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

AUGUST DEKKER, *et al.*,

Plaintiffs,

v.

JASON WEIDA, *et al.*,

Defendants.

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

PLAINTIFFS' MOTION TO EXCLUDE EXPERT TESTIMONY OF DR. PAUL W. HRUZ AND SUPPORTING MEMORANDUM OF LAW

TABLE OF CONTENTS

Page

MEMORANDUM OF LAW 2

LEGAL STANDARD 2

ARGUMENT 3

I. Dr. Hruz is not qualified to offer an expert opinion on the diagnosis and the mental health treatment of gender dysphoria. 3

II. Dr. Hruz's opinions and testimony are not relevant to this case. 8

A. Dr. Hruz's opinions about "desistance" are irrelevant. 9

B. Dr. Hruz's opinions about an "international response" in other countries is irrelevant. 10

C. Dr. Hruz's musings about the causes of gender dysphoria are irrelevant. 11

D. Dr. Hruz's Opinions about WPATH Standards of Care are irrelevant. 12

E. Dr. Hruz's Hypothetical and Speculative opinions are irrelevant. 13

III. Dr. Hruz's opinions and testimony are unreliable. 14

A. Dr. Hruz's opinions are unreliable because they are based on untested hypotheses and speculation. 16

B. Dr. Hruz's opinions are unreliable because they are misleading and therefore do not serve to enlighten the trier of fact. 16

C. Dr. Hruz's opinions are unreliable because they are not generally accepted in the scientific and medical community. 22

D. Dr. Hruz's opinions are unreliable because they have no support and are based on ipse dixit. 24

IV. Dr. Hruz's opinions are so tainted by his personal bias as to render his opinions unreliable. 25

V. Dr. Hruz's opinions lack probative value and are therefore inadmissible under Federal Rule of Evidence 403. 29

CONCLUSION 30

Pursuant to Federal Rules of Civil Procedure 26 and 37, and Federal Rules of Evidence 104, 403, and Rule 702, Plaintiffs move to partially exclude certain testimony of Defendants' expert Dr. Paul Hruz, on the grounds that he fails to meet the qualification, reliability, and helpfulness requirements imposed by Fed. R. Evid. 702 and *Daubert v. Merrell Dow Pharm., Inc.*, 509 U.S. 579 (1993).

Dr. Hruz is a pediatric endocrinologist. Many of the opinions he purports to offer in this case have previously been excluded. *See Kadel v. Folwell,* No. 1:19CV272, 2022 WL 3226731, at *9-10 (M.D.N.C. Aug. 10, 2022). He has no experience treating or diagnosing gender dysphoria; he has never provided gender-affirming care, has never done any original research on the issue, has never published any peer-reviewed literature on the matter, and holds opinions that are purely speculative and far afield from the mainstream of the medical and scientific communities. Indeed, as he does here, in *Kadel,* Dr. Hruz "offer[ed] a wide range of conclusions that fall into five main categories: mental healthcare, medical and surgical care, informed consent, criticism of medical associations, and political criticisms." *Kadel,* 2022 WL 3226731, at *8. Despite the broad ranging categories on which he was offered to testify, after reviewing his qualifications, the *Kadel* Court limited Dr. Hruz's testimony to "the risks associated with puberty blocking medication and hormone therapy." *Id.* at *9.

The Court here should similarly impose the same limitation on Dr. Hruz's

testimony. Accordingly, Dr. Hruz is not a qualified expert on gender dysphoria or its treatment, and his opinions and testimony are neither relevant nor reliable. Additionally, his opinions and testimony are likewise inadmissible because any probative value they may have (and they have none) is substantially outweighed by the danger of unfair prejudice, confusion of the issues, waste of time, undue delay, and needless presentation of cumulative evidence. *See* Fed. R. Evid. 403. In support of this motion, Plaintiffs state as follows:

MEMORANDUM OF LAW

LEGAL STANDARD

Federal Rule of Evidence 702 places gatekeeping obligation on a trial court, to ensure that an expert's testimony "both rests on a reliable foundation and is relevant to the task at hand." *Daubert v. Merrell Dow Pharm., Inc.*, 509 U.S. 579, 597 (1993); *see also United States v. Frazier*, 387 F.3d 1244, 1260 (11th Cir. 2004) ("The importance of Daubert's gatekeeping requirement cannot be overstated."). In determining the admissibility of expert testimony under Rule 702, courts engage in a "rigorous" three-part inquiry and must consider whether:

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

Frazier, at 1260; *see also City of Tuscaloosa v. Harcros Chems., Inc.*, 158 F.3d

548, 562 (11th Cir. 1998), *cert. denied*, 528 U.S. 812 (1999).

The Eleventh Circuit refers to these three considerations separately as "qualification," "reliability," and "helpfulness" and has emphasized that they are "distinct concepts that courts and litigants must take care not to conflate." *Quiet Tech. DC-8, Inc. v. Hurel-Dubois UK Ltd.*, 326 F.3d 1333, 1341 (11th Cir. 2003). The party offering the expert testimony has the "burden of establishing qualification, reliability, and helpfulness." *Frazier*, 387 F.3d at 1260. As detailed below, Dr. Hruz's proposed opinions fail to meet these requirements and should be excluded.

ARGUMENT

I. Dr. Hruz is not qualified to offer an expert opinion on the diagnosis and the mental health treatment of gender dysphoria.

A witness must be "qualified to testify competently regarding the matter he intends to address." *Frazier*, at 1260. "A witness may be qualified as an expert by virtue of his 'knowledge, skill, experience, training, or education." *Quiet Technology DC-8, Inc.*, 326 F.3d at 1342. However, credentials are not dispositive when determining qualification. Each of the three analytical prongs (including qualifications) is assessed in reference to the matter to which the expert seeks to testify—i.e., "to the task at hand." *Daubert*, 509 U.S. at 597. It is for that reason that "expertise in one field does not qualify a witness to testify about others." *Lebron v. Sec'y of Fla. Dep't of Children & Families*, 772 F.3d 1352, 1368 (11th Cir. 2014)

(holding that a psychiatrist was properly prevented from opining on rates of drug use in an economically vulnerable population because he had never conducted research on the subject, and instead relied on studies to form his opinion). Rather, an expert's qualifications must be within the same technical area as the subject matter of the expert's testimony; in other words, a person with expertise may only testify as to matters within that person's expertise." *Id.* at 1369. "A scientist, however well credentialed he may be, is not permitted to be the mouthpiece of a scientist in a different specialty." *Dura Automotive Systems of Indiana, Inc. v. CTS Corp.*, 285 F.3d 609, 614 (7th Cir. 2002). If a proposed expert witness does not "propose to testify about matters growing naturally and directly out of research he had conducted independent of the litigation," such expert should be disqualified. *Lebron*, 772 F.3d at 1369 (quoting Fed. R. Evid. 702 (cleaned up)).

Therefore "[d]etermining whether a witness is qualified to testify as an expert requires the trial court to examine the credentials of the proposed expert in light of the subject matter of the proposed testimony." *Banuchi v. City of Homestead*, 606 F.Supp.3d 1262, 1272 (S.D. Fla. 2022) (cleaned up). Here, Dr. Hruz does not have the medical specialty required to discuss the diagnosis and treatment for gender dysphoria, particularly the diagnosis and assessment of gender dysphoria and non-endocrine treatments that are wholly outside his expertise as an endocrinologist.

The Court in *Kadel* succinctly determined based on Dr. Hruz's deposition

testimony that:

> Hruz is not qualified to offer expert opinions on the diagnosis of gender dysphoria, the DSM, gender dysphoria's potential; causes, the likelihood that a patient will "desist," or the efficacy of mental health treatments. He has never diagnosed a patient with gender dysphoria, treated gender dysphoria, treated a transgender patient, conducted any original research about gender dysphoria diagnosis or its causes, or published any scientific, peer reviewed literature on gender dysphoria.

Kadel, 2022 WL 3226731, at *9; Ex. A at ¶142 Hruz Expert Report[1] ("I have never personally engaged in the delivery of gender affirming medical interventions to children with gender dysphoria"); Ex. C at 88:18-89:8, 89:17-25 (Dr. Hruz discussing his lack of qualifications and treatment for gender dysphoria); Ex. E at 24:11-24:14, 25:20-25:23. Indeed, Dr. Hruz has also not sat in on a meeting with a patient discussing the treatment options for gender dysphoria. Ex. C at 40:6-40:11. Nor has he conducted any original research about transgender people or gender dysphoria. Ex. C at 35:5-36:1; Ex. E at 62:25-63:9; Ex. F at 25:24-28:13. He has not published any scientific, peer-reviewed literature on gender dysphoria or transgender people either. Ex. C at 42:14-49:19; Ex. E at 61:17-64:7, 295:19-

[1] Unless otherwise specified, all exhibits cited herein are attached to the contemporaneously filed Declaration of Shani Rivaux.

295:23.[2] Dr. Hruz is neither a psychiatrist[3], a psychologist, nor a mental health care provider of any kind qualified to diagnose gender dysphoria or to opine on the reliability of the American Psychiatric Association's Diagnostic and Statistical Manual of Mental Disorders, Fifth Edition ("DSM-5"). Ex. C at 112:9-11, 55:23-56:15; Ex. E at 41:21-42:2, 42:11-42:18.

Like the Court in *Kadel,* this Court should exclude Dr. Hruz on these topics due to his lack of expertise. *See Dura Auto. Sys. of Indiana, Inc. v. CTS Corp.*, 285 F.3d 609, 614 (7th Cir. 2002) ("The *Daubert* test must be applied with due regard for the specialization of modern science. A scientist, however well credentialed he may be, is not permitted to be the mouthpiece of a scientist in a different specialty. That would not be responsible science."). Instead, Dr. Hruz bases his opinions solely on his review of literature and conversations he has had with others. The fact that Dr. Hruz has read about gender dysphoria and

[2] Dr. Hruz's only publication relating to gender dysphoria in a peer-reviewed journal is a letter to the editor not based on any original research or scientific study, and for which it is unclear if letters to the editor are subjected to peer-review. Ex. C at 43:9-45:15. *See also* Ex. P (noting that letters to the editor are typically not peer reviewed). His other publications pertaining to gender dysphoria are all in non-scientific, non-medical, non-peer-reviewed journals affiliated with religious organizations.

[3] In his rebuttal report, Dr. Hruz claims that his opinions are supported by his "professional experience as a psychiatrist." Ex. B at ¶3. However, none of his qualifications or his prior testimony have demonstrated any credentials of a psychiatrist.

transgender people does not qualify him as an expert on these issues, however. That is precisely the sort of "generalized knowledge of a particular subject" that courts have rejected as a qualification under Rule 702. As with the disqualified expert in *Lebron* who "reached his opinion instead by relying on studies," this is insufficient to serve as an expert witness. *Lebron*, 772 F.3d at 1369.

Aside from his lack of expertise, Dr. Hruz is the definition of a manufactured "expert witness" as his involvement originates from and dates back to a conference by the Alliance Defending Freedom ("ADF")[4] organized specifically to cultivate professional "experts" who would testify against the gender-affirmation of transgender people. Ex. C at 241:10-246:20; Ex. E at 92:21-93:24; Ex. F at 147:11-21; *cf.* Ex. O at 84:3-85:12, 90:13-91:13 (Dr. Lappert testifying that he attended the same ADF conference as Dr. Hruz in 2017 where the "poverty of [experts] who are willing to testify" against gender-confirming policies was discussed and that attendees "were asked whether they would be

[4] ADF is well-known for pushing anti-LGBT policies across the country and internationally. *See*, *e.g.*, Nico Lang, *A Hate Group Is Reportedly Behind 2021's Dangerous Wave of Anti-Trans Bills*, them. (Feb. 19, 2021), https://bit.ly/3HEqCR9; Julie Compton, *Activists take aim at anti-LGBTQ 'hate group,' Alliance Defending Freedom*, NBC News (Nov. 14, 2018), https://nbcnews.to/3oEe9Es. The Southern Poverty Law Center has designated ADF a hate group. *See* S. Poverty Law Ctr., *Why is Alliance Defending Freedom a Hate Group?* (Apr. 10, 2020), https://bit.ly/3HE6LS1 (accessed Nov. 19, 2021).

willing to participate as expert witnesses"); Ex. Q at 169:18-171:4. Like the disqualified expert in *Lebron*, Dr. Hruz "developed his opinions expressly for purposes of testifying" in an area outside his specialty. *Lebron*, 772 F.3d at 1369.

In sum, Dr. Hruz is not qualified to serve as an expert on the diagnosis or the mental health treatment paradigms for gender dysphoria and his testimony should be limited to "the risks associated with puberty blocking medication and hormone therapy." *Kadel,* 2022 WL 3226731, at *9.

II. Dr. Hruz's opinions and testimony are not relevant to this case.

To satisfy the helpfulness requirement, the testimony must have a justified scientific relationship to the facts at issue. *Daubert*, 509 U.S. at 591. Thus, helpfulness, "goes primarily to relevance." *Id.* at 580. Relevant expert testimony "logically advances a material aspect of the proposing party's case" and "fits" the disputed facts. *McDowell v. Brown*, 392 F.3d 1283, 1298-99 (11th Cir. 2004). "The relationship must be an appropriate 'fit' with respect to the offered opinion and the facts of the case." *Id.* The "court must satisfy itself that the proffered testimony is relevant to the issue at hand, for that is a precondition to admissibility." *Sardis v. Overhead Door Corp.*, 10 F.4th 268, 282 (4th Cir. 2021) (cleaned up). "The touchstone of this inquiry is the concept of relevance." *Prosper v. Martin*, 989 F.3d 1242, 1249 (11th Cir. 2021). Thus, "expert testimony which does not relate to any issue in the case is not relevant and non-helpful." *Knight v. Boehringer Ingelheim*

Pharms., Inc., 323 F.Supp.3d 837, 846 (S.D. W.Va. 2018). In order to be relevant, an opinion needs to "fit" with the facts at issue. *Simmons v. Augusta Aviation, Inc.*, 596 F. Supp. 3d 1363, 1374 (S.D. Ga. 2022) "To satisfy this requirement, the testimony must concern matters beyond the understanding of the average lay person and logically advance a material aspect of the proponent's case." *Id.* Testimony that "offers nothing more than what lawyers for the parties can argue in closing arguments" or that consists of "subjective portrayals of factual information" "generally will not help the trier of fact." *Giusto v. Int'l Paper Co.*, 2021 WL 3603374, at *4 (N.D. Ga. Aug. 13, 2021).

This case is about whether Defendants' exclusion of coverage for medically necessary gender-affirming health care treatments violates Plaintiffs' rights. Many of Dr. Hruz's opinions are not relevant to this inquiry as they do not have a "valid scientific connection to the pertinent inquiry" *Boca Raton Cmty. Hosp., Inc. v. Tenet Health Care Corp.*, 582 F.3d 1227, 1232 (11th Cir.2009). His opinions do not "fit" because they are not sufficiently tied to the facts of the case so that they will aid a factfinder.

A. Dr. Hruz's opinions about "desistance" are irrelevant.

Take for example Dr. Hruz's opinions about purported "desistance" rates as a reason to question the provision of gender-confirming care. Another subject matter area in which the *Kadel* Court excluded Dr. Hruz's testimony. *Kadel*, 2022

WL 3226731, at *9. Dr. Hruz spends considerable time on (and builds most of his testimony questioning the propriety of gender-affirming health care upon) antiquated studies showing that a majority of *prepubertal* children diagnosed with *gender identity disorder*—an outmoded diagnosis *distinct from gender dysphoria* with different diagnostic criteria—"desisted" from their gender nonconformity or cross-gender behavior. *See*, *e.g.*, Ex. A at ¶¶63-64; 141. But not only are such opinions based on faulty propositions, they simply do not fit the facts of this case.

Dr. Hruz's testimony that focuses on the risks associated with providing hormone therapy to prepubescent children—children who have not begun puberty—is not relevant. Ex. C at 125:23-126:5. By his own admission, "no medical and surgical interventions are initiated until after the onset of puberty" under any model of treatment. *Id.* But again, no hormonal or surgical care is recommended for or provided to *prepubertal* children, nor are any of the plaintiffs prepubertal children. Accordingly, Dr. Hruz's opinions regarding "desistance" are thus irrelevant to this case.

B. Dr. Hruz's opinions about an "international response" in other countries is irrelevant.

Dr. Hruz's opinions about a purported "international response" regarding the provision of gender-confirming care in Finland, Sweden, and the United Kingdom are both misleading and wholly irrelevant. Ex. A at ¶¶123-126; Ex. D at 91-96. In the first place, Dr. Hruz has offered no firsthand knowledge of other

countries' policies, so he is not qualified to testify about them. And his testimony is false, or at best, misleading, since, each of these countries *provides and covers* some gender-confirming hormonal and surgical treatment for gender dysphoria for adolescents and adults, whereas AHCA excludes treatment completely from Medicaid coverage. *See*, *e.g.*, Ex. C at 183:23-184:4, 185:3-10, 189:14-190:7; *see also Brandt by & through Brandt v. Rutledge*, 47 F.4th 661, 671 (8th Cir. 2022) ("Similarly, the WPATH Standards of Care and the Finnish council both recommend that cross-sex hormones be considered only where the adolescent is experiencing persistent gender dysphoria, other mental health conditions are well-managed, and the minor is able to meet the standards to consent to the treatment."). Moreover, how care is provided and covered in countries with nationalized health care systems is not relevant to whether gender-confirming care should be covered by Medicaid in Florida.[5]

C. Dr. Hruz's musings about the causes of gender dysphoria are irrelevant.

Dr. Hruz opines, without any evidence, that gender dysphoria *may be* caused by social contagion and social pressure. Ex. A at ¶¶ 31, 91, 116-118; Ex. D at 40-43, 99. But whether gender dysphoria is caused by social contagion is both wholly

[5] For example, in Sweden standards of care are developed through legislation and thus part of a political process, which contrasts with the process in the Florida. *See* Socialstyrelsen, *About the National Board of Health and Welfare*, https://www.socialstyrelsen.se/en/about-us/ (accessed Nov. 19, 2021) (noting that standards are based on legislation).

unsupported, as described below, and irrelevant to the case at hand. It is undisputed that gender dysphoria is a recognized medical condition that necessitates medical treatment. *See*, *e.g.*, Ex. C at 57:24-58:9 ("Q. Would you agree there are transgender people in this world? A. … That's undeniable that … there are individuals that have this experience of discordance between their gender identity and their sex."); *see also Grimm v. Gloucester Cnty. Sch. Bd.*, 972 F.3d 586, 594-95 (4th Cir. 2020). Likewise his musings about as to the difference between gender identity and "biological sex," including as to whether "biological sex" can be changed, are immaterial since this case is about access to gender-affirming care, not changing sex. Ex. A at ¶¶ 14, 58, 66. Because each of these opinions offered lacks any "valid scientific connection to the disputed facts in the case," they should be excluded. *Allison v. McGhan Medical Corp*., 184 F.3d 1300, 1312 (11th Cir. 1999).

D. Dr. Hruz's Opinions about WPATH Standards of Care are irrelevant.

Dr. Hruz opines that WPATH should be disregarded as an "advocacy group" and that its recommendations "represent ideological positions devoid of rigorous scientific evidence"[6] and that the Endocrine Society Guidelines should be rejected because some of the committee members are also WPATH members. Ex. A at ¶¶

[6] Without any support, Dr. Hruz also claims that the American Academy of Pediatrics is a "politically influenced, non-science association." Ex. A at ¶140.

88-97. However, Dr. Hruz has not demonstrated any personal knowledge regarding the internal conversations at WPATH, has not participated in WPATH conferences, is not a member of WPATH and therefore lacks knowledge "of facts which enable him to express a reasonably accurate conclusion as opposed to conjecture or speculation." *Jones v. Otis Elevator Co*., 861 F.2d 655, 662 (11th Cir. 1988). In short, Dr. Hruz does not have "any experience with . . . WPATH. . . upon which to base his criticisms[and] is therefore not qualified to testify about the credibility of th[at] organization[]." *Kadel,* 2022 WL 3226731, at *10.

E. Dr. Hruz's Hypothetical and Speculative opinions are irrelevant.

Finally, and perhaps most crucially, essentially all of Dr. Hruz's opinions are irrelevant because they are not based on fact, let alone "fit" within the facts of case. Dr. Hruz's report in this case is substantially similar to the report he submitted in *Kadel*. *Compare* Ex. A and Ex. D. Two years ago, when asked about his opinions in the report submitted in *Kadel*, he testified that they were hypotheses. More specifically, he testified that the entirety of his opinions is based on *hypotheses*, meaning they are based on speculation. Ex. C at 154:4-8 ("A. You know, all along here, … I've been stating, and I hope very clearly, that much of my opinion is based upon hypotheses and alternative hypotheses, because there is no definitive answer to this question."); *id.* at 57:1-3 ("A. Because I present many things in my report as hypotheses. And without making definitive statements.").

Indeed, Dr. Hruz purportedly has no view as to what modality of treatment should be provided to transgender people suffering gender dysphoria. *Id.* at 61:21-62:2. Such "speculation is unreliable evidence and is inadmissible." *Dunn*, 275 F.Supp.2d at 684; *see Allison v. McGhan Medical Corp.*, 184 F.3d 1300, 1312 (11th Cir. 1999). In other words, Dr. Hruz lacks knowledge "of facts which enable him to express a reasonably accurate conclusion as opposed to conjecture or speculation." *Jones v. Otis Elevator Co.*, 861 F.2d 655, 662 (11th Cir. 1988). And opinions based on "subjective belief or unsupported speculation" should be rejected. *Daubert*, 509 U.S. at 589-590.

