IN THE UNITED STATES DISTRICT COURT
FOR THE MIDDLE DISTRICT OF NORTH CAROLINA

MAXWELL KADEL, *et al.*, *Plaintiffs*, v. DALE FOLWELL, in his official capacity as State Treasurer of North Carolina, *et al.*, *Defendants*.	Case No. 1:19-cv-00272-LCB-LPA

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

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I. STATEMENT OF THE CASE AND FACTUAL BACKGROUND

Plaintiffs, all current or former employees, or dependents of current or former employees, of certain North Carolina public Universities ("NC Universities") or the North Carolina Department of Safety ("NCDPS") filed an Amended Complaint with this Court on March 12, 2021 challenging a discriminatory exclusion in the North Carolina State Health Plan for Teacher and State Employees ("State Health Plan").

Plaintiffs contend that the State Health Plan's exclusion of coverage for gender-confirming healthcare treatment violates their equal protection rights and discriminates against them based on their sex in violation of Title IX and the Affordable Care Act.

II. QUESTION PRESENTED

Whether the testimony of Stephen B. Levine, M.D.,[1] should be excluded because it is irrelevant and unreliable in accordance with *Daubert* v. *Merrell Dow Pharm. Inc.*, 509 U.S. 579 (1993) and the applicable Federal Rules of Evidence.

III. SUMMARY OF THE ARGUMENT

Dr. Levine's proffered opinions fall into three categories of exclusion. First, most of Dr. Levine's opinions are irrelevant because they are not in opposition to the relief Plaintiffs seek and instead align with Plaintiffs' experts. Second, Dr. Levine's opinions fail to create any material disputes of fact because the relevance of his opinions are outside the scope of the parties' dispute which is simply whether an insurance plan can exclude coverage for some people that it does not exclude for others. Further, his opinions cover

[1] Declaration of Stephen B. Levine, M.D., signed April 28, 2021, is attached as Exhibit A to the concurrently filed Declaration of Carl S. Charles ("Charles Decl.").

topics already addressed by Fourth Circuit precedent including the appeal in this case, *Kadel v. N. Carolina State Health Plan for Tchrs. & State Emps.*, 12 F.4th 422 (4th Cir. 2021) and *Grimm v. Gloucester Cnty. Sch. Bd.*, 972 F.3d 586 (4th Cir. 2020), as amended (Aug. 28, 2020), *cert. denied*, 141 S. Ct. 2878 (2021). Third, Dr. Levine's remaining opinions must be excluded because they are unreliable, not based on scientific methodology but rather untested hypotheses, pure speculation, and beliefs that lack any support besides Dr. Levine's own *ipse dixit*. As Dr. Levine's opinions should be excluded pursuant to *Daubert* standards, and – when viewed in the context of Federal Rule of Evidence 403, any probative value is substantially outweighed by the danger of unfair prejudice, confusion of issues confusion of the issues, waste of time, undue delay and needless presentation of cumulative evidence – this Court must exclude them.

Relevant to this Court's consideration is other federal courts' resounding dismissal of Dr. Levine's opinions about transgender people and the treatment of gender dysphoria. This began seven years ago with the holding in *Norsworthy v. Beard*, 87 F. Supp. 3d 1164, 1188–89 (N.D. Cal. 2015) 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." This holding was echoed in *Edmo v. Idaho Dep't of Corr*. 358 F. Supp. 3d 1103, 1125-1126 (D. Idaho 2018) (vacated in part on other grounds in *Edmo v.*

Corizon, Inc., 935 F.3d 757 (9th Cir. 2019)) (holding that Dr. Levine "is an outlier in the field of gender dysphoria" and place[s] "virtually no weight" on his opinions.).

Dr. Levine's opinions were further diminished 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). And in this year alone, two more federal courts strongly discounted his proffered testimony by granting preliminary injunction motions against laws banning gender-confirming medical care and participation in school athletics, respectively. *Brandt v. Rutledge*, No. 4:21CV00450 JM, 2021 WL 3292057 (E.D. Ark. Aug. 2, 2021); *B. P. J.* v. *W. Virginia State Bd. of Educ.*, No. 2:21-CV-00316, 2021 WL 3081883 (S.D.W.Va. July 21, 2021).

IV. ARGUMENT

A. Legal Standard

Federal Rule of Evidence 702 places "a special gatekeeping obligation" on a trial court to ensure that an expert's testimony is "relevant to the task at hand" and "rests on a reliable foundation." *Daubert*, 509 U.S. at 597; *Sardis v. Overhead Door Corp.*, 10 F.4th 268, 281 (4th Cir. 2021); *see* Advisory Committee Note to 2000 Amendments to Rule 702 (amendment "affirms the trial court's role as gatekeeper," and that "all types of expert testimony present questions of admissibility for the trial court in deciding whether the evidence is reliable and helpful"). The party offering the expert carries the burden of

establishing the admissibility of testimony by a preponderance of the evidence. *Cooper v. Smith & Nephew, Inc.*, 259 F.3d 194, 199 (4th Cir. 2001).

The initial step is to determine whether the proposed expert is qualified to render the proffered opinion. In doing so, a trial court considers an expert's professional qualifications and "full range of experience and training." *Belk, Inc. v. Meyer Corp., U.S.*, 679 F.3d 146, 162 (4th Cir. 2012), *as amended* (May 9, 2012) (cleaned up). If the purported expert lacks the knowledge, skill, experience, training or education on the issue for which the opinion is proffered, the trial court must exclude the expert. *See, e.g., Thomas J. Kline, Inc. v. Lorillard, Inc.*, 878 F.2d 791, 799 (4th Cir. 1989); *Mod. Auto. Network, LLC v. E. All. Ins. Co.*, 416 F. Supp. 3d 529, 537 (M.D.N.C. 2019) (Biggs, J.), *aff'd*, 842 F. App'x 847 (4th Cir. 2021). Even if the expert is deemed qualified, the trial court must consider the relevancy of the expert's testimony as "a precondition to admissibility." *Sardis*, 10 F.4th at 282 (cleaned up). To be relevant, the testimony must have "a valid scientific connection to the pertinent inquiry." *Id.* at 281 ("Simply put, if an opinion is not relevant to a fact at issue, *Daubert* requires that it be excluded.").

Finally, if deemed relevant, the trial court will inquire if the opinion is based on a reliable foundation, which focuses on "the principles and methodology" employed by the expert to assess whether it is "based on scientific, technical, or other specialized *knowledge* and not on belief or speculation." *Id.* at 281, 290 (cleaned up). When evaluating whether an expert's methodology is reliable, a court considers, among other things:

> (1) whether the expert's theory can be and has been tested; (2) whether the theory has been subjected to peer review and publication; (3) the known or

> potential rate of error of the particular scientific technique; and (4) whether the technique is generally accepted in the scientific community.

Id.; *see also Kumho Tire Co., Ltd. v. Carmichael*, 526 U.S. 137, 149-150 (1999); *Daubert,* 509 U.S. at 593-94. While trial courts have "broad latitude" to determine reliability, they must engage in the gatekeeping process and not simply "delegate the issue to the jury." *Sardis*, 10 F.4th at 281.

In certain situations, when an expert relies upon his experience and training, and not a specific methodology, the application of *Daubert* is more limited. *See Freeman v. Case Corp.*, 118 F.3d 1011, 1016 n.6 (4th Cir. 1997). When addressing an expert whose methodology is grounded in experience, courts use three factors: "1) how the expert's experience leads to the conclusion reached; 2) why that experience is a sufficient basis for the opinion; and 3) how that experience is reliably applied to the facts of the case." *SAS Inst., Inc. v. World Programming Ltd*., 125 F. Supp. 3d 579, 589 (E.D.N.C. 2015); *see also Nat'l Ass'n for Rational Sexual Offense L. v. Stein*, No. 1:17-cv-53, 2021 WL 736375, at *3 (M.D.N.C. Feb. 25, 2021) (Biggs, J.).

Finally, because "expert evidence can be both powerful and misleading because of the difficulty in evaluating it," "the 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). As such, "the importance of [the] gatekeeping function cannot be overstated." *Sardis*, 10 F.4th at 283 (cleaned up).

B. Many of Dr. Levine's Opinions Have No Relevance To This Case Because They Are Consistent With Plaintiffs' Position.

Nearly all of Dr. Levine's opinions are not relevant and will not help the "trier of fact to understand the evidence or to determine a fact in issue," because, with very limited exception, he simply does not oppose the relief plaintiffs seek. *Nease*, 848 F.3d at 229. For that reason, Dr. Levine's opinions do not "fit" with the facts relevant to resolving Plaintiffs' claims. *Bourne v. E.I. DuPont de Nemours & Co.*, 85 F. App'x 964, 966 (4th Cir. 2004); *Viva Healthcare Packaging USA Inc. v. CTL Packaging USA Inc.*, 197 F. Supp. 3d 837, 846 (W.D.N.C. 2016) ("The test for relevance, or 'fit,' considers 'whether expert testimony proffered in the case is sufficiently tied to the facts of the case that it will aid the jury in resolving a factual dispute.'" (quoting Daubert, 509 U.S. at 591)).

Overwhelmingly, Dr. Levine's opinions align with the relief Plaintiffs seek in this case: that adolescents and adults with gender dysphoria receive and be able to access and afford individualized medical treatments. Charles Decl., Ex. B at 66:21-67:3; 69:18-70:2. For almost fifty years, Dr. Levine's clinical practice has notably adhered to the medical community's widely accepted and authoritative guidance for transgender care, the World Professional Association of Transgender Health ("WPATH") Standards of Care ("SOC"). Charles Decl., Ex. C at 1-100:15-22. As the WPATH's former Chairman of the SOC Committee, Dr. Levine helped to write Version 5 of the WPATH SOC, recognized his own writing in Version 7, and asked if he could help draft the forthcoming Version 8. Charles Decl., Ex. A at ¶3; Ex. D at 37:17-38:7; Ex. C at 1-90:10-20. In accordance with the SOC,

he provides individualized treatment including providing letters of recommendation for gender affirming surgeries and hormone therapy. Charles Decl., Ex. B at 55:13-17; 56:2-5; 112:16-21; 176:8-16. He does not provide such letters unless he has sufficiently informed patients and received a reasonable assurance that they understand. Charles Decl., Ex. B at 176: 8-16; 225:24-226:17. He testified repeatedly that he "is not advocating denying endocrine treatment or surgical treatment" to transgender people, a position he described as "draconian."[2]

Dr. Levine admitted at deposition that he is "not an expert in health insurance," nor an expert about what "health insurance should or should not cover." Charles Decl., Ex. B at 86:1-8. But he supported the idea that patients should be able to access and afford treatment for gender dysphoria.[3] *Id.* at 66:21-67:3. Dr. Levine also confirmed that he has not met with or interviewed any of the Plaintiffs and is not offering any opinions about them, including the veracity of their symptoms of gender dysphoria, the accuracy of their

[2] Charles Decl., Ex. B 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.").

[3] And testified at deposition only nine months earlier that treatment should be afforded through insurance coverage if necessary. Charles Decl., Ex. G at 156:10-157:17.

diagnoses, their mental health histories, or the effects of any treatment they have received. Charles Decl., Ex. A at ¶128; Ex. B at 91:5-92:5. None of these opinions are oppositional to relief Plaintiffs seek, and therefore are not relevant to the issues before this Court. Additionally, his uncertainty about the percentage of transgender people who experience gender dysphoria, ECF No. 137-8, 241:24-242:14, has no relevance to the transgender plaintiffs before the Court who *do* requirement treatment. And his speculation about people "who present themselves as cis gender" but may have cross-gender identification and "really dangerous degrees of substance abuse" is completely untethered to the claims here. ECF No. 137-8, 242:15-243:20.

C. Certain Opinions of Dr. Levine Have No Relevance To This Case Because They Address Issues Beyond The Scope Of The Dispute Or Have Already Been Decided By The Fourth Circuit.

Dr. Levine's opinions fail to create any material disputes of fact because the relevance of his opinions has been disclaimed by the binding admissions of Defendants' witnesses. For example, Dr. Levine proposes to offer the opinion that "sex as defined by biology and reproductive function cannot be changed." Charles Decl., Ex. A at ¶8(a), ¶12. But this is simply an insurance dispute asking whether a state health plan's categorical exclusion of care for transgender people that is covered for cisgender people discriminates based on sex and transgender status. The Court need not resolve questions about the etiology of sex or being transgender, whether "sex is permanently assigned at conception," or, frankly, whether it is okay for a person to be transgender. *Id*. at ¶9. The Court here need only decide whether this insurer can deny the same kinds of treatments to transgender

people that it affords to cisgender people. The Fed. R. Civ. P. 30(b)(6) witness for the health plan, Dee Jones, agrees. She testified that individuals enrolled in the State Health Plan can change their sex identification marker in the Plan's records by simply calling into the call center, talking to a representative, validating their identity and requesting the change. Charles Decl., Ex. E at 85:10-87:22. She further testified that to make such a change the Plan does not require proof of the enrollee's current physical anatomy, their DNA, or their chromosomal make up. *Id*. The Plan thus takes no position on the issues in Dr. Levine's report about the etiology of sex, and instead respects participants' self-reported gender identity as an accurate determinant of their sex designation. Facts provided by Defendants' own witnesses render Dr. Levine's proposed opinions about "immutable biology" irrelevant.

Dr. Levine's opinions do not help this Court because the Fourth Circuit's precedent informs review of the issues. Controlling precedent on these issues in the recently decided *Grimm v. Gloucester Cnty. Sch. Bd.* and the Fourth Circuit appeal in this case render Dr. Levine's opinions irrelevant. His attempts to disparage the credibility of the WPATH and diminish the SOC as ideological and unscientific fail and are ironically contrary to his testimony about treatment he provides transgender patients in private practice, which follows the SOC. Charles Decl., Ex. B at 55:13-17; 56:2-5; 112:16-21; 176:8-16; 225:24-226:17. Further, this "opinion" is directly contrary to the Fourth Circuit's holding in *Grimm*:

> Fortunately, we now have modern accepted treatment protocols for gender dysphoria. Developed by the World Professional Association for Transgender

> Health (WPATH), the Standards of Care for the Health of Transsexual, Transgender, and Gender Nonconforming People (7th Version 2012) (hereinafter "WPATH Standards of Care") represent the consensus approach of the medical and mental health community, Br. of Medical Amici 13, and have been recognized by various courts, including this one, as the authoritative standards of care, see *De'lonta v. Johnson*, 708 F.3d 520, 522–23 (4th Cir. 2013); see also *Edmo*, 935 F.3d at 769; *Keohane v. Jones*, 328 F. Supp. 3d 1288, 1294 (N.D. Fla. 2018), vacated sub nom. *Keohane v. Fla. Dep't of Corrs. Sec'y*, 952 F.3d 1257 (11th Cir. 2020). There are no other competing, evidence-based standards that are accepted by any nationally or internationally recognized medical professional groups." *Edmo*, 935 F.3d at 769 (quoting *Edmo v. Idaho Dep't of Corr*., 358 F. Supp. 3d 1103, 1125 (D. Idaho 2018)).

Grimm, 972 F.3d at 595-596. Further irreconcilable with available data and the consensus of the medical community, Dr. Levine asserts that gender dysphoria is a psychiatric condition, and "educational failure, vocational inconstancy and social isolation" are "clinical errors" of gender confirming treatment. Charles Decl., Ex. A at ¶8(m), ¶23. The Fourth Circuit disagrees, holding that: "Being transgender is also not a psychiatric condition, and implies no impairment in judgment, stability, reliability, or general social or vocational capabilities." *Grimm*, 972 F.3d at 594 (quote marks omitted); *see also*, *Kadel*, 12 F.4th at 427. Dr. Levine espouses the belief that gender dysphoria, or being transgender, is a way of living that people commit to in youth and is a "product of other things," including possibly familial sexual abuse, distress over "their body changing," growing up in a single-parent home, or having an autism diagnosis. Charles Decl., Ex. B at 154:5-8; 235:23-25; 137:10-13; 235:20-22; 235:17-20. Here too, the Fourth Circuit has held conclusively that "[J]ust like being cisgender, being transgender is natural and is not a choice." (*Kadel*, 12 F.4th at 427 (quoting *Grimm*, 972 F.3d at 594)). Dr. Levine admits to

practicing and advocates for the use of "conversion therapy" with transgender youth,[4] but the Fourth Circuit has found that "mental health practitioners' attempts to convert transgender people's gender identity to conform with their sex assigned at birth did not alleviate dysphoria, but rather caused shame and psychological pain." (*Grimm*, 972 F.3d at 595). Fourth Circuit precedent renders much of Dr. Levine's testimony irrelevant.

D. Dr. Levine's Testimony Is Methodologically Unreliable and Unsupported by Science or Medicine.

Expert testimony should only be admitted if its methodology is sufficiently reliable. *Sardis*, 10 F.4th at 281. Dr. Levine's opinions fall far short of each prong of this reliability standard. Dr. Levine admitted at deposition 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. B at 109:20-25; 116:4-7; 122:8-124:22; 131:11-132:1; 200:11-201:25. As such, Dr. Levine cannot and does not offer the known or potential error rates, and perplexingly asserts without any evidence whatsoever that his views are accepted and shared by the amorphous and unspecific "scientific community." Charles Decl., Ex. A at ¶9, ¶10, ¶11, ¶12, ¶13, ¶23 ¶48, ¶121.

Even putting the *Daubert* factors aside, as Dr. Levine claims 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. *See, e.g., Cooper,* 259 F.3d at 200 (affirming the exclusion of an expert because he "asserted

[4] Charles Decl., Ex. A at ¶31, ¶18, ¶119.

what amounted to a wholly conclusory finding based upon his subjective beliefs rather than any valid scientific method."); *SAS Inst.*, 125 F. Supp. 3d at 589; *see also Nat'l Ass'n. for Rational Sexual Offense L*. at *3 (excluding expert where offering party failed to establish how expert's "experience leads to his conclusions nor how those experiences have been reliably applied to the facts").

1. Dr. Levine's Assertion that There are Widely Varying Views about the Appropriate Treatment for Gender Dysphoria Is Simply Wrong.

Chief among Dr. Levine's many unreliable opinions is his assertion that wide disagreement exists about the appropriate treatment for gender dysphoria and that the SOC are not accepted by the scientific community. Charles Decl., Ex. A at ¶8(c). Contrary to Dr. Levine's personal feelings, there ***is broad consensus*** about the appropriate treatment for gender dysphoria. All major medical associations, the largest health systems in the United States (Department of Veterans Affairs, Kaiser-Permanente, the Federal Bureau of Prisons), and most major health insurers endorse and follow the treatment protocols established by the WPATH in the SOC Version 7. Charles Decl., Ex. F at ¶27. This factual reality, combined with Dr. Levine's *own admissions* about his use of the WPATH treatment protocols calls into serious question the reliability of this proffered opinion. Charles Decl., Ex. B at 55:13-17; 56:2-5; 112:16-21; 176:8-16; 225:24-226:17. Dr. Levine even admitted this in his most recent prior deposition in December 2020, acknowledging that he continues to utilize the WPATH SOC when writing letters to authorize hormones or surgery for someone with gender dysphoria. Charles Decl., Ex. G at 29:10-18; 37:2-13; 47:22-49:3;

103:11-19. At the *Claire* deposition, Dr. Levine confessed that he does not dispute that the WPATH SOC is widely accepted, but just maintains, without evidence, that they are "wrong," even though his clinical care continues to be consistent with these standards. Charles Decl., Ex. G at 145:16-24; Charles Decl., Ex. B at 55:13-17; 56:2-5; 112:16-21; 176:8-16; 225:24-226:17; Ex. G at 103:11-19. Dr. Levine fails to show how his experience leads to this conclusion, and when applied to the present facts, he cannot bridge the analytic gap.

2. Dr. Levine's Opinion That Accessing Gender-Confirming Care Is Experimental and Unethical is Unfounded.

Dr. Levine alleges that because transgender adults face increased vulnerability to negative life outcomes, providing any "affirmation treatments," particularly to adolescents, is experimental and unethical. Charles Decl., Ex. A at ¶8(k), ¶81. This opinion cannot satisfy the reliability standard because Dr. Levine authorizes this care for his own patients and either ignores studies contrary to his belief or distorts them beyond the authors' explicit intentions or design. Significantly, he omits recent studies demonstrating that medical treatments for transgender adolescents and adults have favorable outcomes across many measures. Charles Decl., Ex. F at ¶79. A plethora of studies also show that trans people experience pervasive stigma and discrimination, resulting in health disparities. But Dr. Levine baselessly claims that receiving gender-confirming care *causes* those disparities and is therefore experimental, relying most heavily on two articles which do not support this assertion. Charles Decl., Ex. A at ¶74. First, he relies on a study by Cecilia Dhejne, a

scholar in the field who has publicly and specifically said Dr. Levine's assertion is a mischaracterization of her work. Charles Decl., Ex. H at 65. Her study also does not support his assertion because *the study itself* states it is not designed to "evaluate whether or not gender affirming care is beneficial." Charles Decl., Ex. I at 2. And when confronted at deposition, he admitted the study design created a serious limitation in drawing any conclusions about the efficacy of the care. Charles Decl., Ex. B at 156:7-11. The second study that Dr. Levine misrepresents to support his claim that gender confirming care is experimental reached a similar conclusion to Dhejne's. Despite this, Dr. Levine implies that the article demonstrates higher death rates among people who received gender-confirming surgery, but the article itself precisely states that "the present study design does not allow for determination of causal relations between HT (hormone therapy) and SRS (sex reassignment surgery) and somatic morbidity or mortality." Charles Decl., Ex. J at e65-e66.

Ultimately, Dr. Levine fails to cite any literature that supports this belief, and regardless, he confirmed that this should not prevent Plaintiffs from receiving the relief they seek. When asked 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. B at 151:25-152:6. And when asked if all the concerns he has are justifications for denying medical interventions to all people with gender dysphoria, he responded "I'm not advocating denying endocrine treatment or surgical treatment." Charles Decl., Ex. B at 85:4-11.

3. Dr. Levine's Opinions About Gender Dysphoria in Transgender Children and Puberty-Delaying Treatment Are Not Based In Fact.

Another unreliable opinion presented by Dr. Levine is that "a majority" of pre-pubescent children diagnosed with gender dysphoria will cease to be transgender. Charles Decl., Ex. A at ¶8(d); Charles Decl., Ex. B at 178:17-24. This opinion is undermined by Dr. Levine's admission at deposition that some children are transgender and that as they progress into adolescence, they would need medical care that he has, and would, authorize. Charles Decl., Ex. B. at 173:7-15; 137:14-23; 173:22-174:5; 53:16-54:7. Dr. Levine glosses over the lack of peer-reviewed and scientific evidence to support his opinion by providing only vague references to "science articles," and "eleven studies," that support his belief. Charles Decl., Ex. B at 178:17-24. Upon closer inspection, this "evidence" falls apart. Dr. Levine could not name eleven studies, but rather only one article from 2019 which purportedly listed those studies. Charles Decl., Ex. B at 191:20-192:7. But all studies used to support this conclusion suffer from the same malady: they analyze data from children identified under the obsolete and overly broad diagnosis for "Gender Identity Disorder in Children" and not the current DSM-5 diagnostic criteria "Gender Dysphoria in Children." Dr. Levine then notes "the latest one" of the "eleven studies" was published in 2021 by Singh. *Id*. But not only does Singh's article suffer the same infirmity as the "eleven studies," but it also analyzes data initially collected *30 years ago*, with children diagnosed under criteria from the DSM III, which is now four versions old. Charles Decl., Ex. B at 192:5-14. Therefore, the "desistance" rates Dr. Levine discusses reflect children who might

have exhibited gender non-conforming behaviors but did not necessarily identify as transgender and *would not satisfy the current diagnostic criteria*. Charles Decl., Ex. K at ¶89. This illustrates Dr. Levine manipulating available research to assert his personal views as unreliable "opinions."

