these numbers have increased dramatically, particularly in adolescent populations.

Recent surveys estimate that between 2-9% of high school students self- identify as transgender or “gender non-conforming.” with a significantly large increase in adolescents claiming “nonbinary” gender identity as well. (Johns et al. 2019; Kidd et al. 2021.) Consistent with these surveys, gender clinics around the world have seen numbers of referrals increase rapidly in the last decade, with the Tavistock clinic in London seeing a 30-fold increase in the last decade (GIDS 2019), and similar increases being observed in Finland (Kaltiala-Heino et al. 2018), the Netherlands (de Vries 2020), and Canada (Zucker 2019). The rapid change in the number of individuals experiencing gender dysphoria points to social and cultural, not biological, causes.

95. **Large change in sex ratio:** In recent years there has been a marked shift in the sex ratio of patients presenting with gender dysphoria or transgender identification. The Tavistock clinic in London saw a ratio of 4 biological females(F):5 biological males(M) shift to essentially 11F:4M in a decade. (GIDS 2019.) One researcher summarizing multiple sources documented a swing of 1F:2M or 1F:1.4M through 2005 to 2F:1M generally (but as high as 7F:1M) in more recent samples. (Zucker 2019 at 2.) This phenomenon has been noted by Dr. Erica Anderson, who said: “The data are very clear that adolescent girls are coming to gender clinics in greater proportion than adolescent boys. And this is a change in the last couple of years. And it’s an open question: What do we make of that? We don’t really know what’s going on. And we should be concerned about

it.” (Davis 2022.) Again, this large and rapid change in who is experiencing gender dysphoria points to social, not biological, causes.

96. **Clustering:** Dr. Littman’s recent study documented “clustering” of new presentations of gender dysphoria among natal females in specific schools and among specific friend groups. This again points strongly to social causes for gender dysphoria at least among the adolescent female population. (Littman 2018.)

97. **Desistance:** As I discuss later, there are very high levels of desistance among children diagnosed with gender dysphoria, as well as increasing (or at least increasingly vocal) numbers of individuals who first asserted a transgender identity during or after adolescence, underwent substantial medical interventions to “affirm” that trans-identity, and then “desisted” and reverted to a gender identity congruent with their sex. (See Section V.B below.) These narratives, too, point to a social and/or psychological cause, rather than a biological one.

98. **“Fluid” gender identification:** Advocates and some practitioners assert that gender identity is not binary but can span an almost endless range of gender identity self-labels, which a given individual may try on, inhabit, and often discard. (A recent article identifies 72.⁵) I have not heard any theory offered for how there is or could be a biological basis for gender identity as now expansively

⁵ Allarakha, *What Are the 72 Other Genders?*, MedicineNet, available at: https://www.medicinenet.com/what_are_the_72_other_genders/article.html

defined.

99. I frequently read attempts to explain away the points in this Section V. They include: these problems always existed, but children are now learning that there are effective treatments for their dilemma and are simply seeking them. And children have hidden their trans identity throughout childhood and now that trans people are recognized and accepted, they are presenting themselves. And now pediatricians realize that girls can have gender dysphoria and are referring them to gender clinics. But these are all mere hypotheses unsupported by concrete evidence. One set of unproven hypotheses cannot provide support for the unproven hypothesis of biological basis. And none of these hypotheses could even potentially explain the failure of science thus far to identify any predictive biological marker of transgender identification.

100. **Therapies affect gender identity outcomes:** Finally, the evidence shows that therapeutic choices can have a powerful effect on whether and how gender identity does change, or gender dysphoria desists. Social transition of juveniles, for instance, strongly influences gender identity outcomes to such an extent that it has been described a “unique predictor of persistence.” (See Section VI.B below.) Again, this observation cuts against the hypothesis of biological origin.

C. Disorders of sexual development (or DSDs) and gender identity are very different phenomena, and it is an error to conflate the two.

101. Some have pointed individuals who suffer from disorders of sexual development (DSDs) as evidence that sex is not binary or clearly defined, or as somehow supporting the idea that transgender identification has a biological basis. I have extensively detailed that sex is clear, binary, and determined at conception. (Section III.) Here I explain that gender dysphoria is an entirely different phenomenon than DSDs—which unlike transgender identity are indeed biological phenomena. It is an error to conflate the two distinct concepts.

102. Every DSD reflects a genetic enzymatic defect with negative anatomic and physiological consequences. As the Endocrine Society recognized in a 2021 statement: “Given the complexities of the biology of sexual determination and differentiation, it is not surprising that there are dozens of examples of variations or errors in these pathways associated with genetic mutations that are now well known to endocrinologists and geneticists; in medicine, these situations are generally termed *disorders of sexual development* (DSD) or *differences in sexual development*.” Gender Identity on the other hand is uniformly defined as a subjective “sense” of being, a feeling or state of mind. (Section II.C.)

103. The vast majority of those who experience gender dysphoria, or a

transgender identity, do not suffer from any DSD, nor from any genetic enzymatic disorder at all. Conversely, many who suffer from a DSD do not experience a gender identity different from their chromosomal sex (although some may). In short, those who suffer from gender dysphoria are not a subset of those who suffer from a DSD, nor are those who suffer from a DSD a subset of those who suffer from gender dysphoria. The two are simply different phenomena, one physical with psychological effects, the other mental with physical effects only if treated medically or surgically. The issue here is not whether biological forces play a role in personality development; it is whether there is strong evidence that it is determinative. Science has come too far to revert to single explanations for gender dysphoria or any psychiatric diagnosis.

104. The importance of this distinction is evident from the scientific literature. For example, in a recent study of clinical outcomes for gender dysphoric patients, Tavistock Clinic researchers *excluded* from their analysis any patients who did not have “normal endocrine function and karyotype consistent with birth registered sex.” (Carmichael et al. 2021 at 4.) In other words, the researchers specifically *excluded* from their study anyone who suffered from genetic-based DSD, or a DSD comprising any serious defect in hormonal use pathways, to ensure the study was focused only on individuals experiencing the psychological effects of what we might call “ordinary” gender dysphoria.

D. Studies of individuals born with DSDs suggest that there may be a biological predisposition towards *typical* gender identifications, but provide no support for a biological basis for *transgender* identification.

105. Studies of individuals born with serious DSDs have been pointed to as evidence of a biological basis for transgender identification. They provide no such support.

106. One well-known study by Meyer-Bahlburg reviewed the case histories of a number of XY (i.e. biologically male) individuals born with severe DSDs who were surgically “feminized” in infancy and raised as girls. (Meyer-Bahlburg 2005.) The majority of these individuals nevertheless later adopted male gender identity—suggesting a strong biological predisposition towards identification aligned with genetic sex, even in the face of feminized genitalia from earliest childhood, and parental “affirmation” in a transgender identity. But at the same time, the fact that some of these genetically male individuals did *not* later adopt male gender identity serves as evidence that medical and social influences can indeed encourage and sustain transgender identification.

107. Importantly, the Meyer-Bahlburg study did *not* include any individuals who were assigned a gender identity congruent with their genetic sex who subsequently adopted a *transgender* identity. Therefore, the study can provide no evidence of any kind that supports the hypothesis of a biological basis for

transgender identity. A second study in this area (Reiner & Gearhart 2004) likewise considered exclusively XY subjects, and similarly provides evidence only for a biological bias towards a gender identity congruent with one's genetic sex, even in the face of medical and social "transition" interventions. None of this provides any evidence at all of a biological basis for transgender identity.

VI. GENDER IDENTITY IS EMPIRICALLY NOT FIXED FOR MANY INDIVIDUALS.

108. There is extensive evidence that gender identity changes over time for many individuals.⁶ That evidence is summarized below.

A. Most children who experience gender dysphoria ultimately "desist" and resolve to cisgender identification.

109. A distinctive and critical characteristic of juvenile gender dysphoria is that multiple studies from separate groups and at different times have reported that in the large majority of patients, absent a substantial intervention such as social transition or puberty blocking hormone therapy, it does *not* persist through puberty.

110. A recent article reviewed all existing follow-up studies that the author could identify of children diagnosed with gender dysphoria (11 studies), and reported that "every follow-up study of GD children, without exception, found the same thing: By puberty, the majority of GD children ceased to want to transition."

⁶ See n1 *supra*.

(Cantor 2019 at 1.) Another author reviewed the existing studies and reported that in “prepubertal boys with gender discordance . . . the cross gender wishes usually fade over time and do not persist into adulthood, with only 2.2% to 11.9% continuing to experience gender discordance.” (Adelson et al. 2012 at 963; see also Cohen-Kettenis 2008 at 1895.) The Endocrine Society recognized this important baseline fact in its 2017 Guidelines. (Hembree 2017 at 3879.) It should be noted that the reason that the Dutch Protocol waited until age 14 to initiate puberty blockers was that it was well known that many children would desist if left free of hormonal intervention until that age.

111. Findings of high levels of desistance among children who experience gender dysphoria or incongruence have been reaffirmed in the face of critiques through thorough reanalysis of the underlying data. (Zucker 2018.)

112. As I explained in detail in Section V above, it is not yet known how to distinguish those children who will desist from that small minority whose trans identity will persist.

113. It does appear that prevailing circumstances during particularly formative years can have a significant impact on the outcome of a juvenile’s gender dysphoria. A 2016 study reviewing the follow-up literature noted that “the period between 10 and 13 years” was “crucial” in that “both persisters and desisters stated that the changes in their social environment, the anticipated and

actual feminization or masculinization of their bodies, and the first experiences of falling in love and sexual attraction in this period, contributed to an increase (in the persisters) or decrease (in the desisters) of their gender related interests, behaviors, and feelings of gender discomfort.” (Ristori & Steensma 2016 at 16.)

As I discuss in Section VII below, there is considerable evidence that early transition and affirmation causes far more children to persist in a transgender identity.

B. Desistance is increasingly observed among teens and young adults who first manifest GD during or after adolescence.

114. Desistance within a relatively short period may also be a common outcome for post-pubertal youths who exhibit recently described “rapid onset gender disorder.” I have observed an increasingly vocal online community of young women who have reclaimed a female identity after claiming a male gender identity at some point during their teen years, and young “detransitioners” (individuals in the process of reidentifying with their birth sex after having undergone a gender transition) are now receiving increasing attention in both clinical literature and social media channels.

115. Almost all scientific articles on this topic have appeared within the last few years.

Perhaps this historic lack of coverage is not entirely surprising – one academic who undertook an extensive review of the available scientific literature in 2021 noted that the phenomenon was “socially controversial” in that it “poses significant

professional and bioethical challenges for those clinicians working in the field of gender dysphoria.” (Expósito Campos 2021 at 270.) This review reported on the multiple reasons for why individuals were motivated to detransition, which included coming to “understand[] how past trauma, internalized sexism, and other psychological difficulties influenced the experience of GD.”

116. In 2021, Lisa Littman of Brown University conducted a groundbreaking study of 100 teenage and young adults who had transitioned and lived in a transgender identity for a number of years, and then “detransitioned” or changed back to a gender identity matching their sex. Littman noted that the “visibility of individuals who have detransitioned is new and may be rapidly growing.” (Littman 2021 at 1.) Of the 100 detransitioners included in Littman’s study, 60% reported that their decision to detransition was motivated (at least in part) by the fact that they had become more comfortable identifying as their natal sex, and 38% had concluded that their gender dysphoria was caused by something specific such as trauma, abuse, or a mental health condition. (Littman 2021 at 9.)

117. A significant majority (76%) did not inform their clinicians of their detransition. (Littman 2021 at 11.)

118. A similar study that recruited a sample of 237 detransitioners (the large majority of whom had initially transitioned in their teens or early twenties) similarly reported that a common reason for detransitioning was the subject’s

conclusion that his or her gender dysphoria was related to other issues (70% of the sample). (Vandenbussche 2021.)

119. The existence of increasing numbers of youth or young adult detransitioners has also been recently noted by Dr. Edwards-Leeper and Dr. Anderson. (Edwards-Leeper & Anderson 2021.) Edwards-Leeper and Anderson noted “the rising number of detransitioners that clinicians report seeing (they are forming support groups online)” which are “typically youth who experienced gender dysphoria and other complex mental health issues, rushed to medicalize their bodies and regretted it.” Other clinicians working with detransitioners have also noted the recent phenomenon. (Marchiano 2020.)

120. A growing body of evidence suggests that for many teens and young adults, a post-pubertal onset of transgender identification can be a transient phase of identity exploration, rather than a permanent identity, as evidenced by a growing number of young detransitioners (Entwistle 2020; Littman 2021; Vandenbussche 2021). Previously, the rate of detransition and regret was reported to be very low, although these estimates suffered from significant limitations and were likely undercounting true regret (D’Angelo 2018). As gender-affirmative care has become popularized, the rate of detransition appears to be accelerating.

121. A recent study from a UK adult gender clinic observed that 6.9% of those treated with gender-affirmative interventions detransitioned within 16 months, and another 3.4% had a pattern of care suggestive of detransition, yielding

a rate of probable detransition in excess of 10%. Another 21.7%, however, disengaged from the clinic without completing their treatment plan. While some of these individuals later re-engaged with the gender service, the authors concluded, “detransitioning might be more frequent than previously reported.” (Hall et al. 2021).

122. Another study from a UK primary care practice found that 12.2% of those who had started hormonal treatments either detransitioned or documented regret, while the total of 20% stopped the treatments for a wider range of reasons. The mean age of their presentation with gender dysphoria was 20, and the patients had been taking gender-affirming hormones for an average 5 years (17 months-10 years) prior to discontinuing. Comparing these much higher rates of treatment discontinuation and detransition to the significantly lower rates reported by the older studies, the researchers noted: “Thus, the detransition rate found in this population is novel and questions may be raised about the phenomenon of overdiagnosis, overtreatment, or iatrogenic harm as found in other medical fields” (Boyd et al. 2022 at 15.) Indeed, given that regret may take up to 8-11 years to materialize (Dhejne et al., 2014; Wiepjes et al., 2018), many more detransitioners are likely to emerge in the coming years. Detransitioner research is still in its infancy, but the Littman and Vandenbussche studies in 2021 both report that detransitioners from the recently transitioning cohorts feel they were rushed into medical gender-affirmative interventions with irreversible effects, often without

the benefit of appropriate, or in some instances any, psychologic exploration.

VII. TRANSITION AND AFFIRMATION ARE IMPORTANT PSYCHOLOGICAL AND MEDICAL INTERVENTIONS THAT CHANGE GENDER IDENTITY OUTCOMES.

A. If both a typical gender or a transgender long-term gender identity outcome are possible for a particular patient, the alternatives are not medically neutral.

123. Where a juvenile experiences gender dysphoria, the gender identity that is stabilized will have a significant impact on the course of their life. Living in a transgender identity for a time will make desistance, if it is ever considered, more difficult to accomplish.

124. If the juvenile desists from the gender dysphoria and becomes reasonably comfortable with a gender identity congruent with their sex—the most likely outcome from a statistical perspective absent affirming intervention—the child will not require ongoing pharmaceutical maintenance and will not have their fertility destroyed post-puberty.

125. However, if the juvenile persists in a transgender identity, under current practices, the child is most likely to require regular administration of hormones for the rest of their lives, exposing them to significant physical, mental health, and relational risks (which I detail in Section IX below), as well as being irreversibly sterilized chemically and/or surgically. The child is therefore rendered a “patient for life” with complex medical implications further to a scientifically

unproven course of treatment.

B. Social transition of young children is a powerful psychotherapeutic intervention that radically changes outcomes, almost eliminating desistance.

126. Social transition has a critical effect on the persistence of gender dysphoria. It is evident from the scientific literature that engaging in therapy that encourages social transition before or during puberty—which would include participation on athletic teams designated for the opposite sex—is a psychotherapeutic intervention that dramatically changes outcomes. A prominent group of authors has written that “The gender identity affirmed during puberty appears to predict the gender identity that will persist into adulthood.” (Guss et al. 2015 at 421.) Similarly, a comparison of recent and older studies suggests that when an “affirming” methodology is used with children, a substantial proportion of children who would otherwise have desisted by adolescence—that is, achieved comfort identifying with their natal sex—instead persist in a transgender identity. (Zucker 2018 at 7.)

127. Indeed, a review of multiple studies of children treated for gender dysphoria across the last three decades found that early social transition to living as the opposite sex severely reduces the likelihood that the child will revert to identifying with the child’s natal sex, at least in the case of boys. That is, while, as I review above, studies conducted before the widespread use of social transition for young children reported desistance rates in the range of 80-98%, a more recent

study reported that fewer than 20% of boys who engaged in a partial or complete social transition before puberty had desisted when surveyed at age 15 or older. (Zucker 2018 at 7⁷; Steensma et al. 2013.)⁸ Another researcher observed that a partial or complete gender social transition prior to puberty “proved to be a unique predictor of persistence.” (Singh et al. 2021 at 14.)

128. Some vocal practitioners of prompt affirmation and social transition even proudly claim that essentially *no* children who come to their clinics exhibiting gender dysphoria or cross- gender identification desist in that identification and return to a gender identity consistent with their biological sex.⁹ This is a very large change as compared to the desistance rates documented apart from social transition.

129. Even voices generally supportive of prompt affirmation and social transition are acknowledging a causal connection between social transition and this change in outcomes. As the Endocrine Society recognized in its 2017 Guidelines: “If children have completely socially transitioned, they may have great difficulty in returning to the original gender role upon entering puberty. . .

⁷ Zucker found social transition by the child to be strongly correlated with persistence for natal boys, but not for girls. (Zucker 2018 at 5.)

⁸ Only 2 (3.6%) of 56 of the male desisters observed by Steensma et al. had made a complete or partial transition prior to puberty, and of the twelve males who made a complete or partial transition prior to puberty, only two had desisted when surveyed at age 15 or older. Steensma 2013 at 584.

⁹ See, e.g., Ehrensaft 2015 at 34: “In my own clinical practice . . . of those children who are carefully assessed as transgender and who are allowed to transition to their affirmed gender, we have no documentation of a child who has ‘desisted’ and asked to return to his or her assigned gender.”

[S]ocial transition (in addition to GD/gender incongruence) has been found to contribute to the likelihood of persistence.” (Hembree et al. 2017 at 3879.) The fact is that these unproven interventions with the lives of kids and their families have systematically documented outcomes. Given this observed phenomenon, I agree with Dr. Ken Zucker who has written that social transition in children must be considered “a form of psychosocial treatment.” (Zucker 2020 at 1.)

130. Moreover, as I review below, social transition cannot be considered or decided alone. Studies show that engaging in social transition starts a juvenile on a “conveyor belt” path that almost inevitably leads to the administration of puberty blockers, which in turn almost inevitably leads to the administration of cross-sex hormones. The emergence of this well- documented path means that the implications of taking puberty blockers *and* cross-sex hormones must be taken into account even where “only” social transition is being considered or requested by the child or family. As a result, there are a number of important “known risks” associated with social transition.

C. Administration of puberty blockers is a powerful medical and psychotherapeutic intervention that radically changes outcomes, almost eliminating desistance on the historically observed timeline.

131. It should be understood that puberty blockers are usually administered to early-stage adolescents as part of a path that includes social transition. Yet medicine does not know what the long- term health effects on

bone, brain, and other organs are of a “pause” between ages 11-16. Medicine also does not know if the long-term effects of these compounds are different in boys than in girls. The mental health professional establishment likewise does not know the long-term effects on coping skills, interpersonal comfort, and intimate relationships of this “pause” while one’s peers are undergoing their maturational gains in these vital arenas of future mental health. I address medical, social, and mental health risks associated with the use of puberty blockers in Section X. Here, I note that the data strongly suggests that the administration of puberty blockers, too, must be considered to be a component of a “psychosocial treatment” with complex implications, rather than simply a “pause.”

132. Multiple studies show that the large majority of children who begin puberty blockers go on to receive cross-sex hormones. (de Vries 2020 at 2.) A recent study by the Tavistock and Portman NHS Gender Identity Development Service (UK)—the world’s largest gender clinic—found that 98% of adolescents who underwent puberty suppression continued on to cross-sex hormones. (Carmichael et al 2021 at 12.)¹⁰

133. These studies demonstrate that going on puberty blockers virtually eliminates the possibility of desistance in juveniles. Rather than a “pause,” puberty

¹⁰ See also Brik 2020 where Dutch researchers found nearly 97% of adolescents who received puberty blockers proceeded to cross-sex hormones.

blockers appear to act as a psychosocial “switch,” decisively shifting many children to a persistent transgender identity. Therefore, as a practical and ethical matter the decision to put a child on puberty blockers must be considered as the equivalent of a decision to put that child on cross-sex hormones, with all the considerations and informed consent obligations implicit in that decision.

VIII. TRANSITION AND AFFIRMATION ARE EXPERIMENTAL THERAPIES THAT HAVE NOT BEEN SHOWN TO IMPROVE MENTAL OR PHYSICAL HEALTH OUTCOMES BY YOUNG ADULTHOOD.

134. It is undisputed that children and adolescents who present with gender dysphoria exhibit a very high level of mental health comorbidities. (Section III.C.) Whether the gender dysphoria is cause or effect of other diagnosed or undiagnosed mental health conditions, or whether these are merely coincident comorbidities, is hotly disputed, but the basic fact is not.

135. It is important for all sides to admit that the knowledge base concerning the causes and treatment of gender dysphoria has low scientific quality. In evaluating claims of scientific or medical knowledge, it is axiomatic in science that no knowledge is absolute, and to recognize the widely accepted hierarchy of reliability when it comes to “knowledge” about medical or psychiatric phenomena and treatments. Unfortunately, in this field opinion is too often confused with knowledge, rather than clearly locating what exactly is scientifically known. In order of increasing confidence, such “knowledge” may be based upon data

comprising:

a. Expert opinion—it is perhaps surprising to educated laypersons that expert opinion standing alone is the lowest form of knowledge, the least likely to be proven correct in the future. Reliance on a well-known, or well-credentialled “experts” or head of a gender clinic is sometimes referred to as eminence-based medicine. Their opinions do not garner as much respect from professionals as what follows;

b. A single case or series of cases (what could be called anecdotal evidence) (Levine 2016 at 239.);

c. A series of cases with a control group;

d. A cohort study;

e. A randomized double-blind clinical trial;

f. A review of multiple trials;

g. A meta-analysis of multiple trials that maximizes the number of patients treated despite their methodological differences to detect trends from larger data sets.

136. Prominent voices in the field have emphasized the severe lack of scientific knowledge in this field. The American Academy of Child and Adolescent Psychiatry has recognized that “Different clinical approaches have been advocated for childhood gender discordance. . . . There have been no randomized controlled trials of any treatment [T]he proposed benefits of

treatment to eliminate gender discordance ... must be carefully weighed against ... possible deleterious effects.” (Adelson et al. at 968–69.) Similarly, the American Psychological Association has stated, “because no approach to working with [transgender and gender nonconforming] children has been adequately, empirically validated, consensus does not exist regarding best practice with pre-pubertal children.” (APA 2015 at 842.)

137. Critically, “there are no randomized control trials with regard to treatment of children with gender dysphoria.” (Zucker 2018 at 8.) On numerous critical questions relating to cause, developmental path if untreated, and the effect of alternative treatments, the knowledge base remains primarily at the level of the practitioner’s exposure to individual cases, or multiple individual cases. As a result, claims to certainty are not justifiable. (Levine 2016 at 239.)

138. Within the last two years, at least four formal, independent, systematic evidence reviews concerning hormonal interventions for gender dysphoria have been conducted. All four found all of the available clinical evidence to be very low quality.

139. The British National Health Service (NHS) commissioned formal “evidence reviews” of all clinical papers concerning the efficacy and safety of puberty blockers and cross- sex hormones as treatments for gender dysphoria. These evidence reviews were performed by the U.K. National Institute for Health and Care Excellence (NICE), applying the respected “GRADE” criteria for

evaluating the strength of clinical evidence.

140. Both the review of evidence concerning puberty blockers and the review of evidence concerning cross-sex hormones were published in 2020, and both found that *all* available evidence as to both efficacy and safety was “very low quality” according to the GRADE criteria. (NICE 2021a; NICE 2021b.) This work is sometimes referred to as the Cass Report.¹¹ “Very low quality” according to GRADE means there is a high likelihood that the patient *will not experience* the hypothesized benefits of the treatment. (Balshem et al. 2011.)

141. Similarly, the highly respected Cochrane Library—the leading source of independent systematic evidence reviews in health care—commissioned an evidence review concerning the efficacy and safety of hormonal treatments now commonly administered to “transitioning transgender women” (i.e., testosterone suppression and estrogen administration to biological males). That review, also published in 2020, concluded that “We found insufficient evidence to determine the efficacy or safety of hormonal treatment approaches for transgender women in transition.” (Haupt et al. 2020 at 2.) It must be understood that both the NICE and the Cochrane reviews considered *all* published scientific studies concerning these treatments. Similarly, McMaster University’s skillful

¹¹ <https://cass.independent-review.uk/publications/interim-report/>

methodological unit recently reached the same conclusion (Brignardello-Peterson, & Wiercioch, 2022).

142. As to social transition, as I have noted above, considerable evidence suggests that socially transitioning a pre-pubertal child puts him or her on a path from which very few children escape—a path which includes puberty blockers and cross-sex hormones before age 18. And for some, surgery before the age of majority. A decision about social transition for a child must be made in light of what is known and what is unknown about the effects of those expected future interventions. Social transition, therefore, is not merely reversible behavioral change. It is the beginning of a medically dependent future and should be explained as such.

143. I discuss safety considerations in Section IX below. Here, I detail what is known about the effectiveness of social and hormonal transition and affirmation to improve the mental health of individuals diagnosed with gender dysphoria.

B. Youth who adopt a transgender identity show no durable improvement in mental health after social, hormonal, or surgical transition and affirmation.

144. As I noted above, the evidence reviews for the efficacy and safety of hormonal interventions published in 2020 concluded that the supporting evidence is so poor that there is “a high likelihood that the patient will not experience the hypothesized benefits of the treatment.” There is now some concrete evidence that

on average they do not experience those benefits.

145. An important paper published in 2021 by Tavistock clinic clinicians provided the results of the first longitudinal study that measured widely used metrics of general psychological function and suicidality before commencement of puberty blockers, and then at least annually after commencing puberty blockers. After up to three years, they “found no evidence of change in psychological function with GnRHa treatment as indicated by parent report (CBCL) or self-report (YSR) of overall problems, internalizing or externalizing problems or self-harm” as compared to the pre-puberty-blocker baseline evaluations. “Outcomes that were not formally tested also showed little change.” (Carmichael et al. 2021 at 18-19.) Similarly, a study by Bränström and Pachankis of the case histories of a set of individuals diagnosed with GD in Sweden found no positive effect on mental health from hormonal treatment. (Landen 2020.)

146. A cohort study by authors from Harvard and Boston Children’s Hospital found that youth and young adults (ages 12-29) who self-identified as transgender had an elevated risk of depression (50.6% vs. 20.6%) and anxiety (26.7% vs. 10.0%); a higher risk of suicidal ideation (31.1% vs. 11.1%), suicide attempts (17.2% vs. 6.1%), and self-harm without lethal intent (16.7% vs. 4.4%) relative to the matched controls; and a significantly greater proportion of transgender youth accessed inpatient mental health care (22.8% vs. 11.1%) and outpatient mental health care (45.6% vs. 16.1%) services. (Reisner et al. 2015 at 6.)

Similarly, a recent longitudinal study of transgender and gender diverse youth and young adults in Chicago found rates of alcohol and substance abuse “substantially higher than those reported by large population-based studies of youth and adults.” (Newcomb et al. 2020 at 14.) Members of the clinical and research team at the prominent Dutch VU University gender dysphoria center recently compared mental health metrics of two groups of subjects before (mean age 14.5) and after (mean age 16.8) puberty blockers. But they acknowledged that the structure of their study meant that it “can . . . not provide evidence about . . . long-term mental health outcomes,” and that based on what continues to be extremely limited scientific data, “Conclusions about the long-term benefits of puberty suppression should . . . be made with extreme caution.” In other words, we just don’t know. (van der Miesen et al. 2020 at 703.)

147. Kiera Bell, who was diagnosed with gender dysphoria at the Tavistock Clinic, given cross-sex hormones, and treated by mastectomy, before desisting and reclaiming her female gender identity, and a Swedish teen girl who appeared in a recent documentary after walking that same path, have both stated that they feel that they were treated “like guinea pigs,” experimental subjects. They are not wrong.

148. A recent two-year prospective uncontrolled multisite NIMH study of 315 adolescents found that at the average age of 18 the primary benefit of hormones was happiness with their aesthetic appearance. The effects on

depression and anxiety were very small and highly variable. There were two suicides in the study population. (Chen et al, 2023). This work did not address the relevant long term mental health outcomes of such treatment before their two-year finding.

C. Long-term mental health outcomes for individuals who persist in a transgender identity are poor.

149. The responsible MHP cannot focus narrowly on the short-term happiness of the young patient, but must instead consider the happiness and health of the patient from a “life course” perspective. When we look at the available studies of individuals who continue to inhabit a transgender identity across adult years, the results are strongly negative.

150. In the United States, the death rates of trans veterans are comparable to those with schizophrenia and bipolar diagnoses—20 years earlier than expected. These crude death rates include significantly elevated rates of substance abuse as well as suicide. (Levine 2017 at 10.) Similarly, researchers in Sweden and Denmark have reported on almost all individuals who underwent sex-reassignment surgery over a 30-year period. (Dhejne et al. 2011; Simonsen et al. 2016.) The Swedish follow-up study similarly found a suicide rate in the post-SRS population 19.1 times greater than that of the controls; both studies demonstrated elevated mortality rates from medical and psychiatric conditions. (Levine 2017 at 10.)

151. A study in the American Journal of Psychiatry reported high mental

health utilization patterns of adults for ten years after surgery for approximately 35% of patients. (Bränström & Pachankis, 2020.) Indeed, earlier Swedish researchers in a long-term study of all patients provided with SRS over a 30-year period (median time since SRS of > 10 years) concluded that individuals who have SRS exhibit such poor mental health that they should be provided very long-term psychiatric care as the “final” transition step of SRS. (Dhejne et al. 2011, at 6-7.) Unfortunately, across the succeeding decade, in Sweden and elsewhere their suggestion has been ignored.

152. The most recent all-cause mortality study from the UK found a significant excess of deaths among trans individuals compared to age matched controls of both sexes. External causes of death (suicide, homicide, accidental poisoning) were particularly higher than control groups (Jackson et al, 2023).

153. I will note that these studies do not tell us whether the subjects first experienced gender dysphoria as children, adolescents, or adults, so we cannot be certain how their findings apply to each of these subpopulations which represent quite different pathways. But in the absence of knowledge, we should be cautious.

154. Meanwhile, no studies show that affirmation of pre-pubescent children or adolescents leads to more positive outcomes (mental, physical, social, or romantic) by, e.g., age 25 or older than does “watchful waiting” or ordinary therapy.

155. The many studies that I have cited here warn us that as we look ahead to the patient's life as a young adult and adult, the prognosis for the physical health, mental health, and social well-being of the child or adolescent who transitions to live in a transgender identity is not good. Gender dysphoria is not "easily managed" when one understands the marginalized, vulnerable physical, social, and psychological status of adult trans populations.

IX. TRANSITION AND AFFIRMATION DO NOT DECREASE, AND MAY INCREASE, THE RISK OF SUICIDE.

A. The risk of suicide among transgender youth is confused and exaggerated in the public mind.

156. While suicide is closely linked to mental health, I comment on it separately because rhetoric relating to suicide figures so prominently in debates about responses to gender dysphoria.

157. At the outset, I will note that any discussion of suicide when considering younger children involves very long-range and very uncertain prediction. Suicide in pre-pubescent children is extremely rare, and the existing studies of gender identity issues in pre-pubescent children do not report significant incidents of suicide. Any suggestion otherwise is misinformed. Our focus for this topic, then, is on adolescents and adults.

158. Some authors have reported rates of suicidal thoughts and behaviors among trans- identifying teens or adults ranging from 25% to as high as 52%,

generally through non- longitudinal self-reports obtained from non-representative survey samples. (Toomey et al. 2018.) Some advocates of affirmative care assert that the only treatment to avoid this serious harm is to affirm gender identity. Contrary to these assertions, no studies show that affirmation of children (or anyone else) reduces suicide, prevents suicidal ideation, or improves long-term outcomes, as compared to either a “watchful waiting” or a psychotherapeutic model of response, as I have described above. Rhetorical references to figures such as 40%—and some published studies—confuse suicidal thoughts and actions that represent a cry for help, manipulation, or expression of rage with serious attempts to end life. Such statements or studies ignore a crucial and long-recognized distinction.

159. I have included suicidality in my discussion of mental health above. Here, I focus on actual suicide. Too often, in public comment suicidal thoughts are blurred with suicide. Yet the available data tells us that suicide among children and youth suffering from gender dysphoria is extremely rare.

160. An important analysis of data covering patients as well as those on the waiting list (and thus untreated) at the UK Tavistock gender clinic—the world’s largest gender clinic—found a total of only four completed suicides across 11 years’ worth of patient data, reflecting an estimated cumulative 30,000 patient-years spent by patients under the clinic’s care or on its waiting list. This corresponded to an annual suicide rate of 0.013%. The proportion of individual

patients who died by suicide was 0.03%, which is orders of magnitude smaller than trans adolescents who self-report suicidal behavior or thoughts on surveys. (Biggs 2022b.)

161. Thus, only a minute fraction of trans-identifying adolescents who report thoughts or conduct considered to represent “suicidality” commit suicide. I agree with Dr. Zucker that the assertion by, for example, Karasic and Ehrensaft (2015) that completed suicides among transgender youth are “alarmingly high” “has no formal and systematic empirical basis.” (Zucker 2019 at 3.)

162. Professor Biggs of Oxford, author of the study of incidence of suicide among Tavistock clinic patients, rightly cautions that it is “irresponsible to exaggerate the prevalence of suicide.” (Biggs 2022b at 4.) It is my opinion that telling parents—or even allowing them to believe from their internet reading—that they face a choice between “a live son or a dead daughter” is both factually wrong and unethical. Informed consent requires clinicians to tell the truth and ensure that their patients understand the truth. To be kind, the clinicians who believe such figures represent high risk of ultimate suicide in adolescence simply do not know the truth; they are ill-informed.

B. Transition of any sort has not been shown to reduce levels of suicide.

163. Every suicide is a tragedy, and steps that reduce suicide should be adopted. I have noted above that suicidality (that is, suicidal thoughts or behaviors, rather than suicide) is common among transgender adolescents and young adults

before, during, and after social and medical transition. If a medical or mental health professional believes that an individual he or she is diagnosing or treating for gender dysphoria presents a suicide risk, in my view it is unethical for that professional merely to proceed with treatment for gender dysphoria and hope that “solves the problem.” Rather, that professional has an obligation to provide or refer the patient for evidence-based therapies for addressing depression and suicidal thoughts that are well-known to the profession. (Levine 2016 at 242.)

164. This is all the more true because there is in fact no evidence that social and/or medical transition reduces the risk or incidence of actual suicide. As there are no long-term comparative studies of gender dysphoric adolescents with suicidal ideation, per se, let alone a comparative study of those who were given hormones and those who did not take hormones, there is no scientific basis for declaring affirmative care as reducing suicidal risk. In his analysis of those who were patients of or on the waiting list of the Tavistock clinic, Professor Biggs found that the suicide rate was not higher among those on the clinic’s waiting list (and thus as-yet untreated), than for those who were patients under care. (Biggs 2022b.) And as corrected, Bränström and Pachankis similarly acknowledge that their review of records of GD patients “demonstrated no advantage of surgery in relation to . . . hospitalizations following suicide attempts.” (I assume for this purpose that attempts that result in hospitalization are judged to be so serious as to

predict a high rate of future suicide if not successfully addressed.”)¹² Long-term life in a transgender identity, however, correlates with very high rates of completed suicide.

165. As with mental health generally, the patient, parent, or clinician fearing the risk of suicide must consider not just the next month or year, but a life course perspective.

166. There are now four long-term studies that analyze completed suicide among those living in transgender identities into adulthood. The results vary significantly but are uniformly highly negative. Dhejne reported a long-term follow-up study of subjects after sex reassignment surgery. Across the multi-year study, subjects who had undergone SRS committed suicide at 19.1 times the expected rate compared to general population controls matched by age and both sexes. MtF subjects committed suicide at 13.9 times the expected rate, and FtM subjects committed suicide at 40.0 times the expected rate. (Dhejne et al. 2011 Supplemental Table S1.)

167. Asscheman, also writing in 2011, reported results of a long-term follow-up of all transsexual subjects of the Netherlands’ leading gender medicine clinic who started cross-sex hormones before July 1, 1997, a total of 1331

¹² Turban et al. (2020) has been described in press reports as demonstrating that administration of puberty suppressing hormones to transgender adolescents reduces suicide or suicidal ideation. The paper itself does not make that claim, nor permit that conclusion.

patients. Due to the Dutch system of medical and death records, extensive follow-up was achieved. Median follow-up period was 18.5 years. The mortality rate among MtF patients was 51% higher than among the age-matched general population; the rate of completed suicide among MtF patients was six times that of the age-matched general population. (Asscheman et al. 2011.)

168. Importantly, Asscheman et al. found that “No suicides occurred within the first 2 years of hormone treatment, while there were six suicides after 2-5 years, seven after 5-10 years, and four after more than 10 years of CSH treatment at a mean age of 41.5 years.” (Asscheman et al. 2011 at 637-638.) This suggests that studies that follow patients for only a year or two after treatment are insufficient. Asscheman et al.’s data suggest that such short-term follow-up is engaging only with an initial period of optimism, and will simply miss the feelings of disillusion and the increase in completed suicide that follows in later years.

169. A retrospective, long-term study published in 2020 of a very large cohort (8263) of patients referred to the Amsterdam University gender clinic between 1972 and 2017 found that the annual rate of completed suicides among the transgender subjects was “three to four times higher than the general Dutch population.” “[T]he incidence of observed suicide deaths was almost equally distributed over the different stages of treatment.” The authors concluded that “vulnerability for suicide occurs similarly in the different stages of transition.”

(Wiepjes et al. 2020.) In other words, neither social nor medical transition reduced the rate of suicide.

170. As with Asscheman et al., Wiepjes et al. found that the median time between start of hormones and suicide (when suicide occurred) was 6.1 years for natal males, and 6.9 years for natal females. Again, short- or even medium-term studies will miss this suicide phenomenon.

171. A 2021 study analyzed the case histories of a cohort of 175 gender dysphoria patients treated at one of the seven UK adult gender clinics who were “discharged” (discontinued as patients) within a selected one-year period. The authors reported the rather shocking result that 7.7% (3/39) of natal males who were diagnosed and admitted for treatment, and who were between 17 and 24 years old, were “discharged” because they committed suicide during treatment. (Hall et al. 2021, Table 2.)

172. None of these studies demonstrates that the hormonal or surgical intervention *caused* suicide. That is possible, but as we have seen, the population that identifies as transgender suffers from a high incidence of comorbidities that correlate with suicide. What these studies demonstrate—at the least—is that this remains a troubled population in need of extensive and careful psychological care that they generally do not receive, and that neither hormonal nor surgical transition and “affirmation” resolve their underlying problems and put them on the path to a stable and healthy life.

173. In sum, claims that affirmation will reduce the risk of suicide for children and adolescents are not based on science. Instead, transition of any sort must be justified, if at all, as a life-enhancing measure, not a lifesaving measure. (Levine 2016 at 242.) In my opinion, this is an important fact that patients, parents, and even many MHPs fail to understand.

X. HORMONAL INTERVENTIONS ARE EXPERIMENTAL PROCEDURES THAT HAVE NOT BEEN PROVEN SAFE.

174. A number of voices in the field assert that puberty blockers act merely as a “pause” in the process of puberty-driven maturation, suggesting that this hormonal intervention has been proven to be fully reversible. This is also an unproven belief.

175. On the contrary, no studies have been done that meaningfully demonstrate that either puberty blockers or cross-sex hormones, as prescribed for gender dysphoria, are safe in other than the short run. No studies have attempted to determine whether the effects of puberty blockers, as currently being prescribed for gender dysphoria, are fully reversible. There are only pronouncements. In fact, there are substantial reasons for concern that these hormonal interventions are not safe. Multiple researchers have expressed concern that the full range of possible harms have not even been correctly conceptualized.

176. Because, as I have explained in Section VI, recent evidence demonstrates that pre- pubertal social transition almost always leads to progression

on to puberty blockers which in turn almost always leads to the use of cross-sex hormones, physicians bear the ethical responsibility for a thorough informed consent process for parents and patients that includes this fact and its full implications. Informed consent does not mean sharing with the parents and patients what the doctor believes: it means sharing what is known and what is not known about the intervention. So much of what doctors believe is based on mere trust in what they have been taught. Neither they themselves nor their teachers may be aware of the scientific foundation and scientific limitations of what they are recommending.

A. Use of puberty blockers has not been shown to be safe or reversible for gender dysphoria.

177. As I noted above, the recent very thorough literature review performed for the British NHS concluded that *all* available clinical evidence relating to “safety outcomes” from administration of puberty blockers for gender dysphoria is of “very low certainty.” (NHS 2020a at 6.)

178. In its 2017 Guidelines, the Endocrine Society cautioned that “in the future we need more rigorous evaluations of the effectiveness and safety of endocrine and surgical protocols” including “careful assessment of . . . the effects of prolonged delay of puberty in adolescents on bone health, gonadal function, and the brain (including effects on cognitive, emotional, social, and sexual development).” (Hembree et al. 2017 at 3874.) No such “careful” or

“rigorous” evaluation of these very serious safety questions has yet been done.

179. Some advocates assume that puberty blockers are “safe” because they have been approved by the Food and Drug Administration (FDA) for use to treat precocious puberty—a rare condition in which the puberty process may start at eight or younger. No such conclusion can be drawn. As the “label” for Lupron (one of the most widely prescribed puberty blockers) explains, the FDA approved the drug only *until* the “age was appropriate for entry into puberty.” The study provides no information at all as to the safety or reversibility of instead *blocking* healthy, normally-timed puberty’s beginning, and *throughout* the years that body-wide continuing changes normally occur. Given the physical, social, and psychological dangers to the child with precocious puberty, drugs like Lupron are effective in returning the child to a puerile state like their peers without a high incidence of significant side effects—that is, they are “safe” to reverse the condition. But use of drugs to suppress normal puberty has multiple organ system effects whose long-term consequences have not been investigated.

180. Systematic data reviews are scientifically more reliable than individual reports with definable methodologic limitations. Without quoting extensively from the reviews done by Sweden, Finland, UK, and McMasters University, suffice it to say that their conclusions agree that the risks of puberty suppression and cross-sex hormones outweigh the possible benefits. They also point to the great unexplained increase in incidence of gender dysphoria, the

increased incidence of detransition and regret, and the lack of evidence of efficacy.¹³(Swedish National Board of Health and Welfare, 2022).

181. **Fertility:** The Endocrine Society Guidelines rightly say that research is needed into the effect of puberty blockade on “gonadal function” and “sexual development.” The core purpose and function of puberty blockers is to prevent the maturation of the ovaries or testes, the sources of female hormones and male hormones when stimulated by the pituitary gland. From this predictable process fertility is accomplished within a few years. Despite widespread assertions that puberty blockers are “fully reversible,” there has been no study published on the critical question of whether patients ever develop normal levels of fertility if puberty blockers are terminated after a “prolonged delay of puberty.” The 2017 Endocrine Society Guidelines are correct that there are no data on achievement of fertility “following prolonged gonadotropin suppression” (that is, puberty blockade). (Hembree et al. 2017 at 3880.)

182. **Bone strength:** Multiple studies have documented adverse effects from puberty blockers on bone density. (Klink et al. 2015; Vlot et al. 2016; Joseph et al. 2019.) The most recent found that after two years on puberty blockers, the bone density measurements for a significant minority of the children had declined to clinically concerning levels. Density in the spines of some subjects fell to a level found in only 0.13% of the population. (Biggs 2021.) Some other studies have

¹³ <https://www.sociialstyrelsen.se/globalassets/sharepoint-dokument/artikelkatalog/kunskapsstod/2022-7799.pdf>

found less concerning effects on bone density. While the available evidence remains limited and conflicting, it is not possible to conclude that the treatment is “safe.”

183. **Brain development:** Important neurological growth and development in the brain occurs across puberty. The anatomic and functional effect on brain development of blocking the natural puberty process has not been well studied. A prominent Australian clinical team recently expressed concern that “no data were (or are) available on whether delaying the exposure of the brain to a sex steroid affects psychosexual, cognitive, emotional, or other neuropsychological maturation.” (Kozłowska et al. 2021 at 89.) In my opinion, given the observed correlation between puberty and brain development, the default hypothesis must be that there *would* be a negative impact. For the purpose of protecting patients all over the world, the burden of proof should be on advocates to first demonstrate to a reasonable degree of certainty that brain structure and its measurable cognitive and affect processing are not negatively affected. This recalls the ethical principle: Above All Do No Harm.

184. The Endocrine Society Guidelines acknowledge as much, stating that side effects of pubertal suppression “may include . . . unknown effects on brain development,” that “we need more rigorous evaluations of . . . the effects of prolonged delay of puberty in adolescents on . . . the brain (including effects on cognitive, emotional, social, and sexual development),” and stating that “animal

data suggests there may be an effect of GnRH analogs [puberty blockers] on cognitive function.” (Hembree et al. 2017 at 3874, 3882, 3883.) Given this concern, one can only wonder why this relevant question has not been scientifically investigated in a large group of natal males and females.

185. There has been a longitudinal study of one natal male child, assessed before, and again 20 months after, puberty suppression was commenced. It reported a reduction in the patient’s “global IQ,” measured an anomalous absence of certain structural brain development expected during normal male puberty, and hypothesized that “a plausible explanation for the G[lobal] IQ decrease should consider a disruption of the synchronic [i.e., appropriately timed] development of brain areas by pubertal suppression.” (Schneider et al. 2017 at 7.) This should cause parents and practitioners serious concern.

186. Whether any impairment of brain development is “reversed” upon later termination of puberty blockade has, to my knowledge, not been studied at all. As a result, assertions by medical or mental health professionals that puberty blockade is “fully reversible” are unjustified and based on hope rather than science.

187. Without a number of additional case studies—or preferably statistically significant clinical studies—two questions remain unanswered: Are there brain anatomic or functional impairment from puberty blockers? And are the documented changes reversed over time when puberty blockers are stopped? With

these questions unanswered, it is impossible to assert with certainty that the effects of this class of medications are “fully reversible.” Such an assertion is another example of ideas based on beliefs rather than on documentation, on hope not science.

188. **Psycho-social harm:** Puberty is a time of stress, anxiety, bodily discomfort during physical development, and identity formation for *all* humans. No careful study has been done of the long-term impact on the young person’s coping skills, interpersonal comfort, and intimate relationships from remaining puerile for, e.g., two to five years while one’s peers are undergoing pubertal transformations, and of then undergoing an artificial puberty at an older age. However, pediatricians and mental health professionals hear of distress, concern, and social awkwardness in those who naturally have a delayed onset of puberty. In my opinion, individuals in whom puberty is delayed multiple years are likely to suffer at least subtle negative psychosocial and self-confidence effects as they stand on the sidelines witnessing their peers developing the social relationships (and attendant painful social learning experiences) that come with adolescence. (Levine 2018 at 9.) Social anxiety and social avoidance are common findings in the evaluation of trans-identified children and teens. Are we expected to believe that creating years of being further different than their peers has no lasting internal consequences? Do we ignore Adolescent Psychiatry’s knowledge of the importance of peer groups among adolescents?

189. We simply do not know what all the psychological impacts of NOT grappling with puberty at the ordinary time may be, because it has not been studied. And we have no information as to whether that impact is “fully reversible.”

190. In addition, since the overwhelming proportion of children who begin puberty blockers continue on to cross-sex hormones, it appears that there is an important element of “psychological irreversibility” in play. The question of to what extent the physical and developmental impacts of puberty blockers might be reversible is an academic one, if psycho- social realities mean that very few patients will ever be able to make that choice once they have started down the road of social transition and puberty blockers.

B. Use of cross-sex hormones in adolescents for gender dysphoria has not been shown to be medically safe except in the short term.

191. As with puberty blockers, all evidence concerning the safety of extended use of cross-sex hormones is of “very low quality.” The U.K. NICE evidence review cautioned that “the safety profiles” of cross-sex hormone treatments are “largely unknown,” and that several of the limited studies that do exist reported high numbers of subjects “lost to follow-up,” without explanation—a worrying indicator. (NICE 2020b.)

192. The 2020 Cochrane Review reported that: “We found insufficient evidence to determine the . . . safety of hormonal treatment approaches for

transgender women in transition.” (Haupt et al. 2020 at 4.) Even the Endocrine Society tagged all its recommendations for the administration of cross-sex hormones as based on “low quality evidence.” (Hembree et al. 2017 at 3889.)

193. **Sterilization:** It is undisputed, however, that harm to the gonads is an expected effect, to the extent that it must be assumed that cross-sex hormones will sterilize the patient. Thus, the Endocrine Society 2017 Guidelines caution that “[p]rolonged exposure of the testes to estrogen has been associated with testicular damage,” that “[r]estoration of spermatogenesis after prolonged estrogen treatment has not been studied,” and that “[i]n biological females, the effect of prolonged treatment with exogenous testosterone upon ovarian function is uncertain.” (Hembree et al. 2017 at 3880.)¹⁴

194. The Guidelines go on to recommend that the practitioner counsel the patient about the (problematic and uncertain) options available to collect and preserve fertile sperm or ova before beginning cross-sex hormones. The life-long negative emotional impact of infertility on both men and women has been well studied. While this impact has not been studied specifically within the transgender population, the opportunity to be a parent is likely a human, emotional need, and so should be considered an important risk factor when considering gender

¹⁴ See also Guss et al. 2015 at 4 (“a side effect [of cross-sex hormones] may be infertility”) and at 5 (“cross-sex hormones . . . may have irreversible effects”); Tishelman et al. 2015 at 8 (Cross-sex hormones are “irreversible interventions” with “significant ramifications for fertility”).

transition for any patient. What has been documented is the low rate of acceptance of banking sperm or ova in this population.