* * *

The opinions expressed by Dr. Hruz are insufficiently tied to the facts of this case so that they will aid a factfinder and should be excluded as irrelevant.

III. Dr. Hruz's opinions and testimony are unreliable.

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

the court must undertake an independent analysis of each step in the logic leading to the expert's conclusions; if the analysis is deemed unreliable at any step the expert's entire opinion must be excluded." *Hendrix v. Evenflo Co., Inc*., 255 F.R.D. 568, 578 (N.D. Fla. 2009), *aff'd sub nom. Hendrix ex rel. G.P. v. Evenflo Co., Inc.*, 609 F.3d 1183 (11th Cir. 2010). In making this determination the court can consider a variety of factors, including whether the purported expert's theory has been tested, whether it has been subjected to peer review and publication, and whether the theory has been generally accepted in the scientific community. *See Daubert*, 509 U.S. at 593-94; *Rink v. Cheminova, Inc.*, 400 F.3d 1286, 1291-92 (11th Cir. 2005).[7] To be reliable the expert's testimony must always be based on "good grounds." *Daubert,* 509 U.S. at 590. Moreover, *Daubert* requires that reliable expert testimony be more than scientifically unsupported "leaps of faith." *Rider v. Sandoz Pharm. Corp*., 295 F.3d at 1202. Here, Dr. Hruz's opinions fail all indicia of reliability. Dr. Hruz's proffered opinions are based on nothing more than rank speculation, "untested" theories, uncorroborated anecdotes, and assumptions that are obsolete, flawed, unethical, and expressed opinions based upon "unsettled science." What is more, some of his opinions are patently false.

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

A. Dr. Hruz's opinions are unreliable because they are based on untested hypotheses and speculation.

As noted above, ***Dr. Hruz's opinions are hypotheses***; hypotheses that he himself has not tested or studied. *See, e.g.,* Ex. A at ¶¶31; 76; 90-91; 116-118; 130-131. And "[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). "[T]he courtroom is not the place for scientific guesswork, even of the inspired sort." *Rosen v. Ciba-Geigy Corp.*, 78 F.3d 316, 319 (7th Cir. 1996). Indeed, "[w]here an expert's opinion testimony is founded on an unsupported premise, it gives rise to an inference that is based on speculation and has no evidentiary value." *Walker v. Blitz USA, Inc.*, 663 F. Supp. 2d 1344, 1364 (N.D. Ga. 2009). At bottom, such speculation is unreliable evidence and is inadmissible.

B. Dr. Hruz's opinions are unreliable because they are misleading and therefore do not serve to enlighten the trier of fact.

In addition, some of Dr. Hruz's opinions are misleading at best, or flat out false. For example:

One. Dr. Hruz opines that the literature around gender-affirming care is "in a state insufficient to enable sound conclusions about the efficacy of "affirming treatments." Ex. A at ¶¶93; 122; 142; Ex. D at 100 ("treatments – hormones and

surgery – for gender dysphoria and 'transitioning' have not been accepted by the relevant scientific communities (biology, genetics, neonatolgy [sic], medicine, psychology, etc.)."). Not true. It is the official, consensus, evidence-based position of the National Academies of Science, Engineering, and Medicine that, "[a] major success of these guidelines has been identifying evidence and establishing expert consensus that gender-affirming care is medically necessary and, further, that withholding this care is not a neutral option." Ex. H at 361;[8] Ex. C at 205:20-206:22. Indeed, "[a] number of professional medical organizations have joined WPATH in recognizing that gender affirming care is medically necessary for transgender people." Ex. H at 361. This includes, among others, the American Medical Association, American Psychiatric Association, American Psychological Association, American Academy of Family Physicians, American Academy of Pediatrics, American College of Obstetricians and Gynecologists, and the Endocrine Society. *Id.*; Ex. E at 58:21-61:9. It also includes Dr. Hruz's own employer, Washington University in St. Louis. Ex. C at 85:14-86:11.

Two. In his report, Dr. Hruz presented a number of modalities of treatment for the care of patients with gender dysphoria, including: (1) "conversion" or "reparative therapy"; (2) "watchful waiting"; and (3) the "affirming" approach, as

[8] Ex. H, a report of the National Academies, is self-authenticating as a publication issued by a public authority, Fed. R. Evid. 902(5), and is appropriate for judicial notice, *United States v. Doe*, 962 F.3d 139, 147 n.6 (4th Cir. 2020).

if these did not endorse the provision of gender-affirming medical care for adolescents and adults. Ex. A at ¶¶54-65; Ex. D at 49-50. In doing so, Dr. Hruz opined that the approach advocated by Dr. Kenneth Zucker and the "watchful waiting" model use "modern psychotherapeutic approaches to address suicidal ideation in children with gender dysphoria." Ex. A at ¶¶63-64; *see also* Ex. D at 50-51 (Dr. Hruz explaining that treatment "involve[] no medical treatment and is currently the best scientifically supported intervention."). But Dr. Hruz misrepresents these approaches by failing to explain that Dr. Zucker's approach and the "watchful waiting" model, which recommends the provision of gender-affirming medical care if a patient's gender dysphoria persists into adolescence. Ex. G; Ex. C at 121:6-12, 125:11-17. For example, with regards to Dr. Zucker, his approach has been described as follows by the APA:

> For adolescent patients (including those who first came to the clinic as young children), Dr. Zucker follows the Standards of Care Guidelines of the World Professional Association for Transgender Health. The treatment options include helping patients make a satisfactory transition to the opposite sex, including the institution of hormonal treatment to facilitate transition. In some cases, treatment may include helping an interested adolescent obtain sex-reassignment surgery.

Ex. R; Ex. G at 61. Indeed, "All of the three models of care … share in common the administration of hormonal treatment in adolescence." *Id.* at 64.

Three. In that same vein Dr. Hruz falsely presented "reparative therapy" as if it was an accepted modality of treatment. Ex. A at ¶60. Nothing could be further

from the truth, however. The provision of conversion/reparative therapy represents a fringe view completely contrary to the mainstream medical and scientific community in the United States. As Dr. Hruz has previously acknowledged in deposition, the American Psychiatric Association and the American Psychological Association oppose "reparative therapy" or gender identity change efforts as unethical and harmful. Ex. C at 164:1-170:8. The same position adopted by the National Academies. *Id.* at 176:9-177:24; Ex. H at 361-363. Indeed, per the American Psychological Association's Resolution on Gender Identity Change Efforts, "individuals who have experienced pressure or coercion to conform to their sex assigned at birth or therapy that was biased toward conformity to one's assigned sex at birth have reported harm resulting from these experiences such as emotional distress, loss of relationships, and low self-worth." Ex. S. What is more, Dr. Hruz cites to no authority—let alone any original, peer-reviewed study, in support of this so-called approach to treatment.[9]

Four. Dr. Hruz's misrepresents "desistance" rates as a reason to question the provision of gender-confirming care. This is a subject matter area in which the *Kadel* Court excluded Dr. Hruz's testimony. *Kadel v. Folwell,* 2022 WL 3226731at *9.

[9] Hruz cites to Dr. Ken Zucker's work as supportive of this therapeutic approach. However, as outlined above, Dr. Hruz grossly misrepresents Dr. Zucker's approach. What is more, the citation to Dr. Zucker is to an opinion article not any peer-reviewed original research.

Dr. Hruz spends considerable time on (and builds most of his testimony questioning the propriety of gender-affirming health care upon) antiquated studies showing that a majority of *prepubertal* children diagnosed with *gender identity disorder*—an outmoded diagnosis *distinct from gender dysphoria* with different diagnostic criteria—"desisted" from their gender nonconformity or cross-gender behavior. Ex. A at ¶¶ 63-64. But, his presentation of this literature is extremely misleading since, not only due to his reliance on outdated studies, but also because he ignores the more recent literature which has uniformly found that youth who have a diagnosis of gender dysphoria in adolescence overwhelmingly continue to identify as transgender as they age.[10] Moreover, as Dr. Hruz has previously admitted that absolutely no gender-affirming medical or surgical care is provided to *prepubertal* children. Ex. C at 125:23-126:5. That is true for each of the treatment paradigms Dr. Hruz discusses (apart from "conversion" or "reparative therapy"), a fact Dr. Hruz did not disclose.

[10] *See, e.g.,* Kristina R. Olson, *Gender Identity 5 Years After Social Transition*, 150 Ped. e2021056082 (2022) (of 300 youth with gender dysphoria, at the end of the five years, 94% of participants still identified as transgender); Annelou L C de Vries et al., *Puberty Suppression in Adolescents with Gender Identity Disorder: A Prospective Follow-Up Study*, 8 J. Sex. Med. 2276 (2011). Notably, Thomas D Steensma, who co-authored the study on which Dr. Laidlaw improperly cites for the proposition that most youth with gender dysphoria "desist" in their gender identity, also co-authored the de Vries study, which looked 70 youth in the Netherlands referred for treatment of gender dysphoria between 2000 and 2008, found that all of them decided to continue their medical transition after 1-2 years, confirming that "young adolescents who had been carefully diagnosed show persisting gender dysphoria into late adolescence or young adulthood." *Id.* at 2281.

Id. at 119:22-140:12. His opinions are therefore not only misleading, but also irrelevant, since this case is about the coverage for medically necessary gender-affirming medical care, and none of the plaintiffs are prepubertal children.

Five. Dr. Hruz provides no scientific bases for his conclusions that "A currently unknown percentage and number of patients reporting gender dysphoria suffer from mental illness(es) that complicate and may distort their judgments and perceptions of gender identity" or that "A currently unknown percentage and number of patients reporting gender dysphoria may be manipulated by a social contagion and social pressure processes, including peer group, social media, YouTube role modeling, and parental pressures." Ex. A at ¶¶ 130-131. But "Hruz is not a statistician and does not discuss in his report how he came to those conclusions, what data he relied upon, or what methodology he applied to that data." *Kadel*, 2022 WL 3226731, at *9. "This testimony will therefore be excluded as unreliable." *Id.*

* * *

The Court "must ensure that any and all scientific testimony or evidence admitted is not only relevant, but reliable." *Daubert*, 509 U.S. at 589. Here, Dr. Hruz has misrepresented or omitted information that goes to the heart of his opinions and calls into question the reliability of his opinions. While usually the factual basis of an expert opinion goes to credibility, "it is possible for an experts'

omission of articles to render his or her opinion inadmissible on reliability grounds." *Huggins v. Stryker Corp.*, 932 F.Supp.2d 972, 994 (D. Minn. 2013). Such is the case here where Dr. Hruz omits key information, or worse, misrepresents facts that if properly disclosed would contradict his opinions and undermine their foundation. In such circumstances, the "potential to mislead" rather "than to enlighten" is too great. *In re Lipitor*, 892 F.3d at 632.

C. *Dr. Hruz's opinions are unreliable because they are not generally accepted in the scientific and medical community.*

General acceptance in the relevant scientific community is also relevant to the reliability inquiry. *Nease*, 848 F.3d at 229. Not only is widespread acceptance an important factor in assessing the reliability of an expert's opinions, but the fact that a known technique or theory "has been able to attract only minimal support within the community may properly be viewed with skepticism." *Daubert*, 509 U.S. at 594. Here, Dr. Hruz's opinions are outside the mainstream of medical and scientific opinion and have been explicitly rejected by these relevant communities.

The provision of gender-confirming care has been accepted and endorsed, *inter alia*, by the: American Medical Association; American Psychiatric Association; American Psychological Association; Endocrine Society; Pediatric Endocrine Society; American Academy of Pediatrics; National Academies of Science, Engineering, and Medicine; and Dr. Hruz's own employer. Ex. C at 164:5-11; Ex. E at 70:25-71:22; *id.* 57:11-59:14; Ex. H at 361-363. The Fourth

Circuit has described it as "the consensus approach of the medical and mental health community." *Grimm*, 972 F.3d at 595; *Edmo v. Corizon, Inc*., 935 F.3d 757, 771 (9th Cir. 2019) (the provision of gender-affirming care, consistent with the WPATH Standards of Care, represents "the ***broad medical consensus*** in the area of transgender health care," which "requires providers to individually diagnose, assess, and treat individuals' gender dysphoria.") (emphasis added); *see also Brandt v. Rutledge*, 551 F.Supp.3d 882, 890 (E.D. Ark. 2021) ("The consensus recommendation of medical organizations is that the only effective treatment for individuals at risk of or suffering from gender dysphoria is to provide gender-affirming care."), *aff'd*, 47 F.4th 661 (8th Cir. 2022); *Flack v. Wisconsin Dep't of Health Servs*., 395 F.Supp.3d 1001, 1018 (W.D. Wis. 2019).

In fact, another federal district court found as much when it enjoined Arkansas' state law seeking to ban gender-confirming treatment for minors. *See Brandt*, 551 F.Supp.3d 882. In doing so, the *Brandt* court explicitly found that: (a) "Gender-affirming treatment is *supported by medical evidence* that has been *subject to rigorous study*;" and (b) "*Every major expert medical association* recognizes that gender-affirming care for transgender minors may be *medically appropriate and necessary* to improve the physical and mental health of transgender people." *Id.* at 891 (emphasis added). Notably, Dr. Hruz filed an expert declaration in the *Brandt* case that is virtually identical to the report he filed in this

case. As such, the *Brandt* court's findings stand as a stark repudiation of Dr. Hruz's opinion that gender-affirming care is "experimental" and "not medically necessary." Ex. A at ¶¶137-138; Ex. D at 17. It is for these reasons that the Court in *Kadel* excluded much of Dr. Hruz's opinions in that case on these issues. *Kadel v. Folwell,* 2022 WL 3226731at *9.

Conversely, Dr. Hruz's opinions in support of reparative therapy or gender identity change efforts has also been rejected by the general scientific community, among others. Ex. C at 164:1-170:8; Ex. E at 118:7-19, 237:1-23. *See also King v. Governor of the State of New Jersey*, 767 F.3d 216, 221–22 (3d Cir. 2014); *Pickup v. Brown*, 740 F.3d 1208, 1223–24 (9th Cir. 2014). This again shows that Dr. Hruz's opinions are wildly outside the mainstream and his failure to notify the Court of the rejection of these purported alternative treatment renders his testimony unreliable.

D. Dr. Hruz's opinions are unreliable because they have no support and are based on ipse dixit.

As noted herein, Dr. Hruz's opinions are based on untested hypotheses and do not have any factual support. For example, Dr. Hruz opines that gender dysphoria *may be* caused by social contagion and social pressure. Ex. A at ¶131. But he offers no evidence for this hypothesis, which he admits has not been tested. *Id.* Of course, "nothing in either *Daubert* or the Federal Rules of Evidence requires a district court to admit opinion evidence which is connected to existing data only

by the *ipse dixit* of the expert." *Gen. Elec. Co. v. Joiner*, 522 U.S. 136, 146 (1997). And this is one of those circumstances in which "there is simply too great an analytical gap between the data and the opinion proffered." *Id*. In fact, the only study to have looked at this hypothesis found no support for the hypothesis. Ex. N.

* * *

Given that Dr. Hruz's opinions fail to meet the most basic indicia of reliability, the Court should exclude Dr. Hruz's opinions and testimony as unreliable.

IV. Dr. Hruz's opinions are so tainted by his personal bias as to render his opinions unreliable.

While Plaintiffs are cognizant of the fact that bias in an expert witness's testimony is usually an issue of credibility as opposed to one of admissibility, when an expert's opinions are based on bias as opposed to scientific or medical knowledge, then the question of bias becomes one of reliability and admissibility. Indeed, reliability is a flexible inquiry wherein "courts must ensure that an expert's opinion is based on scientific, technical, or other specialized knowledge and not on belief or speculation." *Sardis*, 10 F.4th at 281. Here, there is ample evidence that Dr. Hruz's testimony is so permeated and tainted by his unscientific views and personal bias as to render it unreliable. *See Kadel*, 2022 WL 3226731, at *9 ("Plaintiffs have offered evidence that calls Hruz's motivations—and thereby, his reliability—into serious question."); *cf. Sanchez v. Esso Standard Oil de Puerto*

Rico, Inc., No. CIV 08-2151, 2010 WL 3809990, at *4 (D.P.R. Sept. 29, 2010).

More specifically, Dr. Hruz's testimony appears to be motivated by his personal and religious views regarding transgender people. To be clear, Plaintiffs do not seek to impugn or malign whatever moral or religious views Dr. Hruz may hold. However, to the extent Dr. Hruz's moral and religious views have influenced his purported expert opinions— indeed, they seem to be the motivating factor— that is something the Court must be aware of and should consider as it assesses the reliability of his testimony.

In his report, Dr. Hruz discusses meeting with Dr. Norman Spack, a noted pediatric endocrinologist and the co-founder of Boston Children's Hospital Gender Management Service Program, as someone he consulted when he first began to study issues relating to gender dysphoria from a scientific standpoint. Ex. Ex. A at ¶9; D at 6. But Dr. Spack's account of this encounter is quite different. Dr. Spack asserts that "Dr. Hruz did not discuss or mention that his issues or concerns were based on science." Ex. K at ¶ 13. To the contrary, Dr. Hruz expressed to Dr. Spack that he had "a significant problem with the entire issue" and "whole idea of transgender," and that for him, it was "a matter of [his] faith." *Id.* at ¶¶ 11-12. When confronted with Dr. Spack's account, Dr. Hruz notably did not deny he made such statements. Ex. C at 247:10-251:4.

Similarly, Dr. Hruz misrepresents the nature of his conversations with

"dozens of parents of children with gender dysphoria" as that of seeking "to understand the unique difficulties experienced by this patient population." Ex. A at ¶9; Ex. D at 6. One of these parents gives quite a different account of meeting with Dr. Hruz, however. Dr. Hruz met with Kim Hutton, the mother of a transgender child, in 2013. Ex. E 102:24-103:9, 126:12-129:25. Dr. Hruz says he met with the parent of a transgender child who was affiliated with an organization called TransParent, during a "very early investigative phase" of his study of gender dysphoria. Ex. E 103:25-104-7, 102:24-103:9. By Ms. Hutton's account, the nature of Dr. Hruz's conversation with her revealed that that he was firmly opposed to gender-affirming care, as well as opposed to a having a Transgender Center at St. Louis Children's Hospital, and that this opposition was rooted in his personal moral and religious views. Indeed, Dr. Hruz reportedly told Ms. Hutton, "there will never be a pediatric gender center at St. Louis Children's Hospital. I won't allow it." Ex. L at 30:8-30:11. Dr. Hruz also told Ms. Hutton that her "child was not normal and would never be normal," Ex. L at 28:20-28:23; that "the idea of doing surgeries on transgender people is -- is wrong," *id.* at 21:21-27:24; and repeatedly encouraged Ms. Hutton to "read Pope John Paul II's writings on gender," because it would explain everything. *id.* at 29:17-29:20. And in response to Ms. Hutton's statement that transgender children "are at a 41 percent risk of suicide if they don't have acceptance and -- and care from their parents and -- and

if they don't get their medical needs met," Dr. Hruz responded that, "Some children are born in this world to suffer and die." *Id.* at 29:21-30:4. As a result, Ms. Hutton left her conversation with Dr. Hruz—a conversation Dr. Hruz says he "was approaching [] in a purely investigative manner," Ex. E at 126:16-127:3—"perplexed" due to "the religious tone of the conversation," which she "figured [] would at least be based on science." Ex. L at 37:11-37:19.

The bias illuminated by Dr. Spack's and Ms. Hutton's testimony is further confirmed by the nature of Dr. Hruz's publications and presentations on this issue. With one exception, all of Dr. Hruz's publications pertaining to gender dysphoria have been in religiously affiliated, non-scientific publications. Ex. C at 42:10-49:19. Similarly, aside from a handful of grand rounds, Dr. Hruz has not made any presentations about this topic at scientific conferences, *id.* at 90:17-93:3; instead, presenting on this topic to religious organizations. For instance, in November 2017, Dr. Hruz gave a presentation at the Saint John Paul II Bioethics Center at the Holy Apostles College & Seminary, where he referred to being transgender as something that "probably goes back to some of the early heresies in the church," and to pictures of transgender people as "disturbing." Ex. E at 83:5-85:20. When confronted with these statements, Dr. Hruz did not disavow or deny making them. *Id.* And in February 2018, Dr. Hruz presented at an "International Conference on Gender, Sex and Education" that was billed as "the world's first great public

objection to totalitarian LGBTI laws," "a conference to oppose gender ideology," and "against the LGBTI doctrine… taking hold of Western Countries." Ex. M; Ex. C at 93:4-97:10.

The foregoing, coupled with Dr. Hruz's departure with generally accepted medical and scientific standards, demonstrates that Dr. Hruz's purported expert testimony lacks any indicia of reliability. And while the Federal Rules of Evidence state that "[e]vidence of a witness's religious beliefs or opinions is not admissible to attack or support the witness's credibility," Fed. R. Evid. 610, the Advisory Committee Notes to Rule 610 make clear that "an inquiry for the purpose of showing interest or bias because of them is not within the prohibition." Advisory Committee Notes to Rule 610. Indeed, "[w]ithout this critical information," the Court would be "deprived of the necessary facts from which it could appropriately draw inferences about [Dr. Hruz's] reliability." *State v. Heinz*, 485 A.2d 1321, 1328 (Conn. App. 1984). Here, it is evident that Dr. Hruz has not been candid regarding his experiences or the bases for his "opinions." The record evidence demonstrates a clear bias by Dr. Hruz against transgender people generally, which infects his reliability as a purported expert witness in this case.