Dr. Levine's most strikingly unreliable opinion is his testimony at deposition that puberty blockers should not be available to any transgender adolescents.[5] Charles Decl., Ex. B at 184:14-18; 187:8-11. Dr. Levine's methodological and scientific support for this opinion is woefully insufficient. He states that in the cases he has seen, puberty blocking treatment was "like a treatment for the mother's pathology, not for the child." Charles Decl., Ex. B at 184:25-185:2. He asserts, without evidence, that the cause of gender dysphoria is related to "acting out the ambitions of the mother or father," and puberty "lead[s] to desistance in many, many children." Charles Decl., Ex. B at 185:7-16. If it were up to Dr. Levine, he 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. B at 186:20-25. Taken together with Dr. Levine's view that parents

[5] It is contradictory and newly formed. Dr. Levine's report states, "it is not possible to make a single, categorical statement about the proper treatment of children presenting with gender dysphoria," and yet this new opinion does just that. Charles Decl., Ex. A at ¶43. And a mere nine months earlier, Dr. Levine sat for deposition and opined the exact opposite, i.e., puberty blockers should be available in limited cases "[w]here we had a healthy mother and father, an intact family who was psychologically informed and who has – where a child has come out of toddlerhood acting consistently in a gender atypical fashion, and where the parents are not homophobic people." Charles Decl., Ex. G at 158:6-16.

should be able to subject their children to conversion therapy "to assist their child to achieve comfort with the gender corresponding to his or her sex" assigned at birth, this makes clear that Dr. Levine's believes transgender people should not exist, an opinion he cannot connect to any meaningful data, and that is not reliably applied to the facts of this case. Charles Decl., Ex. A at ¶119. Even Dr. Levine admits the unscientific nature of this opinion, 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. B at 187:20-24.

4. Dr. Levine's Assertion that "Social Contagion," "Rapid Onset Gender Dysphoria," and "Involvement With the Internet," as Causes for Gender Dysphoria Justify Denying Treatment to Transgender People Is Not Supported By Scientific Evidence.

A stark example of Dr. Levine's opinions failing to meet methodological reliability is his assertion that the untested and scientifically unsupported hypotheses of "social contagion," "rapid onset gender dysphoria" and "involvement with the Internet," justifies denying treatment to transgender adolescents and adults. Charles Decl., Ex A at ¶15. "[W]hile hypothesis is essential in the scientific community because it leads to advances in science, speculation in the courtroom cannot aid the fact finder in making a determination … ." *Dunn v. Sandoz Pharms. Corp.*, 275 F. Supp. 2d 672, 684 (M.D.N.C. 2003). Dr. Levine conceded that "social contagion" has not even been tested, let alone proven and could not provide a single citation to a scientific source discussing the theory in any research study. Charles Decl., Ex. A at ¶122(f); Charles Decl., Ex. B at 114:8-11; 116:4-7. When confronted with a news article cited in his report to support the hypothesis,

Dr. Levine confessed he was not familiar with the article, its authors, or whether it was peer-reviewed. Charles Decl., Ex. B at 123:4-124:20. The only publication Dr. Levine *could* name in relation to these hypotheses was withdrawn and republished with a significant correction that Dr. Levine confessed he had not read. Charles Decl., Ex. B at 116:22-117:9. The correction admitted 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. L at 1. Indeed, the only peer-reviewed study to interrogate this hypothesis using adolescent clinical data "did not support the ROGD hypothesis." Charles Decl., Ex. M at 1.

Finally, Dr. Levine uses "the Internet" as a sword to question the veracity of transgender adolescents' identities and deny them medically necessary care and a shield for his unsubstantiated beliefs about the prevalence of "detransition." Charles Decl., Ex. A at ¶14, ¶15, ¶99; *id*. at ¶35, ¶56, ¶98. Again, Dr. Levine admitted that his belief about transgender adolescents being "influenced by the internet" is a hypothesis lacking any support in studies, research, or peer-reviewed publications. Charles Decl., Ex. B at 115:24-116:7. While Dr. Levine even admits he has not performed any research or "scientifically acceptable" studies to support this hypothesis, he claims others have but provided not even a single study in his report or at deposition. Charles Decl., Ex. B at 115:13-19.

Similarly, when confronted about his report's assertion that "the internet housed some 60,000 reports of detransition," in a "subreddit called r/detransition," Dr. Levine admitted this was a substantial numerical error repeated throughout his report, and the figure should be *16,000*. Charles Decl., Ex. B at 196:3-7. Even still, he admitted he had no evidence that *even one* of the 16,000 members of the subreddit had actually "detransitioned." Charles Decl., Ex. B at 200:6-201:25. Given that these hypotheses about the influence of the internet and the evidence of these estimates about "detransition" are entirely unverified, Dr. Levine cannot claim that they are supported by the scientific community or have any known error rate. His reliance on his own *ipse dixit* fails to establish a reliable basis upon which to assert this opinion.

5. Dr. Levine's Assertion That The "Transgender Treatment Industry" Is An Entity That Exists And Is Monetarily And Politically Motivated To Push Medical Treatments On Transgender People Is A Political Not Scientific Opinion.

Ironically, while Dr. Levine invokes the mantra throughout his testimony that interventions should be "based on science and not politics," he brings politics into the discussion by claiming a cabal of medical professionals are part of a "Transgender Treatment Industry." He employs this novel term to malign, stereotype, and diminish the thousands of medical professionals working to provide competent and standards-based psychiatric and medical care to transgender people. Charles Decl., Ex. A at ¶8(l)(n), ¶15, ¶62, ¶65, ¶120, ¶125. As Dr. Levine has confessed with other asserted "opinions," there is no peer-reviewed study or published research that uses this term. Charles Decl., Ex. B at

131:18-24. When asked to describe the term's genesis, Dr. Levine said he long pondered this concept and yet "if it's not the first, it might be the second" time he used the phrase. Charles Decl., Ex. B at 128:9-19. Notably, this term appeared in another of Defendants' expert witness reports who, at deposition, claimed the term was his and admitted it does not appear in a peer-reviewed article or study and is not accepted or commonly used in the scientific or medical community. Charles Decl., Ex. N at 63:3-16. Again, Dr. Levine can point to no data or research to support his theory the "Transgender Treatment Industry" exists as a concept outside of his subjective beliefs, and therefore is not reliable or relevant in application to the facts of Plaintiffs' claims.

E. Dr. Levine Is Not Qualified To Offer Opinions About the Treatment of Pre-Pubescent Transgender Children In This Case.

To render expert testimony, the witness must possess the requisite "knowledge, skill, experience, training, or education" that would assist the trier of fact. *Kopf v. Skyrm*, 993 F.2d 374, 377 (4th Cir. 1993); *Wright v. United States*, 280 F. Supp. 2d 472, 478 (M.D.N.C. 2003) ("A witness may testify as to his specialized knowledge so long as he is qualified as an expert based on any combination of knowledge, skill, experience, training, or education."). If not qualified, the expert's testimony is unreliable. *Reliastar Life Ins. Co. v. Laschkewitsch*, No. 5:13-CV-210-BO, 2014 WL 1430729, at *1 (E.D.N.C. Apr. 14, 2014); *see, e.g., Mod. Auto. Network, LLC* at 537 (affirming the district court's exclusion of an expert because they lacked experience relevant to the matters at issue); *Lebron v. Sec. of Fla. Dept. of Children and Families*, 772 F.3d 1352, 1369 (11th Cir. 2014) (holding

expert witness was properly excluded who did not propose to testify about matters growing naturally and directly out of research he had conducted independent of the litigation).

Dr. Levine admitted at his deposition—as he must—that he has almost no experience researching and writing about or administering psychiatric treatment to transgender children. He confessed that none of the numerous external grants he has received for research and writing during his 48-year career were to study the treatment of transgender children or adolescents. Charles Decl., Ex. A at ¶1; Ex. B at 23:1-8. Indeed, in the voluminous list of articles he has authored or co-authored, only one even mentions transgender children ("Ethical Concerns"), and only to echo Dr. Levine's personal views on their care, not to report any study he has completed. Charles Decl., Ex. A at Exhibit A at 6-16.

Dr. Levine's report states that when he began practicing in 1974 that, "[a]n occasional child was seen during this era." Charles Decl., Ex. A at ¶3. When asked to clarify, he explained that "this era" meant the first twenty years of his practice and that "occasional" meant that "95 percent of the patients that we saw were 16, 17, 18 and up," and "in the first twenty years, transgender issues were primarily an older teenager and adult, mostly adult issues." Charles Decl., Ex. B at 47:5-6; 47:10-13. When asked about more recent experience treating children with gender dysphoria, Dr. Levine confessed that he had treated *no children* with gender dysphoria in the last year and had seen only *one child* under age 11 in the last five years. Charles Decl., Ex. B at 51:14-18; 52:14-22 (he

"personally [has] not delivered a psychotherapeutic care or evaluation directly of a child" in the last five years.).

Dr. Levine is not recognized as an expert in providing treatment to transgender children by his private employer, nor by the university where he is a clinical professor of psychiatry. He does not write or research about providing treatment to transgender children, nor does he deliver any psychiatric care to them in his day-to-day practice. Dr. Levine is not qualified under the *Daubert* standards to offer opinions on matters relating to the care of transgender children, and he cannot use his personal beliefs as evidence in this case.

F. 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 evidence if its introduction will result in unfair prejudice, confusion of the issues, or result in misleading testimony. Fed. R. Evid. 403. As noted above, Dr. Levine offers no opinions on any factual dispute in this case, and, in any event, the opinions he offers are irrelevant and unreliable. Consideration of his testimony would waste time and create confusion. 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 other experiences—issues unrelated to whether this insurer can deny coverage of the same kinds of treatments to transgender people that it provides cisgender people. Accordingly, Dr. Levine's testimony fails to satisfy the requirements of Federal Rule of Evidence 403 and should be excluded.

CONCLUSION

WHEREFORE, based on the foregoing, Plaintiffs respectfully request that this Court grant the instant motion and exclude all of Dr. Levine's purported expert testimony because it is not admissible under *Daubert* and the Federal Rules of Evidence.

Dated: February 2, 2022

Respectfully submitted,

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* Appearing by special appearance pursuant to L.R. 83.1(d).

CERTIFICATE OF COMPLIANCE

I hereby certify that the foregoing brief is in compliance with Local Rule 7.3(d)(1) because the body of this brief, including headings and footnotes, does not exceed 6,250 words as indicated by Microsoft Word, the program used to prepare this document.

Dated: February 2, 2022

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CERTIFICATE OF SERVICE

I hereby certify that the foregoing document was filed electronically with the Clerk of Court using the CM/ECF system which will send notification of such filing to all registered users.

Dated: February 2, 2022

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IN THE UNITED STATES DISTRICT COURT
FOR THE MIDDLE DISTRICT OF NORTH CAROLINA

MAXWELL KADEL, *et al.*, *Plaintiffs*, v. DALE FOLWELL, in his official capacity as State Treasurer of North Carolina, *et al.*, *Defendants*.	Case No. 1:19-cv-00272-LCB-LPA

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 Staff 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, except those stated on information and belief, 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 Dr. Stephen B. Levine.

5. Attached as **Exhibit A** is a true and correct copy of excerpts from the expert witness declaration of Dr. Stephen B. Levine, M.D., (including Exhibit A, a copy of his curriculum vitae) in the above-captioned matter, which is dated April 28, 2021,

was served upon Plaintiffs on May 1, 2021, and was entered as Exhibit 1 to Dr. Levine's deposition in this matter on September 10, 2021.

6. Attached as **Exhibit B** is a true and correct copy of excerpts of the transcript of the deposition of Dr. Stephen B. Levine on September 10, 2021, taken in relation to the above-captioned matter.

7. Attached as **Exhibit C** 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. Stephen B. Levine testified on April 4, 2019, and which was entered as Exhibit 6 to Dr. Levine's deposition in this matter on September 10, 2021.

8. Attached as **Exhibit D** is a true and correct copy of an excerpt of the transcript of the deposition of Dr. Stephen B. Levine taken on August 30, 2018, in relation to *Soneeya v. Turco*, No. 07-12325-DPW (D. Mass. 2019).

9. Attached as **Exhibit E** is a true and correct copy of an excerpt of the transcript of the deposition of Dee Jones on August 3, 2021, taken in relation to the above-captioned matter.

10. Attached as **Exhibit F** is a true and correct of an excerpt of the rebuttal report of Dr. George R. Brown, M.D., signed on June 10, 2021, and served on Defendants on June 11, 2021, in the above-captioned matter.

11. Attached as **Exhibit G** is a true and correct copy of excerpts of the zoomed deposition of Dr. Stephen B. Levine taken in related to *Claire v. Florida Dept. of*

Management Services, 504 F. Supp. 3d 1328 (N.D. Fla. 2020), and which was entered as Exhibit 2 to Dr. Levine's deposition in this matter on September 10, 2021.

12. Attached as **Exhibit H** is a true and correct copy of an excerpt from the published Ph.D. Thesis, "On Gender Dysphoria," written by Cecilia Dhejne in 2017 which was entered as Exhibit 13 to Dr. Levine's deposition in this matter on September 10, 2021.

13. Attached as **Exhibit I** 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, which was entered as Exhibit 12 to Dr. Levine's deposition in this matter on September 10, 2021.

14. Attached as **Exhibit J** is a true and correct copy of the article "Long Term Follow-Up of Individuals Undergoing Sex-Reassignment Surgery: Somatic Morbidity and Cause of Death," published in March 2016 which was entered as Exhibit 14 to Dr. Levine's deposition in this matter on September 10, 2021.

15. Attached as **Exhibit K** is a true and correct copy of an excerpt of the rebuttal report of Dr. Joanna Olson-Kennedy, signed on May 30, 2021, and served on Defendants June 1, 2021, in the above-captioned matter.

16. Attached as **Exhibit L** 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, which was entered as Exhibit 7 to Dr. Levine's deposition in this matter on September 10, 2021.

17. Attached as **Exhibit M** is a true and correct copy of the article "Do Clinical Data From Transgender Adolescents Support the Phenomenon of 'Rapid-Onset Gender Dysphoria'?," accepted for publication in the scientific journal The Journal of Pediatrics on November 10, 2021, and published online on November 15, 2021.

18. Attached as **Exhibit N** is a true and correct copy of an excerpt from Day One of Remote Videotaped Deposition of Dr. Paul McHugh, M.D., from September 8, 2021, taken in relation to the above captioned matter.

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

Dated this 2nd day of February, 2022.

/s/ Carl S. Charles
Carl S. Charles

Exhibit A

IN THE UNITED STATES DISTRICT COURT
FOR THE MIDDLE DISTRICT OF NORTH CAROLINA
Case No.: 1:19-cv-272-LCB-LPA

MAXWELL KADEL, et al.,	)
	)
Plaintiffs;	)
v.	)
	)
DALE FOLWELL, in his official capacity as State Treasurer of North Carolina, et al,	)
	)
Defendants.	)

Declaration of
STEPHEN B. LEVINE, M.D.
Version of APRIL 28, 2021

SECTION I. CREDENTIALS - KNOWLEDGE, TRAINING, and EXPERIENCE:

1. Education - Academic Appointments - Research Grants: I am a Clinical Professor of Psychiatry at Case Western Reserve University School of Medicine, and also 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, and became a Full Professor in 1985. I have been the recipient of the following grants for scientific research and/or program development:

a. 23 separate pharmaceutical company grants to study various prosexual medications

b. U.S. National Institute of Health grant for the study of sexual consequences of Systemic Lupus Erythematosis. Co-principal investigator

3. Founder of the Case Western Gender Identity Clinic - former WPATH Chairman of the Standards of Care Committee: 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 evaluated and 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 WPATH Standards of Care Committee* that developed the 5th version of its Standards of Care. In 1993 the Case Western Reserve University 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. In 2020, the clinic was renamed the Gender Diversity Clinic.

4. Court Appointed Expert: 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. After providing a six-hour workshop to the mental health professionals in the system, I was retained by the Massachusetts Department of Corrections in 2007 as a consultant on the treatment of transgender inmates. I have been in that role continuously since.

5. Experience as an Expert Witness: 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 2019 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,

youth and that for any 16 or 17 year old to obtain hormonal therapy for gender dysphoria they must have court approval for its administration.

k. London 2 : In the High Court of Justice Queen's Bench Division administrative court. The Queen (on the application of) L. and Hampshire County Council. (A matter of education about transgender identities in schools; not yet decided.)

l. Expert in this case Kadal v. Folwell: I have been retained by the defense in this case to serve as an expert witness. My compensation is $400 per hour and such payments are in advance of any written opinions to avoid conflicts of interest and independent judgment.

7. A more complete review of my professional experience, publications, and awards is provided in my curriculum vitae, a copy of which is attached hereto as Exhibit A.

8. Summary of Issues: In this declaration, I offer information and my expert opinions concerning a number of aspects of the phenomenon of Gender Dysphoria and transgender identity (i.e., Gender Discordance, Gender Incongruity), as well as a discussion of competing views among mental health and other professionals as to the appropriate assessment and therapeutic methods-practices for patients who experience gender dysphoria. At many points in this statement, I provide citations to published, peer-reviewed articles that provide foundational or additional supporting or relevant information. A summary of the key points I discuss in this statement includes:

a. Sex as defined by biology and reproductive function 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 II.A.)

b. The diagnosis of "gender dysphoria" encompasses a diverse array of conditions, with widely differing pathways and characteristics depending on age of onset among other things. Data from one population (e.g. adults) cannot be assumed to be applicable to others (e.g. children). (Section II.B.)

c. Among psychiatrists and psychotherapists who practice in the area, there are currently widely varying views concerning both the causes of and appropriate therapeutic response to gender dysphoria. Existing studies do not provide a basis for a reliable scientific conclusion as to which therapeutic responses result in the best long-term outcomes for affected individuals — thus the field remains in an experimental stage. (Sections II.E, II.F.)

d. For example, a majority of children (in several studies, a large majority) who are diagnosed with gender dysphoria "desist"—that is, their gender dysphoria does not persist—by puberty or adulthood. It is not currently known how to distinguish children who will persist from those who will not — thus the majority of patients will do best with no "affirmation" treatments in childhood and we cannot reliably determine which patients would do better with "affirmation" treatments which can involve life-long damage to healthy organs and natural biological processes. (Section IV.) See consistent findings in detailed discussions of the new National Gender Dysphoria Review Guidelines from Sweden, Finland, England, the Cochrane Review, and sciencearticles below.

e. Some recent studies suggest that active affirmation of transgender identity in young children will substantially reduce the number of children naturally outgrowing or "desisting" from transgender identity. This raises ethical and public health concerns that "affirmation" treatments will increase the number of individuals who suffer the multiple long-term

physical, mental, and social limitations that are strongly associated with living life as a transgender person. (Section IV.)

f. Thus, social transition is itself an important intervention with profound implications for the long term mental and physical health of the child. When a mental health professional evaluates a child or adolescent and then recommends social transition, presumably that professional is available to help with interpersonal, familial, and psychological problems that may arise. However, many adolescents transition without mental health assessment and ongoing care, leaving themselves and their families on their own to deal with subsequent problems. (Section IV.)

g. In most cases, parental involvement is necessary for an accurate and thorough diagnosis of a child or adolescent presenting with gender dysphoria or a desire for a transgender identity, as well as for effective psychotherapeutic treatment and support of the young person. (Section V.)

h. The knowledge base concerning the cause and treatment of gender dysphoria available today has been repeatedly characterized in multiple reviews as of "low scientific quality". (Section VI.) (See detailed analysis below).

i. There are currently no studies that show that affirmation of transgender identity in young children reduces suicide, 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 suicide and *negative* physical and mental health conditions than does the general population thus it remains unclear how much benefit, if any, is provided by the experimental treatments required for medical transitioning. (Section VI.)

j. 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 unethical* to assert that a child or adolescent who expresses an interest in a transgender identity will kill him or herself — or is more likely to do so — unless adults and peers affirm that child in a transgender identity. (Section VI.)

k. Putting a child or adolescent on a pathway towards life as a transgender person puts that individual at risk of a wide range of long-term or even life-long harms, including: sterilization (whether chemical or surgical) and associated regret and sense of loss; inability to experience orgasm (for trans women); physical health risks associated with exposure to elevated levels of cross-sex hormones; surgical complications and life-long after-care; alienation of family relationships; inability to form healthy romantic relationships and attract a desirable mate; elevated mental health risks. (Section VII.) In my opinion, putting children through such risks who are very likely to naturally grow out of gender dysphoria into acceptance of their biological sex and gender is an experimental and unethical practice. This is especially true given the affirmation treatments have untested and unproven long-term outcomes.

l. Informed consent is ethically required for potentially life-altering psychological or medical procedures. However, the informed consent process in such complex cases is also complex. In some cases, it may not be possible to obtain meaningful informed consent to place a child on a psychological pathway that carries with it lifetime risks of the serious injuries, harms, and damages (including sterilization, limited sexual response, and social marginalization) that I detail in this report. A child is not competent, of course, to weigh how these potentially devastating life-long risks and issues will impact his or her lifetime happiness. At a minimum, informed consent of parents is essential, although it may not be sufficient. Withholding accurate information

— from patients or parents — on risks and benefits or misrepresenting the current state of research in this controversial field should be viewed as a serious ethics violation and reported to the proper licensing authorities. There is substantial evidence from science publications and also from journalist research that the "affirmation" treatment industry (i.e., often referred to as the Transgender Treatment Industry) is providing misleading information to the public and the legal system. For example, it is not the case that puberty halting hormone treatments are "easily reversed". (Section VIII.)

m. Research reviews support my opinion that gender affirmation treatments remain experimental and have never been accepted by the relevant scientific community and have no known nor published error rate — meaning the rates of clinical errors as manifested by desistance, increased mental suffering, educational failure, vocational inconstancy, or social isolation have not been established. See, e.g., Haupt, C., Henke, M. et. al., Cochrane Database of Systematic Reviews Review Intervention, Antiandrogen or estradiol treatment or both during hormone therapy in transitioning transgender women, 28 November 2020 ; See, e. g., Swedish Agency for Health Technology Assessment and Assessment of Social Services, SBU Policy Support no 307, 2019 www.sbu.se/en • registrator@sbu.se Contact SBU: Jan Adolfsson, Medical Advisor, Project Manager, jan.adolfsson@sbu.se, English Proofreading: Project group and Jan Adolfsson, SBU ["*No relevant randomized controlled (treatment outcome) trials in children and adolescents were found."]*

Within the last two years, detailed research reviews exposing multiple and serious methodological and ethical flaws in the research of Bränström, and Panchankis and Turban, and other "affirmation" supporters have pinpointed fundamental methodological errors in their papers which claim to support affirmation treatment. These reviews, also support my opinions that gender

affirmation treatments remain experimental and have never been accepted by the relevant scientific community and have no known nor published error rate. See, Kalin N. H. (2020). Reassessing Mental Health Treatment Utilization Reduction in Transgender Individuals After Gender-Affirming Surgeries: A Comment by the Editor on the Process. *The American journal of psychiatry*, *177*(8), 764. https://doi.org/10.1176/appi.ajp.2020.20060803; Biggs M. (2020). Puberty Blockers and Suicidality in Adolescents Suffering from Gender Dysphoria. *Archives of sexual behavior*, *49*(7), 2227–2229. https://doi.org/10.1007/s10508-020-01743-6; D'Angelo, R., Syrulnik, E., Ayad, S., Marchiano, L., Kenny, D. T., & Clarke, P. (2020). One Size Does Not Fit All: In Support of Psychotherapy for Gender Dysphoria. *Archives of sexual behavior*, 10.1007/s10508-020-01844-2. Advance online publication. https://doi.org/10.1007/s10508-020-01844-2;

n. Bases for Expert Opinions and Review-Opinions regarding the Expert Declarations in this case by Drs. Schechter and Brown. I have reviewed dozens of scientific articles, national science reviews and guidelines (England (NICE), Sweden, Finland, Cochrane Review, association positions, the Complaint and Answer in this case, the plaintiff's medical records, and all expert declarations in this case. I have formulated opinions regarding the reports by Drs. Schechter and Brown. In my opinion, Drs Schechter and Brown failed to properly disclose and discuss the ongoing international debates and controversies as to whether Transgender Treatment Industry methods and procedures are unproven, experimental, and potentially more harmful than helpful to vulnerable patients. Similarly, Drs Schechter and Brown failed to properly disclose and discuss the recent and very public exposes documenting significant methodological failures and flaws in trans treatment science. Finally, Drs Schechter and Brown failed to report or discuss the recently published national reviews and research documenting the "weak" and methodologically defective

research foundations of the Transgender Treatment Industry including recent reviews from Great Britain (NICE), Sweden, Finland, the Cochrane Review, the 2020 Carmichael report, the Griffin study, the Zucker study and other important work published within the last 24 months.. [See, e.g. Carmichael P, Butler G, Masic U, et al. Short-term outcomes of pubertal suppression in a selected cohort of 12 to 15 year old young people with persistent gender dysphoria in the UK. medRxiv 2020.12.01.20241653; doi:https://doi.org/10.1101/2020.12.01.20241653 https://www.medrxiv.org/content/10.1101/2020.12.01.20241653v1

BBC summary: https://www.bbc.com/news/uk-55282113journal.pone.0243894. pmid:33529227], and Devita Singh, Susan J. Bradley and Kenneth J. Zucker, Frontiers in Psychiatry, March 2021 | Volume 12 | Article 632784, www.frontiersin.org] and related research discussed in detail below.