195. **Sexual response:** Puberty blockers prevent maturation of the sexual organs and response. Some, and perhaps many, transgender individuals who did not go through puberty consistent with their sex and are then put on cross-sex hormones face significantly diminished sexual response as they enter adulthood and are unable ever to experience orgasm. In the case of males, the cross-sex administration of estrogen limits penile genital growth and function. In the case of females, prolonged exposure to exogenous testosterone impairs vaginal function. Much has been written about the negative psychological and relational consequences of anorgasmia among non-transgender individuals that is ultimately applicable to the transgendered. (Levine 2018 at 6.) At the same time, prolonged exposure of females to exogenous testosterone often increases sexual drive to a distracting degree. It is likely that parents and physicians are uncomfortable discussing any aspects of genital sexual activity with patients. And these young often interpersonally sexually inexperienced patients are both too embarrassed to talk about the subject and too young to seriously consider the topic.

196. **Cardiovascular harm:** Several researchers have reported that cross-sex hormones increase the occurrence of various types of cardiovascular disease, including strokes, blood clots, and other acute cardiovascular events. (Getahun et al. 2018; Guss et al. 2015; Asscheman et al. 2011.) With that said, I agree with the

conclusion of the Endocrine Society committee (like that of the NICE Evidence Review) that: “A systematic review of the literature found that data were insufficient (due to very low–quality evidence) to allow a meaningful assessment of patient-important outcomes, such as death, stroke, myocardial infarction, or venous thromboembolism in transgender males. Future research is needed to ascertain the potential harm of hormonal therapies.” (Hembree et al. 2017 at 3891.) Future research questions concerning long-term harms need to be far more precisely defined. The question of whether cross-sex hormones are safe for adolescents and young adults cannot be answered by analogies to hormone replacement therapy in menopausal women (which is not a cross-sex usage). Medicine has answered safety questions for menopausal women in terms of cancer and cardiovascular safety: at what dose, for what duration, and at what age range. The science of endocrine treatment of gender dysphoric youth is being bypassed by short-term clinical impressions of safety even though physicians know that cardiovascular and cancer processes often develop over many years.

197. Further, in contrast to administration for menopausal women, hormones begun in adolescence are likely to be administered for four to six decades. The published evidence of adverse impact, coupled with the lack of data sufficient to reach a firm conclusion, make it irresponsible to assert that cross-sex hormones “are safe.”

198. **Harm to family and friendship relationships:** As a psychiatrist, I recognize that mental health is a critical part of health generally, and that relationships cannot be separated from and profoundly impact mental health. Gender transition routinely leads to isolation from at least a significant portion of one's family in adulthood. In the case of a juvenile transition, this will be less dramatic while the child is young, but commonly increases over time as siblings who marry and have children of their own do not wish the transgender individual to be in contact with those children. By adulthood, the friendships of transgender individuals tend to be confined to other transgender individuals (often "virtual" friends known only online) and the generally limited set of others who are comfortable interacting with transgender individuals. (Levine 2017 at 5.) My concerns about this are based on decades of observations in my professional work with patients and their families. It is important to recognize that the tradition throughout medicine is the focus on the patient. This is true in adolescent medicine as well and seems natural and self-evident. However, when a trans identity occurs in a family, every member—parents, siblings, grandparents, etc—is affected. I am used to watching parents become depressed, siblings take sides, and family dysfunction increase. It is rare to find a medical or mental health professional whose work reflects that each of these family members are deeply connected and share in the uncertainties that are embedded in any trans identity.

199. **Sexual-romantic harms associated with transition:** After adolescence, transgender individuals find the pool of individuals willing to develop a romantic and intimate relationship with them to be greatly diminished. When a trans person who passes well reveals his or her natal sex, many potential mates lose interest. When a trans person does not pass well, options are likely further diminished. But regardless of a person's appearance, these adults soon learn that many of their dates are looking for exotic sexual experiences rather than genuinely loving relationships. (Levine 2017 at 5, 13; Levine 2013 at 40.)

C. The timing of harms.

200. The multi-year delay between start of hormones and the spike in completed suicide observed by Professor Biggs in the Tavistock data (as discussed in Section VIII above) warns us that the safety and beneficence of these treatments cannot be judged based on short- term studies, or studies that do not continue into adulthood. Similarly, several of the harms that I discuss above would not be expected to manifest until the patients reaches at least middle-age. For example, stroke or other serious cardiovascular event is a complication that is unlikely to manifest during teen years even if its likelihood over the patient's lifetime has been materially increased via obesity, lipid abnormalities, and smoking. Regret over sterilization or over an inability to form a stable romantic relationship may occur sooner. Psychological challenges of being a trans adult may become manifest after the medical profession is only doing routine follow up care—or, in

many cases, has lost contact with the patient altogether. Because few, if any, clinics in this country are conducting systematic long-term follow-up with their child and adolescent patients, the doctors who counsel, prescribe, or perform hormonal and surgical therapies are unlikely ever to become aware of the later negative life impacts, however severe. These concerns are compounded by the findings in the recent “detransitioner” research that 76% did not inform their clinicians of their detransition. (Littman 2021.)

201. The possibility that steps along the transition and affirmation pathway, while lessening the pain of gender dysphoria in the short term, could lead to additional sources of crippling emotional and psychological pain, are too often not considered by advocates of social transition and not considered at all by the trans child. (Levine 2016 at 243.) Clinicians must distinguish the apparent short-term safety of hormones from likely or possible long-term consequences, and help the patient or parents understand these implications as well. The young patient may feel, “I don’t care if I die young, just as long I get to live as a woman.” The mature adult may take a different view. Hopefully, so will the child’s physician.

202. Individual patients often pin excessive hope in transition, believing that transition will solve what are in fact ordinary social stresses associated with maturation, or mental health co-morbidities. In this way, transition can prevent them from mastering personal challenges at the appropriate time or directly

addressing conditions that require treatment. When the hoped-for “vanishing” of other mental health or social difficulties does not occur, disappointment, distress, and depression may ensue. It is noteworthy that half of the respondents to the larger “detransitioner” survey reported that their transition had not helped the gender dysphoria, and 70% had concluded that their gender dysphoria was related to other issues. (Vandenbussche 2021.) Without the clinical experience of monitoring the psychosocial outcomes of these young patients as they age into adulthood, many such professionals experience no challenge to their affirmative beliefs. But medical and mental health professionals who deliver trans affirmative care for those with previous and co-existing mental health problems have an ethical obligation to inform themselves, and to inform patients and parents, that these dramatic treatments are not a panacea.

203. In sum, whether we consider physical or mental health, science does not permit us to say that either puberty blockers or cross-sex hormones are “safe,” and the data concerning the mental health of patients before, during, and after such treatments strongly contradict the assertion that gender dysphoria is “easily managed.”

I declare, pursuant to 28 U.S.C. § 1746, under penalty of perjury that
the foregoing is true and correct. Executed this 16th day of February, 2023.

A handwritten signature in black ink, reading "Stephen B. Levine" with a stylized flourish at the end.

Stephen B. Levine, M.D.

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Exhibit “A”

Stephen B. Levine, M.D.

Curriculum Vita
February, 2022

Brief Introduction

Dr. Levine is Clinical Professor of Psychiatry at Case Western Reserve University School of Medicine. He is the author or coauthor of numerous books on topics relating to human sexuality and related relationship and mental health issues. Dr. Levine has been teaching, providing clinical care, and writing since 1973, and has generated original research, invited papers, commentaries, chapters, and book reviews. He has served as a journal manuscript and book prospectus reviewer for many years. Dr. Levine has been co-director of the Center for Marital and Sexual Health/ Levine, Risen & Associates, Inc. in Beachwood, Ohio from 1992 to the present. He received a lifetime achievement Masters and Johnson's Award from the Society for Sex Therapy and Research in March 2005.

Personal Information

Date of birth 1/14/42

Medical license no. Ohio 35-03-0234-L

Board Certification 6/76 American Board of Neurology and Psychiatry

Education

1963 BA Washington and Jefferson College

1967 MD Case Western Reserve University School of Medicine

1967-68 internship in Internal Medicine University Hospitals of Cleveland

1968-70 Research associate, National Institute of Arthritis and Metabolic Diseases, Epidemiology Field Studies Unit, Phoenix, Arizona, United States Public Health Service

1970-73 Psychiatric Residency, University Hospitals of Cleveland

1974-77 Robert Wood Johnson Foundation Clinical Scholar

Appointments at Case Western Reserve University School of Medicine

1973- Assistant Professor of Psychiatry

1979- Associate Professor

1982- Awarded tenure

1985- Full Professor

1993- Clinical Professor

Honors

Summa Cum Laude, Washington & Jefferson

Teaching Excellence Award-1990 and 2010 (Residency program)

Visiting Professorships

- Stanford University-Pfizer Professorship program (3 days)–1995
- St. Elizabeth’s Hospital, Washington, DC –1998
- St. Elizabeth’s Hospital, Washington, DC--2002

Named to America’s Top Doctors consecutively since 2001

Invitations to present various Grand Rounds at Departments of Psychiatry and Continuing Education Lectures and Workshops

Masters and Johnson Lifetime Achievement Award from the Society of Sex Therapy and Research, April 2005 along with Candace Risen and Stanley Althof

2006 SSTAR Book Award for The Handbook of Clinical Sexuality for Mental Health Professionals: Exceptional Merit

2018—Albert Marquis Lifetime Achievement Award from Marquis Who’s Who. (Exceling in one’s field for at least twenty years)

Professional Societies

1971- American Psychiatric Association; fellow; #19909

2005- American Psychiatric Association, Distinguished Life Fellow

1973- Cleveland Psychiatric Society

1973- Cleveland Medical Library Association

- 1985 - Life Fellow
- 2003 - Distinguished Life Fellow

1974-Society for Sex Therapy and Research

- 1987-89-President

1983- International Academy of Sex Research

1983- Harry Benjamin International Gender Dysphoria Association

- 1997-8 Chairman, Standards of Care Committee

1994- 1999 Society for Scientific Study of Sex

Community Boards

1999-2002 Case Western Reserve University Medical Alumni Association

1996-2001 Bellefaire Jewish Children's Bureau

1999-2001 Physicians' Advisory Committee, The Gathering Place (cancer rehabilitation)

Editorial Boards

1978-80 Book Review Editor Journal Sex and Marital Therapy

Manuscript Reviewer for:

- a. Archives of Sexual Behavior
- b. Annals of Internal Medicine
- c. British Journal of Obstetrics and Gynecology
- d. JAMA
- e. Diabetes Care
- f. American Journal of Psychiatry
- g. Maturitas
- h. Psychosomatic Medicine
- i. Sexuality and Disability
- j. Journal of Nervous and Mental Diseases
- k. Journal of Neuropsychiatry and Clinical Neurosciences
- l. Neurology
- m. Journal Sex and Marital Therapy
- n. Journal Sex Education and Therapy
- o. Social Behavior and Personality: an international journal (New Zealand)
- p. International Journal of Psychoanalysis
- q. International Journal of Transgenderism
- r. Journal of Urology
- s. Journal of Sexual Medicine
- t. Current Psychiatry
- u. International Journal of Impotence Research
- v. Postgraduate medical journal
- w. Academic Psychiatry

Prospectus Reviewer

- a. Guilford
- b. Oxford University Press
- c. Brunner/Routledge
- d. Routledge

Administrative Responsibilities

Principal Investigator of approximately 70 separate studies involving pharmacological interventions for sexual dysfunction since 1989.

Co-leader of case conferences at DELRLLC.com

Expert testimony at trial or by deposition within the last 4 years

Provided expert testimony for Massachusetts Dept. of Corrections in its defense of a lawsuit brought by prisoner Katheena Soneeya, including by deposition in October 2018, and in-court testimony in 2019.

Provided expert testimony by deposition and at trial in *In the Interests of the Younger Children* (Dallas, TX), 2019.

Testified in an administrative hearing in *In the matter of Rhys & Lynn Crawford* (Washington State), March 2021.

Testified multiple times in juvenile court in *In the matter of Asha Kerwin* (Tucson, Arizona), 2021.

Provided expert testimony by deposition in *Kadel et al v. Folwell et al.* (North Carolina), 2021.

Consultancies

Massachusetts Department of Corrections—evaluation of 12 transsexual prisoners and the development of a Gender Identity Disorders Program for the state prison system. Monthly consultation with the GID treatment team since February 2009 and the GID policy committee since February 2010.

California Department of Corrections and Rehabilitation; 2012-2015; education, inmate evaluation, commentary on inmate circumstances, suggestions on future policies.

Virginia Department of Corrections —evaluation of an inmate.

New Jersey Department of Corrections—evaluation of an inmate.

Idaho Department of Corrections—workshop 2016.

Grant Support/Research Studies

TAP—studies of Apomorphine sublingual in treatment of erectile dysfunction.

Pfizer–Sertraline for premature ejaculation.

Pfizer–Viagra and depression; Viagra and female sexual dysfunction; Viagra as a treatment for SSRI-induced erectile dysfunction.

NIH- Systemic lupus erythematosus and sexuality in women.

Sihler Mental Health Foundation

- a. Program for Professionals
- b. Setting up of Center for Marital and Sexual Health
- c. Clomipramine and Premature ejaculation
- d. Follow-up study of clergy accused of sexual impropriety
- e. Establishment of services for women with breast cancer

Alza–controlled study of a novel SSRI for rapid ejaculation.

Pfizer–Viagra and self-esteem.

Pfizer- double-blind placebo control studies of a compound for premature ejaculation.

Johnson & Johnson – controlled studies of Dapoxetine for rapid ejaculation.

Proctor and Gamble: multiple studies to test testosterone patch for post menopausal sexual dysfunction for women on and off estrogen replacement.

Lilly-Icos—study of Cialis for erectile dysfunction.

VIVUS – study for premenopausal women with FSAD.

Palatin Technologies- studies of bremelanotide in female sexual dysfunction—first intranasal then subcutaneous administration.

Medtap – interview validation questionnaire studies.

HRA- quantitative debriefing study for Female partners of men with premature ejaculation, Validation of a New Distress Measure for FSD.

Boehringer-Ingelheim- double blind and open label studies of a prosexual agent for hypoactive female sexual desire disorder.

Biosante- studies of testosterone gel administration for post menopausal women with HSDD.

J&J a single-blind, multi-center, in home use study to evaluate sexual enhancement effects of a product in females.

UBC-Content validity study of an electronic FSEP-R and FSDD-DAO and usability of study PRO measures in premenopausal women with FSAD, HSDD or Mixed FSAD/HSDD.

National registry trial for women with HSDD.

Endoceutics—two studies of DHEA for vaginal atrophy and dryness in post menopausal women.

Palatin—study of SQ Bremelanotide for HSDD and FSAD.

Trimel- a double-blind, placebo controlled study for women with acquired female orgasmic disorder.

S1 Biopharma- a phase 1-B non-blinded study of safety, tolerability and efficacy of Lorexys in premenopausal women with HSDD.

HRA – qualitative and cognitive interview study for men experiencing PE.

Publications

A) Books

- 1) Pariser SR, Levine SB, McDowell M (eds.), Clinical Sexuality, Marcel Dekker, New York, 1985
- 2) Sex Is Not Simple, Ohio Psychological Publishing Company, 1988; Reissued in paperback as: Solving Common Sexual Problems: Toward a Problem Free Sexual Life, Jason Aronson, Livingston, NJ. 1997
- 3) Sexual Life: A Clinician's Guide. Plenum Publishing Corporation. New York, 1992
- 4) Sexuality in Midlife. Plenum Publishing Corporation. New York, 1998
- 5) Editor, Clinical Sexuality. Psychiatric Clinics of North America, March, 1995.
- 6) Editor, (Candace Risen and Stanley Althof, associate editors) Handbook of Clinical Sexuality for Mental Health Professionals. Routledge, New York, 2003
 1. 2006 SSTAR Book Award: Exceptional Merit
- 7) Demystifying Love: Plain Talk For The Mental Health Professional. Routledge, New York, 2006
- 8) Senior editor, (Candace B. Risen and Stanley E. Althof, Associate editors), Handbook of Clinical Sexuality for Mental Health Professionals, 2nd edition. Routledge, New York, 2010.
- 9) Barriers to Loving: A Clinician's Perspective. Routledge, New York, 2014.
- 10) Senior editor Candace B. Risen and Stanley E. Althof, Associate editors), Handbook of Clinical Sexuality for Mental Health Professionals. 3rd edition Routledge, New York, 2016

B) Research and Invited Papers

When his name is not listed in a citation, Dr. Levine is either the solo or the senior author.

- 1) Sampliner R. Parotid enlargement in Pima Indians. Annals of Internal Medicine 1970; 73:571-73

- 2) Confrontation and residency activism: A technique for assisting residency change: World Journal of Psychosynthesis 1974; 6: 23-26
- 3) Activism and confrontation: A technique to spur reform. Resident and Intern Consultant 173; 2
- 4) Medicine and Sexuality. Case Western Reserve Medical Alumni Bulletin 1974;37:9-11.
- 5) Some thoughts on the pathogenesis of premature ejaculation. J. Sex & Marital Therapy 1975; 1:326-334
- 6) Marital Sexual Dysfunction: Introductory Concepts. Annals of Internal Medicine 1976;84:448-453
- 7) Marital Sexual Dysfunction: Ejaculation Disturbances 1976; 84:575-579
- 8) Yost MA: Frequency of female sexual dysfunction in a gynecology clinic: An epidemiological approach. Archives of Sexual Behavior 1976;5:229-238
- 9) Engel IM, Resnick PJ, Levine SB: Use of programmed patients and videotape in teaching medical students to take a sexual history. Journal of Medical Education 1976;51:425-427
- 10) Marital Sexual Dysfunction: Erectile dysfunction. Annals of Internal Medicine 1976;85:342-350
- 11) Male Sexual Problems. Resident and Staff Physician 1981:2:90-5
- 12) Female Sexual Problems. Resident and Staff Physician 1981:3:79-92
- 13) How can I determine whether a recent depression in a 40 year old married man is due to organic loss of erectile function or whether the depression is the source of the dysfunction? Sexual Medicine Today 1977;1:13
- 14) Corradi RB, Resnick PJ Levine SB, Gold F. For chronic psychologic impotence: sex therapy or psychotherapy? I & II Roche Reports; 1977
- 15) Marital Sexual Dysfunction: Female dysfunctions 1977; 86:588-597
- 16) Current problems in the diagnosis and treatment of psychogenic impotence. Journal of Sex & Marital Therapy 1977;3:177-186
- 17) Resnick PJ, Engel IM. Sexuality curriculum for gynecology residents. Journal of Medical Education 1978; 53:510-15
- 18) Agle DP. Effectiveness of sex therapy for chronic secondary psychological impotence Journal of Sex & Marital Therapy 1978;4:235-258
- 19) DePalma RG, Levine SB, Feldman S. Preservation of erectile function after aortoiliac reconstruction. Archives of Surgery 1978;113-958-962
- 20) Conceptual suggestions for outcome research in sex therapy Journal of Sex & Marital Therapy 1981;6:102-108

- 21) Lothstein LM. Transsexualism or the gender dysphoria syndrome. *Journal of Sex & Marital Therapy* 1982; 7:85-113
- 22) Lothstein LM, Levine SB. Expressive psychotherapy with gender dysphoria patients *Archives General Psychiatry* 1981; 38:924-929
- 23) Stern RG Sexual function in cystic fibrosis. *Chest* 1982; 81:422-8
- 24) Shumaker R. Increasingly Ruth: Towards understanding sex reassignment surgery *Archives of Sexual Behavior* 1983;12:247-61
- 25) Psychiatric diagnosis of patients requesting sex reassignment surgery. *Journal of Sex & Marital Therapy* 1980; 6:164-173
- 26) Problem solving in sexual medicine I. *British Journal of Sexual Medicine* 1982;9:21-28
- 27) A modern perspective on nymphomania. *Journal of Sex & Marital Therapy* 1982;8:316-324
- 28) Nymphomania. *Female Patient* 1982;7:47-54
- 29) Commentary on Beverly Mead's article: When your patient fears impotence. *Patient Care* 1982;16:135-9
- 30) Relation of sexual problems to sexual enlightenment. *Physician and Patient* 1983 2:62
- 31) Clinical overview of impotence. *Physician and Patient* 1983; 8:52-55.
- 32) An analytical approach to problem-solving in sexual medicine: a clinical introduction to the psychological sexual dysfunctions. II. *British Journal of Sexual Medicine*
- 33) Coffman CB, Levine SB, Althof SE, Stern RG Sexual Adaptation among single young adults with cystic fibrosis. *Chest* 1984;86:412-418
- 34) Althof SE, Coffman CB, Levine SB. The effects of coronary bypass in female sexual, psychological, and vocational adaptation. *Journal of Sex & Marital Therapy* 1984;10:176-184
- 35) Letter to the editor: Follow-up on Increasingly Ruth. *Archives of Sexual Behavior* 1984;13:287-9
- 36) Essay on the nature of sexual desire *Journal of Sex & Marital Therapy* 1984; 10:83-96
- 37) Introduction to the sexual consequences of hemophilia. *Scandinavian Journal of Haemology* 1984; 33:(supplement 40).75-
- 38) Agle DP, Heine P. Hemophilia and Acquired Immune Deficiency Syndrome: Intimacy and Sexual Behavior. *National Hemophilia Foundation*; July, 1985
- 39) Turner LA, Althof SE, Levine SB, Bodner DR, Kursh ED, Resnick MI.

External vacuum devices in the treatment of erectile dysfunction: a one-year study of sexual and psychosocial impact. *Journal of Sex & Marital Therapy*

40) Schein M, Zyzanski SJ, Levine SB, Medalie JH, Dickman RL, Alemagno SA. The frequency of sexual problems among family practice patients. *Family Practice Research Journal* 1988; 7:122-134

41) More on the nature of sexual desire. *Journal of Sex & Marital Therapy* 1987;13:35-44

42) Waltz G, Risen CB, Levine SB. Antiandrogen treatment of male sex offenders. *Health Matrix* 1987; V.51-55.

43) Lets talk about sex. National Hemophilia Foundation January, 1988

44) Sexuality, Intimacy, and Hemophilia: questions and answers . National Hemophilia Foundation January, 1988

45) Prevalence of sexual problems. *Journal Clinical Practice in Sexuality* 1988;4:14-16.

46) Kursh E, Bodner D, Resnick MI, Althof SE, Turner L, Risen CB, Levine SB. Injection Therapy for Impotence. *Urologic Clinics of North America* 1988; 15(4):625-630

47) Bradley SJ, Blanchard R, Coates S, Green R, Levine S, Meyer-Bahlburg H, Pauly I, Zucker KJ. Interim report of the DSM-IV Subcommittee for Gender Identity Disorders. *Archives of Sexual Behavior* 1991;;20(4):333-43.

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Exhibit B

IN THE UNITED STATES DISTRICT COURT
EASTERN DISTRICT OF ARKANSAS
CENTRAL DIVISION

DYLAN BRANDT, et al.,

Plaintiffs,

v.

No. 4:21CV00450 JM

November 28, 2022
Little Rock, Arkansas
8:57 AM

LESLIE RUTLEDGE, et al.,

Defendants.

TRANSCRIPT OF BENCH TRIAL - VOLUME 5
BEFORE THE HONORABLE JAMES M. MOODY, JR.,
UNITED STATES DISTRICT JUDGE

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1
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23 *Proceedings reported by machine stenography. Transcript*
24 *prepared utilizing computer-aided transcription.*
25

INDEX - VOLUME 5 (11/28/22)

WITNESSES FOR THE DEFENDANTS:	Direct	Cross	Redirect	Recross
STEPHEN LEVINE	781	885	955	959

Karen Dellinger, RDR, CRR, CCR
United States Court Reporter

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1 (Proceedings continuing in open court at 8:57 AM.)

2 THE COURT: Are y'all ready?

3 MR. JACOBS: Your Honor, Defendants are ready to
4 call, I guess, our next witness, not our first witness. One
5 thing I wanted to check in on. So Dr. Regnerus is prepared to
6 testify remotely tomorrow, and I wanted to ask at what time the
7 Court could begin tomorrow with the hope that it could begin I
8 guess as early as we can make it happen. Because Dr. Regnerus
9 is testifying late in the evening from where he's located, so
10 just to avoid him having to run into testifying in the wee
11 hours of the early morning, if we could start as early as we
12 can. I recognize that --

13 THE COURT: I expect this will likely make everybody
14 cringe, but courthouse opens at 7:30.

15 MR. JACOBS: Could we -- I think he'd be available
16 to start at like 8:00.

17 THE COURT: That's fine. That would give everybody
18 time to get in the building and get settled and we could make
19 sure stuff is up.

20 MR. JACOBS: Okay. That's all the preliminary
21 matters that we have.

22 THE COURT: So with an asterisk, you've got my
23 entire week. What are your thoughts on how long you're going
24 to take?

25 MR. JACOBS: Our witnesses will be done Thursday and

1 we'll rest on Thursday.

2 THE COURT: I've got two sentencings, one at 1:00
3 and one at 2:00 on Wednesday. Those usually last 30 minutes,
4 so we're probably going to work a little later into lunch on
5 Wednesday.

6 MR. JACOBS: That won't be a problem, Your Honor.

7 THE COURT: And then it looks like I've got a lunch
8 hearing on the 1st. Okay. That's what is on my schedule other
9 than you guys. So are we ready to jump back in?

10 MR. JACOBS: We're ready, Your Honor. Defendants
11 will call Dr. Stephen Levine.

12 THE COURT: Sir, if you could come on the far side
13 of that silver rail. Good morning.

14 **STEPHEN LEVINE, DEFENDANTS' WITNESS, DULY SWORN**

15 DIRECT EXAMINATION

16 BY MR. CANTRELL:

17 Q Good morning, Dr. Levine.

18 A Good morning.

19 Q Can you state your name and spell it for the record.

20 A Stephen, S-t-e-p-h-e-n, Barrett, B-a-r-r-e-t-t, Levine,
21 L-e-v-i-n-e.

22 Q Thank you. Dr. Levine, can you tell us what academic and
23 clinical positions that you currently hold?

24 A I am clinical professor of psychiatry at Case Western
25 Reserve University. I'm a staff psychiatrist in a group

1 dictating a trans identity. As many people have come to
2 realize that teenagers and now especially during COVID when
3 teenagers were at home have spent a great deal of time on the
4 internet and we believe that the internet has many
5 opportunities to learn about trans life, and we think this has
6 been an influence on the rising incidence of transgender
7 identities.

8 But I can say that while I could go on and speculate
9 about why there has been this increase, I don't really think
10 that science can tell you why. We can speculate and various
11 people have various speculations. Some people think it's a
12 social contagion from the internet, other people think it's a
13 social contagion from friends, close relationships, especially
14 among girls who have a friend who's trans. Some people think
15 that it's a retreat from adverse life experiences and family
16 disruptions and inability to like both parents or love both
17 parents, but these are all speculations, and I doubt since
18 there are so many people involved with this that we would find
19 one explanation that would explain everything.

20 We need to understand that in mental health work and
21 trying to grasp what happens to people who become who they
22 become and why, that we can't ever find one explanation for
23 things. Things are multifactorial, so I think this phenomenon
24 must be multifactorial as well, but it is a dramatic worldwide
25 change in how young people are identifying. And they're not

LEVINE - CROSS

1 A. Yes.

2 Q. Have you reviewed any transcripts of the first week
3 of trial?

4 A. No.

5 Q. Has anyone spoken to you about the testimony that was
6 given during the first week of trial?

7 A. No.

8 Q. You've been a psychiatrist seeing patients, I believe
9 you said, since 1973. Is that correct?

10 A. I started my residency three years before and I saw
11 patients then, so officially as credentialed psychiatrist,
12 yes, 1973.

13 Q. And the overwhelming majority of your patients have
14 been adults.

15 A. Over the years, yes.

16 Q. Is that right, that the overwhelming majority have
17 been adults?

18 A. Yes.

19 Q. Is that a yes?

20 And you've estimated that you've seen about 50
21 minors, patients under 18, in your nearly 50-year career.
22 Is that correct?

23 A. Yeah. In a previous testimony, give can you give me
24 that number?

25 Q. I can show you.

LEVINE - CROSS

1 THE COURT: Let's short cut. Is that true?

2 THE WITNESS: It's approximately true.

3 MS. COOPER: Thank you, Your Honor.

4 BY MS. COOPER:

5 Q. And you've testified that you've seen about six
6 prepubertal children in your career over 50-plus years.

7 A. Yes. That's probably approximately true, personally
8 seen.

9 THE COURT: What was the last part? I couldn't
10 hear you?

11 THE WITNESS: I'm sorry?

12 THE COURT: I didn't hear the last couple of
13 words. Did you say something --

14 THE WITNESS: That I personally have been
15 involved.

16 THE COURT: Thank you. You faded off. I
17 couldn't hear.

18 BY MS. COOPER:

19 Q. I believe you testified on direct that there are
20 about 70 gender clinics in the United States. Is that
21 right?

22 A. Yes.

23 Q. And you don't know how different practitioners or
24 clinics provide care, correct?

25 A. There are many, many practitioners. How would I

LEVINE - CROSS

1 possibly know how they all provide care? I've been aware
2 of some instances of care, yes.

3 Q. So there are many practitioners and clinics about
4 which you don't know protocols --

5 A. Many.

6 Q. And you don't know how common it is for clinicians to
7 provide hormone therapy to minors without a careful
8 assessment of the child and their comorbidities. Is that
9 correct?

10 A. Well, I've been in touch with many parents from all
11 over the country who have indicated that to me. But in a
12 numerical sense with a denominator, I'm not aware. I
13 certainly have had many experience where I heard
14 complaints of -- about that.

15 Q. You don't know if it's a small minority, a majority,
16 or something in between?

17 A. I don't know that 38 percent do and 42 percent don't
18 or -- I don't have that kind of information.

19 Q. You wouldn't say whether it's a majority or a
20 minority.

21 A. Couldn't say.

22 Q. You don't have any knowledge about how gender
23 affirming medical care is provided to minors in Arkansas.
24 Is that correct?

25 A. That's correct.

LEVINE - CROSS

1 of rapid onset gender dysphoria versus lifelong gender
2 dysphoria, the parents -- the parents' view is vital, you
3 see.

4 But, you know, today most of the onset of the gender
5 dysphoria presents itself at first in adolescence, not at
6 age four. In that sense, you and I are talking past each
7 other.

8 Q. All right. If we can look at -- just to wrap this
9 question up for clarity, on page 41 -- can you see the
10 screen in front of you --

11 A. Yes.

12 Q. -- beginning on line 22. Question: Does your -- you
13 mentioned that you meet with the parents too. Does that
14 contribute to your assessment whether someone meets the
15 criteria for gender dysphoria, what's reported by the
16 parents.

17 Answer: Of course.

18 That was your testimony?

19 A. I thought I just explained what I meant by that.

20 Q. When you diagnosis patients for other conditions like
21 depression or bipolar disorder, do you rely on self-report
22 of patients?

23 A. And reports from the parents.

24 Q. Reliance on self-report from the patients and
25 information from parents is not unique to the diagnosis of

LEVINE - CROSS

1 gender dysphoria, is it?

2 A. That's right. It's not unique.

3 Q. Diagnosing patients based on self-report and
4 information from families who know the -- people who know
5 the patient, that's how psychiatry works, isn't it?

6 A. Ideally.

7 Q. You were deposed this past March in a case called BPJ
8 in West Virginia. Do you remember that case involving
9 athletics?

10 A. Yes.

11 Q. I'd like to show you a passage from -- well, a
12 passage from your deposition in that case. Can we look at
13 paragraph 6, please?

14 Do you see that in front of you in paragraph 6? It
15 says, if you'll read along with me: In the course of my
16 five decades of practice treating patients -- I'm sorry.
17 This is not your deposition. Let me back up. I misspoke.

18 You remember giving a report in the BPJ case. Is
19 that right?

20 A. I vaguely remember.

21 Q. And is this your expert report?

22 A. I don't know. You just --

23 Q. Can we scroll through this front page just to show?

24 A. It's my signature, yes.

25 Q. So if we can turn back to paragraph 6. And I would

LEVINE - CROSS

1 like you to read along with me. In the course of my five
2 decades of practice treating patients who suffer from
3 gender dysphoria, I have at one time or another
4 recommended or prescribed or supported social transition,
5 cross-sex hormones, and surgery for particular patients,
6 but only after extensive diagnostic and psychotherapeutic
7 work.

8 So you wrote this passage, correct?

9 A. Yes.

10 Q. And you have supported patients' social transition.
11 Is that correct?

12 A. This -- this paragraph or sentence doesn't give an
13 age group.

14 Q. Understood. But I'm just asking generally, you have
15 supported --

16 A. Many four-year-olds.

17 Q. Yes. Okay. You have counseled some parents to
18 support the transgender identification of their child,
19 haven't you?

20 A. I'm not sure that's true. Depending on what you mean
21 by child. Child -- a could be 25. That is a child of a
22 parent can be 25.

23 Q. You've counseled some parents to support their minor
24 child's social transition, haven't you?

25 A. I have on rare occasion, yes.

LEVINE - CROSS

1 Q. And switching back to adults, you've written letters
2 of authorization for adults seeking gender-affirming
3 surgeries. Is that correct?

4 A. I have.

5 Q. And you've done that as recently as the past two
6 years.

7 A. I have.

8 Q. And you've also written letters authorizing hormone
9 therapy for adult patients with gender dysphoria.

10 A. I have.

11 Q. And these are letters they can take to the
12 endocrinologist. Is that right?

13 A. Yes.

14 Q. And you have written such letters approving hormone
15 therapy for minors under 18 in a few cases within the past
16 five years, haven't you?

17 A. I don't think in the past five years.

18 Q. Okay. Can we turn to Dr. Levine's deposition, page
19 78?

20 I would like you to read along with me starting on
21 line 3. So between you and Mrs. Novak, there have been a
22 handful of cases in the past, say, five years where you
23 have approved hormone therapy for minor. Is that right?

24 These are particularly fraught difficult
25 circumstances, yes.

LEVINE - CROSS

1 A. Yes.

2 Q. Mrs. Novak is someone who works in your medical
3 practice -- or your psychiatry practice?

4 A. She's a younger colleague of mine.

5 Q. That was your testimony.

6 A. I'm sorry?

7 Q. That was your testimony that I read correctly.

8 A. Yes. I'm just not sure today whether it's five years
9 or six years now. And in general, there have been a few
10 very fraught cases where we felt that this is a very
11 reasonable thing given the severity, the complexity of the
12 case, and that we would -- we, along with parents, would
13 hold our breath that this would be of help.

14 Q. And you have cosigned letters for hormone therapy for
15 minors written by Mrs. Novak, again, approving some minors
16 for hormone therapy. Is that right?

17 A. Yes, but this has not occurred very recently, Ms.
18 Cooper.

19 Q. You would not write a letter supporting hormone
20 therapy for a minor if you did not believe the patient had
21 gender dysphoria, correct?

22 A. Correct.

23 Q. And you would not write a letter approving a minor
24 for hormone therapy without first determining that they
25 had a longstanding, stable gender identity. Is that

LEVINE - CROSS

1 much more cautious. We will give adolescents hormones,
2 but not as quickly as the Standards of Care would like.

3 That was your testimony in Keohane.

4 A. I have to say yes.

5 Q. And just to clarify, the Standards of Care you're
6 referring to in the 7th Edition, is that the WPATH's
7 Standards of Care 7th Edition?

8 A. Yes.

9 Q. When you were deposed in May of this year in this
10 case, the Brandt case, you testified, did you not, that
11 going forward you have not made a decision to no longer
12 write letters approving hormone therapy for patients under
13 18 years of age.

14 A. Indulge me a minute. In the previous thing you put
15 up, my deposition of adolescents was not the definition I
16 gave to the Judge earlier this morning. It was my
17 definition of an adolescent is somebody 19 years of age.
18 And so if you reread that, it would include 18-year-olds
19 and 19-year-olds.

20 So would you repeat the last question you asked me?

21 Q. Sure. When you were deposed this past May in this
22 case in Arkansas, you testified that, going forward, you
23 have not made a decision to categorically not write
24 letters approving hormone therapy for patients under 18,
25 correct?

LEVINE - CROSS

1 A. I don't remember saying that, but if you have that, I
2 trust you.

3 Q. Yeah. I think we want to put that in the record.

4 Can we look at deposition page 227?

5 And if you go to line 3, part way through beginning
6 with the words, "Have you made a decision." Are you with
7 me? It's highlight.

8 Have you made a decision to no longer consider
9 hormone therapy for anybody who has not reached their 18th
10 birthday since you provided those letters?

11 Answer: I've made a decision to be very cautious and
12 to put a period of time in therapy between me and the
13 letter.

14 You go on to say more, which you're welcome to read
15 if you would like, but I want to continue on to another
16 passage that picks up rather than taking the Court's time
17 reading a lot of discussion in between.

18 If we could turn to page 228, line 3. Let me know if
19 you want to review there.

20 MR. CANTRELL: Your Honor, I would like to just,
21 if we could, take a look at the intervening testimony,
22 glance at that.

23 MS. COOPER: Sure. We can post that.
24 Absolutely.

25 THE COURT: I thought you were in the

LEVINE - CROSS

1 deposition, Mr. Cantrell, but go ahead.

2 BY MS. COOPER:

3 Q. Do you have that in front of you now, Doctor? If you
4 look at line 3 and read along with me.

5 So I'm not sure if that answers my question. Have
6 you made a decision to no longer provide letters?

7 Answer: Oh, I'm sorry. No, I haven't made that
8 decision.

9 Question: So would it be a case-by-case basis if
10 there were a patient that you felt it was appropriate for
11 you -- appropriate for, you would consider doing it, say,
12 a 17-year-old or a 16-year-old?

13 Mr. Cantrell: Object to form.

14 Answer: I don't have a -- yes. The answer to your
15 question is yes.

16 I'm not going to ask you if that was your testimony
17 again --

18 A. Thank you.

19 Q. -- since I see how you love those questions.

20 Now, today you testified that you would not recommend
21 hormone therapy for patients under 18. Do you mean you
22 would not generally recommend hormone therapy as a general
23 matter?

24 A. Yes.

25 Q. So there may be exceptional cases where you would

LEVINE - CROSS

1 still consider it appropriate.

2 A. Yes. These are very fraught circumstances. I think
3 all of us all over the world recognize that we are under
4 very difficult circumstances sometimes. We don't know
5 what to do and we eventually go along with the patient's
6 sincere desire to try hormones.

7 Q. Now, you talked on direct about an article you wrote
8 called, *Reconsidering Informed Consent for*
9 *Trans-identified Children, Adolescents, and Young Adults.*

10 And I just want to ask you a couple of questions
11 about that article.

12 In this article, you recommend informed content
13 process that you think providers should undertake before
14 authorizing medical or surgical transition for minors,
15 correct?

16 A. Yes.

17 Q. I'd like to pull up a passage from that article to
18 show you. If we can look at page 2. And I have some
19 material highlighted. Actually, I would like you to skip
20 to -- sorry. I wasn't in front of the mic. I would like
21 to skip to the second highlighted paragraph.

22 A. I know what you're you talking about.

23 Q. We over highlighted. If you'll read along with me in
24 the second paragraph there.

25 Social transition, hormonal interventions, and

LEVINE - CROSS

1 that is immutable, that it cures suicidal ideation, and
2 that it makes everyone live happily ever after, you see.

3 So in order to understand that last -- the
4 second-last sentence there, it does not preclude
5 transition. It presumes that the doctor is knowledgeable.
6 And what it I have been saying is that all the doctors are
7 not equally knowledgeable about the state of science.

8 Q. But you're not saying that no doctors are
9 knowledgeable.

10 A. Of course I'm not saying that, Ms. Cooper.

11 Q. In that article that we're looking at here, you don't
12 say that gender-affirming medical care, specifically
13 hormone therapy or blockers or surgeries, should be
14 categorically prohibited for minors, do you?

15 A. No, I don't. This is -- that was not the topic of
16 this article.

17 Q. You testified that you would like to see an
18 international committee -- this was today. You testified
19 that you'd like to see an international committee
20 developed standards for informed consent to provide
21 gender-affirming medical care to adolescents. Is that
22 right?

23 A. Yes.

24 Q. So, you're not seeking to prohibit care, but to
25 ensure that patients have been thoroughly provided

LEVINE - CROSS

1 information and take the time and patience to understand
2 it before making this monumental decision.

3 A. Ms. Cooper, when you say "patients," you need to ask
4 -- for me to agree to that, you have to add parents and
5 patients.

6 Q. Thank you. Let me ask it differently.

7 So you're not looking to prohibit care, but to ensure
8 that patients, and particularly their parents when they're
9 minors, have thorough information in order to be able to
10 adequately make that decision. Is that correct?

11 A. I am not motivated to prohibit care. I am motivated
12 to clarify the scientific basis upon which the care is
13 provided, and if the basis is inadequate, to let doctors
14 be cautious about this.

15 Q. And to inform families of this information as well.

16 A. And to inform -- to use their own ethical unease
17 about the wisdom of this in their informing patients and
18 parents about the state of science here and what is not
19 known, the uncertainties, and the risks of harms.

20 Q. And your view is that, if families are -- by
21 "families," I'm specifically focusing on parents -- are
22 fully informed about the risks and the state of the
23 science, the decision about whether to pursue hormone
24 therapy for adolescents -- minor adolescents should be
25 made by the parents, patient, and doctors. Is that

LEVINE - CROSS

1 Q. I'm sorry. Yes?

2 A. Yes.

3 Q. You believe that for youth who are currently
4 receiving hormone therapy, requiring them to discontinue
5 treatment could create a psychological -- could create
6 psychological and physiological problems, correct?

7 A. Most certainly, I think it would be a psychological
8 challenge for those folks, whether physiologically or
9 cause a significant problem is not clear because,
10 depending on their age and depending on the original
11 maturation of their ovaries and testes, stopping estrogen
12 or stopping testosterone abruptly may cause brief periods
13 of thermo-regulatory -- what we call hot flashes.

14 But I think if a person's just had hormones, say,
15 starting at age 15 or 16, their gonads had matured enough,
16 that they would begin the secretion of progesterone and
17 estrogen for biologic girls and testosterone for boys.
18 But I think psychologically, it would be a shocking and
19 devastating thing for them.

20 There are lots of negative things that happen to all
21 of us in life that are shocking and devastating, and we
22 learn to cope with it. And what I said at the deposition
23 is that doctors are compassionate people generally and
24 they would find a way to be of help. And my concern with
25 the law as it was originally written is that it seems to

1 (Proceedings continuing at 3:00 p.m.)

2 BY MS. COOPER:

3 Q. Dr. Levine, you submitted a report in opposition to our
4 plaintiffs' motion for preliminary injunction. Do you remember
5 doing that in this case?

6 A. In this case?

7 Q. In this case, yeah.

8 A. That's too legalese for me.

9 Q. Okay. Let's show you -- if you can put up the report or
10 the rebuttal.

11 If you can look at the document on the screen dated
12 July 9th, '21, or filed. On the top, it says, "July 9th, '21,
13 declaration of Stephen Levine." Is this a report that you
14 prepared in this case?

15 A. That was my original report.

16 Q. Okay. If you can look at page -- excuse me -- paragraph
17 35, and read along, the highlighted material.

18 "To my knowledge, there is no credible scientific evidence
19 beyond anecdotal reports that psychotherapy can enable a return
20 to male identification for genetically male boys, adolescents,
21 and men, or return to female identification for genetically
22 female girls, adolescents and women."

23 That's what you said in your report?

24 A. That's what I did say, yes.

25 Q. Okay. Now, you talked on direct about your clinical

1 experience, and you mentioned that most of your patients were
2 adult patients. It's correct that you've had only two patients
3 who have detransitioned after medically transitioning. Is that
4 correct?

5 A. That I'm aware of at the moment, yeah.

6 Q. Okay. And in your report in this case, you cited a paper
7 by Exposito-Campos about detransition. Correct?

8 A. Yes.

9 Q. And you noted that the Exposito-Campos review of
10 detransitioning claimed to have identified 16,000 entries in a
11 search of proliferating websites devoted to this topic. Is that
12 correct?

13 A. Detransitioning, yes.

14 Q. And, to be clear, this did not represent 16,000
15 detransitioners. Right?

16 A. It's not possible to know what percentage of them are
17 individual people who have detransitioned.

18 Q. That was a reference of the number of people participating
19 in these online groups. Is that right?

20 A. Right.

21 Q. Uh-huh. Okay. Now, you talked some during direct
22 testimony about detransition and studies looking at rates of
23 detransition. I just had a couple of questions about that. You
24 mentioned that there was a study that said that there was a rate
25 of about 30 percent of patients detransitioned.

1 A. Yes.

2 Q. Right? How was detransition defined in that study?

3 A. I think as stopping hormones.

4 Q. People may stop hormones without going back to reverting to
5 their biological sex. Correct?

6 A. Yeah. The study is about the rate, you see. It's not
7 about the details, right?

8 Q. Okay. And I would like to pull up a passage in your
9 rebuttal report in this case. Do you have that, paragraph 17?
10 If you can look at page 1, is this your rebuttal?

11 Oh, is this the same document? I'm sorry. It is the same
12 document.

13 This is your report you wrote in this case?

14 A. I trust you.

15 Q. It has your name on it. Right? Did you look at it? I
16 want to make sure we're on the same page.

17 A. A rebuttal declaration of Dr. Stephen Levine, M.D.

18 Q. Let's look at paragraph 17, please. I would like to have
19 you go down sort of towards the bottom, second-to-last line in
20 that paragraph, beginning with the word "according." And read
21 along with me.

22 It says, "According to a recent study from a UK adult
23 gender clinic, 6.9 percent of those treated with
24 gender-affirmative interventions detransitioned within 16 months
25 of starting treatment, and 3.4 percent had a pattern of care

1 detransition occurs in various forms to various degrees should
2 not be denied any longer. The incidence of using this 1 or
3 2 percent of regret for the whole phenomenon of maybe a mistake
4 has been made somewhere along the line no longer is acceptable.
5 What we need to think is that with the rising number of people
6 getting hormones and the rising number of people saying they are
7 transgender and then the rising number of people getting access
8 to hormones, we should expect that some of those people, given
9 the ordinary ambivalence of the human soul, will change their
10 mind as they get older and detransition to various degrees.
11 These studies are just the first early reports.

12 Q. Understood. But my question has to do with the 30 percent
13 figure you gave. These studies don't show that 30 percent of
14 patients who were on treatment detransitioned. Isn't that
15 right?

16 A. I think -- yes, that's right. They are showing that
17 30 percent dropped out of treatment or were lost to the original
18 treatment plan.

19 Q. So, to be clear, they showed that 6.9 percent, what you
20 described here, 6.9 percent detransitioned, and another
21 3.4 percent had a pattern of care suggestive of detransition.
22 But separately, to get to the remainder, to get to that
23 30 percent are 21.7 percent who are just people who dropped out
24 of the program. Right?

25 A. And that's study No. 1. That's Hall.

1 Q. Just to clarify, we don't know if 21 percent of those
2 people detransitioned.

3 A. No. They may have gotten their care at a different
4 country.

5 Q. In fact, your own description says some of them reengaged
6 in the clinics in those 21 percent.

7 A. That was a quote.

8 Q. That was a quote. Okay. Tell me, so there's another study
9 that showed 30 percent detransitioned? Which one is that?

10 A. If you look down further to No. 9, reference No. 9 to Boyd,
11 that's a study of older people detransitioning.

12 Q. Okay.

13 A. My point, Ms. Cooper, is that people detransition. And we
14 shouldn't be surprised, and we shouldn't sell the public that
15 once a trans always a trans.

16 Q. I want to switch gears for now and ask you about a
17 presentation you gave at the American Psychiatric Association
18 this past May. Correct?

19 A. Correct.

20 Q. Yeah. You presented at an annual conference of the
21 American Psychiatric Association in a symposium on reexamining
22 the best practices for transgender youth. Is that correct?

23 A. That is very correct.

24 Q. And among your co-presenters were Ken Zucker. Correct?

25 A. Yes.

1 Q. And others were Lisa Marchiano and Sasha Ayad? Correct?

2 A. Yes.

3 THE COURT: Ms. Cooper, can you spell that last name?

4 MS. COOPER: I can. Ayad is A-y-a-d.

5 BY MS. COOPER:

6 Q. And all four of you who were on that panel are people who
7 have dissenting views from APA policies on trans healthcare.
8 Correct?

9 A. That's right.

10 Q. Okay. And the APA was aware that the four of you were
11 presenting ideas that were not in keeping with official policies
12 of the APA. Correct?

13 A. Yes. They made an announcement of that before we were
14 allowed to present. And they sent a special person to moderate
15 it. They didn't allow me, the chairman, to moderate it, but
16 they didn't tell me they were going to do that. They just
17 showed up three minutes before the symposium, yes.

18 Q. And while you were talking, the group in the audience was
19 polite, and no one interrupted. Is that correct?

20 A. While I --

21 Q. While you were presenting on the panel.

22 A. Yes. They were very polite until the presentation was --
23 the presentations were finished.

24 Q. Excuse me? Until the presentations were --

25 A. Finished.

1 THE COURT: Dr. Levine, as a psychiatrist, how did
2 that make you feel? No. I'm kidding.

3 THE WITNESS: I can answer that, Your Honor.

4 THE COURT: You don't have to answer it. I'm just
5 trying to shake things up a bit. Keep going.

6 THE WITNESS: You succeeded.

7 BY MS. COOPER:

8 Q. No one interrupted. Correct?

9 A. I'm sorry?

10 Q. No one interrupted the presentations. Correct?

11 A. The only interruption in the presentation was when I began
12 to speak to introduce the symposium, this woman appeared and
13 told me to wait a minute, she was going to make the first
14 comment.