V. Dr. Hruz's opinions lack probative value and are therefore inadmissible under Federal Rule of Evidence 403.

Finally, because of the potentially misleading effect of expert evidence, *see Daubert*, 509 U.S. at 595, on occasion expert opinions that otherwise meet

admissibility requirements may still be excluded under Fed. R. Evid. 403. Exclusion under Rule 403 is appropriate if the probative value of otherwise admissible expert testimony is substantially outweighed by its potential to confuse or mislead the jury, or if the testimony is cumulative or needlessly time consuming. *See, e.g., Hull v. Merck & Co., Inc.*, 758 F.2d 1474, 1477 (11th Cir.1985) (admission of speculative and "potentially confusing testimony is at odds with the purposes of expert testimony as envisioned in Fed. R. Evid. 702"); *Tran v. Toyota Motor Corp.*, 420 F.3d 1310, 1316 (11th Cir. 2005) (affirming exclusion of expert testimony as cumulative). Consequently, "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).

Accordingly, the Court should exclude Dr. Hruz's opinions because its introduction will result in unfair prejudice, confusion of the issues, or in misleading testimony. Fed. R. Evid. 403. Dr. Hruz offers opinions that are irrelevant to the issues in this case, and, in any event, the opinions he offers are speculative and unreliable. The testimony would also result in prejudice, as the testimony seeks to sow confusion about the propriety of gender- confirming care based on speculation, irrelevant, misleading, or biased opinions.

CONCLUSION

For the foregoing reasons, the Court should exclude Dr. Hruz's report,

opinions, and testimony and limit his opinions to those permitted in *Kadel*.

Respectfully submitted this 7th day of April, 2023.

PILLSBURY WINTHROP SHAW PITTMAN, LLP
By: */s/ Shani Rivaux*
Jennifer Altman (Fl. Bar No. 881384)
Shani Rivaux (Fl. Bar No. 42095)
600 Brickell Avenue, Suite 3100
Miami, FL 33131
(786) 913-4900
jennifer.altman@pillsburylaw.com
shani.rivaux@pillsburylaw.com

William C. Miller*
Gary J. Shaw*
1200 17th Street N.W.
Washington, D.C. 20036
(202) 663-8000
william.c.miller@pillsburylaw.com
gary.shaw@pillsburylaw.com

Joe Little*
500 Capitol Mall, Suite 1800
Sacramento, CA 95814
(916) 329-4700
joe.little@pillsburylaw.com

NATIONAL HEALTH LAW PROGRAM
Abigail Coursolle*
3701 Wilshire Boulevard, Suite 315
Los Angeles, CA 90010
(310) 736-1652
coursolle@healthlaw.org

Catherine McKee*
1512 E. Franklin Street, Suite 110
Chapel Hill, NC 27514
(919) 968-6308
mckee@healthlaw.org

LAMBDA LEGAL DEFENSE AND EDUCATION FUND, INC.

Omar Gonzalez-Pagan*
120 Wall Street, 19th Floor
New York, NY 10005
(212) 809-8585
ogonzalez-pagan@lambdalegal.org

Carl S. Charles*
1 West Court Square, Suite 105
Decatur, GA 30030
(404) 897-1880
ccharles@lambdalegal.org

SOUTHERN LEGAL COUNSEL, INC.

Simone Chriss (FBN 124062)
Chelsea Dunn (FBN 1013541)
1229 NW 12th Avenue
Gainesville, FL 32601
(352) 271-8890
Simone.Chriss@southernlegal.org
Chelsea.Dunn@southernlegal.org

FLORIDA HEALTH JUSTICE PROJECT

Katy DeBriere (Fl. Bar No. 58506)
3900 Richmond Street
Jacksonville, FL 32205
(352) 278-6059
debriere@floridahealthjustice.org

* *Admitted pro hac vice.*

CERTIFICATE OF SERVICE

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

CERTIFICATE OF WORD COUNT

As required by Local Rule 7.1(F), I certify that this Memorandum of Law contains 7,463 words.

/s/ Shani Rivaux
Counsel for Plaintiffs

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

AUGUST DEKKER, *et al.*,

Plaintiffs,

v.

JASON WEIDA, *et al.*,

Defendants.

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

DECLARATION OF SHANI RIVAUX

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

1. I am over 18 years of age.

2. I am a Partner at the law firm of Pillsbury Winthrop Shaw Pittman LLP and serve as counsel of record for the plaintiffs in the above-captioned matter.

3. I have personal knowledge of the 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. Paul W. Hruz and Supporting Memorandum of Law.

5. Attached as **Exhibit A** is a true and correct copy of the expert witness report of Dr. Paul W. Hruz, M.D., Ph.D. that was submitted by Defendants in this

matter.

6. Attached as **Exhibit B** is a true and correct copy of the expert witness rebuttal report of Dr. Paul W. Hruz, M.D., Ph.D. that was submitted by Defendants in this matter.

7. Attached as **Exhibit C** is a true and correct copy of excerpts of the transcript of the deposition of Dr. Paul W. Hruz on September 29, 2021, taken in *Kadel v. Folwell*, No. 1:19-cv-00272-LCB-LPA (M.D.N.C.) ("*Kadel*").

8. Attached as **Exhibit D** is a true and correct copy of the expert witness report of Dr. Paul W. Hruz, M.D., Ph.D. (including a copy of his curriculum vitae) dated April 30, 2021 and was entered as Exhibit 1 to Dr. Hruz's deposition in *Kadel* on September 29, 2021.

9. Attached as **Exhibit E** is a true and correct copy of excerpts of the transcript of the deposition of Dr. Paul W. Hruz on November 20, 2017 taken in relation to *Adams by & through Kasper v. Sch. Bd. of St. Johns Cty., Fla.*, 318 F. Supp. 3d 1293 (M.D. Fla. 2018), and which was entered as Exhibit 2 to Dr. Hruz's deposition in *Kadel* on September 29, 2021.

10. Attached as **Exhibit F** is a true and correct copy of the transcript of the deposition of Dr. Paul W. Hruz on July 16, 2018 taken in relation to *Bruce v. South Dakota*, No. 17-cv-05080 (D.S.D), and which was entered as Exhibit 3 to Dr. Hruz's deposition in *Kadel* on September 29, 2021.

11. Attached as **Exhibit G** is a true and correct copy of the article "Gender nonconforming youth: current perspectives," published in the scientific journal *Adolescent Health, Medicine and Therapeutics* on May 25, 2017, and which was entered as Exhibit 8 to Dr. Hruz's deposition in *Kadel* on September 29, 2021.

12. Attached as **Exhibit H** is a true and correct copy of excerpts of *Understanding the Well-Being of LGBTQI+ Populations*, a Consensus Study Report of the National Academies of Sciences, Engineering, and Medicine published in 2020.

13. Attached as **Exhibit I** is a true and correct copy of a printout of the webpage "Understanding Unapproved Use of Approved Drugs 'Off Label,'" published by the U.S. Food and Drug Administration, and which was entered as Exhibit 15 to Dr. Hruz's deposition in *Kadel* on September 29, 2021.

14. Attached as **Exhibit J** is a true and correct copy of "Policy Statement: Off- Label Use of Drugs in Children" from the American Academy of Pediatrics, which was published in the scientific journal *Pediatrics* on March 2014 and was entered as Exhibit 17 to Dr. Hruz's deposition in *Kadel* on September 29, 2021.

15. Attached as **Exhibit K** is a true and correct copy of Declaration of Dr. Norman P. Spack, M.D., dated December 5, 2017, which was filed in *Adams by & through Kasper v. Sch. Bd. of St. Johns Cty., Fla.*, 318 F. Supp. 3d 1293 (M.D. Fla.

2018), and which was entered as Exhibit 19 to Dr. Hruz's deposition in *Kadel* on September 29, 2021.

16. Attached as **Exhibit L** is a true and correct copy of excerpts of the transcript of the deposition of Kim Hutton on December 5, 2017 taken in relation to *Adams by & through Kasper v. Sch. Bd. of St. Johns Cty., Fla.*, 318 F. Supp. 3d 1293 (M.D. Fla. 2018).

17. Attached as **Exhibit M** is a true and correct copy of a printout of the web- page "I International Conference on Gender, Sex and Education in Madrid against the LGBTI doctrine which is taking hold of Western countries is a resounding success," published by the Gender and Sex Conference on February 28, 2018, and which was entered as Exhibit 6 to Dr. Hruz's deposition in *Kadel* on September 29, 2021.

18. Attached as **Exhibit N** 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.

19. Attached as **Exhibit O** is a true and correct copy of excerpts of the transcript of the deposition of Dr. Patrick Lappert on September 30, 2021, taken in *Kadel*.

20. Attached as **Exhibit P** is a true and correct copy of an email from Lisa Tetrault to Omar Gonzalez-Pagan dated April 4, 2023.

21. Attached as **Exhibit Q** is a true and correct copy of excerpts of the transcript of the deposition of Dr. Van Metter taken in this case.

22. Attached as **Exhibit R** is a true and correct copy of the *APA,* Statement on Dr. Kenneth Zucker and Gender Identity Disorder (May 23, 2008), which was entered as Ex. 10 in the deposition of Dr. Van Metter in this case.

23. Attached as **Exhibit S** is a true and correct copy of the American Psychological Association Resolution on Gender Identify Change Efforts, dated February 2021.

I declare under penalty of perjury that the foregoing is true and correct. Executed on this 7th day of April, 2023.

By: */s/ Shani Rivaux*

Shani Rivaux (Fl. Bar No. 42095)
600 Brickell Avenue, Suite 3100
Miami, Florida 33131
(786) 913-4900
shani.rivaux@pillsbury.com

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

AUGUST DEKKER, legally known as KORI DEKKER; BRIT ROTHSTEIN; SUSAN DOE, a minor, by and through her parents and next friends, JANE DOE and JOHN DOE; and K.F., a minor, by and through his parent and next friend, JADE LADUE,	)
Plaintiffs,	) Civil Action No. 4:22-cv-00325-RH-MAF
	) COMPLAINT FOR DECLARATORY, INJUNCTIVE, AND OTHER RELIEF
JASON WEIDA, in his official capacity as Secretary of the Florida Agency for Health Care Administration; and FLORIDA AGENCY FOR HEALTH CARE ADMINISTRATION,	) **Expert Report of Paul W. Hruz, M.D., Ph.D.**
Defendants.	

Pursuant to 28 U.S.C. 1746, I declare:

1. I have been retained by counsel for Defendants as an expert witness in connection with the above-captioned litigation. I have actual knowledge of the matters stated in this report. My professional background, experience, and publications are detailed in my curriculum vitae. A true and accurate copy of my CV is attached as Exhibit A to this report.

2. I received my Doctor of Philosophy degree from the Medical College of Wisconsin in 1993. I received my Medical Degree from the Medical College of Wisconsin in 1994. I am an Associate Professor of Pediatrics in the Division of Pediatric Endocrinology and Diabetes at Washington University School of Medicine. I also have a secondary appointment as Associate Professor of Cellular Biology and Physiology in the Division of Biology and Biological Sciences at Washington University School of Medicine. I served as Chief of the Division of Pediatric Endocrinology and Diabetes at Washington University from 2012-2017. I served as the Director of the Pediatric Endocrinology Fellowship Program at Washington University from 2008-2016. I am currently serving as Associate Fellowship Program Director at Washington University in St. Louis.

3. I am board certified in Pediatrics and Pediatric Endocrinology. I have been licensed to practice medicine in Missouri since 2000. I also have a temporary license to practice telemedicine in Illinois during the COVID-19 pandemic. My professional memberships include the American Diabetes Association, the Pediatric Endocrine Society, and the Endocrine Society.

4. I have published 62 scholarly articles over my academic career spanning over two decades. This includes peer-reviewed publications in the leading

journals in the fields of metabolism, cardiology, HIV, and ethics including the Gastroenterology, Circulation, Diabetes, Science Signaling, the Journal of Biological Chemistry and FASEB Journal. See Exhibit A.

5. I have served as a Reviewer for a number of leading science journals in relevant fields including the Journal of Clinical Endocrinology and Metabolism, the Journal of Biological Chemistry, Diabetes, Scientific Reports and PlosOne, assessing the quality of evidence that is put forward for publication. I have also been involved in the evaluation of clinical trials with colleagues. I have received over $4.6 million in governmental and non-governmental funding for scientific research including grants from the National Institutes of Health, the American Diabetes Association, The American Heart Association, the March of Dimes, and the Harrington Discovery Institute. I am a member of the Alpha Omega Alpha Medical Honor Society and have received the Armond J. Quick Award for Excellence in Biochemistry, the Eli Lilly Award for Outstanding Contribution to Drug Discovery, and the Julio V. Santiago Distinguished Scholar in Pediatrics Award.

6. During the more than 22 years that I have been in clinical practice, I have participated in the care of hundreds of infants and children, including adolescents, with disorders of sexual development. I was a founding member of the multidisciplinary Disorders of Sexual Development (DSD) program at Washington

University. I continue to contribute to the discussion of complex cases and the advancement of research priorities in this field. In the care of these patients, I have acquired expertise in the understanding and management of associated difficulties in gender identification and gender transitioning treatment issues. I have trained and/or supervised hundreds of medical students, residents and clinical fellows in the practice of medicine.

7. My CV (Exhibit A) contains a complete list of the cases I have testified in as an expert witness either at trial or in deposition. Related to the litigation of issues of sex and gender, I have been designated as an expert witness in Joaquín Carcaño et al. v. Patrick McCrory (United States District Court, M.D. North Carolina), Jane Doe v. Board of Education of the Highland School District (United States District Court For the Southern District of Ohio Eastern Division, Case No. 2:16-CV-524), Adams v. St John's School Board (United States District Court For the Middle District of Florida, FL Civil Action No. 3:17-cv-00739-TJCJBT), Ashton Whitaker v. Kenosha Unified School District (United States District Court Eastern District of Wisconsin, Civ. Action No. 2:16-cv-00943), Terri Bruce v. State of South Dakota (The United States District Court District of South Dakota Western Division, Case No. 17-5080), Kadel vs. Falwell (The United States District Court For The Middle District Of North Carolina, Case No.: 1:19-cv-272-LCB-LPA), Brandt v Rutledge (The United States District Court Eastern District

of Arkansas Central Division, Case No. 4:21-CV-00450-JM), Eknes-Tucker vs Ivy (United States District Court Middle District of Alabama Northern Division, Case 2:22-cv-00184-LCB-SRW), D.H. et al. v. Snyder (United States District Court of Arizona, Case No. 4:20-cv-00335-SHR), Cause DF-15-09887-SD of the 255th Judicial Circuit of Dallas County, TX regarding the dispute between J.A. D.Y. and J.U. D.Y., Children, and Bo v. Marshall (United States District Court For The Middle District Of Alabama Northern Division). I have also served as a science consultant or subjected written testimony for court cases in Canada (B.C. Supreme Court File No. E190334) and Great Britain (Bell v. Tavistock).

8. I am being compensated at an hourly rate for actual time devoted, at the rate of $400 per hour including report drafting, travel, testimony, and consultation. My compensation does not depend on the outcome of this litigation, the opinions I express, or the testimony I provide.

9. In my role as a scientist and as the Director of the Division of Pediatric Endocrinology at Washington University, I extensively studied the existing scientific research literature related to the incidence, potential etiology, and treatment of gender dysphoria as efforts were made to develop a Transgender Medicine Clinic at Saint Louis Children's Hospital. I have participated in local, national, and international meetings where the endocrine care of children with gender dysphoria has been discussed in detail and debated in depth. I have met individually

and consulted with several pediatric endocrinologists (including Dr. Norman Spack) and other professionals specializing in sexual health (including Eli Coleman) who have developed and led transgender programs in the United States. I have also consulted with, met with, and had detailed discussions with dozens of parents of children with gender dysphoria to understand the unique difficulties experienced by this patient population. I continue to evaluate the ongoing experimental investigation of this condition. I am frequently consulted by other medical professionals to help them understand the complex medical and ethical issues related to this emerging field of medicine.

10. In my 25 years of clinical practice, I have cared for children from birth to the completion of college in their early twenties who have a variety of hormone related diseases. This includes disorders of growth, puberty (both precocious and delayed), glucose homeostasis (both hypoglycemia and diabetes mellitus), adrenal function (both adrenal insufficiency and steroid excess), thyroid function, skeletal abnormalities, gonadal dysfunction (including polycystic ovarian syndrome and ovarian failure), hypopituitarism, and disorders of sexual development. Pediatric patients referred to our practice for the evaluation and treatment of gender dysphoria are cared for by an interdisciplinary team of providers that includes a psychologist and pediatric endocrinologist who have been specifically chosen for

this role based upon a special interest and professional knowledge and training in this patient population.

11. My opinions as detailed in this report are based upon my:

a. knowledge, training, and clinical experience in caring for thousands of patients over many years;
b. detailed methodological reviews of hundreds of relevant peer-reviewed science publications;
c. consults, discussions, and team analyses with colleagues and other experts in the field, including attendance and participation in various professional conferences;
d. publications in peer reviewed scientific journals;
e. editorial work for peer reviewed scientific journals; and,
f. peer reviewed research grant receipt and review work.

The materials that I have relied upon are the same types of materials that other experts in my field of clinical practice rely upon when forming opinions on the subject, including hundreds of published, peer reviewed scientific research (and professional) articles.

12. My opinions and hypotheses in this matter are—as all expert reports—subject to the limitations of documentary and related evidence, the impossibility of absolute predictions, and the limitations of social, biological, and medical science. I have not met with, or 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.

Background on Sex and Gender

13. Sex is an objective biological trait intrinsically oriented toward specific roles in the conception and development of new members of a species. Both males and females contribute genetic information in distinct yet complimentary ways. Males have the role of delivering sperm produced by testes and the unique paternal DNA contained therein to a female. Females have the role of receiving this male genetic information to join with the maternal genetic information contained in ova produced by ovaries. Sex is not "assigned at birth"; it is permanently determined by biology at conception. This remains the standard definition that has been accepted by the relevant scientific community and used worldwide by scientists, medical personnel, and society in general for decades.

14. The scientific and clinical measurement of sex is done with highly reliable and valid objective methodologies. Visual medical examination of the appearance of the external genitalia is the primary methodology used by clinicians to

recognize sex. In cases where genital ambiguity is present, additional testing modalities including chromosomal analysis, measurement of hormone levels, radiographic imaging of internal sexual anatomy and biological response to provocative testing are utilized. The measurement and assessment of biological sex has been documented by valid and reliable research published in credible journals, and is accepted by the relevant scientific community. Medical recognition of an individual as male or female is correctly made at birth in nearly 99.98% of cases according to external phenotypic expression of primary sexual traits (i.e., the presence of a penis for males and presence of labia and vagina for females).

15. For members of the human species (and virtually all mammals), sex is normatively aligned in a binary fashion (i.e., either male or female) in relation to biologic purpose. The presence of individuals with disorders of sexual development (along the range of the established Prader scale) does not alter this fundamental reality.

16. Due to genetic and hormonal variation in the developing fetus, normative development of the external genitalia in any individual differs with respect to size and appearance while maintaining an ability to function with respect to biologic purpose (i.e., reproduction). Internal structures (e.g., gonad, uterus, vas deferens) normatively align in more than 99.9%+ of mammals with external genitalia, including humans.

17. Due to the complexity of the biological processes that are involved in normal sexual development, it is not surprising that a very small number of individuals are born with defects in this process (1 in 5,000 births).[1] Defects can occur through either inherited or *de novo* mutations in genes that are involved in sexual determination or through environmental insults during critical states of sexual development. Persons who are born with such abnormalities are considered to have a disorder of sexual development (DSD). Most often, this is first detected as ambiguity in the appearance of the external genitalia. Such detection measurements are reliable and valid and accepted by the relevant scientific community.

18. The medical care of persons with DSDs is primarily directed toward identification of the etiology of the defect and treatment of any associated complications. Similar to other diseases, diagnostic tools such as the Prader scale are used to assess, measure, and assign a "stage" to the severity of the deviation from normal (e.g., assessments of objective, reliable evidence). In children with DSDs, characterization based upon phenotype alone does not reliably predict the sex chromosomes present nor does it necessarily correlate with potential for biological sexual function. Decisions on initial sex assignment in these very rare cases require detailed assessment of objective, reliable medical evidence by a team of expert

[1] See Sax, How common is Intersex? A response to Anne Fausto-Sterling, The Journal of Sex Research, 39:3, 174-178, DOI: 10.1080/00224490209552139 (2002).

medical providers. Previously, it was felt that a definitive sex assignment was necessary shortly after birth with the belief that this would allow patients with a disorder of sexual development to best conform to the assigned sex and so parents-caregivers could help socialize the child to the assigned sex. Current practice is to defer sex assignment until the etiology of the disorder is determined and, if possible, a reliable prediction can be made on likely biologic and psychologic outcomes. When this cannot be done with confidence, a presumptive sex assignment is made. Factors used in making such decisions include karyotype (46XX, 46XY, or other), phenotypic appearance of the external genitalia, and parental desires. The availability of new information can, in rare circumstances, lead to a change in sex determination. Decisions on whether to surgically alter the external genitalia to align with sex are generally deferred until the patient is able to provide consent.[2]

19. "Gender," a term that had traditionally been reserved for grammatical purposes, is currently used to describe the psychological and cultural characteristics of a person in relation to biological sex. Gender in such new definitions would therefore exist only in reference to subjective personal perceptions and feelings and societal expectations, not biology. The reliability and validity of various usages of the term "gender" is currently controversial and the relevant scientific community

[2] See Lee et al., Global Disorders of Sex Development Update since 2006: Perceptions, Approach and Care, Horm Res Paediatr 85, 158-180, doi:10.1159/000442975 (2016).

has accepted no use other than in relation to biological sex, which includes participate in activities related to reproduction. The dangers of incorrectly using the term "gender" in place of "sex" have been acknowledged by the Endocrine Society.[3]

20. "Gender identity" refers to a person's individual experience and perception and unverified verbal patient reports of how they experience being male or female or a combination of these or other categories. The term "gender identity" is controversial. There is no current worldwide definition of "gender identity" accepted by the relevant clinical communities. The measurement error rate for non-biological "gender identity" is unknown.