SECTION II. BACKGROUND IN THIS FIELD

A. The biological base line of sex

9. Sex is permanently "assigned" at conception by DNA: 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. Sex determination occurs at the instant of conception, depending on whether a sperm's X or Y chromosome fertilizes the egg. Medical technology can be used to determine a fetus's sex before birth. It is thus not scientifically correct to talk of doctors "assigning" the sex of a child at birth; almost anyone can accurately and reliably identify the sex of an infant by genital inspection. What the general public may not understand, however, is that every nucleated cell of an individual's body is chromosomally identifiably male or female—XY or XX. Claims that patients can obtain a "sex change" or a "gender transition" process are misleading and scientifically impossible. In reality, the typical "transgender" Gender Discordant patient has normal healthy sex organs but struggles

with Gender Discordant feelings and perceived identity. Such patients can receive cosmetic surgeries and hormone treatment — but such methods never actually "transition" a patient to "another sex." In my opinion, these views are generally accepted by the relevant scientific community in the fields of biology, zoology, neonatology, genetics, pediatrics, and psychiatry.

10. The self-reported gender of a child, in contrast, arises 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 natural outcome in >99% of children everywhere, anomalous gender discordant identity formation begs for understanding. Is it biologically shaped or influenced? Is it biologically determined? Is it the product of how the child was privately regarded and treated? Does it stem from trauma-based rejection of maleness or femaleness, and if so flowing from what trauma? Is it a symptom of another, as of yet unrevealed emotional disturbance? Is it the result of a social contagion process — such as anorexia or bulimia may be, or from Internet involvement with trans websites? The ongoing scientific, clinical, and societal debate over such issues awaits reliable answers; while some offer authoritative opinions on these questions, they are not scientifically proven. In my opinion, these views are generally accepted by the relevant scientific community.

11. 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 and development, musculature, body fat levels and distribution, and hair patterns, as well as physiological differences such as menstruation. These are genetically programmed biological

consequences of sex which also serve to influence the consolidation of gender identity during and after puberty. In my opinion, these views are generally accepted by the relevant scientific community.

12. 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. It is possible for some adolescents and adults to pass unnoticed as the opposite gender that they aspire to be—but with limitations, costs, and risks, as I detail later. See, S. Levine (2018), Informed Consent for Transgendered Patients, J. of Sex and Marital Therapy, at 6, DOI: 10.1080/0092623X.2018.1518885 ("Informed Consent"); S. Levine (2016), Reflections on the Legal Battles Over Prisoners with Gender Dysphoria, J. American Academy of Psychiatry and Law 44, 236 at 238 ("Reflections"). In my opinion, these views are generally accepted by the relevant scientific community.

B. Definition and diagnosis of gender dysphoria

13. 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 sex as determined by their chromosomes and their thousands of genes, and the gender with which they eventually subjectively identify or to which they aspire. Today's American Psychiatric

Association's *Diagnostic and Statistical Manual of Mental Disorders* (DSM-5) 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. It is important to note that the DSM is not a reliable-valid scientific journal publication. The DSM began as an attempt to create a dictionary for psychiatry.The process by which DSM classifications are created involves voting by committee — this is nota reliable-valid scientific process. The committees' recommendations are approved or rejected by superordinate committees. DSM content is largely decided by consensus-seeking methodologies — such as "voting" by small committees of advocates and activist practitioners whose judgment may suffer from significant financial conflicts of interest — as appears to be the case with all three of the plaintiff's experts in this case. The limitations of the DSM methodology are well known in the relevant scientific community. See, e.g., Lee, C., *The NIMH Withdraws Support for DSM-5: The latest development is a humiliating blow to the APA*. Psychology Today News Blog at https://www.psychologytoday.com/us/blog/side-effects/201305/the-nimh-withdraws-support-dsm-5 ["Just two weeks before DSM-5 is due to appear, the National Institute of Mental Health, the world's largest funding agency for research into mental health, has indicated that it is withdrawing support for the APA's manual. In a humiliating blow to the American Psychiatric Association, Thomas R. Insel, M.D., Director of the NIMH, made clear the agency would no longer fund research projects that rely exclusively on DSM criteria. Henceforth, the NIMH, which had thrown its weight and funding behind earlier editions of the manual, would be "re-orienting its research away from DSM categories."] In my opinion, these views are generally accepted by the relevant scientific community.

14. 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 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. The early childhood onset pathway and the more recently observed onset around puberty pathway are relevant to this matter. Whereas, the onset of cross-gender identifications in the preschool years suggests temperamental and intrafamilial shaping forces, the post pubertal onset of what is now commonly referred to a rapid onset gender dysphoria seems to be heavily influenced by social forces. These derive primarily from the Internet and educational environments. The vulnerability to such social contagion may stem from conspicuous or subtle mental health problems or the child's misunderstanding of the normality of early pubertal discomfort with one's body, previous peer relationships, and despair about future gender-based social roles. The newly acquired trans identity is often passionately held as it explains away past and current unhappiness and emotional or behavioral problems.

Changing Complexities in Young Gender Dysphoric (GD) Patients

15. The Social Contagion Hypothesis. To avoid the methodological error of confirmation bias, clinicians and researchers generate and test alternative hypotheses. It is currently unclear how many new gender discordant patients have been influenced by social contagion processes. During the last 10-15 years, there have been multiple reports from multiple nations reporting a dramatic increase in the number of gender discordant patients as well as a dramatic change in the reported sex ratio of young patients presenting to clinics with trans gender identities. In the 20th century, the biologic male to biologic female ratio was consistently 3-4:1 in most North American and European clinics. Now some clinics are reporting a 7:1 ratio of girls to boys. Biological theories of gender dysphoria (e.g., "immutable", genetic, brain structures, etc.) appear unlikely to explain large, rapid demographic shifts in gender discordant patients. A social contagion - social influence theory has arisen in an attempt to help explain these dramatic demographic changes. In decades

past, gender discordant children and teens typically aspired to become a member of the opposite sex while more recently, patients are increasingly likely to define themselves as "non-binary persons" meaning that they have elements of both sex-genders within them or they have none of these elements. Such teens often report being influenced by trans websites and trans "influencers" on internet sources such as video blogs on YouTube. These onsite shows reportedly reach millions and teach adolescents to consider their problems, worries, discomforts, and anticipated social roles to be typical experiences of the unfolding of a biologically-determined trans self. In addition to YouTube and other internet sources, patients reportedly have been influenced by school trans awareness training programs teaching the normality of trans current and future lives — without an accurate discussion or depiction of the known risks and benefits.

A multi-disciplinary analysis that includes developmental psychology and the history of psychiatry provides additional support for the socialization hypothesis. Mental health professionals have long experience with adolescent females experiencing social worries that help to create anorexia nervosa, bulimia, and self-harm through cutting, burning, and piercings. Prof. Amanda Rose at the University of Missouri has conducted research to understand why adolescent girls demonstrate heightened susceptibility to a social contagion of psychiatric symptoms. She reports that" teenage girls share symptoms via social contagions because their friendship processes involve "co-rumination"— that is, taking on the emotional pain and concerns of their friends. This is a potential — and as yet uninvestigated hypothesis — as to the reports of" clusters" and "friend groups" of teen girls who are adopting trans identity and "transitioning" together (See, L. Littman (2018), *Parent Reports of Adolescents & Young Adults Perceived to Show Signs of a Rapid Onset of Gender Dysphoria*, PLoS ONE 13(8): e0202330 at 13). Prof. Rose's investigations note that adolescent girls seem more willing to adopt a friend's pain and even suspend reality to "get on the

symptom team" of their friends. (See, R. Schwatz-Mette and A. Rose, Co-Rumination Mediates Contagion of Internalizing Symptoms Within Youths' Friendships, Developmental Psychology 48(5):1355-65, February 2012, DOI: 10.1037/a0027484 Further, reliable-valid scientific research is needed to address these complex issues. See also, McCall, B. andNainggolan, L., Medscape *Transgender Teens: Is the Tide Starting to Turn?* https://www.medscape.com/viewarticle/949842#vp_1 ["The vast majority of youth now presenting with gender dysphoria are adolescents who suddenly express revulsion with their sex from birth, and 70% of them were born female. Many of them have comorbidities such as anxiety, attention deficit hyperactivity disorder, autism spectrum traits, and depression, Malone explains, which need to be considered. This newer presentation — which has been termed late-, adolescent-, or rapid-onset gender dysphoria — has now been seen in every gender clinic in the western world, and there has been a huge surge in the number of cases. One recent US survey found a 4000% increase (over 40-fold) since 2006, and there have been similar large increases reported in Finland, Norway, the Netherlands, Canada, and Australia. The London GIDS clinic reported a 30-fold increase in referrals over the past decade – and again they were primarily adolescent girls who said they now identify as boys.

It should be noted that rapid, unpredicted changes in the demographics of trans patients (i.e., from chronically discordant, early onset males to rapid onset adolescent females) calls into question the usefulness and accuracy of predictions emanating from research conducted on previous, demographically and clinically different patient groups. This again highlights the complex, little known, and experimental nature of trans phenomenon as well as the experimental treatment methods of the current Transgender Treatment Industry. See, rapid and unpredicted demographic changes: [A US survey found a 4000% increase (over 40-fold) since 2006]

"National College Health Assessment: ACHA-NCHA s://www.acha.org/NCHA/ACHA-NCHA_Data/Publications_and_Reports/NCHA/Data/Publications_and_Reports.aspx?hkey=d5fb767c-d15d-4efc-8c41-3546d92032c5 ; similar large increases have been reported in Finland: Kaltiala-Heino, Riittakerttu, Hannah Bergman, Marja Työläjärvi, and Louise Frisen. "Gender Dysphoria in Adolescence: Current Perspectives." *Adolescent Health, Medicine and Therapeutics* Volume 9 (March 2018): 31–41. https://doi.org/10.2147/AHMT.S135432 ; and in Norway ; and in the Netherlands: de Vries, Annelou L.C. de. "Challenges in Timing Puberty Suppression for Gender-Nonconforming Adolescents." *Pediatrics* 146, no. 4 (October 2020): e2020010611. https://doi.org/10.1542/peds.2020-010611. ; and in Canada: Zucker, Kenneth J. "Adolescents with Gender Dysphoria: Reflections on Some Contemporary Clinical and Research Issues." *Archives of Sexual Behavior* 48, no. 7 (October 2019): 1983–92. https://doi.org/10.1007/s10508-019-01518-8, and others.

16. 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. (See, K. Zucker (2018), The Myth of Persistence: Response to "A Critical Commentary on Follow-Up Studies & 'Desistance 'Theories about Transgender & Gender Non-Conforming Children" by Temple Newhook et al., Int'l J. of Transgenderism at 10, DOI: 10.1080/15532739.2018.1468293 ("Myth of Persistence"). 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.

17. The criteria used in DSM-5 to identify Gender Dysphoria ("Gender Incongruence" is another term used) 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. When these criteria in children, (or adolescents, or adults) are not met, two other diagnoses may be given. These are: Other Specified Gender Dysphoria and Unspecified Gender Dysphoria. Specialists sometimes refer to children who do not meet criteria as being "subthreshold."

18. In a complex, experimental, and little understood field such as transgender medicine, generating and exploring alternative hypotheses is essential to our efforts to help alleviate the tragic suffering of our patients. One such alternative is to teach coping and resilience skills to gender discordant children. Such training could include a realization that a wide range of behaviorsare available within their biologically concordant gender roles. Acquiring a broader perspective on the patient's natal sex roles might be a better solution for some than permanent damage to healthy sex organs via hormone and surgical "transitioning" procedures. Children who conclude that they are transgender are often unaware of a vast array of adaptive possibilities for how to livelife as a man or a woman—possibilities that become increasingly apparent over time to both malesand 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 are based on constrictive notions of what men and women can be. See, S. Levine (2017), Ethical Concerns About Emerging Treatment Paradigms for Gender Dysphoria, J. of Sex & Marital Therapy at 7, DOI: 10.1080/0092623X.2017.1309482 ("Ethical Concerns"). A young child's, even an adolescent's, understanding of this topic is quite limited. Nor do they have the perspective that discomfort with the body and perceived social role is not new to civilization; what is new is the option to become a trans person.

With most complex behavioral problems of child and adolescents, patients and families receive psychiatric attention that includes a thorough developmental history from parents, prolonged interviews with the patient, and a therapeutic approach which involves to some extent the parents, the patient, and the three together with or without medication assistance. Tragically, in too many gender clinics, young patients are not treated with the standard of care, complex, multi-disciplinary, evidence-based approach. Children are too often quickly referred to gender "specialists" — which generally means therapists who deeply believe (based on clinical-political ideology and not the relevant science) that every young person who is questioning his or her gender identity or declaring a trans identity should be quickly affirmed and supported in their atypical identity. Moreover, the ideological fashions of these therapists and the organizations that support them have effectively convinced many — contrary to the relevant science — that any other approach to these youth is dangerous, harmful, and might even lead to suicide. Other evidence-based, more methodologically sound approaches such as the generation and testing of alternative hypotheses as required by proper health care standards — are denigrated and ideologically labeled "conversion therapy."

The ideologically based indoctrination efforts to ban evidence based alternative treatments as "conversion therapy" can have harmful effects on our vulnerable patients. For example, many traditional therapists claim to not know how to take care of these gender discordant patients, as though they are not children who are suffering. This rationalization may only be a reflection of the fear of being attacked for performing dreaded, and now in some locations, illegal, "conversion therapy". In this way, qualified mental health professionals have failed to develop a robust experience with alternative ways of investigating patients 'and their families 'lives as they do with all other child and adolescent psychiatric problems. [The recently released National Guidelines

for Gender Dysphoria patients from Sweden and Finland do appear to be moving towards a much greater emphasis on alternative methods including psychosocial support, therapy, and long-term psycho-social evaluations — perhaps for years — prior to engaging in any "affirmation" medical interventions (hormones or surgery) See, e.g. "Finland Issues Strict Guidelines for Treating Gender Dysphoria" at https://genderreport.ca/finland-strict-guidelines-for-treating-gender-dysphoria/ ["Western countries around the world are *grappling with how to treat the exponentially growing number of children and adolescents being referred to gender clinics* for puberty blockers, cross-sex hormones and gender-affirming surgery. Finland recently issued very strict clinical guidelines for the treatment of children with gender dysphoria including: … clear differentiation in treatment guidelines between early-onset childhood gender dysphoria and adolescent-onset gender dysphoria…the guidelines acknowledge and recognize that identity exploration is a natural phase of adolescence and *restrict medical interventions* until "identity and personality development appear to be stable"….There is a *prioritization of psychotherapeutic non-invasive interventions* as the first course of action "due to variations in gender identity in minors"…. A *requirement* that there be *"no contraindications" prior to initiation of puberty blocker or cross-sex hormone interventions*… [such contraindications should include the presence of psychiatric illnesses such as depression, anxiety, or autistic conditions. Such disorders are reportedly present in over 50% of all gender discordant patients]…. and no surgical interventions are allowed for children underthe age of 18." ; See also, a Swedish National Investigative Report regarding cases of gender incongruence in children and young people, Article number 2021-3-7302 Published www.socialstyrelsen.se, March 2021. [Since our initial investigative report was published in 2015, the number of young people referred for investigation has *increased sharply, both in Sweden and internationally*. … *The reasons for the increase are not yet clear.*]

Such external pressures on providers should not be underestimated. Leaders in the field of gender dysphoria have been attacked, dissenters have been fired, and reputations have been sullied by activists who believe they know best how other people's children should be treated. The fact that science has not yet established the ideal treatment approaches to the diversity of situations does not seem to matter to these passionate persons.

19. Confirmation bias is a hazardous cognitive error that occurs throughout all of medicine and science. Confirmation bias is the methodologically defective tendency to process information by only looking for, and interpreting, evidence consistent with existing beliefs, favorite theories, and pre-conceived notions. This bias is a serious and potentially dangerous methodological error that leads a person or a field to ignore information that is contrary to what is common, fashionable, or has been taught to be the popular or "politically correct" theory of the day. It is often associated with a weak understanding of how science establishes the legitimacy of a therapy. Confirmation bias is often associated with the belief that because a therapeutic approach has been long employed or supported by powerful forces, adequate reliable-valid science must have previously established the popular approach. Both of the essential concepts of "gender affirmative treatment" and "conversion therapy" are based on such a misunderstanding.

20. The expected initial evaluation of a trans person typically begins with the patient who tells the evaluator, " "I am trans." The patient relates his or her symptoms of discomfort which may or may not fulfill DSM-5 criteria for Gender Dysphoria. Ideally a developmental history is taken from the parents and the patient to consider what is known as a differential diagnostic process to determine what other conditions may underlie these symptoms. The extent to which this latter process is undertaken depends upon the therapists *beliefs* about the origin of trans identities and the long term effectiveness of affirmative responses. To the extent that life-changing affirmative

distinctions. I attempt to summarize these three as though they are equally valid. I do not actually consider this to be true.

23. Gender dysphoria is conceptualized and described by some professionals and laypersons as though it were a serious, physical medical illness that causes suffering, comparable, for example, to prostate cancer, a disease that is curable before it spreads. 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 alleviatethe illness. The promise of these interventions is the cure of the gender dysphoria. The underlyingassumption is that all types of gender dysphoria have their ultimate origin in "brain structures", often determined embryonically. Although numerous studies have been undertaken to attempt todemonstrate a distinctive physical "brain structure" associated with transgender identity, as of yetthere is no credible, reliable-valid scientific evidence that these patients have any defining abnormality in brain structure that precedes the onset of gender dysphoria. See, Mueller, De Cuypere & T'Sjoen. Transgender research in the 21st century: A selective critical review from a neurocognitive perspective. American Journal of Psychiatry 174: 12, 2017.

It should be noted that gender dysphoria is *a psychiatric rather than a medical diagnosis*. Since its inception in DSM-III, it has always and only been specified in the psychiatric DSM 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 (cf body integrity identity disorder (BIID) (See, Levine, *Reflections,* at 240.) In my opinion, the "affirmation" treatment protocols using endocrine and surgical "treatments" to change a psychiatric condition are not accepted by the relevant scientific community, are supported by

only "weak evidence" from methodologically defective research studies, and have no known, nor published error rates. Actual attempts at publishing error rates has come under the concept of "regrets" focused only only on patient injuries and misery following genital re-assignment surgery. There is much more to the human experience of trans patients regrets over time than the questionable, methodologically defective claims quoted by some of 2%. For example, in the Bränström., et.al., study, an enormous part of the sample was "lost" and never followed up. The authors failed to explore available data to see how many of these patients have de-transitioned, died via suicide, etc. One has to wonder why the suicide rate is reportedly so very high for patients who received trans genital surgery. In sum, these "treatments" remain experimental and poorly studied and we'll need much more and much higher quality scientific research before we will know if such "treatments" are actually helping or injuring patients. Is is essential to note that hormonal and surgical treatments for gender discordant patients have been increasingly done over a 50 year period and yet no reliable-valid protocols for evaluation or treatment have been properly researched, nor generally accepted by the relevant scientific community, nor published with methodologically sound error rates**.** For decades, vulnerable patients struggling with gender identity issues have deserved better, more effective, less experimental, less hazardous, less ideologically tainted, and properly researched treatments — they are still waiting.

24. Gender dysphoria can be effectively and alternatively conceptualized in developmental terms, as an adaptation to a psychological problem that was 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, *Reflections*, 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

29. When a pre-adolescent child presents with gender dysphoria, a "watchful waiting" approach avoids hormonal treatments to allow for the developmental nature of gender identity in children to naturally resolve —that is, take its course from forces within and surrounding the child. Watchful waiting has two versions:

a. (Model 1 of watchful waiting) Treating any other psychological co-morbidities—that is, other mental illnesses as defined by the DSM-5—that the child may exhibit (separation anxiety, be bedwetting, attention deficit disorder, obsessive-compulsive disorder, depression) without a focus on gender

b. (Model 2 of watchful waiting) No treatment at all for anything, but a regular follow-up appointment. This might be labeled a "hands off" approach

The psychotherapy model: Alleviate distress by identifying and addressing causes

30. 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.

31. 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, *Ethical Concerns*, at 8.) I and others have reported success in alleviating distress in this way for at least some patients, whether or not the patient's sense of discomfort or incongruence with his or her natal sex entirely disappeared. Relieving accompanying psychological co-morbidities leaves the patient freer to consider the pros and cons of transition as he or she matures.

is no sharp line between "watchful waiting" and the psychotherapy model in the case of prepubescent children.

35. To my knowledge, there is no credible, reliable-valid scientific 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. *Controlled studies have never been attempted*. On the other hand, anecdotal case report 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 published a paper recently 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, *Transitioning*, at 1.) I have seen children desist even before puberty in response to thoughtful parental interactions and a few meetings of the child with a therapist. Recently, a paper reviewing the phenomenon of de-transition has been published in which the authors claims to have identified *60,000 case reports world wide* on the Internet. See Expósito-Campos P. A Typology of Gender Detransition and Its Implications for Healthcare Providers. J Sex Marital Ther. 2021;47(3):270-280. doi: 10.1080/0092623X.2020.1869126. Epub 2021 Jan 10. PMID: 33427094.

The affirmation therapy model

36. 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. These advocates treat any question about the causes of the

a precondition for a diagnosis of gender dysphoria, precisely because of the risk of "transitory" symptoms and "hasty" diagnosis that might lead to "inappropriate" treatments. See, K. Zucker (2015), *The DSM-5 Diagnostic Criteria for Gender Dysphoria*, in C. Trombetta et al. (eds.), Management of Gender Dysphoria: Multidisciplinary Approach, DOI 10.1007/978-88-470-5696-1_4 (Springer-Verlag Italia 2015).

41. 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 credible, reliable-valid scientific evidence**.** Rather, 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 over time by each of them.

42. 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.

F. Patients Differ Widely and Must Be Considered Individually.

43. In my opinion, it is not possible to make a single, categorical statement about the proper treatment of children presenting with gender dysphoria or other gender-related issues. There is no single pathway of development and outcomes governing transgender identity, nor one that predominates over the large majority of cases. Instead, as individuals grow up and age, depending on their differing psychological, social, familial, and life experiences, their outcomes differ widely. I can, however, categorically opine that unproven, experimental affirmation "treatments"should not be used on uninformed or misinformed patients and families.

45. In almost any discussion of the diagnosis and care of patients suffering gender dysphoria or exhibiting transgender characteristics, the World Professional Association for Transgender Health (WPATH) and its Standards of Care will be mentioned. Accordingly, I provide some context concerning that private, activist, non-science, organization.

46. 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 proper, reliable scientific methodologies, as was its mission years earlier. In approximately 2007, the Henry Benjamin International Gender Dysphoria Association changed its name to the World Professional Association for Transgender Health.

47. WPATH is a voluntary membership, activist advocacy 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 'perceived needs, values, and sensibilities into consideration, it limits the ability for honest, methodologically competent scientific debate. It also means that WPATH can no longer be considered a purely professional or scientific organization.

48. WPATH takes a very narrow and politically-ideologically driven view on increasingly controversial 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. *These are, obviously, conflicted, incompatible, and contradictory goals*. (Levine, *Reflections*, at 240.) WPATH is supportive to those who want Sex Reassignment Surgery ("SRS") even though such surgery is *not supported by credible, reliable-valid scientific research*, not accepted by the

relevant scientific community, and has no known error rates, and no careful systematic follow-up using agreed upon criteria to even assess multifaceted failure rates. Skepticism as to the benefits of SRS to patients, and strong alternate views, are not well tolerated in discussions within the organization. Such views have been literally shouted down and effectively silenced by the large numbers of nonprofessional adults who attend the organization's biennial meetings. Such "mob rule" is quite incompatible with appropriate, competent methodological discussions.

49. The Standards of Care ("SOC") is the product of an enormous effort, but it is not a politically neutral document. WPATH aspires to be both a scientific organization and an advocacy group for the transgendered. These aspirations are clearly in sharp conflict. The most serious limitations and defects of the Standards of Care, however, are not primarily political. They are caused by the decades-long and continuing lack of credible, rigorous research in the field, which allows room for passionate convictions and ongoing controversies on how to care for the transgendered. See, e.g. Vrouenraets et al, *Early Medical Treatment of Children and Adolescents With Gender Dysphoria: An Empirical Ethical Study,* Journal of Adolescent Health 57 (2015) 367e373. [The Endocrine Society and the World Professional Association for Transgender Health published guidelines for the treatment of adolescents with gender dysphoria (GD). The guidelines recommend the use of gonadotropin-releasing hormone agonists in adolescence to suppress puberty. However, in actual practice, *no consensus exists whether to use these early medical interventions* … Conclusions: As long as *debate* remains on these seven themes and *onlylimited long-term data are available*, *there will be no consensus on treatment*. Therefore, more systematic interdisciplinary and (worldwide) multi-center research is required.]