15 Q. But there wasn't a disruption of the content of the
16 presentations?

17 A. That's right.

18 Q. We just mentioned Ken Zucker, who was on the panel with
19 you. Is it correct that he is called -- excuse me -- he is a
20 proponent of what some call watchful waiting for prepubertal
21 children?

22 A. That's not what he presented about.

23 Q. But your understanding is he's a proponent. I'm sorry if
24 that wasn't clear. Putting aside his presentation at the panel,
25 he is a person who supports watchful waiting for prepubertal

1 for off-label use."

2 That was your testimony. Correct?

3 A. Oh, yes, yes. That was my testimony.

4 Q. Okay. Off-label drug use is very common in probably every
5 field of medicine. Correct?

6 A. Yes.

7 Q. Uh-huh. And the fact that a drug is being used off label
8 does not make the use experimental. Correct?

9 A. In some sense it is experimental. It's not approved.
10 There hasn't been evidence other than in a clinical fashion to
11 do it. It's not experimental in the same serious way we're
12 talking about using the various drugs for gender dysphoria off
13 label and perhaps experimental.

14 Q. You would agree, though, that the fact that a drug is being
15 used off label does not alone mean that it's experimental.
16 Correct?

17 A. I would agree with that.

18 Q. People in your field know the difference between articles
19 that are peer reviewed in a scientific journal and different
20 kinds of publications. Right?

21 A. Yes.

22 Q. Speaking generally about psychiatric conditions, you would
23 agree that because of the complexity of the human psyche and the
24 difficulty of running controlled experiments in this area,
25 substantial disagreements among professionals about the causes

1 WPATH's principles.

2 Q. But, again, you don't know how most practitioners around
3 the country, how credentialed they are and how they provide
4 care.

5 A. Who in the world knows?

6 Q. But you don't.

7 A. I don't and you don't.

8 Q. Okay. Now, I want to switch gears and talk about some of
9 the European reports that you talked about. Let's start with
10 Finland. You talked about a report from Finland. Do you
11 remember talking about that? Okay. And you mentioned that a
12 committee of, I believe you said, blue ribbon experts put
13 together these international reports. Which were the experts
14 who were the blue ribbon experts who put together the Finnish
15 report?

16 A. Their names?

17 Q. Anything about them.

18 A. I don't know their names.

19 Q. Do you know anything about them?

20 A. Well, I know the head of this national program. I know
21 her, but I don't know her colleagues.

22 Q. And do you know what organization put that report out?

23 A. Well, it's called COHERE. Please don't ask me what the
24 COHERE stands for.

25 Q. How many experts were on that blue ribbon committee that

1 THE COURT: Is that true, Doctor?

2 THE WITNESS: It is true.

3 BY MS. COOPER:

4 Q. Okay. Now, the French report, the French document that you
5 talk about, that's not a review of the literature. Right?

6 A. I'm sorry. Which one?

7 Q. The French application.

8 A. The French, I don't think -- I don't want to testify it's
9 based on a review.

10 Q. So you don't know if that was done by a blue ribbon
11 committee of experts?

12 A. I don't know who did it, just there was a national body in
13 France.

14 Q. Okay. Thank you. That helped clarify that. I want to go
15 back to some of these individual reports and just a few
16 questions. The Finnish report did not recommend banning
17 gender-affirming medical care for minors, did it?

18 A. I think in special cases they thought it could be
19 continued.

20 Q. In fact, it allowed puberty blockers on a case-by-case
21 basis after careful consideration. Isn't that what it says?

22 A. I think so.

23 Q. And it says in the Finnish report that hormone therapy
24 could be provided to minors based on a thorough case-by-case
25 consideration if it can be ascertained that the identity as the

1 other sex is of a permanent nature and causes severe dysphoria.

2 Is that correct?

3 A. Yes.

4 Q. Now --

5 A. Ms. Cooper, then how could a bunch of doctors know that a
6 nine year-old's gender identity is permanent? It only could be
7 based on the fact it has existed for three years.

8 Q. Is anybody providing hormone therapy -- cross-sex hormone
9 therapy to nine year-olds?

10 A. Yes, yes, yes.

11 Q. Cross-sex hormone therapy?

12 A. No, no.

13 Q. That's what we're talking about.

14 A. Puberty blocking hormones.

15 Q. This was about cross-sex hormone therapy.

16 A. Oh, I'm sorry.

17 Q. Yeah.

18 A. Even so, if somebody has consistent cross-gender
19 identification from 12 to 16, there's no guarantee that that
20 person will be cross-gender identified at 25.

21 Q. But that's what the Finnish report said, what I described.

22 A. Right. You see the limitations inherent even in policy.

23 Q. So, turning to the French report, just to be clear, they
24 did not recommend prohibiting gender-affirming medical care for
25 minors, did they?

1 A. I don't know.

2 Q. You don't know?

3 A. At this moment.

4 Q. Uh-huh. So you don't know if in France minors can receive
5 gender-affirming medical care to treat gender dysphoria?

6 A. I think this was a general recommendation rather than a
7 prohibition. And the recommendation was psychotherapy and
8 psychiatric evaluation first.

9 Q. Okay.

10 A. I think what we have in common here in all of these
11 countries we're talking about is the recommendation, the prudent
12 recommendation that psychiatric evaluation and attention to
13 associate a psychopathology and worry about both detransition
14 and the rapid rise in the number of people calling themselves
15 transgender calls for a different approach, not the preclusion
16 of individual cases getting a particular treatment, but, in
17 general, doctors of our country think psychotherapy first, not
18 hormones first, not transition first. That's what these things
19 have in common, whether I remember one phrase or another from
20 the report.

21 Q. And your assumption is in the U.S. doctors are doing
22 medical transition before psychotherapy?

23 A. Oh, yes.

24 Q. But you don't actually know how many doctors do that.
25 Right?

1 get these drugs.

2 Q. And you mentioned a report from Canada. Hormone therapy
3 and puberty blockers are not prohibited for minors in Canada,
4 are they?

5 A. No. This was done for the State of Florida. It was not
6 done by the Canadian National Service. But what it did was
7 reiterate the low quality of evidence for puberty blockers being
8 beneficial and for cross-gender hormones being beneficial or
9 them in sequence being beneficial. Based on international
10 standards, blue ribbon people, sophisticated people, every
11 review says that the scientific objective review of the evidence
12 supporting these treatments is of very low quality.

13 Q. I'm not asking about the quality of evidence. I'm asking
14 about the recommendations in the reports. That's what my
15 questions were focused on. And going back to the Canadian
16 report, do I understand from what you said earlier that that's a
17 report that was prepared to be used in litigation to support a
18 ban on treatment in Florida?

19 A. I don't know exactly why it was done. What I was trying to
20 help you not make a mistake in thinking, that it was part of
21 Canadian national policy. It was an academic center. That
22 place does reviews, does all kind of reviews. And somebody I
23 think from the State of Florida commissioned and paid for the
24 review. And the review said, and it was objectively done, the
25 same thing that the other reviews have said, low quality and

1 taking that into consideration in comorbidities, but in Europe
2 they are focusing on that. But when I pointed out that the
3 standards of care here actually require that, you said, well,
4 they don't really follow the standards.

5 A. Ms. Cooper, what I was trying to say to you, you can read
6 these wonderful words in the standards of care, but it turns out
7 the devil is in the details. The devil is how it's translated,
8 who is doing the psychiatric assessments, what mindset do they
9 have, what knowledge do they have, and how long do they have to
10 do it. Every clinic can say we do comprehensive care. Every
11 clinic will say we do these evaluations. But from the parents'
12 point of view or the educated parents' point of view, that is
13 not what is happening to their child frequently.

14 Q. For some families you've talked to.

15 A. Frequently.

16 Q. For some families you've talked to. Correct?

17 A. I'm sorry?

18 Q. For some families you've talked to.

19 A. Almost for all the families I've talked to.

20 Q. Which is a tiny amount, representing a very tiny amount of
21 the clinics around the country. Correct?

22 A. And I don't know what percentage of the clinics, but they
23 are from many states.

24 Q. I just have a few more questions. I want to go back to the
25 second study on detransition that you mentioned showing the

1 30 percent detransition rate.

2 A. The Boyd study?

3 Q. That was the one by Boyd. Thank you. We're going to put
4 that up so we can get clarity on that. Looking at a study
5 called "Care of Transgender Patients: A General Practice
6 Quality Improvement Approach" by Isabel Boyd, et al., that's the
7 study you are talking about?

8 A. That was I think a primary care study.

9 Q. Okay. You have the highlighted portion in front of you?

10 A. Yes.

11 Q. "3.2.4. Undesired Treatment Outcomes (stopping hormones,
12 abnormal blood test results, side effects and complications)."
13 It says here, "Nine patients had stopped hormone therapy, one
14 related to practice policy because they had not attended any GIC
15 follow-up (the patient has restarted since the audit). Thus,
16 eight patients had stopped hormones voluntarily (20 percent
17 stopping rate; six trans men, two trans women). These patients
18 had been on treatment for a mean of five years (range 17 months
19 to 10 years). Four trans men had comments in the record that
20 related to a change in gender identity or detransitioning (4 out
21 of 41, 9.8 percent) quote: Would like to gradually
22 detransition. No longer wish to live your life as a male. Has
23 decided to detransition. Feels comfortable having decided to
24 dress and appear more feminine. Feels it was a mistake
25 identifying as non-binary now, close quotes.

1 None of these patients had undergone any gender-related
2 surgery. They had presented at a mean of 18 years of age, taken
3 testosterone for a mean of 18 months and currently presented as
4 female (three) or non-binary (one). The other four patients who
5 had stopped hormones continued to present as trans (two women,
6 two men): One, who had experienced orchidectomy, had a record
7 of regret (no hormonal treatment currently, regrets gender
8 reassignment); one had a medical reason noted for stopping,
9 quote, problems with PV bleeding despite androgen; two had no
10 specific reason for stopping in their record, but it was
11 documented that they had stopped."

12 So I see a 20 percent stopping rate, but I don't see a
13 30 percent detransition rate anywhere in there. Is this the
14 study you are talking about?

15 A. Yes. But, you know, I haven't read this study since it
16 came out. And you've picked out one paragraph. And perhaps we
17 could sit down and read it together and figure out whether I'm
18 right or wrong. And if I'm wrong, I'm wrong by 10 percent. The
19 point is, Ms. Cooper, the detransition for various reasons
20 happens. If it happens in this clinic, we should assume it
21 happens in Arkansas and in Missouri and everywhere else. And
22 the idea that people think it's a mistake is one of the things
23 I've tried to talk about this morning. We can't be sure that a
24 14 or 15 or 17 year-old knows what his or her future is going to
25 be. And if they cannot be prudent, we have to be prudent. And

1 if the medical profession isn't prudent about this, isn't
2 careful, isn't aware of the limitations, I guess legislatures
3 make a decision.

4 So I'm just asking the medical profession to be prudent and
5 to know about the evolution of gender identity. Even after it's
6 been solid during adolescence for three years or four years, it
7 doesn't mean that when you are 23 you don't think differently.
8 We must be prudent, and we must protect people sometimes against
9 things that we have reason to believe that a majority of people
10 may come to regret. Now, you see the real question here is not
11 the Boyd study.

12 Q. Well, I do want to stay on the Boyd study for a minute. I
13 understand your point that detransition happens. And that is
14 not the question I want to -- I'm not arguing about that.

15 A. Good.

16 Q. I'm asking about this 30 percent number that you testified.
17 I understand now you may be not standing by that 30 percent
18 figure?

19 A. Yeah. Maybe I'm going back to 20 percent.

20 Q. Then, even the 20 percent you would agree is not a
21 representation of detransition, but it represents the number of
22 people who stop medical transition for various reasons, some
23 medical reasons and unknown reasons. Correct?

24 A. I don't think you are going to make compelling points in my
25 view by picking out one paragraph and not looking at the whole

1 thing.

2 Q. You used the number 30 percent, and this appears to be
3 where it came from, so I need to pick it apart.

4 A. I do not represent myself as infallible. And my
5 statements, I can't imagine every statement is verifiable that I
6 ever make in my life. I'm doing the best I can with my memory.

7 Q. Fair enough. It's not a memory test. Looking at it here
8 now, though, you would agree that this study does not even say
9 20 percent detransitioned. It says 20 percent stopped the
10 medical transition for various reasons.

11 A. Well, can you tell what the denominator here is?

12 Q. Well, 20 percent. Twenty is a percentage.

13 A. That requires a denominator. What number of people are we
14 talking about?

15 THE COURT: Twenty out of a hundred.

16 THE WITNESS: That's not --

17 BY MS. COOPER:

18 Q. 41 is the N. If you want to know the number, it's 41 I
19 think it says. Four out of 41 were the ones who --

20 A. Is 41 the denominator?

21 Q. 4 out of 41 detransitioned.

22 A. So nine of 41 people stopped their hormones. Is that what
23 you are saying? So we do that math. 9 of 41.

24 Q. Twenty percent stopped.

25 A. It's over 20 percent.

1 Q. Stopped hormones?

2 A. Yeah.

3 Q. I just want to be clear, though, that doesn't represent
4 detransition. It represents stopping hormones for a variety of
5 different reasons.

6 A. And I want to be clear. I want to be clear that you don't
7 know it doesn't represent detransition. It means stopping
8 hormones. Why does a person stop hormones?

9 Q. Well, it says right here problems with bleeding despite
10 androgen, and two had no specific reasons. You don't understand
11 people stopping hormones besides detransition?

12 A. What are you quizzically asking?

13 Q. Do you think the only reason somebody who is on hormone
14 therapy for gender dysphoria would stop treatment, that the only
15 reason would be because they detransitioned?

16 A. No. Some stop because they get hypertension. Some stop
17 because they get obese. Some stop because they get blood clots.
18 Some stop because their hemoglobin levels go way up and they are
19 threatened with stroke.

20 Q. But they may still maintain their trans identity. Correct?

21 A. And, of course, if that would happen to a person, that
22 would make them rethink everything.

23 Q. I think we can put this study aside, and just a couple of
24 questions. Prior to this case, you had never heard of Mark
25 Regnerus. Correct?

1 Q. I understand you are speculating about the connection
2 there. But the national review board of Sweden did not ban
3 blockers. Correct? We talked about that before.

4 A. If Karolinska blocked blockers and if Karolinska is the
5 primary site for the Swedish people to get gender-affirming
6 care --

7 Q. Is it your understanding that's the only place you could
8 get gender-affirming medical care if you are a minor in Sweden?

9 A. I'm not sure. Sweden is a small country compared to the
10 United States. Those countries tend to create clinics like the
11 Portman Clinic in the UK that funnel these patients to the
12 centers of excellence, the centers of study.

13 Q. But you don't know how it's done in Sweden?

14 A. I don't know for sure how it's done in Sweden. I do know
15 Sweden, we're very concerned about the suicide rates of their
16 transgender population. The last report I had, it was
17 3.5 percent higher than the general population.

18 Q. I lied. I have a second question, if that's okay, related
19 to the same topic. I would like to put up another document, the
20 Swedish national report that we have discussed. This is, for
21 reference, DX17. This is the Swedish report you were discussing
22 earlier. Correct?

23 A. The translation of it?

24 Q. The English translation. If we can scroll, if you can look
25 at the first highlighted paragraph with me. "To minimize the

1 risk that a young person with gender incongruence later will
2 regret a gender-affirming treatment, the NBHW deems that the
3 criteria for offering GnRH analog and gender-affirming hormones
4 should link more closely to those used in the Dutch protocol,
5 where the duration of gender incongruence over time is
6 emphasized. Accordingly, an early childhood onset of gender
7 incongruence, persistence of gender incongruence until puberty
8 and a marked psychological strain in response to a pubertal
9 development is among the recommended criteria."

10 I'm sorry. I'm reading the wrong paragraph.

11 Apologies. I'm going to read the highlighted second
12 paragraph. "To ensure that new knowledge is gathered, the NBHW
13 further deems that treatment with GnRH analogs and sex hormones
14 for young people should be provided within a research context,
15 which does not necessarily imply the use of randomized
16 controlled trials, RCTs. As in other healthcare areas where it
17 is difficult to conduct RCTs while retaining sufficient internal
18 validity, it is also important that other prospective study
19 designs are considered for ethical review and that register
20 studies are made possible. Until a research study is in place,
21 the NBHW deems that treatment with GnRH analogs and sex hormones
22 may be given in exceptional cases, in accordance with the
23 updated recommendations and criteria described in the
24 guidelines." This is the requirement or provision in the
25 Swedish national report. Correct?

1 eight o'clock tomorrow.

2 MR. JACOBS: Yes, Your Honor.

3 (Overnight recess at 4:19 p.m.)

4 REPORTER'S CERTIFICATE

5 I certify that the foregoing is a correct transcript from
6 the record of proceedings in the above-entitled matter.

7 /s/Elaine Hinson, RMR, CRR, CCR
8 United States Court Reporter

Date: December 4, 2022.

Exhibit C

IN THE UNITED STATES DISTRICT COURT
FOR THE SOUTHERN DISTRICT OF WEST VIRGINIA
HUNTINGTON DIVISION

Christopher Fain, individually and on behalf of all
others similarly situated, et al.,

Plaintiffs,

vs.

CIVIL ACTION NO. 3:20-cv-00740

William Crouch, et al.,

Defendants.

REMOTE VIDEOTAPED DEPOSITION OF DR. STEPHEN LEVINE

DATE: April 27, 2022

TIME: 8:00 a.m. CST

PLACE: Veritext Virtual Videoconference

REPORTED BY: KELLEY E. ZILLES, RPR (Via Videoconference)

JOB NUMBER: 5176996

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INDEX

WITNESS: DR. STEPHEN LEVINE PAGE

EXAMINATION BY MR. CHARLES..... 10
AFTERNOON SESSION..... 111
EXAMINATION BY MR. DAVID..... 229

OBJECTIONS... 14, 71, 73, 85, 86, 91, 92, 93, 94, 119,
133, 134, 163, 231, 232, 233, 235, 238, 239, 240

EXHIBITS MARKED AND REFERRED TO:

Exhibit 1 Expert Disclosure Report of Dr.
Stephen B. Levine, M.D..... 18

1	Exhibit 2	Curriculum Vitae.....	20
2			
3	Exhibit 3	BPJ vs. West Virginia State Board of	
4		Education, et al Deposition of	
5		Stephen Levine, Volume I, 3/30/22.....	53
6			
7	Exhibit 4	Special Programs.....	64
8			
9	Exhibit 5	Kadel vs. Folwell, et al Deposition of	
10		Stephen B. Levine, M.D., 9/10/21.....	76
11			
12	Exhibit 6	Case Western Health Care Coverage for	
13		Staff and Students.....	88
14			
15	Exhibit 7	Considering Sex as a Biological Variable	
16		in Basic and Clinical Studies: An	
17		Endocrine Society Scientific Statement.	97
18			
19	Exhibit 8	Reflections on the Clinician's Role with	
20		Individuals Who Self-identify as	
21		Transgender Paper.....	100
22			
23	Exhibit 9	One Year Since Finland Broke with WPATH	
24		Standards of Care, 7/2/21.....	105
25			

1	Exhibit 10	International Clinical Practice Guidelines	
2		for Gender Minority/Trans People:	
3		Systematic Review and Quality Assessment	
4		Article.....	113
5			
6	Exhibit 11	Dear Colleagues, Clients and Friends,	
7		by Marci Bowers, M.D.....	125
8			
9	Exhibit 12	Gender Dysphoria and Gender	
10		Reassignment Surgery Article.....	131
11			
12	Exhibit 13	Canadian Gender Report.....	140
13			
14	Exhibit 14	Detransition-Related Needs and Support: A	
15		Cross-Sectional Online Survey Article..	155
16			
17	Exhibit 15	Individuals Treated for Gender Dysphoria	
18		with Medical and/or Surgical Transition	
19		Who Subsequently Detransitioned: A	
20		Survey of 100 Detransitioners.....	161
21			
22	Exhibit 16	Endocrine Treatment of	
23		Gender-Dysphoric/Gender-Incongruent	
24		Persons: An Endocrine Society Clinical	
25		Practice Guideline.....	163

1	Exhibit 17	Pediatric Obesity–Assessment, Treatment,	
2		and Prevention: An Endocrine Society	
3		Clinical Practice Guideline.....	177
4			
5	Exhibit 18	26 Swedish Review Unavailable.....	189
6			
7	Exhibit 19	Finnish Article.....	189
8			
9	Exhibit 20	Gender-Affirming Hormone in Children	
10		and Adolescents Blog Screen Shot.....	193
11			
12	Exhibit 21	Gender-Affirming Hormone in Children	
13		and Adolescents Article, 2/25/19.....	194
14			
15	Exhibit 22	Fain vs. Crouch, et al Deposition	
16		Transcript of Cynthia Beane, 3/29/22...	217
17			
18	Exhibit 23	Transgender and Gender Diverse Children	
19		and Adolescents: Fact-Checking of AAP	
20		Policy.....	221
21			
22	Exhibit 24	A Follow-Up Study of Boys with Gender	
23		Identity Disorder Article.....	224
24			
25			

1 Exhibit 25 Gender Dysphoria in Childhood Article.. 227

2

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4 (Original exhibits attached to original transcript.

5 Copies attached to transcript copies.)

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1 of your career, right?

2 A. Yes.

3 Q. Okay. You listed 23 separate pharmaceutical
4 company grants to study various pro-sexual medications,
5 right?

6 A. Yes.

7 Q. Were any of these 23 grants related to the
8 treatment of gender dysphoria in transgender people?

9 A. No.

10 Q. And were any of the grants related to the
11 treatment, any kind of treatment of prepubertal children
12 with gender dysphoria?

13 A. No.

14 Q. Or adolescents with gender dysphoria?

15 A. No.

16 Q. You also list in that same section in your
17 report, Dr. Levine, that you received a U.S. National
18 Institute of Health grant for the study of sexual
19 consequences of systemic lupus erythematosus and that
20 you were a co-principle investigator. Does that ring a
21 bell, is that accurate?

22 A. It is accurate.

23 Q. Okay. And did this grant have to do with the
24 study of anything related to gender dysphoria?

25 A. No.

1 A. Only to the extent that the grant helped us to
2 set up the Center For Marital & Sexual Health. The
3 Center For Marital & Sexual Health had a program called
4 the Case Western Reserve Gender Identity Clinic, and so
5 this was, this was not a grant for research, this was a
6 grant for the establishment, the administrative
7 establishment of our center that dealt with many sexual,
8 all sexual things including trans phenomenon. We didn't
9 in those days call it so much trans phenomenon, but we
10 called it gender identity problems.

11 Q. Right. So one of the grants was used to start
12 the Center for Marital & Sexual Health, but those five
13 separate grants were not for the study or, or direct
14 treatment under the Sihler Mental Health Foundation?

15 A. That's correct.

16 Q. Okay. But the Center For Marital & Sexual
17 Health, as a clinician there you saw a wide range of
18 patients there, right?

19 A. Yes.

20 Q. With a variety of problems related to sexuality
21 or sexual well-being?

22 A. Yes.

23 Q. Okay. And did you treat any children with
24 gender dysphoria at the Center For Marital & Sexual
25 Health?

1 A. If I can clarify your question, by you do you
2 mean me personally or do you mean under me as the
3 supervisor of people who did that?

4 Q. Let's start with you personally.

5 A. Yes, I have only on a rare occasion personally
6 treated or directly or indirectly treated a child. My
7 center, however, over the years has, has seen children
8 and, and I've been involved in the, the treatment as a
9 supervisor of those children.

10 Q. Okay. So you've reviewed their cases by way of
11 your supervision of clinicians at the center, but not
12 individually?

13 A. That's right.

14 Q. Okay. And is that the same for any adolescents
15 with gender dysphoria who were seen at the center? In
16 the early years I'm talking about now, not in recent
17 times.

18 A. Well, in the early years I occasionally saw
19 personally an older teenager, older adolescent, but in
20 the early years you must understand most of the patients
21 were adults.

22 Q. Okay. So to your knowledge, Dr. Levine, have
23 you received any grants to study the treatment -- I'm
24 sorry, excuse me. Have you received any grants to study
25 treatment for adults with gender dysphoria?

1 April 27, 2022. We're going back on the record at
2 10:36 a.m.

3 BY MR. CHARLES:

4 Q. Okay. Dr. Levine, talking about your writing
5 credentials, you've testified previously that you were
6 involved in drafting portions of the WPATH standards of
7 care Version 5, right?

8 A. Yes, I was the chairman of that group.

9 Q. And besides that, have you developed -- let me
10 back up. Have you helped to develop treatment
11 guidelines for the treatment of children or adolescents
12 with gender identity issues?

13 A. If you mean have I been part of a national or
14 international group that tried to, to publish, that
15 published guidelines about the treatment of these
16 individuals, the answer is no. But in my November of
17 2021 article I gave, I offered my opinions about what
18 the evaluation of adolescents and children ought to
19 consist of. In that sense I'm hoping that would
20 influence the guidelines of those committees who might
21 function in the future.

22 Q. I see. When we spoke in September of 2021 for
23 the Kadel vs. Folwell deposition, you said that you were
24 working with SEGM to develop some treatment guidelines.
25 What, what happened to those?

1 Q. Yes, Exhibit 01.

2 A. Would you give me the pages again.

3 Q. Sure, Page 2, Paragraph 3, so that will be the
4 top of Page 2, the paragraph does begin on Page 1.

5 A. Yeah.

6 Q. Okay. So in that paragraph your report states
7 that, "During this era an occasional child was seen."
8 By this era do you mean from around 1974 to 1993?

9 A. Yes.

10 Q. Okay. And by occasional do you mean infrequent?

11 A. Infrequent is a good word.

12 Q. So is it fair to say during that period your
13 clinic did not see many children with gender dysphoria?

14 A. It's fair to say that.

15 Q. And in your deposition on March 30th you
16 estimated that over the course of your career you've
17 probably only seen regularly six prepubertal children,
18 right?

19 A. It's an estimate, yes.

20 Q. And around 50 adolescents, give or take?

21 A. Give or take an unknown number, yeah, ten, 12,
22 five.

23 Q. Sorry, so you --

24 A. I've had extensive experience talking to
25 adolescents over the course of my career, adolescents

1 A. Page 51.

2 Q. Okay. Can you please scroll to Page 55.

3 A. I'm there.

4 Q. Okay. So at line 13 on Page 55, "Question,
5 okay, and I'm sorry, just by recent, when was the last
6 time you wrote a letter of authorization for a gender
7 affirming surgery for an adult? Answer, probably
8 12 months ago." So have you written a letter of
9 authorization for a gender affirming surgery in the last
10 seven months, Dr. Levine?

11 A. I think the last letter -- you, I need to, I
12 need to help you qualify your question. I have in the
13 last seven months given my, my approval to several
14 letters for bilateral mastectomies for members in Mass
15 at Framingham, the correctional institution in
16 Massachusetts. I don't know if that would number two or
17 three, but since September the 10th I believe at least
18 two and possibly three letters. I haven't personally
19 written the letter, but I am the consultant to a group
20 of team that approves such surgeries, and so the answer
21 to the question is yes.

22 Q. Okay. Thank you. And to your recollection,
23 any, any such letter outside the, outside of that
24 context?

25 A. Since September the 10th?

1 Q. That's correct, yes.

2 A. Yes, I think the answer is that, no, but I
3 believe at our center someone else has written one
4 letter for bilateral mastectomies.

5 Q. Okay. Thank you. Dr. Levine, are you familiar
6 with the, the exclusion for gender affirming surgical
7 care in the West Virginia Medicaid Program that's at
8 issue in this case?

9 MR. DAVID: Objection to form.

10 Q. You can answer.

11 A. I'm vaguely familiar that surgical care is
12 excluded currently, but endocrine care is not excluded.

13 Q. Have you reviewed any documents that, that show
14 that exclusion or was that information just communicated
15 to you by counsel?

16 A. Verbally communicated.

17 Q. Okay. And so you're aware that there are
18 categorical exclusions, which means that the exclusions
19 prohibit surgical care related to the treatment of
20 gender dysphoria regardless of a West Virginia Medicaid
21 member's need for it or appropriateness for such
22 intervention?

23 MR. DAVID: Objection to form.

24 Q. Let me simplify my question.

25 A. Thank you.

1 Q. The categorical, the exclusion does not
2 investigate or contemplate whether someone receiving
3 West Virginia Medicaid needs or is an appropriate
4 candidate for such intervention, it just prohibits it,
5 period?

6 MR. DAVID: Objection to form.

7 A. The categorical exclusion would include surgery
8 for teenagers and surgery for adults, so it would cover
9 removing the breasts or removing the scrotum of a
10 15-year-old who feels like --

11 Q. Not my question, Dr. Levine. Let me, let me
12 rephrase again. The, the West Virginia Medicaid Program
13 and the exclusion it maintains, which excludes surgical
14 care for members for whom it is appropriate, it, it just
15 excludes it, you're, you're aware it just excludes it,
16 there's no, there's no conditional considerations or any
17 investigation done into the member's health at all, it
18 just, there's no coverage for that care, you understand
19 that?

20 A. I, I --

21 MR. DAVID: Objection to form.

22 A. I think that's what categorical means, so I
23 think the answer is I understand that at the moment,
24 yes.

25 Q. Okay. But you don't view your testimony here in

1 your expert report as being in support of that exclusion
2 or whether it should exist, right?

3 A. Yeah, it's my understanding that, that the
4 lawyers who hired me wanted me to testify to the state
5 of science in this field, and, and so I have not been
6 involved with the legal questions, per se, or giving an
7 opinion about those matters. As I sort of indicated to
8 you before, I don't really feel that the, my expertise
9 extends to how the insurance industry works and how
10 governments and legislatives works and so forth. So I,
11 I think the answer to the question is that I'm not
12 considering myself to be expert on the question that
13 you're asking me.

14 Q. Right. So you're, you, you are an expert about
15 what your testimony is about though, right, and you're
16 saying your testimony is not about whether or not that
17 exclusion should exist?

18 A. Yes, I'm not offering an opinion about pro or
19 con about that question.

20 Q. I see. Because you're, you're, as you say,
21 you're not a politician or a law maker?

22 A. Or an insurance expert.

23 Q. Right. Or a public health expert, right?

24 A. Well, I'm a little more ambivalent about public
25 health matters, yeah. I'm not as, I'm not, I really

1 think that public health is the issue here and so I, I
2 don't want to say I'm not an expert. I'm not an expert
3 in public health, but I do have opinions about the
4 long-term public health of people who are prematurely
5 having their bodies changed because I do think this has
6 public health implications for the future of each of
7 these, these adolescence children and young adults.

8 Q. Understood.

9 A. And adults as well.

10 Q. And you, generally speaking, don't advocate to
11 deny all forms of medical intervention to people with
12 gender dysphoria though, right?

13 A. That's right.

14 Q. Okay. I'm going to introduce another exhibit,
15 Dr. Levine, give me just a moment.

16 (Exhibit 6 marked for identification.)

17 Q. Okay. It should be now or shortly visible, you
18 might need to refresh.

19 A. I now have Exhibit 6 here.

20 Q. Okay.

21 MR. CHARLES: So I'm showing Dr. Levine
22 what has been marked as SL06.

23 Q. Dr. Levine, this is a short document, please
24 just take a minute and scroll through it.

25 A. Okay, I, I've scrolled.

1 (A break was taken at 11:33 a.m.)

2 VIDEO TECHNICIAN: We're going back on the
3 record at 12:34 p.m.

4 MR. CHARLES: Okay. So I'm showing Dr.
5 Levine what has been marked as SL09, an article from
6 Society for Evidence Based Gender Medicine entitled,
7 "One year since Finland broke with WPATH standards of
8 care."

9 BY MR. CHARLES:

10 Q. Dr. Levine, do you see the date of publication
11 in the left corner of that first page?

12 A. July 2nd.

13 Q. And, and the year is 2021, right?

14 A. Yes.

15 Q. So looking at the first paragraph there, I'm
16 just going to read that, "A year ago the Finnish Health
17 Authority (PALKO/COHERE) deviated from WPATH standards
18 of care 7 by issuing new guidelines that state that
19 psychotherapy rather than puberty blockers and cross sex
20 hormones should be a first line treatment for gender
21 dysphoric youth. This change occurred following a
22 systematic evidence review which found a body of
23 evidence for pediatric transition inconclusive."

24 And then the next paragraph, the first sentence,
25 "Although pediatric medical transition is still allowed

1 in Finland, the guidelines urge caution given the
2 unclear nature of the benefits and the interventions,
3 largely reserving puberty blockers and cross sex
4 hormones for minors with early onset gender dysphoria
5 and no co-occurring mental health conditions." Did I
6 read that correctly?

7 A. Yes, you did.

8 Q. Okay. So as this article states, medical
9 interventions are still available in Finland for youth
10 experiencing gender dysphoria, right?

11 A. On a case-by-case basis I think.

12 Q. And --

13 A. I should say on a case-by-case basis and two
14 research centers as opposed to in any practitioner's
15 office throughout the country.

16 Q. Right. But it's, it's not been completely
17 prohibited is what I'm asking?

18 A. Oh, it's been, it's been, the brakes have been
19 put on.

20 Q. But it's not been completely prohibited is what
21 I'm asking?

22 A. That's what you and I have agreed on, yes.

23 Q. So it's not been completely prohibited, right?

24 A. Right.

25 Q. So then in the third paragraph beginning with,

1 "The qualifying criteria for gender reassignment of
2 youth articulated in the 2020 Finnish treatment
3 guidelines are consistent with the original Dutch
4 protocol, but represent a significant tightening of the
5 more recent practices promoted by WPATH." So the
6 article describes it as a tightening of the standards
7 which WPATH allows for, right?

8 A. Yes.

9 Q. So you, you've talked about in your report an
10 idea of rapid affirmation treatment where you allege
11 that diagnoses of gender dysphoria are being made in an
12 hour and then, and then prescriptions provided for
13 medical interventions, right?

14 A. Yes.

15 Q. Do you have, or I should say, your evidence for
16 that is anecdotal in nature, right?

17 A. My evidence for that is what has been told to me
18 by parents, what has been told to me by patients and
19 what this, what the third paragraph of this document
20 says.

21 Q. Right. So --

22 A. So I don't really think the answer is simply
23 anecdotal, it's based upon a considerable consistent
24 range of, of experiences, both of my personal
25 experiences, of my patient's personal experiences, and

1 paragraph -- actually, hang on a second. Dr. Levine,
2 let's go ahead and go to Page 26 of your report,
3 Exhibit 1.

4 A. Okay. Let me, I have to scroll back. Did you
5 say page or Paragraph 26?

6 Q. That would be Page 26.

7 A. Okay, I'm on Page 26.

8 Q. Okay. Okay. So, Dr. Levine, you've testified
9 previously that you generally provide care along some of
10 the same guidelines as WPATH, right?

11 A. In a general way, sure.

12 Q. And the difference from your view is that you
13 require psychotherapy for some not necessarily
14 predetermined length of time for patients that you see
15 before you will authorize any kind of like medical
16 intervention, right?

17 A. I don't want to answer that question right or
18 wrong because embedded in the question is the word
19 psychotherapy and I don't know what you understand by
20 psychotherapy, I mean, you're a lawyer and I'm a
21 practitioner of psychotherapy. And I think when a
22 lawyer uses psychotherapy it is a certain concept about
23 I'm trying to achieve a certain aim, you see. And in
24 the context of the question that you've asked, you could
25 substitute an extended period of time with the patient

1 working with patients.

2 Q. Okay. So back to my question. On some, on some
3 level that that is, that universe of care that you are
4 providing, which again, I think I'm still going to call
5 it psychotherapy, but I understand your explanation that
6 it is, that encompasses a lot that you do in your, in
7 your clinical practice, but again, the difference for
8 you between the Levine way, if we can shorthand, and
9 WPATH is that you cultivate, you engage in that process
10 as a requirement before you will authorize any kind of
11 medical intervention for a patient for the treatment of
12 gender dysphoria?

13 A. That's true.

14 Q. Okay. Thank you. But even still as a part of
15 your practice as we discussed earlier, you still
16 occasionally write letters of authorization for medical
17 interventions, like endocrine treatments or surgical
18 interventions?

19 A. Yes.

20 Q. Okay. Okay. Let's go back to your report,
21 please, to Page 35.

22 A. I am there.

23 Q. Okay. And looking at Paragraph 70, let's start
24 with Paragraph 70. I take that back, let's go with
25 Paragraph 71 at the bottom of the page, "In recent years

1 WPATH has fully adopted some mix of the medical and
2 rights paradigm discussed above. It has downgraded the
3 role of counseling or psychotherapy as a requirement for
4 these life-changing processes. WPATH no longer
5 considers pre-operative psychotherapy to be a
6 requirement. It is important to WPATH if the person has
7 gender dysphoria, the pathway to the true, the
8 development of this state is not. Cited Levine,
9 Reflections, at 240. Two separate evaluations, one from
10 Canada and one from the UK reviewed WPATH's guidelines
11 and found them untrustworthy."

12 So for that footnote 113 you've cited the Dahlen
13 study which we talked about and then there's also a
14 citation here that says, "See also," and then there's a,
15 a Web address, do you see that, the very last line?

16 A. Yeah, yeah, right.

17 Q. It says, "Gender report, CA"?

18 A. Yeah.

19 (Exhibit 13 marked for identification.)

20 Q. Okay. There should be another exhibit there for
21 you, Exhibit 13. Just let me know when you can see
22 that.

23 A. Okay. Okay.

24 Q. Okay.

25 A. Yeah, okay.

1 Q. Have you, have you seen this article before
2 either on the Internet or printed out perhaps?

3 A. The reason I cited it is that I had read it
4 before.

5 Q. Okay. And this is not a peer reviewed journal,
6 is it?

7 A. This is a journalist, but if you look very
8 carefully at the, its length and its content, it's very
9 impressive.

10 Q. Okay. Is this the review from Canada that you
11 were talking about in that sentence --

12 A. Yes, yes, it is.

13 Q. Okay. But it's, it's not a systematic review
14 like the one from the UK?

15 A. It's not systematic in that it wasn't done by a
16 community of scientists, a committee of scientists.

17 Q. Okay. And the --

18 A. It is systematic and it is a review, but it's
19 one person's review.

20 Q. Right. So it's more, we were discussing the
21 difference between systematic reviews earlier today,
22 it's a, it's, it's not a scientific committee that's
23 done in a, in a formal way that we were discussing, it's
24 more akin to that latter one person reviewing things
25 kind of --

1 A. It's an investigative report by a journalist.

2 Q. Right. And you see in the first page, Dr.
3 Levine, it says, "The following investigative report was
4 developed by @LisaMacRichards (a pseudonym)"?

5 A. Yeah, okay, right.

6 Q. Okay.

7 A. I see I'm wrong, she wasn't the journalist.

8 Q. So we, you don't know who this author is, right?

9 A. Well, her real identity?

10 Q. Correct, yeah.

11 A. No, I don't know who Lisa Mac Richards really
12 is.

13 Q. Okay. So it's hard to know if she's an actual
14 person?

15 A. If she's an actual person, is that what you
16 said?

17 Q. What I mean to say is, because she's using a
18 pseudonym, you can't confirm her identity is what she
19 represents it is, right?

20 A. Well, she says it's a pseudonym, so I presume
21 the rest of the paragraph is correct, that she works at
22 a Canadian hospital and holds a master's of science
23 degree and, yeah.

24 Q. But what I mean is there's no way to confirm
25 that because we don't know what her name is?

1 A. It could be written by a man, I don't know, it
2 could be written by a committee, I have no idea.

3 Q. Okay. Okay. So going back to what we were
4 talking about just a few minutes ago, Dr. Levine, about
5 your approach versus WPATH. You, you've said before,
6 not, not necessarily today, but you've testified in
7 other depositions that your approach has the limitation
8 that there's not any scientific evidence or long-term
9 studies to support it, right?

10 A. I think in particular what I said is that, that
11 the status of the outcome, the outcome status and the
12 methodologic status of psychotherapy as a first line
13 approach to the trans adolescent has, does not have a
14 firm evidence base just as trans affirmative care does
15 not have a firm evidence base.

16 So oftentimes that's, that's, I get a question
17 just like you ask, you just posed sort of implying that
18 there's no evidence that my, my recommendations have a
19 scientific proven basis to it. And that is correct,
20 except that all other psychiatric difficulties are
21 treated with, in our society both European and American
22 and Asian societies by a psychotherapeutic extended
23 evaluation and treatment approach before, with or
24 without psychiatric medications, you see.

25 And so we are trying to make a, you, some people

1 centers have cropped up that are providing affirming
2 care in one hour, again, we talked about the 35 parents
3 you had talked to, you've mentioned a couple of patients
4 you've talked to, but you don't have, or I should say
5 what evidence can you provide me today that is, is
6 scientific peer reviewed published data showing that
7 this is actually what's happening in these clinics?

8 A. Well, if I look at Exhibit 6. Do you know what
9 the, the first name for this center was and the name of
10 so many of the 50 or so centers are? And it has the
11 term gender affirming care, the clinic, you see. If you
12 look at all of the materials in Exhibit 6, it's about
13 support and affirmation, it's not about investigation,
14 it's not about psychotherapy. And, and you see, gender
15 affirming care has been taken over, it's been taking
16 over the world's sensibilities without any scientific,
17 first demonstrating its efficacy with scientifically
18 respectable methods.

19 Q. I understand that, Dr. Levine, but that's not my
20 question. My question is, what evidence can you point
21 to that these kinds of interactions are happening in
22 clinics? Is your basis that the, are you basing that on
23 the way these centers are named?

24 A. I'm basing it on what they're named and I'm
25 looking at the document that you are, are talking about.

1 friendly especially designed specialty clinic. Those
2 clinics exist to take care of trans people, to give them
3 hormones and to get them surgery, that exists.

4 Q. But what you're describing --

5 A. It exists to do psychotherapy.

6 Q. Okay. And what you described, Dr. Levine, is
7 the basis for your, for this opinion, right?

8 A. The basis for my opinion is my collective
9 experience of dealing, watching, participating in the
10 evolution of the study of transsexual care over, over
11 since 1974.

12 Q. Okay. So your report states that you were
13 involved with WPATH before it was called WPATH, when it
14 was called the Harry Benjamin --

15 A. Can I help you?

16 Q. Yes. Harry Benjamin?

17 A. International Gender Dysphoria Association.

18 Q. Thank you. And you were involved around 1999
19 when the 6th version of the standards of care was
20 released, right, we talked about that?

21 A. Yes.

22 Q. Okay. And it's, it's true that you helped to
23 draft portions of that version, right?

24 A. Actually, my report misstates me as the
25 co-chair. If I remember correctly, I was the chairman.

1 Q. The chairman of that committee, okay. Thank
2 you.

3 A. And most, with very little exception I had a
4 significant editorial role in creating every sentence in
5 that 21-page document.

6 Q. Okay. And you've testified in other depositions
7 that even though the, there have been changes made to
8 the standards of care in subsequent versions, you still
9 continue to see your work reflected in those versions,
10 right?

11 A. Yes, my language.

12 Q. Yes, mm-hmm.

13 A. Yeah, my language, right. In fact, the next
14 version which came out I think three years later or two
15 years later I think was pretty much word for word except
16 for a requirement for one letter for endocrine treatment
17 rather than two, which is what my committee of eight
18 people recommended.

19 Q. Okay. And you've testified before that even
20 Version 7, which is, you know, one more, obviously one
21 more removed from Version 6, that that, as you read it
22 much of the language you had actually still, it was
23 still reflecting your language in that version even,
24 even though it's a much longer document?

25 A. Well, yeah, I think the introduction section

1 about what guidelines were and, and the problems of
2 cross culture, cross country rules affecting the laws
3 are different and the, that we wanted this to be a
4 information guide for, for patients and parents and
5 wives and husbands and so forth.

6 I think, you know, once, once we got, I mean, I
7 don't have it in front of me and I'm not sure I could
8 recognize every sentence I wrote anyway, but, but they
9 did, they did continue to use some of my sentences, some
10 of my concepts. It was my concept that there is a
11 difference between readiness criteria and eligibility
12 criteria, that was one of my contributions

13 Q. Thank you. And, and I think also you testified
14 in the Soneeya trial that you had asked to be involved
15 in helping to write standards of care 8 but were told
16 that you, in order to do so you had to be a WPATH
17 member, right?

18 A. Yes.

19 Q. And looking back at your report -- actually,
20 give me just a minute here. Actually, Dr. Levine,
21 let's --

22 MR. CHARLES: Sorry, Kelley and Kraig, can
23 we go off the record real quick.

24 VIDEO TECHNICIAN: We're going off the
25 record at 2:26 p.m.

1 be trans boys or trans males.

2 The historic pattern throughout most of the
3 world was 3.5 to 4 biologic males who wanted to be women
4 to biologic females who wanted to be men dominated
5 dramatically for decades in the '70s and the '80s and
6 the '90s and the early 2000s. But since 2005 there's
7 been a growing incidence of request for services and
8 particularly request for services from girls assigned at
9 birth who wanted to be males.

10 Some of us have come to in recent years call
11 this delayed or pubertal or rapid onset of gender
12 dysphoria, meaning it's a pubertal phenomenon because
13 there was no evidence prior to that except in the
14 retrospective subjective histories given by these kids
15 that they had any indication, parents and themselves,
16 had no behavioral indications that they were trans
17 identified or even sort of leaning in that direction.

18 Q. I understand that, Dr. Levine, and I'm not
19 talking necessarily about the, the increase in
20 referrals, I'm talking about this phenomenon that you
21 referenced called rapid onset gender dysphoria. So not
22 just adolescent onset gender dysphoria, which I
23 understand you're saying has somewhat increased since
24 2005, but rapid onset gender dysphoria. And I'm
25 specifically asking what peer reviewed studies, what

1 papers and what research would you refer me to or is
2 referenced in your report as evidence that this
3 hypothesis actually exists or that there's any
4 scientific study to support it?

5 A. No. 1, this is not a hypothesis, this is a
6 demonstrated fact.

7 Q. Okay. Based on what, Dr. Levine, that's what
8 I'm asking, what are the peer reviewed studies?

9 A. If you look up the presentations of Kenneth
10 Zucker, if you look at papers, I can't give you the
11 authors at the moment from Europe, this has been
12 documented by DiAngelo I believe in Australia, by
13 Clayton in Australia.

14 It seems to me there is no disagreements about
15 this except I've heard the cynical response that what
16 rapid onset gender dysphoria really means is that the
17 parents have suddenly discovered that their kids have
18 been transgender, meaning to deny the parental reports
19 that the children were not cross gender identified prior
20 to that, even though the kids say, well, I was never
21 comfortable with being a boy or a girl.

22 Q. Okay. So you, for this contention in your
23 report you cite one thing and that is Midgen A.
24 Hutchinson and her study is entitled, "In support of
25 research into rapid onset gender dysphoria." So that

1 was published in 2020 and I don't, I'm not seeing here
2 any of the other --

3 A. One, one of the reasons you're not seeing it is
4 that I assume that everyone understands that this is
5 true.

6 Q. Well, Dr. Levine, this is an expert report and
7 you have to include all of your expert opinions, and
8 you're also required under Rule 26 to disclose all of
9 the data and research that you considered for those
10 opinions. That's the purpose of our deposition today is
11 for me to understand and to have you put on the record
12 what you relied on to establish your opinions, so that's
13 what I'm trying to get at. And, and I understand what
14 you're saying that from your vantage point as a
15 clinician outside of the legal sphere that there are
16 things you think are givens, but we can't operate like
17 that unfortunately. So I need to, I need to understand,
18 and all I see here is the Midgen A. Hutchinson study
19 that's asking for support of, that's offering that she
20 wants to support research into this phenomenon, not that
21 the phenomenon has been evidenced to exist. Does that
22 make sense?

23 A. Yes. May I comment on that?

24 Q. On Hutchinson, yeah. Let me pull it up
25 actually.

1 makes reference to it as well. This is not to be
2 denied.

3 So if you're questioning whether, whether this
4 is really true, I think you're just simply wrong, but
5 you're not, you may not be questioning that. I'm wrong
6 and I didn't document adequately that sentence and I
7 apologize, I stand corrected.

8 Q. Okay. So let's turn in your report, Dr. Levine,
9 here to the following sentence which says, "There is
10 also no chapter on detransition despite the evidence
11 that a growing number of young people regret transition
12 and wish to reverse it," do you see that, are you still
13 on Page 38 there?

14 A. I do.

15 Q. Okay. So for this sentence here you have
16 provided a couple of citations. The first is an article
17 by Vanderbussche I believe, if I'm pronouncing it
18 correctly, and then a second article by Littman. So
19 let's, let's take each of those in turn. And I'll just
20 introduce the Vanderbussche exhibit, give me just a
21 moment.

22 (Exhibit 14 marked for identification.)

23 A. Is it up now?

24 Q. Let me know when you can see it.

25 A. This will be 14?

1 Q. Yes, correct.

2 A. Okay. All right, I see it.

3 MR. CHARLES: So this is, for the record
4 I'm showing Dr. Levine what has been marked as
5 Vanderbussche article entitled, "Detransition related
6 needs and support: A cross-sectional online survey, by
7 Elie" -- oh, excuse me, it's Elie Vandenbussche, not
8 Vanderbussche.

9 Q. And, and you've seen this article before, Dr.
10 Levine?

11 A. Yes.

12 Q. Okay. Scroll please to the, the first page of
13 text. Let me know if you can see that or if you need a
14 minute to zoom in.

15 A. You mean, "Introduction"?

16 Q. Yes, it has, it's the page that has introduction
17 on it, yes.

18 A. Okay.

19 Q. So from the abstract, the first sentence, the
20 abstract is in a, set off in a blue box there at the
21 top?

22 A. Yes, yes.

23 Q. It says, "The aim of this study is to analyze
24 the specific needs of detransitioners from online
25 detrans communities and discover to what extent they are

1 being met. For this purpose a cross-sectional online
2 survey was conducted and gathered a sample of 237 male
3 and female detransitioners. The results showed
4 important psychological means in relation to gender
5 dysphoria, co-morbid conditions, feelings of regret and
6 internalized homophobic and sexist prejudices. It also
7 found that many detransitioners need medical support
8 notably in relation to stopping/changing hormone
9 therapy, surgery/treatment complications and reversal
10 interventions." So the aim of this study as outlined
11 here in the abstract is to analyze the specific needs of
12 detransitioners, right?