21. People who identify as "transgender" transiently or persistently experience a sex-discordant gender identity.[4]

Puberty

22. Puberty is "the morphological and physiological changes that occur in the growing boy or girl as the gonads change from the infantile to the adult state. These changes involve nearly all the organs and structures of the body but they do not begin at the same age nor take the same length of time to reach completion in

[3] See Bhargava et al., Considering Sex as a Biological Variable in Basic and Clinical Studies: An Endocrine Society Scientific Statement, 42 *Endocrine reviews*, No. 3, pp. 219-58, https://doi.org/10.1210/endrev/bnaa034 (2021).
[4] APA, DSM-5, 451.

all individuals. Puberty is not complete until the individual has the physical capacity to conceive and successfully rear children."[5]

23. The principal manifestations of puberty are:

- The adolescent growth spurt; i.e., an acceleration followed by a deceleration of growth in most skeletal dimensions and in many internal organs.
- The development of the gonads.
- The development of the secondary reproductive organs and the secondary sex characters.
- Changes in body composition, i.e., in the quantity and distribution of fat in association with growth of the skeleton and musculature.
- Development of the circulatory and respiratory systems leading, particularly in boys, to an increase in strength and endurance.[6]

24. The ability to physically conceive children is made possible by the maturation of the primary sex characteristics, the organs and structures that are involved directly in reproduction. In boys, these organs and structures include the scrotum, testes, and penis while in girls they include the ovaries, uterus, and

[5] William A. Marshall and James M. Tanner, "Puberty," in Human Growth: A Comprehensive Treatise, Second Edition, Volume 2, eds. Frank Falkner and James M. Tanner (New York: Springer, 1986), 171.
[6] *Id.* at 171–72.

vagina. In addition to these primary sex characteristics, secondary sex characteristics also develop during puberty — the distinctive physical features of the two sexes that are not directly involved in reproduction. Secondary sex characteristics that develop in girls include "the growth of breasts and the widening of the pelvis" and in boys "the appearance of facial hair and the broadening of shoulders," while other patterns of body hair and changes in voice and skin occur during puberty in both girls and boys.[7]

25. Physicians characterize the progress of puberty by marking the onset of different developmental milestones. The earliest visible event, the initial growth of pubic hair, is known as "pubarche"; it occurs between roughly ages 8 and 13 in girls, and between ages 9.5 and 13.5 in boys.[8] In girls, the onset of breast development, known as "thelarche," occurs around the same time as pubarche.[9] "Menarche" is another manifestation of sexual maturation in females, referring to the onset of menstruation, which typically occurs at around 13 years of age and is generally a sign of the ability to conceive.[10] Roughly corresponding to menarche in girls is "spermarche" in boys; this refers to the initial presence of viable sperm in semen,

[7] Robert V. Kail and John C. Cavanaugh, Human Development: A Life-Span View, Seventh Edition (Boston, Mass.: Cengage Learning, 2016), 276.
[8] Jamie Stang and Mary Story, "Adolescent Growth and Development," in Guidelines for Adolescent Nutrition Services, eds. Jamie Stang and Mary Story (Minneapolis, Minn.: University of Minnesota, 2005), 4.
[9] *Id.* at 3.
[10] Marshall and Tanner, "Puberty," 191–192.

which also typically occurs around 13.[11] (The "-arche" in the terms for these milestones comes from the Greek for beginning or origin.)

26. Scientists distinguish three main biological processes involved in puberty: adrenal maturation, gonadal maturation, and somatic growth acceleration. "Adrenarche"—the beginning of adrenal maturation—begins between ages 6 and 9 in girls, and ages 7 and 10 in boys. The hormones produced by the adrenal glands during adrenarche are relatively weak forms of androgens (masculinizing hormones) known as dehydroepiandrosterone and dehydroepiandrosterone sulfate. These hormones are responsible for signs of puberty shared by both sexes: oily skin, acne, body odor, and the growth of axillary (underarm) and pubic hair.[12]

27. "Gonadarche"—the beginning of the process of gonadal maturation—normally occurs in girls between ages 8 and 13 and in boys between ages 9 and 14.[13] The process begins in the brain, where specialized neurons in the hypothalamus secrete gonadotropin-releasing hormone (GnRH).[14] This hormone is secreted in a cyclical or "pulsatile" manner—the hypothalamus releases bursts of GnRH,

---

[11] *Id.* at 185.
[12] Sharon E. Oberfield, Aviva B. Sopher, and Adrienne T. Gerken, "Approach to the Girl with Early Onset of Pubic Hair," Journal of Clinical Endocrinology and Metabolism 96, no. 6 (2011): 1610–1622, http://dx.doi.org/10.1210/jc.2011-0225.
[13] Selma Feldman Witchel and Tony M. Plant, "Puberty: Gonadarche and Adrenarche," in Yen and Jaffe's Reproductive Endocrinology, Sixth Edition, eds. Jerome F. Strauss III and Robert L. Barbieri (Philadelphia, Penn.: Elsevier, 2009), 395.
[14] Allan E. Herbison, "Control of puberty onset and fertility by gonadotropin-releasing hormone neurons," Nature Reviews Endocrinology 12 (2016): 452, http://dx.doi.org/10.1038/nrendo.2016.70.

and when the pituitary gland is exposed to these bursts, it responds by secreting two other hormones.[15] These are luteinizing hormone (LH) and follicle-stimulating hormone (FSH), which stimulate the growth of the gonads (ovaries in women and testes in men).[16] (The "follicles" that the latter hormone stimulates are not hair follicles but ovarian follicles, the structures in the ovaries that contain immature egg cells.) In addition to regulating the maturation of the gonads and the production of sex hormones, these two hormones also play an important role in regulating aspects of human fertility.[17]

28. As the gonadal cells mature under the influence of LH and FSH, they begin to secrete androgens (masculinizing sex hormones like testosterone) and estrogens (feminizing sex hormones).[18] These hormones contribute to the further development of the primary sex characteristics (the uterus in girls and the penis and scrotum in boys) and to the development of secondary sex characteristics (including breasts and wider hips in girls, and wider shoulders, breaking voices, and increased muscle mass in boys). The ovaries and testes both secrete androgens as

[15] *Id.* at 453.
[16] *Id.* at 454.
[17] *Id.* at 452.
[18] Michael A. Preece, "Prepubertal and Pubertal Endocrinology," in Human Growth: A Comprehensive Treatise, Volume 2, 212.

well as estrogens, however the testes secrete more androgens and the ovaries more estrogens.[19]

29. The gonads and the adrenal glands are involved in two separate but interrelated pathways (or "axes") of hormone signaling. These are the hypothalamic-pituitary-gonadal (HPG) axis and the hypothalamic-pituitary-adrenal (HPA) axis.[20] Though both play essential roles in puberty, it is, as just noted, the HPG axis that results in the development of the basic reproductive capacity and the external sex characteristics that distinguish the sexes.[21]

30. The third significant process that occurs with puberty, the somatic growth spurt, is mediated by increased production and secretion of human growth hormone, which is influenced by sex hormones secreted by the gonads (both testosterone and estrogen). Similar to the way that the secretion of GnRH by the hypothalamus induces the pituitary gland to secrete FSH and LH, in this case short

[19] Rex A. Hess, "Estrogen in the adult male reproductive tract: A review," Reproductive Biology and Endocrinology 1, (2003), https://dx.doi.org/10.1186/1477-7827-1-52; Henry G. Burger, "Androgen production in women," Fertility and Sterility 77 (2002): 3–5, http://dx.doi.org/10.1016/S0015-0282(02)02985-0.
[20] Russell D. Romeo, "Neuroendocrine and Behavioral Development during Puberty: A Tale of Two Axes," Vitamins and Hormones 71 (2005): 1–25, http://dx.doi.org/10.1016/S0083-6729(05)71001-3.
[21] Margaret E. Wierman and William F. Crowley, Jr., "Neuroendocrine Control of the Onset of Puberty," in Human Growth, Volume 2, 225.

pulses of a hormone released by the hypothalamus cause the pituitary gland to release human growth hormone.[22] This process is augmented by testosterone and estrogen. Growth hormone acts directly to stimulate growth in certain tissues, and also stimulates the liver to produce a substance called "insulin-like growth factor 1," which has growth-stimulating effects on muscle.[23]

31. The neurological and psychological changes occurring in puberty are less well understood than are the physiological changes. Men and women have distinct neurological features that may account for some of the psychological differences between the sexes, though the extent to which neurological differences account for psychological differences, and the extent to which neurological differences are caused by biological factors like hormones and genes (as opposed to environmental factors like social conditioning), are all matters of debate.

32. Scientists distinguish between two types of effects hormones can have on the brain: organizational effects and activational effects. Organizational effects are the ways in which hormones cause highly stable changes in the basic architecture of different brain regions. Activational effects are the more immediate and temporary effects of hormones on the brain's activity. During puberty, androgens

[22] Preece, *supra*, at 218–19.
[23] Udo J. Meinhardt and Ken K. Y. Ho, "Modulation of growth hormone action by sex steroids," Clinical Endocrinology65, no. 4 (2006): 414, http://dx.doi.org/10.1111/j.1365-2265.2006.02676.x.

and estrogens primarily have activating effects, but long before then they have organizational effects in the brains of developing infants and fetuses.[24]

33. In sum: Puberty involves a myriad of complex, related, and overlapping physical processes, occurring at various points and lasting for various durations. During this period of life, adrenarche and changes in the secretion of growth hormone contribute to the child's growth and development. With gonadarche, the maturation of sex organs begins and with normal maturation will lead to the emergence of reproductive capacity, as well as the development of the other biological characteristics that distinguish males and females.

Pediatric Endocrine Disorders and Treatments

34. The field of endocrinology is directed toward the care of hormone related diseases. Pediatric endocrine diseases include disorders of glucose regulation (hypoglycemia and diabetes mellitus), disorders of thyroid function (hyper and hypothyroidism), disorders of growth (e.g. short stature, acromegaly, obesity and poor weight gain), disorders of sexual development and function (e.g. genital am-

[24] Herting MM, Sowell ER. Puberty and structural brain development in humans. Front Neuroendocrinol. 2017 Jan;44:122-137. doi: 10.1016/j.yfrne.2016.12.003; Hornung J, Lewis CA, Derntl B. Sex hormones and human brain function. Handb Clin Neurol. 2020;175:195-207. doi: 10.1016/B978-0-444-64123-6.00014-X

biguity, precocious and delayed puberty, hypogonadism, polycystic ovarian syndrome), disorders of adrenal function (e.g. adrenal insufficiency and Cushing's syndrome), disorders of pituitary function, lipid disorders, and disorders of bone and mineral metabolism. For all of these conditions, there are objective physical and biochemical criteria for diagnosis and treatment with well-established normal reference ranges for hormones and metabolites.

35. Hormone interventions to suppress puberty were not developed for the purpose of treating children with gender dysphoria. Rather, they were first used as a way to normalize puberty for children who undergo puberty too early, a condition known as "precocious puberty."

36. For females, precocious puberty is defined by the onset of puberty before age 8, while for males it is defined as the onset of puberty before age 9.[25] Premature thelarche (the appearance of breast development) is usually the first clinical sign of precocious puberty in girls. For males, precocious puberty is

[25] Karen Oerter Klein, "Precocious Puberty: Who Has It? Who Should Be Treated?," Journal of Clinical Endocrinology and Metabolism 84, no. 2 (1999): 411, http://doi.org/10.1210/jcem.84.2.5533. See also: Frank M. Biro et al., "Onset of Breast Development in a Longitudinal Cohort," Pediatrics 132, no. 6 (2013): 1019–1027, http://dx.doi.org/10.1542/peds.2012-3773; Carl-Joachim Partsch and Wolfgang G. Sippell, "Pathogenesis and epidemiology of precocious puberty. Effects of exogenous oestrogens," Human Reproduction Update 7, no. 3 (2001): 293, http://dx.doi.org/10.1111/j.1600-0463.2001.tb05760.x.

marked by premature testicular enlargement.[26] In addition to the psychological and social consequences that a child might be expected to suffer, precocious puberty can also lead to reduced adult height, since the early onset of puberty interferes with later bone growth.[27]

37. Precocious puberty is divided into two types, central precocious puberty (sometimes labeled "true precocious puberty") and peripheral precocious puberty (sometimes labeled "precocious pseudopuberty").[28] Central precocious puberty is caused by the early activation of the gonadal hormone pathway by GnRH, and is amenable to treatment by physicians. Peripheral precocious puberty, which is caused by secretion of sex hormones by the gonads or adrenal glands independent of signals from the pituitary gland, is less amenable to treatment. Effects of androgen or estrogen hypersecretion can be reduced by administration of drugs that block the activity of the sex hormone receptors. If a tumor is causing the disorder, surgical removal may be necessary.

38. Precocious puberty is rare, especially in boys. A recent Spanish study of central precocious puberty estimated the overall prevalence to be 19 in 100,000

[26] Anne-Simone Parent et al., "The Timing of Normal Puberty and the Age Limits of Sexual Precocity: Variations around the World, Secular Trends, and Changes after Migration," Endocrine Reviews 24, no. 5 (2011): 675, http://dx.doi.org/10.1210/er.2002-0019.
[27] Jean-Claude Carel et al., "Precocious puberty and statural growth," Human Reproduction Update 10, no. 2 (2004): 135, http://dx.doi.org/10.1093/humupd/dmh012.
[28] Partsch and Sippell, *supra*, at 294–95.

(37 in 100,000 girls affected, and 0.46 in 100,000 boys).[29] A Danish study of precocious puberty (not limited to central precocious puberty) found the prevalence to be between 20 to 23 per 10,000 in girls and less than 5 in 10,000 in boys.[30]

39. To diagnose central precocious puberty, hormones from the pituitary gland, LH and FSH, are objectively measured. This can sometime be done by measurement of baseline levels but often requires assessment after transient stimulation with GnRH. As discussed, these are two hormones that are made in the pituitary gland that signal to the gonads. In males, they lead to production of testosterone. In females, they lead to the production of estrogen. LH and FSH signaling are essential for normal sperm production and ovarian maturation in males and females, respectively.

40. Also subject to objective measurement when diagnosing and treating central precocious puberty are sex steroid hormones, either testosterone or estrogen, and bone growth.

41. Treatment for precocious puberty is somewhat counterintuitive. Rather than stopping the production of GnRH, physicians actually provide patients

[29] Leandro Soriano-Guillén et al., "Central Precocious Puberty in Children Living in Spain: Incidence, Prevalence, and Influence of Adoption and Immigration," Journal of Clinical Endocrinology and Metabolism 95, no. 9 (2011): 4307, http://dx.doi.org/10.1210/jc.2010-1025. In some cases, peripheral precocious puberty is caused by an underlying condition, such as a tumor, that can be treated.

[30] Grete Teilmann et al., "Prevalence and Incidence of Precocious Pubertal Development in Denmark: An Epidemiologic Study Based on National Registries," Pedriatics 116, no. 6 (2005): 1323, http://dx.doi.org/10.1542/peds.2005-0012.

more constant levels of synthetic GnRH (called GnRH analogues or GnRH agonists).[31] As discussed above, when produced endogenously (that is, by the body naturally), GnRH stimulates the pituitary gland to release gonad-stimulating hormones (gonadotropins, LH and FSH). When added exogenously, the additional GnRH "desensitizes" the pituitary, leading to a decrease in the secretion of gonadotropins, which in turn leads to the decreased maturation of and secretion of sex hormones by the gonads (ovaries and testes). The intent and effect of giving puberty blockers is identical when it is given to a male as when it is given to a female in this context: suppressing the secretion of gonadotropin hormones. Even the dosing is the same for males and females, and depends on the person's weight.

42. The first publication describing the use of GnRH analogues in children for precocious puberty appeared in 1981.[32] In the time since GnRH analogues were first proposed, they have become fairly well accepted as a treatment of precocious puberty, with one prominent GnRH analogue, Lupron, approved for that use by the FDA in 1993.[33] However, there remain some questions concerning the ef-

[31] William F. Crowley, Jr. et al., "Therapeutic use of pituitary desensitization with a long-acting LHRH agonist: a potential new treatment for idiopathic precocious puberty," Journal of Clinical Endocrinology and Metabolism 52, no. 2 (1981): 370–372, http://dx.doi.org/10.1210/jcem-52-2-370. (LHRH refers to "lutenizing hormone releasing hormone," another term for GnRH.)
[32] Crowley et al., *supra*, at 370–72.
[33] "Full Prescribing Information" for Lupron Depot-Ped, FDA.gov (undated), https://www.accessdata.fda.gov/drugsatfda_docs/label/2011/020263s036lbl.pdf.

fectiveness of treatment with GnRH analogues. A 2009 consensus statement of pediatric endocrinologists concluded that GnRH analogues are an effective way to improve the height of girls with onset of puberty at less than 6 years of age, and also recommended the treatment be considered for boys with onset of precocious puberty who have compromised height potential.[34] Regarding the negative psychological and social outcomes associated with precocious puberty, the authors found that the available data were unconvincing, and that additional studies are needed.[35] Puberty blockers have recently been recognized to carry a risk of increased brain pressure that can adversely affect vision and cause severe headaches.[36]

43. When used to treat precocious puberty, the process of desensitization of the pituitary gland by synthetic GnRH is not permanent. After a patient stops taking the GnRH analogues, the pituitary will resume its normal response to the pulsatile secretion of GnRH by the hypothalamus, as evidenced by the fact that

[34] Jean-Claude Carel et al., "Consensus Statement on the Use of Gonadotropin-Releasing Hormone Analogs in Children," Pediatrics 123, no. 4 (2009): e753, http://dx.doi.org/10.1542/peds.2008-1783.
[35] *Id.*
[36] *Risk of pseudotumor cerebri added to labeling*, AAP (July 1, 2022), https://publications.aap.org/aapnews/news/20636/Risk-of-pseudotumor-cerebri-added-to-labeling-for.

children treated for precocious puberty using GnRH analogues will resume normal pubertal development, usually about a year after they withdraw from treatment.[37]

44. The goal of this treatment is to allow the child to have pubertal development enter the normal quiescence that is present at that age. This treatment helps to preserve their final adult height, by slowing the rate of bone age advancement. The goal is *not* to delay puberty beyond other children, as delaying too long can be adverse effects, including reduced bone marrow density, as discussed below.

45. In addition to being prescribed for children with precocious puberty, GnRH analogues have also been used in adults for a variety of indications, including hormone-sensitive tumors.[38] GnRH analogues have also been given to post-pubertal adolescents undergoing chemotherapy with drugs that can have toxic effects on the gonads.[39]

[37] Marisa M. Fisher, Deborah Lemay, and Erica A. Eugster, "Resumption of Puberty in Girls and Boys Following Removal of the Histrelin Implant," The Journal of Pediatrics 164, no. 4 (2014): 3, http://dx.doi.org/10.1016/j.jpeds.2013.12.009.
[38] See Kumar & Sharma, Gonadotropin-Releasing Hormone Analogs: Understanding Advantages and Limitations, Journal of Human Reproductive Sciences 7, no. 3 (2014).
[39] Meli M, et al. Triptorelin for Fertility Preservation in Adolescents Treated With Chemotherapy for Cancer. J Pediatr Hematol Oncol. 40(4):269-276 (2018).

46. Sex steroids such as testosterone and estrogen are frequently used in the treatment of disorders of normal gonadal function. This includes hypogonadotropic hypogonadism, primary gonadal failure and delayed puberty.[40] In each of these conditions, there are objective laboratory tests that are used to diagnose these conditions and monitor response to treatment. Deficiency of sex steroids has bodily effects that extend beyond sexual function.[41] This includes significant effect on bone density, lean body mass, metabolism, immunity, and neural function.