50. In recent years, WPATH has fully adopted — in the absence of reliable-valid scientific research — some mix of the medical and civil rights paradigms. It has downgraded the role of

"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." A third summarized the existing data as showing that "Symptoms of GID at prepubertal ages decrease or disappear in a considerable percentage of children (estimates range from 80-95%)." A 2021 publication found that 12% of previously evaluated grade school aged children persisted in their trans identities many years later. (Singh, Bradley, and Zucker, Frontiers of Psychiatry. See, P. T. Cohen-Kettenis, H. A. Delemarre-van de Waal et al. (2008), *The Treatment of Adolescent Transsexuals: Changing Insights*, J. Sexual Medicine 5(8) 1892 at 1895.

55. It is not yet known how to distinguish those children who will desist from that small minority whose trans identity will persist. (Zucker, Gender Dysphoria in Children and Adolescents, in Principles and Practices of Sex Therapy 6th edition, Guilford Press, 2020; Levine, *Ethical Concerns*, at 9.) Even severity of gender dysphoria is not a strong predictor of persistence. It is also apparent in the adolescent phenomenon of rapid onset of gender dysphoria following a gender normative childhood that childhood gender identity is not inherently stable. Some of these individuals desist and others evolve dramatically to become more non-binary and accepting of their complex male and female identifications.

56. Desistance (a patients' willing reacceptance of their biological sex through normal developmental processes) within a relatively short period may also be a common outcome for post-pubertal youths who exhibit recently described "rapid onset gender disorder." I observe 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. However, reliable-valid scientific data on outcomes for this age group with and without therapeutic interventions is not yet available. A recent review of de-transitioning claimed to have identified 60,000 case histories in

a search of proliferating websites devoted to this topic (Pablo Exposito-Campos. A typology of gender detransition and its implications for health care providers J Sex & Marital Therapy 2020 https:..doi.org/101080/0092623x.2020.1869126). In the past WPATH has simply declined to discuss this vital topic, another example of WPATH's political consensus-seeking, *increasingly anti-science methodology*.

57. In contrast, there is now data that suggests that a therapy that encourages social transition dramatically changes outcomes and often "locks in" a patient's journey into a life course of dependence on experimental hormone "treatments". 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." Similarly, a comparison of recent and older studies suggests that when an "affirming" methodology is used with young 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, *Myth of Persistence*, at 7.)18

58. Indeed, a review of multiple studies of boys 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, Studies that began 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 transition prior to puberty desisted when surveyed at age 15. See (T.D. Steensma, J.K. McGuire et al. (2013), *Factors Associated with Desistance & Persistence of Childhood Gender Dysphoria: A Qualitative Follow-up Study*, J. of the Am. Academy of Child and Adolescent Psychiatry. 52, 582. ; See, C. Guss et al. (2015), Transgender and Gender

population, or to the notably worse outcomes exhibited by the transgender population generally. *See, e.g.,* B. Ehrensaft (2015), *Listening and Learning from Gender-Nonconforming Children,* The Psychoanalytic Study of the Child 68(1) 28 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 returnto his or her assigned gender."

61. However, I agree with Zucker who has written, "…we cannot rule out the possibility that early successful treatment of childhood GID [Gender Identity Disorder] will diminish the role of a continuation of GID into adulthood. If so, successful treatment would also reduce the need for the long and difficult process of sex reassignment which includes hormonal and surgical procedures with substantial medical risks and complications." See, Zucker, *Myth of Persistence*,at 8 (citing H. Meyer-Bahlburg (2002), *Gender Identity Disorder in Young Boys: A Parent- & Peer-Based Treatment Protocol*, Clinical Child Psychology & Psychiatry 7, 360 at 362.).

By the same token, a therapeutic methodology for children that *increases* the likelihood that the child will continue to identify as the opposite gender into adulthood will *increase* the need for the long and potentially problematic processes of hormonal and genital and cosmetic surgical procedures.

62. Given these facts, *encouraging social transition in children remains controversial*. Supporters of such transition acknowledge that "Controversies among providers in the mental health and medical fields are abundant . . . These include differing assumptions regarding . . . the age at which children . . . should be encouraged or permitted to socially transition These are complex and providers in the field continue to be at odds in their efforts to work in the best interests of the youth they serve." See, A. Tishelman et al. (2015), *Serving Transgender Youth: Challenges,*

Dilemmas and Clinical Examples, Prof. Psychol. Res. PR. at 11, DOI: 10.1037/a0037490 ("*Serving TG Youth*") Transition then, should be undertaken only subject to standards, protocols, and reviews appropriate to actual clincial experiments [Clincial experiments involve time-honored careful processes with Institutional Review Board — human subjects protections — approval required, a predetermined method of evaluation, primary and secondary endpoints and safeguards to protect the rights of patients to truly informed consent. These protections are not present in the Transgender Treatment Industry when vulnerable patients are receving "treatments" that lack sufficient proof of efficacy and safety.]

63. In sum, therapy for young children that encourages transition cannot be considered to be neutral, but instead *is an experimental procedure* that has a high likelihood of changing the life path of the child, with highly unpredictable effects on mental and physical health, suicidality, and life expectancy. Claims that a civil right is at stake do not change the fact that what is proposed is a social and medical experiment on vulnerable patients. (Levine, *Reflections,* at 241.)

IV. THE AVAILABLE DATA DOES NOT SUPPORT THE CONTENTION THAT "AFFIRMATION" OF TRANSGENDER IDENTITY REDUCES SUICIDE OR RESULTS IN BETTER PHYSICAL OR MENTAL HEALTH OUTCOMES GENERALLY.

64. I am aware that organizations including The Academy of Pediatrics and Parents, Families and Friends of Lesbians and Gays (PFLAG)) have published statements that suggest that all children who express a desire for a transgender identity should be promptly supported in that claimed identity. This position appears to rest on the belief —which is widely promulgated by certain advocacy organizations—that science has already established that prompt "affirmance" is best for all patients, including all children, who present indicia of transgender identity. As I discuss later below, this belief is scientifically incorrect, and ignores both what is known and what is unknown.

65. It is instructive to consider how policies are constructed by professional and lay organizations. Professional association vote on policies that are formulated in small committees. Such consensus processes are not a reliable valid scientific methodology. These professional, political, or community support groups do not rely upon scientifically tested methodologies, although they claim to have done so. All methodologically informed workers, even among those who work in this arena, have in the past and continue to conclude that there is low level science underlying treatment patterns and the policies that encourage them. A "low" level is defined by specific criteria of validity or trustworthiness.

Professional associations have a tainted history of supporting unproven, controversial notions that were later shown to be improper, unreliable, and/or unethical. For example, the American Medical Association supported eugenic proposals to "improve the quality of the human stock" by coercive sterilization of "defective and undesirable Americans" and selective breeding. During the 1890s the renowned surgeon Albert Ochsner was invited to speak about his vasectomy procedure to the meeting of the American Medical Association. He recommended vasectomies to prevent the reproduction of "criminals, chronic inebriates, imbeciles, perverts, and paupers." (See, Oshsner, AJ, Surgical treatment of habitual criminals. JAMA, 1899:32:867-868). The AMA's support was a political not a scientific process.

Similarly, the American Breeders Association founded a Eugenics Record Office with an advisory board that included a Harvard physiologist, a Princeton psychiatrist, a University of Chicago economist, and a Rockefeller Institute for Medical Research recipient of the Nobel Prize in Medicine. This movement was focused on "terminating the bloodlines" of the "submerged lower ten percent of the population with 'defective germ-plasm'". (See, Black, E. War Against the Weak, New York, NY, 2003).

such multi-disciplinary research, analysis, and treatment is now being blocked and threatened as "conversion therapy" by political advocates. [See, Olson-Kennedy, J, Cohen-Kettenis, P., et al., Research priorities for gender nonconforming/transgender youth gender identity development and biopsychosocial outcomes, Current Opinion in Endocrinology & Diabetes and Obesity: April 2016 - Volume 23 - Issue 2 - p 172-179, doi: 10.1097/MED.0000000000000236]

Suicide, suicidal ideation, suicide attempts, suicidal manipulations

74. With respect to suicide risks, individuals with gender dysphoria are well known to have a higher risk of committing suicide or otherwise suffering increased mortality before and after not only social transition, but also before and after SRS. (Levine*, Reflections,* at 242.) For example, in the United States, the death rates of trans veterans are *comparable to those with schizophrenia and bipolar diagnoses but 20 years earlier* than expected. These crude death rates include significantly elevated suicide rates. (Levine, *Ethical Concerns,* at 10.) Similarly, researchers in Sweden and Denmark have reported on almost all individuals who underwent sex-reassignment surgery over a 30-year period. The Swedish follow-up study found a suicide rate in the post-Sex Reassignment Surgery (SRS) population *19.1 times greater than that of the controls after affirmation treatment*; both studies demonstrated elevated mortality rates from *medical and psychiatric conditions*. (Levine, *Ethical Concerns,* at 10.) See, C. Dhejne et al. (2011), Long-Term Follow-Up of Transsexual Persons Undergoing Sex Reassignment Surgery: Cohort Study in Sweden, PLOS ONE 6(2) e16885 ("Long Term"); R. K. Simonsen et al. (2016), Long-Term Follow-Up of Individuals Undergoing Sex Reassignment Surgery: Psychiatric Morbidity & Mortality, Nordic J. of Psychiatry 70(4).

75. Advocates of immediate and unquestioning affirmation of social transition in children who indicate a desire for a transgender identity sometimes assert that any other course will result

79. Thus, given the lack of credible science evidence for suicide reduction, transition of any sort must be justified, if at all, as a life-*enhancing* measure, not a lifesaving measure — although there is no credible to support either hypothesis. (Levine, *Reflections,* at 242.) In my opinion, this is an important fact that patients, parents, and even many MHPs fail to understand. They also often do not understand that the current gender affirmation "treatment" datafor life saving or enhancement are so weak, sparse, and poorly gathered that they do not permit usto know if gender affirmation interventions will increase or decrease a patient's risk of suicide orreduced depression ***or even an improved life.*** How many years will go by before such research is competently completed? See, C. Dragon, P. Guerino, et al. (2017), *Transgender Medicare Beneficiaries & Chronic Conditions: Exploring Fee-for-Service Claims Data*, LGBT Health 4(6) 404, DOI: 10.1089/lgbt.2016.0208.

V. KNOWN, LIKELY, OR POSSIBLE DOWNSIDE RISKS ATTENDANT ON MOVING QUICKLY TO "AFFIRM" TRANSGENDER IDENTITY IN CHILDREN.

80. As some research has already demonstrated, enabling and affirming social transition in a prepubescent child appears to be highly likely to increase the odds that the child will in time pursue pubertal suppression and persist in a transgender identity into adulthood. I consider the ethical implications of this intervention in the next section. Here, I emphasize that the Mental Health Professional (MHP), pediatrician, and parent must consider long-term as well as short - term implications of life as a transgender individual when deciding whether to permit or encourage a child to socially transition.

81. The multiple studies from different nations that have documented ***the increased vulnerability of the adult transgender population to substance abuse, mood and anxiety disorders, suicidal ideation, and other health problems stand as a warning***: Given these well-documented data, ***assisting a child down the road to becoming a transgender adult is an ominous***

decision. Data about trans adults remind all concerned that a casual assumption that transition will improve the child's life is ***not*** justified beyond his or her short term happiness about gender expression. The possibility that steps along this pathway, while lessening the relatively minor pain of gender dysphoria, *could lead to additional future sources of crippling emotional and psychological pain*, are too often not properly considered by advocates of social transition and not considered at all by the trans child. (Levine, *Reflections,* at 243.). The informed consent process for parents considering this option ethically should spell out short-term gains and long-term risks (beginning at early puberty risks). What follows is a discussion of the medical, social, and psychological risks of affirmation interventions ("transition").

A. Physical risks associated with transition

82. Sterilization. Sex Reassignment Surgery (SRS) that removes testes, ovaries, or the uterus is ***inevitably sterilizing and irreversible***. While by no means all transgender adults elect SRS, many patients do ultimately feel compelled to take this serious step in their effort to "live fully as the opposite sex". More immediately, practitioners recognize that the administration of cross-sex hormones, which is often viewed as a less radical measure, and is now increasingly done to minors, creates a risk of irreversible sterility. These risks have never been properly studied nor quantified in a systematic manner. As a result, even when treating a child, the MHP, patient, and parents must consider ***permanent loss of reproductive capacity (sterilization)*** *to be one of the major risks of starting down the road*. The risk that supporting social transition may put the child on a pathway that leads to intentional or unintentional permanent sterilization is particularly concerning given ***the disproportionate representation of minority and other vulnerable groups*** among children reporting a transgender or gender-nonconforming identity. *See* C. Guss etal., *TGN Adolescent Care* at 4 ("a side effect [of cross-sex hormones] may be infertility") and 5

98. I noted above an increasingly visible online community of young women who have desisted after claiming a male gender identity at some point during their teen years. Given the rapid increase in the number of girls presenting to gender clinics within the last few years, the phenomena of regret and desistance by young women deserves careful attention and study by MHPs. As reported by one author in 2021, *60,000 testimonies of personal de-transition can be found on the Internet*. See, Pablo Exposito-Campos. A typology of gender detransition and its implications for health care providers J Sex & Marital Therapy 2020 https:..doi.org/101080/0092623x.2020.1869126).

99. Thus, misleading reports of clinical experience, publications that misreport evidence, and the unregulated content of the Internet - many falsely claiming transitions are "easily reversible" — prevent the sobering acceptance of what has previously been asserted for decades — for most all such patients "once a transgendered person, always a transgendered person", whether referring to a child, adolescent, or adult, male or female.

VI. MEDICAL ETHICS & INFORMED CONSENT

A. The obligation of the mental health professional to enable and obtain informed consent

100. I have reviewed above the knowledge and experience that, in my view, a mental health professional should have before undertaking the responsibility to counsel or treat a child who is experiencing gender dysphoria or transgender identification. The MHP who undertakes this type of responsibility must also be guided by the ethical principles that apply to all health care professionals. 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

119. In light of the profound uncertainties in the field, and the many highly predictable or probable lifetime costs to the child if he or she persists in a transgender identity into adulthood, in my opinion it is not consistent with principles of medical ethics for physicians or other MHPs to suggest that parents should not or have no right to explore possible therapeutic options to assist their child to achieve comfort with the gender corresponding to his or her sex. The use of the label "reparative therapy" or "conversion therapy" by some advocates to lump all such possible therapies together and disparage them does not change this equation. (Levine, *Informed Consent,* at 7.)

120. The transgender clinical arena is growing increasingly uncertain as more attention has been paid to the lack of fundamental studies to support the current widespread fashions of professional recommendations and confirmation bias has been identified in recent highly acclaimed but deeply flawed work. While the general public is now accustomed to reading about trans culture wars, my opinion is that of a clinician who respects scientific methods of ascertaining best treatments. More caution is indicated when the consequences are greater. It has been repeatedly demonstrated in medicine that one size does not fit all. One must reject the idea that if a young person is trans, nothing else matters—the treatment should be immediate affirmation and endocrine support. All must realize that 50 years after trans treatment began to spread across the world, despite more than 10,000 publications, it is not known whether the burgeoning Transgender Treatment Industry is helping or damaging most GD patients.

121. It is my opinion that the scientific community finds the following matters to be uncertain, controversial, or incorrect.

— Gender dysphoria is a serious, physical brain based medical illness that causes suffering that must be treated by hormones and surgery if patients seek such treatments.

— All patients who label themselves as transgendered, regardless of the >120 sub-labels that may be invoked, gender all should be offered the same physical body-changing treatments, if they so desire.

— Hormones and surgery improve the lives of the transgendered in the long run.

— "Above all do no harm" principle can be sidestepped when administering hormones and removing healthy breast and genital tissues in the case of trans persons because it is "medically necessary" –that is, these patients represent a special exception to 2500 years of medical ethics.

-The uncertain long-term adjustments of trans adults, the rates of detransition, disappointment, and chronic depressive, anxiety, and substance abuse disorders do not need to be calculated nor should what is known about high psychiatric morbidity following hormonal and/or surgical treatment should not slow the affirmative treatment policy of trans youth.

--Civil rights considerations are more important than unanswered relevant scientific questions.

XX. SUMMARY OPINIONS:

122. There are no long-term, peer-reviewed published, credible, reliable and valid, research studies documenting or establishing:

a. The percentage of patients receiving gender transition procedures who are helped by such procedures according to well known criteria.

b. The percentage of patients receiving gender transition procedures who are harmed by such procedures according to well known criteria.

c. The reliability and validity of assessing gender identity by relying solely upon the expressed desires of a patient.

d. The mental health outcomes of trans behaving children who are either affirmed or not affirmed in childhood.

e. The percentage of various types of childhood functional challenges and psychiatric diagnoses of trans identified children

f. The percentage of patients whose new trans identity has been created by involvement in social media.

123. The above list of six issues can stimulate new research whose results may shape future trans care. In the meantime, those with gender dysphoria or a trans identity have a right to be more fully informed about what is known as do their physicians. Physicians, psychologists, parents, and patients have a right to be *protected* from these current experimental, politically tainted, fashionable "treatments".

124. Informed consent is designed to protect the rights of patients and families, the cognitive and ethical processes of physicians, and the ethical and legal duties of health care institutions. The need for credible, reliable-valid science is also essential to protect each of these entities. The informed consent document for affirmative treatments of youth should specify that up to 88% of children without affirmation will desist (heal naturally without treatment) from their childhood- onset trans preoccupations. Physicians always need to know the patient's original sex because while gender identity can dramatically change, biological sex and its unique susceptibilities to disease does not.

125. The Transgender Treatment Industry's policies and advocacies are a niche group of well meaning mental health professionals, endocrinologists, plastic and urological surgeons, and transgendered individuals. Many in their individual professions have differing opinions. They should not be viewed as speaking for all of medicine on these highly controversial issues.

126. Science not politics needs to drive trans care. The medical professions has many tragic examples of when political sensibilities drive medical treatments. When policy is made by voting in the face of low quality science, claims that treatments are evidence-based should be considered misleading and deceptive.

127. No medical, surgical, or psychiatric treatment is invariably successful in producing an agreed upon outcome. In other branches of medicine and psychiatry risks and benefits, outcomes and error rates are better known, far less controversial, and much better proven by credible, reliable-valid scientific research. Error rates for gender affirmation diagnoses, errors rates for predictions of effective vs. harmful affirmation treatments, error rates for increases or decreases in suicidal risk following affirmation treatments, remain unknown. In the field of gender affirmation intervention there has been a rush to treat and a remarkable absence of ethical concern based on obvious scientific limitations as outlined in this report.

128. **Expert Witness Report Methodological Limitations**: My opinions and hypotheses in this matter are — as in all expert witness reports — subject to the limitations of documentary and related evidence, the impossibility of absolute predictions, as well as the limitations of social, biological, and medical science. I have not met with, nor personally interviewed, anyone in this case. As always, I have no expert opinions regarding the veracity of witnesses in this case. I have not yet reviewed all of the evidence in this case and my opinions are subject to change at any time as new information becomes available to me. Only the trier of fact can determine the credibility of witnesses and how scientific research may or may not be related to the specific facts of any particular case. In my opinion, a key role of an expert witness is to help the court, lawyers, parties, and the public understand and apply reliable scientific, technical, and investigative principles, hypotheses, methods, and information. I have transmitted this confidential expert report directly

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

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Exhibit B

Deposition of:

Stephen B. Levine , MD

September 10, 2021

In the Matter of:

Kadel, et al vs. Folwell

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IN THE UNITED STATES DISTRICT COURT
FOR THE MIDDLE DISTRICT OF NORTH CAROLINA

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MAXWELL KADEL, et al.,

Plaintiffs,

vs. Case No. 1:19-cv-272-LCB-LPA

DALE FOLWELL, in his official capacity as State Treasurer of North Carolina, et al.,