13 A. Yes.

14 Q. Okay. Not to demonstrate that there is a
15 growing number of young people who regret transition or
16 wish to reverse it, right?

17 A. It's true. But you see, you're, you're taking
18 the reference out of that sentence and missing the first
19 phrase of that sentence. This sentence that you're
20 drawing attention to is that WPATH's standards of care
21 draft did not have any section on the phenomenon of
22 detransition.

23 Detransition exists and detransition is a
24 reflection of those adolescents or people, or adults who
25 have at one time in their lives thought that they needed

1 this care and then after they lived following the care
2 they decided that their problems have not been solved
3 and they decided to return to the gender expression --

4 Q. I understand that, Dr. Levine, and I'm not
5 actually contesting the assertion in your, in your
6 report that detransition exists at all.

7 A. All right.

8 Q. What I'm asking about is your assertion in the
9 latter half of that sentence that says that there is a
10 growing number of young people who regret transition and
11 wish to reverse it. Again, I'm just trying to
12 understand what you're saying here and on what basis you
13 are making those assertions.

14 So I'm not asserting whether or not
15 detransitioning exists, my question is, this study did
16 not look at how many detransitioners are there now as
17 opposed to any other time in history, it was not a
18 qualitative or quantitative analysis. It was a study
19 according to the abstract here, and I'm just asking you
20 to confirm that, about the specific needs of
21 detransitioners, both psychological, medical, other
22 kinds of support, right? So that's what I'm saying is
23 this study is not, the aim is not to quantify the number
24 of, whether the number of detransitioners is growing or
25 shrinking or staying the same, right?

1 A. Yes, I can answer to your question, correct.

2 Q. Okay.

3 A. But it doesn't mean that -- I think you're
4 missing the point. And, and by, by having me say yes,
5 that it doesn't quantify the incidents of detransition,
6 it's missing the point.

7 Q. I understand that, Dr. Levine. But if your
8 point was, if your point in your report was detransition
9 is a thing and here are the psychological supports that
10 these people need, that's what you should have written,
11 but that's not what you wrote. You wrote that a growing
12 number of young people regret transition and wish to
13 reverse it.

14 So my question to you about the article you rely
15 on for that contention is, this article doesn't say
16 that, this article is not a study of the growing numbers
17 or small or diminishing numbers or staying the same
18 numbers of people who detransitioned. That's what I'm
19 asking you to confirm.

20 A. What I am confirming is that this particular
21 paper talks about 237 people who have detransitioned and
22 that WPATH has no serious discussion of detransition,
23 there's no chapter on this, on this phenomenon which is
24 extremely relevant to the care of transgender people,
25 especially transgender young people.

1 The reason I cited this is 237, and the reason,
2 the next thing, Littman is another additional 100
3 people. And if you, if you read closely some of the
4 references in this particular article, there is
5 Exposito-Campos' article talking about subreddit and the
6 number of people who were discussing detransition.

7 So what I'm saying if WPATH is responsible for,
8 for providing a scientific basis for affirmative care,
9 they must talk about the error rate as represented by
10 detransitioned people. And four years ago we had no
11 idea about the, the rate of detransitioned people and
12 today we have two studies that have been published from
13 the UK that begin to give us a rate of detransition.

14 And so to me you are making the wrong point and
15 that I have not been in error. You just have
16 misunderstood the difference of why I cited these
17 particular papers. These particular papers just
18 demonstrate that detransition is a real problem and, and
19 it is a moral and ethical and scientific problem. And
20 that WPATH if it's going to deal with the science of
21 transition, it has to deal with the error rates and what
22 happens to people who detransition, you see. And so I
23 don't, I don't have nothing more to say about that, I
24 just think your point is quite irrelevant.

25 Q. Okay. Well, I'm going to continue to ask you

1 about evidence that you cite in your report that you use
2 as support for assertions you're making, so I'm just
3 going to flag that for you now. And again, this --
4 let's actually, let me, let me just ask one more time.
5 This study does not speak to the numbers of people who
6 have detransitioned now as opposed to any other time in
7 history, right?

8 A. As far as I remember this paper, the answer to
9 your question is right.

10 Q. Sorry, the answer to my question is -- okay,
11 right, okay. So let's actually now that you mention it,
12 let me just pull up really quickly the Littman study
13 that you mentioned.

14 (Exhibit 15 marked for identification.)

15 Q. This will be Exhibit 15.

16 A. Okay.

17 Q. Okay.

18 MR. CHARLES: So for the record, I'm
19 showing Dr. Levine what has been marked as SL15,
20 "Individuals treated for gender dysphoria with medical
21 and/or surgical transition who subsequently
22 detransitioned, a survey of 100 detransitioners by Lisa
23 Littman, received," well, published online 19 October
24 '21.

25 Q. Okay. So looking at the abstract again, the

1 first sentence, "The study's purpose was to describe a
2 population of individuals who experienced gender
3 dysphoria, chose to undergo medical and/or surgical
4 transition, and then detransitioned by discontinuing
5 medications, having surgery to reverse the effects of
6 transition, or both. Recruitment" -- oh, wait, let me
7 stop there, just a second. And then the last sentence
8 of the abstract -- oh, wait, hang on. So then actually
9 if you'll look please to page -- okay, go to two pages
10 down, Dr. Levine, it's going to be numbered Page 3355 in
11 the upper right-hand corner.

12 A. Okay, I'm on the page.

13 Q. Okay. In the left-hand corner the paragraph
14 starts on that page with, "Individuals," but I'm going
15 to start reading from the second to last sentence. It
16 begins, "This study does not describe the population of
17 individuals who undergo medical or surgical transition
18 without issue, nor is it designed to assess the
19 prevalence of detransition as an outcome of transition.
20 Instead, the goal was to identify detransition reasons
21 and narratives in order to inform clinical care and
22 future research."

23 So again, my question here, Dr. Levine, is this
24 study by design and by the admission of Lisa Littman is
25 not about assessing the prevalence of detransition or

1 whether or not the numbers of detransitioners are
2 growing, right?

3 MR. DAVID: Objection to form.

4 A. You know, I, I don't know if I should just
5 repeat what I said before. Detransition is a
6 phenomenon, science is only now beginning to get, we
7 have two studies that were published within the last I
8 think four months or five months.

9 Q. Okay. So, Dr. Levine, are you refusing to
10 answer my question because --

11 A. Not at all, I'm answering your question, I'm
12 answering.

13 Q. No, you're not.

14 A. Well, then ask me the question again. I'm
15 sorry, I apologize. You want to confine me to an answer
16 and so, so set me up for the answer you want, please.

17 Q. Okay. What I'm asking is, this sentence by the
18 admission of the author was not designed to assess the
19 prevalence of detransition?

20 A. That's true.

21 Q. Okay. Instead the purpose of this study was to
22 identify detransition reasons and narratives in order to
23 inform clinical care and future research, right?

24 A. Correct.

25 Q. Okay. Thank you. Okay. Let's, I'm going to

1 A. This is --

2 Q. Well, let me just ask you, Dr. Levine, you don't
3 speak Finnish, do you?

4 A. I'm an American, which means I have one
5 language.

6 Q. Okay. Okay.

7 A. I only speak English.

8 Q. Okay. Are you saying you have read a
9 translation of this document at some point?

10 A. Yes.

11 Q. And do you know if it was an official
12 translation, a certified official translation?

13 A. I don't know if it was a certified one. I think
14 I, I accessed it through SEGM.

15 Q. Okay. All right. Let's go, let's go back to
16 your report, Exhibit 1.

17 A. God, I'm having the same damn problem again.
18 All right. Exhibit 1, I'm going to get there. All
19 right, here I am.

20 Q. Okay. And you, you said earlier that the UK was
21 also changing some of their guidelines with regard to
22 medical interventions for the treatment of gender
23 dysphoria, right?

24 A. Yes.

25 Q. Give me just a second here. But the UK has also

1 not completely banned all medical interventions, right,
2 they're just adjusting them?

3 A. That's correct, you're correct.

4 Q. And then are you aware of the Cass review?

5 A. Yes.

6 Q. That the UK is doing?

7 A. Yes.

8 Q. Okay. And, and as a part of that review you're
9 aware that the, that the national, what do they call it,
10 the National Health Service acknowledges that some
11 children do experience gender dysphoria and will need
12 clinical support and interventions?

13 A. Yes.

14 Q. Okay.

15 A. That's the clinical perception around many
16 people, yeah.

17 Q. Okay. All right. Let's take a look, hopefully
18 you still have it up, Page 51 of your report,
19 Paragraph 103.

20 A. Getting there. Okay, I'm here.

21 Q. Okay. So in Paragraph 103 you're talking about
22 a review by Professor, excuse me, Professor Carl
23 Heneghan, the editor of the British Medical Journal.
24 And the citation provided to that review is at the end
25 of the paragraph, do you see that, footnote 165?

1 (Exhibit 23 marked for identification.)

2 Q. Okay. Dr. Levine, you talk in your report,
3 let's see here, it's going to be Page 42 of your report
4 about, "That many professionals are unfamiliar with
5 these 11 research studies indicating a high natural
6 resolution rate of gender dysphoria," I think that's
7 supposed to say gender dysphoria in children, but it
8 just says, "gender dysphoria children by late
9 adolescence," do you see that?

10 A. I don't see it, but I don't think I want to go
11 to the report.

12 Q. Okay.

13 A. It just takes time.

14 Q. Okay. That's fine. I'll just represent to you
15 that's where I'm reading that from. And your citation
16 is to this study here, or this article rather by James
17 M. Cantor.

18 MR. CHARLES: And for the record, I'm
19 showing Dr. Levine what has been marked as SL23,
20 "Transgender and gender diverse children and
21 adolescents: Fact checking of AAP policy."

22 Q. And the 11 studies you mentioned, Dr. Levine,
23 are included by Mr. -- I'm sorry, I don't know if it's
24 Dr. Cantor, is it Dr. Cantor, do you know?

25 A. Yeah, I definitely know, it's Dr. Cantor.

1 Q. Okay. Thank you. The 11 studies are referenced
2 by Dr. Cantor in this article in an appendix, but let me
3 point you to the sentence where he says that. So
4 it's --

5 A. I have the appendix in front of me.

6 Q. Okay, perfect. Let's just look at that. Okay.
7 So looking at that list of studies, the, the, how do I
8 say this, the, the oldest study is listed first, so
9 that's a study by P.S. Lebovitz published in 1972, do
10 you see that?

11 A. Yes.

12 Q. Okay. And then the second study by B. Zuger?

13 A. Yes.

14 Q. Published in 1978. A study by J. Money and A.
15 Russo published in 1979?

16 A. I see all those.

17 Q. Okay. I just, I'm just confirming the dates of
18 publication. So C.W. Davenport was published in 1986;
19 R. Green was published in 1987; it looks like R.J.
20 Kosky was published in 1987; Cohen-Kettenis and M.
21 Wallien was published in 2008; Drummond, et al. was
22 published in 2008; Singh, unpublished doctoral
23 dissertation was published in 2012; and lastly the
24 Steensma, et al. was published in 2013, right?

25 A. That's, although you didn't ask, I should tell

1 you that the Singh, et al. article, this 2012, has been
2 published now that it's, there's more years, it was
3 published in Frontiers of Psychiatry in April 2021.

4 Q. Okay.

5 A. And so, you know, that's --

6 Q. I'll, I'll, thank you for that, I'll turn to
7 that in a minute. So I just want to confirm, these
8 studies were all published, with the exception of
9 Steensma, they were all published before 2013, right?

10 A. Yes, these were follow-up studies, these are
11 long-term follow-up studies.

12 Q. And the datasets, none of the data that was
13 collected in any of these studies was collected after
14 2013, right?

15 A. Even after the DSM-V criteria.

16 Q. None of them, none of the data was collected
17 after 2013, right?

18 A. None of the original.

19 Q. Which, which data of any of these studies was
20 collected after 2013?

21 A. Oh, I see what you mean.

22 Q. Yeah.

23 A. I see. All right.

24 Q. I, I agree with you they are follow-up studies,
25 they, they follow youth sometimes as far back as the

1 late '60s all the way through as I understand it the
2 latest was corrected in 2011. So I just, I'm confirming
3 that that's your understanding of the scope of the
4 follow-up studies as well?

5 A. Yeah, I confirm.

6 Q. Okay. And the, let me, the Singh dissertation
7 which was later published in the Frontiers of
8 Psychiatry, that did not include any data that was
9 collected after 2013, right?

10 A. I don't remember one way or the other.

11 Q. Okay. Let's, I'll just, we'll just take a look
12 really quickly.

13 (Exhibit 24 marked for identification.)

14 Q. Okay. That should be available to you, Dr.
15 Levine --

16 A. Okay.

17 Q. -- as a new exhibit, it will be Exhibit 24.

18 A. The Singh article.

19 Q. That's correct, yeah, from Frontiers of
20 Psychiatry.

21 A. Oh, good.

22 Q. Okay. And you can see that now?

23 A. I do.

24 Q. Okay. So then just looking at the first page.

25 A. The abstract or the instruction?

1 Q. It's, I don't see a label abstract, but I'm
2 assuming that's what it is, just that intro paragraph on
3 the first page.

4 A. Mm-hmm.

5 Q. Okay. So I'm assuming, Dr. Singh, et al. is
6 writing this. And, let's see, we've got, okay. So,
7 "This study reports follow-up data on the largest sample
8 to date of boys clinic-referred for gender dysphoria
9 (n=139) with regards to gender identity and sexual
10 orientation. In childhood, the boys were assessed at a
11 mean age of 7.49 years with a range of 3.33-12.99 at a
12 mean year of 1989 and followed up at a mean age of 20.58
13 years with a range of 13.07-39.15 at a mean year of
14 2002." Do you see that, have I read that correctly?

15 A. You did.

16 Q. Okay. Let's go to page -- give me just a minute
17 here.

18 MR. CHARLES: Kraig, let me go off the
19 record real quickly.

20 VIDEO TECHNICIAN: Okay. One moment,
21 please. We're going off the record at 5:04 p.m.

22 (A break was taken at 4:04 p.m.)

23 VIDEO TECHNICIAN: We're going back on the
24 record at 5:08 p.m.

25 BY MR. CHARLES:

1 Q. Okay. So, Dr. Levine, back to the Singh
2 article. And if you would, please, scroll to Page 4,
3 and you're looking for the heading, "Method."

4 A. I'm there.

5 Q. Okay. So there in the first paragraph, "The
6 participants were 139 boys ('birth-assigned males') who
7 in childhood had been referred to and then assessed in
8 the Gender Identity Service, Child, Youth and Family
9 Program at the Centre for Addiction and Mental Health
10 (CAMH) in Toronto, Ontario between 1975 and 2009 (mean
11 year of assessment, 1989) and were adolescents or adults
12 at follow-up (mean year at follow-up, 2002)"

13 Continuing on there to the second paragraph,
14 "Participants entered the follow-up study through two
15 methods of recruitment. The majority of participants
16 (77%) were recruited for research follow-up. There were
17 two main waves of participant recruitment through
18 research contact, from 1986 to 1993 (n=32), and then
19 from 2009 to 2011 (n=71)."

20 So just, I just wanted to confirm with you
21 that's the, that's the same dataset that Dr. Singh, then
22 Ph.D. candidate Dr. Singh, presented in the dissertation
23 as well. So there, there was a, a follow-up collection
24 period from 2009 to 2011, but nothing beyond 2011, is
25 that, that's your understanding there of that, of those

1 sentences?

2 A. So isn't it -- let's see. During the period of
3 data collection 32 patients recontacted service for
4 clinical reasons and they were informed about the
5 opportunity to participate in a follow-up site. Okay.
6 So some were purely research, they agreed to
7 participate, and some asked for various services from
8 CAMH again.

9 Q. Right. And that collection in total, both the
10 initial contacts that was either patient initiated or
11 follow-up research requested, that all happened before,
12 collectively before 2013?

13 A. Yep.

14 Q. Okay. And let's take a look at one more article
15 here.

16 (Exhibit 25 marked for identification.)

17 Q. This should be available, Dr. Levine, if you
18 refresh your screen.

19 A. Are we done with the Cantor article?

20 Q. Oh, yes, you can put that to the side. Thank
21 you.

22 A. Okay. Okay.

23 Q. And do you see what's been marked as SL25?

24 A. Yes.

25 Q. Okay. And this article is entitled, "Gender

1 dysphoria in childhood, Jiska Ristori and Thomas D.
2 Steensma, published 2015." Oh, sorry, published, yes,
3 published online January 2016, accepted October 2015.
4 You cite this and the Singh article we just looked at in
5 your report for the, for the proposition that, "The
6 majority of children," and you put in parentheses,
7 "between 61 and 98 percent of them who identifies
8 transgender will reidentify with their sex before
9 reaching maturity absent interventions." So I just
10 wanted to locate that in context, in the context of your
11 report. So let's take a look at this article. Okay.
12 So if you would scroll to page, it's the third page of
13 this article, but it's numbered Page 15.

14 A. Okay, I'm on Page 15.

15 Q. Okay. And you'll see that the, this study is
16 listing the follow-up studies it's referencing in the
17 Table 1 at the bottom right-hand corner, do you see
18 that?

19 A. Yes.

20 Q. Okay. And do you see any overlap between the
21 studies cited in Dr. Cantor's article and this table
22 here in terms of on the left-hand side the, the names of
23 the authors and the year of publication?

24 A. Well, the Bakwin, was the Bakwin article in
25 Cantor?

1 Q. Now that you mention it, I don't think it was.

2 A. Yes.

3 Q. Okay.

4 A. And, and what about the Davenport?

5 Q. Yeah, Davenport was there, that was the
6 follow-up study of ten boys.

7 A. Yeah, I see. Of course Green was, yeah, and the
8 girls weren't in there because, yeah, all right.

9 Q. Okay. So is, is it your understanding that this
10 study is also looking at that, again that historical
11 dataset that begins back in the late '60s, early '70s
12 and continues through at the latest point 2011, right,
13 for the follow-up?

14 A. I'm going to trust you on that.

15 Q. Okay. Okay.

16 MR. CHARLES: Kraig, can we go off the
17 record.

18 VIDEO TECHNICIAN: Yeah, one moment please.
19 We're going off the record at 5:15 p.m.

20 (A break was taken at 4:15 p.m.)

21 VIDEO TECHNICIAN: We're going back on the
22 record at 5:25 p.m.

23 EXAMINATION

24 BY MR. DAVID:

25 Q. Dr. Levine, I'm going to be as brief as I

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Exhibit D

1 IN THE UNITED STATES DISTRICT COURT
2 FOR THE MIDDLE DISTRICT OF NORTH CAROLINA

3 ~~~~~

4 MAXWELL KADEL, et al.,

5 Plaintiffs,

6 vs. Case No. 1:19-cv-272-LCB-LPA

7
8 DALE FOLWELL, in his official
9 capacity as State Treasurer of
10 North Carolina, et al.,

11 Defendants.

12 ~~~~~

13 Video Deposition of
14 STEPHEN B. LEVINE, M.D.

15 September 10, 2021
16 9:05 a.m.

17 Taken at:
18 Veritext Legal Solutions
19 1100 Superior Avenue
20 Cleveland, Ohio

21 Tracy Morse, RPR
22
23
24
25

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TRANSCRIPT INDEX

APPEARANCES.....	2
INDEX OF EXHIBITS.....	4
EXAMINATION OF STEPHEN B. LEVINE, M.D.	
By MR. CHARLES.....	7
By MR. KNEPPER.....	227
By MR. CHARLES.....	244
REPORTER'S CERTIFICATE.....	249
EXHIBIT CUSTODY	
EXHIBITS RETAINED BY COURT REPORTER, 1-21	
(No Exhibit 16)	

1		INDEX OF EXHIBITS	
2	NUMBER	DESCRIPTION	MARKED
3	Exhibit 1	4/28/2021 Declaration....	14
4		of Stephen B. Levine,	
		M.D. With Attachment	
5	Exhibit 2	12/21/2020 Zoom.....	56
		Deposition of Stephen	
		Levine, M.D.	
6	Exhibit 3	Typewritten Three-Page...	62
		Document Entitled,	
7		"Special Programs,"	
8	Exhibit 4	1/1/2019-12/31/2019.....	78
		North Carolina State	
		Health Plan Benefits	
9		Booklet, Bates Numbers	
		PLAN DEF0001785-0001900	
10	Exhibit 5	Lesbian Gay Bisexual.....	89
		Transgender Center	
11		Document Entitled,	
		"Transgender Resources"	
12	Exhibit 6	4/8/19 Soneeya v. Turco..	104
		Trial Transcript, Day 1	
13	Exhibit 7	"Correction: Parent.....	116
		Reports of adolescents	
14		And young adults	
		Perceived to show signs	
15		Of a rapid onset of	
		Gender dysphoria,"	
16		Article	
	Exhibit 8	"Transgender Teens: Is...	122
17		The Tide Starting To	
		Turn?" Article	
18	Exhibit 9	"Finland Issues Strict...	139
		Guidelines for Treating	
19		Gender Dysphoria,"	
		Article	
20	Exhibit 10	"Recommendation of the...	140
		Council for Choices in	
21		Health Care in Finland	
		(PALKO/COHERE Finland),"	
22		Article	
	Exhibit 11	"Stod och utredning vid...	145
23		konsinkongruens hos barn	
		Och ungdomar," Article	

24
25

1	INDEX OF EXHIBITS (Continued)		
2	NUMBER	DESCRIPTION	MARKED
3	Exhibit 12	"Long-Term Follow-Up of..154 Transsexual Persons Undergoing Sex Reassignment Surgery: Cohort Study in Sweden," Article	
6	Exhibit 13	2017 "On Gender.....156 Dysphoria," Booklet From Department of Clinical Neuroscience, Karolinska Institutet	
9	Exhibit 14	"Long-Term Follow-Up of..161 Individuals Undergoing Sex-Reassignment Surgery: Somatic Morbidity and Cause of Death," Article	
11	Exhibit 15	5/15/2017 Telephonic.....170 Deposition of Stephen Levine, M.D.	
13	Exhibit 17	"A Typology of Gender....196 Detransition and Its Implications for Healthcare Providers," Article	
15	Exhibit 18	DSM-5: Frequently Asked..202 Questions	
17	Exhibit 19	"Endocrine Treatment of..213 Gender-Dysphoric/Gender Incongruent Persons: An Endocrine Society Clinical Practice Guideline," Article	
19	Exhibit 20	"Pediatric Obesity.....217 Assessment, Treatment, And Prevention: An Endocrine Society Clinical Practice Guideline," Article	
22	Exhibit 21	"Practice Parameter on...223 Gay, Lesbian, or Bisexual Sexual Orientation, Gender Nonconformity, and Gender Discordance In Children and Adolescents," Article	

1 Q. Okay. And so then were there any
2 external grants to research and publish about
3 the treatment of children or adolescents --

4 A. No.

5 Q. -- with gender dysphoria?

6 Okay. Is that a, "No," when I included
7 the, "Gender dysphoria," as well?

8 A. That is a, no.

9 Q. Okay. Thank you. Okay. So on
10 page 3 of your report -- actually, I'm sorry.
11 It's going to be the bottom of page 4 and to
12 the top of page 5. Your report lists your
13 experience as an expert witness, which we
14 talked about a little bit earlier. I just --
15 I'm wondering if you would confirm this is not
16 an exhaustive list of your experience as an
17 expert witness either via deposition or report.

18 A. I wouldn't want to testify that
19 this is absolutely complete, given the fact
20 that I don't keep a list compiled. This is
21 kind of compiled retrospectively from memory
22 and documents. And so this is the best I could
23 have done on April of 2021 --

24 Q. Understood. Thank you. So --

25 A. -- you might find something else.

1 two, two and a half years ago.

2 Q. Oh, okay. And what kind of
3 treatment -- I should say, have you referred
4 any of those adolescent patients for additional
5 treatment, besides psychotherapy, for the
6 treatment of gender dysphoria?

7 A. Yes.

8 Q. And what kinds of treatment have
9 you referred them for?

10 A. For endocrine treatment.

11 Q. Okay. And approximately what
12 percentage of those adolescent patients have
13 you referred for endocrine treatment?

14 A. Give me the timeframe of that
15 question, please.

16 Q. Sure. So you said a few moments
17 ago, in the last five years, you saw maybe,
18 asterisk, 12 to 15 adolescent individually
19 yourself. Of those 12 to 15, what would be the
20 approximate percentage you referred for
21 endocrine treatment?

22 A. I'm hesitating to answer the
23 question, because some of those children have
24 been taking testosterone or estrogen
25 surreptitiously from their parents. And while

1 where the number of adults has diminished and
2 the number of adolescents has increased
3 dramatically.

4 Q. Okay. Thank you. So as a part of
5 your private practice, do you write letters of
6 authorization for endocrine treatments?

7 A. Yes.

8 Q. And do you write letters of
9 authorization for gender affirming surgeries?

10 A. I have. I have not recently,
11 because most of my patients are 13 or 15 or 16,
12 you know.

13 Q. Okay. And I'm sorry. Just by,
14 "Recent," when was the last time you wrote a
15 letter of authorization for a gender affirming
16 surgery for an adult?

17 A. Probably twelve months ago.

18 Q. Okay. And over the course of your
19 career focusing on your treatment of adults
20 experiencing gender identity issues, for what
21 percentage of those patients would you estimate
22 you wrote a letter of authorization for gender
23 affirming surgery for?

24 MR. KNEPPER: Objection, form.

25 A. Again, I would like to put an

1 asterisk to whatever I answer this question as.
2 I have not kept track of those figures. I have
3 written -- I've written or cosigned letters for
4 hormone treatments and for gender confirming
5 surgeries for many people. There were more
6 people in the '70s and '80s than in recent
7 decades. In part as a reflection of my own
8 evolution of understanding of these problems
9 and in part it's a reflection of the demography
10 of patients who are coming to see me. I really
11 would not like to answer that question, only
12 because I don't know if the word, "Fifteen," or
13 the word, "Twenty-five," or the word,
14 "Thirty-five," is more accurate --

15 Q. Understood.

16 A. -- but I can tell you, I have
17 written letters, especially in the early years,
18 for the things that you're making reference to.

19 - - - - -

20 (Thereupon, Deposition Exhibit 2,
21 12/21/2020 Zoom Deposition of
22 Stephen B. Levine, M.D., was marked
23 for purposes of identification.)

24 - - - - -

25 Q. Okay. For the record, I'm showing

1 patient be able to afford it?

2 MR. KNEPPER: Objection, form.

3 A. May I say, of course?

4 Q. You may. You may say anything you
5 would like.

6 A. Of course.

7 Q. Thank you. Well, anything you
8 would like within reason.

9 If you make a letter of authorization for
10 a patient for the treatment of gender dysphoria
11 specifically related to a surgical treatment,
12 do you think it is good that they be able to
13 access that treatment that you've authorized?

14 MR. KNEPPER: Objection, form.

15 A. Not to be cagey, I want to talk
16 about one word you just used in that sentence.
17 I need you to understand that historically in
18 our clinic for those 47 years, our clinics
19 for 47 years, we are not in the business and we
20 have never been in the business of recommending
21 surgery or recommending hormones. We recommend
22 a continued evaluation so that we -- the person
23 can make up their mind how to proceed.

24 It is not our knowledge base to know
25 who's going to do better and who's going to do

1 worse and who is not going to have any
2 difference at all with hormones or with
3 surgery. So what we do is we say, we will
4 write a letter of support for endocrine
5 treatment or for hormones if this is what you
6 want. And we say what our concerns are. We
7 tell the endocrinologist and we tell the
8 surgeon what our concerns are and that we
9 see -- we have reservations about this, and
10 these are our reservations, but the patient has
11 decided this is what he or she wants to do.

12 And so we write a letter of support, but
13 I don't -- every time you use the word,
14 "Recommendation," there's part of me that wants
15 to say, no, we do not recommend. We have never
16 recommended. We have not had the knowledge
17 base. We have not had the clinical experience
18 and the knowledge base to say, I'm a doctor. I
19 know this field. This is what I recommend to
20 make you better. We do not talk that way. We
21 do not think that way. And so I may want to
22 always put an asterisk to any sentence that you
23 use the word, "Recommend." I need you to
24 understand that that's where I'm coming from.

25 MR. CHARLES: Thank you,

1 concept of agency and being a doctor, I think
2 is different than the implication of your
3 question.

4 Q. Is the worrisomeness for a
5 patient's future health, is that a reason to
6 deny all medical care for gender dysphoria?

7 A. Absolutely not.

8 Q. Dr. Levine, I'd like to return back
9 to, I believe it's Exhibit 2, the Claire
10 deposition. And please, if you would turn to
11 page 156.

12 A. I'm sorry. 150 what?

13 Q. Page 156. And beginning at line 10
14 on page 156, Dr. Levine, I'll read it, if
15 you'll just follow along, please.

16 Question: "Are you aware that this case
17 concerns an insurance exclusion that is
18 categorical at preventing" --

19 Skipping to line 15.

20 "-- hormones and surgery as a treatment
21 for gender dysphoria?"

22 Answer: "I am aware that your plaintiffs
23 are suing to get coverage for -- that is not
24 provided by their particular insurance. I am
25 aware of that."

1 demonstrate their efficacy. This is the
2 problem.

3 This is the essence of the problem. This
4 is, I think the essence of my testimony with
5 you today. It's not whether I personally as a
6 doctor would like this patient to have
7 insurance to cover their hormones. It's about,
8 is this the right thing to do for this person
9 and can I help the person see clearly what the
10 dangers are and what the benefits are. That's
11 the issue for a doctor, for Stephen Levine as a
12 doctor. I hope that's a cogent answer --

13 Q. It is --

14 A. -- to your question.

15 Q. -- it is cogent. Thank you.

16 Given all of that, is that -- so you just
17 explained, testified that there are
18 complications, some lack of -- and I'm
19 summarizing here, so I will confirm that this
20 is an accurate summary of what you just shared,
21 but I can't possibly repeat all of that. Given
22 all of those concerns that you have, is that a
23 reason to deny all medical interventions to
24 people with gender dysphoria?

25 MR. KNEPPER: Objection, form.

1 A. No, but that's not -- that's a
2 separate question about insurance.

3 Q. Yes, it is a separate question. So
4 now I'm asking: Are those concerns you raised
5 justifications in your mind for denying medical
6 interventions to all people with gender
7 dysphoria?

8 MR. KNEPPER: Objection, form.

9 A. You know, I'm not advocating
10 denying endocrine treatment or surgical
11 treatment. I'm just saying that we as a
12 medical profession need to walk the walk that
13 we talk. We say as a principle of ethics that
14 our interventions should be based upon the best
15 current knowledge, it should be based on
16 science. It should not be based on politics.
17 It should not be based on fashion. It should
18 not be based on civil rights considerations.
19 They should be based on the kinds of studies
20 that I just described to you with predetermined
21 outcome majors that are agreed upon --

22 Q. Sorry?

23 A. -- period.

24 Q. I was --

25 A. I forgot to put the period.

1 Q. That's okay. Did you just say,
2 Dr. Levine, you're not an expert in health
3 insurance?

4 A. I am not an expert in health
5 insurance.

6 Q. Okay. Or what insurance should or
7 should not cover?

8 A. Yes.

9 Q. Do you recall what the insurance
10 billing code typically is for psychotherapy for
11 gender dysphoria? I know it's been a long time
12 since you've accepted commercial insurance, so
13 I'm not sure if the billing codes are the same,
14 but do you recall --

15 A. The billing code is 90837.

16 Q. Okay. Is there a code that you're
17 familiar with that is F64.0?

18 A. That's not a billing -- that's
19 diagnostic code --

20 Q. Thank you.

21 A. -- there's a separate code for
22 diagnosis and a separate code for procedure.

23 Q. I see. So F64.0 is a diagnostic
24 code?

25 A. Yes.

1 VIDEOGRAPHER: Off the record 11:26.

2 (Recess taken.)

3 VIDEOGRAPHER: On the record 11:31.

4 BY MR. CHARLES:

5 Q. Okay. Dr. Levine, in your report,
6 you stated that you had not met with any of the
7 plaintiffs in this case, correct?

8 A. Yes.

9 Q. Okay. And you have not interviewed
10 any of the plaintiffs in this case, correct?

11 A. Correct.

12 Q. And so you are not offering any
13 opinions about the plaintiffs in this case,
14 correct?

15 A. Correct.

16 Q. Okay. And that would include the
17 veracity of their experiences of gender
18 dysphoria, correct?

19 A. Yes, correct.

20 Q. And that would not include the
21 accuracy of their gender dysphoria diagnoses,
22 correct?

23 A. Correct.

24 Q. Okay. You're not offering any
25 opinions about their mental health histories?

1 methodology and are capable of critically
2 reviewing the literature. So your statement is
3 true on the most superficial level, but is
4 totally incorrect when it comes to scientific
5 standards of care for issuing guidelines for
6 the medical profession. So I don't know how to
7 answer the question. On the surface, the
8 answer is, yes. And underneath the surface,
9 the answer is, no.

10 Q. So the International Journal For
11 Transgender Health is still a peer-reviewed
12 source, though, right?

13 A. It's peer reviewed by people who
14 make their living supporting transgender care.

15 Q. But it's still peer reviewed,
16 right?

17 A. It's peer reviewed --

18 Q. And as for your --

19 A. -- I think it's peer reviewed.

20 Q. Okay. Understood. And as for your
21 more conservative approach, can you cite to any
22 studies or research that resulted in better
23 outcomes than people who adhere strictly to the
24 WPATH standards of care version 7?

25 A. No. This is part of the problem in

1 evaluation leading to a therapeutic process, it
2 seems prudent, given the fact that we are
3 changing people's bodies, especially teenagers'
4 bodies, and they are not of developmental
5 sophistication yet that court systems or at
6 least one court system thinks they're certainly
7 too young to make these life-altering
8 decisions. So people in SEGM are biased in the
9 direction of being conservative and providing
10 psychotherapeutic evaluations of the child, of
11 the teenager and of their parents, of their
12 family systems to see if we can find a way to
13 help them be informed about what is going --
14 what they think they want to do in their
15 future.

16 Q. And so when you provide letters of
17 authorization for hormones or for surgery, do
18 you do so in accordance with the WPATH
19 standards of care?

20 A. Yes. That is the standard, to
21 provide a letter of recommendation.

22 Q. Okay. So turning back to your
23 report, Dr. Levine. You can go ahead and put
24 away the trial transcript there.

25 A. I'm sorry. Did you say, "Turning

1 hours and hours of their time getting counseled
2 or participating with the virtual trans
3 community. That's a hypothesis.

4 Q. So no scientific citation?

5 A. When we use the word, "Scientific,"
6 in the best sense, yes, the answer to your
7 question is, no scientific.

8 Q. Okay. No studies of citations you
9 can point to today to support that hypothesis?

10 A. Oh, I think Lisa Littman's studies
11 are in the literature and/or in press that
12 documents this.

13 - - - - -

14 (Thereupon, Deposition Exhibit 7,
15 "Correction: Parent reports of
16 adolescents and young adults
17 perceived to show signs of a rapid
18 onset of gender dysphoria," Article,
19 was marked for purposes of
20 identification.)

21 - - - - -

22 Q. Okay. For the record, please note
23 I'm showing to Dr. Levine what has been marked
24 as Exhibit 7. "Correction: Parent reports of
25 adolescents and young adults perceived to show

1 signs of a rapid onset of gender dysphoria," by
2 Lisa Littman published March 19, 2019. Have
3 you seen this material before, Dr. Levine?

4 A. I've seen of it. I don't think
5 I've read it.

6 Q. Okay. Were you aware that the Lisa
7 Littman article had to be withdrawn, corrected
8 and republished?

9 A. Yes.

10 Q. Okay. And were you aware that the
11 initial article was based on a survey of
12 parents --

13 A. Yes.

14 Q. -- of purportedly transgender
15 children and the parents were recorded -- I'm
16 sorry. Let me start over. Were you aware that
17 the Littman article was based on a survey of
18 parents who were recruited through some parent
19 groups?

20 MR. KNEPPER: Objection, form.

21 A. I knew it was a survey of parents.

22 Q. Okay. And did you know there were
23 no report-outs from the young adults of those
24 parents in the article?

25 A. It was a report of parents'

1 transitioning. However, it is...important to
2 note that there are other survey items where
3 the parent would have direct access to
4 information about their child and that those
5 answers reflect items that can be directly
6 observed." Did I read that correctly?

7 A. Yes, you did.

8 Q. All right. Your report also cites
9 as support for the social contagion hypothesis
10 to an article from Medscape.com written by
11 Becky McCall and Lisa Nainggolan as support for
12 the social contagion theory. Is that correct?
13 I'm sorry. It's not going to be on this
14 article, Doctor.

15 A. I don't know that article.

16 Q. Okay.

17 A. You haven't asked me a question
18 about this. Did I misunderstand something?

19 Q. No, no. Sorry. We're just --

20 A. You haven't asked my opinions about
21 that, yeah.

22 - - - - -

23 (Thereupon, Deposition Exhibit 8,
24 "Transgender Teens: Is the Tide
25 Starting To Turn?" Article, was

1 marked for purposes of
2 identification.)

3 - - - - -

4 Q. Yeah. So, for the record, I'm
5 showing Dr. Levine what has been marked as
6 Exhibit 8. "Transgender Teens: Is the Tide
7 Starting To Turn?" by Becky McCall and Lisa
8 Nainggolan, April 26, 2021. Dr. Levine, you
9 said you have not reviewed this article before?

10 A. Which one are you referring to?

11 Q. I'm sorry. That one to your left.

12 A. This?

13 Q. Yes. Take your time.

14 A. Have I reviewed it, no. You know,
15 I've seen the picture of Keira Bell. I've seen
16 news reports of this in the past, but they were
17 just news reports, yeah.

18 Q. Do you know if either of the
19 authors of this article is a scientist?

20 A. I have no idea.

21 Q. Okay. Or a psychiatrist?

22 A. (Indicating.)

23 Q. I'm sorry. Could you make your
24 responses verbal? I'm forgetting.

25 A. I have no idea.

1 Q. Okay. Thank you. Have either of
2 them ever treated transgender children or
3 adolescents?

4 A. I would have no idea.

5 Q. Okay. To your knowledge, is the
6 information provided on Medscape.CA subject to
7 peer review?

8 A. I don't know how Medscape works.
9 I've heard there have been retractions, but I
10 don't know how their peer reviewed is made.
11 Perhaps people write in that, This is
12 ridiculous what you've been teaching or what
13 you've been saying, but whether they're peer
14 reviewed or not, I have no idea.

15 Q. So you probably -- I'm sorry. So
16 do you know if this article has been published
17 in a peer-reviewed journal to your knowledge?

18 A. "Transgender teens: Is the
19 Tides" -- that article?

20 Q. Yes.

21 A. I don't know. I don't know this
22 article. I don't know where it's from.

23 Q. Okay. So your report includes a
24 quotation from this article. "The vast
25 majority of youth now presenting with gender

1 multi-continental set of observations from
2 Europe, from Australia, from North America --

3 Q. Okay.

4 A. -- it almost doesn't even need
5 citations it's so clinically apparent.

6 Q. Okay. But there's no citation in
7 your report?

8 A. In my report, yes.

9 Q. Okay. So on page 18, going back to
10 your report, at the bottom of page 18, you use
11 a term, "Transgender Treatment Industry." Is
12 this the first time you have used this term?

13 A. In this report?

14 Q. No.

15 A. You mean, did I ever use it in
16 another report?

17 Q. Yeah, yeah.

18 A. I'm not sure. If this is -- if
19 it's not the first, it might be the second.

20 Q. And where did the term originate?

21 A. I think it -- the term originated
22 from Dwight Eisenhower at the end of his --
23 when he was leaving the presidency in 1952, he
24 warned the people about the military industrial
25 complex and that there was a very comfortable

1 A. No. Their gender dysphoria may be
2 a product, you see, of these other things. For
3 example, if you have someone who has been
4 sexually abused by her stepfather and becomes a
5 trans person in adolescents, we want to talk
6 about the sexual abuse and the process between
7 that person and what fears for the present and
8 the future that has caused the child. And
9 we're not attacking their trans identity.
10 We're trying to help them understand where they
11 came from and what they're coping with and why
12 they're so fearful or so distressed by their
13 body changing.

14 Q. And their gender dysphoria could be
15 separate and apart from that traumatic
16 experience?

17 A. Theoretically it could be, yes.

18 Q. And if it persisted sufficiently
19 enough, you would consider a letter of
20 authorization for --

21 A. Yes.

22 Q. -- hormones?

23 A. Yes.

24 MR. KNEPPER: Objection, form.

25 Q. Okay. If you would, please, turn

1 A. That is correct. And may I add
2 that it's very, very difficult to understand.
3 The natural question would be, how do you
4 compare the general population with the trans
5 people who did not have surgery with the trans
6 people who did have surgery.

7 Q. Thank you, Dr. Levine. That's not
8 my question, though. I just wanted to confirm
9 that was not the control group. You mentioned
10 this study later in your report, page 66
11 beginning at paragraph 74. Do you see that?

12 A. Um-hum.

13 Q. Okay. And basically that -- well,
14 here, let me point you exactly. The sentence
15 starts with, "Similarly," about halfway down
16 the page, third sentence of that paragraph.

17 A. Um-hum.

18 Q. And, as you mentioned, you cite the
19 Dhejne study and I believe -- or I should ask:
20 Is the Denmark study you're referencing the
21 study directly after it --

22 A. The Simonsen study.

23 Q. -- the Simonsen study?

24 A. Yes.

25 Q. Okay. So beginning with the Dhejne

1 study, do you think because that study showed
2 that some people committed suicide after gender
3 affirming surgery that no patient should be
4 able to access gender affirming surgery?

5 MR. KNEPPER: Objection, form.

6 A. That would be illogical.

7 Q. Okay. Dr. Levine, I understand you
8 said that would be illogical, but just to be
9 clear. You're not recommending -- sorry. I'm
10 not using that word. You're not saying that
11 the fact that some people commit suicide
12 following gender affirming surgery means that
13 there should be a ban on access to that
14 surgery. Is that right?

15 A. Not for that reason, no.

16 MR. KNEPPER: Objection, form.

17 Q. Not for that reason. Okay. Are
18 you recommending that there would be bans on
19 gender affirming surgery for any reason?

20 A. I think there are -- you know, I
21 think most prudent people in this field, just
22 to use the example of what you read out loud
23 about the Finland study, a case-by-case basis.
24 That's how doctor need to decide things, but
25 there are many, many reasons to be cautious

1 fashion and to be very hesitant about going
2 forward.

3 Q. But you're not recommending total
4 bans on gender affirming surgery?

5 A. I'm not recommending total bans.
6 I'm aware of the individual circumstances of
7 individual people's lives and their commitment
8 to transgender living. And I don't want to be
9 draconian about this. I want to be
10 compassionate about this.

11 Q. I understand. I appreciate that.
12 I just want to make sure I'm understanding you
13 correctly.

14 - - - - -

15 (Thereupon, Deposition Exhibit 12,
16 "Long-Term Follow-Up of Transsexual
17 Persons Undergoing Sex Reassignment
18 Surgery: Cohort Study in Sweden,"
19 Article, was marked for purposes of
20 identification.)

21 - - - - -

22 Q. So for the record, I'm presenting
23 to Dr. Levine what has been marked as
24 Exhibit 12. "Long-Term Follow-Up of
25 Transsexual Persons Undergoing Sex Reassignment

1 For the 22nd time today, did I read that
2 correctly?

3 A. It's the 23rd time.

4 Q. Oh, okay.

5 A. Yes.

6 Q. I was hoping you weren't counting,
7 but, okay. Did you testify earlier today that
8 the limitation of the Dhejne study is that the
9 controls were not transgender persons who had
10 not undergone gender affirming surgery?

11 A. Yes.

12 MR. KNEPPER: Objection, form.

13 Q. Okay. You can set that aside,
14 Dr. Levine.

15 - - - - -

16 (Thereupon, Deposition Exhibit 13,
17 2017 "On Gender Dysphoria," Booklet
18 From Department of Clinical
19 Neuroscience, Karolinska Institutet,
20 Stockholm, Sweden, was marked for
21 purposes of identification.)

22 - - - - -

23 Q. For the record, Dr. Levine has an
24 exhibit that has been marked as Exhibit 13.
25 "On Gender Dysphoria," by Cecilia Dhejne from

1 ideation in transgender people.

2 A. Well, you know about the
3 Branstrom-Pachankis study and the criticism of
4 the study --

5 Q. But I'm not talking about the
6 study.

7 A. -- and part of the study
8 demonstrated that it increased suicidal
9 ideation and attempts in the first two and a
10 half years after surgery, especially in the
11 first year --

12 Q. Right. Is your testimony --

13 A. -- so I'm not testifying that. I
14 thought you were asking me about this, which I
15 need to comment on, because this is not an
16 accurate depiction of my statement in the
17 reference. (Indicating.)

18 Q. Well, that's not what I'm asking
19 about, Dr. Levine.

20 A. Well, you're reading this and I'm
21 misquoted here. So I don't want you to imply
22 that she is accurately representing my views,
23 because I did not say that gender affirming
24 treatment in general should be stopped. I've
25 never said that. This is an article about

1 at different times have reported that in the
2 large majority of patients, absent a
3 substantial intervention such as social
4 transition and/or hormone therapy, gender
5 dysphoria does not," continue, "through
6 puberty."

7 So there are some children who persist in
8 their asserted gender identity through puberty,
9 correct?

10 MR. KNEPPER: Objection, form.

11 A. Correct.

12 Q. And some who persist in wanting to
13 transition via medical treatments?

14 MR. KNEPPER: Objection, form.

15 A. Yes. Some of the children have
16 learned about medical treatments somewhere
17 along the line and they feel instantly that
18 this is for them.

19 Q. And then looking at paragraph 56,
20 which is on page 41, so just the very next page
21 on the bottom, the second sentence in that
22 paragraph. "I observe an increasingly vocal
23 online community of young women who have
24 reclaimed a female identity after claiming a
25 male...identity at some point during their teen

1 years."

2 But there are some patients who assert a
3 male gender identity in their teen years and
4 continue to assert it into adulthood, correct?

5 A. Yes.

6 MR. KNEPPER: Objection, form.

7 Q. Okay. Can social transition be
8 used to treat gender dysphoria in adults? Not
9 looking at your report, now, Dr. Levine.
10 Sorry. Can social transition treat gender
11 dysphoria in adults?

12 A. Yes. As a matter of fact, that
13 used to be the recommendation in the '70s
14 and '80s, prior to taking hormones, was to try
15 living, what was sometimes called the real-life
16 experience or the real-life test for one year.
17 And then if when you confront the new issues of
18 confronting you in your new neo gender, if you
19 still want to do that, then we'll come back and
20 we'll think about using hormones to facilitate
21 your transition. But in the 7th edition of the
22 standards of care that was removed. There's no
23 real-life experience, real-life test anymore.
24 If persons want it, they should have it.
25 Patient autonomy was valued far greater than

1 transgender people is individual based, right?

2 A. Well, it's both --

3 MR. KNEPPER: Objection, form.

4 A. -- yes, that's partially true. And
5 ideally that's true, but it's obviously not
6 entirely true. It's why we're here, is it's
7 categorically based.

8 Q. Let me rephrase that. You design
9 treatment for your patients based on what that
10 patient in front of you, what they need, what
11 they want, what you determine -- sorry. Not
12 what you determine, but what you might
13 authorize?

14 MR. KNEPPER: Objection, form.

15 A. What the patient and I discern
16 together.

17 Q. Thank you. Okay. Let's jump to,
18 again, still in your report, page 68.

19 A. We've left 40 and 41? 68.

20 Q. Okay. Looking at the bottom of
21 page 68, Dr. Levine, paragraph 78. It states,
22 "Similarly, the American Psychological
23 Association has stated because approach" --

24 A. Sorry.

25 Q. I apologize.

1 Gender Nonconforming People (2015)."

2 So is that lack of consensus that you
3 discuss a justification to categorically ban
4 social transition for children as a treatment
5 for gender dysphoria?

6 MR. KNEPPER: Objection, form.

7 A. By, "Children," you mean 6 and 7
8 year olds?

9 Q. Those for whom medical intervention
10 is not indicated.

11 A. Is that a reason to ban it?

12 Q. Correct, social transition.

13 MR. KNEPPER: Objection, form.

14 A. The reason to -- so let me qualify
15 that. There's a, yes, answer, there's a reason
16 to ban it. And the reason to ban it is both a
17 developmental and an ethical reason. There
18 have been eleven studies of these cross-gender
19 identity children who are not socially
20 transitioned and the vast majority of them
21 de-transition by the time they're mid
22 adolescents or older adolescents. They become
23 homosexual individuals usually or bisexual
24 individuals, but they are cis gender.

25 So if we take a 6-year-old child and

1 her peers or his peers and I don't think this
2 is a prudent idea.

3 And if you wanted me to suggest a ban on
4 anything, it would be a ban on using puberty
5 blocking hormones, especially when the
6 evaluation of those children are focused on the
7 gender dysphoria of the child and not on the
8 background of the child and not on what's going
9 on. So I think that's an answer to your
10 question.

11 If we're going to use these drugs, if
12 we're going to use social transformation of
13 children, if we're going to use puberty
14 blocking hormones, it should only be used in a
15 carefully designed protocol. And follow up has
16 to be guaranteed so in one year and in two
17 years and in three years and before we start
18 giving cross-gender hormones we have data --

19 Q. Sorry.

20 A. -- so the answer to your question
21 is, I would consider banning puberty blocking
22 hormones even for children who have been
23 cross-gender identified for four years to give
24 them a chance to desist, which is exactly what
25 the Dutch protocol did, by the way.

1 Q. Sorry. So you just said you would
2 ban -- you would recommend a ban on --

3 A. If --

4 MR. KNEPPER: Objection, form.

5 A. -- look, I'm a doctor. I'm not a
6 policy maker --

7 Q. I understand, yes.

8 A. -- if you ask me my political
9 opinion about, should we ban this, is that a
10 reasonable thing, I think there's a very strong
11 argument for banning puberty blocking hormones.