47. There are major and highly significant differences between male and female responses to sex hormones.[42] Giving estrogen to a biological male is not equivalent to giving the same hormone to a biological female. Likewise, giving testosterone to a biological female is not equivalent to giving the same hormone to a biological male.[43] Differences are not limited to pharmacokinetic effect (i.e. how

[40] Kumar P, Kumar N, Thakur DS, Patidar A. Male hypogonadism: Symptoms and treatment. J Adv Pharm Technol Res. 2010 Jul;1(3):297-301. doi: 10.4103/0110-5558.72420. PMID: 22247861; PMCID: PMC3255409; Voutsadaki K, Matalliotakis M, Ladomenou F. Hypogonadism in adolescent girls: treatment and long-term effects. Acta Biomed. 2022 Oct 26;93(5):e2022317. doi: 10.23750/abm.v93i5.13719. PMID: 36300209; PMCID: PMC9686158.
[41] Alemany M. The Roles of Androgens in Humans: Biology, Metabolic Regulation and Health. Int J Mol Sci. 2022 Oct 8;23(19):11952. doi: 10.3390/ijms231911952. PMID: 36233256; PMCID: PMC9569951; Patel S, Homaei A, Raju AB, Meher BR. Estrogen: The necessary evil for human health, and ways to tame it. Biomed Pharmacother. 2018 Jun;102:403-411. doi: 10.1016/j.biopha.2018.03.078. Epub 2018 Mar 22. PMID: 29573619.
[42] See Madla et al., Let's talk about sex: Differences in drug therapy in males and females, *Advanced drug delivery reviews*, 113804. Advance online publication. https://doi.org/10.1016/j.addr.2021.05.014 (2021).
[43] See Soldin et al., Sex differences in pharmacokinetics and pharmacodynamics, Clinical pharmacokinetics, 48(3), 143–157 (2009); Pogun et al., Sex Differences in Drug Effects. In: Stolerman I.P. (eds) Encyclopedia of Psychopharmacology, Springer, Berlin, Heidelberg (2010).

drugs are absorbed, distributed throughout the body and metabolized) but are present even at the cellular level.[44] Sex steroids act by altering the expression of the genetic information present in all nucleated cells of the body. Epigenetic differences (i.e. chemical changes to DNA structure) result in sex-differential expression of over 6,500 genes in the body.[45] Consequences of a failure to recognize these differences can result in drug overdose, lack of treatment response, or serious side effects.

48. Several conditions in minors may indicate endocrinologic treatment with testosterone. For instance, primary hypogonadism from gonadal failure is caused damage or impaired function of the male testes. Secondary hypogonadism is caused by abnormalities in pituitary structure or function. Hypogonadism can be objectively diagnosed by measurement of testosterone (or its derivatives) and gonadotropin (LH and FSH) levels. When used for the treatment of affected males with hypogonadism, testosterone is administered to achieve levels that are normal

[44] See, e.g., Walker et al., Matters of the heart: Cellular sex differences, *Journal of molecular and cellular cardiology*, S0022-2828(21)00087-0. Advance online publication. https://doi.org/10.1016/j.yjmcc.2021.04.010 (2021).
[45] Gershoni, M., Pietrokovski, S. The landscape of sex-differential transcriptome and its consequent selection in human adults. *BMC Biol* **15**, 7 (2017). https://doi.org/10.1186/s12915-017-0352-z

for the individual's age. This requires careful monitored of serum testosterone levels, as excess levels can have serious adverse effects, including elevations of red blood cell counts, changes in blood pressure, and brain changes.[46]

49. Testosterone may also be used in males to treat delayed puberty. To treat the condition of constitutional delay (where the person has means to progress through puberty, but onset was delayed), the male would normally be given low doses of testosterone for 3-4 months to "prime the pump" for normal puberty. Assessment of this condition includes measuring levels of LH, FSH, and testosterone, as well as observation of testicular size. Once puberty has been initiated and is progressing, there is no need to administer ongoing testosterone therapy. The normal signals present within the body with the pituitary gland signaling to the testicles continue with maturation of the gonad leading to reproductive capacity.

50. Continuing to give external testosterone to a male in normal puberty would suppress the normal function of the testes and can lead to infertility—a result contrary to the goal of endocrinology, which is to restore health. Thus, for instance, a male adolescent undergoing normal puberty who simply desired increased

[46] Ohlander SJ, Varghese B, Pastuszak AW. Erythrocytosis Following Testosterone Therapy. Sex Med Rev. 2018 Jan;6(1):77-85. doi: 10.1016/j.sxmr.2017.04.001; Kienitz T, Quinkler M. Testosterone and blood pressure regulation. Kidney Blood Press Res. 2008;31(2):71-9. doi: 10.1159/000119417; Scarth M, Bjørnebekk A. Androgen abuse and the brain. Curr Opin Endocrinol Diabetes Obes. 2021 Dec 1;28(6):604-614. doi: 10.1097/MED.0000000000000675.

lean body mass (i.e., higher muscle mass) should not normally be given testosterone for that purpose, both because it is considered medically unnecessary and because of the adverse effects of extra testosterone. Among other reasons, these effects explain why testosterone is a controlled substance.

51. Outside the context of gender dysphoria, testosterone is not an indicated treatment for a female child or adolescent. Testosterone, or any androgen, would lead to virilization, which can come with serious adverse effects. This includes impaired fertility, alopecia (hair loss), disfiguring acne, and metabolic changes that increase risk of heart disease and diabetes.[47]

52. Estrogen can be given to young females for the same types of indications in males of either constitutional delay or hypogonadism, which could be either primary or secondary. Primary hypogonadism is caused by a defect in the presence or function of the ovaries. Secondary hypogonadism is caused by a defect in the structure or function of the pituitary gland. A female can experience premature ovarian insufficiency where the ovaries become inactive over time, both genetically and through environmental incidents. To diagnose these conditions, hormone levels can be objectively measured. This includes LH, FSH, estradiol, and

[47] Yang R, Yang S, Li R, Liu P, Qiao J, Zhang Y. Effects of hyperandrogenism on metabolic abnormalities in patients with polycystic ovary syndrome: a meta-analysis. Reprod Biol Endocrinol. 2016 Oct 18;14(1):67. doi: 10.1186/s12958-016-0203-8. PMID: 27756332; PMCID: PMC5069996

other levels. (Estradiol is a form of estrogen, and generally the main hormone followed and measured in female endocrinologic practice.) The physical response to the intervention can also be measured.

53. Estrogen treatments carry risks, including stroke, elevated blood pressure, and changes to bone development. Males are not generally prescribed estrogen (again, outside the context of gender dysphoria), and there is concern that the risks of estrogen are even higher in males.

Gender Dysphoria and Treatments

I. Diagnosis

54. In contrast to the conditions discussed above, gender dysphoria is not an endocrine disorder. Instead, it is a diagnostic term for "the distress that may accompany the incongruence between one's experienced or expressed gender and one's" biological sex.[48] Gender dysphoria is associated with high rates of comorbidity, including suicidal ideation, depression, anxiety, poverty, homelessness, eating disorders, and HIV infection.[49] Gender dysphoria as a psychiatric disorder should be distinguished from identifying as transgender and transsexual. As noted,

[48] APA, DSM-5, 451.
[49] M. D. Connolly et al., "The Mental Health of Transgender Youth: Advances in Understanding," J Adolesc Health 59, no. 5 (2016); Pinna F, et al. Italian Working Group on LGBTQI Mental Health. Mental health in transgender individuals: a systematic review. Int Rev Psychiatry.34(3-4):292-359 (2022).

people who identify as transgender "transiently or persistently identify with a gender different from their natal gender." Transsexual has an even more specific meaning; it "denotes an individual who seeks, or has undergone, a social transition from male to female or female to male, which in many, but not all, cases also involved a somatic transition by cross-sex hormone treatment and genital surgery."[50]

55. The clinical assessment methodology in sex discordant gender medicine is currently limited to self-reported information from patients without objective scientific markers or medical tests. There are no reliable radiological, genetic, physical, hormonal, or biomarker tests that can establish gender identity or reliably predict treatment outcomes.

56. The diagnosis of "gender dysphoria" encompasses a diverse array of conditions. While the contributors to sex discordant gender identity remain to be fully identified and characterized, differences both in kind and degree within individuals and across varied populations creates challenges in establishing specific approaches to alleviate associated suffering. For example, data from adults cannot be assumed to apply equally to children. Nor can data from children who present with sex discordant gender pre-pubertally be presumed to apply to the growing number of post-pubertal adolescent females presenting with this condition.

[50] APA, DSM-5, 451.

57. Assessment of gender dysphoria currently depends almost entirely upon unverified, self-reported evidence provided by patients. A patient's spoken or written reports of alleged "memories" of symptoms and behaviors are the only source of evidence for the diagnosis in many cases. This is a source of potentially profound unreliability in patient care as the relevant science documents that physicians are poor "lie detectors"—often no more reliable in discerning false reports than flipping a coin—and sometimes much worse. The relevant research also documents that even though humans (including therapists) are poor "lie detectors," many health professionals personally—and falsely—believe they are "experts" at this complex and difficult task.[51]

58. Although gender perceptions, feelings, and "identity" usually align with biological sex, some individuals report experiencing discordance in these distinct traits. Specifically, for example, biological females may report experiencing that they identify as males and biological males may report experiencing that they identify as females. As gender by definition is distinct from biological sex, one's gender identity does not change a person's biological sex. There is currently no

[51] See, e.g., Vrij, Aldert, Granhag, P. and Porter, S. (2010) Pitfalls and opportunities in nonverbal and verbal lie detection. Psychological Science In The Public Interest, 11 (3). pp. 89-121. ISSN 1529-1006 10.1177/1529100610390861.

known reliable and valid methodology for assessing the accuracy or nature of unverified, verbal reports of discordant "identity." There is thus no known "error rate" for relying upon such reports to engage in hormonal and surgical treatments.

II. Treatments

59. Moving from diagnosis to treatment, three approaches have been proposed for treating children with gender dysphoria.[52]

A. Reparative Therapy

60. The first approach, sometimes called "reparative therapy," is directed toward actively supporting and encouraging children to identify with their biological sex. Reparative therapy views sex/gender identity discordance as a pathologic condition. Accordingly, understanding and addressing factors that lead to this condition form the primary focus of reparative therapy, with an explicit goal of realigning one's gender identity with one's biological sex. Components of this approach have included play therapy for children and adolescents, counseling for patients and their families to help them understand and address underlying psycho-

[52] See Zucker, On the "natural history" of gender identity disorder in children, J. Am. Acad. Child Adolesc. Psychiatry 47, 1361-1363, doi:10.1097/CHI.0b013e31818960cf (2008).

logical dysfunction, and instruction on setting specific boundaries for behavior according to stereotypical gender norms.[53] Some have used the term conversion therapy to label efforts to realign gender identity with biological sex, but this ideologically loaded label has been used extensively in reference to same-sex attraction.[54]

B. Watchful Waiting

61. The second "neutral" or "watchful waiting" approach, motivated by understanding of the natural history of transgender identification in children, is to neither encourage nor discourage transgender identification, recognizing existing evidence (discussed next) showing that the vast majority of affected children if left alone are likely to eventually realign their reports of gender identification with their sex. This realignment of expressed gender identity to be concordant with sex is sometimes called "desistance."

62. The "watchful waiting" approach does not advocate doing nothing. Rather, it focuses on affirming the inherent dignity of affected people and supporting them in other aspects of their lives, including the diagnosis and treatment of any comorbidities, as individuals proceed through the various stages of physical and psychological development. For instance, the approach may include the use of

[53] Kenneth J. Zucker et al., "A Developmental, Biopsychosocial Model for the Treatment of Children with Gender Identity Disorder," Journal of Homosexuality 59, no. 3 (2012).
[54] D. C. Haldeman, "The Practice and Ethics of Sexual Orientation Conversion Therapy," J Consult Clin Psychol 62, no. 2 (1994)Kenneth J. Zucker, "Editorial: The Politics and Science of "Reparative Therapy"," Archives of Sexual Behavior 32, no. 5 (2003).

scientifically validated treatments (e.g., cognitive behavioral therapy) for the patient's anxiety, depression, social skills deficits, or other issues.[55]

63. Despite differences in country, culture, decade, follow-up length and method, multiple studies have come to a remarkably similar conclusion: Very few gender dysphoric children still want to transition by the time they reach adulthood. Many turn out to have been struggling with sexual orientation issues rather than gender discordant "transgender" identity. The exact number of children who experience realignment of gender identity with biological sex by early adult life varies by study. Estimates within the peer reviewed published literature range from 50-98%, with most reporting desistance in approximately 85% of children before the widespread adoption of the "affirming" model discussed below.[56] In 2018, for instance, studies found that 67% of children meeting the diagnostic criteria for gender dysphoria no longer had the diagnosis as adults, with an even higher rate (93%) of natural resolution of gender-related distress for the less significantly impacted

[55] See van Bentum et al., Cognitive therapy and interpersonal psychotherapy reduce suicidal ideation independent from their effect on depression, 38 Depression & Anxiety 940 (2021).
[56] T. D. Steensma et al., "Factors Associated with Desistence and Persistence of Childhood Gender Dysphoria: A Quantitative Follow-up Study," J Am Acad Child Adolesc Psychiatry 52, no. 6 (2013); K. D. Drummond et al., "A Follow-up Study of Girls with Gender Identity Disorder," Dev Psychol 44, no. 1 (2008); M. S. Wallien and P. T. Cohen-Kettenis, "Psychosexual Outcome of Gender-Dysphoric Children," J Am Acad Child Adolesc Psychiatry 47, no. 12 (2008); K. J. Zucker and S. J. Bradley, Gender Identity Disorder and Psychosexual Problem in Children and Adolescents (New York: Guilford Press., 1995).

cases.[57] A March 2021 study, with one of the largest samples in the relevant literature, suggests that most young gender dysphoric children grow out of the condition without medical interventions.[58] Thus, desistance (i.e., the child accepting their natal, biological sex identity and declining "transitioning" treatments) is the outcome for the vast majority of affected children who are not actively encouraged to proceed with sex-discordant gender affirmation.

64. Decades of peer-reviewed, published scientific research, including the pioneering work of Dr. Kenneth Zucker, have supported the efficacy of the psychological approaches for the majority of patients experiencing gender dysphoria.[59] Cognitive therapy and interpersonal psychotherapy have been found to reduce suicidal ideation independent of their effect on depression.[60] Within the "watchful

[57] See, e.g., Zucker, K. J. (2018). 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). International Journal of Transgenderism, 19(2), 231–245.
[58] See Devita Singh1, Susan J. Bradley 2 and Kenneth J. Zucker, Frontiers in Psychiatry, March 2021, Volume 12, Article 632784, www.frontiersin.org.
[59] See Zucker, K. J. On the "natural history" of gender identity disorder in children. J Am Acad Child Adolesc Psychiatry 47, 1361-1363, doi:10.1097/CHI.0b013e31818960cf (2008); Bradley, S. J. & Zucker, K. J. Gender Identity Disorder: A Review of the Past 10 YearsG. Journal of the American Academy of Child & Adolescent Psychiatry 36, 872-880, doi:10.1097/00004583-199707000-00008.).
[60] van Bentum JS et al. Cognitive therapy and interpersonal psychotherapy reduce suicidal ideation independent from their effect on depression. Depress Anxiety. 9:940-949 (2021). doi: 10.1002/da.23151.; Gallagher, M. W., Phillips, C. A., D'Souza, J., Richardson, A., Long, L. J., Boswell, J. F., Farchione, T. J., & Barlow, D. H. (2020). Trajectories of change in well-being during cognitive behavioral therapies for anxiety disorders: Quantifying the impact and covariation with improvements in anxiety. *Psychotherapy (Chicago, Ill.)*, *57*(3), 379–390. https://doi.org/10.1037/pst0000283.

waiting" model, these data support the investigative use of modern psychotherapeutic approaches to address suicidal ideation in children with gender dysphoria.

C. Gender Affirming

65. The third, so-called "gender affirming," approach is to affirm the child's present gender identity. This affirmation may have social, medical, legal, and behavioral dimensions. Typically, the "affirming" approach encourages children to embrace transgender identity with social transitioning followed by puberty blockage and hormonal therapy (cross-sex hormones), and potential surgical interventions.[61] This approach is considered below.

66. Before analyzing this course of treatment, it is important to understand that underlying biology is not changed by altering bodily features to appear as the opposite sex, and such alterations do not change disease vulnerabilities associated with genetically defined sex. 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 genetic makeup, normatively by his (XY) or her (XX) chromosomes, including cellular, anatomic, and physiologic characteristics and the particular disease vulnerabilities

[61] See Walch et al., Proper Care of Transgender and Gender Diverse Persons in the Setting of Proposed Discrimination: A Policy Perspective, J. Clin. Endocrinol Metab. 106(2):305-308. doi:10.1210/clinem/dgaa816 (2021).

associated with that chromosomally-defined sex.[62] 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. 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.[63] And their underlying biology does not change.

Puberty Blockers

67. Only in the 1990s did GnRH analogues begin being used to suppress puberty in children who identify as the opposite sex. In 1998, Peggy Cohen-Kettenis and Stephanie van Goozen, psychologists at a Dutch gender clinic, described the case of a 13-year-old female gender-dysphoria patient, on whom a GnRH analogue was used to suppress puberty before the patient received a definitive diagnosis of gender identity disorder at age 16. At age 18, the patient underwent sex-reassignment surgery.[64]

---

[62] See "Institute of Medicine (US) Committee on Understanding the Biology of Sex and Gender Differences. Exploring the Biological Contributions to Human Health: Does Sex Matter?" Wizemann TM, Pardue ML, editors. Washington (DC): National Academies Press (US); 2001. PMID: 25057540.

[63] See S. Levine (2018), Informed Consent for Transgendered Patients, J. of Sex & 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. Am. Acad Psychiatry Law 44, 236 at 238 ("Reflections").

[64] Cohen-Kettenis and van Goozen, "Pubertal delay as an aid in diagnosis and treatment of a transsexual adolescent," 246. See also Peggy T. Cohen-Kettenis, Thomas D. Steensma, and Annelou L.C. de Vries, "Treatment of Adolescents With Gender Dysphoria in the Netherlands," Child Adolescent Psychiatric Clinics of North America 20, (2011): 689–700, http://dx.doi.org/10.1016/j.chc.2011.08.001.

68. The clinic's scientists developed an influential protocol, often referred to as the "Dutch protocol," which involved puberty suppression followed by cross-sex hormones and potential surgical interventions. In many clinics that adhere to the gender affirmation model, the ages for initiating sex-discordant gender affirming sex steroid hormones has deviated substantially from the original Dutch protocol. The typical protocol is to initiate puberty blockers (GnRH analogs) as soon as puberty begins (Tanner stage 2) which can occur as early as 8 years in females and 9 years in males. While in the Dutch protocol, cross-sex hormones are started at 16 years, many programs in the United States offer these hormones earlier to coincide with the start of normal pubertal development in males (13-14 years) and females (12-13 years). Gender-affirming surgery in the Dutch model was reserved to patients 18 years or older. Again, programs in the United States have advocated for individualization of decisions on ages for surgery in minors. GnRH analogs are discontinued after gonadectomy is performed as this medication is no longer needed to suppress gonads that are no longer present. Due to the suppressive effect of exogenous sex-steroids on gonadal function, GnRH analogs are often stopped after gender affirming hormone administration has been titrated to maximal doses required to achieve the desired change in secondary sex characteristics.

69. This gender "affirming" model would make gender dysphoria unique: it would be "the only psychiatric condition to be treated by surgery, even though

no endocrine or surgical intervention package corrects any identified biological abnormality."[65]

70. These scientists, along with others, have claimed that puberty suppression is "fully reversible."[66] On this view, puberty suppression "give[s] adolescents, together with the attending health professional, more time to explore their gender identity, without the distress of the developing secondary sex characteristics. The precision of the diagnosis may thus be improved."[67]

71. This claim appears to presume that natural sex characteristics interfere with the "exploration" of gender identity, when one would expect that the development of natural sex characteristics might contribute to the natural consolidation of one's gender identity. It is based upon an untested scientific premise that interfering with the development of natural sex characteristics can allow for a more accurate diagnosis of the gender identity of the child. It seems equally plausible that the interference with normal pubertal development will influence the gender identity

[65] 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"), at 240.
[66] Henriette A. Delemarre-van de Waal and Peggy T. Cohen-Kettenis, "Clinical management of gender identity disorder in adolescents: a protocol on psychological and paediatric endocrinology aspects," European Journal of Endocrinology 155 (2006): S133, http://dx.doi.org/10.1530/eje.1.02231.
[67] Peggy T. Cohen-Kettenis, Henriette A. Delemarre-van de Waal, and Louis J.G. Gooren, "The Treatment of Adolescent Transsexuals: Changing Insights," Journal of Sexual Medicine 5, no. 8 (2008): 1894, http://dx.doi.org/10.1111/j.1743-6109.2008.00870.x.

of the child by reducing the prospects for developing a gender identity corresponding to his or her biological sex.

72. Given their potential importance in the lives of the affected children, claims about reversibility are worth careful examination. In developmental biology, it makes little sense to describe anything as "reversible." If a child does not develop certain characteristics at age 12 because of a medical intervention, then his or her developing those characteristics at age 18 is not a "reversal," since the sequence of development has already been disrupted. This is especially important since there is a complex relationship between physiological and psychosocial development during adolescence. Gender identity is shaped during puberty and adolescence as young people's bodies become more sexually differentiated and mature. Given how little we understand about gender identity and how it is formed and consolidated, we should be cautious about interfering with the normal process of sexual maturation.