Defendants.

~~~~~~~~~~~~~~~~~~~~

Video Deposition of
STEPHEN B. LEVINE, M.D.

September 10, 2021
9:05 a.m.

Taken at:
Veritext Legal Solutions
1100 Superior Avenue
Cleveland, Ohio

Tracy Morse, RPR

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~ ~ ~ ~ ~

ALSO PRESENT:

Joseph Vandetta, Videographer

TRANSCRIPT INDEX

EXHIBIT CUSTODY
EXHIBITS RETAINED BY COURT REPORTER, 1-21
(No Exhibit 16)

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INDEX OF EXHIBITS (Continued)

Q. Okay. And so then were there any external grants to research and publish about the treatment of children or adolescents --

A. No.

Q. -- with gender dysphoria?

Okay. Is that a, "No," when I included the, "Gender dysphoria," as well?

A. That is a, no.

Q. Okay. Thank you. Okay. So on page 3 of your report -- actually, I'm sorry. It's going to be the bottom of page 4 and to the top of page 5. Your report lists your experience as an expert witness, which we talked about a little bit earlier. I just -- I'm wondering if you would confirm this is not an exhaustive list of your experience as an expert witness either via deposition or report.

A. I wouldn't want to testify that this is absolutely complete, given the fact that I don't keep a list compiled. This is kind of compiled retrospectively from memory and documents. And so this is the best I could have done on April of 2021 --

Q. Understood. Thank you. So --

A. -- you might find something else.

Q. Was it --

A. -- in a commercial building where our clinic was. It was just, you know, a conference room in our clinic.

Q. And that was within -- was that within a business --

A. It was --

Q. -- a psychiatric practice?

A. I'm sorry. I interrupted you.

It was within The Center For Marital Health, which was a business that I and two other people started and owned and ran. And in that business, we continued the same kind of work we did with the University minus the large number of trainees.

Q. You mentioned that after '93, you were not being paid by the University. Were you providing your clinical psychiatric professorship gratuitously?

A. Meaning without pay? Yes.

Q. Okay. Do you know if, after you moved the clinic away from Case Western Reserve, if Case Western Reserve University Medical School created a separate gender identity clinic?

A. Years later they did --
Q. Oh, sorry.
A. -- I would say, they created a separate clinic perhaps in 2017, 2016.
Q. Do you know the name of that clinic?
A. I don't think it's in the department of psychiatry. I think it's in the department of pediatrics. And the answer to your question is, no.
Q. Does The LGBTQ and Gender Care Program sound familiar?
A. No.
Q. But have you -- sorry. Have you evaluated any patients through that separate clinic that Case Western Reserve has?
A. No. Much to my dismay, that clinic was formed and maintained without any input from me, who I thought was one of the experts in the field.
Q. Do you know if they have psychiatrists, within that clinic?
A. I -- I'm not knowledgeable about the composition of that clinic. There is a very strong liaison between our department of

What do you mean by, "This era"?

A. Before 1993.

Q. Okay. And what do you mean by, "Occasional"?

A. I would say that 95 percent of the patients that we saw were 16 and 17, 18 and up. We could debate what the word, "Child," means, but to me an 11-year-old is a child, even a 13-year-old is a child, especially when my children were 13. And so we -- in the first twenty years, transgender issues were primarily an older teenager and adult, mostly adult issues. In recent years, I would say, 12, 15 years, the number of adolescents appearing in gender clinics at our place and everywhere as far as I can see has increased exponentially, especially the number of teenage girls who are declaring themselves trans boys.

Q. So how many -- sorry. So the first twenty or so years, you said approximately 5 percent of all patients were children.

A. Were younger -- on the younger end of the spectrum --

Q. Right.

A. -- yes.

it, you see? But at this moment -- this week, I have one patient that I see weekly, who is a transgender teen. My staff -- if I can be presumptuous to call them, "My staff" -- our staff sees more.

Q. And thinking about the last year, approximately how many adult patients did you see -- and let's use your framing of, "Regular." So that could be one, for one followup visit or that could be for more -- how many adult patients did you see for treatment of gender dysphoria?

A. Approximately six.

Q. And using that same framing of, "Regular," how many children, so under age 11?

A. In the last year?

Q. Yes, yes. In the last year.

A. Zero.

Q. How many adolescents in regular treatment for gender dysphoria would you approximate you've seen in the last five years individually, exclusive of your supervision of other clinicians?

A. If you ask me the question in the last year, I would have told you five or six,

but since you ask it as a five-year period, I'm at a loss to tell you whether it's twelve or fifteen. I --

Q. An approximate is fine. Thank you.

A. -- let's just say a dozen with an asterisk, very approximate.

Q. And jumping a little bit more in terms of time. How about the last ten years?

A. Again, using the same asterisk, I would say, double it.

Q. Okay. And you said zero people under age 11, so children this last year. What about in the last five years?

A. Oh, two years ago, we had this charming little 6-year-old. One of my colleagues specializes in children and I get to hear about these cases. Occasionally I get to meet the parents, but I personally have not delivered a psychotherapeutic care or evaluation directly of a child with the exception of this one person that I was involved with.

Q. And that was this last year, you said?

A. That was -- I think it was probably

two, two and a half years ago.

Q. Oh, okay. And what kind of treatment -- I should say, have you referred any of those adolescent patients for additional treatment, besides psychotherapy, for the treatment of gender dysphoria?

A. Yes.

Q. And what kinds of treatment have you referred them for?

A. For endocrine treatment.

Q. Okay. And approximately what percentage of those adolescent patients have you referred for endocrine treatment?

A. Give me the timeframe of that question, please.

Q. Sure. So you said a few moments ago, in the last five years, you saw maybe, asterisk, 12 to 15 adolescent individually yourself. Of those 12 to 15, what would be the approximate percentage you referred for endocrine treatment?

A. I'm hesitating to answer the question, because some of those children have been taking testosterone or estrogen surreptitiously from their parents. And while

I didn't refer them for the treatment, I was seeing them while they were taking the treatment. So if we're only talking about adolescent -- referrals of adolescents for hormones, I would say a very small percentage of those, say, I guess you would say 10 percent.

Q. Fair enough. Have you had yourself individually as a clinician, have you had any non-transgender children who you have made a referral for endocrine treatments related to other conditions?

A. No.

Q. Okay. So then zooming out 30,000 foot view of your 48-year career now, would you say overall, you have provided treatment -- that is, psychiatric treatment -- to mostly adults experiencing gender dysphoria, gender identity issues?

MR. KNEPPER: Objection, form.

A. I would say that throughout my career, we should divide my career into the first twenty years where mostly adults were seen by our team and myself. And then we ought to talk about the last ten or fifteen years

where the number of adults has diminished and the number of adolescents has increased dramatically.

Q. Okay. Thank you. So as a part of your private practice, do you write letters of authorization for endocrine treatments?

A. Yes.

Q. And do you write letters of authorization for gender affirming surgeries?

A. I have. I have not recently, because most of my patients are 13 or 15 or 16, you know.

Q. Okay. And I'm sorry. Just by, "Recent," when was the last time you wrote a letter of authorization for a gender affirming surgery for an adult?

A. Probably twelve months ago.

Q. Okay. And over the course of your career focusing on your treatment of adults experiencing gender identity issues, for what percentage of those patients would you estimate you wrote a letter of authorization for gender affirming surgery for?

MR. KNEPPER: Objection, form.

A. Again, I would like to put an

asterisk to whatever I answer this question as. I have not kept track of those figures. I have written -- I've written or cosigned letters for hormone treatments and for gender confirming surgeries for many people. There were more people in the '70s and '80s than in recent decades. In part as a reflection of my own evolution of understanding of these problems and in part it's a reflection of the demography of patients who are coming to see me. I really would not like to answer that question, only because I don't know if the word, "Fifteen," or the word, "Thirty-five," is more accurate --

Q. Understood.

A. -- but I can tell you, I have written letters, especially in the early years, for the things that you're making reference to.

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(Thereupon, Deposition Exhibit 2, 12/21/2020 Zoom Deposition of Stephen B. Levine, M.D., was marked for purposes of identification.)

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Q. Okay. For the record, I'm showing

Q. Do you think as a general matter that it's good for patients who come to DELR for services related to gender dysphoria to be able to have insurance coverage of that care?

MR. KNEPPER: Objection, form. Beyond the scope.

A. Well, the people who come to DELR are generally coming for evaluation and psychotherapy services. And I believe it's very important that people have access to mental health care and that mental health care for many of our patients are not wealthy, affluent people. And the fees that even masters prepared people charge can become prohibitive. And so I think it's a very nice idea, the psychiatric services, mental health services evaluation and ongoing treatments, with or without medication, it would be nice to be able to cover those things, yes. I think that's a long answer, yes.

Q. Understood. And thinking about the treatment that you refer patients out for, the endocrine treatments in particular, do you think it is generally good if you provide authorization for that treatment that the

patient be able to afford it?

MR. KNEPPER: Objection, form.

A. May I say, of course?

Q. You may. You may say anything you would like.

A. Of course.

Q. Thank you. Well, anything you would like within reason.

If you make a letter of authorization for a patient for the treatment of gender dysphoria specifically related to a surgical treatment, do you think it is good that they be able to access that treatment that you've authorized?

MR. KNEPPER: Objection, form.

A. Not to be cagey, I want to talk about one word you just used in that sentence. I need you to understand that historically in our clinic for those 47 years, our clinics for 47 years, we are not in the business and we have never been in the business of recommending surgery or recommending hormones. We recommend a continued evaluation so that we -- the person can make up their mind how to proceed.

It is not our 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. So what we do is we say, we will write a letter of support for endocrine treatment or for hormones if this is what you want. And we say what our concerns are. We tell the endocrinologist and we tell the surgeon what our concerns are and that we see -- we have reservations about this, and these are our reservations, but the patient has decided this is what he or she wants to do.

And so we write a letter of support, but I don't -- every time you use the word, "Recommendation," there's part of me that wants to say, no, we do not recommend. We have never recommended. We have not had the knowledge base. We have not had the clinical experience and the knowledge base to say, I'm a doctor. I know this field. This is what I recommend to make you better. We do not talk that way. We do not think that way. And so I may want to always put an asterisk to any sentence that you use the word, "Recommend." I need you to understand that that's where I'm coming from.

MR. CHARLES: Thank you,

Dr. Levine.

Excuse me just a moment. Can you read back my question. I don't recall if I used, "Recommend." I thought I used, "Authorization." I just want to make sure.

(Record was read.)

MR. CHARLES: If we could just go off the record for a second.

VIDEOGRAPHER: Off the record 10:52.

(Discussion held off the record.)

VIDEOGRAPHER: On the record 10:53.

BY MR. CHARLES:

Q. Okay. Thank you for that clarification, Dr. Levine. I'll be more careful about using terminology more close to, "Authorization," rather than, "Recommendation," and I understand your distinction in your practice. So do you, though, think it's good, if you are authorizing a treatment, a patient has said, This is the treatment I would like, and you have done an evaluation and determined that you will write, as you said, a letter of support, do you then, as a practitioner, think it's good that they can access it, that they can afford it?

concept of agency and being a doctor, I think is different than the implication of your question.

Q. Is the worrisomeness for a patient's future health, is that a reason to deny all medical care for gender dysphoria?

A. Absolutely not.

Q. Dr. Levine, I'd like to return back to, I believe it's Exhibit 2, the Claire deposition. And please, if you would turn to page 156.

A. I'm sorry. 150 what?

Q. Page 156. And beginning at line 10 on page 156, Dr. Levine, I'll read it, if you'll just follow along, please.

Question: "Are you aware that this case concerns an insurance exclusion that is categorical at preventing" --

Skipping to line 15.

"-- hormones and surgery as a treatment for gender dysphoria?"

Answer: "I am aware that your plaintiffs are suing to get coverage for -- that is not provided by their particular insurance. I am aware of that."

demonstrate their efficacy. This is the problem.

This is the essence of the problem. This is, I think the essence of my testimony with you today. It's not whether I personally as a doctor would like this patient to have insurance to cover their hormones. It's about, is this the right thing to do for this person and can I help the person see clearly what the dangers are and what the benefits are. That's the issue for a doctor, for Stephen Levine as a doctor. I hope that's a cogent answer --

Q. It is --

A. -- to your question.

Q. -- it is cogent. Thank you.

Given all of that, is that -- so you just explained, testified that there are complications, some lack of -- and I'm summarizing here, so I will confirm that this is an accurate summary of what you just shared, but I can't possibly repeat all of that. Given all of those concerns that you have, is that a reason to deny all medical interventions to people with gender dysphoria?

MR. KNEPPER: Objection, form.

A. No, but that's not -- that's a separate question about insurance.

Q. Yes, it is a separate question. So now I'm asking: Are those concerns you raised justifications in your mind for denying medical interventions to all people with gender dysphoria?

MR. KNEPPER: Objection, form.

A. You know, I'm not advocating denying endocrine treatment or surgical treatment. I'm just saying that we as a medical profession need to walk the walk that we talk. We say as a principle of ethics that our interventions should be based upon the best current knowledge, it should be based on science. It should not be based on politics. It should not be based on fashion. It should not be based on civil rights considerations. They should be based on the kinds of studies that I just described to you with predetermined outcome majors that are agreed upon --

Q. Sorry?

A. -- period.

Q. I was --

A. I forgot to put the period.

Q. That's okay. Did you just say, Dr. Levine, you're not an expert in health insurance?

A. I am not an expert in health insurance.

Q. Okay. Or what insurance should or should not cover?

A. Yes.

Q. Do you recall what the insurance billing code typically is for psychotherapy for gender dysphoria? I know it's been a long time since you've accepted commercial insurance, so I'm not sure if the billing codes are the same, but do you recall --

A. The billing code is 90837.

Q. Okay. Is there a code that you're familiar with that is F64.0?

A. That's not a billing -- that's diagnostic code --

Q. Thank you.

A. -- there's a separate code for diagnosis and a separate code for procedure.

Q. I see. So F64.0 is a diagnostic code?

A. Yes.

VIDEOGRAPHER: Off the record 11:26.

(Recess taken.)

VIDEOGRAPHER: On the record 11:31.

BY MR. CHARLES:

Q. Okay. Dr. Levine, in your report, you stated that you had not met with any of the plaintiffs in this case, correct?

A. Yes.

Q. Okay. And you have not interviewed any of the plaintiffs in this case, correct?

A. Correct.

Q. And so you are not offering any opinions about the plaintiffs in this case, correct?

A. Correct.

Q. Okay. And that would include the veracity of their experiences of gender dysphoria, correct?

A. Yes, correct.

Q. And that would not include the accuracy of their gender dysphoria diagnoses, correct?

A. Correct.

Q. Okay. You're not offering any opinions about their mental health histories?

A. Correct.

Q. Nor any of the affects of the gender affirming treatment they may have received?

A. Correct.

Q. Okay. Thank you. Let's return to your report. I don't know if you have that --

A. My report?

Q. Yes. You can put away that document in your hand.

So if you would, please, turn to page 6 of your report.

Okay. So on page 6, paragraph a. at the bottom of the page there, Dr. Levine. The report states that this is one of the opinions you're offering, which is, "Sex as defined by biology and reproductive function 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." Did I read that correctly?

methodology and are capable of critically reviewing the literature. So your statement is true on the most superficial level, but is totally incorrect when it comes to scientific standards of care for issuing guidelines for the medical profession. So I don't know how to answer the question. On the surface, the answer is, yes. And underneath the surface, the answer is, no.

Q. So the International Journal For Transgender Health is still a peer-reviewed source, though, right?

A. It's peer reviewed by people who make their living supporting transgender care.

Q. But it's still peer reviewed, right?

A. It's peer reviewed --

Q. And as for your --

A. -- I think it's peer reviewed.

Q. Okay. Understood. And as for your more conservative approach, can you cite to any studies or research that resulted in better outcomes than people who adhere strictly to the WPATH standards of care version 7?

A. No. This is part of the problem in

evaluation leading to a therapeutic process, it seems prudent, given the fact that we are changing people's bodies, especially teenagers' bodies, and they are not of developmental sophistication yet that court systems or at least one court system thinks they're certainly too young to make these life-altering decisions. So people in SEGM are biased in the direction of being conservative and providing psychotherapeutic evaluations of the child, of the teenager and of their parents, of their family systems to see if we can find a way to help them be informed about what is going -- what they think they want to do in their future.

Q. And so when you provide letters of authorization for hormones or for surgery, do you do so in accordance with the WPATH standards of care?

A. Yes. That is the standard, to provide a letter of recommendation.

Q. Okay. So turning back to your report, Dr. Levine. You can go ahead and put away the trial transcript there.

A. I'm sorry. Did you say, "Turning

Q. Okay. So is a, "Hypothesis," an idea about why something happens, but doesn't provide evidence for why something is happening?

MR. KNEPPER: Objection, form.

A. A, "Hypothesis," generates the pursuit of evidence.

Q. Has social contagion as an explanation for increased cases of gender dysphoria been scientifically proven yet?

A. No. But when you seek -- when you see -- actually see patients and talk to them about their friends and hear about the influence of the Internet and the gurus on the Internet who tell 13 and 12-year-old children who are concerned about menses or concerned about breast development or concerned about their bodies changing and then they're told that they're transsexual by somebody that they've never met that they talked to on the Internet, that would be social contagion or social education.

Or when you hear about a friend who declares themselves trans and then your patient six months later declares themselves trans, you

wonder about the -- the interpersonal, psychological link between best friends in young puberty, young years of puberty and how one can identify with one's friends and that would be a social contagion. Those are 3the kinds of ideas that people like me get when we sit with people week after week talking about their lives. You see, that's not science.

But that is clinician and this is the kind of thing that leads to intuition, clinical intuition and that's the source of the generation of the hypothesis. But we think as clinicians, when we hear -- I mean, I don't think I've ever seen a teenager trans person who hasn't been heavily involved and influenced by the Internet, for example, but I have not done studies to document that in a way that would be scientifically acceptable. There are other people who have.

And I doubt very much if you'll ever find a clinician on any side of this issue, you see, who would say, oh, no most of my patients have never talked to anyone on the Internet about transgender. The Internet is just part of life today and -- but transgender teenagers spend

hours and hours of their time getting counseled or participating with the virtual trans community. That's a hypothesis.

Q. So no scientific citation?

A. When we use the word, "Scientific," in the best sense, yes, the answer to your question is, no scientific.

Q. Okay. No studies of citations you can point to today to support that hypothesis?

A. Oh, I think Lisa Littman's studies are in the literature and/or in press that documents this.

- - - - -

(Thereupon, Deposition Exhibit 7, "Correction: Parent reports of adolescents and young adults perceived to show signs of a rapid onset of gender dysphoria," Article, was marked for purposes of identification.)

- - - - -

Q. Okay. For the record, please note I'm showing to Dr. Levine what has been marked as Exhibit 7. "Correction: Parent reports of adolescents and young adults perceived to show

signs of a rapid onset of gender dysphoria," by Lisa Littman published March 19, 2019. Have you seen this material before, Dr. Levine?

A. I've seen of it. I don't think I've read it.

Q. Okay. Were you aware that the Lisa Littman article had to be withdrawn, corrected and republished?

A. Yes.

Q. Okay. And were you aware that the initial article was based on a survey of parents --

A. Yes.

Q. -- of purportedly transgender children and the parents were recorded -- I'm sorry. Let me start over. Were you aware that the Littman article was based on a survey of parents who were recruited through some parent groups?

MR. KNEPPER: Objection, form.

A. I knew it was a survey of parents.

Q. Okay. And did you know there were no report-outs from the young adults of those parents in the article?

A. It was a report of parents'

transitioning. However, it is...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." Did I read that correctly?

A. Yes, you did.

Q. All right. Your report also cites as support for the social contagion hypothesis to an article from Medscape.com written by Becky Mccall and Lisa Nainggolan as support for the social contagion theory. Is that correct? I'm sorry. It's not going to be on this article, Doctor.

A. I don't know that article.

Q. Okay.

A. You haven't asked me a question about this. Did I misunderstand something?

Q. No, no. Sorry. We're just --

A. You haven't asked my opinions about that, yeah.

- - - - -

(Thereupon, Deposition Exhibit 8, "Transgender Teens: Is the Tide Starting To Turn?" Article, was

marked for purposes of identification.)

- - - - -

Q. Yeah. So, for the record, I'm showing Dr. Levine what has been marked as Exhibit 8. "Transgender Teens: Is the Tide Starting To Turn?" by Becky McCall and Lisa Nainggolan, April 26, 2021. Dr. Levine, you said you have not reviewed this article before?

A. Which one are you referring to?

Q. I'm sorry. That one to your left.

A. This?

Q. Yes. Take your time.

A. Have I reviewed it, no. You know, I've seen the picture of Keira Bell. I've seen news reports of this in the past, but they were just news reports, yeah.

Q. Do you know if either of the authors of this article is a scientist?

A. I have no idea.

Q. Okay. Or a psychiatrist?

A. (Indicating.)

Q. I'm sorry. Could you make your responses verbal? I'm forgetting.

A. I have no idea.

Q. Okay. Thank you. Have either of them ever treated transgender children or adolescents?

A. I would have no idea.

Q. Okay. To your knowledge, is the information provided on Medscape.CA subject to peer review?

A. I don't know how Medscape works. I've heard there have been retractions, but I don't know how their peer reviewed is made. Perhaps people write in that, This is ridiculous what you've been teaching or what you've been saying, but whether they're peer reviewed or not, I have no idea.

Q. So you probably -- I'm sorry. So do you know if this article has been published in a peer-reviewed journal to your knowledge?

A. "Transgender teens: Is the Tides" -- that article?

Q. Yes.

A. I don't know. I don't know this article. I don't know where it's from.

Q. Okay. So your report includes a quotation from this article. "The vast majority of youth now presenting with gender

multi-continental set of observations from Europe, from Australia, from North America --

Q. Okay.

A. -- it almost doesn't even need citations it's so clinically apparent.

Q. Okay. But there's no citation in your report?

A. In my report, yes.

Q. Okay. So on page 18, going back to your report, at the bottom of page 18, you use a term, "Transgender Treatment Industry." Is this the first time you have used this term?

A. In this report?

Q. No.

A. You mean, did I ever use it in another report?

Q. Yeah, yeah.

A. I'm not sure. If this is -- if it's not the first, it might be the second.

Q. And where did the term originate?

A. I think it -- the term originated from Dwight Eisenhower at the end of his -- when he was leaving the presidency in 1952, he warned the people about the military industrial complex and that there was a very comfortable

the methods we made reference to before, the efficacy of the treatment and the downsides of the treatment. But because WPATH is an advocacy organization and the scientific establishment of the efficacy of their treatments are not important to them, what they are doing is teaching young mental health professionals and medical professionals as a whole what their ideology is. They say it's scientifically established.

I'm here to tell you to the extent that I understand science, it is not scientifically established. In a sense, there is an industry that has different elements that feed each other; that's the transgender treatment industry. I think if we put our heads together, we could find another term.

Q. So did you coin that phrase then?

A. No --

Q. Okay.

A. -- no.

Q. Have you seen it used before in any peer-reviewed articles?

A. Not in a peer-reviewed article. I've seen it used in these kind of expert

opinion -- (Indicating.)

Q. Okay.

A. -- I would -- you know, if I had time and I had a committee of people, I -- I would probably find a different term for it. But I don't mean it in a disparaging way. I mean that this is a group of compassionate people trying to help other people who actually believe that the science has established the best practices when in fact they're not well informed.

Q. Do you need a sip of water after that?

A. No. I'm just a long-winded guy.

I want to add, if I may, that we should make a distinction between education and indoctrination. Education can be based on science. Indoctrination is based on preferred beliefs that, if you allow me to use this term again. The transgender treatment industry is heavy on indoctrination and has declared, if you look at the standards of care, if you don't believe these systems, you're not a competent -- you're not competent to take care of people. That of course is the height of