12 Q. Okay. And, right. So you're here
13 as an expert offering an expert opinion. So
14 are you separating that from -- like are you
15 saying your political views that you would
16 advocate for bans or are you saying your expert
17 opinion you're offering in this case is you
18 would recommend ban?

19 MR. KNEPPER: Objection, form.

20 A. I would recommend ban. To what
21 extent it's from my politics or from my being a
22 parent or from my being a doctor, I don't know.
23 I would recommend we not use puberty blocking
24 hormones.

25 Q. In Claire, in this case that we

1 Answer: "Where we had a healthy mother
2 and father, an intact family who was
3 psychologically informed and who has -- where a
4 child has come out of toddlerhood acting
5 consistently in a gender atypical fashion, and
6 where the parents are not homophobic..."

7 Question: "The parents are not what kind
8 of people?"

9 Answer: "Homophobic."

10 For the 27th time, did I read that
11 correctly? Did I read that correctly?

12 A. Yes.

13 MR. CHARLES: Okay. All right.
14 Let's go ahead and take a break for a few
15 minutes.

16 VIDEOGRAPHER: Off the record 3:20.

17 (Recess taken.)

18 VIDEOGRAPHER: On the record 3:38.

19 BY MR. CHARLES:

20 Q. So, Dr. Levine, before the break,
21 you were talking about 6 and 7 year olds and
22 you mentioned there were eleven studies. Can
23 you identify which eleven studies from your
24 report you're referring to?

25 A. Cantor, the reference Cantor lists

1 the eleven studies and these eleven studies
2 have been done over probably thirty years.

3 Q. Okay. So Cantor was one review of
4 eleven studies?

5 A. Cantor was a review of the eleven
6 studies. I can't list to you the eleven
7 individual studies. The latest one is written
8 by Singh, S-i-n-g-h. It was published in April
9 of 2021, in the Frontiers of Psychiatry. And
10 that perhaps is the most comprehensive of them.
11 And that's the one that confirms -- that's a
12 study of boys and it confirmed that 12.2, I
13 think percentage of them persisted over a
14 thirteen-year period.

15 Q. So that was one -- that was the
16 Singh study that came out. Is that same study
17 mentioned in the Cantor review?

18 A. (Nodding.)

19 Q. Okay. And you said that
20 established that 12.2 percent of prepubertal
21 boys persisted into adolescents? Okay.

22 A. Yes. This harkens back to the
23 ethical issue that I talked about before. You
24 know, if you know that 88 percent of them are
25 going to persist -- desist, why in the world

1 identified 60,000 case reports world wide on
2 the Internet. See Exposito-Campos..." --

3 A. That is an error, by the way.

4 Q. Sorry. Which part of that is an
5 error?

6 A. That, "60,000," is my error. It
7 should say, "16,000."

8 - - - - -

9 (Thereupon, Deposition Exhibit 17,
10 "A Typology of Gender Detransition
11 and Its Implications for Healthcare
12 Providers," Article, was marked for
13 purposes of identification.)

14 - - - - -

15 Q. Okay. So for the record, I'm
16 showing Dr. Levine what has been marked as
17 Exhibit 17. "A Typology of Gender Detransition
18 and Its Implications for Healthcare Providers,"
19 Pablo Exposito-Campos, 2021. Okay. Have you
20 seen this study before, Dr. Levine?

21 A. Yes.

22 Q. Okay. So on page 1 of this report,
23 about halfway through the very first paragraph
24 in the introduction beginning with, "As a
25 consequence." Do you see that there?

1 important to note that this typology does not
2 suggest two clear-cut categories, for a
3 secondary detransition can lead to a primary
4 detransition" -- oh, sorry. Let me start over.
5 Sorry.

6 Okay. Let me start from a different
7 place, Dr. Levine. The second sentence.
8 "In r/detrans" --

9 And there's an HTTP address --

10 A. Okay.

11 Q. Okay. You see that.

12 -- "a subreddit for detransitioners to
13 share their experiences with more than 16,000
14 members, one can find several stories of people
15 who call their transgender status into question
16 after stopping transitioning due to medical
17 complications or feeling dissatisfied with
18 their treatment results"?

19 Do you know what a, "Subreddit," is,
20 Dr. Levine?

21 A. I believe it's just a division of a
22 larger website where people, you know, with
23 similar interests.

24 Q. Okay. Do you understand this
25 sentence to be suggesting that all 16,000 of

1 those members have offered a story of
2 detransition?

3 MR. KNEPPER: Objection, form.

4 A. I think -- I think it may be true
5 that either they have offered a personal story
6 or they're fascinated because of their own
7 considerations of that story. They're thinking
8 about it themselves, which would be in keeping
9 with the idea that even people who have
10 transitioned begin to doubt whether they made a
11 wise decision and they're considering
12 detransition. I'm not so sure it means that
13 all 16,000. I would have no way of
14 ascertaining that. You know, in my worry, I
15 would lean towards most of them are seriously
16 considering or have detransitioned. And in my
17 skepticism, I would say I'm not sure whether
18 it's 15,000 or 12,000 or 8,000.

19 Q. But you have no way to confirm
20 that --

21 A. I have no way.

22 Q. -- if it's all of them or a few of
23 them or three of them?

24 A. You're absolutely right. I have no
25 way of confirming that.

1 where hormones are safe and surgery is a good
2 thing to do. If a person said that, you know,
3 skeptically, I think that would disappoint
4 certain patients, but how it was said and when
5 it was said in response to what would either
6 determine whether the person is engaged with
7 the mental health professional or leaves the
8 mental health professional. You know, all
9 mental health professionals are not created
10 equal.

11 Q. So it sounds like you're saying it
12 could do harm to that patient?

13 MR. KNEPPER: Objection, form.

14 A. No, I'm not saying that. I'm
15 saying it could be disappointing to that
16 person. What that person did with the
17 disappointment may prove harmful just because
18 of that person or it may prove in fact
19 beneficial.

20 Q. Are you satisfied -- let's orient
21 this question around the patients you've seen
22 in the last 12 months. Are you satisfied that
23 those patients -- actually, sorry. Let me
24 start over. Are you satisfied that the
25 patients you have seen historically for whom

1 you provide letters of authorization for
2 hormones give sufficiently informed consent?

3 MR. KNEPPER: Objection, form.

4 A. From my point of view, I did what I
5 could to reach the standard of having the
6 person internalize and think about, digest,
7 dream about and come back and talk to me about
8 it. That's all I can do. I can't guarantee
9 that if I do what I do that it's going to
10 change your mind or help you steer your ship in
11 a slightly different angle --

12 Q. So --

13 A. -- so I would not write a letter of
14 recommendation if I didn't feel like I did my
15 part. And if the person indicated that they
16 couldn't pay attention to me, I wouldn't write
17 the letter.

18 MR. CHARLES: Understood.

19 Okay. John, finished.

20 MR. KNEPPER: You're finished?

21 MR. CHARLES: I mean, barring --

22 MR. KNEPPER: Barring --

23 MR. CHARLES: We can't tell the
24 future.

25 MR. KNEPPER: I wasn't ready for

Exhibit E

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UNITED STATES DISTRICT COURT
DISTRICT OF MASSACHUSETTS

KATHEENA SONEEYA,

Plaintiff,

Civil Action
No. 07-12325-DPW

V.

April 8, 2019

THOMAS A. TURCO III, in his official
capacity as Commissioner of the
Massachusetts Department of Correction, 10:23 a.m.

Defendant.

TRANSCRIPT OF BENCH TRIAL DAY 1
BEFORE THE HONORABLE DOUGLAS P. WOODLOCK

UNITED STATES DISTRICT COURT
JOHN J. MOAKLEY U.S. COURTHOUSE
1 COURTHOUSE WAY
BOSTON, MA 02210

DEBRA M. JOYCE, RMR, CRR, FCRR
KELLY MORTELLITE, RMR, CRR
Official Court Reporters
John J. Moakley U.S. Courthouse
1 Courthouse Way, Room 5204
Boston, MA 02210
joycedebra@gmail.com

1 witness, ask me.

2 MS. HANCOCK: Okay. Apologies, your Honor.

3 BY MS. HANCOCK:

4 Q. So two versions were released since 1999, correct?

5 A. Correct.

6 Q. And one in 2001, as you just testified, right?

7 A. Right.

8 Q. And another one in 2011; is that right?

9 A. Yes.

10 Q. And as you understand it, there's going to be an eighth
11 version coming out soon, correct?

12 A. Yes.

13 Q. And you're not involved in drafting that version, correct?

14 A. I am not.

15 Q. And you requested to participate in drafting that version,
16 correct?

17 A. I'm not sure that's correct.

18 Q. You did not ask to be involved in drafting that version?

19 A. I think -- I think I actually might have, now that you
20 bring it up, but I was told I had to be a member of WPATH.

21 Q. Now, you've worked as a consultant for the DOC since
22 around 2007 or 2008. Does that sound right?

23 A. That sounds right.

24 Q. And you're not technically engaged by the DOC, though,
25 right?

Exhibit F

Stephen Levine
December 21, 2020

IN THE UNITED STATES DISTRICT COURT
NORTHERN DISTRICT OF FLORIDA
TALLAHASSEE DIVISION

CASE NO. 4:20-cv-00020-MW/MAF

JAMI CLAIRE, KATHRYN LANE and
AHMIR MURPHY,

Plaintiffs,

vs.

FLORIDA DEPARTMENT OF
MANAGEMENT SERVICES, et al,

Defendants.

ZOOMED DEPOSITION OF STEPHEN B. LEVINE, M.D.

Monday, December 21, 2020

9:30 a.m. - 2:51 p.m.

Via Zoom

Tallahassee, Florida 32308

STENOGRAPHICALLY REPORTED BY:

SANDRA L. NARGIZ
RPR, CM, CRR, CRC, FPR, CCR-GA

Job No. 166551

Stephen Levine
December 21, 2020

Page 2

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ALSO PRESENT:

Samantha Howell

Stephen Levine
December 21, 2020

Page 3

I N D E X

2	WITNESS	PAGE
3	STEPHEN B. LEVINE, M.D.	5
4	Direct Examination by Mr. Tilley	5
5	Cross Examination by Ms. Coles	171

5

6

7

8 (STENOGRAPHER'S NOTE: Exhibits were received
9 premarked electronically; only Exhibits 1, 2, 3, 7,
10 10, 11 and 13 were referred to in deposition.)

10

11

INDEX OF EXHIBITS

12

13	NO.	DESCRIPTION	ID
14	1	Levine expert report	70
15	2	Psychotherapeutic Approaches to Sexual Problems: An Essential Guide for Mental Health Professionals	109
16	3	Dhejne study	165
17	7	Standards of Care, V7	48
18	10	Kosilek report	83
19	11	Soneeya 2011 report	94
20	13	Soneeya case trial transcript	167

18

19

20

21

22

23	CERTIFICATE OF OATH	181
24	CERTIFICATE OF REPORTER	182
25	READ AND SIGN LETTER	183
	ERRATA SHEET	184

25

Stephen Levine
December 21, 2020

Page 29

1 **right?**

2 A No, that is. I think -- we'll quibble
3 over the word only. If you use the word
4 predominantly, I would say they are predominantly
5 taking care of. They are a specialty clinic for the
6 transgender.

7 Q **So predominantly treating transgender**
8 **people, but not 100 percent?**

9 A That's my guess.

10 Q **Okay. What sorts of treatments do you**
11 **provide for your patients with gender dysphoria?**

12 A Psychiatric evaluation of the patient and
13 the family, the parents and the other siblings;
14 psychotherapy to further the process of
15 understanding this whole phenomenon; recommendations
16 for hormones and occasionally recommendations for --
17 depending on the biologic sex of the patient, for
18 genital or breast surgery.

19 Q **How many patients have you recommended**
20 **hormone therapy for?**

21 A You mean over 47 years?

22 Q **Let's start with the 47 years, yeah.**

23 A I don't know. Can I give you a gross
24 estimate?

25 Q **Sure.**

Stephen Levine
December 21, 2020

Page 37

1 to be directed to the surgeon.

2 Q Okay. If a surgeon told you I require a
3 letter for this facial feminization surgery, are
4 there circumstances under which you could see
5 yourself providing a letter, not of recommendation
6 but of authorization, for a person to receive this
7 surgery from the surgeon?

8 A I could see myself under certain
9 circumstances, if I understood the patient's motives
10 and had a lot of time to discover and discuss this,
11 the history and alternative approaches and wondering
12 about the psychology of wanting this, I could see
13 theoretically.

14 That's what I do, you know, as a
15 psychiatrist; I am trying to investigate the meaning
16 of the wish and the solution that the patient is
17 hoping for, the problem the patient is hoping this
18 would be a solution for.

19 And so I want to be able to consider this
20 and have a respectful, mutual, slow dialogue that is
21 slow, meaning multiple sessions, to consider the
22 nuances of this because, you know, all of us have a
23 self-concept of how handsome we are or pretty we
24 are, and most everyone wants to get a little more
25 handsome and a little more pretty and we are -- we

Stephen Levine
December 21, 2020

Page 47

1 Q Okay.

2 A I believe that if a surgeon is going to do
3 this, he ought to know what I think -- what I know
4 about the person's history and the person's
5 intellectual capacities and the prices they paid for
6 their gender dysphoria already.

7 For example, the loss of a family and no
8 relations to children, or the inability to have a
9 relationship, an intimate relationship with other
10 people. I believe the surgeon needs to have an
11 understanding of the person.

12 I don't have an understanding whatsoever
13 of the techniques of surgery. You see? I am just a
14 psychiatrist. And the psychiatrist -- and the
15 surgeon has very little understanding of how a
16 person got to be in his office. And I believe that
17 the letters of recommendation should capture the
18 humanness of this person and the desperation of this
19 person and the justification that the person uses
20 and the hopes they have for this surgery. But
21 that's Levine, you know.

22 Q I want to show you the WPATH Centers of
23 Care section that discusses letters. This is
24 Exhibit 7 which we are going to put on the screen.
25

Stephen Levine
December 21, 2020

Page 48

1 (Exhibit 7 was marked for identification.)

2 BY MR. TILLEY:

3 Q Let's go to page 27. It looks like the
4 document page 27, it's .pdf page 33, Bates stamp
5 PL 0450524.

6 You see, Dr. Levine --

7 MS. COLES: Can you read that, Dr. Levine?
8 It looks a little small on my computer.

9 THE WITNESS: I can read it. It says
10 referral for surgery.

11 MS. COLES: Okay. Just making sure.

12 BY MR. TILLEY:

13 Q At the bottom, I am going to start there
14 and then we'll go on to the following page. At the
15 bottom it says, The recommended content of the
16 referral letters for surgery is as follows: 1, the
17 client's general identifying characteristics -- now
18 we are continuing on to the next page -- number 2,
19 results of the client's psychosocial assessment,
20 including any diagnoses.

21 And then it goes on to 3, 4, 5, and 6.

22 Dr. Levine, can you just review those if
23 you can read it and then let me know if you agree
24 with those statements.

25 (Short pause.)

Stephen Levine
December 21, 2020

Page 49

1 A I don't disagree with the statements, but
2 each of those statements, of course, need to be
3 operationalized by the letter writer. For example,
4 the first one, identifying characteristics,
5 oftentimes identifying characteristics would be like
6 this is a 63-year-old Caucasian veterinarian. But
7 there are many other identifying characteristics
8 that might be included.

9 So you can interpret these things with
10 terse statements or elaborate statements. I favor
11 elaborate statements. For example, I would like to
12 say a divorced father of four, or a roller derby
13 official. I would like to identify him as much as a
14 person as possible. But in the history of medicine,
15 race, age, and nourishment passes for identifying
16 information.

17 So the results of the psychosocial
18 assessment, including any diagnosis. Psychosocial
19 assessment would be the processes in his life
20 history, including any current or past diagnoses,
21 you see. So substance abuse might be a very
22 important part of number 2.; and the duration. So
23 if I am writing a letter, if I am one of two people
24 who have been hired to write a letter for genital
25 surgery, and I might have had three visits with the

Stephen Levine
December 21, 2020

Page 103

1 not inquiring about your medical history and your
2 psychiatric history. But it may be psychologically
3 beneficial to you and an M.D. may recommend that you
4 do that. And that recommendation would be based on
5 his or her knowledge that you are likely to suffer
6 from seasonal affective disorder, and the treatment
7 is bright lights and sunshine. And sunshine would
8 be far superior because of its luminescence, the
9 number of lumens exposed, than bright lights.

10 BY MR. TILLEY:

11 Q Let's go back just briefly to WPATH. And
12 I know you mentioned you have a more conservative
13 approach. So let me ask you this.

14 Is it fair to say that if you personally
15 believed that you would authorize hormones or
16 surgery for someone with gender dysphoria, someone
17 following the WPATH Standards of Care would also
18 believe that?

19 A Yes.

20 Q Okay. Let's talk about insurance for a
21 little bit. If you recommended that -- if you
22 authorized some form of treatment for gender
23 dysphoria, whether it be hormones or some form of
24 surgery, would you expect that that treatment would
25 be covered by your patient's insurance?

Stephen Levine
December 21, 2020

Page 156

1 You see?

2 So I am saying, please, let me talk to you
3 about human beings here and how important having
4 ongoing lifelong relations with one's children are
5 and being a grandfather or grandmother, and being
6 connected to a family of origin. I am not talking
7 about categorical bans. I am talking about being
8 smart.

9 BY MR. TILLEY:

10 Q Are you aware that this case concerns an
11 insurance exclusion that is categorical at
12 preventing --

13 MS. COLES: Form.

14 BY MR. TILLEY:

15 Q -- hormones and surgery as a treatment for
16 gender dysphoria?

17 MS. COLES: Form.

18 A I am aware that your plaintiffs are suing
19 to get coverage for -- that is not provided by their
20 particular insurance. I am aware of that.

21 BY MR. TILLEY:

22 Q Do you think that exclusion is
23 appropriate?

24 MS. COLES: Form.

25 A I've already answered that question, I

Stephen Levine
December 21, 2020

Page 157

1 believe.

2 BY MR. TILLEY:

3 Q What is the answer?

4 A That it's a political decision that varies
5 from state to state, and it belongs to the process
6 of political science and the courts and not doctors.

7 Q And if you yourself were treating them and
8 determined that they understood the risks and you
9 thought the treatment would be psychologically
10 beneficial and provided letters of authorization to
11 them, you would want that treatment to be covered by
12 insurance; is that correct?

13 MS. COLES: Form.

14 A I am an agent of the patient, I want
15 what's best for the patient, and especially if the
16 patient couldn't otherwise afford it, I would wish
17 for my patient to have it, yes.

18 BY MR. TILLEY:

19 Q I know you said you are not about
20 categorical bans, but let me ask you about minors
21 again.

22 Would you support a categorical ban on
23 access to puberty blockers to treat gender
24 dysphoria?

25 MS. COLES: Form.

Exhibit G

BMJ Open International clinical practice guidelines for gender minority/trans people: systematic review and quality assessment

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To cite: Dahlen S, Connolly D, Arif I, *et al.* International clinical practice guidelines for gender minority/trans people: systematic review and quality assessment. *BMJ Open* 2021;**11**:e048943. doi:10.1136/bmjopen-2021-048943

► Prepublication history and additional supplemental material for this paper are available online. To view these files, please visit the journal online (<http://dx.doi.org/10.1136/bmjopen-2021-048943>).

Received 15 January 2021

Revised 22 March 2021

Accepted 12 April 2021

Abstract

Objectives To identify and critically appraise published clinical practice guidelines (CPGs) regarding healthcare of gender minority/trans people.

Design Systematic review and quality appraisal using AGREE II (Appraisal of Guidelines for Research and Evaluation tool), including stakeholder domain prioritisation.

Setting Six databases and six CPG websites were searched, and international key opinion leaders approached.

Participants CPGs relating to adults and/or children who are gender minority/trans with no exclusions due to comorbidities, except differences in sex development.

Intervention Any health-related intervention connected to the care of gender minority/trans people.

Main outcome measures Number and quality of international CPGs addressing the health of gender minority/trans people, information on estimated changes in mortality or quality of life (QoL), consistency of recommended interventions across CPGs, and appraisal of key messages for patients.

Results Twelve international CPGs address gender minority/trans people's healthcare as complete (n=5), partial (n=4) or marginal (n=3) focus of guidance. The quality scores have a wide range and heterogeneity whichever AGREE II domain is prioritised. Five higher-quality CPGs focus on HIV and other blood-borne infections (overall assessment scores 69%–94%). Six lower-quality CPGs concern transition-specific interventions (overall assessment scores 11%–56%). None deal with primary care, mental health or longer-term medical issues. Sparse information on estimated changes in mortality and QoL is conflicting. Consistency between CPGs could not be examined due to unclear recommendations within the World Professional Association for Transgender Health Standards of Care Version 7 and a lack of overlap between other CPGs. None provide key messages for patients.

Conclusions A paucity of high-quality guidance for gender minority/trans people exists, largely limited to HIV and transition, but not wider aspects of healthcare, mortality or QoL. Reference to AGREE II, use of systematic reviews, independent external review, stakeholder participation and patient facing material might improve future CPG quality.

PROSPERO registration number CRD42019154361.

Strengths and limitations of this study

- First systematic review to identify and use a validated quality appraisal instrument to assess all international clinical practice guidelines (CPGs) addressing gender minority/trans health.
- International CPGs were studied due to their influential status in gender minority/trans health, though further research is needed on national and local CPGs.
- An innovative prioritisation exercise was performed to elicit stakeholders' priorities and inform the setting of AGREE II (Appraisal of Guidelines for Research and Evaluation tool) quality thresholds, however these stakeholder priorities may not be applicable outside the UK.
- An inclusive approach using wide criteria, extensive searches and approaching key opinion leaders should have allowed the study to identify all relevant international CPGs, however it is possible some may have been missed.

INTRODUCTION

Assessing the quality of clinical practice guidelines

Evidence-based practice integrates best available research with clinical expertise and the patient's unique values and circumstances. High-quality clinical practice guidelines (CPGs) support high-quality healthcare delivery. They can guide clinicians and policymakers to improve care, reduce variation in clinical practice, thereby affecting patient safety and outcomes. The Institute of Medicine defines CPGs as: 'statements that include recommendations intended to optimise patient care that are informed by a systematic review of evidence and an assessment of the benefits and harms of alternative care options',¹ although other definitions exist.² Recommendations are used alongside professional judgement, directly or within decision aids, in training and practice. CPGs are important but have limitations depending on evidence selection and



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development processes.³ Grading of Recommendations, Assessment, Development and Evaluation (GRADE) was developed to address the evidence that is selected and appraised during CPG development.⁴⁻⁶ Using a systematic approach and transparent framework for developing and presenting summaries of evidence, GRADE is the most widely adopted tool worldwide for grading the quality of evidence and making recommendations,⁷ but does not alone ensure a CPG is high quality. Strength of evidence is only one component of what makes a 'good' CPG; factors such as transparency, rigour, independence, multidisciplinary input, patient and public involvement, avoidance of commercial influences and rapidity^{8,9} should also be considered. Broader domains of CPG quality are included in the Appraisal of Guidelines for Research and Evaluation instrument AGREE II.¹⁰⁻¹² Despite widely recognised principles and methods for developing sound CPGs, current research shows that guidelines on various topics lack appropriate uptake of systematic review methodologies in their development,¹³ give recommendations that conflict with scientific evidence¹⁴ or do not adequately take into account existing CPG quality and reporting assessment tools.¹⁵ This emphasises the ongoing need to appraise guidelines to ensure evidence-informed care.

Healthcare for gender minority/trans people

'Trans' is an umbrella term for individuals whose inner sense of self (gender identity) or how they present themselves using visual or behavioural cues (gender expression) differs from the expected stereotypes (gender) culturally assigned to their biological sex.¹⁶ 'Gender minority' is an often-used alternative population description. Some gender minority/trans people may seek medical transition, which involves interventions such as hormones or surgery that alter physical characteristics and align appearance with gender identity. Patient numbers referred to UK gender identity clinics and length of waiting lists have increased in the last decade, particularly for adolescents,¹⁷ a phenomenon seen elsewhere.¹⁸ Gender minority/trans people may have continuing, sometimes complex, life-long healthcare needs whether they undergo medical transition or not. Gender minority/trans people may experience more mental health issues such as mood and anxiety disorders,¹⁹ substance use²⁰ and higher rates of suicidal ideation.²¹ They may seek assistance with sexual health, mental health,²² substance use disorders,²³ prevention and/or management of HIV²⁴ as well as usual general health enquiries. However, they may encounter difficulties in accessing healthcare,²⁵ reporting negative healthcare experiences,²⁶ discrimination and stigma.^{27,28} Like all individuals, gender minority/trans people require high-quality evidence-based healthcare^{25,29} addressing general and specific needs.

Guidelines used internationally and in the UK

The quality of current guidelines on gender minority/trans health is unclear. The World Professional Association for Transgender Health (WPATH) Standards of

Care Version 7 (SOCv7)³⁰ represent normative standards for clinical care, acting as a benchmark in this field.³¹ Globally, many national and local guidelines³²⁻³⁵ are adaptations of, acknowledge being influenced by, or are intended to complement WPATH SOCv7,³⁰ despite expressed reservations that WPATH SOCv7³⁰ is based on lower-quality primary research, the opinions of experts and lacks grading of evidence.³⁶

In the UK, an advocacy group worked to incorporate WPATH SOCv7³⁰ into national practice.³⁷ WPATH SOCv7³⁰ informs National Health Service (NHS) gender identity clinics³⁸ and guidelines produced by the Royal College of Psychiatrists (without use of GRADE).³⁹ No CPGs were available from the National Institute for Health and Care Excellence (NICE), Scottish Intercollegiate Guidelines Network (SIGN), British Association of Gender Identity Specialists, or medical Royal Colleges, although the Royal College of General Practitioners issued a position statement on gender minority/trans healthcare in 2019.⁴⁰ Assessing quality of international CPGs such as WPATH SOCv7³⁰ has practice implications for the NHS³⁸ and private sector. CPGs with international scope may present additional challenges (eg, the implementability of key recommendations might not be easily translated among different contexts) but they seem to influence discourse around gender minority/trans health.³⁶ No prior study has investigated the number and quality of guidelines to support the care and well-being of gender minority/trans people. The purpose of this research was to identify and critically appraise all published international CPGs relating to the healthcare of gender minority/trans people.

METHODS

Approach/research design

The rationale was to identify the key CPGs available to healthcare practitioners in this field of clinical practice. Following preliminary searches, we chose international CPGs in view of WPATH's influence within the UK and elsewhere, and to avoid 'double-counting'. We considered AGREE II¹⁰⁻¹² the most appropriate tool; it is the most comprehensively validated and evaluated instrument available for assessing CPGs,^{41,42} designed for use by non-expert stakeholders¹⁰ such as healthcare providers, practicing clinicians and educators.¹¹ It benefits from clear instructions and prompts regarding scoring and several people applying the criteria independently (a minimum of two reviewers, but four are recommended). AGREE II synthesis calculates quality scores from 23 appraisal criteria organised into six key domains (scope and purpose, stakeholder involvement, rigour of development, clarity of presentation, applicability, editorial independence) and an overall assessment of 'Recommend for use?' (answer options; yes, no, yes if modified). This systematic review was conducted according to a pre-specified PROSPERO protocol https://www.crd.york.ac.uk/prospero/display_record.php?RecordID=154361

uploaded 19 December 2019. The MEDLINE strategy was straightforward; although not formally processed,⁴³ it was peer-reviewed by an information specialist.

Inclusion and exclusion criteria

We defined a CPG as a systematically developed set of recommendations that assist practitioners and patients in the provision of healthcare in specific circumstances, produced after review and assessment of available clinical evidence.^{12 44–46} CPGs published after 1 January 2010 were eligible if they (or part thereof) specifically targeted patients/population with gender minority/trans status and/or gender dysphoria, were evidence-based, with some documentation of development methodology, had international scope (more than one country, defined as a Member State of the United Nations) and were an original source. We chose the time frame to focus on the most recent guidelines, currently applicable to practice and to include WPATH SOCv7.³⁰ CPGs were eligible if they met the following inclusion criteria: participants/population was adults and/or children who are gender minority/trans with no exclusion due to comorbidities or age although differences/disorders in sex development (intersex) were excluded; exposure/intervention was any health intervention related to gender dysphoria or gender affirmation, or health concerns of gender minority/trans people, including screening, assessment, referral, diagnosis and interventions. We excluded previous versions of the same CPG. We used broad criteria because terminology has been in flux with changes made in both International Classification of Diseases and Diagnostic and Statistical Manual of Mental Disorders diagnostic criteria.¹⁶ There were no restrictions on setting or language.

Search strategy and guideline selection

We conducted the searches up to 11 June 2020 (CM), using search terms and appropriate synonyms (as Medical Subject Heading (MeSH) terms and text words) that we developed based on population and exposures (online supplemental table 1). We searched six databases (Embase, MEDLINE, Web of Science, PsycINFO, CINAHL, LILACS) and six CPG websites (Agency for Healthcare Research and Quality National Guideline Clearinghouse (NGC), eGuidelines and Guidelines, NICE National Library for Health, SIGN, EBSCO DynaMed Plus, Guidelines International Network Library) and the World Health Organization (WHO). The NGC closed in 2017 but CM hand-searched the archive. In addition to protocol, individual reviewers (IA, DC and MHJ) hand-searched four specialty journals (International Journal of Transgender Health, Transgender Health, LGBT Health, Journal of Homosexuality) to ensure key subject-relevant sources of abstracts were thoroughly checked. In order to find potential grey literature CPGs outwith the scholarly literature, two reviewers (IA and SD) independently performed four separate Google searches (not Google Scholar as misstated in the protocol) by

using one generic (clinical practice guidelines) plus one specific term (transgender, gender dysphoria, trans health or gender minority) and examining the first 100 hits. We identified International Key Opinion Leaders (n=24) via publications known to reviewers (DC and SD) and contacted them via email, with one reminder, to identify further guidelines. Reference lists of relevant reviews and all full-text studies were hand-searched to identify any relevant papers or CPGs not found by database searching. Two reviewers (SB and SD) independently read all titles and abstracts and assessed for inclusion. If there was uncertainty or disagreement, or reasonable suspicion that the full-text might lead to another relevant CPG, the full-text was obtained. Non-English abstracts were Google-translated but if a possible CPG could not be reliably excluded, the full-text paper was obtained and translated. Where full-text publications could not be accessed, we contacted authors directly. Two reviewers (SB and either DC/MHJ) independently carried out full-text assessment to determine inclusion or exclusion from the systematic review based on the above criteria, and noted reasons for excluding full-texts. The whole team discussed uncertainties and disagreements to achieve consensus, with voting and final adjudication by the senior author (CM).

Data extraction

Two reviewers (SB and SD) independently collected formal descriptive data of included CPGs. All ambiguities or discrepancies were referred to the team for discussion and to re-examine original texts and extract data. Information collected was title, author, year of publication, number of countries covered, originating organisation, audience, methods used, page and reference numbers (excluding accompanying materials) and funding. Key recommendations were extracted for comparison between CPGs. We searched for all text mentions of mortality or any measures of quality of life (QoL), and noted if accompanied by a citation. All patient facing material was extracted. In addition, we extracted data about publication outlet (journal/website), and whether the quantity of information pertaining to the health of gender minority/trans people represented a complete, partial or marginal proportion of recommendations in the CPG.

Outcomes

Outcomes were: the number and quality assessment scores (using AGREE II) of international CPGs addressing the health of gender minority/trans people; analysis and comparison of the presence or absence of information on estimated changes in mortality or QoL (any measure) following any specific recommended intervention, over any time interval; the consistency (or lack thereof) of recommendations across the CPGs; and the presence (or absence) of key messages for patients.

Quality assessment

All authors completed AGREE II video training, a practice assessment and two pilots whose results were discussed. The six reviewers (IA, SB, DC, SD, MHJ and CM) independently and anonymously completed quality scoring on every CPG by rating each of the items using the standard proforma on the My AGREE PLUS online platform (AGREE enterprise website),¹¹ which also calculated group appraisal scores.

Patient and public involvement

The AGREE II instrument generates quality scores but does not set specific parameters for what constitutes high quality, recommending that decisions about defining such thresholds should be made prior to performing appraisals, considering relevant stakeholders and the context in which the CPG is used.¹¹ To help set quality thresholds, we conducted an AGREE II domain prioritisation exercise in January 2020 via email, with one reminder. It was considered impossible to ensure comprehensive representation of international stakeholders. We chose the UK for feasibility, although validity might be limited to UK-based clinicians. Fifty-two UK service-user stakeholder groups and gender minority/trans advocacy organisations, identified via reviewer knowledge and internet searches (IA, SB, DC, SD, MHJ and CM), were informed about the study. They were invited to participate in a stakeholder prioritisation of the AGREE II domains, created using SurveyMonkey and with an option to remain anonymous (<https://www.surveymonkey.co.uk/r/WLZ55NQ> gives invitation wording, links to resources and protocol). The reviewer team performed an anonymous prioritisation for comparison.

Strategy for data and statistical analyses

Simple frequencies were used to present the stakeholder and reviewer priorities, and outcomes. Following team discussion of the prioritisation exercise results, no prespecified quality threshold score was used to define high or low quality, although colour was superimposed ($\leq 30\%$, 31% – 69% and $\geq 70\%$) on the final scores table to aid visual comparisons and interpretation.

RESULTS

Search results

Figure 1 (Preferred Reporting Items for Systematic Reviews and Meta-Analyses flow chart⁴⁷) shows that 1815 citations were identified, of which 134 full-text publications were read (all available, three supplied by authors) and 122 excluded (online supplemental table W2 with reasons).

Data extraction

Table 1 shows the characteristics of the CPGs. Online supplemental tables W3 and W4 show raw data of key recommendations and mortality and QoL evidence.

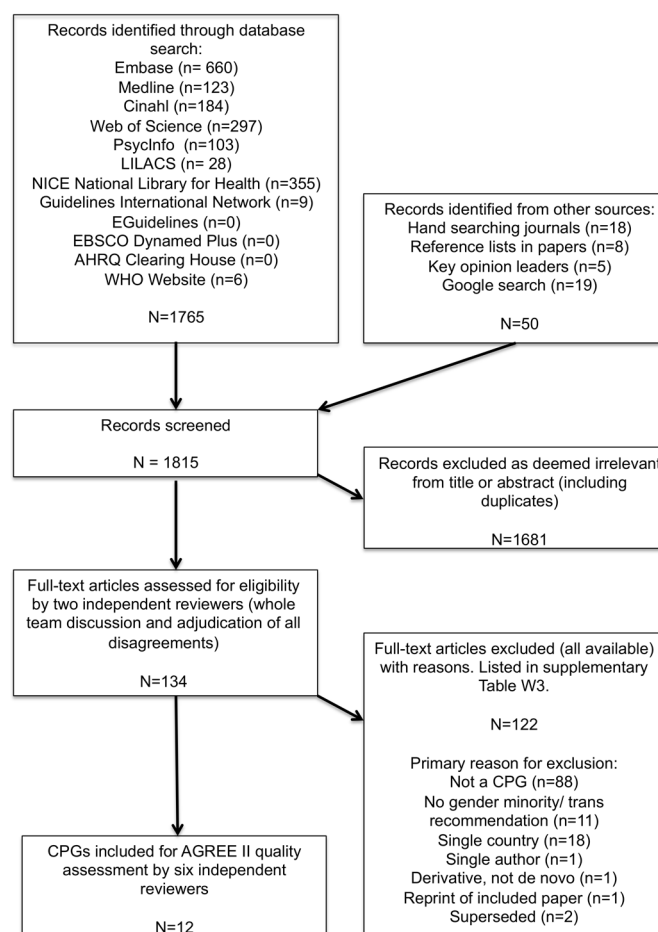


Figure 1 Preferred Reporting Items for Systematic Reviews and Meta-Analyses flow diagram. AGREE II, Appraisal of Guidelines for Research and Evaluation tool; CPG, clinical practice guideline; NICE, National Institute for Health and Care Excellence.

Number and characteristics of clinical practice guidelines

Twelve CPGs (table 1) originated from: WHO (n=3),^{48–50} WPATH (n=2),^{30 51} professional specialist/special-interest societies (n=4),^{52–55} small groups of experts (n=2)^{56 57} and one consortium.⁵⁸ All were published in English, in journals,^{51–57} the organisation's website^{48–50 58} or both.³⁰ Guideline development methodology was variable, including use of systematic reviews (table 1). Ten CPGs had no external review, eight had no update plans. Gender minority/trans health recommendations made up complete (n=5),^{30 51 53 55 57} partial (n=4)^{48–50 56} or marginal (n=3)^{52 54 58} focus of content. CPGs contained 10 to 155 pages, and 20 to 505 references. Funding sources were wide-ranging and sometimes multiple, from government agencies, professional societies, charities and private donations. Two CPGs provided no funding details.^{52 56}

A 13th CPG was excluded post-scoring as it had been superseded by a 2020 version without recommendations for gender minority/trans people.⁵⁹ It was arguable if four included CPGs did meet criteria: one had not been withdrawn⁴⁸; one contained minimal relevant content⁵²; one might not have been intended as a CPG³⁰ (although

Table 1 General characteristics of included clinical practice guidelines (n=12)

Number	Author (year)	Full title	Countries covered	Origin	Primary audience	Design (systematic review, SR, used and methods thereafter)	Planned update given	Funding
1	Coleman <i>et al</i> (2012) ³⁰	Standards of care for the health of transsexual, transgender and gender non-conforming people V.7	Global	WPAT	Health professionals	Work groups submit manuscripts based on prior literature reviews, no explicit links of recommendations to evidence, expert consensus. No independent external review	No	Tawani Foundation and gift from anonymous donor
2	Davies <i>et al</i> (2015) ⁵¹	Voice and communication change for gender non-conforming individuals: giving voice to the person inside	Global	WPAT	Speech-language therapists	Review of evidence. Expert consensus. No independent external review	No	Transgender Health Information Program of British Columbia Canada
3	ECDC (2018) ⁵⁸	Public health guidance on HIV, hepatitis B and C testing in the EU/EEA	EU/EEA	ECDC consortium CHIP, PHE, SSAT and EATG	Member states' public health professionals who coordinate the development of national guidelines or programmes for HBV, HCV and HIV testing	Four SRs, SIGN, NICE and AXIS checklists. Ad hoc internal and external expert panel, independent chair, expert consensus. No independent external review	No	Commissioned by ECDC, contractor Rigshospitalet CHIP
4	Gilligan <i>et al</i> (2017) ⁵²	Patient-clinician communication: American Society of Clinical Oncology consensus guideline	USA and others	ASCO	Clinicians who care for adults with cancer	Nine questions (one SR), expert consensus and a Delphi exercise. No independent external review	Regular review 3-year check	None declared
5	Hembree <i>et al</i> (2017) ⁵³	Endocrine treatment of gender-dysphoric/gender-incongruent persons: an Endocrine Society clinical practice guideline	Global	Endocrine Society	Endocrinologists, trained mental health professionals and trained physicians	Two SRs and GRADE, rest expert consensus. No independent external review	No	Endocrine Society
6	IAPHCCO (2015) ⁵⁴	IAPAC guidelines for optimising the HIV care continuum for adults and adolescents	Global	IAPAC	Care providers, programme managers, policymakers, affected communities, organisations, and health systems involved with implementing HIV programmes and/or delivering HIV care	A systematic search of CDC database, expert consensus. No independent external review	No	IAPAC, US NIH and Office of AIDS Research
7	Ralph <i>et al</i> (2010) ⁵⁶	Trauma, gender reassignment and penile augmentation	Not specified (international publication)	Author group	Not stated (urological surgeons)	No SR. Unclear if literature review. Leading experts' consensus opinion. No independent external review	No	None declared
8	Strang <i>et al</i> (2018) ⁵⁷	Initial clinical guidelines for co-occurring autism spectrum disorder and gender dysphoria or incongruence in adolescents	Not specified (international publication)	Author group	Clinicians	No SR or literature review. Two-stage Delphi consensus. No independent external review	No	Isadore and Bertha Gudelsky Family Foundation
9	T'Sjoen <i>et al</i> (2020) ⁵⁵	ESSM Position Statement 'Assessment and hormonal management in adolescent and adult trans people, with attention for sexual function and satisfaction'	Europe	ESSM	European clinicians working in transgender health, sexologists and other healthcare professionals	No SR. Leading experts' consensus opinion. No independent external review	No	ESSM
10	WHO (2011) ⁴⁸	Prevention and treatment of HIV and other sexually transmitted infections among men who have sex with men and transgender people. Recommendations for a public health approach	Global	WHO	National public health officials and managers of HIV/AIDS and STI programmes, NGOs including community and civil society organisations, and health workers	13 SRs for PICO and GRADE, external GDG, and independent external review	Yes in 2015	BMZ and PEPFAR through CDC and USAID
11	WHO (2012) ⁴⁹	Guidance on oral pre-exposure prophylaxis for serodiscordant couples, men and transgender women who have sex with men at high risk of HIV. Recommendations for use in the context of demonstration projects	Global	WHO	Countries/member states	Four SRs (including values and preferences reviews) and GRADE, external GDG and independent external review group	Yes in 2015	Bill & Melinda Gates Foundation

Continued

Table 1 Continued

Number	Author (year)	Full title	Countries covered	Origin	Primary audience	Design (systematic review, SR, used and methods thereafter)	Planned update given	Funding
12	WHO (2016) ⁵⁰	Consolidated guidelines on HIV prevention, diagnosis, treatment and care for key populations. 2016 update	Global	WHO	National HIV programme managers and other decision-makers within ministries of health and those responsible for health policies, programmes and services in prisons	Two new SRs in revised guidance, GRADE, external GDGs and 79 independent external peer reviewers	Regular updates; no detail	UNAIDS, PEPFAR, Global Fund

AACE, American Association of Clinical Endocrinologists; ASA, American Society of Andrology; ASCO, American Society of Clinical Oncology; ASD, autism spectrum disorder; AXIS, Appraisal Tool for Cross-Sectional Studies; BMZ, German Federal Ministry for Economic Cooperation and Development; CDC, the Centers for Disease Control and Prevention; CHIP, CHIP/Region H, Rigshospitalet, University of Copenhagen; CPG, clinical practice guideline; EATG, European AIDS Treatment Group; EAU, European Association of Urology; ECDC, European Centre for Disease Prevention and Control; ESE, European Society for Endocrinology; ESPE, European Society for Pediatric Endocrinology; ESSM, European Society for Sexual Medicine; EU/EEA, European Union/European Economic Area; GDG, guideline development group; Global Fund, Global Fund to Fight AIDS, Tuberculosis and Malaria; GRADE, Grading of Recommendations, Assessment, Development and Evaluation; HBV, hepatitis B virus; HCV, hepatitis C virus; IAPAC, International Association of Providers of AIDS Care; IAPHCCO, International Advisory Panel on HIV Care Continuum Optimization; NGO, non-governmental organisations; NICE, National Institute of Health and Care Excellence; NIH, National Institutes of Health; PEPFAR, US President's Emergency Plan for AIDS Relief; PES, Pediatric Endocrine Society; PHE, Public Health England; PICO, Participants/patients, Intervention, Comparators, Outcomes; SIGN, Scottish Intercollegiate Guidelines Network; SR, systematic review; SSAT, St Stephen's AIDS Trust; STI, sexually transmitted infection; UNAIDS, The United Budget, Results and Accountability Framework of the Joint United Nations Programme on HIV/AIDS; USAID, US Agency for International Development; WPATH, World Professional Association for Transgender Health.

WPATH SOCv7's stated overall goal is 'to provide clinical guidance for health professionals'³⁰ it contains no list of key recommendations nor auditable quality standards, yet is widely used to compare procedures covered by US providers^{60 61}; one variously described itself as 'position statement' and 'position study' (stating it did 'not aim to provide detailed clinical guidelines for professionals such as... [named]^{30 53}, but evidence was obviously linked to key recommendations for clinicians⁵⁵). After discussion it was decided not to exclude these borderline CPGs, as the definition of CPG in the protocol was intended to favour an inclusive approach.

Quality prioritisation and assessment

Results of the domain prioritisation by stakeholders (n=19 replies, response rate 39% excluding 3 'undeliverable') and reviewers (n=6) showed that stakeholders prioritised stakeholder involvement, whereas the reviewer team prioritised methodological rigour (online supplementary table W5). No stakeholder asked for clarification or more information.

Table 2 shows AGREE II scores by domain (8%–94%), and overall (11%–94%). The quality scores have a wide range and heterogeneity. Five CPGs focused on trans people as a key population for HIV and other blood-borne infections (overall assessment scores 69%–94%). Six CPGs concerned transition-specific interventions (overall assessment scores 11%–56%). Transition-related CPGs tended to lack methodological rigour and rely on patchier, lower-quality primary research. The two prioritised domain scores were usually comparable with the overall AGREE II quality assessment (ranges; stakeholder involvement 14%–93%, methodological rigour 17%–87%). Four CPGs obtained a majority opinion 'recommend for use',^{48–50 58} five CPGs had unanimous 'do not recommend',^{30 51 55–57} and three had minority support with division about the extent of 'yes, if modified',^{52–54} (table 2). Despite wide variation there was a pattern; HIV and blood-borne infection guidelines^{48–50 54 58} were higher quality, and those focusing on transition were lower quality.^{30 53 55–57}

Content

Four CPGs concerning HIV prevention, transmission and care^{48–50 54} and one public health guideline on population screening for blood-borne viruses,⁵⁸ contained recommendations for gender minority/trans people as a 'key population'. Three CPGs were devoted to overall transition care for all gender minority/trans people,^{30 53 55} two to an aspect of transition^{51 56} and one to transition in a specific group.⁵⁷ One oncology communication guideline contained a single recommendation relating to gender minority/trans people.⁵² No international guidelines were found that addressed primary care, psychological support/mental health interventions, or general medical/chronic disease care (such as cardiovascular, cancer or elderly care).

Table 2 AGREE II (Appraisal of Guidelines for Research and Evaluation tool) domain percentages and overall assessment of included guidelines, and summary of mortality/quality of life measures (n=12)

Number	Author (year)	Scope and purpose	Stakeholder involvement	Rigour of development	Clarity and presentation	Applicability	Editorial independence	Overall assessment	Recommendation to use	Mortality	Quality of life	Mortality (any comment) and quality of life (any formal measure)
1	Coleman <i>et al</i> (2012) ³⁰	63%	47%	20%	37%	16%	15%	31%	Yes 0 No 5 If modified 1	Y	Y	M: Higher in post SRS vs matched no SRS, and both pre and post SRS vs gen popn. QoL: FtM<gen popn, FtM post breast/chest surgery >not surgery, mixed results at 15 years.
2	Davies <i>et al</i> (2015) ⁵¹	62%	38%	17%	61%	28%	14%	28%	Yes 0 No 3 If modified 3	N	Y	QoL: A voice-related TG QoL measure correlated with own and others' perception.
3	ECDC (2018) ⁵⁸	94%	56%	55%	76%	68%	38%	69%	Yes 4 No 0 If modified 2	Y	Y	M: Reduced by early diagnosis. QoL: Cost/QALY in anti-HCV birth cohort screening is acceptable. Universal offer HIV testing in hospital settings is highly cost effective.
4	Gilligan <i>et al</i> (2017) ⁵²	84%	67%	66%	81%	47%	61%	78%	Yes 2 No 0 If modified 4	N	N	
5	Hembree <i>et al</i> (2017) ⁵³	65%	40%	41%	73%	29%	65%	56%	Yes 1 No 2 If modified 3	Y	Y	M: TW/TM's CV mortality same ('insufficient very low quality data' for TM) and younger age at death after SRS. QoL: long-term psychological and psychiatric issues post SRS.
6	IAPHCCO (2015) ⁵⁴	85%	56%	61%	87%	40%	63%	81%	Yes 3 No 0 If modified 3	Y	Y	M: Lower if early ART, easy access, immediate ART, and community distribution. QoL: ART preserves QoL, and stigma and mental health impact on QoL.
7	Ralph <i>et al</i> (2010) ⁵⁶	45%	14%	19%	64%	5%	32%	28%	Yes 0 No 5 If modified 1	N	N	
8	Strang <i>et al</i> ⁵⁷ (2018)	57%	33%	19%	39%	8%	25%	11%	Yes 0 No 6 If modified 0	N	N	
9	T'Sjoen <i>et al</i> (2020) ⁵⁵	59%	37%	35%	58%	15%	33%	42%	Yes 0 No 4 If modified 2	N	Y	QoL: Sexual life improves after GAMI, but not to non-TG levels.
10	WHO (2011) ⁴⁸	94%	89%	87%	86%	64%	82%	83%	Yes 5 No 0 If modified 1	Y	Y	M: Looked for mortality evidence but none found. QoL: Positive QALYs if HIV averted.
11	WHO (2012) ⁴⁹	85%	60%	81%	76%	41%	72%	72%	Yes 4 No 0 If modified 2	N	Y	QoL: Positive QALYs modelled if PrEP.
12	WHO (2016) ⁵⁰	94%	93%	81%	89%	84%	65%	94%	Yes 5 No 0 If modified 1	Y	N	M: Better if access and if adhere to OST, and at prison release; if early ART and completed TB Rx, HBV/ HCV managed; and access to post-abortion care. Worse if food insecure, poor nutrition, low body mass index.

Colours to aid interpretation (not thresholds) ≤30% RED, 31–69% AMBER, ≥70% GREEN.

ART, antiretroviral therapy; CV, cardiovascular; ECDC, European Centre for Disease Prevention and Control; FtM, female-to-male; GAMI, gender affirming medical intervention; gen popn, general population; HBV, hepatitis B virus; HCV, hepatitis C virus; HIV, human immunodeficiency virus; IAPHCCO, International advisory panel on HIV care continuum optimization; M, mortality; OST, opiate substitute therapy; PrEP, pre-exposure prophylaxis; QALY, quality adjusted life year; QoL, Quality of life; Rx, treatment; SR, systematic review; SRS, sex reassignment surgery; TB, tuberculosis; TG, trans people/gender-minority; TM, trans man; TW, trans woman.