73. A more relevant question is whether the physiological and psychosocial development that occurs during puberty can resume in something resembling a normal way after puberty-suppressing treatments are withdrawn. In children with precocious puberty, this does appear to be the case. Puberty-suppressing hormones are typically withdrawn around the average age for the normal onset of gonadarche, at about age 12, and normal hormone levels and pubertal development

gradually resume. For one common method of treating precocious puberty, girls reached menarche approximately a year after their hormone treatments ended, at an average age of approximately 13, essentially the same average age as the general population.[68] The evidence for the safety and efficacy of puberty suppression in boys is less robust, chiefly since precocious puberty is much rarer in boys. Although the risks are speculative and based on limited evidence, boys who undergo puberty suppression may be at greater risk for the development of testicular microcalcifications, which may be associated with an increased risk of testicular cancer, and puberty suppression in boys may also be associated with obesity.[69]

74. Unlike children affected by precocious puberty, adolescents with gender dysphoria do not have any physiological disorders of puberty that are being corrected by the puberty-suppressing drugs. The fact that children with suppressed precocious puberty between ages 8 and 12 resume puberty at age 13 does not mean that adolescents suffering from gender dysphoria whose puberty is suppressed beginning at age 12 will simply resume normal pubertal development down the road if they choose to withdraw from the puberty-suppressing treatment and choose not

[68] Marisa M. Fisher, Deborah Lemay, and Erica A. Eugster, "Resumption of Puberty in Girls and Boys Following Removal of the Histrelin Implant," The Journal of Pediatrics 164, no. 4 (2014): 3, http://dx.doi.org/10.1016/j.jpeds.2013.12.009.

[69] Silvano Bertelloni and Dick Mul, "Treatment of central precocious puberty by GnRH analogs: long-term outcome in men," Asian Journal of Andrology 10, no. 4 (2008): 531, http://dx.doi.org/10.1111/j.1745-7262.2008.00409.x.

to undergo other sex-reassignment procedures. Interrupting puberty in this manner may have significant effects on final stature and bone density.[70]

75. After an extended period of pubertal suppression one cannot "turn back the clock" and reverse changes in the normal coordinated pattern of adolescent psychological development and puberty.[71] Once puberty is blocked, even if eventually unblocked (and assuming signaling from the pituitary gland resumes), the person cannot "buy back" the time when the physical process of puberty has been disrupted at the time when it would normally occur with complementary psychological processes in that stage in the person's life.

76. A possible effect of blocking normally timed puberty is alteration of normal adolescent brain maturation.[72]

---

[70] Joseph T, Ting J, Butler G. The effect of GnRH analogue treatment on bone mineral density in young adolescents with gender dysphoria: findings from a large national cohort. J Pediatr Endocrinol Metab. 32(10):1077-1081 (2019); Klink, D., Caris, M., Heijboer, A., van Trotsenburg, M. & Rotteveel, J. Bone Mass in Young Adulthood Following Gonadotropin-Releasing Hormone Analog Treatment and Cross-Sex Hormone Treatment in Adolescents With Gender Dysphoria. The Journal of Clinical Endocrinology & Metabolism 100, E270-E275, doi:10.1210/jc.2014-2439 (2015).

[71] See Hruz, Mayer, and McHugh, "Growing Pains, The New Atlantis: A Journal of Technology and Society, Spring 2017, pg 3-36; see also Vijayakumar N, Op de Macks Z, Shirtcliff EA, Pfeifer JH. Puberty and the human brain: Insights into adolescent development. Neurosci Biobehav Rev. 2018 Sep;92:417-436. doi: 10.1016/j.neubiorev.2018.06.004. Epub 2018 Jul 1. PMID: 29972766; PMCID: PMC6234123; see also Choudhury S, Culturing the adolescent brain: what can neuroscience learn from anthropology?, *Social Cognitive and Affective Neuroscience*, Volume 5, Issue 2-3, June/September 2010, Pages 159–167, https://doi.org/10.1093/scan/nsp030.

[72] See Arain, M., Haque, M., Johal, L., Mathur, P., Nel, W., Rais, A., Sandhu, R., & Sharma, S. (2013). Maturation of the adolescent brain. *Neuropsychiatric disease and treatment*, *9*, 449–461. https://doi.org/10.2147/NDT.S39776.

77. Another troubling question that has been largely uninvestigated is what psychological consequences there might be for children with gender dysphoria whose puberty has been suppressed and who later come to identify as their biological sex.

78. In addition to the reasons to suspect that puberty suppression may have side effects on physiological, psychological, and brain development, the evidence that something like normal puberty will resume for these patients after puberty-suppressing drugs are removed is very weak.

Cross-Sex Hormones

79. Rather than resuming biologically normal puberty, adolescents treated on the "affirming" model overwhelmingly go from suppressed puberty to medically conditioned cross-sex puberty, when they are administered cross-sex hormones. Specifically, exogenous estrogen is administered to biological men to induce gynecomastia (i.e., the enlargement of breast tissues), and testosterone is administered to biological women to induce virilization (i.e., the development of facial hair and other desired male features) and to interfere with normal ovarian function. Nearly all of the children that have been studied that have received puberty blockers go on to cross-sex hormones.[73]

[73] https://www.thelancet.com/journals/lanchi/article/PIIS2352-4642(22)00254-1/fulltext

80. Along with (and often before) estrogen is administered to biological males in this treatment, spironolactone may be used as an androgen blocker. Spironolactone is primarily used for the treatment of blood pressure and heart failure. It is a mineralocorticoid antagonist. But it also has effects in blocking the action of androgens. As discussed, androgens are masculinizing hormones that lead to virilization. Testosterone is a prime androgen, but other androgens are also made in the gonads and adrenal gland. Spironolactone is sometimes used in the treatment of polycystic ovarian syndrome, in which females will undergo virilization due to excess androgen production in the ovaries. This syndrome can have adverse effects on fertility, metabolic health, and cardiovascular health.[74] The diagnosis of polycystic ovarian syndrome is a clinical diagnosis based upon the physical evidence of virilization or androgen effects, insulin resistance, and irregular periods. There are objective biological measures to assess those androgen levels, most notably elevated free testosterone levels. And there are objective measures of dysregulation of relevant signals from the pituitary gland, the LH and the FSH, to complement the clinical diagnosis by looking at the degree of virilization that is present in the patient.

[74] Hunter MH, Sterrett JJ. Polycystic ovary syndrome: it's not just infertility. Am Fam Physician. 2000 Sep 1;62(5):1079-88, 1090

81. Spironolactone would not be prescribed to male patients for an endocrinologic purpose related to androgen production. Once again, this reflects a fundamental biological difference between males and females. Though spironolactone can be used to regulate the levels of potassium and sodium in the body, such treatment would be based on objective markers of those levels.

82. Likewise, the administration of the sex steroid hormones differ by the sex of the individual. It is not identical to give testosterone to a male as it is to give it to a female, nor is it the same treatment to give estrogen to a male versus female. This difference has an established scientific basis. The differences between males and females occurs in every nucleated cell of the body, for males and females have different genetic programming. This is a process known as epigenetics, meaning that there are modifications of the DNA itself that alter the expression of genes when exposed to the same stimulus. There are over 6,000 sex-differentially expressed genes. So, if one gives testosterone to a male, the physiologic effects of that treatment, even in the measurement at which genes are turned on and turned off, will be different than if one gives testosterone to a female.[75]

83. When a patient with gender dysphoria is placed on cross-sex hormones, per the Dutch protocol, puberty-suppressing GnRH analogues continue to

[75] Gershoni M, Pietrokovski S. The landscape of sex-differential transcriptome and its consequent selection in human adults. BMC Biol. 2017 Feb 7;15(1):7

be administered until exogenous administration of cross-sex hormones (i.e. sex hormones normally produced the gonads of the opposite sex) leads to sufficient suppression of endogenous sex hormone production or the gonads are surgically removed. Sex hormones that are normally secreted by the maturing gonads are not produced. This means that adolescents undergoing cross-sex hormone treatment circumvent the most fundamental form of sexual maturation—the maturation of their reproductive organs.

84. Patients undergoing gender affirming surgery discontinue GnRH treatment after having their gonads removed, since the secretion of sex hormones that the treatment is ultimately intended to prevent will no longer be possible. These patients are then sterile, as loss or alteration of primary sexual organs leads directly to impairment of reproductive potential.

85. Although the long-term effect of exposing immature gonads to cross-sex hormones is currently unknown, it is generally accepted, even by advocates of transgender hormone therapy, that hormonal treatment impairs fertility, which may be irreversible.[76] Specifically, estrogen administration to males who identify as women results in impaired spermatogenesis and an absence of Leydig cells in the

[76] See Nahata, L., Tishelman, A. C., Caltabellotta, N. M. & Quinn, G. P. Low Fertility Preservation Utilization Among Transgender Youth. Journal of Adolescent Health 61, 40-44, doi:https://doi.org/10.1016/j.jadohealth.2016.12.012 (2017).

testis.[77] Exogenous testosterone administration to females who identify as men causes ovarian stromal hyperplasia and follicular atresia.[78] Recognition of these consequences is the basis for the development of new arenas of medical practice where there is an attempt to restore fertility that has been intentionally destroyed.[79]

86. Gametes (sperm and ova) require natural puberty to mature to the point that they are viable for reproduction.[80] While it is expected that the exposure of immature gonads to cross-sex hormones will lead to infertility, whether affected individuals have permanent sterility has not been established. Much of the uncertainty arises from the novelty of this intervention and the lack of long term follow up. There are limited reports of successful pregnancies after cross-sex hormones, but all of the subjects started gender affirming hormones as adults after completing

[77] Schulze C. Response of the human testis to long-term estrogen treatment: Morphology of Sertoli cells, Leydig cells and spermatogonial stem cells. Cell Tissue Res 251:31e43 (1988)..
[78] [2] Pache TD, Chadha S, Gooren LJ, et al. Ovarian morphology in long-term androgen-treated female to male transsexuals. A human model for the study of polycystic ovarian syndrome? Histopathology 19: 445e52 (1991); Ikeda K, Baba T, Noguchi H, et al. Excessive androgen exposure in female-to-male transsexual persons of reproductive age induces hyperplasia of the ovarian cortex and stroma but not polycystic ovary morphology. Hum Reprod 28:453e61 (2013).
[79] See, e.g., Ainsworth AJ, Allyse M, Khan Z. Fertility Preservation for Transgender Individuals: A Review. Mayo Clin Proc. 2020 Apr; 95(4):784-792. doi: 10.1016/j.mayocp.2019.10.040. Epub 2020 Feb 27. PMID: 32115195.
[80] Howard E. Kulin, et al., "The Onset of Sperm Production in Pubertal Boys. Relationship to Gonadotropin Excretion," American Journal of Diseases in Children 143(2), 190-193 (1989).

puberty.[81] I am not aware of any reports that show this for children who were exposed to puberty blockers before completing puberty followed by cross-sex hormones.

87. There are many other known risks to puberty suppression followed by cross-sex hormones beyond fertility concerns. As noted, emerging data show that treated patients have lower bone density, which may lead to increased fracture risk later in life.[82] Other potential adverse effects include disfiguring acne, high blood pressure, weight gain, abnormal glucose tolerance, breast cancer, liver disease, thrombosis, and cardiovascular disease.[83] In addition, non-physiological levels of

[81] de Nie I, van Mello NM, Vlahakis E, Cooper C, Peri A, den Heijer M, Meißner A, Huirne J, Pang KC. Successful restoration of spermatogenesis following gender-affirming hormone therapy in transgender women. Cell Rep Med. 2023 Jan 17;4(1):100858. doi: 10.1016/j.xcrm.2022.100858.

[82] See Klink, D., Caris, M., Heijboer, A., van Trotsenburg, M. & Rotteveel, J. Bone Mass in Young Adulthood Following Gonadotropin-Releasing Hormone Analog Treatment and Cross-Sex Hormone Treatment in Adolescents With Gender Dysphoria. The Journal of Clinical Endocrinology & Metabolism 100, E270-E275, doi:10.1210/jc.2014-2439 (2015).

[83] See Seal, L. J. A review of the physical and metabolic effects of cross-sex hormonal therapy in the treatment of gender dysphoria. Annals of Clinical Biochemistry 53, 10-20, doi:10.1177/0004563215587763 (2016); Banks, K., Kyinn, M., Leemaqz, S. Y., Sarkodie, E., Goldstein, D., & Irwig, M. S. (2021). See also, Blood Pressure Effects of Gender-Affirming Hormone Therapy in Transgender and Gender-Diverse Adults. *Hypertension (Dallas, Tex.: 1979)*, HYPERTENSIONAHA12016839. Advance online publication. https://doi.org/10.1161/HYPERTENSIONAHA.120.16839; Getahun, D., Nash, R., Flanders, W. D., Baird, T. C., Becerra-Culqui, T. A., Cromwell, L., Hunkeler, E., Lash, T. L., Millman, A., Quinn, V. P., Robinson, B., Roblin, D., Silverberg, M. J., Safer, J., Slovis, J., Tangpricha, V., & Goodman, M. (2018). Cross-sex Hormones and Acute Cardiovascular Events in Transgender Persons: A Cohort Study. *Annals of internal medicine*, *169*(4), 205–213. https://doi.org/10.7326/M17-2785; Spyridoula Maraka, Naykky Singh Ospina, Rene Rodriguez-Gutierrez, Caroline J Davidge-Pitts, Todd B Nippoldt, Larry J Prokop, M Hassan Murad, Sex Steroids and Cardiovascular Outcomes in Transgender Individuals: A Systematic Review and Meta-Analysis, *The Journal of Clinical Endocrinology & Metabolism*, Volume 102, Issue 11, 1 November 2017, Pages 3914–3923, https://doi.org/10.1210/jc.2017-01643.

estrogen in males has been shown to increase the risk of thromboembolic stroke above the incidence observed in females.[84]

Endocrine Society and WPATH Guidelines

88. A reasonable understanding of relative risk versus benefit for medical products or procedures is a fundamental obligation in providing appropriate clinical care. This is the bedrock standard of "evidence based medical practice." When considering clinical practice guidelines, it is essential that physicians recognize the relative risks and benefits of such documents. If done properly, they can distill large data sets into actionable clinical recommendations. However, there is a long history of clinical practice guidelines that have later been found to be deficient, resulting in wasted medical resources, have failed to achieve desired benefits, or have caused substantial harm to patients.[85]

89. As detailed throughout this report, this foundational standard of "evidence based medical practice" has never been met as to so-called gender affirming care. The field of "affirming care" is characterized by a poor quality of evidence

[84] E.g. Getahun, D., Nash, R., Flanders, W. D., Baird, T. C., Becerra-Culqui, T. A., Cromwell, L., Hunkeler, E., Lash, T. L., Millman, A., Quinn, V. P., Robinson, B., Roblin, D., Silverberg, M. J., Safer, J., Slovis, J., Tangpricha, V., & Goodman, M. (2018). Cross-sex Hormones and Acute Cardiovascular Events in Transgender Persons: A Cohort Study. Annals of internal medicine, 169(4), 205–213. https://doi.org/10.7326/M17-2785.

[85] See Woolf et al., Clinical guidelines: potential benefits, limitations, and harms of clinical guidelines. *BMJ (Clinical research ed.)*, 318(7182), 527–530, https://doi.org/10.1136/bmj.318.7182.527 (1999).

regarding safety and efficacy, as well as attempts to silence standard scientific discussion and consideration of alternative hypotheses, failures to acknowledge existing data showing persistence of suicidality after intervening, the intentional impairment and destruction of normally formed and functioning male and female sexual organs to address psychological-psychiatric distress, the manipulation of language from standard medical definitions, and widespread failures to properly report research data related to gender transitioning.

90. Because of ideological and political pressure, health providers in many fields are now not permitted to openly asks questions, properly investigate alternative diagnoses, or explore alternative hypotheses for the symptoms of gender dysphoric patients.[86] Providers are instead compelled (sometimes under fear of employment termination or legal attacks) to adopt a patient's self-diagnosis and only support "affirming" medical interventions. These providers are thus being pressured and/or compelled to commit the scientific and medical malpractice of confirmation bias—one of the most serious of all methodological diagnostic failures. As one paper explained, "physicians' desire to confirm a preliminary diagno-

[86] See https://store.samhsa.gov/sites/default/files/d7/priv/sma15-4928.pdf and https://williamsinstitute.law.ucla.edu/publications/conversion-therapy-and-lgbt-youth/

sis while failing to seek contradictory evidence" appears to be "an important reason for wrong diagnoses."[87] Such "[d]iagnostic errors can have tremendous consequences because they can result in a fatal chain of wrong decisions."[88]

91. Despite the dangers of confirmation basis, existing guidelines base recommendations for "affirming" medical interventions on uncorroborated patient self-reports, assessed by mental health professionals with no methodology for discerning true from false patient reports, with no ability to decipher accurate from contaminated "memories," with no alternative treatments offered, and no alternative explanations (e.g., social contagion) explored. Clinicians tasked with providing GnRH analogs to suppress normally timed puberty and gender affirming cross-sex hormones to induce secondary sexual characteristics coinciding with a sex-discordant gender identity rely upon subjective criteria to establish a diagnosis of sex-gender incongruence. There is no biological test to verify the diagnosis.

[87] Mendel et. al., Confirmation bias: why psychiatrists stick to wrong preliminary diagnoses, Psychological Medicine, Oxford University Press (2011).
[88] *Id.*; see also Doherty et al., Believing in Overcoming Cognitive Biases, American Medical Association Journal of Ethics 22(9):E773-778 (2020) ("Confirmation bias is the selective gathering and interpretation of evidence consistent with current beliefs and the neglect of evidence that contradicts them."); Hershberger et al., Teaching awareness of cognitive bias in medical decision making. *Acad Med*. 70(8):661 (1995).

I. Endocrine Society

92. In 2009, the Endocrine Society published clinical guidelines for the treatment of patients with persistent gender dysphoria.[89] The recommendations include temporary suppression of pubertal development of children with GnRH agonists followed by hormonal treatments to induce the development of secondary sexual traits consistent with one's gender identity. In developing these guidelines, the authors assessed the quality of evidence supporting the recommendations made with use of the GRADE (Grading of Recommendations, Assessment, Development, and Evaluation) system for rating clinical guidelines. As stated in the Endocrine Society publication, "the strength of recommendations and the quality of evidence was low or very low." According to the GRADE system, low recommendations indicate that "[f]urther research is very likely to have an important impact on our confidence in the estimate of effect and is likely to change the estimate." Very low recommendations mean that **"**any estimate of effect is very uncertain."[90]

[89] See Hembree et al., Endocrine treatment of transsexual persons: an Endocrine Society clinical practice guideline, *The Journal of clinical endocrinology and metabolism*, *94*(9), 3132–3154, https://doi.org/10.1210/jc.2009-0345 (2009).
[90] Guyatt et al., GRADE: an emerging consensus on rating quality of evidence and strength of recommendations, BMJ; 336:924 doi:10.1136/bmj.39489.470347 (2008).

93. The Endocrine Society published an updated set of guidelines in September 2017.[91] Those guidelines show that all recommendations as to "affirming" treatment of adolescents are supported by low or very low quality evidence.

94. It is highly misleading to imply that the current Endocrine Society guidelines represent the opinions of the Society's 18,000 members. The committee that drafted these guidelines was composed of *less than a dozen* members. The guidelines were never submitted to the entire Endocrine Society membership for comment and approval prior to publication. They also did not undergo external review. Such methodologies are common in association "statements" and "endorsement"; they are not scientific or generally reliable.

95. The panel that drafted the Endocrine Society guidelines was heavily composed of individuals who have significant associations with WPATH. Specifically, all but one of the committee members were leaders in WPATH. Two of the authors served as WPATH's president (Walter J. Meyer and Vin Tangpricha); at least four have served, or are serving, on WPATH's Board of Directors (Peggy Cohen-Kettenis, Louis Gorren, Stephen Rosenthal, Guy T'Sjoen); and at least four (Stephen Rosenthal, Joshua Safer, Vin Tangpricha, and Guy T'Sjoen) were authors

[91] See Hembree et al., Endocrine Treatment of Gender-Dysphoric/Gender-Incongruent Persons: An Endocrine Society Clinical Practice Guideline, *The Journal of clinical endocrinology and metabolism*, *102*(11), 3869–3903, https://doi.org/10.1210/jc.2017-01658 (2017).

of WPATH SOC 8. Three (Peggy Cohen-Kettenis, Walter Meyer, and Vin Tangpricha) were authors of WPATH SOC 7.

II. WPATH

96. The World Professional Association for Transgender Health (WPATH) has also issued several iterations of guidelines. The first set of clinical practice guidelines was published in 1979. WPATH published its latest version of their "Standards of Care for the Health of Transgender and Gender Diverse People" (SOC 8) in September of 2022. [92] While this document has been presented as "authoritative" and "evidenced based", numerous concerns have been raised about the updated recommendations. This includes removal of age limits for initiation of cross sex hormones and gender affirming surgery, recommendations for excluding parents in the decision making process if they question or challenge medical interventions, elimination of safeguards for addressing underlying mental health illness before the start of gender affirming medical interventions, and the addition of a section on "eunuch-identified" people. [93] Many of the recommendations made reflect WPATH's acknowledged agenda as an advocacy group. In SOC8 they specifically state "Health is promoted through public policies and legal reforms that ad-

[92] ibid
[93] Coleman et al, Standards of Care for the Health of Transgender and Gender Diverse People, Version 8. Int J Transgend Health. 2022 Sep 6;23(Suppl 1):S1-S259. doi: 10.1080/26895269.2022.2100644..

vance tolerance and equity for gender diversity and that eliminate prejudice, discrimination, and stigma. WPATH is committed to advocacy for these policy." Despite the claim that the SOC8 guidelines are based upon solid scientific evidence, such recommendations represent ideological positions devoid of rigorous scientific evidence. Scientific data on long-term outcomes in adolescents who are exposed to the U.S. affirmation model simply do not exist.