A. No. Their gender dysphoria may be a product, you see, of these other things. For example, if you have someone who has been sexually abused by her stepfather and becomes a trans person in adolescents, we want to talk about the sexual abuse and the process between that person and what fears for the present and the future that has caused the child. And we're not attacking their trans identity. We're trying to help them understand where they came from and what they're coping with and why they're so fearful or so distressed by their body changing.

Q. And their gender dysphoria could be separate and apart from that traumatic experience?

A. Theoretically it could be, yes.

Q. And if it persisted sufficiently enough, you would consider a letter of authorization for --

A. Yes.

Q. -- hormones?

A. Yes.

MR. KNEPPER: Objection, form.

Q. Okay. If you would, please, turn

A. That is correct. And may I add that it's very, very difficult to understand. The natural question would be, how do you compare the general population with the trans people who did not have surgery with the trans people who did have surgery.

Q. Thank you, Dr. Levine. That's not my question, though. I just wanted to confirm that was not the control group. You mentioned this study later in your report, page 66 beginning at paragraph 74. Do you see that?

A. Um-hum.

Q. Okay. And basically that -- well, here, let me point you exactly. The sentence starts with, "Similarly," about halfway down the page, third sentence of that paragraph.

A. Um-hum.

Q. And, as you mentioned, you cite the Dhejne study and I believe -- or I should ask: Is the Denmark study you're referencing the study directly after it --

A. The Simonsen study.

Q. -- the Simonsen study?

A. Yes.

Q. Okay. So beginning with the Dhejne

study, 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?

MR. KNEPPER: Objection, form.

A. That would be illogical.

Q. Okay. Dr. Levine, I understand you said that would be illogical, but just to be clear. You're not recommending -- sorry. I'm not using that word. You're not saying that the fact that some people commit suicide following gender affirming surgery means that there should be a ban on access to that surgery. Is that right?

A. Not for that reason, no.

MR. KNEPPER: Objection, form.

Q. Not for that reason. Okay. Are you recommending that there would be bans on gender affirming surgery for any reason?

A. I think there are -- you know, I think most prudent people in this field, just to use the example of what you read out loud about the Finland study, a case-by-case basis. That's how doctor need to decide things, but there are many, many reasons to be cautious

fashion and to be very hesitant about going forward.

Q. But you're not recommending total bans on gender affirming surgery?

A. I'm not recommending total bans. I'm aware of the individual circumstances of individual people's lives and their commitment to transgender living. And I don't want to be draconian about this. I want to be compassionate about this.

Q. I understand. I appreciate that. I just want to make sure I'm understanding you correctly.

- - - - -

(Thereupon, Deposition Exhibit 12, "Long-Term Follow-Up of Transsexual Persons Undergoing Sex Reassignment Surgery: Cohort Study in Sweden," Article, was marked for purposes of identification.)

- - - - -

Q. So for the record, I'm presenting to Dr. Levine what has been marked as Exhibit 12. "Long-Term Follow-Up of Transsexual Persons Undergoing Sex Reassignment

For the 22nd time today, did I read that correctly?

A. It's the 23rd time.

Q. Oh, okay.

A. Yes.

Q. I was hoping you weren't counting, but, okay. Did you testify earlier today that the limitation of the Dhejne study is that the controls were not transgender persons who had not undergone gender affirming surgery?

A. Yes.

MR. KNEPPER: Objection, form.

Q. Okay. You can set that aside, Dr. Levine.

- - - - -

(Thereupon, Deposition Exhibit 13, 2017 "On Gender Dysphoria," Booklet From Department of Clinical Neuroscience, Karolinska Institutet, Stockholm, Sweden, was marked for purposes of identification.)

- - - - -

Q. For the record, Dr. Levine has an exhibit that has been marked as Exhibit 13. "On Gender Dysphoria," by Cecilia Dhejne from

ideation in transgender people.

A. Well, you know about the Branstrom-Pachankis study and the criticism of the study --

Q. But I'm not talking about the study.

A. -- and part of the study demonstrated that it increased suicidal ideation and attempts in the first two and a half years after surgery, especially in the first year --

Q. Right. Is your testimony --

A. -- so I'm not testifying that. I thought you were asking me about this, which I need to comment on, because this is not an accurate depiction of my statement in the reference. (Indicating.)

Q. Well, that's not what I'm asking about, Dr. Levine.

A. Well, you're reading this and I'm misquoted here. So I don't want you to imply that she is accurately representing my views, because I did not say that gender affirming treatment in general should be stopped. I've never said that. This is an article about

at different times have reported that in the large majority of patients, absent a substantial intervention such as social transition and/or hormone therapy, gender dysphoria does not," continue, "through puberty."

So there are some children who persist in their asserted gender identity through puberty, correct?

MR. KNEPPER: Objection, form.

A. Correct.

Q. And some who persist in wanting to transition via medical treatments?

MR. KNEPPER: Objection, form.

A. Yes. Some of the children have learned about medical treatments somewhere along the line and they feel instantly that this is for them.

Q. And then looking at paragraph 56, which is on page 41, so just the very next page on the bottom, the second sentence in that paragraph. "I observe an increasingly vocal online community of young women who have reclaimed a female identity after claiming a male...identity at some point during their teen

transgender people is individual based, right?

A. Well, it's both --

MR. KNEPPER: Objection, form.

A. -- yes, that's partially true. And ideally that's true, but it's obviously not entirely true. It's why we're here, is it's categorically based.

Q. Let me rephrase that. You design treatment for your patients based on what that patient in front of you, what they need, what they want, what you determine -- sorry. Not what you determine, but what you might authorize?

MR. KNEPPER: Objection, form.

A. What the patient and I discern together.

Q. Thank you. Okay. Let's jump to, again, still in your report, page 68.

A. We've left 40 and 41? 68.

Q. Okay. Looking at the bottom of page 68, Dr. Levine, paragraph 78. It states, "Similarly, the American Psychological Association has stated because approach" --

A. Sorry.

Q. I apologize.

Gender Nonconforming People (2015)."

So is that lack of consensus that you discuss a justification to categorically ban social transition for children as a treatment for gender dysphoria?

MR. KNEPPER: Objection, form.

A. By, "Children," you mean 6 and 7 year olds?

Q. Those for whom medical intervention is not indicated.

A. Is that a reason to ban it?

Q. Correct, social transition.

MR. KNEPPER: Objection, form.

A. The reason to -- so let me qualify that. There's a, yes, answer, there's a reason to ban it. And the reason to ban it is both a developmental and an ethical reason. There have been eleven studies of these cross-gender identity children who are not socially transitioned and the vast majority of them de-transition by the time they're mid adolescents or older adolescents. They become homosexual individuals usually or bisexual individuals, but they are cis gender.

So if we take a 6-year-old child and

A. -- nor you didn't ask me to comment on that.

Q. It was related to what you had said before. So this is related but not related to what we just read. So you can put that aside.

A. Okay. But your next question was about puberty blocking hormones, which are not being used for 6-year-old's and 7-year-old's --

Q. Correct, yes, a separate group of people.

A. -- so we're on a different category.

Q. Yes.

A. Okay. So you asked me if I think puberty blocking hormones should be used on a case-by-case basis?

Q. Correct, yes.

A. I don't think so.

Q. So that is to say, there are no circumstances you would advocate for a total ban on that intervention?

MR. KNEPPER: Objection, form.

A. Number one, I've never seen a child where that has come up where I thought it was a good idea. In the cases I've seen, it was like

a treatment for the mother's pathology, not for the child. And it's like a warning sign, boy, be careful. You see, if you see one case like that, you wonder -- and it's so conspicuous, you wonder in the next case, if the same thing is going on in a more subtle way.

Is the child acting out the ambitions of the mother or the father? I just think prudence -- I think considering the child has not gone through puberty or has not gone far into puberty and puberty brings all kind of psychological, physical and social changes to a child and those changes lead to desistance in many, many children, to put them into a state where all their peers are developing physically and they're going to be poirot (phonetic).

And then most of those children have social anxiety problems and they avoid -- they don't have friends, right. And this is going to make them even more different than their peers and it's gone to deprive them of the sexualization of their mind and the discovery of masturbation and the discovery of sexual desire for partners, you see. This is only going to increase the child's difference from

her peers or his peers and I don't think this is a prudent idea.

And if you wanted me to suggest a ban on anything, it would be a ban on using puberty blocking hormones, especially when the evaluation of those children are focused on the gender dysphoria of the child and not on the background of the child and not on what's going on. So I think that's an answer to your question.

If we're going to use these drugs, if we're going to use social transformation of children, if we're going to use puberty blocking hormones, it should only be used in a carefully designed protocol. And follow up has to be guaranteed so in one year and in two years and in three years and before we start giving cross-gender hormones we have data --

Q. Sorry.

A. -- so the answer to your question is, I 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, which is exactly what the Dutch protocol did, by the way.

Q. Sorry. So you just said you would ban -- you would recommend a ban on --

A. If --

MR. KNEPPER: Objection, form.

A. -- look, I'm a doctor. I'm not a policy maker --

Q. I understand, yes.

A. -- if you ask me my political opinion about, should we ban this, is that a reasonable thing, I think there's a very strong argument for banning puberty blocking hormones.

Q. Okay. And, right. So you're here as an expert offering an expert opinion. So are you separating that from -- like are you saying your political views that you would advocate for bans or are you saying your expert opinion you're offering in this case is you would recommend ban?

MR. KNEPPER: Objection, form.

A. I would recommend ban. To what extent it's from my politics or from my being a parent or from my being a doctor, I don't know. I would recommend we not use puberty blocking hormones.

Q. In Claire, in this case that we

Answer: "Where we had a healthy mother and father, an intact family who was psychologically informed and who has -- where a child has come out of toddlerhood acting consistently in a gender atypical fashion, and where the parents are not homophobic..."

Question: "The parents are not what kind of people?"

Answer: "Homophobic."

For the 27th time, did I read that correctly? Did I read that correctly?

A. Yes.

MR. CHARLES: Okay. All right. Let's go ahead and take a break for a few minutes.

VIDEOGRAPHER: Off the record 3:20.

(Recess taken.)

VIDEOGRAPHER: On the record 3:38.

BY MR. CHARLES:

Q. So, Dr. Levine, before the break, you were talking about 6 and 7 year olds and you mentioned there were eleven studies. Can you identify which eleven studies from your report you're referring to?

A. Cantor, the reference Cantor lists

the eleven studies and these eleven studies have been done over probably thirty years.

Q. Okay. So Cantor was one review of eleven studies?

A. Cantor was a review of the eleven studies. I can't list to you the eleven individual studies. The latest one is written by Singh, S-i-n-g-h. It was published in April of 2021, in the Frontiers of Psychiatry. And that perhaps is the most comprehensive of them. And that's the one that confirms -- that's a study of boys and it confirmed that 12.2, I think percentage of them persisted over a thirteen-year period.

Q. So that was one -- that was the Singh study that came out. Is that same study mentioned in the Cantor review?

A. (Nodding.)

Q. Okay. And you said that established that 12.2 percent of prepubertal boys persisted into adolescents? Okay.

A. Yes. This harkens back to the ethical issue that I talked about before. You know, if you know that 88 percent of them are going to persist -- desist, why in the world

identified 60,000 case reports world wide on the Internet. See Exposito-Campos..." --

A. That is an error, by the way.

Q. Sorry. Which part of that is an error?

A. That, "60,000," is my error. It should say, "16,000."

- - - - -

(Thereupon, Deposition Exhibit 17, "A Typology of Gender Detransition and Its Implications for Healthcare Providers," Article, was marked for purposes of identification.)

- - - - -

Q. Okay. So for the record, I'm showing Dr. Levine what has been marked as Exhibit 17. "A Typology of Gender Detransition and Its Implications for Healthcare Providers," Pablo Exposito-Campos, 2021. Okay. Have you seen this study before, Dr. Levine?

A. Yes.

Q. Okay. So on page 1 of this report, about halfway through the very first paragraph in the introduction beginning with, "As a consequence." Do you see that there?

important to note that this typology does not suggest two clear-cut categories, for a secondary detransition can lead to a primary detransition" -- oh, sorry. Let me start over. Sorry.

Okay. Let me start from a different place, Dr. Levine. The second sentence. "In r/detrans" --

And there's an HTTP address --

A. Okay.

Q. Okay. You see that.

-- "a subreddit for detransitioners to share their experiences with more than 16,000 members, one can find several stories of people who call their transgender status into question after stopping transitioning due to medical complications or feeling dissatisfied with their treatment results"?

Do you know what a, "Subreddit," is, Dr. Levine?

A. I believe it's just a division of a larger website where people, you know, with similar interests.

Q. Okay. Do you understand this sentence to be suggesting that all 16,000 of

those members have offered a story of detransition?

MR. KNEPPER: Objection, form.

A. I think -- I think it may be true that either they have offered a personal story or they're fascinated because of their own considerations of that story. They're thinking about it themselves, which would be in keeping with the idea that even people who have transitioned begin to doubt whether they made a wise decision and they're considering detransition. I'm not so sure it means that all 16,000. I would have no way of ascertaining that. You know, in my worry, I would lean towards most of them are seriously considering or have detransitioned. And in my skepticism, I would say I'm not sure whether it's 15,000 or 12,000 or 8,000.

Q. But you have no way to confirm that --

A. I have no way.

Q. -- if it's all of them or a few of them or three of them?

A. You're absolutely right. I have no way of confirming that.

where hormones are safe and surgery is a good thing to do. If a person said that, you know, skeptically, I think that would disappoint certain patients, but how it was said and when it was said in response to what would either determine whether the person is engaged with the mental health professional or leaves the mental health professional. You know, all mental health professionals are not created equal.

Q. So it sounds like you're saying it could do harm to that patient?

MR. KNEPPER: Objection, form.

A. No, I'm not saying that. I'm saying it could be disappointing to that person. What that person did with the disappointment may prove harmful just because of that person or it may prove in fact beneficial.

Q. Are you satisfied -- let's orient this question around the patients you've seen in the last 12 months. Are you satisfied that those patients -- actually, sorry. Let me start over. Are you satisfied that the patients you have seen historically for whom

you provide letters of authorization for hormones give sufficiently informed consent?

MR. KNEPPER: Objection, form.

A. From my point of view, I did what I could to reach the standard of having the person internalize and think about, digest, dream about and come back and talk to me about it. That's all I can do. I can't guarantee that if I do what I do that it's going to change your mind or help you steer your ship in a slightly different angle --

Q. So --

A. -- so I would not write a letter of recommendation if I didn't feel like I did my part. And if the person indicated that they couldn't pay attention to me, I wouldn't write the letter.

MR. CHARLES: Understood.

Okay. John, finished.

MR. KNEPPER: You're finished?

MR. CHARLES: I mean, barring --

MR. KNEPPER: Barring --

MR. CHARLES: We can't tell the future.

MR. KNEPPER: I wasn't ready for

history and current psychiatric diagnosis, it's more complicated than just the internet.

But we need to understand who these children are and how they're different from their peers and what we could possibly do to help them to have a better life. I know some of the conversation today was, we'll help them have a better life by giving them puberty blocking hormones, but that doesn't address -- I think it has a risk of harming them further. And it doesn't address the comorbid developmental challenges that these children face.

And I'm afraid -- and it's controversial, because I don't have the answer. I'm afraid there's a possibility we're making these children have a worse outcome. And until you can demonstrate to me in a very careful controlled study that separates the autistic from the non-autistic, you see? That separates the kids who come from a family that's intact from a family where there's a single parent. Where you can separate the kids who were sexually abused from the kids who were not sexually abused. I'm not sure puberty blocking

Exhibit C

UNITED STATES DISTRICT COURT
DISTRICT OF MASSACHUSETTS

KATHEENA SONEEYA,

Plaintiff,

V.

THOMAS A. TURCO III, in his official capacity as Commissioner of the Massachusetts Department of Correction,

Defendant.

Civil Action No. 07-12325-DPW

April 8, 2019

10:23 a.m.

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

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witness, ask me.

MS. HANCOCK: Okay. Apologies, your Honor.

BY MS. HANCOCK:

Q. So two versions were released since 1999, correct?

A. Correct.

Q. And one in 2001, as you just testified, right?

A. Right.

Q. And another one in 2011; is that right?

A. Yes.

Q. And as you understand it, there's going to be an eighth version coming out soon, correct?

A. Yes.

Q. And you're not involved in drafting that version, correct?

A. I am not.

Q. And you requested to participate in drafting that version, correct?

A. I'm not sure that's correct.

Q. You did not ask to be involved in drafting that version?

A. I think -- I think I actually might have, now that you bring it up, but I was told I had to be a member of WPATH.

Q. Now, you've worked as a consultant for the DOC since around 2007 or 2008. Does that sound right?

A. That sounds right.

Q. And you're not technically engaged by the DOC, though, right?

Exhibit D

STEPHEN B. LEVINE, M.D.

IN THE UNITED STATES DISTRICT COURT

FOR THE DISTRICT OF MASSACHUSETTS

Civil Action No. 07-12325-DPW

----------x

KATHEENA NEVIA SONEEYA,

f/k/a Kenneth Hunt,

Plaintiff,

V.

THOMAS A. TURCO III,

in his official capacity as

Commissioner of the Massachusetts

Department of Corrections,

Defendant.

----------x

DEPOSITION OF STEPHEN B. LEVINE, M.D.

Thursday, August 30th, 2018, 9:42 a.m.

Regus

2000 Auburn Drive, Beachwood, OH 44122

Reported by:

Jill A. Kulewsky, RPR

JOB NO. 146861

answer to it. I think the verbiage of the criteria may have changed in very subtle ways, but practically speaking, it did not.

The name change came about, in part, because one can be gender dysphoric without having a disorder. So there are many people who objected to the D in GID. The assumption that this variation in identity was a disorder was politically objectionable to many people in the trans community and those people who advocate for those -- for those what used to be patients.

So this is probably going to change again, and if we had this deposition in two years, we would probably call this not gender dysphoria but gender incongruence.

Q. Could you tell me a little bit more about that, why you think it's changing, what's changing about it?

A. This is fraught -- this is a political subject. The psychiatric

conditions, what constitutes a disorder changes with the time, and afterall, the DSM changes every 10, 12 years.

We in psychiatry and mental health, we reconfigure our concepts about every decade about what is a disorder and how to name them, and both scientific data, clinical experience and politics all influence the DSM.

And the DSM is in controversy with the World Health Organization that produces the ICD, the International Classification of Diseases. So the proposed ICD-11 is to stop calling this a disorder, stop implying by nosology that there is anything wrong with these people, and that this is just going to be considered a phenomenon that affects one's mental health.

So that's why there are people who are advocating to get rid of gender dysphoria and just call it gender incongruence because some people have gender incongruence who are not

dysphoric, they just accept the fact that they have the body of one -- an anatomic body and mental identity that is somewhat different from their body, and at various times in their life they struggle with that incongruence, but they're not mentally distressed, and therefore, they don't have a disorder or they're not dysphoric.

So when you see in the development of one's gender sense, for in the population there are enormous variations in the degree to which one is consonant or happy with or feels masculine in a male body, where to draw a line between disorder, disease, mental condition, emotional distress and just ordinary human diversity is unclear.

And the changes in nosology are reflecting the increased awareness over time, both within the trans community and the mental health community, of great diversity and the lack of invariability of distress over

the diversity or over the incongruence. So you and I are caught up at a certain point in time where our concepts are rapidly changing, and none of us are very sure what's going on.

It's not like schizophrenia. It's not like somebody who's tried to jump off a bridge six times in his or her life.

Q. So would you --

A. Okay.

Q. Is GD a medical or psychiatric condition, in your opinion?

A. In my opinion, it is definitely a psychiatric condition.

Q. Are you familiar with WPATH?

A. Oh, yes.

Q. What is it?

A. Well, it used to be the Harry Benjamin International Gender Dysphoria Association. I, in fact, was the chairman in writing the standards of care for the 19 -- the 5th version. It was published in 1999. Most of the

language -- as I read the seventh version, much of the language I actually wrote.

And the seventh version is just lifted from the fifth version, so I'm sort of familiar with it.

Q. We'll get to the standards in just a second. What's your understanding of what that organization does?

A. That organization initially arose to study the phenomenon of men who wanted to live as women and women who wanted to live as men. It was -- it began in the '70s -- in the '60s, actually, late '60s, I think, and it was funded by somebody who himself was a transgendered person, and we began developing -- I joined it in the '70s, and we began to articulate the standards of care for how these people ought to be handled by psychiatry, by endocrinology and by surgery.

So it began as a bunch of academics interested in this subject, and

it became over the years not just an academic institution, but it became -- well, an organization that invited the trans people themselves to be part of it.

By doing that, the organization became an advocate of trans people, and it always claims to be a scientific organization, but in fact, there is a great distinction between science and behavior that science dictates for professionals and advocacy, which leads to entirely different things far beyond science.

So what kind of organization is this today, I think you're asking me? Well, it's a mixture -- it's a minority rights organization that feels very strongly that there's nothing inherently wrong with anybody who has an incongruence in their gender identity, and it's not a symptom of anything, it's just the way people are, and that these people are marginalized and discriminated against just like homosexual people used

to be by psychiatry in the mid '70s, and that anyone who is interested in trans people needed to be their strong advocate at all times.

So that became a standard of -- I would say if you're a credentialed person, if you know about this, you must be an advocate. If you're a cynic, if you're a scientific, if you have skepticism, well, you may be the enemy.

So what has happened is that over the years, WPATH has become an advocacy organization that lawyers or the legal profession, in trying to understand how medicine operates, relies very heavily on the collective wisdom of organizations.

So WPATH has great respect in the courtroom and great respect as the international standard for how people ought to be treated, even though there are parts of WPATH that say these are case-by-case decisions, and that patients

elect surgeries, doctors don't recommend surgeries.

It seems that the WPATH standards have stimulated a social phenomenon in this society, and not just in America but elsewhere, where if a person wants something, the doctors should be providing them. If a doctor is skeptical about providing what this teenager or 70-year-old person wants, then the doctor is obviously not competent.

As a result of that, there are many people who just abandon interest in these patients because they just feel like WPATH is much more political than it is scientific, and the doctors need to be skeptical and need to be humble, and there's too much certainty embodied in the behavior that, I would say, rests upon the standards of care.

The standards of care are actually more conservative sounding than the people who quote them are, and so

Exhibit E

Deposition of:

Dee Jones

August 3, 2021

In the Matter of:

Kadel, et al vs. Folwell

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IN THE UNITED STATES DISTRICT COURT FOR
THE MIDDLE DISTRICT OF NORTH CAROLINA

MAXWELL KADEL, et al.,
Plaintiffs,
V.
DALE FOLWELL, et al.,
Defendants.

No. 1:19-cv-272-LCB-LPA

DEPOSITION
OF
DEE JONES

IN HER INDIVIDUAL CAPACITY
and
30(b)(6) DESIGNEE FOR NC STATE HEALTH PLAN

AUGUST 3, 2021

THIS TRANSCRIPT IS NOT COMPLETE
PORTIONS OF THIS TRANSCRIPT AND/OR EXHIBITS
MAY BE DESIGNATED CONFIDENTIAL/ATTORNEYS EYES ONLY
AFTER REVIEW OF TRANSCRIPT BY ATTORNEYS WITHIN 30
DAYS OF DATE OF DEPOSITION PER PROTECTIVE ORDER

PNC PLAZA DOWNTOWN
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A. Yes.

Q. So looking at all enrollees in the Plan, 15 percent of those enrollees account for 85 percent of the cost of treatment?

A. Correct.

Q. Can an individual enrolled in the State Health Plan request that the State Health Plan change the pronoun associated with that enrollee?

A. Please rephrase.

Q. Can an individual that's enrolled in the State Health Plan request that the Plan change in its records the pronoun that's associated with that individual?

A. The member can change his or her own pronoun.

Q. How does that process occur?

A. The member logs in to eBenefits or calls into the call center, benefit-focused call center, and either changes it him or herself, or requests that it be changed.

Q. Okay.

A. It's not validated.

Q. What does that mean for it not to be validated?

A. You could put in whatever you want. There's two options, male or female.

And if I were female and put in female, I could do that. Or if I wanted to put in male, I can do that. If I make an error, I can do that too.

Q. And you said an individual can either log in and change that themselves or they can make a request that the Plan make that change?