Mortality and quality of life

Six CPGs referred to mortality^{30 48 50 53 54 58} and eight to QoL^{30 48 49 51 53–55 58} (table 2). Online supplemental table W4 shows all extractions of sentences relating to mortality or morbidity, associated references and which CPGs included no such data. More robust evidence was linked to the recommendations in the HIV and blood-borne virus CPGs whereas there was little, inconsistent data and poorer linking to evidence in transition-related CPGs.

Consistency of recommendations across the CPGs

Online supplemental table W5 contains all extracted key recommendations where these could be distinguished. It shows little overlap of topic content across the CPGs. Many recommendations in WHO 2011⁴⁸ and 2016⁵⁰ were similar, but not identical, the former not being stood down after the latter was published. No statements were highlighted by the WPATH SOCv7³⁰ authors as key recommendations, and it proved impossible for all six reviewers independently performing data extraction to identify them. The total number of extracted recommendations ranged between 0 and 168 with little consistency or agreement on what passages were selected. Some extracted statements might have been intended as recommendations or standards, but many were flexible, disconnected from evidence and could not be used by individuals or services to benchmark practice. After discussion of this incoherence within WPATH SOCv7³⁰ and our inability therefore to compare recommendations across all CPGs, it was decided not to revisit inclusions post hoc but to abandon this protocol aim.

Patient facing material

No patient-facing material was found in any guideline.

DISCUSSION

Statement of principal findings

Variable quality international CPGs regarding gender minority/trans people's healthcare contain little, conflicting information on mortality and QoL, no patient facing messages and inconsistent use of systematic reviews in generating recommendations. A major finding is that the scope of the guidelines is confined to HIV/STI prevention or management of transition with an absence of guidelines relating to other medical issues. WPATH SOCv7³⁰ cannot be considered 'gold standard'.

Strengths and weaknesses of this study

Strengths include protocol preregistration, stakeholder involvement, piloting all stages, an extensive systematic search without language restriction for any relevant current guidelines, wide inclusion criteria including grey literature, use of key opinion leaders, close attention to avoidance of bias, double full-text reading and data entry and careful presentation of results. Six trained reviewers, exceeding AGREE II recommendations,¹¹ compensated for expected variation in scoring. Extensive searches

should have mitigated loss of CPGs. Limitations include some uncertainty about stakeholder understanding despite a good response rate, and generalisability of the prioritisation only to the UK; stakeholders elsewhere might have different priorities. Focusing only on international CPGs might have missed higher quality national and local CPGs derived from them or written de novo. The social acceptance and consequent healthcare system coverage of gender minority/trans health related interventions vary among different countries, which may limit the space for international and multinational guidelines. While the search strategy yielded an oncology communication CPG with a single recommendation for gender minority/trans people,⁵² other general health CPGs with similar solo statements might have been missed.

Comparison with other studies, discussing important differences in results

This is the first systematic review using a validated quality appraisal instrument of international CPGs addressing gender minority/trans health. It may act as a benchmark to monitor and improve population healthcare. CPG quality results correspond with, and quantitatively confirm, previously noted concerns about the evidence-base^{36 62 63} and variable use of quality assessment in systematic reviews,^{64–66} in a healthcare field with unknown or unclear longitudinal outcomes.¹⁷ AGREE II has been applied to CPGs in other medical areas, including cancer,⁶⁷ diabetes,⁶⁸ pregnancy⁶⁹ and depression.⁷⁰ These exercises tend to show room for improvement. Developers have been criticised for not using methodological rigour when writing reliable evidence-based guidelines,⁷¹ as well as not implementing high-quality CPGs.⁷² Thus, finding poor quality CPGs is not confined to this area of healthcare.⁷³ Improvement messages are generalisable to other specialties.

Meaning of the study: possible explanations

The finding of higher-quality, but narrow, focus on gender minority/trans people's healthcare for blood-borne infections may relate to the global HIV pandemic and the WHO applying twin lenses of public health and human rights (ie, the population as 'means' and 'ends'). The lower-quality CPGs focus on transition. WPATH SOCv7³⁰ originated nearly a decade ago from a special-interest association; diagnostic criteria and CPG methodology have since changed. Although HIV and transition are important, it is puzzling to have found so little else, maybe suggesting CPGs for gender minority/trans people have been driven by provider-interests rather than healthcare needs. Including gender minority/trans people in guidelines can be considered a matter of health equity, where CPGs have a role to play.⁷⁴ GRADE suggests CPG developers may consider equity at various stages in creating guidelines, such as deciding guideline questions, evidence searching and assembly of the guideline group.⁷⁵ How CPGs may impact more vulnerable members of

society should be reflected-upon during guideline development,⁷⁶ and implementation.⁷⁷

Implications for clinicians, UK and international policymakers and patients

Clinicians should be made aware that gender minority/trans health CPGs outside of HIV-related topics are linked to a weak evidence base, with variations in methodological rigour and lack of stakeholder involvement. While patient care plans ought to take into account the individual needs of each gender minority/trans person, a gap appears to exist between clinical practice and research in this field.⁷⁸ Clinicians should proceed with caution, explain uncertainties to patients and recruit to research.

Policymakers ought to invest in both primary research and high-quality systematic reviews in areas relevant for CPG and service development. Organisations producing guidelines and aspiring to higher-level quality could use more robust methods, handling of competing interests^{79 80} and quality assessment. CPG developers should label key recommendations clearly. Although editorial independence was lowest priority for stakeholders, independent external review is important to avoid biases and bad practices, examine use of resources, resist commercial interests and gain widespread credibility outside the field.

The UK is fortunate in being familiar with developing priority-setting partnerships (eg, James Lind Initiative⁸¹) and generating suites of clinical questions that might cover all steps in patient pathways (eg, in partnership with Cochrane Collaboration⁸²). These could underpin multidisciplinary and funded research priorities whose results feed into future better evidence-based CPGs. Implications for UK education and curricular content (eg, new gender identity healthcare credentials⁸³), should be carefully scrutinised.

Internationally, CPG development and implementation will vary depending on local country contexts and available resources. Those countries with quality assurance agencies might use them for external assurance. Countries might reconsider the wisdom of adapting low-quality 'off the shelf' international CPGs without due assessment of the evidence for recommendations (eg, using the GRADE-ADOLOPMENT framework⁸⁴). WHO demonstrates how CPGs can achieve high quality.

Patients should be positively encouraged to engage with CPG development as stakeholders. The lack of patient-facing material should be addressed, especially as medical and non-medical online material contains jargon, is unreliable and potentially misleading.⁸⁵ Future CPGs should be populated with patient-facing decision aids (eg, fact boxes⁸⁶ and icon arrays⁸⁷) that explain sizes of benefits and harms to support informed patient choice. Patients and carers will benefit from a more focused approach to throughout-life healthcare. As the figures for gender minority/trans patients increase within the NHS and internationally, so does the need for consistent guidance to clinicians across specialisms on specific risks to, and means of treating, this population. Current patients should be welcomed to contribute, where they are

comfortable, to any research being undertaken by their clinicians, in order to improve data and future practice for gender minority/trans health.

Unanswered questions and future research

This study should be replicated as new iterations of international CPGs become available. It can be applied to national guidelines and countries should perform their own stakeholder prioritisation. When 'best available evidence' is poor, quality improvement can be driven both from inside and outside the field. International guideline developers require more primary research for this population, and impetus from clinicians and scientists to build a better evidence base using robust data from randomised controlled trials and long-term observational cohort studies, especially regarding chronic diseases, health behaviours, substance use, screening and how interventions (eg, hormones) might impact on long-term health (eg, risk of cardiovascular and thromboembolic disease). Mortality and QoL data are required to address questions of clinical and cost-effectiveness.

CONCLUSION

Gender minority/trans health in current international CPGs seems limited to a focus on HIV or transition-related interventions. WPATH SOCv7³⁰ is due for updating and this study should be used positively to accelerate improvement. Future guideline developers might better address the holistic healthcare needs of gender minority/trans people by enhancing the evidence-base, upgrading the quality of CPGs and increasing the breadth of health topics wherein this population is considered.

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Acknowledgements We thank Richard Wakeford and Leena Järveläinen (information specialists, British Library and Turku University Library), Gillian Claire Evans (German translations), Sarah Peitzmeier, Sam Winter, Christina Richards and Riittakerttu Kaltiala (opinion leaders), Paul Seed (statistician), researchers who shared copies of their papers, the UK stakeholders who participated in the prioritisation exercise and the peer reviewers whose feedback improved the work.

Contributors The authors were involved as follows: SB, IA, CM conception. All authors (SD, DC, IA, MHJ, SB, CM) were involved in design, execution, analysis, drafting manuscript and critical discussion; all were responsible for revision and final approval of the manuscript. All authors had full access to all the data (including statistical reports and tables) in the study and can take responsibility for the integrity of the data and the accuracy of the data analysis. CM acts as guarantor.

Funding The authors have not declared a specific grant for this research from any funding agency in the public, commercial or not-for-profit sectors.

Competing interests None declared.

Patient consent for publication Not required.

Provenance and peer review Not commissioned; externally peer reviewed.

Data availability statement Data sharing statement: Additional data are available upon request.

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Exhibit H

About the Review



An Introduction to the Cass Review



Hear from Hilary about why she got involved in the Review

Children and young people accessing the NHS deserve timely and supportive services, and clinical staff with the training and expertise to meet their healthcare needs.

Not all children and young people who are exploring their gender identity require clinical support from the NHS. However, some young people whose gender identity differs from their gender assigned at birth can experience extreme distress; this is referred to by clinicians as gender dysphoria. These children and young people need clinical support to help them understand the options available to them and to provide appropriate treatment.

The aim of the Cass Review is to ensure that children and young people who are questioning their gender identity or experiencing gender dysphoria, and who need support from the NHS, receive a high standard of care that meets their needs and is safe, holistic and effective.

About the Review (<https://cass.independent-review.uk/about-the-review/>)

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Exhibit I

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

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

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

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

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

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

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

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

Summary of Recommendations

1.0 Evaluation of youth and adults

- 1.1. We advise that only trained mental health professionals (MHPs) who meet the following criteria should diagnose gender dysphoria (GD)/gender incongruence in adults: (1) competence in using the Diagnostic and Statistical Manual of Mental Disorders (DSM) and/or the International Statistical Classification of Diseases and Related Health Problems (ICD) for diagnostic purposes, (2) the ability to diagnose GD/gender incongruence and make a distinction between GD/gender incongruence and conditions that have similar features (e.g., body dysmorphic disorder), (3) training in diagnosing psychiatric conditions, (4) the ability to undertake or refer for appropriate treatment, (5) the ability to psychosocially assess the person's understanding, mental health, and social conditions that can impact gender-affirming hormone therapy, and (6) a practice of regularly attending relevant professional meetings. (Ungraded Good Practice Statement)

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

Natural History of Children With GD/Gender Incongruence

With current knowledge, we cannot predict the psychosexual outcome for any specific child. Prospective follow-up studies show that childhood GD/gender incongruence does not invariably persist into adolescence and adulthood (so-called “desisters”). Combining all outcome studies to date, the GD/gender incongruence of a minority of prepubertal children appears to persist in adolescence (20, 40). In adolescence, a significant number of these desisters identify as homosexual or bisexual. It may be that children who only showed some gender nonconforming characteristics have been included in the follow-up studies, because the DSM-IV text revision criteria for a diagnosis were rather broad. However, the persistence of GD/gender incongruence into adolescence is more likely if it had been extreme in childhood (41, 42). With the newer, stricter criteria of the DSM-5 (Table 2), persistence rates may well be different in future studies.

1.0 Evaluation of Youth and Adults

Gender-affirming treatment is a multidisciplinary effort. After evaluation, education, and diagnosis, treatment may include mental health care, hormone therapy, and/or surgical therapy. Together with an MHP, hormone-prescribing clinicians should examine the psychosocial impact of the potential changes on people’s lives, including mental health, friends, family, jobs, and their role in society. Transgender individuals should be encouraged to experience living in the new gender role and assess whether

this improves their quality of life. Although the focus of this guideline is gender-affirming hormone therapy, collaboration with appropriate professionals responsible for each aspect of treatment maximizes a successful outcome.

Diagnostic assessment and mental health care

GD/gender incongruence may be accompanied with psychological or psychiatric problems (43–51). It is therefore necessary that clinicians who prescribe hormones and are involved in diagnosis and psychosocial assessment meet the following criteria: (1) are competent in using the DSM and/or the ICD for diagnostic purposes, (2) are able to diagnose GD/gender incongruence and make a distinction between GD/gender incongruence and conditions that have similar features (e.g., body dysmorphic disorder), (3) are trained in diagnosing psychiatric conditions, (4) undertake or refer for appropriate treatment, (5) are able to do a psychosocial assessment of the patient’s understanding, mental health, and social conditions that can impact gender-affirming hormone therapy, and (6) regularly attend relevant professional meetings.

Because of the psychological vulnerability of many individuals with GD/gender incongruence, it is important that mental health care is available before, during, and sometimes also after transitioning. For children and adolescents, an MHP who has training/experience in child and adolescent gender development (as well as child and adolescent psychopathology) should make the diagnosis, because assessing GD/gender incongruence in children and adolescents is often extremely complex.

During assessment, the clinician obtains information from the individual seeking gender-affirming treatment. In the case

Table 2. DSM-5 Criteria for Gender Dysphoria in Adolescents and Adults

- A. A marked incongruence between one’s experienced/expressed gender and natal gender of at least 6 mo in duration, as manifested by at least two of the following:
 1. A marked incongruence between one’s experienced/expressed gender and primary and/or secondary sex characteristics (or in young adolescents, the anticipated secondary sex characteristics)
 2. A strong desire to be rid of one’s primary and/or secondary sex characteristics because of a marked incongruence with one’s experienced/expressed gender (or in young adolescents, a desire to prevent the development of the anticipated secondary sex characteristics)
 3. A strong desire for the primary and/or secondary sex characteristics of the other gender
 4. A strong desire to be of the other gender (or some alternative gender different from one’s designated gender)
 5. A strong desire to be treated as the other gender (or some alternative gender different from one’s designated gender)
 6. A strong conviction that one has the typical feelings and reactions of the other gender (or some alternative gender different from one’s designated gender)
 - B. The condition is associated with clinically significant distress or impairment in social, occupational, or other important areas of functioning.
- Specify if:
1. The condition exists with a disorder of sex development.
 2. The condition is posttransitional, in that the individual has transitioned to full-time living in the desired gender (with or without legalization of gender change) and has undergone (or is preparing to have) at least one sex-related medical procedure or treatment regimen—namely, regular sex hormone treatment or gender reassignment surgery confirming the desired gender (e.g., penectomy, vaginoplasty in natal males; mastectomy or phalloplasty in natal females).

Reference: American Psychiatric Association (14).

of adolescents, the clinician also obtains information from the parents or guardians regarding various aspects of the child's general and psychosexual development and current functioning. On the basis of this information, the clinician:

- decides whether the individual fulfills criteria for treatment (see Tables 2 and 3) for GD/gender incongruence (DSM-5) or transsexualism (DSM-5 and/or ICD-10);
- informs the individual about the possibilities and limitations of various kinds of treatment (hormonal/surgical and nonhormonal), and if medical treatment is desired, provides correct information to prevent unrealistically high expectations;
- assesses whether medical interventions may result in unfavorable psychological and social outcomes.

In cases in which severe psychopathology, circumstances, or both seriously interfere with the diagnostic work or make satisfactory treatment unlikely, clinicians should assist the adolescent in managing these other issues. Literature on postoperative regret suggests that besides poor quality of surgery, severe psychiatric comorbidity and lack of support may interfere with positive outcomes (52–56).

For adolescents, the diagnostic procedure usually includes a complete psychodiagnostic assessment (57) and an assessment of the decision-making capability of the youth. An evaluation to assess the family's ability to endure stress, give support, and deal with the complexities of the adolescent's situation should be part of the diagnostic phase (58).

Social transitioning

A change in gender expression and role (which may involve living part time or full time in another gender role that is consistent with one's gender identity) may test the person's resolve, the capacity to function in the affirmed gender, and the adequacy of social, economic, and psychological supports. It assists both the individual and the clinician in their judgments about how to proceed (16). During social transitioning, the person's feelings about the social transformation (including coping with the responses of others) is a major focus of the counseling. The optimal timing for social transitioning may differ between individuals. Sometimes people wait until they

start gender-affirming hormone treatment to make social transitioning easier, but individuals increasingly start social transitioning long before they receive medically supervised, gender-affirming hormone treatment.

Criteria

Adolescents and adults seeking gender-affirming hormone treatment and surgery should satisfy certain criteria before proceeding (16). Criteria for gender-affirming hormone therapy for adults are in Table 4, and criteria for gender-affirming hormone therapy for adolescents are in Table 5. Follow-up studies in adults meeting these criteria indicate a high satisfaction rate with treatment (59). However, the quality of evidence is usually low. A few follow-up studies on adolescents who fulfilled these criteria also indicated good treatment results (60–63).

Recommendations for Those Involved in the Gender-Affirming Hormone Treatment of Individuals With GD/Gender Incongruence

- 1.1. We advise that only trained MHPs who meet the following criteria should diagnose GD/gender incongruence in adults: (1) competence in using the DSM and/or the ICD for diagnostic purposes, (2) the ability to diagnose GD/gender incongruence and make a distinction between GD/gender incongruence and conditions that have similar features (*e.g.*, body dysmorphic disorder), (3) training in diagnosing psychiatric conditions, (4) the ability to undertake or refer for appropriate treatment, (5) the ability to psychosocially assess the person's understanding, mental health, and social conditions that can impact gender-affirming hormone therapy, and (6) a practice of regularly attending relevant professional meetings. (Ungraded Good Practice Statement)
- 1.2. We advise that only MHPs who meet the following criteria should diagnose GD/gender incongruence in children and adolescents: (1) training in child and adolescent developmental psychology and psychopathology, (2) competence in using the DSM and/or ICD for diagnostic

Table 3. ICD-10 Criteria for Transsexualism

Transsexualism (F64.0) has three criteria:

1. The desire to live and be accepted as a member of the opposite sex, usually accompanied by the wish to make his or her body as congruent as possible with the preferred sex through surgery and hormone treatments.
2. The transsexual identity has been present persistently for at least 2 y.
3. The disorder is not a symptom of another mental disorder or a genetic, DSD, or chromosomal abnormality.

Table 4. Criteria for Gender-Affirming Hormone Therapy for Adults

1. Persistent, well-documented gender dysphoria/gender incongruence
2. The capacity to make a fully informed decision and to consent for treatment
3. The age of majority in a given country (if younger, follow the criteria for adolescents)
4. Mental health concerns, if present, must be reasonably well controlled

Reproduced from World Professional Association for Transgender Health (16).

purposes, (3) the ability to make a distinction between GD/gender incongruence and conditions that have similar features (*e.g.*, body dysmorphic disorder), (4) training in diagnosing psychiatric conditions, (5) the ability to undertake or refer for appropriate treatment, (6) the ability to psychosocially assess the person's understanding and social conditions that can impact gender-affirming hormone therapy, (7) a practice of regularly attending relevant professional meetings, and (8) knowledge of the criteria for puberty blocking and gender-affirming hormone treatment in adolescents. (Ungraded Good Practice Statement)

Evidence

Individuals with gender identity issues may have psychological or psychiatric problems (43–48, 50, 51, 64, 65). It is therefore necessary that clinicians making the diagnosis are able to make a distinction between GD/gender incongruence and conditions that have similar features. Examples of conditions with similar features are body dysmorphic disorder, body identity integrity disorder (a condition in which individuals have a sense that their anatomical configuration as an able-bodied person is somehow wrong or inappropriate) (66), or certain forms of eunuchism (in which a person is preoccupied with or engages in castration and/or penectomy for

Table 5. Criteria for Gender-Affirming Hormone Therapy for Adolescents

Adolescents are eligible for GnRH agonist treatment if:

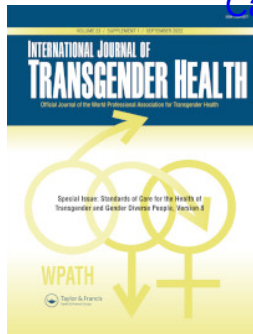
1. A qualified MHP has confirmed that:
 - the adolescent has demonstrated a long-lasting and intense pattern of gender nonconformity or gender dysphoria (whether suppressed or expressed),
 - gender dysphoria worsened with the onset of puberty,
 - any coexisting psychological, medical, or social problems that could interfere with treatment (*e.g.*, that may compromise treatment adherence) have been addressed, such that the adolescent's situation and functioning are stable enough to start treatment,
 - the adolescent has sufficient mental capacity to give informed consent to this (reversible) treatment,
2. And the adolescent:
 - has been informed of the effects and side effects of treatment (including potential loss of fertility if the individual subsequently continues with sex hormone treatment) and options to preserve fertility,
 - has given informed consent and (particularly when the adolescent has not reached the age of legal medical consent, depending on applicable legislation) the parents or other caretakers or guardians have consented to the treatment and are involved in supporting the adolescent throughout the treatment process,
3. And a pediatric endocrinologist or other clinician experienced in pubertal assessment
 - agrees with the indication for GnRH agonist treatment,
 - has confirmed that puberty has started in the adolescent (Tanner stage $\geq$ G2/B2),
 - has confirmed that there are no medical contraindications to GnRH agonist treatment.

Adolescents are eligible for subsequent sex hormone treatment if:

1. A qualified MHP has confirmed:
 - the persistence of gender dysphoria,
 - any coexisting psychological, medical, or social problems that could interfere with treatment (*e.g.*, that may compromise treatment adherence) have been addressed, such that the adolescent's situation and functioning are stable enough to start sex hormone treatment,
 - the adolescent has sufficient mental capacity (which most adolescents have by age 16 years) to estimate the consequences of this (partly) irreversible treatment, weigh the benefits and risks, and give informed consent to this (partly) irreversible treatment,
2. And the adolescent:
 - has been informed of the (irreversible) effects and side effects of treatment (including potential loss of fertility and options to preserve fertility),
 - has given informed consent and (particularly when the adolescent has not reached the age of legal medical consent, depending on applicable legislation) the parents or other caretakers or guardians have consented to the treatment and are involved in supporting the adolescent throughout the treatment process,
3. And a pediatric endocrinologist or other clinician experienced in pubertal induction:
 - agrees with the indication for sex hormone treatment,
 - has confirmed that there are no medical contraindications to sex hormone treatment.

Reproduced from World Professional Association for Transgender Health (16).

Exhibit J



International Journal of Transgender Health

ISSN: (Print) (Online) Journal homepage: <https://www.tandfonline.com/loi/wijt21>

Standards of Care for the Health of Transgender and Gender Diverse People, Version 8

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To cite this article: E. Coleman, A. E. Radix, W. P. Bouman, G. R. Brown, A. L. C. de Vries, M. B. Deutsch, R. Ettner, L. Fraser, M. Goodman, J. Green, A. B. Hancock, T. W. Johnson, D. H. Karasic, G. A. Knudson, S. F. Leibowitz, H. F. L. Meyer-Bahlburg, S. J. Monstrey, J. Motmans, L. Nahata, T. O. Nieder, S. L. Reisner, C. Richards, L. S. Schechter, V. Tangpricha, A. C. Tishelman, M. A. A. Van Trotsenburg, S. Winter, K. Ducheny, N. J. Adams, T. M. Adrián, L. R. Allen, D. Azul, H. Bagga, K. Başar, D. S. Bathory, J. J. Belinky, D. R. Berg, J. U. Berli, R. O. Bluebond-Langner, M.-B. Bouman, M. L. Bowers, P. J. Brassard, J. Byrne, L. Capitán, C. J. Cargill, J. M. Carswell, S. C. Chang, G. Chelvakumar, T. Corneil, K. B. Dalke, G. De Cuypere, E. de Vries, M. Den Heijer, A. H. Devor, C. Dhejne, A. D'Marco, E. K. Edmiston, L. Edwards-Leeper, R. Ehrbar, D. Ehrensaft, J. Einfeld, E. Elaut, L. Erickson-Schroth, J. L. Feldman, A. D. Fisher, M. M. Garcia, L. Gijs, S. E. Green, B. P. Hall, T. L. D. Hardy, M. S. Irwig, L. A. Jacobs, A. C. Janssen, K. Johnson, D. T. Klink, B. P. C. Kreukels, L. E. Kuper, E. J. Kvach, M. A. Malouf, R. Massey, T. Mazur, C. McLachlan, S. D. Morrison, S. W. Mosser, P. M. Neira, U. Nygren, J. M. Oates, J. Obedin-Maliver, G. Pagkalos, J. Patton, N. Phanuphak, K. Rachlin, T. Reed, G. N. Rider, J. Ristori, S. Robbins-Cherry, S. A. Roberts, K. A. Rodriguez-Wallberg, S. M. Rosenthal, K. Sabir, J. D. Safer, A. I. Scheim, L. J. Seal, T. J. Sehoole, K. Spencer, C. St. Amand, T. D. Steensma, J. F. Strang, G. B. Taylor, K. Tilleman, G. G. T'Sjoen, L. N. Vala, N. M. Van Mello, J. F. Veale, J. A. Vencill, B. Vincent, L. M. Wesp, M. A. West & J. Arcelus (2022) Standards of Care for the Health of Transgender and Gender Diverse People, Version 8, *International Journal of Transgender Health*, 23:sup1, S1-S259, DOI: [10.1080/26895269.2022.2100644](https://doi.org/10.1080/26895269.2022.2100644)



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REPORT



Standards of Care for the Health of Transgender and Gender Diverse People, Version 8

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ABSTRACT

Background: Transgender healthcare is a rapidly evolving interdisciplinary field. In the last decade, there has been an unprecedented increase in the number and visibility of transgender and gender diverse (TGD) people seeking support and gender-affirming medical treatment in parallel with a significant rise in the scientific literature in this area. The World Professional Association for Transgender Health (WPATH) is an international, multidisciplinary, professional association whose mission is to promote evidence-based care, education, research, public policy, and respect in transgender health. One of the main functions of WPATH is to promote the highest standards of health care for TGD people through the Standards of Care (SOC). The SOC was initially developed in 1979 and the last version (SOC-7) was published in 2012. In view of the increasing scientific evidence, WPATH commissioned a new version of the Standards of Care, the SOC-8.

Aim: The overall goal of SOC-8 is to provide health care professionals (HCPs) with clinical guidance to assist TGD people in accessing safe and effective pathways to achieving lasting personal comfort with their gendered selves with the aim of optimizing their overall physical health, psychological well-being, and self-fulfillment.

Methods: The SOC-8 is based on the best available science and expert professional consensus in transgender health. International professionals and stakeholders were selected to serve on the SOC-8 committee. Recommendation statements were developed based on data derived from independent systematic literature reviews, where available, background reviews and expert opinions. Grading of recommendations was based on the available evidence supporting interventions, a discussion of risks and harms, as well as the feasibility and acceptability within different contexts and country settings.

Results: A total of 18 chapters were developed as part of the SOC-8. They contain recommendations for health care professionals who provide care and treatment for TGD people. Each of the recommendations is followed by explanatory text with relevant references. General areas related to transgender health are covered in the chapters Terminology, Global Applicability, Population Estimates, and Education. The chapters developed for the diverse population of TGD people include Assessment of Adults, Adolescents, Children, Nonbinary, Eunuchs, and Intersex Individuals, and people living in Institutional Environments. Finally, the chapters related to gender-affirming treatment are Hormone Therapy, Surgery and Postoperative Care, Voice and Communication, Primary Care, Reproductive Health, Sexual Health, and Mental Health.

Conclusions: The SOC-8 guidelines are intended to be flexible to meet the diverse health care needs of TGD people globally. While adaptable, they offer standards for promoting optimal health care and guidance for the treatment of people experiencing gender incongruence. As in all previous versions of the SOC, the criteria set forth in this document for gender-affirming medical interventions are clinical guidelines; individual health care professionals and programs may modify these in consultation with the TGD person.

KEYWORDS

adolescents; assessment; children; communication; education; endocrinology; eunuch; gender diverse; health care professional; institutional settings; intersex; mental health; nonbinary; population; postoperative care; primary care; reproductive health; sexual health; SOC8; Standards of Care; surgery; terminology; transgender; voice

	Table of contents	Page No.
	Introduction	S5
Chapter 1.	Terminology	S11
Chapter 2.	Global Applicability	S15
Chapter 3.	Population Estimates	S23
Chapter 4.	Education	S27
Chapter 5.	Assessment of Adults	S31
Chapter 6.	Adolescents	S43
Chapter 7.	Children	S67
Chapter 8.	Nonbinary	S80
Chapter 9.	Eunuchs	S88
Chapter 10.	Intersex	S93
Chapter 11.	Institutional Environments	S104
Chapter 12.	Hormone Therapy	S110
Chapter 13.	Surgery and Postoperative Care	S128
Chapter 14.	Voice and Communication	S137
Chapter 15.	Primary Care	S143
Chapter 16.	Reproductive Health	S156
Chapter 17.	Sexual Health	S163
Chapter 18.	Mental Health	S171
	Acknowledgements	S177
	References	S178
	Appendix A: Methodology	S247
	Appendix B: Glossary	S252
	Appendix C: Gender-Affirming Hormonal Treatments	S254
	Appendix D: Summary Criteria for Hormonal and Surgical Treatments for Adults and Adolescents	S256
	Appendix E: Gender-Affirming Surgical Procedures	S258

Statements of Recommendations

6.1- We recommend health care professionals working with gender diverse adolescents:

6.1.a- Are licensed by their statutory body and hold a postgraduate degree or its equivalent in a clinical field relevant to this role granted by a nationally accredited statutory institution.

6.1.b- Receive theoretical and evidenced-based training and develop expertise in general child, adolescent, and family mental health across the developmental spectrum.

6.1.c- Receive training and have expertise in gender identity development, gender diversity in children and adolescents, have the ability to assess capacity to assent/consent, and possess general knowledge of gender diversity across the life span.

6.1.d- Receive training and develop expertise in autism spectrum disorders and other neurodevelopmental presentations or collaborate with a developmental disability expert when working with autistic/neurodivergent gender diverse adolescents.

6.1.e- Continue engaging in professional development in all areas relevant to gender diverse children, adolescents, and families.

6.2- We recommend health care professionals working with gender diverse adolescents facilitate the exploration and expression of gender openly and respectfully so that no one particular identity is favored.

6.3- We recommend health care professionals working with gender diverse adolescents undertake a comprehensive biopsychosocial assessment of adolescents who present with gender identity-related concerns and seek medical/surgical transition-related care, and that this be accomplished in a collaborative and supportive manner.

6.4- We recommend health care professionals work with families, schools, and other relevant settings to promote acceptance of gender diverse expressions of behavior and identities of the adolescent.

6.5- We recommend against offering reparative and conversion therapy aimed at trying to change a person's gender and lived gender expression to become more congruent with the sex assigned at birth.

6.6- We suggest health care professionals provide transgender and gender diverse adolescents with health education on chest binding and genital tucking, including a review of the benefits and risks.

6.7- We recommend providers consider prescribing menstrual suppression agents for adolescents experiencing gender incongruence who may not desire testosterone therapy, who desire but have not yet begun testosterone therapy, or in conjunction with testosterone therapy for breakthrough bleeding.

6.8- We recommend health care professionals maintain an ongoing relationship with the gender diverse and transgender adolescent and any relevant caregivers to support the adolescent in their decision-making throughout the duration of puberty suppression treatment, hormonal treatment, and gender-related surgery until the transition is made to adult care.

6.9- We recommend health care professionals involve relevant disciplines, including mental health and medical professionals, to reach a decision about whether puberty suppression, hormone initiation, or gender-related surgery for gender diverse and transgender adolescents are appropriate and remain indicated throughout the course of treatment until the transition is made to adult care.

6.10- We recommend health care professionals working with transgender and gender diverse adolescents requesting gender-affirming medical or surgical treatments inform them, prior to initiating treatment, of the reproductive effects including the potential loss of fertility and available options to preserve fertility within the context of the youth's stage of pubertal development.

6.11- We recommend when gender-affirming medical or surgical treatments are indicated for adolescents, health care professionals working with transgender and gender diverse adolescents involve parent(s)/guardian(s) in the assessment and treatment process, unless their involvement is determined to be harmful to the adolescent or not feasible.

The following recommendations are made regarding the requirements for gender-affirming medical and surgical treatment (All of them must be met):

6.12- We recommend health care professionals assessing transgender and gender diverse adolescents only recommend gender-affirming medical or surgical treatments requested by the patient when:

6.12.a- The adolescent meets the diagnostic criteria of gender incongruence as per the ICD-11 in situations where a diagnosis is necessary to access health care. In countries that have not implemented the latest ICD, other taxonomies may be used although efforts should be undertaken to utilize the latest ICD as soon as practicable.

6.12.b- The experience of gender diversity/incongruence is marked and sustained over time.

6.12.c- The adolescent demonstrates the emotional and cognitive maturity required to provide informed consent/assent for the treatment.

6.12.d- The adolescent's mental health concerns (if any) that may interfere with diagnostic clarity, capacity to consent, and gender-affirming medical treatments have been addressed.

6.12.e- The adolescent has been informed of the reproductive effects, including the potential loss of fertility and the available options to preserve fertility, and these have been discussed in the context of the adolescent's stage of pubertal development.

6.12.f- The adolescent has reached Tanner stage 2 of puberty for pubertal suppression to be initiated.

6.12.g- The adolescent had at least 12 months of gender-affirming hormone therapy or longer, if required, to achieve the desired surgical result for gender-affirming procedures, including breast augmentation, orchiectomy, vaginoplasty, hysterectomy, phalloplasty, metoidioplasty, and facial surgery as part of gender-affirming treatment unless hormone therapy is either not desired or is medically contraindicated.

adolescent SOC statements. For example, allowing irreversible puberty to progress in adolescents who experience gender incongruence is not a neutral act given that it may have immediate and lifelong harmful effects for the transgender young person (Giordano, 2009; Giordano

& Holm, 2020; Kreukels & Cohen-Kettenis, 2011). From a human rights perspective, considering gender diversity as a normal and expected variation within the broader diversity of the human experience, it is an adolescent's right to participate in their own decision-making

process about their health and lives, including access to gender health services (Amnesty International, 2020).

Short summary of statements and unique issues in adolescence

These guidelines are designed to account for what is known and what is not known about gender identity development in adolescence, the evidence for gender-affirming care in adolescence, and the unique aspects that distinguish adolescence from other developmental stages.

Identity exploration: A defining feature of adolescence is the solidifying of aspects of identity, including gender identity. Statement 6.2 addresses identity exploration in the context of gender identity development. Statement 6.12.b accounts for the length of time needed for a young person to experience a gender diverse identity, express a gender diverse identity, or both, so as to make a meaningful decision regarding gender-affirming care.

Consent and decision-making: In adolescence, consent and decision-making require assessment of the individual's emotional, cognitive, and psychosocial development. Statement 6.12.c directly addresses emotional and cognitive maturity and describes the necessary components of the evaluation process used to assess decision-making capacity.

Caregivers/parent involvement: Adolescents are typically dependent on their caregivers/parents for guidance in numerous ways. This is also true as the young person navigates through the process of deciding about treatment options. Statement 6.11 addresses the importance of involving caregivers/parents and discusses the role they play in the assessment and treatment. No set of guidelines can account for every set of individual circumstances on a global scale.

Statement 6.1

We recommend health care professionals working with gender diverse adolescents:

- a. Are licensed by their statutory body and hold a postgraduate degree or its equivalent in a clinical field relevant to this role granted by a nationally accredited statutory institution.**
- b. Receive theoretical and evidenced-based training and develop expertise in general**

child, adolescent, and family mental health across the developmental spectrum.

- c. Receive training and have expertise in gender identity development, gender diversity in children and adolescents, have the ability to assess capacity to assent/consent, and possess general knowledge of gender diversity across the life span.**
- d. Receive training and develop expertise in autism spectrum disorders and other neurodevelopmental presentations or collaborate with a developmental disability expert when working with autistic/neurodivergent gender diverse adolescents.**
- e. Continue engaging in professional development in all areas relevant to gender diverse children, adolescents, and families.**

When assessing and supporting TGD adolescents and their families, care providers/health care professionals (HCPs) need both general as well as gender-specific knowledge and training. Providers who are trained to work with adolescents and families play an important role in navigating aspects of adolescent development and family dynamics when caring for youth and families (Adelson et al., 2012; American Psychological Association, 2015; Hembree et al., 2017). Other chapters in these standards of care describe these criteria for professionals who provide gender care in more detail (see Chapter 5—Assessment for Adults; Chapter 7—Children; or Chapter 13—Surgery and Postoperative Care). Professionals working with adolescents should understand what is and is not known regarding adolescent gender identity development, and how this knowledge base differs from what applies to adults and prepubertal children. Among HCPs, the mental health professional (MHP) has the most appropriate training and dedicated clinical time to conduct an assessment and elucidate treatment priorities and goals when working with transgender youth, including those seeking gender-affirming medical/surgical care. Understanding and managing the dynamics of family members who may share differing perspectives regarding the history and needs of the

young person is an important competency that MHPs are often most prepared to address.

When access to professionals trained in child and adolescent development is not possible, HCPs should make a commitment to obtain training in the areas of family dynamics and adolescent development, including gender identity development. Similarly, considering autistic/neurodivergent transgender youth represent a substantial minority subpopulation of youth served in gender clinics globally, it is important HCPs seek additional training in the field of autism and understand the unique elements of care autistic gender diverse youth may require (Strang, Meagher et al., 2018). If these qualifications are not possible, then consultation and collaboration with a provider who specializes in autism and neurodiversity is advised.

Statement 6.2

We recommend health care professionals working with gender diverse adolescents facilitate the exploration and expression of gender openly and respectfully so that no one particular identity is favored.

Adolescence is a developmental period that involves physical and psychological changes characterized by individuation and the transition to independence from caregivers (Berenbaum et al., 2015; Steinberg, 2009). It is a period during which young people may explore different aspects of identity, including gender identity.

Adolescents differ regarding the degree to which they explore and commit to aspects of their identity (Meeus et al., 2012). For some adolescents, the pace to achieving consolidation of identity is fast, while for others it is slower. For some adolescents, physical, emotional, and psychological development occur over the same general timeline, while for others, there are certain gaps between these aspects of development. Similarly, there is variation in the timeline for gender identity development (Arnoldussen et al., 2020; Katz-Wise et al., 2017). For some young people, gender identity development is a clear process that starts in early childhood, while for others pubertal changes contribute to a person's experience of themselves as a particular gender (Steensma, Kreukels et al., 2013), and for many others a process may begin well after pubertal

changes are completed. Given these variations, there is no one particular pace, process, or outcome that can be predicted for an individual adolescent seeking gender-affirming care.

Therefore, HCPs working with adolescents should promote supportive environments that simultaneously respect an adolescent's affirmed gender identity and also allows the adolescent to openly explore gender needs, including social, medical, and physical gender-affirming interventions should they change or evolve over time.

Statement 6.3

We recommend health care professionals working with gender diverse adolescents undertake a comprehensive biopsychosocial assessment of adolescents who present with gender identity-related concerns and seek medical/surgical transition-related care, and that this be accomplished in a collaborative and supportive manner.

Given the many ways identity may unfold during adolescence, we recommend using a comprehensive biopsychosocial assessment to guide treatment decisions and optimize outcomes. This assessment should aim to understand the adolescent's strengths, vulnerabilities, diagnostic profile, and unique needs to individualize their care. As mentioned in Statement 6.1, MHPs have the most appropriate training, experience, and dedicated clinical time required to obtain the information discussed here. The assessment process should be approached collaboratively with the adolescent and their caregiver(s), both separately and together, as described in more detail in Statement 6.11. **An assessment should occur prior to any medically necessary medical or surgical intervention under consideration (e.g., puberty blocking medication, gender-affirming hormones, surgeries). See medically necessary statement in Chapter 2—Global Applicability, Statement 2.1; see also Chapter 12—Hormone Therapy and Chapter 13—Surgery and Postoperative Care.**

Youth may experience many different gender identity trajectories. Sociocultural definitions and experiences of gender continue to evolve over time, and youth are increasingly presenting with a range of identities and ways of describing their experiences and gender-related needs (Twist & de

Graaf, 2019). For example, some youth will realize they are transgender or more broadly gender diverse and pursue steps to present accordingly. For some youth, obtaining gender-affirming medical treatment is important while for others these steps may not be necessary. For example, a process of exploration over time might not result in the young person self-affirming or embodying a different gender in relation to their assigned sex at birth and would not involve the use of medical interventions (Arnoldussen et al., 2019).

The most robust longitudinal evidence supporting the benefits of gender-affirming medical and surgical treatments in adolescence was obtained in a clinical setting that incorporated a detailed comprehensive diagnostic assessment process over time into its delivery of care protocol (de Vries & Cohen-Kettenis, 2012; de Vries et al., 2014). Given this research and the ongoing evolution of gender diverse experiences in society, a comprehensive diagnostic biopsychosocial assessment during adolescence is both evidence-based and preserves the integrity of the decision-making process. In the absence of a full diagnostic profile, other mental health entities that need to be prioritized and treated may not be detected. There are no studies of the long-term outcomes of gender-related medical treatments for youth who have not undergone a comprehensive assessment. Treatment in this context (e.g., with limited or no assessment) has no empirical support and therefore carries the risk that the decision to start gender-affirming medical interventions may not be in the long-term best interest of the young person at that time.

As delivery of health care and access to specialists varies globally, designing a particular assessment process to adapt existing resources is often necessary. In some cases, a more extended assessment process may be useful, such as for youth with more complex presentations (e.g., complicating mental health histories (Leibowitz & de Vries, 2016)), co-occurring autism spectrum characteristics (Strang, Powers et al., 2018), and/or an absence of experienced childhood gender incongruence (Ristori & Steensma, 2016). Given the unique cultural, financial, and geographical factors that exist for specific populations, providers should design assessment models that are flexible and allow for appropriately timed care for as many

young people as possible, so long as the assessment effectively obtains information about the adolescent's strengths, vulnerabilities, diagnostic profile, and individual needs. Psychometrically validated psychosocial and gender measures can also be used to provide additional information.

The multidisciplinary assessment for youth seeking gender-affirming medical/surgical interventions includes the following domains that correspond to the relevant statements:

- **Gender Identity Development:** Statements 6.12.a and 6.12.b elaborate on the factors associated with gender identity development within the specific cultural context when assessing TGD adolescents.
- **Social Development and Support; Intersectionality:** Statements 6.4 and 6.11 elaborate on the importance of assessing gender minority stress, family dynamics, and other aspects contributing to social development and intersectionality.
- **Diagnostic Assessment of Possible Co-Occurring Mental Health and/or Developmental Concerns:** Statement 6.12.d elaborates on the importance of understanding the relationship that exists, if at all, between any co-occurring mental health or developmental concerns and the young person's gender identity/gender diverse expression.
- **Capacity for Decision-Making:** Statement 6.12.c elaborates on the assessment of a young person's emotional maturity and the relevance when an adolescent is considering gender affirming-medical/surgical treatments.

Statement 6.4

We recommend health care professionals work with families, schools, and other relevant settings to promote acceptance of gender diverse expressions of behavior and identities of the adolescent.

Multiple studies and related expert consensus support the implementation of approaches that promote acceptance and affirmation of gender diverse youth across all settings, including families, schools, health care facilities, and all other organizations and communities with which they

Exhibit K

**IN THE UNITED STATES DISTRICT COURT
FOR THE NORTHERN DISTRICT OF FLORIDA
Tallahassee Division**

AUGUST DEKKER, et al.,

Plaintiffs,

v.

JASON WEIDA, et al.,

Defendants.

Case No. 4:22-cv-00325-RH-
MAF

EXPERT REPORT OF JOHANNA OLSON-KENNEDY, M.D., M.S.

I, Johanna Olson-Kennedy, M.D., M.S., hereby declare and state as follows:

1. I have been retained by counsel for Plaintiffs as an expert in connection with the above-captioned litigation.
2. I am over the age of 18. I have actual knowledge of the matters stated herein. If called to testify in this matter, I would testify truthfully and based on my expert opinion.

BAKCGROUND AND QUALIFICATIONS

3. I have been retained by counsel for Plaintiffs in the above-captioned lawsuit to provide an expert opinion on gender identity; the treatment and diagnosis of gender dysphoria; the *Florida Medicaid Generally Accepted*

74. One of the intrinsic elements of rating the quality of evidence is the study design. Randomized controlled trials (RCTs) are considered the highest quality in the grading of evidence. Many of the research studies on gender-affirming care get a “low quality” grade due to the lack of RCTs.

75. But it is well-established that utilizing an untreated control group is unethical in this context – gender-affirming medical interventions have been used for decades, resulting in a vast amount of clinical knowledge about their efficacy. That said, we have a large de facto group of untreated individuals with gender dysphoria who experience significant psychiatric symptoms because of widespread barriers to access to care.

76. Clinicians who are competent in the care of transgender individuals practice according to a “first do no harm” ethic which understands that doing nothing is not a neutral option for those with gender dysphoria. Multiple studies have demonstrated the safety of gender-affirming hormones, and a growing body

of evidence does the same with regards to the safety of GnRH analogues.⁵⁷ The same is true with regards to surgery.⁵⁸

77. In addition, RCTs are ill-suited to studying the effects of gender-affirming interventions on psychological wellbeing and quality of life of trans people. Adequate masking, adherence, and generalizability are severely impeded in transgender care, thereby negating the superior scientific value of RCTs.

78. Gender-affirming interventions have physiologically evident effects, making it impossible to mask RCTs. The purpose of puberty blockers, hormone therapy, and transition-related surgeries is to inhibit or produce visible bodily changes.

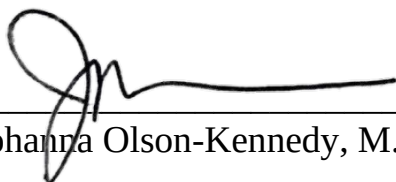
79. In an RCT, adolescents who are on puberty blockers would notice that their endogenous pubertal development had stopped, whereas those not on puberty blockers will notice that they had not. Hormonal suppression is achieved

⁵⁷ Kuper, et al. (2020); Chew, D., Anderson, J., Williams, K., May, T., & Pang, K. (2018). Hormonal Treatment in Young People With Gender Dysphoria: A Systematic Review. *Pediatrics*, 141(4), e20173742; Colton-Meier, S. L., Fitzgerald, K. M., Pardo, S. T., & Babcock, J. (2011). The effects of hormonal gender affirmation treatment on mental health in female-to-male transsexuals. *Journal of Gay & Lesbian Mental Health*, 15(3), 281-299.

⁵⁸ Marano, A. A., Louis, M. R., & Coon, D. (2021). Gender-Affirming Surgeries and Improved Psychosocial Health Outcomes. *JAMA surgery*, 156(7), 685–687; Olson-Kennedy, et al. (2018); Murad, et al. (2010); Smith, et al. (2005); Pfafflin & Junge (1998).

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

Executed this 16 day of February, 2023.



Johanna Olson-Kennedy, M.D., M.S.

Exhibit L

Long-Term Follow-Up of Transsexual Persons Undergoing Sex Reassignment Surgery: Cohort Study in Sweden

Cecilia Dhejne¹, Paul Lichtenstein², Marcus Boman², Anna L. V. Johansson², Niklas Långström^{2,3}, Mikael Landén^{1,2,4*}

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Abstract

Context: The treatment for transsexualism is sex reassignment, including hormonal treatment and surgery aimed at making the person's body as congruent with the opposite sex as possible. There is a dearth of long term, follow-up studies after sex reassignment.

Objective: To estimate mortality, morbidity, and criminal rate after surgical sex reassignment of transsexual persons.

Design: A population-based matched cohort study.

Setting: Sweden, 1973–2003.

Participants: All 324 sex-reassigned persons (191 male-to-females, 133 female-to-males) in Sweden, 1973–2003. Random population controls (10:1) were matched by birth year and birth sex or reassigned (final) sex, respectively.

Main Outcome Measures: Hazard ratios (HR) with 95% confidence intervals (CI) for mortality and psychiatric morbidity were obtained with Cox regression models, which were adjusted for immigrant status and psychiatric morbidity prior to sex reassignment (adjusted HR [aHR]).

Results: The overall mortality for sex-reassigned persons was higher during follow-up (aHR 2.8; 95% CI 1.8–4.3) than for controls of the same birth sex, particularly death from suicide (aHR 19.1; 95% CI 5.8–62.9). Sex-reassigned persons also had an increased risk for suicide attempts (aHR 4.9; 95% CI 2.9–8.5) and psychiatric inpatient care (aHR 2.8; 95% CI 2.0–3.9). Comparisons with controls matched on reassigned sex yielded similar results. Female-to-males, but not male-to-females, had a higher risk for criminal convictions than their respective birth sex controls.

Conclusions: Persons with transsexualism, after sex reassignment, have considerably higher risks for mortality, suicidal behaviour, and psychiatric morbidity than the general population. Our findings suggest that sex reassignment, although alleviating gender dysphoria, may not suffice as treatment for transsexualism, and should inspire improved psychiatric and somatic care after sex reassignment for this patient group.

Citation: Dhejne C, Lichtenstein P, Boman M, Johansson ALV, Långström N, et al. (2011) Long-Term Follow-Up of Transsexual Persons Undergoing Sex Reassignment Surgery: Cohort Study in Sweden. PLoS ONE 6(2): e16885. doi:10.1371/journal.pone.0016885

Editor: James Scott, The University of Queensland, Australia

Received: September 30, 2010; **Accepted:** January 9, 2011; **Published:** February 22, 2011

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Funding: Financial support was provided through the regional agreement on medical training and clinical research (ALF) between Stockholm County Council and the Karolinska Institutet, and through grants from the Swedish Medical Research Council (K2008-62x-14647-06-3) and the Royal Swedish Academy of Sciences (Torsten Amundson's Foundation). The sponsors of the study had no role in study design, data collection, data analysis, data interpretation, or writing of the report. All authors had full access to the data in the study and the final responsibility for the decision to submit for publication was made by the corresponding author.