97. In sum, clinical guidelines or standards of care should provide practitioners with evidence-based standards by which they may reliably inform the patient of projected outcomes, and do so with a known error rate. Such data is the starting point for obtaining informed consent. This information is not provided by either WPATH or Endocrine Society's guidelines.

Informed Consent

98. The fundamental purpose of the practice of medicine is to treat disease and alleviate suffering. An essential tenet of medical practice is to avoid doing harm in the process. As discussed above, relying on clear, valid, reliable, and definitive evidence on how to best accomplish treatment goals is the essential ethical, professional, scientific, and clinical goals of physicians. Using "affirming"

treatments on minors violates this essential principle by using experimental treatments on vulnerable populations without properly informing them of the actual risks and limitations of the treatments.[94]

99. It is now universally agreed that medical and psychotherapy patients have a right to proper informed consent. Professional ethics codes, licensing rules and regulations, hospital rules and regulations, state and federal laws, and biomedical conventions and declarations all protect patients' right to informed consent discussions of the risks and benefits of proposed treatments and alternative treatments including no treatment.[95]

100. Essential requirements for informed consent include the ability of the patient or study subject to understand the proposed procedure, full disclosure of known and potential risks and benefits, discussion of alternative treatments, and freedom to act voluntarily. This information is presented verbally and in written form with allowance of sufficient time for the patient to ask questions and for the provider to assess adequate comprehension by the patient. It is well recognized that

[94] See Jonson et al., Clinical Ethics, New York: McGraw Hill (1998).
[95] See Jonson AR, Siegler M, Winslade, WJ: Clinical Ethics, New York: McGraw Hill, 1998, ("Informed consent is defined as the willing acceptance of a medical intervention by a patient after adequate disclosure by the physician of the nature of the intervention, its risks, and benefits, as well as of alternatives with their risks and benefits.") See also Katz, A., Webb, S., and Committee on Bioethics, Informed Consent in Decision-Making in Pediatric Practice, Pediatrics, August 2016, 138 (2) e20161485; DOI: https://doi.org/10.1542/peds.2016-1485 at https://pediatrics.aappublications.org/content/138/2/e20161485.

the signing of a formal consent form does not guarantee that informed consent has been obtained.

101. Several aspects of the care of individuals with gender dysphoria may substantially interfere with proper application of these foundational principles.[96] For adolescent children seeking medical gender affirmation medical, well established limitations in decision making ability raise serious concerns about their ability to consent to hormonals and surgical interventions. Adolescents have a known tendency to engage in risky behaviors, exercise poor impulse control, and show frequent failure to appreciate long-term consequences of current choices.[97]

102. For example, the ability of a child to understand implications for future fertility while still developmentally immature can pose a significant barrier to meeting the criterion of appreciating decision consequence. Children are often unlikely to be capable of giving truly informed consent, particularly when it comes to hormonal or surgical treatments that will result in lifelong sterility.[98] Adolescents' inability to adequately weigh potential short-term benefits against long-term risks

[96] Paul S. Appelbaum and Thomas Grisso, "Assessing Patients' Capacities to Consent to Treatment," New England Journal of Medicine 319, no. 25 (1988).
[97] Sarah-Jayne Blakemore and Trevor W. Robbins, "Decision-Making in the Adolescent Brain," *Nature Neuroscience* 15 (2012); Neuroscientists have found that the adolescent brain is too immature to make reliably rational decisions. B.J. Casey, Rebecca M. Jones, and Todd A. Hare, "The Adolescent Brain," Annals of the New York Academy of Sciences 1124 (2008): 111, http://dx.doi.org/10.1196/annals.1440.010.
[98] See Geier, Adolescent cognitive control and reward processing: Implications for risk taking and substance use, Hormones and Behavior 64, 333-342, doi:https://doi.org/10.1016/j.yhbeh.2013.02.008 (2013).

seems supported by the observation that few adolescents express concern over loss of fertility even when directly told of the potential sterilizing effect of medical intervention.[99]

103. Similarly, individuals with transgender identity who also have clinical depression or other serious psychiatric comorbidity may have limited capacity to objectively weight proposed clinical interventions with potentially irreversible consequences and would therefore fail to meet psychological abilities criteria.[100]

104. In addition, a study subject's underlying belief that he or she was born in the wrong body is the primary reason for seeking medical intervention. Thus any challenge to this underlying premise is seen as a threat to the affected individual. Under such conditions, an individual will find it difficult, if not impossible, to give truly informed consent.

105. A model relying on parental consent with child assenting to affirmative medical interventions does not remove concerns about the difficulty in obtaining truly informed consent. Since many of the long-term outcomes of gender affirming interventions are unknown, prospective patients are being asked to consent

[99] Leena Nahata et al., "Low Fertility Preservation Utilization among Transgender Youth," Journal of Adolescent Health 61, no. 1 (2017).
[100] H. Helmchen, "Ethics of Clinical Research with Mentally Ill Persons," Eur Arch Psychiatry Clin Neurosci 262, no. 5 (2012).

without sufficient knowledge of inherent risk versus benefit. Without understanding that nearly all adolescents who are put on puberty blockers will proceed to gender affirming hormones, with many subsequently opting for gender affirming surgeries, focus on gaining consent for this first stage of the affirmative model is difficult if not impossible.

106. Parents are often told by gender affirmation activists or providers that the failure to allow a gender dysphoric child to medically transition will result in suicide. These "threats" ignore data that challenge this biased assumption.[101]

107. While any cases of suicide are of utmost concern, suicide rates in children with sex-discordant gender identity must be put in context of overall suicidality in the pediatric population independent of gender dysphoria. When considered in this context, the rates of suicidal ideation and attempt in transgender adolescents are similar to those found in adolescents without gender dysphoria who present for psychological care (ref). Furthermore, it is necessary to critically assess, with rigorous scientific data, whether gender affirming medical interventions succeed in preventing suicides. While long-term data are not available for pediatric patients,

[101] See D'Angelo et al., One Size Does Not Fit All: In Support of Psychotherapy for Gender Dysphoria, *Arch Sex Behav* 50**,** 7–16, https://doi.org/10.1007/s10508-020-01844-2 (2021).

the adult literature consistently reports continued elevated suicidality after undergoing gender affirming medical interventions.[102]

108. Researchers have noted that in the "affirming" context, "the informed consent process rarely adequately discloses" either "the uncertain permanence of a child's or an adolescent's gender identity" or "the uncertain long-term physical and psychological health outcomes of gender transition."[103] Levine et al. recently noted the following major deficiencies in the informed consent process under existing "affirming" guidelines and approaches:

- "High rate of desistance/natural resolution of gender dysphoria in children is not disclosed";
- "Implications of very low-quality evidence that underlies the practice of pediatric gender transition are not explained"; and,
- "The question of suicide is inappropriately handled".[104]

As discussed above, the informed consent process for "affirming" treatments is further "limited by" "erroneous professional assumptions" and "poor quality of the initial evaluations."[105]

---

[102] Adams N, Hitomi M, Moody C. Varied Reports of Adult Transgender Suicidality: Synthesizing and Describing the Peer-Reviewed and Gray Literature. Transgend Health. 2017 Apr 1;2(1):60-75. doi: 10.1089/trgh.2016.0036; Dhejne, C. et al. Long-term follow-up of transsexual persons undergoing sex reassignment surgery: cohort study in Sweden. PLoS One 6, e16885, doi:10.1371/journal.pone.0016885 (2011).
[103] Levine et al., Reconsidering Informed Consent for Trans-Identified Children, Adolescents, and Young Adults, *Journal of sex & marital therapy*, 1–22, https://doi.org/10.1080/0092623X.2022.2046221 (2022).
[104] *Id.*
[105] *Id.*

109. Using experimental procedures on uninformed, vulnerable patients is unethical and improper. Some of the most tragic chapters in the history of medicine include violations of informed consent and improper experimentation on patients using methods and procedures that have not been tested and validated by methodologically sound science—such is the case with the gender transition industry. The infamous Tuskegee studies, Nazi and Imperial Japanese wartime experiments, lobotomies (e.g., Dr. Egas Moniz received the 1949 Nobel Prize in Medicine for inventing lobotomies as a "treatment" for schizophrenia[106]), recovered memory therapy-multiple personality disorders, rebirthing therapy,[107] coercive holding therapy,[108] and other tragic examples should serve as a stark warning to medical providers to properly protect the rights of patients and their families to a proper informed consent process and to not be subjected to experimental, unproven interventions.

Existing Literature and Its Limitations

110. Before turning to the existing literature on gender dysphoria and its treatments, it is important to understand the varying types of studies conducted in this and other medical fields, as well as the general approach to scientific testing.

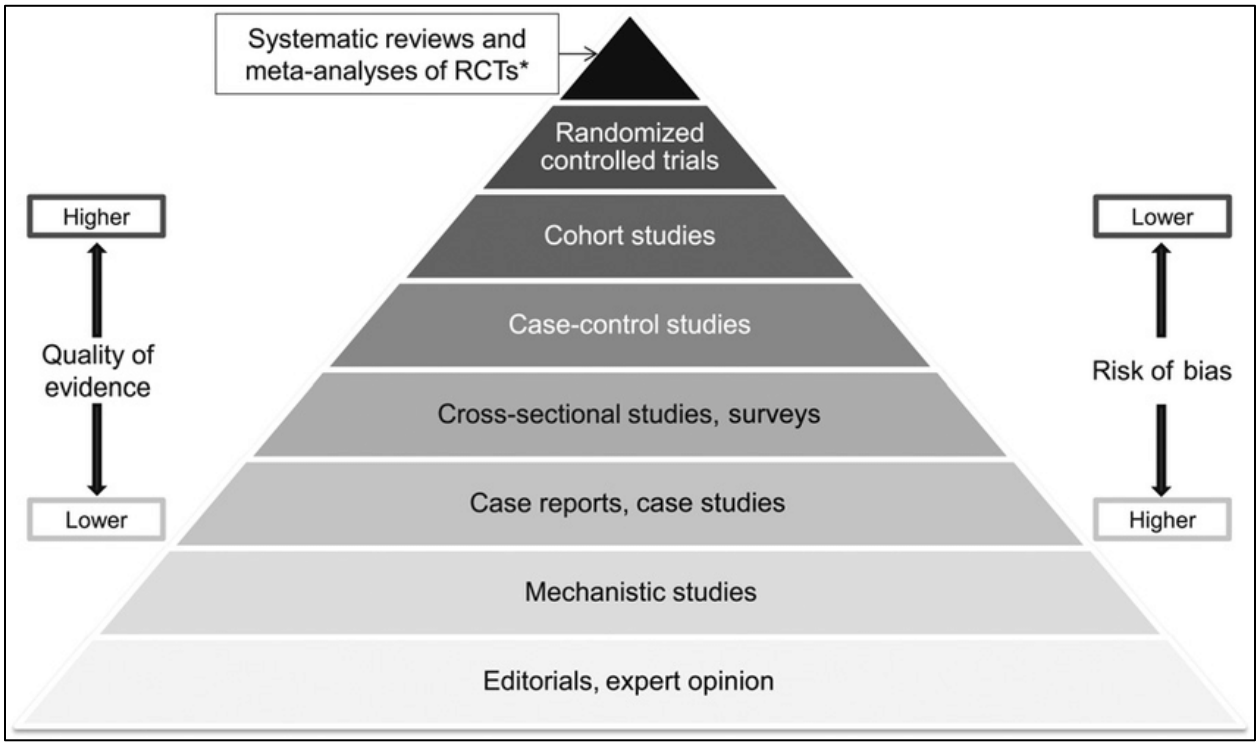
---

[106] See https://www.nobelprize.org/prizes/medicine/1949/moniz/article.
[107] See, e.g., Janofsky, M. Girl's Death Brings Ban on Kind of 'Therapy'. New York Times. April 18, 2001; see also Peggy Lowe, Rebirthing team convicted: Two therapists face mandatory terms of 16 to 48 years in jail, Rocky Mountain News, April 21, 2001.
[108] See, Hyde, J. "Holding therapy appears finished, State orders the last practitioner of holding therapy to end controversial method" Deseret News, Feb 13, 2005.

Appropriate testing of medical and other scientific hypothesis requires proper study design. First, the research formulates a hypothesis as to whether there is a difference—a cause and effect relationship—from the studied intervention. The study starts by assuming the "null hypothesis"—there is no difference—and then one looks for evidence sufficient to disprove the null hypothesis. When conducting the study, statistical significance is of central importance, for it states the likelihood that the observation would exist if the null hypothesis were true. Only if there is a very small likelihood that the null hypothesis is true is it generally appropriate to treat a study as providing evidence that the null hypothesis is, in fact, false. Accordingly, if a study finding does not reach statistical significance, it would be improper to use the finding as a rejection of the null hypothesis.

111. Case reports or experts' opinions are recognized as the lowest level of evidence. Those are based upon general experiences, not scientific testing. They can be useful for generating a novel hypotheses, which can then be tested through experimental testing to establish if there are cause/effect relationships. Next up on the pyramid of quality of evidence would be, for example, cross-sectional studies that are done where one looks at a condition at one point in time. One can merely infer associations from these types of studies. Randomized longitudinal studies can permit, to some extent, the elimination of unrecognized variables that may distort the results. The highest part of the evidence-based pyramid (for individual studies)

is randomized controlled trials, in which the investigator attempts to control all aspects of the study with the exception of the independent variable that is being tested. When done properly, this type of study can provide strong evidence of causation. The following illustrates this pyramid:[109]



112. Since the "affirming" model of treating transgender children, as summarized by the World Professional Association for Transgender Health (WPATH) and Endocrine Society guidelines discussed below, are relatively new, long-term outcomes are unknown. Evidence presented as support for short-term reductions

[109] https://www.researchgate.net/figure/Hierarchy-of-evidence-pyramid-The-pyramidal-shape-qualitatively-integrates-the-amount-of_fig1_311504831

in psychological distress following social transition in a "gender affirming" environment remains inconclusive. Multiple potential confounders are evident. The most notable deficiencies of existing research are the absence of proper control subjects and lack of randomization in study design.[110] No randomized control trials have been performed, and the existing longitudinal studies have serious limitations—most significantly, that they follow cohorts of patients in a non-controlled, unrandomized manner. This design severely limits any conclusions that can be drawn.

113. Moreover, many studies find no improvement—or negative effects—from "affirming" care. For instance, a 2020 British study (Carmichael et al.[111]) found "no evidence of change (no improvement) in psychological function with GnRHa treatment as indicated by parent report (CBCL) or self-report (YSR) of overall problems, internalizing or externalizing problems or self-harm." Puberty blockers used to treat children aged 12 to 15 who had severe and persistent gender dysphoria had no significant effect on their psychological function, thoughts of self-harm, or body image. However, as expected, the children experienced reduced growth in height and bone strength by the time they finished their treatment at age

[110] See Hruz, P. W. Deficiencies in Scientific Evidence for Medical Management of Gender Dysphoria. *Linacre Q* 87, 34-42, doi:10.1177/0024363919873762 (2020).
[111] 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.

16. As Oxford's Professor Michael Biggs summarized the study's findings, "After a year on GnRHa [puberty blockers] children reported greater self-harm, and girls experienced more behavioral and emotional problems and expressed greater dissatisfaction with their body—so puberty blockers actually exacerbated gender dysphoria."[112]

114. The widely respected Cochrane Review examined hormonal treatment outcomes for male-to-female transitioners over 16 years.[113] They found "insufficient evidence to determine the efficacy or safety of hormonal treatment approaches for transgender women in transition." Thus, decades after the first transitioned male-to-female patient, quality evidence for the benefit of transitioning remains lacking.

115. Although appropriate caution is warranted in extrapolating the outcomes observed from prior studies with current treatments, adults who have undergone social transition with or without surgical modification of external genitalia

---

[112] https://www.transgendertrend.com/tavistock-experiment-puberty-blockers/; Dyer, C. Puberty blockers: children under 16 should not be referred without court order, says NHS England. BMJ2020;371:m4717.doi:10.1136/bmj.m4717 pmid:33268453. See, Dyer, C., Puberty blockers do not alleviate negative thoughts in children with gender dysphoria, finds study, BMJ 2021;372:n356 doi: https://doi.org/10.1136/bmj.n356 (Published 08 February 2021); see also Dyer, C. Puberty blockers do not alleviate [suicidal] negative thoughts in children with gender dysphoria, finds study. BMJ 372, n356, doi:10.1136/bmj.n356 (2021). https://www.medrxiv.org/content/10.1101/2020.12.01.20241653v1; BBC summary: https://www.bbc.com/news/uk-55282113

[113] See 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 and https://www.cochranelibrary.com/cdsr/doi/10.1002/14651858.CD013138.pub2/full.

continue to have rates of depression, anxiety, substance abuse and suicide far above the background population.[114]

A. Change in Patient Population

116. One important (and contentious) issue requiring more study is the recent trend of adolescent female to male gender discordant patients. In the United Kingdom, where centralized medical care provides data to track health care phenomenon, the number of adolescent girls seeking sex transitioning exploded over 4,000% in the last decade. Similarly, in the United States, where we lack the same kinds of centralized health care data, it has been reported that in 2018, 2% of high school students identified on surveys as "transgender"—this is 200 times greater response, a 20,000% increase—over reports during past decades which showed a rate of only .01 percent.[115]

117. Along with this increase in transgender patients and identifiers has come a radical and recent transformation of the patient population from early onset males to rapid onset adolescent girls. Currently the majority of new patients with

[114] See Adams, N., Hitomi, M. & Moody, C. Varied Reports of Adult Transgender Suicidality: Synthesizing and Describing the Peer-Reviewed and Gray Literature. Transgend Health 2, 60-75, doi:10.1089/trgh.2016.0036 (2017); see also Dhejne, C. et al. Long-term follow-up of transsexual persons undergoing sex reassignment surgery: cohort study in Sweden. PLoS One 6, e16885, doi:10.1371/journal.pone.0016885 (2011).

[115] See Johns MM, Lowry R, Andrzejewski J, et al. Transgender Identity and Experiences of Violence Victimization, Substance Use, Suicide Risk, and Sexual Risk Behaviors Among High School Students—19 States and Large Urban School Districts, 2017. MMWR Morb Mortal Wkly Rep 2019; 68:67–71.

sex-gender discordance are not males with a long, stable history of gender dysphoria since early childhood—as they were for decades, and under the Dutch protocols—but instead adolescent females with no documented long-term history of gender dysphoria. One might say, as Dr. Lisa Littman has theorized, [116] that these females experienced "rapid onset" transgender identification.

118. This recent change in the typical patient raises questions about our understanding of the origins of transgender identity. For instance, a genetics or "immutable" theory of transgender identity cannot explain the rapid expansion of new GD cases (a 4,000% to 20,000% increase), given that our genome is simply not changing that fast. Nor can that theory explain the explosion of adolescent females presented with GD. A "brain structures" theory has only weak medical evidence, and it also cannot explain the rapid expansion of new gender dysphoria cases. As for the theory that increased social acceptance of the transgender lifestyle is leading many people who were transgender all along to come out. Yet this theory fails to explain why males and older women are not also coming out in the same large numbers and not coming out in "social peer group clusters," as adolescent females are reportedly doing.

[116] See Littman L. Parent reports of adolescents and young adults perceived to show signs of a rapid onset of gender dysphoria. PLoS One. 2018 Aug 16;13(8):e0202330. doi: 10.1371/journal.pone.0202330. Erratum in: PLoS One. 2019 Mar 19;14(3):e0214157. PMID: 30114286; PMCID: PMC6095578.

B. Methodological Problems with "Affirming" Literature

119. The published literature relied on to advocate for the use of puberty blockers, cross-sex hormones and gender affirming surgeries in minors consists almost entirely of studies with major methodological limitations.[117] As detailed next, these include:

- Significant recruitment biases, including internet-based convenience sampling;
- Relatively small sample sizes for addressing a condition that is likely to be multifactorial;
- Short term follow-up;
- Lack of randomization to different treatment arms;
- Failure to consider alternate hypotheses;
- Failure to include proper control groups;
- Reliance on cross sectional sampling that may identify associations, but cannot establish causal relationships between intervention and outcome;
- A high rate of patients lost to follow up in longitudinal analyses, which is relevant to questions of regret, desistance and completed suicide;
- Biased interpretation of study findings with a goal of validating *a priori* conclusions rather than seeking evidence to disprove the null hypothesis; and
- Ignoring starkly contradictory research documenting the lack of effectiveness of "transitioning" procedures, the low quality of research in this area, and the ongoing contentions and disagreements over this highly controversial, experimental medical field.

[117] See generally Hruz, Deficiencies in Scientific Evidence for Medical Management of Gender Dysphoria, Linacre Q 87(1), 34-42, doi:10.1177/0024363919873762 (2020).

120. Some or all of these methodological and statistical flaws are present in the following studies, which are commonly relied on by advocates of "affirming" treatments.

The Branstrom Long-Term Treatment Outcome Study: The historic Branstrom study is a long-term treatment (10+ years) outcome research investigation testing the effects of hormonal and surgical "transitioning" treatments on patients. This historic research found no reliable benefits from these treatments, as well as evidence suggesting *increased* suicide attempts and anxiety disorders following the "gender transitioning" treatments. In addition, detailed methodological critiques discovered significant research errors by the authors that appear to support the investigative theory that the authors had initially attempted to manipulate and misreport the findings of the study. The authors ultimately recanted their initial misreporting and agreed that their study produced *no reliable evidence* of benefits for gender reassignment hormone and surgical treatments. This historic investigation has helped to generate a profound collapse of support for these experimental procedures across Europe.[118]

[118] See SEGM, *Correction of a Key Study: No Evidence of "Gender-Affirming" Surgeries Improving Mental Health*, https://segm.org/ajp_correction_2020 (Aug. 30, 2020); Van Mol et al., *Gender-Affirmation Surgery Conclusion Lacks Evidence.* Am. J. Of Psych., 177(8), 765-766 (2020).