A. No. They call into the call center, talk to a call center rep who will record the call. And then they can be requested to make that change.

Q. To whom is that request made?

A. The call center rep.

Q. If a call center rep gets that kind of request, what happens next?

A. They comply with the request.

Q. And how does that process occur?

A. They go into the system and check yes or no or male or female or exactly -- I guess it's male or female.

Q. And prior to going into the system, is any validation requested?

A. Absolutely. Whatever -- like the member would call in, and there would be validation questions from the call center rep back to the member to confirm any number of demographic statistics.

Q. What are those validation questions?

A. I don't know them specifically. But it's something that would be similar to what we all do, which is your address, your full name, possibly your Social Security number, you know, phone numbers, whatever, to try to --

they're a vendor. I don't tell them how to do their job. I just tell them they have to validate it. It's not my obligation how to exactly do it.

Q. So is it fair to say that validation is with respect to making sure that the person calling in and making this request is who they say they are?

A. Yes.

Q. Does the Plan require proof of any enrollee's chromosomes before it goes into the system and complies with that question?

A. No.

Q. Does it require proof of an enrollee's anatomy?

A. No.

Q. And does it require proof of an enrollee's DNA?

A. No.

Q. Everything we just talked about with regard to changing the pronoun in the system, does that also apply to a request to change an individual enrollee's gender marker in the system?

A. We don't track gender markers in the system other than male or female. We only have but two options right now.

Q. Is participation in the Plan required for state agency employees?

A. No. They have a choice. I mean the benefit

Exhibit F

IN THE UNITED STATES DISTRICT COURT
FOR THE MIDDLE DISTRICT OF NORTH CAROLINA

MAXWELL KADEL, *et al.*, *Plaintiffs*, v. DALE FOLWELL, *et al.*, *Defendants*.	No. 1:19-cv-00272-LCB-LPA

EXPERT REBUTTAL DISCLOSURE REPORT OF
GEORGE RICHARD BROWN, M.D., DFAPA

I, George R. Brown, declare as follows:

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

2. I have actual knowledge of the matters stated and would so testify if called as a witness. I reserve the right to supplement or amend this report based on any future information that is provided to me, including but not limited to information produced by Defendants in discovery or in response to Defendants' expert disclosures.

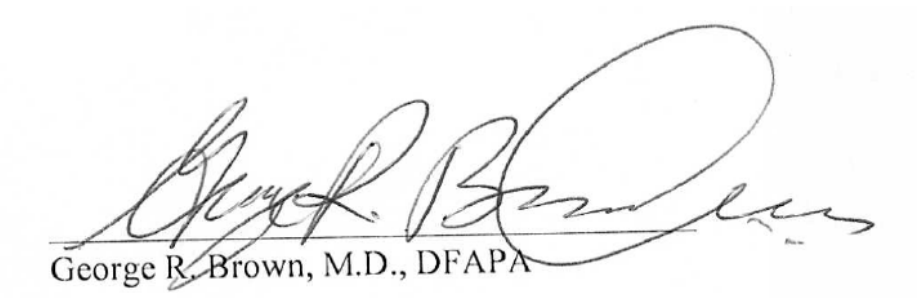
3. I previously submitted an expert report that was served on March 1, 2021 setting forth my opinions on: (1) the medical condition known as Gender Dysphoria; (2) the prevailing treatment protocols for a diagnosis of Gender Dysphoria, their efficacy, and the cost-effectiveness of this care; (3) whether there is a legitimate medical basis for the exclusions in the health plans offered by the North Carolina State Health Plan for Teachers

following the WPATH Standards of Care (SOC). This is likely because, in my understanding and experience, no such scientifically-reliable literature has been published in at least the last 15 years.

27. Defendants' experts also erroneously generalize about the appropriate course of treatment for Gender Dysphoria in adults or adolescents based on data about pre-pubertal children. This is inappropriate. The Diagnostic and Statistical Manual of Mental Disorders, Fifth Edition ("DSM-5") recognizes separate criteria for diagnosing Gender Dysphoria in children, on the one hand, and adults and adolescents on the other. The WPATH Standards of Care (SOC) have distinct standards of care for pre-pubertal children, adolescents and adults. As noted in my original report, the WPATH SOC, version 7 (Coleman, et al, 2011), are the nationally and internationally accepted standards of care for the evaluation and treatment of a diagnosis of Gender Dysphoria in adolescents and adults. These standards of care are also specifically followed by the largest healthcare systems in the United States (Department of Veterans Affairs, Kaiser-Permanente) as well as most major insurers of healthcare in the United States, including the corporate policy for Blue Cross and Blue Shield which specifically references these WPATH standards. *See* Blue Cross Blue Shield of North Carolina, Corporate Medical Policy, *Gender Affirmation Surgery and Hormone Therapy* (2021). They are also utilized as standards of care by many Departments of Corrections, the Federal Bureau of Prisons, the National Health Service of the UK, and many other countries as well. Coverage for transgender health care has been considered medically necessary for appropriately diagnosed individuals suffering from

to transition to the male gender role. This is a misinterpretation of that statement, and is an example of Dr. Lappert engaging in the "confirmation bias" that he claims to be present in all of the clinicians' records and in my evaluations of the Plaintiffs. Had Dr. Lappert interviewed C.B., as I did, he would have learned that that comment meant that C.B. was tired of the lengthy process of "being trans" and wanted to get to the point where "trans" no longer identified him and he could just be identified as a "man" and not as a "transgender man." It should also be noted that no fewer than seven clinicians have diagnosed C.B. as having the diagnosis of Gender Dysphoria.

I declare under penalty of perjury that the foregoing is true and correct. Executed this 10th day of June, 2021.



George R. Brown, M.D., DFAPA

CERTIFICATE OF SERVICE

I hereby certify that on June 11, 2021, I caused a copy of the foregoing document and all attachments to be served upon the following parties via email:

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Dated: June 11, 2021

/s/ Amy E. Richardson

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Exhibit G

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

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ALSO PRESENT:

Samantha Howell

I N D E X

(STENOGRAPHER'S NOTE: Exhibits were received premarked electronically; only Exhibits 1, 2, 3, 7, 10, 11 and 13 were referred to in deposition.)

INDEX OF EXHIBITS

right?

A No, that is. I think -- we'll quibble over the word only. If you use the word predominantly, I would say they are predominantly taking care of. They are a specialty clinic for the transgender.

Q So predominantly treating transgender people, but not 100 percent?

A That's my guess.

Q Okay. What sorts of treatments do you provide for your patients with gender dysphoria?

A Psychiatric evaluation of the patient and the family, the parents and the other siblings; psychotherapy to further the process of understanding this whole phenomenon; recommendations for hormones and occasionally recommendations for -- depending on the biologic sex of the patient, for genital or breast surgery.

Q How many patients have you recommended hormone therapy for?

A You mean over 47 years?

Q Let's start with the 47 years, yeah.

A I don't know. Can I give you a gross estimate?

Q Sure.

to be directed to the surgeon.

Q Okay. If a surgeon told you I require a letter for this facial feminization surgery, are there circumstances under which you could see yourself providing a letter, not of recommendation but of authorization, for a person to receive this surgery from the surgeon?

A I could see myself under certain circumstances, if I understood the patient's motives and had a lot of time to discover and discuss this, the history and alternative approaches and wondering about the psychology of wanting this, I could see theoretically.

That's what I do, you know, as a psychiatrist; I am trying to investigate the meaning of the wish and the solution that the patient is hoping for, the problem the patient is hoping this would be a solution for.

And so I want to be able to consider this and have a respectful, mutual, slow dialogue that is slow, meaning multiple sessions, to consider the nuances of this because, you know, all of us have a self-concept of how handsome we are or pretty we are, and most everyone wants to get a little more handsome and a little more pretty and we are -- we

Q Okay.

A I believe that if a surgeon is going to do this, he ought to know what I think -- what I know about the person's history and the person's intellectual capacities and the prices they paid for their gender dysphoria already.

For example, the loss of a family and no relations to children, or the inability to have a relationship, an intimate relationship with other people. I believe the surgeon needs to have an understanding of the person.

I don't have an understanding whatsoever of the techniques of surgery. You see? I am just a psychiatrist. And the psychiatrist -- and the surgeon has very little understanding of how a person got to be in his office. And I believe that the letters of recommendation should capture the humanness of this person and the desperation of this person and the justification that the person uses and the hopes they have for this surgery. But that's Levine, you know.

Q I want to show you the WPATH Centers of Care section that discusses letters. This is Exhibit 7 which we are going to put on the screen.

(Exhibit 7 was marked for identification.)

BY MR. TILLEY:

Q Let's go to page 27. It looks like the document page 27, it's .pdf page 33, Bates stamp PL 0450524.

You see, Dr. Levine --

MS. COLES: Can you read that, Dr. Levine? It looks a little small on my computer.

THE WITNESS: I can read it. It says referral for surgery.

MS. COLES: Okay. Just making sure.

BY MR. TILLEY:

Q At the bottom, I am going to start there and then we'll go on to the following page. At the bottom it says, The recommended content of the referral letters for surgery is as follows: 1, the client's general identifying characteristics -- now we are continuing on to the next page -- number 2, results of the client's psychosocial assessment, including any diagnoses.

And then it goes on to 3, 4, 5, and 6.

Dr. Levine, can you just review those if you can read it and then let me know if you agree with those statements.

(Short pause.)

A I don't disagree with the statements, but each of those statements, of course, need to be operationalized by the letter writer. For example, the first one, identifying characteristics, oftentimes identifying characteristics would be like this is a 63-year-old Caucasian veterinarian. But there are many other identifying characteristics that might be included.

So you can interpret these things with terse statements or elaborate statements. I favor elaborate statements. For example, I would like to say a divorced father of four, or a roller derby official. I would like to identify him as much as a person as possible. But in the history of medicine, race, age, and nourishment passes for identifying information.

So the results of the psychosocial assessment, including any diagnosis. Psychosocial assessment would be the processes in his life history, including any current or past diagnoses, you see. So substance abuse might be a very important part of number 2.; and the duration. So if I am writing a letter, if I am one of two people who have been hired to write a letter for genital surgery, and I might have had three visits with the

not inquiring about your medical history and your psychiatric history. But it may be psychologically beneficial to you and an M.D. may recommend that you do that. And that recommendation would be based on his or her knowledge that you are likely to suffer from seasonal affective disorder, and the treatment is bright lights and sunshine. And sunshine would be far superior because of its luminescence, the number of lumens exposed, than bright lights.

BY MR. TILLEY:

Q Let's go back just briefly to WPATH. And I know you mentioned you have a more conservative approach. So let me ask you this.

Is it fair to say that if you personally believed that you would authorize hormones or surgery for someone with gender dysphoria, someone following the WPATH Standards of Care would also believe that?

A Yes.

Q Okay. Let's talk about insurance for a little bit. If you recommended that -- if you authorized some form of treatment for gender dysphoria, whether it be hormones or some form of surgery, would you expect that that treatment would be covered by your patient's insurance?

offering an opinion on transgender people accessing sex-specific public places; is that right?

A No.

Q It's correct that that's not right?

A You mean like bathrooms, and so forth?

Q Right. You are not making an expert opinion in this case concerning sex-specific spaces; is that correct?

A That's right.

Q Okay. Let's go to page 13. You say that plaintiffs assert that the WPATH Standards of Care are widely accepted. Do you see that statement?

A Please tell me what paragraph it's in.

Q Under heading number 4.

A Yes. Okay.

Q Do you disagree that the WPATH Standards of Care are widely accepted by the major medical and mental health associations?

A No.

Q Okay. You just think that they are wrong; is that correct?

A Yes, and widely accepted doesn't tell you 60 percent or 40 percent. It just says widely accepted.

Q Okay. Is it -- how would -- how would you

You see?

So I am saying, please, let me talk to you about human beings here and how important having ongoing lifelong relations with one's children are and being a grandfather or grandmother, and being connected to a family of origin. I am not talking about categorical bans. I am talking about being smart.

BY MR. TILLEY:

Q Are you aware that this case concerns an insurance exclusion that is categorical at preventing --

MS. COLES: Form.

BY MR. TILLEY:

Q -- hormones and surgery as a treatment for gender dysphoria?

MS. COLES: Form.

A I am aware that your plaintiffs are suing to get coverage for -- that is not provided by their particular insurance. I am aware of that.

BY MR. TILLEY:

Q Do you think that exclusion is appropriate?

MS. COLES: Form.

A I've already answered that question, I

believe.
BY MR. TILLEY:
Q What is the answer?
A That it's a political decision that varies from state to state, and it belongs to the process of political science and the courts and not doctors.
Q And if you yourself were treating them and determined that they understood the risks and you thought the treatment would be psychologically beneficial and provided letters of authorization to them, you would want that treatment to be covered by insurance; is that correct?
MS. COLES: Form.
A I am 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.
BY MR. TILLEY:
Q I know you said you are not about categorical bans, but let me ask you about minors again.
Would you support a categorical ban on access to puberty blockers to treat gender dysphoria?
MS. COLES: Form.

Exhibit H

From DEPARTMENT OF CLINICAL NEUROSCIENCE
Karolinska Institutet, Stockholm, Sweden

ON GENDER DYSPHORIA

Cecilia Dhejne

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Friday, March 31, 2017 at 9:00 a.m.

By

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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 I

OPEN ACCESS Freely available online

PLoS one

Long-Term Follow-Up of Transsexual Persons Undergoing Sex Reassignment Surgery: Cohort Study in Sweden

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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.

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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.
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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.
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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).

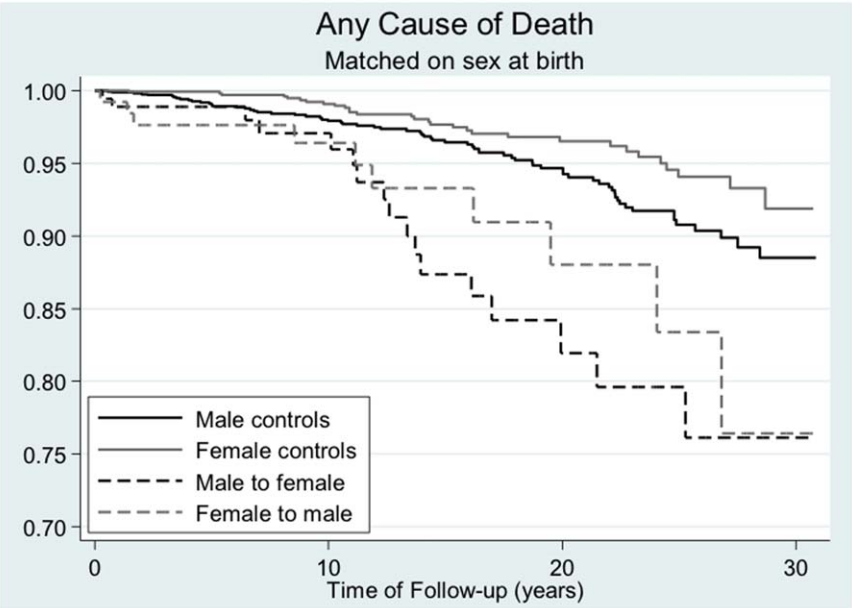

Figure 1. Death from any cause as a function of time after sex reassignment among 324 transsexual persons in Sweden (male-to-female: N = 191, female-to-male: N = 133), and population controls matched on birth year.
doi:10.1371/journal.pone.0016885.g001

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 J

Long-Term Follow-Up of Individuals Undergoing Sex-Reassignment Surgery: Somatic Morbidity and Cause of Death

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BASIC SCIENCE

Long-Term Follow-Up of Individuals Undergoing Sex-Reassignment Surgery: Somatic Morbidity and Cause of Death

Rikke Kildevæld Simonsen, MA,[1] Gert Martin Hald, PhD,[2] Ellids Kristensen, MD, FECSM,[3] and Annamaria Giraldi, PhD, MD, FECSM[3]

ABSTRACT

Introduction: Studies of mortality and somatic well-being after sex-reassignment surgery (SRS) of transsexual individuals are equivocal. Accordingly, the present study investigated mortality and somatic morbidity using a sample of transsexual individuals who comprised 98% (n = 104) of all surgically reassigned transsexual individuals in Denmark.

Aims: To investigate somatic morbidity before and after SRS and cause of death and its relation to somatic morbidity after SRS in Danish individuals who underwent SRS from 1978 through 2010.

Methods: Somatic morbidity and mortality in 104 sex-reassigned individuals were identified retrospectively by data from the Danish National Health Register and the Cause of Death Register.

Main Outcome Measures: Somatic morbidity and cause of death.

Results: Overall, 19.2% of the sample were registered with somatic morbidity before SRS and 23.1% after SRS (P = not significant). In total, 8.6% had somatic morbidity before and after SRS. The most common diagnostic category was cardiovascular disease, affecting 18 individuals, 9 before and 14 after SRS, and 5 of those 14 who were affected after SRS had cardiovascular disease before and after SRS. Ten individuals died after SRS at an average age of 53.5 ± 7.9 years (male to female) and 53.5 ± 7.3 years (female to male).

Conclusion: Of 98% of all Danish transsexuals who officially underwent SRS from 1978 through 2010, one in three had somatic morbidity and approximately 1 in 10 had died. No significant differences in somatic morbidity or mortality were found between male-to-female and female-to-male individuals. Despite the young average age at death and the relatively larger number of individuals with somatic morbidity, the present study design does not allow for determination of casual relations between, for example, specific types of hormonal or surgical treatment received and somatic morbidity and mortality.

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Key Words: Follow-Up; Gender Identity Disorder; Somatic Morbidity; Sex-Reassignment Surgery; Transsexualism

INTRODUCTION

Transsexualism refers to a condition in which the core characteristic is an individual's experience of profound incongruence between assigned sex at birth and the experienced gender.[1] According to the *International Statistical Classification of Diseases and Related Health Problems, 10th Edition* (*ICD-10*),[2] the diagnostic criteria of transsexualism are (i) the desire to live and be accepted as the opposite sex, (ii) usually a sense of discomfort with or inappropriateness of one's anatomic sex, and (iii) a wish to have surgery and/or hormonal treatment (HT) to make the body as congruent as possible with the preferred sex. To develop characteristics of the opposite sex, treatment with cross-sex hormones (HT), castration, and genital reconstructive surgery (sex-reassignment surgery [SRS]) might be conducted.

The parent category of transsexualism in the *ICD-10* is gender identity disorder (GID).[2] In Denmark, individuals with GID are referred to the Gender Identity Unit, University of Copenhagen (GIUUC) under *ICD-8*[3] code 302.39 and 1993 *ICD-10*[2] codes DF64.0 to DF64.9 by a general practitioner or psychiatrist. Assessment, in accordance with Danish Health Authority

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guidelines,[4] includes blood sample analyses for chromosomal and hormonal abnormalities, screening for psychiatric and somatic morbidities, psychological testing, and sessions with a psychologist or psychiatrist.

If SRS is desired by the individual diagnosed with transsexualism, an observational period of at least 1 year 6 months (in the study period, 2 years), including 1 year of HT and living in the gender role as the opposite sex, is obligatory before applying for SRS to the Danish Health Authority. The Danish legal criteria for SRS and castration are an *ICD-10* diagnosis of transsexualism (F64.0), persistent wish for and understanding of the consequences of castration, and a minimum age of 18 years (during the study period, ie,1978–2010, the minimum age was 21 years).[5] All treatment is paid for by the public Danish medical system. Treatment with cross-sex hormones and genital reconstructive surgery has existed for more than 60 years, but findings on mortality and somatic well-being after SRS in long-term follow-up studies are equivocal.[6] For possible somatic consequences of HT, the following outcomes have been studied the most: cardiovascular disease (CVD), bone growth, and hormone-sensitive cancer malignancies.

A review and meta-analysis of 16 studies, including 1,471 male-to-female (MtF) and 651 female-to-male (FtM) individuals, found no overall significant effect of HT on CVD.[7] However, the type of HT (ethinyl estradiol) and the manner in which HT (oral estrogens) was administered in MtF patients were significantly associated with CVD.[8,9] Further, in a Swedish study, increased CVD mortality in FtM and MtF individuals at least 10 years after HT was found,[6] indicating a possible delay of adverse somatic consequences from HT on cardiovascular pathology.[10]

Studies of muscle and musculoskeletal diseases, bone growth, and bone deficiencies overall did not show an increased risk of osteoporosis in FtM individuals.[11–16] However, in MtF individuals, lower bone mass density, possibly from androgen deprivation, was found after treatment compared with before treatment with HT.[17–19] However, because of increased bone density before treatment and no loss of bone density from menopause, MtF individuals maintain a lower risk of osteoporosis than assigned women.[20]

In cancer studies involving transsexuals receptive of SRS and/or HT, the focus has been on breast cancer, although the overall number of studies in relation to this issue is limited. The conclusions emerging from these studies suggest that for MtF individuals[20–23] the risk of breast cancer is lower than the expected risk of breast cancer in assigned women but similar to that expected in assigned men. For FtM individuals, male sex hormones might have an antiproliferative effect on breast cancer cell lines.[24,25] Thus, few cases of breast cancer in FtM individuals have been reported,[26,27] indicating FtM individuals have similar risk as expected for male breast cancer.

Concerning cancer malignancies, a Belgian study, in which the average time of HT was 6 years (FtM) or 7 years (MtF), found no increase in cancer malignancies among included transsexuals compared with controls randomly selected from the population.[28] In contrast, a Swedish study found borderline significant risk of death from neoplasms compared with controls.[6] Lifestyle habits such as smoking and avoidance of the health care system were suggested as possible mediating mechanisms.

When studying increased and decreased risks of cancer in transsexuals receiving HT, it is important to note that HT has been used for 60 years in some transsexual individuals. Accordingly, the duration of exposure to HT might not be long enough for tumors to manifest and the number of individuals exposed is small.[29] Further, it has been suggested that inconsistency in reporting cancer incidents among transsexuals might lead to an underreporting of cancer in this cohort,[21,30] likely affecting prevalence and incidence rates.

Studies of mortality in transsexuals have suggested an increased mortality risk compared with controls.[6,10] For example, a Swedish study of 324 MtF and FtM individuals after SRS (follow-up = 11.4 years) found that the all-cause mortality rate was three times higher in this cohort compared with controls.[6] Similarly, in a Dutch long-term follow-up study of 966 MtF and 365 FtM individuals (follow-up = 18.5 years), a 51% higher mortality rate was found in MtF subjects compared with the general population.[10] For FtM subjects, no increased mortality was found compared with the general population. A Dutch study of 1,109 individuals receiving HT found no increased mortality overall, but in MtF subjects 25 to 39 years old, mortality was significantly increased because of suicide, acquired immune deficiency syndrome, CVD, drug abuse, and unknown causes.[31] The only Danish study on transsexualism conducted thus far, which included 37 individuals, reported three deaths of 29 reassigned MtF individuals and no deaths of 8 FtM individuals studied from 1956 through 1978.[32]

Somatic morbidity after alcohol abuse has not been investigated previously, although studies of substance abuse in individuals with transsexualism have been conducted. A Belgian study (N = 35) conducted at the University Hospital of Gent found alcohol and drug abuse in 50% of MtF and 61.5% of FtM individuals.[33] A Spanish study (N = 230) of individuals with complaints of GID seen at the Hospital Clinic (Barcelona, Spain) found current alcohol- and substance-related disorders in 11% MtF and 1.4% of FtM subjects.[34] A Swiss study found that 45% of 31 GID individuals diagnosed by the *Diagnostic and Statistical Manual of Mental Disorders, Fourth Edition, Text Revision*[35] had lifetime substance abuse (MtF = 50%, FtM = 36.4%).[36] A Swedish study of 233 individuals found substance abuse in 18.2% of FtM and 11.9% MtF individuals.[37] However, in a different Swedish study of 324 MtF and FtM transsexual individuals, no significant risk of being hospitalized for substance abuse was found compared with the general Swedish population.[6] Lung diseases related to or caused by smoking have not been investigated previously in persons with transsexualism, although lesbian, gay, bisexual, and transgender persons have a higher incidence of smoking.[38,39] Accordingly, this was included as an outcome in the present study.

For many of the studies that have focused on somatic morbidity and mortality, including those reviewed earlier, the following methodologic shortcomings apply: small sample, recruitment and diagnostic biases and inconsistencies (eg, place of participant recruitment and differences in diagnostic criteria), heterogeneity of treatment regimens, and varied duration of follow-up periods.[6]

The aim of the present study was to (re)investigate somatic morbidity and mortality using registry data in a cohort including 98% of all Danish individuals referred to a public GID clinic in Denmark who underwent SRS from 1978 through 2010 after a diagnosis of transsexualism.

AIMS

The specific aims of the study were to investigate (i) somatic morbidity before and after SRS and (ii) cause of death and its relation to somatic morbidity.

METHODS

Procedure

The study was approved by the Danish Data Protection Agency and the Danish Health Authority. Permission was obtained from the Civil Law Board to identify names and social security numbers of individuals who underwent SRS from 1978 through 2010 and who were treated at the GIUUC.

National Registers

The Danish National Health Register (LPR) was used to draw data on somatic morbidity. The LPR contains diagnoses and dates of onset and end of treatment of all somatic episodes at hospitals from 1977 (inpatients) and from 1995 (outpatients). In the LPR, diagnoses are coded according to the *ICD-8* (1969−1993) or *ICD-10* (1994−).[2,3] Data from the LPR from 1977 to January 2013 were included in the study.

The Cause of Death Register has recorded all deaths and causes of death in Denmark since 1970. Death events occurring up to April 2014 were included in the study.

Study Population

Included in the study were 104 individuals (56 MtF and 48 FtM) diagnosed with transsexualism according to the *ICD-8*[3] or *ICD-10*[2] at the GIUUC. All participants underwent castration with permission from the Danish Health Authority from 1978 through 2010. Verification that an individual had undergone SRS was accomplished using social security numbers (ie, Danish Cause of Death Register numbers); numbers ending in even numbers indicate female-assigned sex and those ending with odd numbers indicate male-assigned sex. Accordingly, changes in this number from even to odd or vice versa indicate the official change of assigned sex (ie, successful completion of SRS). Baseline data (Table 1) were obtained from medical records.

Table 1. Baseline Data

Variables	Male to female (n = 56)	Female to male (n = 48)
Mean age at referral (y), mean (SD)	30.3 (9.8)	27.0 (8.7)