Competing Interests: The authors have declared that no competing interests exist.

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Introduction

Transsexualism (ICD-10),[1] or gender identity disorder (DSM-IV),[2] is a condition in which a person's gender identity - the sense of being a man or a woman - contradicts his or her bodily sex characteristics. The individual experiences gender dysphoria and desires to live and be accepted as a member of the opposite sex.

The treatment for transsexualism includes removal of body hair, vocal training, and cross-sex hormonal treatment aimed at making the person's body as congruent with the opposite sex as possible to alleviate the gender dysphoria. Sex reassignment also involves the surgical removal of body parts to make external sexual characteristics resemble those of the opposite sex, so called sex reassignment/confirmation surgery (SRS). This is a unique

intervention not only in psychiatry but in all of medicine. The present form of sex reassignment has been practised for more than half a century and is the internationally recognized treatment to ease gender dysphoria in transsexual persons.[3,4]

Despite the long history of this treatment, however, outcome data regarding mortality and psychiatric morbidity are scant. With respect to suicide and deaths from other causes after sex reassignment, an early Swedish study followed 24 transsexual persons for an average of six years and reported one suicide.[5] A subsequent Swedish study recorded three suicides after sex reassignment surgery of 175 patients.[6] A recent Swedish follow-up study reported no suicides in 60 transsexual patients, but one death due to complications after the sex reassignment surgery.[7] A Danish study reported death by suicide in 3 out of 29 operated male-to-female transsexual persons followed for an average of six years.[8] By contrast, a Belgian study of 107 transsexual persons followed for 4–6 years found no suicides or deaths from other causes.[9] A large Dutch single-centre study (N=1,109), focusing on adverse events following hormonal treatment, compared the outcome after cross-sex hormone treatment with national Dutch standardized mortality and morbidity rates and found no increased mortality, with the exception of death from suicide and AIDS in male-to-females 25–39 years of age.[10] The same research group concluded in a recent report that treatment with cross-sex hormones seems acceptably safe, but with the reservation that solid clinical data are missing.[11] A limitation with respect to the Dutch cohort is that the proportion of patients treated with cross-sex hormones who also had surgical sex-reassignment is not accounted for.[10]

Data is inconsistent with respect to psychiatric morbidity post sex reassignment. Although many studies have reported psychiatric and psychological improvement after hormonal and/or surgical treatment,[7,12,13,14,15,16] other have reported on regrets,[17] psychiatric morbidity, and suicide attempts after SRS.[9,18] A recent systematic review and meta-analysis concluded that approximately 80% reported subjective improvement in terms of gender dysphoria, quality of life, and psychological symptoms, but also that there are studies reporting high psychiatric morbidity and suicide rates after sex reassignment.[19] The authors concluded though that the evidence base for sex reassignment “is of very low quality due to the serious methodological limitations of included studies.”

The methodological shortcomings have many reasons. First, the nature of sex reassignment precludes double blind randomized controlled studies of the result. Second, transsexualism is rare [20] and many follow-ups are hampered by small numbers of subjects.[5,8,21,22,23,24,25,26,27,28] Third, many sex reassigned persons decline to participate in follow-up studies, or relocate after surgery, resulting in high drop-out rates and consequent selection bias.[6,9,12,21,24,28,29,30] Forth, several follow-up studies are hampered by limited follow-up periods.[7,9,21,22,26,30] Taken together, these limitations preclude solid and generalisable conclusions. A long-term population-based controlled study is one way to address these methodological shortcomings.

Here, we assessed mortality, psychiatric morbidity, and psychosocial integration expressed in criminal behaviour after sex reassignment in transsexual persons, in a total population cohort study with long-term follow-up information obtained from Swedish registers. The cohort was compared with randomly selected population controls matched for age and gender. We adjusted for premorbid differences regarding psychiatric morbidity and immigrant status. **This study design sheds new light on transsexual persons' health after sex reassignment. It does not, however, address whether sex reassignment is an effective treatment or not.**

Methods

National registers

The study population was identified by the linkage of several Swedish national registers, which contained a total of 13.8 million unique individuals. The Hospital Discharge Register (HDR, held by the National Board of Health and Welfare) contains discharge diagnoses, up to seven contributory diagnoses, external causes of morbidity or mortality, surgical procedure codes, and discharge date. Discharge diagnoses are coded according to the 8th (1969–1986), 9th (1987–1996), and 10th editions (1997–) of the International Classification of Diseases (ICD). The register covers virtually all psychiatric inpatient episodes in Sweden since 1973. Discharges that occurred up to 31 December 2003 were included. Surgical procedure codes could not be used for this study due to the lack of a specific code for sex reassignment surgery. The Total Population Register (TPR, held by Statistics Sweden) is comprised of data about the entire Swedish population. Through linkage with the Total Population Register it was possible to identify birth date and birth gender for all study subjects. The register is updated every year and gender information was available up to 2004/2005. The Medical Birth Register (MBR) was established in 1973 and contains birth data, including gender of the child at birth. National censuses based on mandatory self-report questionnaires completed by all adult citizens in 1960, 1970, 1980, and 1990 provided information on individuals, households, and dwellings, including gender, living area, and highest educational level. Complete migration data, including country of birth for immigrants for 1969–2003, were obtained from the TPR. In addition to educational information from the censuses, we also obtained highest educational level data for 1990 and 2000 from the Register of Education. The Cause of Death Register (CDR, Statistics Sweden) records all deaths in Sweden since 1952 and provided information on date of death and causes of death. Death events occurring up to 31 December 2003 are included in the study. The Crime Register (held by the National Council of Crime Prevention) provided information regarding crime type and date on all criminal convictions in Sweden during the period 1973–2004. Attempted and aggravated forms of all offences were also included. All crimes in Sweden are registered regardless of insanity at the time of perpetration; for example, for individuals who suffered from psychosis at the time of the offence. Moreover, conviction data include individuals who received custodial or non-custodial sentences and cases where the prosecutor decided to caution or fine without court proceedings. Finally, Sweden does not differ considerably from other members of the European Union regarding rates of violent crime and their resolution.[31]

Study population, identification of sex-reassigned persons (exposure assessment)

The study was designed as a population-based matched cohort study. We used the individual national registration number, assigned to all Swedish residents, including immigrants on arrival, as the primary key through all linkages. The registration number consists of 10 digits; the first six provide information of the birth date, whereas the ninth digit indicates the gender. In Sweden, a person presenting with gender dysphoria is referred to one of six specialised gender teams that evaluate and treat patients principally according to international consensus guidelines: Standards of Care.[3] With a medical certificate, the person applies to the National Board of Health and Welfare to receive permission for sex reassignment surgery and a change of legal sex status. A new national registration number signifying the new gender is assigned after sex reassignment surgery. The National

Board of Health and Welfare maintains a link between old and new national registration numbers, making it possible to follow individuals undergoing sex reassignment across registers and over time. Hence, sex reassignment surgery in Sweden requires (i) a transsexualism diagnosis and (ii) permission from the National Board of Health and Welfare.

A person was defined as exposed to sex reassignment surgery if two criteria were met: (i) at least one inpatient diagnosis of gender identity disorder diagnosis without concomitant psychiatric diagnoses in the Hospital Discharge Register, and (ii) at least one discrepancy between gender variables in the Medical Birth Register (from 1973 and onwards) or the National Censuses from 1960, 1970, 1980, or 1990 and the latest gender designation in the Total Population Register. The first criterion was employed to capture the hospitalization for sex reassignment surgery that serves to secure the diagnosis and provide a time point for sex reassignment surgery; the plastic surgeons namely record the reason for sex reassignment surgery, i.e., transsexualism, but not any co-occurring psychiatric morbidity. The second criterion was used to ensure that the person went through all steps in sex-reassignment and also changed sex legally.

The date of sex reassignment (start of follow-up) was defined as the first occurrence of a gender identity disorder diagnosis, without any other concomitant psychiatric disorder, in the Hospital Discharge Register after the patient changed sex status (any discordance in sex designation across the Censuses, Medical Birth, and Total Population registers). If this information was missing, we used instead the closest date in the Hospital Discharge Register on which the patient was diagnosed with gender identity disorder without concomitant psychiatric disorder prior to change in sex status. The reason for prioritizing the use of a gender identity disorder diagnosis *after* changed sex status over *before* was to avoid overestimating person-years at risk of sex-reassigned person.

Using these criteria, a total of 804 patients with gender identity disorder were identified, whereof 324 displayed a shift in the gender variable during the period 1973–2003. The 480 persons that did not shift gender variable comprise persons who either did not apply, or were not approved, for sex reassignment surgery. Moreover, the ICD 9 code 302 is a non specific code for sexual disorders. Hence, this group might also comprise persons that were hospitalized for sexual disorders other than transsexualism. Therefore, they were omitted from further analyses. Of the remaining 324 persons, 288 were identified with the gender identity diagnosis *after* and 36 *before* change of sex status. Out of the 288 persons identified *after* changed sex status, 185 could also be identified *before* change in sex status. The median time lag between the hospitalization *before* and *after* sex change for these 185 persons was 0.96 years (mean 2.2 years, SD 3.3).

Gender identity disorder was coded according to ICD-8: 302.3 (transsexualism) and 302.9 (sexual deviation NOS); ICD-9: 302 (overall code for sexual deviations and disorders, more specific codes were not available in ICD-9); and ICD-10: F64.0 (transsexualism), F64.1 (dual-role transvestism), F64.8 (other gender identity disorder), and F64.9 (gender identity disorder NOS). Other psychiatric disorders were coded as ICD-8: 290-301 and 303-315; ICD-9: 290-301 and 303-319; and ICD-10: F00-F63 as well as F65-F99.

Identification of population-based controls (unexposed group)

For each exposed person ($N = 324$), we randomly selected 10 unexposed controls. A person was defined as unexposed if there were no discrepancies in sex designation across the Censuses, Medical Birth, and Total Population registers *and* no gender

identity disorder diagnosis according to the Hospital Discharge Register. Control persons were matched by sex and birth year and had to be alive and residing in Sweden at the estimated sex reassignment date of the case person. To study possible gender-specific effects on outcomes of interest, we used two different control groups: one with the same sex as the case individual at birth (birth sex matching) and the other with the sex that the case individual had been reassigned to (final sex matching).

Outcome measures

We studied mortality, psychiatric morbidity, accidents, and crime following sex reassignment. More specifically, we investigated: (1) all-cause mortality, (2) death by definite/uncertain suicide, (3) death by cardiovascular disease, and (4) death by tumour. Morbidity included (5) any psychiatric disorder (gender identity disorders excluded), (6) alcohol/drug misuse and dependence, (7) definite/uncertain suicide attempt, and (8) accidents. Finally, we addressed court convictions for (9) any criminal offence and (10) any violent offence. Each individual could contribute with several outcomes, but only one event per outcome. Causes of death (Cause of Death Registry from 1952 and onwards) were defined according to ICD as suicide (ICD-8 and ICD-9 codes E950-E959 and E980-E989, ICD-10 codes X60-X84 and Y10-Y34); cardiovascular disease (ICD-8 codes 390-458, ICD-9 codes 390-459, ICD-10 codes I00-I99); neoplasms (ICD-8 and ICD-9 codes 140-239, ICD-10 codes C00-D48), any psychiatric disorder (gender identity disorders excluded); (ICD-8 codes 290-301 and 303-315, ICD-9 codes 290-301 and 303-319, ICD-10 codes F00-F63 and F65-F99); alcohol/drug abuse and dependence (ICD-8 codes 303-304, ICD-9 codes 303-305 (tobacco use disorder excluded), ICD-10 codes F10-F16 and F18-F19 (x5 excluded); and accidents (ICD-8 and ICD-9 codes E800-E929, ICD-10 codes V01-X59).

Any criminal conviction during follow-up was counted; specifically, violent crime was defined as homicide and attempted homicide, aggravated assault and assault, robbery, threatening behaviour, harassment, arson, or any sexual offense.[32]

Covariates

Severe psychiatric morbidity was defined as inpatient care according to ICD-8 codes 291, 295-301, 303-304, and 307; ICD-9 codes 291-292, 295-298, 300-301, 303-305 (tobacco use disorder excluded), 307.1, 307.5, 308-309, and 311; ICD-10 codes F10-F16, F18-F25, F28-F45, F48, F50, and F60-F62. Immigrant status, defined as individuals born abroad, was obtained from the Total Population Register. All outcome/covariate variables were dichotomized (i.e., affected or unaffected) and without missing values.

Statistical analyses

Each individual contributed person-time from study entry (for exposed: date of sex reassignment; for unexposed: date of sex reassignment of matched case) until date of outcome event, death, emigration, or end of study period (31 December 2003), whichever came first. The association between exposure (sex reassignment) and outcome (mortality, morbidity, crime) was measured by hazard ratios (HR) with 95% CIs, taking follow-up time into account. HRs were estimated from Cox proportional hazard regression models, stratified on matched sets (1:10) to account for the matching by sex, age, and calendar time (birth year). We present crude HRs (though adjusted for sex and age through matching) and confounder-adjusted HRs [aHRs] for all outcomes. The two potential confounders, immigrant status (yes/no) and history of severe psychiatric morbidity (yes/no) prior to sex

reassignment, were chosen based on previous research[18,33] and different prevalence across cases and controls (Table 1).

Gender-separated analyses were performed and a Kaplan-Meier survival plot graphically illustrates the survival of the sex-reassigned cohort and matched controls (all-cause mortality) over time. The significance level was set at 0.05 (all tests were two-sided). All outcome/covariate variables were without missing values, since they are generated from register data, which are either present (affected) or missing (unaffected). The data were analysed using SAS version 9.1 (SAS Institute Inc., Cary, NC, USA).

Ethics

The data linking of national registers required for this study was approved by the IRB at Karolinska Institutet, Stockholm. All data were analyzed anonymously; therefore, informed consent for each individual was neither necessary nor possible.

Results

We identified 324 transsexual persons (exposed cohort) who underwent sex reassignment surgery and were assigned a new legal sex between 1973 and 2003. These constituted the sex-reassigned (exposed) group. Fifty-nine percent (N = 191) of sex-reassigned persons were male-to-females and 41% (N = 133) female-to-males, yielding a sex ratio of 1.4:1 (Table 1).

The average follow-up time for all-cause mortality was 11.4 (median 9.1) years. The average follow-up time for the risk of being hospitalized for any psychiatric disorder was 10.4 (median 8.1).

Characteristics prior to sex reassignment

Table 1 displays demographic characteristics of sex-reassigned and control persons prior to study entry (sex reassignment). There were no substantial differences between female-to-males and male-to-females regarding measured baseline characteristics. Immigrant status was twice as common among transsexual individuals compared to controls, living in an urban area somewhat more common, and higher education about equally prevalent. Transsexual individuals had been hospitalized for psychiatric morbidity other than gender identity disorder prior to sex reassignment about four times more often than controls. To adjust for these baseline discrepancies, hazard ratios adjusted for immigrant status and psychiatric morbidity prior to baseline are presented for all outcomes [aHRs].

Mortality

Table 2 describes the risks for selected outcomes during follow-up among sex-reassigned persons, compared to same-age controls of the same birth sex. Sex-reassigned transsexual persons of both genders had approximately a three times higher risk of all-cause mortality than controls, also after adjustment for covariates. Table 2

Table 1. Baseline characteristics among sex-reassigned subjects in Sweden (N = 324) and population controls matched for birth year and sex.

Characteristic at baseline	Sex-reassigned subjects (N = 324)	Birth-sex matched controls (N = 3,240)	Final-sex matched controls (N = 3,240)
Gender			
Female at birth, male after sex change	133 (41%)	1,330 (41%)	1,330 (41%)
Male at birth, female after sex change	191 (59%)	1,910 (59%)	1,910 (59%)
Average age at study entry [years] (SD, min-max)			
Female at birth, male after sex change	33.3 (8.7, 20–62)	33.3 (8.7, 20–62)	33.3 (8.7, 20–62)
Male at birth, female after sex change	36.3 (10.1, 21–69)	36.3 (10.1, 21–69)	36.3 (10.1, 21–69)
Both genders	35.1 (9.7, 20–69)	35.1 (9.7, 20–69)	35.1 (9.7, 20–69)
Immigrant status			
Female at birth, male after sex change	28 (21%)	118 (9%)	100 (8%)
Male at birth, female after sex change	42 (22%)	176 (9%)	164 (9%)
Both genders	70 (22%)	294 (9%)	264 (8%)
Less than 10 years of schooling prior to entry vs. 10 years or more			
Females at birth, males after sex change	49 (44%); 62 (56%)	414 (37%); 714 (63%)	407 (36%); 713 (64%)
Males at birth, females after sex change	61 (41%); 89 (59%)	665 (40%); 1,011 (60%)	595 (35%); 1,091 (65%)
All individuals with data	110 (42%); 151 (58%)	1,079 (38%); 1,725 (62%)	1,002 (36%); 1,804 (64%)
Psychiatric morbidity* prior to study entry			
Female at birth, male after sex change	22 (17%)	47 (4%)	42 (3%)
Male at birth, female after sex change	36 (19%)	76 (4%)	72 (4%)
Both genders	58 (18%)	123 (4%)	114 (4%)
Rural [vs. urban] living area prior to entry			
Female at birth, male after sex change	13 (10%)	180 (14%)	195 (15%)
Male at birth, female after sex change	20 (10%)	319 (17%)	272 (14%)
Both genders	33 (10%)	499 (15%)	467 (14%)

Note:

*Hospitalizations for gender identity disorder were not included.

doi:10.1371/journal.pone.0016885.t001

Table 2. Risk of various outcomes among sex-reassigned subjects in Sweden (N = 324) compared to population controls matched for birth year and birth sex.

	Number of events cases/ controls 1973–2003	Outcome incidence rate per 1000 person-years 1973–2003 (95% CI)		Crude hazard ratio (95% CI) 1973–2003	Adjusted* hazard ratio (95% CI) 1973–2003	Adjusted* hazard ratio (95% CI) 1973–1988	Adjusted* hazard ratio (95% CI) 1989–2003
		Cases	Controls				
Any death	27/99	7.3 (5.0–10.6)	2.5 (2.0–3.0)	2.9 (1.9–4.5)	2.8 (1.8–4.3)	3.1 (1.9–5.0)	1.9 (0.7–5.0)
Death by suicide	10/5	2.7 (1.5–5.0)	0.1 (0.1–0.3)	19.1 (6.5–55.9)	19.1 (5.8–62.9)	N/A	N/A
Death by cardiovascular disease	9/42	2.4 (1.3–4.7)	1.1 (0.8–1.4)	2.6 (1.2–5.4)	2.5 (1.2–5.3)	N/A	N/A
Death by neoplasm	8/38	2.2 (1.1–4.3)	1.0 (0.7–1.3)	2.1 (1.0–4.6)	2.1 (1.0–4.6)	N/A	N/A
Any psychiatric hospitalisation‡	64/173	19.0 (14.8–24.2)	4.2 (3.6–4.9)	4.2 (3.1–5.6)	2.8 (2.0–3.9)	3.0 (1.9–4.6)	2.5 (1.4–4.2)
Substance misuse	22/78	5.9 (3.9–8.9)	1.8 (1.5–2.3)	3.0 (1.9–4.9)	1.7 (1.0–3.1)	N/A	N/A
Suicide attempt	29/44	7.9 (5.5–11.4)	1.0 (0.8–1.4)	7.6 (4.7–12.4)	4.9 (2.9–8.5)	7.9 (4.1–15.3)	2.0 (0.7–5.3)
Any accident	32/233	9.0 (6.3–12.7)	5.7 (5.0–6.5)	1.6 (1.1–2.3)	1.4 (1.0–2.1)	1.6 (1.0–2.5)	1.1 (0.5–2.2)
Any crime	60/350	18.5 (14.3–23.8)	9.0 (8.1–10.0)	1.9 (1.4–2.5)	1.3 (1.0–1.8)	1.6 (1.1–2.4)	0.9 (0.6–1.5)
Violent crime	14/61	3.6 (2.1–6.1)	1.4 (1.1–1.8)	2.7 (1.5–4.9)	1.5 (0.8–3.0)	N/A	N/A

Notes:

*Adjusted for psychiatric morbidity prior to baseline and immigrant status.

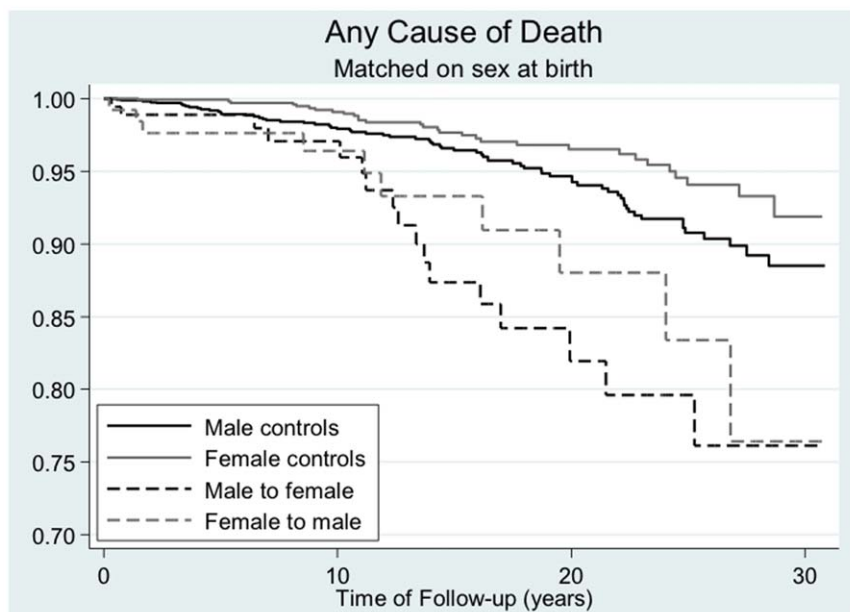
‡Hospitalisations for gender identity disorder were excluded.

N/A Not applicable due to sparse data.

doi:10.1371/journal.pone.0016885.t002

separately lists the outcomes depending on when sex reassignment was performed: during the period 1973–1988 or 1989–2003. Even though the overall mortality was increased across both time periods, it did not reach statistical significance for the period 1989–2003. The Kaplan-Meier curve (Figure 1) suggests that survival of transsexual persons started to diverge from that of matched controls after about 10 years of follow-up. The cause-specific mortality from

suicide was much higher in sex-reassigned persons, compared to matched controls. Mortality due to cardiovascular disease was moderately increased among the sex-reassigned, whereas the numerically increased risk for malignancies was borderline statistically significant. The malignancies were lung cancer (N = 3), tongue cancer (N = 1), pharyngeal cancer (N = 1), pancreas cancer (N = 1), liver cancer (N = 1), and unknown origin (N = 1).

**Figure 1.** Death from any cause as a function of time after sex reassignment among 324 transsexual persons in Sweden (male-to-female: N = 191, female-to-male: N = 133), and population controls matched on birth year.

doi:10.1371/journal.pone.0016885.g001

Psychiatric morbidity, substance misuse, and accidents

Sex-reassigned persons had a higher risk of inpatient care for a psychiatric disorder other than gender identity disorder than controls matched on birth year and birth sex (Table 2). This held after adjustment for prior psychiatric morbidity, and was true regardless of whether sex reassignment occurred before or after 1989. In line with the increased mortality from suicide, sex-reassigned individuals were also at a higher risk for suicide attempts, though this was not statistically significant for the time period 1989–2003. The risks of being hospitalised for substance misuse or accidents were not significantly increased after adjusting for covariates (Table 2).

Crime rate

Transsexual individuals were at increased risk of being convicted for any crime or violent crime after sex reassignment (Table 2); this was, however, only significant in the group who underwent sex reassignment before 1989.

Gender differences

Comparisons of female-to-males and male-to-females, although hampered by low statistical power and associated wide confidence intervals, suggested mostly similar risks for adverse outcomes (Tables S1 and S2). However, violence against self (suicidal behaviour) and others ([violent] crime) constituted important exceptions. First, male-to-females had significantly increased risks for suicide attempts compared to both female (aHR 9.3; 95% CI 4.4–19.9) and male (aHR 10.4; 95% CI 4.9–22.1) controls. By contrast, female-to-males had significantly increased risk of suicide attempts only compared to male controls (aHR 6.8; 95% CI 2.1–21.6) but not compared to female controls (aHR 1.9; 95% CI 0.7–4.8). This suggests that male-to-females are at higher risk for suicide attempts after sex reassignment, whereas female-to-males maintain a female pattern of suicide attempts after sex reassignment (Tables S1 and S2).

Second, regarding any crime, male-to-females had a significantly increased risk for crime compared to female controls (aHR 6.6; 95% CI 4.1–10.8) but not compared to males (aHR 0.8; 95% CI 0.5–1.2). This indicates that they retained a male pattern regarding criminality. The same was true regarding violent crime. By contrast, female-to-males had higher crime rates than female controls (aHR 4.1; 95% CI 2.5–6.9) but did not differ from male controls. This indicates a shift to a male pattern regarding criminality and that sex reassignment is coupled to increased crime rate in female-to-males. The same was true regarding violent crime.

Discussion

Principal findings and comparison with previous research

We report on the first nationwide population-based, long-term follow-up of sex-reassigned transsexual persons. We compared our cohort with randomly selected population controls matched for age and gender. The most striking result was the high mortality rate in both male-to-females and female-to-males, compared to the general population. This contrasts with previous reports (with one exception[8]) that did not find an increased mortality rate after sex reassignment, or only noted an increased risk in certain subgroups.[7,9,10,11] Previous clinical studies might have been biased since people who regard their sex reassignment as a failure are more likely to be lost to follow-up. Likewise, it is cumbersome to track deceased persons in clinical follow-up studies. Hence, population-based register studies like the present are needed to improve representativity.[19,34]

The poorer outcome in the present study might also be explained by longer follow-up period (median >10 years) compared to previous studies. In support of this notion, the survival curve (Figure 1) suggests increased mortality from ten years after sex reassignment and onwards. In accordance, the overall mortality rate was only significantly increased for the group operated before 1989. However, the latter might also be explained by improved health care for transsexual persons during 1990s, along with altered societal attitudes towards persons with different gender expressions.[35]

Mortality due to cardiovascular disease was significantly increased among sex reassigned individuals, albeit these results should be interpreted with caution due to the low number of events. This contrasts, however, a Dutch follow-up study that reported no increased risk for cardiovascular events.[10,11] A recent meta-analysis concluded, however, that data on cardiovascular outcome after cross-sex steroid use are sparse, inconclusive, and of very low quality.[34]

With respect to neoplasms, prolonged hormonal treatment might increase the risk for malignancies,[36] but no previous study has tested this possibility. Our data suggested that the cause-specific risk of death from neoplasms was increased about twice (borderline statistical significance). These malignancies (see Results), however, are unlikely to be related to cross-hormonal treatment.

There might be other explanations to increased cardiovascular death and malignancies. Smoking was in one study reported in almost 50% by the male-to-females and almost 20% by female-to-males.[9] It is also possible that transsexual persons avoid the health care system due to a presumed risk of being discriminated.

Mortality from suicide was strikingly high among sex-reassigned persons, also after adjustment for prior psychiatric morbidity. In line with this, sex-reassigned persons were at increased risk for suicide attempts. Previous reports [6,8,10,11] suggest that transsexualism is a strong risk factor for suicide, also after sex reassignment, and our long-term findings support the need for continued psychiatric follow-up for persons at risk to prevent this.

Inpatient care for psychiatric disorders was significantly more common among sex-reassigned persons than among matched controls, both before and after sex reassignment. It is generally accepted that transsexuals have more psychiatric ill-health than the general population prior to the sex reassignment.[18,21,22,33] It should therefore come as no surprise that studies have found high rates of depression,[9] and low quality of life[16,25] also after sex reassignment. Notably, however, in this study the increased risk for psychiatric hospitalisation persisted even after adjusting for psychiatric hospitalisation prior to sex reassignment. This suggests that even though sex reassignment alleviates gender dysphoria, there is a need to identify and treat co-occurring psychiatric morbidity in transsexual persons not only before but also after sex reassignment.

Criminal activity, particularly violent crime, is much more common among men than women in the general population. A previous study of all applications for sex reassignment in Sweden up to 1992 found that 9.7% of male-to-female and 6.1% of female-to-male applicants had been prosecuted for a crime.[33] Crime after sex reassignment, however, has not previously been studied. In this study, male-to-female individuals had a higher risk for criminal convictions compared to female controls but not compared to male controls. This suggests that the sex reassignment procedure neither increased nor decreased the risk for criminal offending in male-to-females. By contrast, female-to-males were at a higher risk for criminal convictions compared to female controls and did not differ from male controls, which suggests increased crime proneness in female-to-males after sex reassignment.

Strengths and limitations of the study

Strengths of this study include nationwide representativity over more than 30 years, extensive follow-up time, and minimal loss to follow-up. Many previous studies suffer from low outcome ascertainment,[6,9,21,29] whereas this study has captured almost the entire population of sex-reassigned transsexual individuals in Sweden from 1973–2003. Moreover, previous outcome studies have mixed pre-operative and post-operative transsexual persons,[22,37] while we included only post-operative transsexual persons that also legally changed sex. Finally, whereas previous studies either lack a control group or use standardised mortality rates or standardised incidence rates as comparisons,[9,10,11] we selected random population controls matched by birth year, and either birth or final sex.

Given the nature of sex reassignment, a double blind randomized controlled study of the result after sex reassignment is not feasible. We therefore have to rely on other study designs. For the purpose of evaluating whether sex reassignment is an effective treatment for gender dysphoria, it is reasonable to compare reported gender dysphoria pre and post treatment. Such studies have been conducted either prospectively[7,12] or retrospectively,[5,6,9,22,25,26,29,38] and suggest that sex reassignment of transsexual persons improves quality of life and gender dysphoria. The limitation is of course that the treatment has not been assigned randomly and has not been carried out blindly.

For the purpose of evaluating the safety of sex reassignment in terms of morbidity and mortality, however, it is reasonable to compare sex reassigned persons with matched population controls. The caveat with this design is that transsexual persons before sex reassignment might differ from healthy controls (although this bias can be statistically corrected for by adjusting for baseline differences). It is therefore important to note that the current study is only informative with respect to transsexuals persons health after sex reassignment; no inferences can be drawn as to the effectiveness of sex reassignment as a treatment for transsexualism. In other words, the results should not be interpreted such as sex reassignment *per se* increases morbidity and mortality. Things might have been even worse without sex reassignment. As an analogy, similar studies have found increased somatic morbidity, suicide rate, and overall mortality for patients treated for bipolar disorder and schizophrenia.[39,40] This is important information, but it does not follow that mood stabilizing treatment or antipsychotic treatment is the culprit.

Other facets to consider are first that this study reflects the outcome of psychiatric and somatic treatment for transsexualism provided in Sweden during the 1970s and 1980s. Since then, treatment has evolved with improved sex reassignment surgery, refined hormonal treatment,[11,41] and more attention to psychosocial care that might have improved the outcome. Second, transsexualism is a rare condition and Sweden is a small country (9.2 million inhabitants in 2008). Hence, despite being based on a

comparatively large national cohort and long-term follow-up, the statistical power was limited. Third, regarding psychiatric morbidity after sex reassignment, we assessed inpatient psychiatric care. Since most psychiatric care is provided in outpatient settings (for which no reliable data were available), underestimation of the *absolute* prevalences was inevitable. However, there is no reason to believe that this would change the *relative risks* for psychiatric morbidity unless sex-reassigned transsexual individuals were more likely than matched controls to be admitted to hospital for any given psychiatric condition.

Finally, to estimate start of follow-up, we prioritized using the date of a gender identity disorder diagnosis *after* changed sex status over *before* changed sex status, in order to avoid overestimating person-years at risk after sex-reassignment. This means that adverse outcomes might have been underestimated. However, given that the median time lag between the hospitalization before and after change of sex status was less than a year (see Methods), this maneuver is unlikely to have influenced the results significantly. Moreover, all deaths will be recorded regardless of this exercise and mortality hence correctly estimated.

Conclusion

This study found substantially higher rates of overall mortality, death from cardiovascular disease and suicide, suicide attempts, and psychiatric hospitalisations in sex-reassigned transsexual individuals compared to a healthy control population. This highlights that post surgical transsexuals are a risk group that need long-term psychiatric and somatic follow-up. Even though surgery and hormonal therapy alleviates gender dysphoria, it is apparently not sufficient to remedy the high rates of morbidity and mortality found among transsexual persons. Improved care for the transsexual group after the sex reassignment should therefore be considered.

Supporting Information

Table S1 Risk of various outcomes in sex-reassigned persons in Sweden compared to population controls matched for birth year and birth sex.

(DOCX)

Table S2 Risk of various outcomes in sex-reassigned persons in Sweden compared to controls matched for birth year and final sex.

(DOCX)

Author Contributions

Conceived and designed the experiments: CD PL AJ NL ML. Performed the experiments: MB AJ. Analyzed the data: CD PL MB AJ NL ML. Contributed reagents/materials/analysis tools: PL NL AJ. Wrote the paper: CD PL MB AJ NL ML.

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Exhibit M

From DEPARTMENT OF CLINICAL NEUROSCIENCE
Karolinska Institutet, Stockholm, Sweden

ON GENDER DYSPHORIA

Cecilia Dhejne



**Karolinska
Institutet**

Stockholm 2017

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Published by Karolinska Institutet.

Printed by Printed by Eprint AB 2017

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ISBN 978-91-7676-583-8

On Gender Dysphoria

THESIS FOR DOCTORAL DEGREE (Ph.D.)

at Karolinska Institutet, to be publicly defended in lecture hall Nanna Svartz,
Karolinska University Hospital Solna.

Friday, March 31, 2017 at 9:00 a.m.

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6 ON THE IMPACT OF RESEARCH FINDINGS

Researchers are happy if their findings are recognized and have an impact. However, once published, the researcher loses control of how results are used. Study III is the first long-term cohort study of mortality and psychiatric inpatient care following gender transition (Dhejne et al., 2011). This paper has also had an impact outside the scientific world. Our findings have been used to argue that gender-affirming treatment should be stopped since it could be dangerous (Levine, 2016). But the results have also been used to show the vulnerability of the group and that better transgender health care is needed (Arcelus & Bouman, 2015; Zeluf et al., 2016). Despite the paper clearly stating that the study is not designed to evaluate whether or not gender-affirming is beneficial, it has been interpreted as such. But we do not know what would have happened without gender-affirming treatment; the situation may have been even worse. As an analogy, similar studies have found increased somatic morbidity, suicide rates, and overall mortality for patients treated for depression and bipolar disorder (Ösby, Brandt, Correia, Ekbom, & Sparen, 2001). This is important information, but it does not follow that antidepressant or mood stabilizing treatment cause the mortality. Most of the articles that use the study to argue against gender-affirming health care are published in non-peer reviewed papers and the public media in general. These non-scientific publications are difficult to keep track of. I am grateful to friends, colleagues, patients, LGBT organizations, and journalists who have alerted me when the results of the study have been misinterpreted, giving me a possibility to respond to the authors. One could argue that the results should never have been published due to the hurt caused to transgender persons. However, not publishing the results would also hurt the transgender group and take away an opportunity to receive better health care.

Exhibit N

Gender Dysphoria

In this chapter, there is one overarching diagnosis of gender dysphoria, with separate developmentally appropriate criteria sets for children and for adolescents and adults. The area of sex and gender is highly controversial and has led to a proliferation of terms whose meanings vary over time and within and between disciplines. An additional source of confusion is that in English “sex” connotes both male/female and sexuality. This chapter employs constructs and terms as they are widely used by clinicians from various disciplines with specialization in this area. In this chapter, *sex* and *sexual* refer to the biological indicators of male and female (understood in the context of reproductive capacity), such as in sex chromosomes, gonads, sex hormones, and nonambiguous internal and external genitalia. Disorders of sex development denote conditions of inborn somatic deviations of the reproductive tract from the norm and/or discrepancies among the biological indicators of male and female. *Cross-sex* hormone treatment denotes the use of feminizing hormones in an individual assigned male at birth based on traditional biological indicators or the use of masculinizing hormones in an individual assigned female at birth.

The need to introduce the term *gender* arose with the realization that for individuals with conflicting or ambiguous biological indicators of sex (i.e., “intersex”), the lived role in society and/or the identification as male or female could not be uniformly associated with or predicted from the biological indicators and, later, that some individuals develop an identity as female or male at variance with their uniform set of classical biological indicators. Thus, *gender* is used to denote the public (and usually legally recognized) lived role as boy or girl, man or woman, but, in contrast to certain social constructionist theories, biological factors are seen as contributing, in interaction with social and psychological factors, to gender development. *Gender assignment* refers to the initial assignment as male or female. This occurs usually at birth and, thereby, yields the “natal gender.” *Gender-atypical* refers to somatic features or behaviors that are not typical (in a statistical sense) of individuals with the same assigned gender in a given society and historical era; for behavior, *gender-nonconforming* is an alternative descriptive term. *Gender reassignment* denotes an official (and usually legal) change of gender. *Gender identity* is a category of social identity and refers to an individual’s identification as male, female, or, occasionally, some category other than male or female. *Gender dysphoria* as a general descriptive term refers to an individual’s affective/cognitive discontent with the assigned gender but is more specifically defined when used as a diagnostic category. *Transgender* refers to the broad spectrum of individuals who transiently or persistently identify with a gender different from their natal gender. *Transsexual* denotes an individual who seeks, or has undergone, a social transition from male to female or female to male, which in many, but not all, cases also involves a somatic transition by cross-sex hormone treatment and genital surgery (*sex reassignment surgery*).

Gender dysphoria refers to the distress that may accompany the incongruence between one’s experienced or expressed gender and one’s assigned gender. Although not all individuals will experience distress as a result of such incongruence, many are distressed if the desired physical interventions by means of hormones and/or surgery are not available. The current term is more descriptive than the previous DSM-IV term *gender identity disorder* and focuses on dysphoria as the clinical problem, not identity per se.

Gender Dysphoria

Diagnostic Criteria

Gender Dysphoria in Children 302.6 (F64.2)

- A. A marked incongruence between one's experienced/expressed gender and assigned gender, of at least 6 months' duration, as manifested by at least six of the following (one of which must be Criterion A1):
1. A strong desire to be of the other gender or an insistence that one is the other gender (or some alternative gender different from one's assigned gender).
 2. In boys (assigned gender), a strong preference for cross-dressing or simulating female attire; or in girls (assigned gender), a strong preference for wearing only typical masculine clothing and a strong resistance to the wearing of typical feminine clothing.
 3. A strong preference for cross-gender roles in make-believe play or fantasy play.
 4. A strong preference for the toys, games, or activities stereotypically used or engaged in by the other gender.
 5. A strong preference for playmates of the other gender.
 6. In boys (assigned gender), a strong rejection of typically masculine toys, games, and activities and a strong avoidance of rough-and-tumble play; or in girls (assigned gender), a strong rejection of typically feminine toys, games, and activities.
 7. A strong dislike of one's sexual anatomy.
 8. A strong desire for the primary and/or secondary sex characteristics that match one's experienced gender.
- B. The condition is associated with clinically significant distress or impairment in social, school, or other important areas of functioning.

Specify if:

With a disorder of sex development (e.g., a congenital adrenogenital disorder such as 255.2 [E25.0] congenital adrenal hyperplasia or 259.50 [E34.50] androgen insensitivity syndrome).

Coding note: Code the disorder of sex development as well as gender dysphoria.

Gender Dysphoria in Adolescents and Adults 302.85 (F64.1)

- A. A marked incongruence between one's experienced/expressed gender and assigned gender, of at least 6 months' duration, as manifested by at least two of the following:
1. A marked incongruence between one's experienced/expressed gender and primary and/or secondary sex characteristics (or in young adolescents, the anticipated secondary sex characteristics).
 2. A strong desire to be rid of one's primary and/or secondary sex characteristics because of a marked incongruence with one's experienced/expressed gender (or in young adolescents, a desire to prevent the development of the anticipated secondary sex characteristics).
 3. A strong desire for the primary and/or secondary sex characteristics of the other gender.
 4. A strong desire to be of the other gender (or some alternative gender different from one's assigned gender).
 5. A strong desire to be treated as the other gender (or some alternative gender different from one's assigned gender).
 6. A strong conviction that one has the typical feelings and reactions of the other gender (or some alternative gender different from one's assigned gender).

- B. The condition is associated with clinically significant distress or impairment in social, occupational, or other important areas of functioning.

Specify if:

With a disorder of sex development (e.g., a congenital adrenogenital disorder such as 255.2 [E25.0] congenital adrenal hyperplasia or 259.50 [E34.50] androgen insensitivity syndrome).

Coding note: Code the disorder of sex development as well as gender dysphoria.

Specify if:

Posttransition: The individual has transitioned to full-time living in the desired gender (with or without legalization of gender change) and has undergone (or is preparing to have) at least one cross-sex medical procedure or treatment regimen—namely, regular cross-sex hormone treatment or gender reassignment surgery confirming the desired gender (e.g., penectomy, vaginoplasty in a natal male; mastectomy or phalloplasty in a natal female).

Specifiers

The posttransition specifier may be used in the context of continuing treatment procedures that serve to support the new gender assignment.

Diagnostic Features

Individuals with gender dysphoria have a marked incongruence between the gender they have been assigned to (usually at birth, referred to as *natal gender*) and their experienced/expressed gender. This discrepancy is the core component of the diagnosis. There must also be evidence of distress about this incongruence. Experienced gender may include alternative gender identities beyond binary stereotypes. Consequently, the distress is not limited to a desire to simply be of the other gender, but may include a desire to be of an alternative gender, provided that it differs from the individual's assigned gender.

Gender dysphoria manifests itself differently in different age groups. Prepubertal natal girls with gender dysphoria may express the wish to be a boy, assert they are a boy, or assert they will grow up to be a man. They prefer boys' clothing and hairstyles, are often perceived by strangers as boys, and may ask to be called by a boy's name. Usually, they display intense negative reactions to parental attempts to have them wear dresses or other feminine attire. Some may refuse to attend school or social events where such clothes are required. These girls may demonstrate marked cross-gender identification in role-playing, dreams, and fantasies. Contact sports, rough-and-tumble play, traditional boyhood games, and boys as playmates are most often preferred. They show little interest in stereotypically feminine toys (e.g., dolls) or activities (e.g., feminine dress-up or role-play). Occasionally, they refuse to urinate in a sitting position. Some natal girls may express a desire to have a penis or claim to have a penis or that they will grow one when older. They may also state that they do not want to develop breasts or menstruate.

Prepubertal natal boys with gender dysphoria may express the wish to be a girl or assert they are a girl or that they will grow up to be a woman. They have a preference for dressing in girls' or women's clothes or may improvise clothing from available materials (e.g., using towels, aprons, and scarves for long hair or skirts). These children may role-play female figures (e.g., playing "mother") and often are intensely interested in female fantasy figures. Traditional feminine activities, stereotypical games, and pastimes (e.g., "playing house"; drawing feminine pictures; watching television or videos of favorite female characters) are most often preferred. Stereotypical female-type dolls (e.g., Barbie) are often favorite toys, and girls are their preferred playmates. They avoid rough-and-tumble play and competitive sports and have little interest in stereotypically masculine toys (e.g., cars, trucks). Some may pretend not to have a penis and insist on sitting to urinate. More

rarely, they may state that they find their penis or testes disgusting, that they wish them removed, or that they have, or wish to have, a vagina.

In young adolescents with gender dysphoria, clinical features may resemble those of children or adults with the condition, depending on developmental level. As secondary sex characteristics of young adolescents are not yet fully developed, these individuals may not state dislike of them, but they are concerned about imminent physical changes.

In adults with gender dysphoria, the discrepancy between experienced gender and physical sex characteristics is often, but not always, accompanied by a desire to be rid of primary and/or secondary sex characteristics and/or a strong desire to acquire some primary and/or secondary sex characteristics of the other gender. To varying degrees, adults with gender dysphoria may adopt the behavior, clothing, and mannerisms of the experienced gender. They feel uncomfortable being regarded by others, or functioning in society, as members of their assigned gender. Some adults may have a strong desire to be of a different gender and treated as such, and they may have an inner certainty to feel and respond as the experienced gender without seeking medical treatment to alter body characteristics. They may find other ways to resolve the incongruence between experienced/expressed and assigned gender by partially living in the desired role or by adopting a gender role neither conventionally male nor conventionally female.

Associated Features Supporting Diagnosis

When visible signs of puberty develop, natal boys may shave their legs at the first signs of hair growth. They sometimes bind their genitals to make erections less visible. Girls may bind their breasts, walk with a stoop, or use loose sweaters to make breasts less visible. Increasingly, adolescents request, or may obtain without medical prescription and supervision, hormonal suppressors ("blockers") of gonadal steroids (e.g., gonadotropin-releasing hormone [GnRH] analog, spironolactone). Clinically referred adolescents often want hormone treatment and many also wish for gender reassignment surgery. Adolescents living in an accepting environment may openly express the desire to be and be treated as the experienced gender and dress partly or completely as the experienced gender, have a hairstyle typical of the experienced gender, preferentially seek friendships with peers of the other gender, and/or adopt a new first name consistent with the experienced gender. Older adolescents, when sexually active, usually do not show or allow partners to touch their sexual organs. For adults with an aversion toward their genitals, sexual activity is constrained by the preference that their genitals not be seen or touched by their partners. Some adults may seek hormone treatment (sometimes without medical prescription and supervision) and gender reassignment surgery. Others are satisfied with either hormone treatment or surgery alone.

Adolescents and adults with gender dysphoria before gender reassignment are at increased risk for suicidal ideation, suicide attempts, and suicides. After gender reassignment, adjustment may vary, and suicide risk may persist.

Prevalence

For natal adult males, prevalence ranges from 0.005% to 0.014%, and for natal females, from 0.002% to 0.003%. Since not all adults seeking hormone treatment and surgical reassignment attend specialty clinics, these rates are likely modest underestimates. Sex differences in rate of referrals to specialty clinics vary by age group. In children, sex ratios of natal boys to girls range from 2:1 to 4.5:1. In adolescents, the sex ratio is close to parity; in adults, the sex ratio favors natal males, with ratios ranging from 1:1 to 6.1:1. In two countries, the sex ratio appears to favor natal females (Japan: 2.2:1; Poland: 3.4:1).

Development and Course

Because expression of gender dysphoria varies with age, there are separate criteria sets for children versus adolescents and adults. Criteria for children are defined in a more con-

crete, behavioral manner than those for adolescents and adults. Many of the core criteria draw on well-documented behavioral gender differences between typically developing boys and girls. Young children are less likely than older children, adolescents, and adults to express extreme and persistent anatomic dysphoria. In adolescents and adults, incongruence between experienced gender and somatic sex is a central feature of the diagnosis. Factors related to distress and impairment also vary with age. A very young child may show signs of distress (e.g., intense crying) only when parents tell the child that he or she is “really” not a member of the other gender but only “desires” to be. Distress may not be manifest in social environments supportive of the child’s desire to live in the role of the other gender and may emerge only if the desire is interfered with. In adolescents and adults, distress may manifest because of strong incongruence between experienced gender and somatic sex. Such distress may, however, be mitigated by supportive environments and knowledge that biomedical treatments exist to reduce incongruence. Impairment (e.g., school refusal, development of depression, anxiety, and substance abuse) may be a consequence of gender dysphoria.

Gender dysphoria without a disorder of sex development. For clinic-referred children, onset of cross-gender behaviors is usually between ages 2 and 4 years. This corresponds to the developmental time period in which most typically developing children begin expressing gendered behaviors and interests. For some preschool-age children, both pervasive cross-gender behaviors and the expressed desire to be the other gender may be present, or, more rarely, labeling oneself as a member of the other gender may occur. In some cases, the expressed desire to be the other gender appears later, usually at entry into elementary school. A small minority of children express discomfort with their sexual anatomy or will state the desire to have a sexual anatomy corresponding to the experienced gender (“anatomic dysphoria”). Expressions of anatomic dysphoria become more common as children with gender dysphoria approach and anticipate puberty.

Rates of persistence of gender dysphoria from childhood into adolescence or adulthood vary. In natal males, persistence has ranged from 2.2% to 30%. In natal females, persistence has ranged from 12% to 50%. Persistence of gender dysphoria is modestly correlated with dimensional measures of severity ascertained at the time of a childhood baseline assessment. In one sample of natal males, lower socioeconomic background was also modestly correlated with persistence. It is unclear if particular therapeutic approaches to gender dysphoria in children are related to rates of long-term persistence. Extant follow-up samples consisted of children receiving no formal therapeutic intervention or receiving therapeutic interventions of various types, ranging from active efforts to reduce gender dysphoria to a more neutral, “watchful waiting” approach. It is unclear if children “encouraged” or supported to live socially in the desired gender will show higher rates of persistence, since such children have not yet been followed longitudinally in a systematic manner. For both natal male and female children showing persistence, almost all are sexually attracted to individuals of their natal sex. For natal male children whose gender dysphoria does not persist, the majority are *androphilic* (sexually attracted to males) and often self-identify as gay or homosexual (ranging from 63% to 100%). In natal female children whose gender dysphoria does not persist, the percentage who are *gynephilic* (sexually attracted to females) and self-identify as lesbian is lower (ranging from 32% to 50%).

In both adolescent and adult natal males, there are two broad trajectories for development of gender dysphoria: early onset and late onset. *Early-onset gender dysphoria* starts in childhood and continues into adolescence and adulthood; or, there is an intermittent period in which the gender dysphoria desists and these individuals self-identify as gay or homosexual, followed by recurrence of gender dysphoria. *Late-onset gender dysphoria* occurs around puberty or much later in life. Some of these individuals report having had a desire to be of the other gender in childhood that was not expressed verbally to others. Others do not recall any signs of childhood gender dysphoria. For adolescent males with late-onset gender dysphoria, parents often report surprise because they did not see signs of gender

dysphoria during childhood. Expressions of anatomic dysphoria are more common and salient in adolescents and adults once secondary sex characteristics have developed.