Mean age at permission for SRS (y), mean (SD)	37.1 (9.7)	32.6 (8.0)
Mean age at initiating cross-sex hormones (y), mean (SD)	32.0 (9.9)	29.8 (8.4)
Mean length of follow-up (y), mean (SD)	16.38 (7.1)	10.21 (6.1)

SRS = sex-reassignment surgery.

Sociodemographic data (Table 2) were obtained from medical records and are further described by Simonsen et al.[40]

Because of the lack of a specific code for SRS, the date of start of follow-up was defined as the date of permission to undergo SRS.

Measures

Baseline data (Table 1) were obtained from medical records based on interviews performed by specialized psychiatrists, psychologists, and medical doctors at the GIUUC during the treatment period.

Using the LPR and death registers, we obtained information pertaining to somatic morbidity before and after permission to undergo SRS and time and cause of death after obtaining this permission. More specifically, somatic diagnoses given to the patient from 1977 to January 2013 were investigated. Accordingly, each individual could present with different diagnoses, but multiple contacts with the somatic care system with the same diagnosis only had one outcome before SRS and one outcome after SRS. In addition, data on time and cause of death after permission to undergo SRS were drawn from the death registers until April 2014.

For each diagnosis, specifically chronic heart disease (*ICD-10* diagnoses F400−490), chronic lung disease (*ICD-10* diagnoses J40−47, *ICD-8* diagnoses 490−493), cancer (*ICD-10* diagnoses C00−C97.9, D00−D10.9, *ICD-8* diagnoses 140−209), alcohol-related liver morbidity (*ICD-10* K70−77, *ICD-8* 303−304), or muscle and musculoskeletal diseases (*ICD-10* M80−85, *ICD-8* 720−729), individuals were stratified by diagnostic group membership (ie, had received the diagnosis or had not received the diagnosis) and assigned sex (ie, MtF or FtM).

Mortality was determined by the cause-of-death certificate. Hence, each individual was dead or alive. For death, data related to cause of death were drawn from the death certificate.

Statistics

Statistical analyses were conducted in SPSS 19.0 (SPSS, Inc, Chicago, IL, USA). Clinical variables were analyzed using descriptive statistics. Means and SDs were calculated for

Table 2. Sociodemographics by Male to Female and Female to Male*

	Male to female (n = 58)	Female to male (n = 50)
Primary and secondary education (y), n (%)		
≤11	40 (69.0)	38 (76.0)
12–13 (completion of high school)	16 (27.6)	12 (24.0)
Missing information	2 (3.4)	0
Education beyond primary and secondary school at time of referral, n (%)		
None	29 (50.0)	30 (60.0)
≤3 y or apprenticeship	21 (36.2)	8 (16.0)
≥4 y	5 (8.6)	10 (20.0)
Unknown	3 (5.2)	2 (4.0)
Education beyond primary and secondary school when permission for SRS was granted, n (%)		
None	25 (43.1)	25 (50.0)
≤3 y or apprenticeship	21 (36.2)	13 (26.0)
≥4 y	8 (13.8)	10 (20.0)
Unknown	4 (6.9)	2 (4.0)
Employment at time of referral, n (%)		
Employed	36 (62.1)	31 (62.0)
Unemployed		
Sickness or unemployment benefits	12 (20.7)	7 (14.0)
Social welfare or pension	10 (17.3)	12 (24.0)
Employment when permission for SRS was granted, n (%)		
Employed	32 (55.2)	27 (54.0)
Unemployed		
Sickness or unemployment benefits	5 (8.6)	11 (22.0)
Social welfare or pension	20 (34.5)	11 (22.0)
Unknown	1 (1.7)	1 (2.0)

From Simonsen et al.[40]
SRS = sex-reassignment surgery.
*The χ^2 and Fisher exact tests were conducted but showed no significance ($P < 0.05$).

continuous variables. Frequencies and percentages were generated for nominal and categorical variables. Between-group differences were analyzed using χ^2 test, t-test, and Fisher exact test.

No missing values were found for somatic outcome variables because they were obtained from the register data, where values are present (affected) or absent (unaffected).

RESULTS

Baseline data related to age at referral, permission for SRS, cross-sex hormonal initiation, and years of follow-up after SRS are presented in Table 1.

To investigate the first study aim concerning somatic morbidity before and after SRS, the total number of included individuals who received a somatic diagnosis was identified (Table 3). As presented in Table 3, 20 FtM and MtF individuals (19.2%) before SRS and 24 FtM and MtF individuals (23.1%) after SRS had somatic morbidity, with no significant difference. Nine individuals (eight MtF and one FtM) had somatic morbidity before and after SRS, resulting in 35 individuals (33.7%) overall who had somatic morbidity. Table 4 lists the specific diagnoses of somatic morbidity.

As presented in Table 4, 25 somatic diagnoses were reported before SRS and 27 diagnoses after SRS from a total of 20 individuals before SRS and 24 individuals after SRS. Nine of the 24 individuals had somatic morbidity before and after SRS. The most common diagnostic category was CVD, affecting a total of 18 individuals, 9 before and 14 after (23 diagnoses) SRS, and 5 of the 14 individuals had CVD before and after SRS. The second most common diagnostic category was muscle and musculoskeletal diseases, with 12 diagnoses, six before and six after SRS, affecting a total of 11 individuals, with only one individual having muscle and musculoskeletal disease before and after SRS.

To investigate differences in somatic morbidity between MtF and FtM individuals, χ^2 test, Fisher exact, and t-test were used. Across diagnostic categories, no significant differences in somatic morbidity between MtF and FtM individuals were found. When comparing somatic diagnoses using χ^2 test, no significant differences between the number of somatic diagnoses given before and after SRS were found.

Concerning the second study aim, cause of death and its relation to somatic morbidity was investigated from after SRS until April 2014. Ten individuals (9.6%; six MtF [10.7%] and four FtM [8.3%]) died from after SRS to April 2014. Mean age at death was 53.5 ± 7.9 years (median = 55.5) for MtF individuals and 53.5 ± 7.3 years (median = 52.5) for FtM individuals ($P > .05$ by t-test). Somatic morbidity (ie, official cause of death) included two suicides (19 and 26 years after SRS, respectively), heart disease (n = 2), cancer (n = 1), ulcer (n = 1), and smoking- and alcohol-related diseases (n = 4).

Because the results might be influenced by changes in clinical procedures and guidelines over time and the cultural acceptance of transsexualism, data were checked for systematic differences in permission to undergo SRS from the first 16 years (1978–1994) to the next 16 years (1994–2010). Significantly ($P < .05$) more individuals with transsexualism received permission to undergo SRS from 1995 through 2010 (28 individuals in 1978–1994 and 76 individuals in 1995–2010).

DISCUSSION

We report the first nationwide register-based SRS follow-up study in Denmark of 98% of individuals who officially underwent SRS from 1978 through 2010.

For the first study aim (ie, investigation of somatic morbidity before and after SRS), we found that 19.2% of the cohort had a somatic diagnosis before and 23.1% after SRS. This difference

Table 3. Individuals with Somatic Morbidity Before and After SRS*

	Before SRS		After SRS		Before and after SRS	
Diagnosis, n (%)	Male to female (n = 56)	Female to male (n = 48)	Male to female (n = 56)	Female to male (n = 48)	Male to female (n = 56)	Female to male (n = 48)
Cancer	0	3	2	1	0	1
CVD	5	4	6	8	5	0
Musculoskeletal	3	3	3	3	1	0
Lung	2	1	3	1	2	0
Alcoholic liver	1	3	0	0	0	0
Individuals with somatic diagnosis						
Yes	8 (14.3)	12 (25.0)	12 (21.4)	12 (25.0)	8 (14.3)	1 (2.1)
No	48 (85.7)	36 (75.0)	44 (78.6)	36 (75.0)	48 (85.7)	47 (97.9)

CVD = cardiovascular disease; SRS = sex-reassignment surgery.
*The χ^2 and Fisher exact tests were conducted but showed no significance ($P < 0.05$).

was found not to be statically significant. Further, no significant difference in somatic morbidity between FtM and MtF cohorts was found. For the second study aim (ie, investigation of mortality), no significant difference in mortality between MtF and FtM cohorts was found. Average age at death was 53.5 years, and 10 individuals died after SRS.

For somatic morbidity, CVD was found in 6 MtF individuals (10.7%) and 12 FtM individuals (25.0%). In comparison, 4.4% of assigned men and 3.6% of assigned women older than 35 years in the general Danish population were found to have CVD.[41] In the present study, CVD might have been due to long-term follow-up after HT (16.3 years for MtF cohort, 10.8 years for FtM cohort) as reported by other studies,[6,10] or the observed prevalence of CVD might be explained by a correlation between depression and anxiety and CVD as suggested by previous research.[42,43] Socioeconomic status and CVD are related,[44,45] and the present study group was characterized not only by anxiety and depression[46] but also by social marginalization[47] and difficulties in school, education, and employment.[40] Hence, these factors could be important underlying mediating and/or moderating mechanisms driving or affecting prevalence rates of CVD in transsexuals, although the design of this study did not enable us to explore this further.

Muscle and musculoskeletal morbidity was found in 11 individuals (10.5%). From 1997 through 2002, 13.9% of the general Danish population was diagnosed with muscle and

Table 4. Number of Somatic Diagnoses*

	Before SRS		After SRS	
Diagnosis, n (%)	Male to female (n = 56)	Female to male (n = 48)	Male to female (n = 56)	Female to male (n = 48)
Alcohol related				
Yes	1 (1.8)	3 (6.2)	0	0
No	55 (98.2)	45 (93.8)	56 (100.0)	48 (100.0)
Cancer				
Yes	0	3 (6.3)	2 (3.8)	1 (2.0)
No	56 (100.0)	45 (93.8)	55 (98.2)	47 (97.9)
Heart				
Yes	5 (8.9)	4 (8.3)	6 (10.7)	8 (16.7)
No	51 (91.1)	44 (91.7)	50 (89.3)	40 (83.3)
Lung				
Yes	2 (1.8)	1 (2.1)	3 (5.4)	1 (2.1)
No	54 (96.4)	47 (97.9)	53 (94.6)	47 (97.9)
Musculoskeletal				
Yes	3 (5.4)	3 (6.3)	3 (5.4)	3 (6.3)
No	53 (94.6)	45 (93.8)	53 (94.6)	45 (93.7)
Positive somatic diagnosis	11	14	14	13

SRS = sex-reassignment surgery.
*The χ^2 and Fisher exact tests were conducted but showed no significance ($P < 0.05$).

musculoskeletal disease by hospital care.[48] Smoking and excessive alcohol consumption have been linked to low bone mass and increased fracture risk in MtF and FtM individuals,[49,50] and such lifestyle issues might characterize the present cohort.[6,46,51,52] However, given the limited number of individuals presenting with skeletal morbidity in this study, more comparable studies are needed to confirm the possible increased risk of skeletal morbidity in this cohort.

Concerning cancer malignancies, five individuals (6.2% of FtM and 3.6% of MtF) were found to have a diagnosis of cancer compared with 2.4% of assigned women and 1.56% of assigned men older than 15 years in the Danish general population.[53] Previous studies involving transsexual individuals have found hormone-sensitive tumors.[16,20,54] Further, in the present study, two deaths were caused by cancer and by leukemia and lung cancer, respectively. However, as in the present study, small samples and the sample design preclude causal inferences regarding relations between treatment of SRS individuals and cancer or cancer-related deaths.

In Denmark, alcohol-related diseases cause 5% of the total number of deaths,[55] with more alcohol and substance abuse in sexual minority groups.[51,52,56–58] Four individuals had a diagnosis of alcohol-related diseases before SRS with none after SRS. Further, in the present cohort, two individuals died of the effects of alcohol abuse after SRS. In a previous study on psychiatric morbidity of the present cohort, four diagnoses indicative of alcohol abuse after SRS were found.[46] Alcohol-related diseases are often the consequence of long-lasting alcohol abuse. Therefore, the actual number of individuals in the present cohort with alcohol abuse could be larger.

Four individuals had a diagnosis indicative of chronic lung disease (3.8%). In comparison, 1.3% of individuals older than 35 years in the in the general Danish population had a diagnosis of severe chronic lung disease.[59] Lung diseases have, to our knowledge, not been investigated previously in individuals with transsexualism, and therefore we lack and call for comparable studies in which to situate our findings.

Somatic morbidity in the present study group could be due to long-term HT and/or, as suggested by numerous previous studies, influenced by poor mental health, low economic status, social exclusion,[60] harassment, negative experiences with school[61] and the employment system,[34,37,62] and discrimination in the health care system.[46,63,64] Thus, previous studies of the present group have found that 50% of the cohort did not complete further education beyond primary and secondary school. Also, at the time of SRS, only 55% were employed[40] and 25% presented with psychiatric morbidity before and after SRS.[46]

For the second study aim (ie, cause of death and its relation to somatic morbidity), the study found that 9.6% of the cohort had died at an average age of 53.5 years, with the main cause of death related to smoking and alcohol abuse. The life expectancy of assigned women and men in Denmark is 81.9 and 78.0 years, respectively. Previous studies of mortality in transsexual individuals in countries comparable to Denmark[6,10] have found an increased risk of death in transsexual individuals. The present study had a lack of statistical power, and further long-term studies are needed to draw firm conclusions about transsexualism and increased risk of death.

Two individuals in the study group committed suicide 19 and 26 years after SRS, respectively. A Swedish study of SRS individuals (N = 324) found significantly increased mortality from suicide and significantly higher risk for suicide attempts compared with the general Swedish population.[6] A Dutch study (N = 1,109) of SRS and non-SRS individuals found a high incidence of attempted suicide and completed suicide in the study cohort compared with the general Dutch population.[31] An Italian study of 163 SRS MtF individuals found that four had attempted suicide before SRS and one had attempted suicide 12 to 18 months after SRS.[65] A Danish study reported death from suicide in 3 of 29 SRS MtF individuals (follow-up = 6 years).[32] Many explanations can be considered for suicide and attempted suicide. One might be regret for undergoing SRS,[32] but in the present study suicide occurred more than 19 years after SRS and therefore does not seem to be an immediate consequence of SRS. Because reasons for suicide attempts and manifest suicide often are multifactorial and because of the low incidence in the present study, further research is needed to contextualize these results further.

Limitations

The strength of this study is the unique cohort studied. Thus, on a national basis and over a 30-year period, 98% of all SRS individuals were included. This provides a unique opportunity to assess differences between MtF and FtM individuals on variables for somatic morbidity and mortality. The cohort included only individuals who received permission to undergo SRS during a period with strict criteria for obtaining permission to undergo SRS. Accordingly, the group is highly selected and might not reflect transsexuals per se in Denmark. Although we had a very large cohort for this type of study, some of our statistics had small cell sizes, limited numbers, and thus low statistical power, increasing the chances for type II errors. Because most somatic care in Denmark is provided by general practitioners, an underestimation of the prevalence of somatic morbidity in the study is plausible. Thus, somatic morbidity as presented in this study might be substantially higher.

CONCLUSION

Using a sample comprised of 98% of all individuals who underwent SRS in Denmark from 1978 through 2010, this study found somatic morbidity in 19.1% of the study group before and 23.2% after SRS. Mortality rates were 9.6%, with an average age at death of 53.5 years. No significant differences in somatic morbidity or mortality were found between MtF and FtM individuals. No firm conclusions can be drawn from the

present study, because the present study design does not allow for determination of causal relations between HT or SRS and somatic morbidity or mortality. One can speculate as to whether the increased risk of psychiatric problems and lifestyle issues in sexual minority groups influenced the risk of mortality and CVD in the present study. The findings underline the importance of supporting individuals with transsexualism to contact and be treated in the public health care system and to pay more attention to lifestyle issues in general.

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Exhibit K

IN THE UNITED STATES DISTRICT COURT
FOR THE MIDDLE DISTRICT OF NORTH CAROLINA

MAXWELL KADEL, *et al.*, *Plaintiffs*, v. DALE FOLWELL, *et al.*, *Defendants*.	No. 1:19-cv-00272-LCB-LPA

EXPERT REBUTTAL REPORT OF DR. JOHANNA OLSON-KENNEDY, M.D., M.S.

1. My name is Johanna Olson-Kennedy. I have been retained by counsel for plaintiffs Maxwell Kadel, Jason Fleck, Connor Thonen-Fleck, Julia Mckeown, Michael D. Bunting, Jr., C.B., Sam Silvaine, and Dana Caraway (collectively, "Plaintiffs") as an expert in connection with the above-captioned litigation.

2. I have been asked by Plaintiffs' counsel to provide my expert opinion on gender identity, the treatment and diagnosis of gender dysphoria, particularly as it pertains to children and adolescents, and to respond to, rebut, and provide my expert opinion regarding the reports by Dr. Stephen R. Levine, Dr. Paul R. McHugh, Dr. Paul W. Hruz, and Dr. Patrick W. Lappert in this case.

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

I. BACKGROUND AND QUALIFICATIONS

4. I received my Doctor of Medicine (M.D.) degree from the Chicago Medical School in 1997. In 2000, I completed my residency in pediatrics at the Children's Hospital of Orange

align with one's gender, as well as later medical interventions after the onset of puberty, such as puberty blockers, hormones, or surgery. Because care is individualized, it also may not.

89. Dr. Levine asserts that there is a growing body of evidence that suggests that affirmation of gender diverse children results in a higher likelihood of persistence of gender incongruence. He cites an article entitled "The myth of persistence: Response to 'A critical commentary on follow-up studies and 'desistance' theories about transgender and gender non-conforming children'" by Temple Newhook et al. (2018) written by Ken Zucker. This is not a research article. It simply provides a rebuttal by Dr. Zucker to a previous manuscript. In it Dr. Zucker reviews some of the existing literature about persistence and desistance of gender incongruence among children over time. As previously noted, though, the studies upon which Dr. Zucker relies were based on the now obsolete and overly broad categorizations contained in the diagnosis for "Gender Identity Disorder in Children." None of the studies use the current DSM-5 "Gender Dysphoria in Children" diagnosis. Thus, the desistance rates of which Dr. Levine speaks include children who did not identify as transgender to begin with or would be considered "sub-threshold" for a Gender Dysphoria diagnosis. In addition, research shows that children who identify as transgender into adolescence, which is when any medical treatment begins, persist in their transgender identity. (de Vries, et al., 2011).

90. Dr. Levine attempts to create a causal relationship by asserting that gender affirmation (social transition specifically) in childhood *causes* children to continue to assert a gender incongruent with the sex they assigned at birth and that they would not have done so had they not undergone social transition. There is a failure to consider the clinical observation that children who end up socially transitioning are often experiencing the greatest distress about their gender incongruence, a discussed predictor of persistence. He presents an argument against

carrying out necessary investigations. The denial of much needed care only serves to harm transgender people.

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

Executed this 30th day of May, 2021.

Johanna Olson-Kennedy, M.D., M.S.

CERTIFICATE OF SERVICE

I hereby certify that on June 1, 2021, I caused a copy of the foregoing document and all attachments to be served upon the following parties via email:

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Exhibit L

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
(PDF)

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Exhibit M

Do Clinical Data From Transgender Adolescents Support the Phenomenon of "Rapid-Onset Gender Dysphoria"?

Greta R. Bauer, PhD, MPH, Margaret L. Lawson, MD, MSc, FRCPC, Daniel L. Metzger, MD, FAAP, FRCPC, for the Trans Youth CAN! Research Team

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Title: **Do Clinical Data From Transgender Adolescents Support the Phenomenon of "Rapid-Onset Gender Dysphoria"?**

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Abbreviations: ; OASIS = Overall Anxiety Severity and Impairment Scale; MDS = Modified Depression Scale; K6 = Kessler-6 Scale; TYC-GDS = Trans Youth CAN! Gender Distress Scale

Although emergence of gender dysphoria at puberty is long established, a distinct pathway of "rapid onset gender dysphoria" (ROGD) 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 ROGD hypothesis.

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 gonadotropic-releasing hormone agonist (GnRHa), 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" or "ROGD" 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) methodological 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, ROGD 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 "ROGD" 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 (e.g. 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 aged <16 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 one 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 (OASIS),(21) the Modified Depression Scale (MDS),(22) and the Kessler-6 (K6) scale for psychological distress.(23) *Mental health diagnoses* extracted from chart included anxiety, depression, personality disorder, eating disorder, and *neurodevelopmental disorder diagnoses* included autism, obsessive compulsive disorder, or attention deficit hyperactivity disorder. *Gender dysphoria symptoms* were assessed using the Trans Youth CAN! Gender Distress Scale (TYC-GDS).(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 version 9.4.1, 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 (e.g., 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 (PR=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=0.0677).

Discussion

We did not find support within a clinical population for a new etiologic phenomenon of "ROGD" during adolescence. Among adolescents under age 16 seen in specialized gender clinics, associations between more recent gender knowledge and factors hypothesized to be involved in ROGD 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 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.

Acknowledgment: 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 contributions of the local site teams to participant recruitment, in particular the team of research assistants involved in data collection.

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Figure 1. Recency of gender knowledge among adolescents age <16 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 1. 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 variable	B [a]	SE	p	PR [a]	95% CI [b]
Mental health scales					
Anxiety severity/impairment (OASIS)	-3.272	0.961	0.0008		(-5.172 -1.373)
Depressive symptoms (MDS)	-1.276	0.845	0.1328		(-2.944, 0.392)
Psychological distress (K6)	-1.156	1.060	0.2771		(-3.248, 0.936)
Record of diagnosis with mental health disorder [c]	-0.509	0.315	0.1059	0.60	(0.32, 1.11)
Record of diagnosis with neurodevelopmental disorder [d]	0.066	0.362	0.8563	1.07	(0.52, 2.17)
Gender dysphoria/distress (TYC-GDS)	-0.193	0.122	0.1139		(-0.434, 0.047)
Mental health related behaviors					
Self harm, past year	-0.052	0.191	0.7833	0.95	(0.65, 1.38)
Marijuana use, past year	-2.178	1.010	0.0310	0.11	(0.02, 0.82)
Past-year suicide attempt	-0.592	0.785	0.4505	0.55	(0.12, 2.58)
Social connection indicators [e]					
Reports having online friends supportive of gender	-0.050	0.157	0.7505	0.95	(0.70, 1.29)

Indicates online friends as source of general support	-0.223	0.286	0.4366	0.80	(0.46, 1.40)
Indicates trans friends as source of general support	-0.049	0.298	0.1016	0.61	(0.34, 1.10)
All parents supportive of gender identity/expression	-0.004	0.202	0.9836	1.00	(0.67, 1.48)

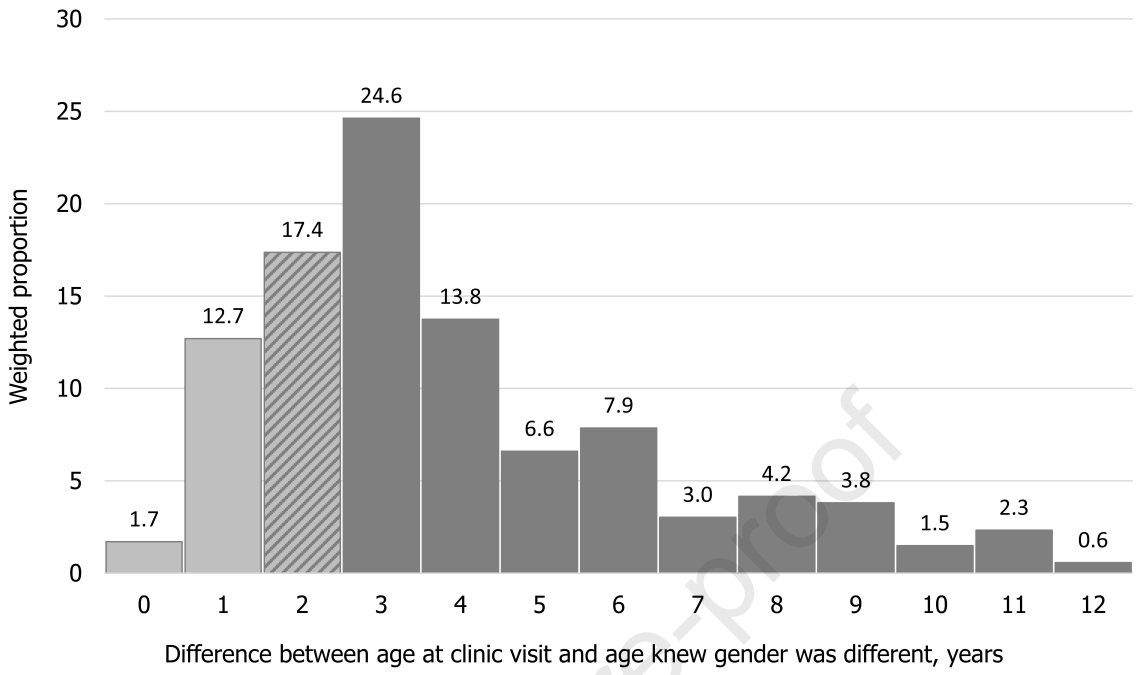
a. Estimates adjusted for age in years and sex assigned at birth. B = beta, regression parameter estimate; PR = prevalence ratio.

b. 95% confidence intervals for betas (for linear regressions) or PRRs (for modified Poisson regressions)

c. 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.

d. Extracted from medical record: any diagnosis from clinic or referrer of attention deficit hyperactivity disorder (ADHD), obsessive compulsive disorder (OCD), or autism.

e. Hypothesized by other authors based on a survey of parents recruited from websites generally unsupportive of gender-affirming care.(10)



Appendix

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Online content to accompany the following Brief Report:

Bauer GR, Lawson ML, Metzger DL, for the Trans Youth CAN! Research Team. Do clinical data from transgender adolescents support the phenomenon of "rapid-onset gender dysphoria"? *Journal of Pediatrics*, 2021.

Online Table 2.
Weighted frequencies or means for sociodemographic and study variables (n=173)

Variable	Value
Age, n (%$_w$)	
10–11 years	17 (8.5)
12-13 years	37 (22.6)
14–15 years	119 (68.9)
Ethnoracial background,[a] , n (%$_w$)	
Indigenous	33 (18.4)
Non-Indigenous visible minority [b]	10 (6.6)
Non-Indigenous white	128 (75.0)
Immigration background, n (%$_w$)	
1 or more immigrant parent	126 (28.7)
No immigrant parents	44 (71.3)
Living environment, n (%$_w$)	
City	87 (55.2)
Suburb	59 (33.9)
Rural	27 (10.9)
Gender identity, n (%$_w$)	
Male or primarily a boy	125 (75.7)
Female or primarily a girl	32 (15.9)
Non-binary [c]	14 (8.3)
Mental health scales, mean$_w$ (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,[d] n (%$_w$)	92 (51.6)
Record of diagnosis with neurodevelopmental disorder,[e] , n (%$_w$)	44 (25.9)
Gender dysphoria/distress (TYC-GDS), mean$_w$ (SD)	4.048 (0.557)
Mental health related behaviors, n (%$_w$)	
Self harm, past year	110 (67.9)
Marijuana use, past year	29 (20.0)
Past-year suicide attempt	24 (16.9)
Social connection indicators,[f] n (%$_w$)	
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)

a. Coded to match Statistics Canada categories of Indigenous, visible minority, and white. Non-white, Non-Indigenous 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 one).
b. The Canadian government defines visible minorities as "persons, other than Aboriginal peoples, who are non-Caucasian in race or non-white in colour".(1)
c. Response option was "non-binary or something other than male or female".
d. 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.
e. Extracted from medical record: any diagnosis from clinic or referrer of attention deficit hyperactivity disorder (ADHD), obsessive compulsive disorder (OCD), or autism.
f. Hypothesized by other authors based on a survey of parents.(2)

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Exhibit N

Deposition of:

Dr. Paul McHugh

September 8, 2021

In the Matter of:

Kadel, et al vs. Folwell

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IN THE UNITED STATES DISTRICT COURT FOR THE MIDDLE DISTRICT OF NORTH CAROLINA

* * * * *

MAXWELL KADEL, et. al., *

Plaintiffs * Case No.:

vs. * 1:19-CV-00272-LCB-LPA

DALE FOLWELL, et.al., *

Defendants *

* * * * *

Remote videotaped deposition of PAUL McHUGH, M.D., was taken on Wednesday, September 8, 2021, commencing at 9:40 a.m., before Allison L. Shearer, RPR, a Notary Public.

Reported By: Allison L. Shearer, RPR

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A. Well, I don't think so. It might have been something that I thought.

Q. Okay. Is it a term -- is the term Transgender Treatment Industries a term that is commonly used and accepted within the scientific community?

A. I don't think so. As I say, it's probably just mine.

Q. Is the term Transgender Treatment Industry a term that is commonly used and accepted within the medical community?

A. No, I -- I don't suppose so.

Q. Is there a peer-reviewed article or study you can point me to that utilizes the term Transgender Treatment Industry?

A. No, I -- I couldn't do that for you. No.

Q. I'll be honest. I never encountered this term until I saw your report and that of your colleagues in this case. So...

A. It -- it's okay.

Q. So I have questions because I, myself --