Adolescent and adult natal males with early-onset gender dysphoria are almost always sexually attracted to men (androphilic). Adolescents and adults with late-onset gender dysphoria frequently engage in transvestic behavior with sexual excitement. The majority of these individuals are gynephilic or sexually attracted to other posttransition natal males with late-onset gender dysphoria. A substantial percentage of adult males with late-onset gender dysphoria cohabit with or are married to natal females. After gender transition, many self-identify as lesbian. Among adult natal males with gender dysphoria, the early-onset group seeks out clinical care for hormone treatment and reassignment surgery at an earlier age than does the late-onset group. The late-onset group may have more fluctuations in the degree of gender dysphoria and be more ambivalent about and less likely satisfied after gender reassignment surgery.

In both adolescent and adult natal females, the most common course is the early-onset form of gender dysphoria. The late-onset form is much less common in natal females compared with natal males. As in natal males with gender dysphoria, there may have been a period in which the gender dysphoria desisted and these individuals self-identified as lesbian; however, with recurrence of gender dysphoria, clinical consultation is sought, often with the desire for hormone treatment and reassignment surgery. Parents of natal adolescent females with the late-onset form also report surprise, as no signs of childhood gender dysphoria were evident. Expressions of anatomic dysphoria are much more common and salient in adolescents and adults than in children.

Adolescent and adult natal females with early-onset gender dysphoria are almost always gynephilic. Adolescents and adults with the late-onset form of gender dysphoria are usually androphilic and after gender transition self-identify as gay men. Natal females with the late-onset form do not have co-occurring transvestic behavior with sexual excitement.

Gender dysphoria in association with a disorder of sex development. Most individuals with a disorder of sex development who develop gender dysphoria have already come to medical attention at an early age. For many, starting at birth, issues of gender assignment were raised by physicians and parents. Moreover, as infertility is quite common for this group, physicians are more willing to perform cross-sex hormone treatments and genital surgery before adulthood.

Disorders of sex development in general are frequently associated with gender-atypical behavior starting in early childhood. However, in the majority of cases, this does not lead to gender dysphoria. As individuals with a disorder of sex development become aware of their medical history and condition, many experience uncertainty about their gender, as opposed to developing a firm conviction that they are another gender. However, most do not progress to gender transition. Gender dysphoria and gender transition may vary considerably as a function of a disorder of sex development, its severity, and assigned gender.

Risk and Prognostic Factors

Temperamental. For individuals with gender dysphoria without a disorder of sex development, atypical gender behavior among individuals with early-onset gender dysphoria develops in early preschool age, and it is possible that a high degree of atypicality makes the development of gender dysphoria and its persistence into adolescence and adulthood more likely.

Environmental. Among individuals with gender dysphoria without a disorder of sex development, males with gender dysphoria (in both childhood and adolescence) more commonly have older brothers than do males without the condition. Additional predisposing

factors under consideration, especially in individuals with late-onset gender dysphoria (adulthood), include habitual fetishistic transvestism developing into autogynephilia (i.e., sexual arousal associated with the thought or image of oneself as a woman) and other forms of more general social, psychological, or developmental problems.

Genetic and physiological. For individuals with gender dysphoria without a disorder of sex development, some genetic contribution is suggested by evidence for (weak) familiality of transsexualism among nontwin siblings, increased concordance for transsexualism in monozygotic compared with dizygotic same-sex twins, and some degree of heritability of gender dysphoria. As to endocrine findings, no endogenous systemic abnormalities in sex-hormone levels have been found in 46,XY individuals, whereas there appear to be increased androgen levels (in the range found in hirsute women but far below normal male levels) in 46,XX individuals. Overall, current evidence is insufficient to label gender dysphoria without a disorder of sex development as a form of intersexuality limited to the central nervous system.

In gender dysphoria associated with a disorder of sex development, the likelihood of later gender dysphoria is increased if prenatal production and utilization (via receptor sensitivity) of androgens are grossly atypical relative to what is usually seen in individuals with the same assigned gender. Examples include 46,XY individuals with a history of normal male prenatal hormone milieu but inborn nonhormonal genital defects (as in cloacal bladder exstrophy or penile agenesis) and who have been assigned to the female gender. The likelihood of gender dysphoria is further enhanced by additional, prolonged, highly gender-atypical postnatal androgen exposure with somatic virilization as may occur in female-raised and noncastrated 46,XY individuals with 5-alpha reductase-2 deficiency or 17-beta-hydroxysteroid dehydrogenase-3 deficiency or in female-raised 46,XX individuals with classical congenital adrenal hyperplasia with prolonged periods of non-adherence to glucocorticoid replacement therapy. However, the prenatal androgen milieu is more closely related to gendered behavior than to gender identity. Many individuals with disorders of sex development and markedly gender-atypical behavior do not develop gender dysphoria. Thus, gender-atypical behavior by itself should not be interpreted as an indicator of current or future gender dysphoria. There appears to be a higher rate of gender dysphoria and patient-initiated gender change from assigned female to male than from assigned male to female in 46,XY individuals with a disorder of sex development.

Culture-Related Diagnostic Issues

Individuals with gender dysphoria have been reported across many countries and cultures. The equivalent of gender dysphoria has also been reported in individuals living in cultures with institutionalized gender categories other than male or female. It is unclear whether with these individuals the diagnostic criteria for gender dysphoria would be met.

Diagnostic Markers

Individuals with a somatic disorder of sex development show some correlation of final gender identity outcome with the degree of prenatal androgen production and utilization. However, the correlation is not robust enough for the biological factor, where ascertainable, to replace a detailed and comprehensive diagnostic interview evaluation for gender dysphoria.

Functional Consequences of Gender Dysphoria

Preoccupation with cross-gender wishes may develop at all ages after the first 2–3 years of childhood and often interfere with daily activities. In older children, failure to develop age-typical same-sex peer relationships and skills may lead to isolation from peer groups and to distress. Some children may refuse to attend school because of teasing and harass-

ment or pressure to dress in attire associated with their assigned sex. Also in adolescents and adults, preoccupation with cross-gender wishes often interferes with daily activities. Relationship difficulties, including sexual relationship problems, are common, and functioning at school or at work may be impaired. Gender dysphoria, along with atypical gender expression, is associated with high levels of stigmatization, discrimination, and victimization, leading to negative self-concept, increased rates of mental disorder comorbidity, school dropout, and economic marginalization, including unemployment, with attendant social and mental health risks, especially in individuals from resource-poor family backgrounds. In addition, these individuals' access to health services and mental health services may be impeded by structural barriers, such as institutional discomfort or inexperience in working with this patient population.

Differential Diagnosis

Nonconformity to gender roles. Gender dysphoria should be distinguished from simple nonconformity to stereotypical gender role behavior by the strong desire to be of another gender than the assigned one and by the extent and pervasiveness of gender-variant activities and interests. The diagnosis is not meant to merely describe nonconformity to stereotypical gender role behavior (e.g., "tomboyism" in girls, "girly-boy" behavior in boys, occasional cross-dressing in adult men). Given the increased openness of atypical gender expressions by individuals across the entire range of the transgender spectrum, it is important that the clinical diagnosis be limited to those individuals whose distress and impairment meet the specified criteria.

Transvestic disorder. Transvestic disorder occurs in heterosexual (or bisexual) adolescent and adult males (rarely in females) for whom cross-dressing behavior generates sexual excitement and causes distress and/or impairment without drawing their primary gender into question. It is occasionally accompanied by gender dysphoria. An individual with transvestic disorder who also has clinically significant gender dysphoria can be given both diagnoses. In many cases of late-onset gender dysphoria in gynephilic natal males, transvestic behavior with sexual excitement is a precursor.

Body dysmorphic disorder. An individual with body dysmorphic disorder focuses on the alteration or removal of a specific body part because it is perceived as abnormally formed, not because it represents a repudiated assigned gender. When an individual's presentation meets criteria for both gender dysphoria and body dysmorphic disorder, both diagnoses can be given. Individuals wishing to have a healthy limb amputated (termed by some *body integrity identity disorder*) because it makes them feel more "complete" usually do not wish to change gender, but rather desire to live as an amputee or a disabled person.

Schizophrenia and other psychotic disorders. In schizophrenia, there may rarely be delusions of belonging to some other gender. In the absence of psychotic symptoms, insistence by an individual with gender dysphoria that he or she is of some other gender is not considered a delusion. Schizophrenia (or other psychotic disorders) and gender dysphoria may co-occur.

Other clinical presentations. Some individuals with an emasculation desire who develop an alternative, nonmale/nonfemale gender identity do have a presentation that meets criteria for gender dysphoria. However, some males seek castration and/or penectomy for aesthetic reasons or to remove psychological effects of androgens without changing male identity; in these cases, the criteria for gender dysphoria are not met.

Comorbidity

Clinically referred children with gender dysphoria show elevated levels of emotional and behavioral problems—most commonly, anxiety, disruptive and impulse-control, and de-

pressive disorders. In prepubertal children, increasing age is associated with having more behavioral or emotional problems; this is related to the increasing non-acceptance of gender-variant behavior by others. In older children, gender-variant behavior often leads to peer ostracism, which may lead to more behavioral problems. The prevalence of mental health problems differs among cultures; these differences may also be related to differences in attitudes toward gender variance in children. However, also in some non-Western cultures, anxiety has been found to be relatively common in individuals with gender dysphoria, even in cultures with accepting attitudes toward gender-variant behavior. Autism spectrum disorder is more prevalent in clinically referred children with gender dysphoria than in the general population. Clinically referred adolescents with gender dysphoria appear to have comorbid mental disorders, with anxiety and depressive disorders being the most common. As in children, autism spectrum disorder is more prevalent in clinically referred adolescents with gender dysphoria than in the general population. Clinically referred adults with gender dysphoria may have coexisting mental health problems, most commonly anxiety and depressive disorders.

Other Specified Gender Dysphoria

302.6 (F64.8)

This category applies to presentations in which symptoms characteristic of gender dysphoria that cause clinically significant distress or impairment in social, occupational, or other important areas of functioning predominate but do not meet the full criteria for gender dysphoria. The other specified gender dysphoria category is used in situations in which the clinician chooses to communicate the specific reason that the presentation does not meet the criteria for gender dysphoria. This is done by recording “other specified gender dysphoria” followed by the specific reason (e.g., “brief gender dysphoria”).

An example of a presentation that can be specified using the “other specified” designation is the following:

The current disturbance meets symptom criteria for gender dysphoria, but the duration is less than 6 months.

Unspecified Gender Dysphoria

302.6 (F64.9)

This category applies to presentations in which symptoms characteristic of gender dysphoria that cause clinically significant distress or impairment in social, occupational, or other important areas of functioning predominate but do not meet the full criteria for gender dysphoria. The unspecified gender dysphoria category is used in situations in which the clinician chooses *not* to specify the reason that the criteria are not met for gender dysphoria, and includes presentations in which there is insufficient information to make a more specific diagnosis.

Exhibit O

Correction: Parent reports of adolescents and young adults perceived to show signs of a rapid onset of gender dysphoria

Lisa Littman

Published: March 19, 2019 • <https://doi.org/10.1371/journal.pone.0214157>

Notice of republication

After publication of this article [1], questions were raised that prompted the journal to conduct a post-publication reassessment of the article, involving senior members of the journal's editorial team, two Academic Editors, a statistics reviewer, and an external expert reviewer. The post-publication review identified issues that needed to be addressed to ensure the article meets *PLOS ONE*'s publication criteria. Given the nature of the issues in this case, the *PLOS ONE* Editors decided to republish the article, replacing the original version of record with a revised version in which the author has updated the Title, Abstract, Introduction, Discussion, and Conclusion sections, to address the concerns raised in the editorial reassessment. The Materials and methods section was updated to include new information and more detailed descriptions about recruitment sites and to remove two figures due to copyright restrictions. Other than the addition of a few missing values in Table 13, the Results section is unchanged in the updated version of the article. The Competing Interests statement and the Data Availability statement have also been updated in the revised version. The original version of the published article is appended to this Correction as [S1 File](#).

This Correction Notice serves to provide additional clarifications and context for the article in response to questions raised during the post-publication review of this work.

Emphasis that this is a study of parental observations which serves to develop hypotheses

This study of parent observations and interpretations serves to develop the hypotheses that rapid-onset gender dysphoria is a phenomenon and that social influences, parent-child conflict, and maladaptive coping mechanisms may be contributing factors for some individuals. Rapid-onset gender dysphoria (ROGD) is not a formal mental health diagnosis at this time. This report did not collect data from the adolescents and young adults (AYAs) or clinicians and therefore does not validate the phenomenon. Additional research that includes AYAs, along with consensus among experts in the field, will be needed to determine if what is described here as rapid-onset gender dysphoria (ROGD) will become a formal diagnosis. Furthermore, the use of the term, rapid-onset gender dysphoria should be used cautiously by clinicians and parents to describe youth who appear to fall into this category. The term should not be used in a way to imply that it explains the experiences of all gender dysphoric youth nor should it be used to stigmatize vulnerable individuals. This article has been revised to better reflect that these parent reports provide information that can be used to develop hypotheses about factors that may contribute to the onset and/or expression of gender dysphoria among this demographic group.

Because this is a study of parent reports, there is some information about the AYAs that the parents would not have access to and the answers might reflect parent perspectives. Examples where parent answers reflect their perspective of the AYA include answers concerning the child's mental well-being, the parent-child relationship, and whether the child has high expectations about transitioning. However, it is also important to note that there are other survey items where the parent would have direct access to information about their child and that those answers reflect items that can be directly observed. Examples of this type include age, natal sex, diagnoses given by medical providers in the presence of the parent, directly observed behaviors of the child and the child's friend group, school performance, whether the child has dropped out or required a leave of absence from school, has been unable to hold a job, whether the child went to a clinic, or received treatment. Readers are reminded to keep in mind that this is a study of parent report and consideration of what information parents may or may not have access to is an important element of the findings.

Questions on whether the article describes adolescent-onset gender dysphoria or if it describes something new

There is some controversy over whether what is described as rapid onset of gender dysphoria, particularly in natal females, falls under the existing definition of late-onset or adolescent-onset gender dysphoria or whether it represents a new kind of development or presentation. This controversy might be a false dichotomy because both might be true. Although recent observations of adolescents and young adults who are predominantly natal female having a sudden onset of gender dysphoria symptoms beginning during or after puberty might technically fall under the existing definitions and criteria for adolescent and adult gender dysphoria [2], the substantial change in the demographics of patients presenting for care, the inversion of the sex ratio with disproportionate increase in adolescent natal females [3–5], and the new phenomenon of natal females exhibiting adolescent-onset and late-onset gender dysphoria [6–8] signal that something new may be happening as well. These changes may indicate that there are new etiologies leading to gender dysphoria and it is unclear, particularly without research about these new populations, whether gender dysphoria in this context has the same outcomes, desistence and persistence rates, and response to treatment as the gender dysphorias that have been previously studied.

Expanded discussion of qualitative analyses

Because this is a descriptive, exploratory study into a new topic with very little existing data, the addition of the qualitative analysis of two questions in addition to the quantitative analysis allowed for a greater depth of information to be used in the development of hypotheses. A grounded theory approach was selected as the strategy of choice for handling the qualitative data. There were two reviewers consisting of a professor with a PhD degree and expertise in qualitative methods (MM) [9] and the author (LL) who holds an MD and MPH degree, and has published both qualitative and quantitative research papers [10–11]. Each reviewer independently read and re-read the open-text responses in an iterative process to identify major themes arising from the data. Once each reviewer independently listed major themes and coded the open-text responses according to those themes, both reviewers compared notes to collaboratively revise and refine the major themes identified. Once an agreed-upon final list of themes was developed, attention was turned back to the data to code the open-text response with the final list of themes. After this task was completed, LL selected salient quotes to reflect each major theme, shared the quotes with MM, and both discussed collaboratively until agreement for the final list of major themes and associated quotes was reached. The incorporation of both the qualitative and quantitative analysis allowed for a more vivid picture of parent perspectives about the friendship group dynamics and behaviors and clinician interactions than could have been obtained from just one type of analysis.

Clarification of study design, methods, and related limitations

As mentioned in the article, the study design of this research falls under descriptive research: as such, it did not assign an exposure, there were no comparison groups, and the study's output was hypothesis-generating rather than hypothesis-testing [12]. Descriptive studies often represent a first inquiry into an area of research and the findings of descriptive studies are used to generate new hypotheses that can be tested in subsequent research [12–13]. Because of the known limitations of descriptive studies, claims about causal associations cannot be made [12], and there were none made in the article. The conclusions of the current study are that the findings raise certain hypotheses and that more research is needed. Simple descriptive metrics to describe the quantitative characteristics of a sample in a descriptive study are the appropriate measures to use in this study. Additionally, because the data were collected at one point in time, no claims of cause and effect can be made.

All research methods have advantages and limitations. Obtaining information from parents (and guardians) about the health and well-being of children and adolescents is an established method of research [14]. Parental report, used elsewhere and in this study, offers the advantages of collecting data from adults who are knowledgeable about the child, who are able and willing to complete research activities such as detailed surveys, and who can provide details that are not available by other methods. Limitations of parental report include information that parents may not be aware of and parental biases. Anonymous surveys, used elsewhere and in this study, are advantageous for topics that might be stigmatized and can allow participants to be more honest in their responses but introduce the limitation that the researcher cannot verify the identity and experiences of the participants. The use of targeted recruitment and convenience samples, used elsewhere and in this study, offers the benefit of connecting with hard-to-reach populations but introduces limitations associated with selection bias that can subsequently be addressed by further studies. For the current study, selection bias may have resulted in findings that are more positive or more negative than would be found in a larger and less self-selected population. Subsequent studies should address these issues.

Updated Information about recruitment

Concerns were raised that this study only posted links to the recruitment information on selected sites that are viewed as being unsupportive of transition. However, announcements about the study included requests to distribute the recruitment information and link, and because information about where the participants encountered the announcement was not collected, it is not known which populations were ultimately reached. It has come to light that a link to the recruitment information and research survey was posted on a private Facebook group perceived to have a pro-gender-affirming perspective during the first week of the recruitment period (via snowball sampling). This private Facebook group is called "Parents of Transgender Children" and has more than 8,000 members. This means that parents participating in this research may have viewed the recruitment information from one of at least four sites with varied perspectives. Specifically, three of the sites that posted recruitment information expressed cautious or negative views about medical and surgical interventions for gender dysphoric adolescents and young adults and cautious or negative views about categorizing gender dysphoric youth as transgender. And, one of the sites that posted recruitment information is perceived to be pro-gender-affirming. The rest of the Correction notice will refer to recruitment from the four sites that are known to have posted the survey in the first week of recruitment: 4thwavenow, transgendertrend, Youth Trans Critical Professionals, and Parents of Transgender Children.

Parental approaches to gender dysphoria and views on medical interventions

To oversimplify parental approaches as simply "accepting" or "rejecting" misrepresents the range of responses and complexity of approaches that parents take when addressing the needs of their gender dysphoric children. Parental approaches are complex and cover many variables. For example, one parental approach might be to affirm the child as a person, support gender nonconformity, support gender exploration, support mental health evaluation and treatment as needed, support the exploration of potential underlying causes for the dysphoria while expressing caution about medical interventions. Another approach might be to affirm the child's newly declared gender identity, support gender nonconformity, support a liberal approach to medical intervention while expressing caution about mental health evaluation and caution about the exploration of potential underlying causes for the dysphoria. To categorize the former as "rejecting" and the latter as "accepting" would be inaccurate.

This study recruited participants based on whether participants thought their child exhibited a sudden or rapid onset of gender dysphoria beginning during or after puberty and did not recruit based on parental beliefs about what types of approaches toward gender dysphoric AYAs are best. Although one of the sites posting recruitment information might be considered to hold a pro-gender affirming perspective and three sites might be considered to hold a cautious or even negative perspective about medical or surgical interventions, the site where a participant first heard about the study may not be an accurate reflection of their beliefs and whether they endorse or disagree with the content of the websites. Data about where participants first heard about this study were not collected. Future studies should seek a wider array of websites to post recruitment information, recruit from clinicians with varied approaches to gender dysphoria, and ask specific questions about parental beliefs regarding their approach to their child's gender dysphoria, including: whether parents support or don't support gender exploration, gender nonconformity, mental health

evaluation and treatment, exploration of potential underlying causes for dysphoria, non-heterosexual sexual identity, and whether they hold a liberal, cautious or negative view about the use of medical and surgical interventions for gender dysphoric youth. Exploration about what types of affirmation are endorsed by parents including affirmation of the child as a person and affirmation of the child's gender identity would also be valuable.

Expanded discussion about limitations and biases

Regarding the reporting of gender dysphoria, an absence of childhood gender dysphoria and whether the AYA was gender dysphoric at the time of survey completion were based on parent report of whether certain indicators of gender dysphoria were observed prior to puberty or at the time of the survey. These determinations were not diagnoses made by clinicians. Three of the indicators listed in the DSM-5 include information that a parent might not have access to (unless the child told them directly) [2], and therefore answers based on parent perceptions may not accurately reflect the experiences or traits of the AYAs themselves. However, the other five indicators include readily observable behaviors and preferences that would seem difficult for a parent not to notice such as: strong preference or strong resistance to wearing certain kinds of clothing; strong preference or strong rejection of specific toys, games and activities; and strong preference for playmates of the other gender [2]. It is possible that a parent could have ignored some of these indicators, though other people in the child's life may have observed them. To improve the reliability of this measure, future studies should include evaluation from clinicians with input from parents, AYAs and from third party informants such as teachers, pediatricians, mental health professionals, babysitters, and other family members who knew the youth during childhood to verify the whether the readily observable behaviors and preferences were present or absent during childhood.

For a clinician to make a diagnosis of gender dysphoria in childhood, a child would need to exhibit at least six of the eight indicators. Given that 97.6% of the participants reported 2 or fewer readily observable indicators, even if hypothetically all participants incorrectly under-reported all three of the subtler indicators, 97.6% would still have fewer than six indicators. So, although no clinical evaluation was performed and a clear presence or absence of a diagnosis cannot be verified, given the reports of the easily observed behaviors and preferences, it can be said that it would be very unlikely for these AYAs to have met criteria for childhood gender dysphoria if they had seen a clinician for an evaluation.

There is expected variation in how objective parents can be about their own children. Some individual biases may limit the objectivity of parents. This descriptive study was not designed to explore or measure the objectivity of participants. Participants may have first learned about this study from one of four (or more) sites described previously where recruitment information was posted. It is possible that exposure to websites that take a cautious or negative approach to transition during adolescence and young adulthood and exposure to websites that take a pro-gender-affirming approach might influence how parents report about their children's experiences. There have not been any studies to determine if parents who seek information from online sites in general, don't seek information from online sites, or seek information from specific online sites, including the four sites noted for this study, differ in their ability to provide objective assessments of their children. However, if there were an excess of participants who, compared to other parents who take surveys reporting on their children, were less able to be objective about their children, it could limit some of the findings of the study, particularly for findings that are more interpretive rather than the findings that are more concrete.

The research survey did not specifically ask whether parents supported their AYAs' exploration of gender identity, so whether and what numbers of participants supported their child's exploration of gender identity is unknown. However, if there were an excess of parents who did not support the exploration of gender identity, it could potentially result in higher reports of declining mental health. The parents' perception that their child's mental health and the parent-child relationship were worse after the child announced a transgender-identification could be due to several variables such as conflict between parent and child, maladaptive coping mechanisms, or worsening psychiatric issues unrelated to gender. The trajectories for adolescent-onset gender dysphoria are not well understood and additional research is desperately needed.

There are many ways that parents can provide support for their child which include: affirming them as a unique and valuable person and as a loved member of the family; supporting their emotional and financial needs; supporting them in pursuing their interests; supporting them to develop the skills needed for self-sufficiency; supporting their choices of gender nonconforming clothing and interests; supporting their exploration of their identity; and supporting them in their critical thinking skills. Parental support is multifaceted and should not be oversimplified into a binary of whether a parent agrees or disagrees with a specific medical course. This study was not designed to measure different types of support provided by parents or levels of support. If there were an excess of parents who were unsupportive of their children, it might affect some of these initial findings. The nature and extent of parental support—including the many different ways that parents can support their children in becoming healthy, self-sufficient adults—is well worth further study.

Clarification of Fig 1

The purpose of Fig 1 was to provide the reader with a quick sense of what kinds of advice can be found and shared on Reddit and Tumblr. One example includes an excerpt from a publicly available Tumblr blog that posted a list of purported indirect signs of gender dysphoria. This excerpt is indeed an example of advice that can be found on Tumblr. Note, however, that the excerpted Tumblr post itself does not reflect the full content of the original blog it refers to, nor does the excerpt in Fig 1. The original blog is titled, "That was dysphoria? 8 signs and symptoms of indirect gender dysphoria" [15].

Discussion of the ICD-11 change from "gender dysphoria" to "gender incongruence"

The ICD-11 will go into effect in January 2022, and, with this change, the new diagnosis of "gender incongruence" will replace "gender dysphoria." Because the current descriptive, exploratory study raises hypotheses about factors that may contribute to the onset and/or expression of gender dysphoria and concludes that more research is needed, it is unlikely that the change in diagnostic criteria will appreciably change the conclusion of the study, although the terminology may become outdated.

Supporting information

S1 File. PDF of the original article version that was published on August 16, 2018 (two figures removed due to copyright restrictions).
<https://doi.org/10.1371/journal.pone.0214157.s001>
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Citation: Littman L (2019) Correction: Parent reports of adolescents and young adults perceived to show signs of a rapid onset of gender dysphoria. PLoS ONE 14(3): e0214157. <https://doi.org/10.1371/journal.pone.0214157>

Published: March 19, 2019

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Exhibit P



Do Clinical Data from Transgender Adolescents Support the Phenomenon of “Rapid Onset Gender Dysphoria”?

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Although emergence of gender dysphoria at puberty is long established, a distinct pathway of rapid onset gender dysphoria was recently hypothesized based on parental data. Using adolescent clinical data, we tested a series of associations that would be consistent with this pathway, however, our results did not support the rapid onset gender dysphoria hypothesis. (*J Pediatr* 2022;243:224-7).

Puberty has long been understood as one period when gender dysphoria often first emerges.¹ Although most transgender (trans) older adolescents and adults report needing gender-affirming medical care (hormones and/or surgeries), and also report having been aware of their gender at young ages,² only a small proportion receive gender-affirming care as adolescents. Use of hormonal suppression with a gonadotropin-releasing hormone agonist, and hormones such as estrogen and testosterone therapies in trans and gender-diverse adolescents is supported by the American Academy of Pediatrics, the Pediatric Endocrine Society, the Endocrine Society, and the World Professional Association for Transgender Health.^{1,3-5} Referrals to adolescent gender clinics have increased internationally, particularly among those assigned female at birth.⁶⁻⁹

In 2018, a phenomenon of rapid onset gender dysphoria was hypothesized as a distinct pathway involving social contagion among youth vulnerable due to mental or neurodevelopmental disorders,¹⁰⁻¹² raising public concerns regarding potential for later regret following gender-affirming medical care. This discussion has occurred primarily in the context of data from a single online parental survey.^{10,11} Although this parental study has generated controversy,¹³ methodologic and social critique,^{12,14,15} and calls for additional research,^{16,17} its hypotheses have not yet been tested on data from youth themselves. Specifically, rapid onset gender dysphoria is hypothesized as a phenomenon in youth with gender dysphoria emerging at or after puberty, socially influenced through peer contagion, and with contributing factors including poor mental health, neurodevelopmental disabilities, parent-child conflict, and maladaptive coping strategies.^{10,11}

If the rapid onset gender dysphoria hypothesis indeed characterizes a distinct clinical phenomenon, and these youth access referrals for hormone suppression or gender-affirming hormones, then we would expect to see differentiation within clinical samples between those with more-recent (ie, rapid-onset) vs more-remote knowledge regarding their gender. Based on the published hypothesis,¹⁰ we would expect more recent gender knowledge to be associated with self-reported mental health measures, mental health and neurodevelopmental disability diagnoses, behaviors consistent with maladaptive coping (eg, self-harm), support from

online and/or transgender friends but not parents, and lesser gender dysphoria. We aim to test these hypotheses.

Methods

Baseline data (2017-2019) from the Trans Youth CAN! Cohort included pubertal/postpubertal adolescents age <16 years attending a first referral visit for hormone suppression or gender-affirming hormones at 10 Canadian medical clinics that provide specialized gender-affirming care to adolescents through a range of different care models. Ethics approval was received from all study sites. Years gender was known was missing for 1 participant (excluded), for a final sample of $n = 173$. Methods and measures are described in detail elsewhere.¹⁸

Self-reported measures were obtained from baseline interviewer-administered adolescent surveys,¹⁹ and diagnoses from baseline clinical records.²⁰ Recent gender knowledge was coded by subtracting age in years from age adolescents self-reported they “realized your gender was different from what other people called you.” As ages were whole numbers, a difference of 1 could indicate <1 year to just under 2 years. Values ≤ 1 were coded as recent gender knowledge, with an alternate definition (values ≤ 2) for sensitivity analysis. Mental health symptoms were assessed with the Overall Anxiety Severity and Impairment Scale,²¹ the Modified Depression Scale,²² and the Kessler-6 scale for psychological distress.²³ Mental health diagnoses extracted from chart included anxiety, depression, personality disorder, eating disorder, and neurodevelopmental disorder diagnoses

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*List of additional members of the Trans Youth CAN! Study Group is available at www.jpeds.com (Appendix).

Funded by the Canadian Institutes of Health Research (MOP-148641 [to G.B.]). Canadian Institutes of Health Research played no role in the design, conduct, writing, or submission decisions for this study. The authors declare no conflicts of interest.

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<https://doi.org/10.1016/j.jpeds.2021.11.020>

included autism, obsessive compulsive disorder, or attention deficit hyperactivity disorder. Gender dysphoria symptoms were assessed using the Trans Youth CAN! Gender Distress Scale.²⁴ Self-reported mental health behaviors included self-harm, substance use, and suicidal behavior. Three measures captured social connections to online and trans communities: having gender-supportive online friends was coded if adolescents reported online friends who knew their gender and were “very supportive,” and having online or trans friends as general sources of support was indicated in checklist items. Parental support was coded if youth indicated all biological/step/foster parents were “very supportive” of their gender identity or expression.

Statistical analyses were conducted using SAS v 9.4.1 (SAS Institute, Inc), weighted to account for clinics’ different recruitment periods due to staggered start dates, to improve generalizability.¹⁸ For analyses of associations between recency of gender knowledge and hypothesized correlates, a series of multiple regressions was conducted, with recency as the independent variable of interest, controlling for age and sex assigned at birth. Linear regressions were used for continuous dependent variables (eg, psychometric scales). For dichotomous dependent variables, modified Poisson regression with robust variance estimation was used.²⁵ As “rapid-onset” has not been precisely defined, we conducted a sensitivity analysis repeating these analyses using the alternate (value ≤ 2) definition of recent gender knowledge.

Results

Recency of gender knowledge is presented in the [Figure](#), results of hypothesized associations (recency value ≤ 1) in [Table I](#), and

variable means and frequencies in [Table II](#) (available at www.jpeds.com). Controlling for age and sex assigned at birth, recent gender knowledge was not significantly associated with depressive symptoms, psychological distress, past diagnoses with mental health issues or neurodevelopmental disorders, gender dysphoria symptoms, self-harm, past-year suicide attempt, having gender-supportive online friends, general support from online friends or transgender friends, or gender support from parents. Recent gender knowledge was associated with lower scores on anxiety severity/impairment ($b = -3.272$; 95% CI $-5.172, -1.373$), and lower prevalence of marijuana use (prevalence ratio = 0.11; 95% CI 0.02, 0.82), counter to hypothesized directions of effect. For sensitivity analysis using the alternate (value ≤ 2) definition of recent gender knowledge, we found all results substantively the same in statistical significance and direction of effect, except past-year marijuana use, which now only approached statistical significance ($P = .0677$).

Discussion

We did not find support within a clinical population for a new etiologic phenomenon of rapid onset gender dysphoria during adolescence. Among adolescents under age 16 years seen in specialized gender clinics, associations between more recent gender knowledge and factors hypothesized to be involved in rapid onset gender dysphoria were either not statistically significant, or were in the opposite direction to what would be hypothesized. This putative phenomenon was posited based on survey data from a convenience sample of parents recruited from websites,¹⁰ and may represent the perceptions or experiences of those parents, rather than of

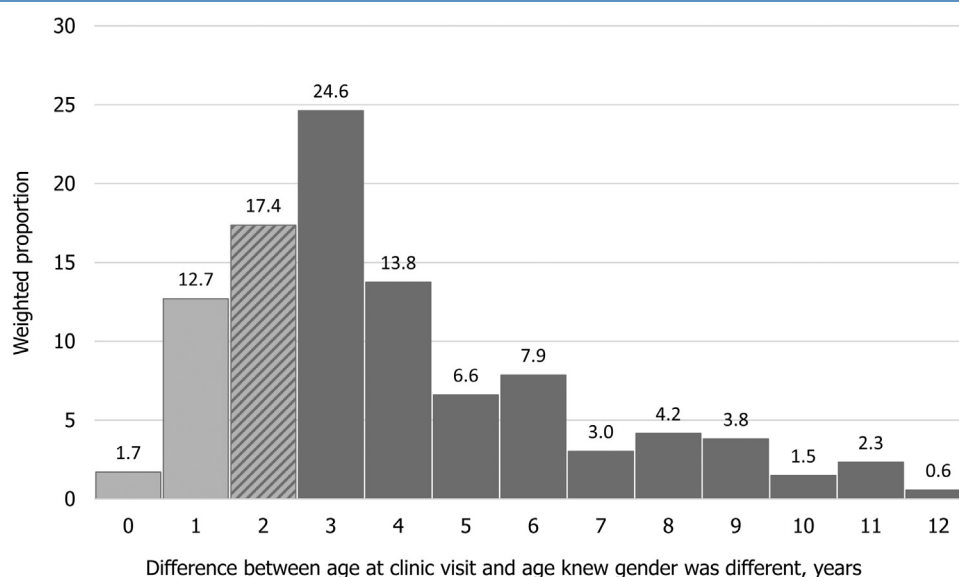


Figure. Recency of gender knowledge among adolescents age <16 years referred to Canadian clinics for hormone suppression or gender-affirming hormones ($n = 173$). Age at which knew gender was different was subtracted from current age in years; thus, “2 years” could range from more than 1 year to less than 3 years. Lighter gray represents recent gender knowledge in this analysis, with a sensitivity analysis also including the patterned bar.

Table I. Associations between short-term awareness of gender and variables hypothesized to be associated with rapid-onset gender dysphoria, controlling for age and sex assigned at birth

Dependent variables	B*	SE	P	PR*	95% CI†
Mental health scales					
Anxiety severity/impairment (OASIS)	−3.272	0.961	.0008		(−5.172, −1.373)
Depressive symptoms (MDS)	−1.276	0.845	.1328		(−2.944, 0.392)
Psychological distress (K6)	−1.156	1.060	.2771		(−3.248, 0.936)
Record of diagnosis with mental health disorder‡	−0.509	0.315	.1059	0.60	(0.32, 1.11)
Record of diagnosis with neurodevelopmental disorder§	0.066	0.362	.8563	1.07	(0.52, 2.17)
Gender dysphoria/distress (TYC-GDS)	−0.193	0.122	.1139		(−0.434, 0.047)
Mental health related behaviors					
Self-harm, past year	−0.052	0.191	.7833	0.95	(0.65, 1.38)
Marijuana use, past year	−2.178	1.010	.0310	0.11	(0.02, 0.82)
Past-year suicide attempt	−0.592	0.785	.4505	0.55	(0.12, 2.58)
Social connection indicators¶					
Reports having online friends supportive of gender	−0.050	0.157	.7505	0.95	(0.70, 1.29)
Indicates online friends as source of general support	−0.223	0.286	.4366	0.80	(0.46, 1.40)
Indicates trans friends as source of general support	−0.049	0.298	.1016	0.61	(0.34, 1.10)
All parents supportive of gender identity/expression	−0.004	0.202	.9836	1.00	(0.67, 1.48)

B, beta regression; K6, Kessler-6 Scale; MDS, Modified Depression Scale; OASIS, Overall Anxiety Severity and Impairment Scale; PR, prevalence ratio; TYC-GDS, Trans Youth CAN! Gender Distress Scale.

*Estimates adjusted for age in years and sex assigned at birth.

†95% CIs for betas (for linear regressions) or PRs (for modified Poisson regressions).

‡Extracted from medical record: any diagnosis from clinic or referrer of anxiety, depression, personality disorder, eating disorder. Personality disorder diagnoses were uncommon (n = 2) and no youth had a record of eating disorder diagnosis.

§Extracted from medical record: any diagnosis from clinic or referrer of attention deficit hyperactivity disorder, obsessive compulsive disorder, or autism.

¶Hypothesized by other authors based on a survey of parents recruited from websites generally unsupportive of gender-affirming care.¹⁰

adolescents, particularly those who may enter into clinical care. Similar analyses should be replicated using additional clinical and community data sources. Our finding of lower anxiety severity/impairment scores in adolescents with more recent gender knowledge suggests the potential for longstanding experiences of gender dysphoria (or their social complications) playing a role in development of anxiety, which could also be explored in future research. ■

The Trans Youth CAN! Study Team thank the trans youth and their families who have generously shared their time and experience with us. We acknowledge the contribution of the local site teams to participant recruitment, in particular the team of research assistants involved in data collection.

Submitted for publication Aug 31, 2021; last revision received Oct 8, 2021; accepted Nov 10, 2021.

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What Changed the Prognosis of Juvenile Dermatomyositis?

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The addition of systemic corticosteroids to the treatment of juvenile dermatomyositis played a pivotal role in changing the outcome of this disease. This commentary published 50 years ago summarized the demographic, clinical, laboratory, pathology, treatment, and outcome of 18 children with dermatomyositis seen between 1960 and 1969 in a single center. The medical treatment consisted of systemic corticosteroids with tapering over 2 years. In a previous classic report from 1964,¹ on which we wrote a commentary in 2014,² only 33% were treated with corticosteroids. The outcomes were grim: one-third died, another one-third remained crippled, and only one-third recovered completely. However, in this study merely 8 years later, no deaths from dermatomyositis were recorded. Seventeen of the 18 children were functionally independent after treatment, but 8 of 18 developed calcinosis. Four patients had residual skin scarring, 4 developed mild joint contractures, and 6 had muscle atrophy. It is important to note that most of the cases in this series (13/18) were mild and monophasic, and only 5 patients had dyspnea or dysphagia indicative of a more severe disease, thus contributing to the good prognosis.

Modern aggressive therapy includes corticosteroid-sparing medications. Methotrexate is given as first-line treatment together with corticosteroids. Other medications for severe or chronic disease include intravenous immunoglobulin, calcineurin inhibitors, cyclophosphamide, and biologic modifiers (rituximab and tumor necrosis factor inhibitors). Janus kinase inhibitors have shown promise. Overall, mortality has decreased to 2.5%. However, even today, between 30% and 40% of the patients manifest a chronic disease course with functional impairments and develop calcinosis, and they require long-term immunosuppressive therapy with many potential complications.³ Thus, despite the improvement in prognosis, there is still a long way to optimize treatment of this rare disease. Precision medicine, using specific myositis autoantibodies and analysis of immune pathways in individual patients, may further improve the outcome of our patients.³ In addition, early diagnosis and treatment are key!

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Appendix

Additional members of the Trans Youth CAN! Study Group Members

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Table II. Weighted frequencies or means for sociodemographic and study variables (n = 173)

Variables	Value
Age, n (% _{weighted})	
10-11 y	17 (8.5)
12-13 y	37 (22.6)
14-15 y	119 (68.9)
Ethnoracial background,* n (% _{weighted})	
Indigenous	33 (18.4)
Nonindigenous visible minority [†]	10 (6.6)
Nonindigenous white	128 (75.0)
Immigration background, n (% _{weighted})	
1 or more immigrant parent	126 (28.7)
No immigrant parents	44 (71.3)
Living environment, n (% _{weighted})	
City	87 (55.2)
Suburb	59 (33.9)
Rural	27 (10.9)
Gender identity, n (% _{weighted})	
Male or primarily a boy	125 (75.7)
Female or primarily a girl	32 (15.9)
Nonbinary [‡]	14 (8.3)
Mental health scales, mean _{weighted} (SD)	
Anxiety severity/impairment (OASIS)	8.842 (4.548)
Depressive symptoms (MDS)	15.077 (4.030)
Psychological distress (K6)	10.746 (5.100)
Record of diagnosis with mental health disorder, [§] n (% _{weighted})	92 (51.6)
Record of diagnosis with neurodevelopmental disorder, [¶] n (% _{weighted})	44 (25.9)
Gender dysphoria/distress (TYC-GDS), mean _w (SD)	4.048 (0.557)
Mental health related behaviors, n (% _{weighted})	
Self-harm, past year	110 (67.9)
Marijuana use, past year	29 (20.0)
Past-year suicide attempt	24 (16.9)
Social connection indicators,** n (% _{weighted})	
Reports having online friends supportive of gender	109 (69.9)
Indicates online friends as source of general support	79 (49.3)
Indicates trans friends as source of general support	92 (55.8)
All parents supportive of gender identity/expression	109 (61.8)

K6, Kessler-6 Scale; MDS, Modified Depression Scale; OASIS, Overall Anxiety Severity and Impairment Scale; TYC-GDS, Trans Youth CAN! Gender Distress Scale.

*Coded to match Statistics Canada categories of Indigenous, visible minority, and white. Nonwhite, nonindigenous ethnoracial backgrounds were indicated by the following numbers of participants: 6 Black Canadian or African American, 2 Black African, 4 Latin American, 4 East Asian, 1 Indo-Caribbean, 3 Black Caribbean, 1 Middle Eastern, and 1 Southeast Asian (participants could indicate more than 1).

†The Canadian government defines visible minorities as “persons, other than Aboriginal peoples, who are non-Caucasian in race or nonwhite in color.”²⁶

‡Response option was “nonbinary or something other than male or female.”

§Extracted from medical record: any diagnosis from clinic or referrer of anxiety, depression, personality disorder, eating disorder. Personality disorder diagnoses were uncommon (n = 2) and no youth had a record of eating disorder diagnosis.

¶Extracted from medical record: any diagnosis from clinic or referrer of attention deficit hyperactivity disorder, obsessive compulsive disorder, or autism.

**Hypothesized by other authors based on a survey of parents.¹⁰

Exhibit Q

**IN THE UNITED STATES DISTRICT COURT
FOR THE NORTHERN DISTRICT OF FLORIDA
TALLAHASSEE DIVISION**

AUGUST DEKKER, et al.,

Plaintiffs,

v.

JASON WEIDA, et al.,

Defendants.

Case No. 4:22-cv-00325-RH-MAF

**REBUTTAL EXPERT REPORT OF
STEPHEN B. LEVINE, M.D.**

Detransition

30. There now exists a growing awareness of detransition after affirmative care. The assumption that this was a rare occurrence began to lose traction when it was realized that 16,000 individuals had been on a detransition website, many of whom wrote of their process. (Exposito-Campos, 2021). Then, three studies approximating the rate of detransition within 16 months to five years were published (Hall et al., 2021; Boyd et al., 2022; Roberts et al., 2022). In March 2022, an international detransition day was held. Most recently, an abstract of research found that within a 36-month period, 64% of trans adolescents fluctuated in their gender identities. This brings us to the important question of the natural history of childhood onset and adolescent onset of gender dysphoria. Natural history means what happens to these individuals if they are not affirmatively treated.

31. Beginning on paragraph 85 of his report, Dr. Karasic goes to great length to undermine Dr. Cantor's report of 11 studies of the follow up of trans-identified children, each of which reported that the majority of these boys and girls outgrew their earlier trans sense of self (Cantor, 2020). Dr. Karasic demeans Dr. Cantor's observations in part because of his research on pedophilia and that he said in a legal document he does not deal with young children. Dr. Cantor, a respected scholar, pointed out the fact that the American Academy of Pediatrics' (AAP) 2018 recommendations for affirmative treatment of children (social transition only) was

reasons did not obtain affirmative care (typically too impaired psychiatrically). A previous Dutch study showed that almost the entire group was no longer trans (Smith et al., 2001).

I declare under penalty of perjury, pursuant to 28 U.S.C. § 1746, that the foregoing is true and correct.

Executed this 10th day of March 2023.

/s/ Stephen B. Levine

Stephen B. Levine, M.D.

Exhibit R

IN THE UNITED STATES DISTRICT COURT
FOR THE WESTERN DISTRICT OF WEST VIRGINIA
CHARLESTON DIVISION

B.P.J. by her next friend and)
mother, HEATHER JACKSON,)

Plaintiff,)

vs.)

No. 2:21-cv-00316

WEST VIRGINIA STATE BOARD OF)
EDUCATION, HARRISON COUNTY)
BOARD OF EDUCATION, WEST)
VIRGINIA SECONDARY SCHOOL)
ACTIVITIES COMMISSION, W.)
CLAYTON BURCH in his official)
capacity as State)
Superintendent, DORA STUTLER,)
in her official capacity as)
Harrison County)
Superintendent, and THE STATE)
OF WEST VIRGINIA,)

Defendants,)

LAINIEY ARMISTEAD,)

Defendant-Intervenor.)

VIDEOTAPED DEPOSITION OF
STEPHEN LEVINE
Wednesday, March 30, 2022
Volume I

Reported by:
ALEXIS KAGAY
CSR No. 13795
Job No. 5122884
PAGES 1 - 289

IN THE UNITED STATES DISTRICT COURT
FOR THE WESTERN DISTRICT OF WEST VIRGINIA
CHARLESTON DIVISION

B.P.J. by her next friend and
mother, HEATHER JACKSON,

Plaintiff,

vs.

No. 2:21-cv-00316

WEST VIRGINIA STATE BOARD OF
EDUCATION, HARRISON COUNTY
BOARD OF EDUCATION, WEST
VIRGINIA SECONDARY SCHOOL
ACTIVITIES COMMISSION, W.
CLAYTON BURCH in his official
capacity as State
Superintendent, DORA STUTLER,
in her official capacity as
Harrison County
Superintendent, and THE STATE
OF WEST VIRGINIA,

Defendants,

LAINIEY ARMISTEAD,

Defendant-Intervenor.)

Remote videotaped deposition of
STEPHEN LEVINE, Volume I, taken on behalf of Plaintiff,
with all participants appearing remotely, beginning at
9:09 a.m. and ending at 5:46 p.m. on Wednesday,
March 30, 2022, before ALEXIS KAGAY, Certified
Shorthand Reporter No. 13795.

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15 Also Present:

16 MITCH REISBORD - VERITEXT CONCIERGE

17

18 Videographer:

19 KIMBERLEE DECKER

20

21

22

23

24

25

1 Q Why don't you give me your estimate of how
2 many prepubertal children you've ever seen as patients,
3 and then we can ask more questions.

4 A I would say a handful. Six.

5 Q And how many of those -- of those 11:15:35
6 approximately six did you see more than one time?

7 A I can't recall one.

8 Q And then I'll ask the same question about
9 adolescents, which I'll mean minors from puberty
10 through being a minor. 11:16:00

11 How many adolescent patients have you had in
12 your career, approximately?

13 A 50.

14 Q And how many of those have you seen more than
15 once? 11:16:14

16 A Most.

17 Q And were most of those, of the adolescent
18 patients you've seen, late adolescence?

19 A No.

20 Q Turning back to your CV, you list yourself -- 11:16:27
21 you're listed as a clinical professor at Case Western
22 Reserve University School of Medicine; correct?

23 A Yes.

24 Q Do you work at Case Western Reserve University
25 School of Medicine full-time? 11:16:51

1 three months because I'm part of a committee to plan
2 the curriculum on sexuality and gender.

3 Speaking of education, the university --
4 other -- other institutions also asked me to teach
5 about this subject. And on August -- on April 7th, I'm 12:07:39
6 going to Akron to teach -- or virtually I'm going to
7 teach a three -- a two-and-a-half-hour seminar.

8 And I forgot to mention to you before, and I'd
9 like you to hear this, that when you were questioning
10 me about my credentials or not having a certificate 12:07:57
11 about -- in child psychiatry, you should know, I forgot
12 to tell you that Cleveland Clinic, department of child
13 psychiatry, and the University Hospitals, the
14 department of child psychiatry, sends residents to be
15 with me as part of their training in child development 12:08:18
16 and child clinical issues, child and adolescent
17 clinical issues.

18 So I think -- I just forgot to mention that.

19 Q Are you familiar with the University
20 Hospitals' LGBTQ and gender care program? 12:08:48

21 A I'm aware that it exists, yes.

22 Q Have you ever talked to any clinicians in that
23 practice?

24 A No one has ever talked to me in that practice.

25 The only time I have interaction with them is when -- 12:09:00

1 if I present grand rounds, some of those people ask me
2 a question. But they've never consulted me whatsoever
3 in the formation of their clinic and in the ongoing
4 work of their clinic.

5 Although, Cleveland Clinic has a very similar 12:09:20
6 program, and they have called me up and -- for some
7 advice sometimes.

8 But my -- my, quote, own University Hospitals'
9 place I don't really think has any people from child
10 psychiatry in it, but I'm not sure because they have 12:09:38
11 kept me away.

12 Q What do you mean they have kept you away?

13 A Just what I explained. They have never
14 communicated with me. It is -- you know, other people
15 know me as being published in this area. You know, I 12:09:54
16 think I've written 20 articles on this -- you know, I
17 have 20 or so publications in this area. You would
18 think that they would invite me or consult with me or
19 ask me questions, but I think they recognized that they
20 are part of what is called affirmative care and what I 12:10:18
21 would say, rapidly affirmative care, and -- and they
22 sense that I'm not so interested in rapid, that -- that
23 I believe that -- that I have long believed that people
24 who have this kind of dilemma need some patient time in
25 talking about this matter. 12:10:45