A 2011 Dutch study by de Vries et al.[119] is often cited to support longitudinal evidence of benefit from pubertal blockade. Although the study found slight improvements in mood improved and the risk of behavioral disorders with pubertal blockade over baseline, the study included no control group, and all 70 participants received ongoing psychological support. Thus, the authors were unable to determine the basis of the limited observed improvement. The authors acknowledge that psychological support or other reasons may have contributed to (or wholly caused) this observation. By the very nature of the trial, at best the study can provide a rationale for doing further studies that could show whether "affirming" interventions provide a benefit. The study does not (and cannot) answer the central question: whether the administration of puberty blockers is the solution to the problem and whether alternative approaches that do not carry the same risks relative to purported benefits (i.e., psychological interventions) may have the same or superior benefits.

Moreover, there remain questions about the extent to which the protocol used in these early Dutch studies may be relevant to the patient population presenting today. For decades transgender patients were mostly older adults or very young boys. As noted, over the last few years, a tsunami of teenaged girls has

[119] de Vries AL, Steensma TD, Doreleijers TA, Cohen-Kettenis PT. Puberty suppression in adolescents with gender identity disorder: a prospective follow-up study. *J Sex Med*. 8(8):2276-2283 (2011).

flipped the demographics of transgender patients—now up to 7 to 1 teen girls. The newly presenting cases are vastly overrepresented by adolescent females, the majority of whom also have significant mental health problems and neurocognitive comorbidities such as autism-spectrum disorder or ADHD.[120] Furthermore, estimates of gender dysphoria-transgenderism are rocketing upwards from 1 in 10,000 to "the number of U.S. transgender-identified youth may be as high as 9%."[121] This unexplained, radical transformation of patient demographics raises questions about the applicability even of the limited existing literature on this issue, particularly as to the Dutch protocol. Dr. Thomas Steensma, a prominent investigator of the Dutch protocol—the original model for transitioning treatments—has recently noted that "[w]e don't know whether studies we have done in the past can still be applied to this time," specifically because of the unexplained surge in female adolescents reporting gender dysphoria. "Many more children are registering, but also of a different type… Suddenly there are many more girls applying who feel like a boy." He concluded with the warning that "[w]e conduct structural

[120] See de Graaf, Nastasja M., and Polly Carmichael. "Reflections on Emerging Trends in Clinical Work with Gender Diverse Children and Adolescents." Clinical Child Psychology and Psychiatry, vol. 24, no. 2, Apr. 2019, pp. 353–64.
[121] See Kidd, Kacie M., et al. "Prevalence of Gender-Diverse Youth in an Urban School District." Pediatrics, vol. 147, no. 6, June 2021, p. e2020049823.

research in the Netherlands. But the rest of the world is blindly adopting our research."[122]

A 2014 follow-up study by de Vries et al.[123] encompassed 55 of the original 70 patients; 15 were lost to follow-up or not included. It has the same limitations that was present in assessing the original 2011 study, including a carefully selected patient population that is not representative of the broader population, especially now. Having a longer study does not obviate the limitations of the study design in making a conclusion that can be applied to the gender clinics that are operating in the United States.

In addition to the concerns of the Dutch studies already exposed, "[t]he linchpin result of the Dutch studies is the reported resolution of gender dysphoria, as measured by the Utrecht Gender Dysphoria Scale (UGDS)." Yet, as several researchers recently explained, the observed "drop was an artifact of switching the scale from 'female' to 'male' versions (and vice versa) before and after treatment, prompting a problematic reversal in the scoring."[124] "The same gender dysphoric

[122] See https://www.voorzij.nl/more-research-is-urgently-needed-into-transgender-care-for-young-people-where-does-the-large-increase-of-children-come-from/.
[123] de Vries AL, McGuire JK, Steensma TD, Wagenaar EC, Doreleijers TA, Cohen-Kettenis PT. Young adult psychological outcome after puberty suppression and gender reassignment. Pediatrics. 2014 Oct;134(4):696-704. doi: 10.1542/peds.2013-2958
[124] Abbruzzese E, Levine SB, Mason JW. The Myth of "Reliable Research" in Pediatric Gender Medicine: A critical evaluation of the Dutch Studies-and research that has followed. J Sex Marital Ther. 2023 Jan 2:1-27. doi: 10.1080/0092623X.2022.2150346.

individual, effectively answering the same question (albeit linguistically inverted)"—e.g., "Every time someone treats me like a girl [or boy] I feel hurt"—"results in either the maximum or the minimum 'gender dysphoria' score—depending on which sexed version of the scale was used." Thus, because researches used different scales of the UGDS before and after treatment, "it is impossible to determine if [the result shows] a real difference in gender dysphoria between groups or if this is an artifact of measurement error." Indeed, if anything, "[t]he fact that after gender reassignment, the UGDS scores were low on the opposite-sex scale indicates that the subjects would have scored high on the natal sex scale, which corresponds to a *persistence in transgender identity*." This, of course, is the opposite result purportedly reached by the study.

The 2018 paper by Wiepjies, et al.[125] is a retrospective review of records from all patients of the Center of Expertise on Gender Dysphoria gender clinic in Amsterdam from 1972-2015. While the study appears to report on the regret rates among a large cohort of adolescents (812) and children (548), regret is only reported for children and adolescents who had undergone gonadectomy once over 18 years of age. Of the adolescents, 41% started puberty suppression. Of those who started GnRH agonists, only 2% stopped this intervention (meaning that 98% of

[125] Wiepjes et al., The Amsterdam Cohort of Gender Dysphoria Study (1972-2015): Trends in Prevalence, Treatment, and Regrets, *The Journal of Sexual Medicine*, *15*(4), 582–590 (2018).

those who started puberty suppression progressed to cross-sex hormone therapy). An additional 32%, having already completed puberty, started cross-sex hormone therapy without use of a GnRH agonist. Classification of regret was very stringent, requiring physician documentation of patient verbalized regret after gonadectomy and start of sex-concordant hormones to treat the iatrogenic hypogonadism. This means there are significant limitations to the conclusions that can be drawn from this paper. There is no discussion in the paper regarding adolescent regret of use of puberty blockers, cross-sex hormones or mastectomies. Importantly, 36% of patients were lost to follow up. This is notable given that gonadectomy iatrogenically induces the pathologic state of primary hypogonadism. Affected patients have a lifelong dependency for exogenously administered sex-steroid hormones, and thus an acute need for ongoing follow-up. Their failure to return to the physicians who provided gender affirming interventions raises serious questions about their outcome. It is reasonable to hypothesize that some may have experienced regret or completed suicide. Yet due to missing data, their fate remains unknown. It is also significant that the average time to regret was 130 months. The authors themselves acknowledge that it may be too early to predict regret in patients who started hormone therapy in the past 10 years.

The 2018 Olson-Kennedy et al. paper[126] presents the results of a survey of biologically female patients with male gender identity at the lead author's institution using a novel rating system for "chest dysphoria" created by the study authors. There were an equal number (68) of nonsurgical and post-surgical subjects surveyed. Those who had undergone bilateral mastectomies were reported to have less chest dysphoria than those who did not receive this intervention. Limitations of this study include convenience sampling of nonsurgical study subjects with high potential for selection bias, cross-sectional design, lack of validation of the primary outcome measure, and short follow-up time (about 2 years). Test validation is particularly relevant in assessing adolescent questionnaires due to a variety of cognitive and situational factors in this population.[127] Rigorous validation methods have been previously used in several other established questionnaires addressing adolescent self-perception.[128] As previously noted, this study cannot provide information about a causal relationship between the intervention and outcomes observed.

---

[126] Olson-Kennedy et al., Chest Reconstruction and Chest Dysphoria in Transmasculine Minors and Young Adults: Comparisons of Nonsurgical and Postsurgical Cohorts, *JAMA Pediatr.* 172(5):431–436 (2018).

[127] See Brener et al., Assessment of Factors Affecting the Validity of Self-Reported Health-Risk Behavior among Adolescents: Evidence from the Scientific Literature, *Journal of Adolescent Health* 33 (6): 436–57 (2003).

[128] See Palenzuela-Luis et al., Questionnaires Assessing Adolescents' Self-Concept, Self-Perception, Physical Activity and Lifestyle: A Systematic Review, *Children (Basel, Switzerland)*, *9*(1), 91 (2022).

A 2019 study by Allen et al.[129] considered suicidality after cross-sex hormones. It was limited by a very small patient population (47), had no control group, had a short follow-up period (mean < 1 year), and again ignored that patients receiving the interventions also received psychological support.

A 2020 study by Turban et al.[130] is often cited as proof that pubertal blockade prevents suicide in transgender youth. However, this study used an unreliable, biased sampling methodology. As stated in the paper, the authors considered "a cross-sectional online survey of 20,619 transgender adults aged 18 to 36 years" from the 2015 U.S. Transgender Survey. This was an online survey of transgender and "genderqueer" adults recruited from trans-friendly websites. Among the many problems with this sampling methodology, there is no evidence of study subject identities, no way to assess for potential false subjects, and no medical diagnosis for entry. No causation can be determined from this retrospective, cross-sectional design. Furthermore, the study failed to even assess individuals who may have desisted or regretted transitions. Turban claimed that desisters and regretters would "not be likely" in this study group, which also only included

[129] Allen, L. R., Watson, L. B., Egan, A. M., & Moser, C. N. (2019). Well-being and suicidality among transgender youth after gender-affirming hormones. Clinical Practice in Pediatric Psychology, 7(3), 302–311. https://doi.org/10.1037/cpp0000288

[130] Turban et al., Pubertal Suppression for Transgender Youth and Risk of Suicidal Ideation. *Pediatrics*, *145*(2), e20191725 (2020).

adults. Thus, the study "does not include outcomes for people who may have initiated pubertal suppression and subsequently no longer identify as transgender."

Turban's misleading claim of lower suicidal ideation for treated patients is based upon "lifetime suicidality". It fails to recognize or acknowledge that the decision to grant the wish to provide puberty blockers was likely influenced by the mental health of the subjects at the time of presentation. Specifically, the most seriously mentally ill patients would have been denied affirmation treatment. Those who received treatment with pubertal suppression, when compared with those who wanted pubertal suppression but did not receive it, had lower odds of lifetime suicidal ideation (adjusted odds ratio = 0.3; 95% confidence interval = 0.2– 0.6). In Table 3 of the paper, under "Suicidality (past 12 months)" reductions for suppressed group versus non-suppressed were seen for ideation (50.6% v 64.8%) and "ideation with plan" (55.6% v 58.2%). However, it is important to note that differences in suicidal "ideation with plan and suicide attempt" and "attempt resulting for inpatient care" did not reach statistical significance. This was ignored by the authors. It would be reasonable to be concerned from an observation of over 40% attempted suicide in the treated group that the intervention was unsuccessful in improving health.[131]

[131] See generally Biggs, Puberty Blockers and Suicidality in Adolescents Suffering from Gender Dysphoria. Archives of Sexual Behavior, DOI: 10.1007/s10508-020-01743-6 (2020) and the multiple Letters to the Editor that criticized the multiple methodological errors in this study,

A 2020 study by van der Miesen, et al.[132] was a cross-sectional Dutch study that measured some patients who received puberty blockers and some who did not. The study had three populations of subjects: One was patients presenting to the gender clinic who had not received any intervention. The second was patients who had received puberty blockers. The third was adolescents from the general population. Because of this study's cross-sectional nature, it cannot establish a causal relationship between intervention and effect. It also represents a non-probability sample with potential for significant biases in subject recruitment. In addition, the subjects assessed before and after treatment are difference populations. Among the differences between these groups is patient age (mean of 14.5 and 16.8 years before and after treatment, respectively). This two year age difference is important as developmental progress during adolescence is known to influence psychological well-being.[133] There was also the same limitation noted in the 2011 de Vries study, that the treated population also received psychological support.

https://pediatrics.aappublications.org/content/145/2/e20191725/tab-e-letters#re-pubertal-suppression-for-transgender-youth-and-risk-of-suicidal-ideation.

[132] van der Miesen AIR, Steensma TD, de Vries ALC, Bos H, Popma A. Psychological Functioning in Transgender Adolescents Before and After Gender-Affirmative Care Compared With Cisgender General Population Peers. J Adolesc Health. 2020 Jun;66(6):699-704. doi: 10.1016/j.jadohealth.2019.12.018

[133] He J, Sun S, Zickgraf HF, Lin Z, Fan X. Meta-analysis of gender differences in body appreciation. Body Image. 2020 Jun;33:90-100. doi: 10.1016/j.bodyim.2020.02.011.

A 2021 study by Bustos, et al.[134] attempts to provide a systematic review of 27 observational or interventional studies that report on regret or detransition following gender-transition surgeries. A total of 7,928 subjects were included in their meta analysis. The authors concluded that only 1% or less of those who had gender-transition surgeries expressed regret. It is important to understand the serious methodological limitations and high risk of bias contained within this study's analysis.[135] This includes failure to include major relevant studies addressing this question,[136] inaccurate analysis within one of the studies considered,[137] and the general lack of controlled studies, incomplete and generally short-term follow-up, large numbers of lost subjects, and lack of valid assessment measures in the published literature addressing this question. As noted by Expósito-Campos and D'Angelo (2021), moderate to high risk of bias was present in 23 of the 27 studies included in the analysis. Furthermore, 97% of subjects analyzed were found

[134] Bustos et al., Regret after Gender-affirmation Surgery: A Systematic Review and Meta-analysis of Prevalence. *Plastic and reconstructive surgery. Global open*, *9*(3), e3477 (2021).
[135] See Expósito-Campos, P., & D'Angelo, R. (2021). Letter to the Editor: Regret after Gender-affirmation Surgery: A Systematic Review and Meta-analysis of Prevalence. *Plastic and reconstructive surgery. Global open*, *9*(11), e3951.
[136] E.g. Dhejne, C., Öberg, K., Arver, S., & Landén, M. (2014). An analysis of all applications for sex reassignment surgery in Sweden, 1960-2010: prevalence, incidence, and regrets. *Archives of sexual behavior*, *43*(8), 1535–1545.
[137] Wiepjes CM, Nota NM, de Blok CJM, et al. The Amsterdam Cohort of Gender Dysphoria Study (1972–2015): Trends in Prevalence, Treatment, and Regrets. J Sex Med 2018; 15: 582–590.

within studies deemed to be of fair to poor scientific quality. Thus, this study cannot be used as strong support for the contention that regret is rare.

The 2021 study by Narayan et al.[138] examines anonymous survey results from 154 surgeons affiliated with WPATH. The response rate for this survey was 30%. Of the respondents, 57% had encountered patients with surgical regret. It is important to recognize that this study was specifically directed toward patients who had undergone surgical transition. Acknowledged biases of this study include selection bias, recall bias, and response bias. This type of study cannot accurately identify the prevalence in the transgender population as a whole, and is particularly limited in the ability to assess potential for regret in the pediatric population.

The 2021 Almazan study[139] attempts to address mental health outcomes in relation to gender-transition surgery. This study relies upon data from the 2015 US Transgender Survey. Limitations and weaknesses of this survey tool includes convenience sampling, recruitment of patients through transgender advocacy organizations, demand bias (i.e., the good subject effect[140]), a high number of respondents

[138] Narayan et al., Guiding the conversation-types of regret after gender-affirming surgery and their associated etiologies, *Annals of translational medicine*, *9*(7), 605 (2021).
[139] Almazan et al., Association Between Gender-Affirming Surgeries and Mental Health Outcomes. *JAMA Surgery, 156*(7): 611–618 (2021).
[140] Nichols AL, Maner JK. The good-subject effect: investigating participant demand characteristics. J Gen Psychol. 2008 Apr;135(2):151-65. doi: 10.3200/GENP.135.2.151-166. PMID: 18507315.

who reported having not transitioned medically or surgically (and reported no desire to do so in the future), and several data irregularities. One notable data irregularity was that a high number of respondents reported that their age was exactly 18 years. As noted by D'Angelo and colleagues, these irregularities raise serious questions about the reliability of the USTS data and therefore the reliability of conclusions based on that data.[141]

The **2022 van der Loos** study[142] is a Dutch cohort study that investigates the continuation rate of gender affirming interventions in people who began puberty blockers and gender affirming hormones during adolescence. The authors claim that the study provides evidence against desistance after receiving gender affirming hormones. While the paper gives the impression that subjects represent a period of study extending from 1972 to 2018, the majority of subjects recently started hormone interventions. The length of time for follow-up (mean of 3.5 years for males and 2.3 years for females) and the average age at follow-up (20.2 years for males and 19.3 years for females) are inadequate to support the authors' claim. Notably,

[141] D'Angelo et al., One Size Does Not Fit All: In Support of Psychotherapy for Gender Dysphoria, *Archives of sexual behavior*, *50*(1): 7–16. https://doi.org/10.1007/s10508-020-01844-2 (2021).

[142] van der Loos MATC, Hannema SE, Klink DT, den Heijer M, Wiepjes CM. Continuation of gender-affirming hormones in transgender people starting puberty suppression in adolescence: a cohort study in the Netherlands. Lancet Child Adolesc Health. 2022 Dec;6(12):869-875. doi: 10.1016/S2352-4642(22)00254-1.

research from these same investigators has suggested that the average time to de-transition is over 10 years.[143] Thus, it would be necessary for the study to assess patients at least a decade after starting gender affirming hormones to make any meaningful conclusions on desistance. Furthermore, as a retrospective cohort study without a control group, the study design cannot determine the effect of gender affirming therapy on whether or not the intervention influences the rate of desistance that would have occurred without the provision of gender affirming hormones.

The **2022 Nos** study[144] is a retrospective cohort study that reports on the likelihood of starting on gender affirming hormones (GAH) based upon whether or not subjects were treated with puberty blockers. While the title and abstract give the impression that puberty blocker use is not linked to subsequent GAH, the data fail to support this conclusion. Since nearly all of the patients in this study who did not receive GnRHa were given GAH, it is not possible to determine whether GnRHa could increase this outcome. The comparison groups differed by age at time of initial presentation (age 10-13 years versus 14-17 years). GnRHa use was higher among the younger patients owing to the fact that they had not completed

[143] Wiepjes CM, Nota NM, de Blok CJM, Klaver M, de Vries ALC, Wensing-Kruger SA, de Jongh RT, Bouman MB, Steensma TD, Cohen-Kettenis P, Gooren LJG, Kreukels BPC, den Heijer M. The Amsterdam Cohort of Gender Dysphoria Study (1972-2015): Trends in Prevalence, Treatment, and Regrets. J Sex Med. 2018 Apr;15(4):582-590. doi: 10.1016/j.jsxm.2018.01.016.
[144] Nos AL, Klein DA, Adirim TA, Schvey NA, Hisle-Gorman E, Susi A, Roberts CM. Association of Gonadotropin-Releasing Hormone Analogue Use With Subsequent Use of Gender-Affirming Hormones Among Transgender Adolescents. JAMA Netw Open. 2022 Nov 1;5(11):e2239758. doi: 10.1001/jamanetworkopen.2022.39758.

puberty at the time of first visit. A lag in progression to GAH use in this group is heavily influenced by the difference in age at time of initial presentation. The older group was eligible to start GAH at the time of study entry while those in the younger group were not. When adjusted for age, the rates of progression to GAH use is nearly identical. Importantly, among the patients who received GnRHa, **94% (64 out of 70)** went on to take gender affirming hormones. Thus, the study further confirms that rather than serving as a "pause button" for gender dysphoric adolescents, it is an intervention that will lead to progression to gender affirming hormones.

The 2022 Green at al. study[145] purported to measure suicide attempts and access to cross-sex hormones. Though this study had a large cohort of patients, it suffered many biases in patient recruitment—which was done over the Internet and provided a cross-sectional analysis which can, at best, demonstrate correlation but not causation. Similar to other studies, it not assess the effect of psychiatric medications or psychotherapy on outcomes. It also failed to include variables to assess at what age youth began puberty blockers or the duration which they had received gender affirming hormones.

[145] Green AE, DeChants JP, Price MN, Davis CK. Association of Gender-Affirming Hormone Therapy With Depression, Thoughts of Suicide, and Attempted Suicide Among Transgender and Nonbinary Youth. J Adolesc Health. 2022 Apr;70(4):643-649.

The 2022 Turban et al. study[146] is retrospective cross-sectional investigation to assess whether there is an association between adolescent access to gender affirming hormones and mental health. The authors claim that there is an association between getting gender affirming hormones and favorable mental health outcomes compared to those who desired but did not receive this intervention. The methodology used is similar to the author's 2020 study on the effects of access to puberty blockers on lifetime suicidality already discussed above. Specifically, it used the same 2015 U.S. Transgender Survey (USTS), with all of the associated limitations and biases.[147] Participants in the USTS were recruited through transgender advocacy organizations and subjects were asked to 'pledge' to promote the survey among friends and family. Thus, there are serious concerns of selection bias.[148] It also suffers from recall bias[149] and an inability to verify the veracity of the claims of treatments given to the study respondents. Even if one dis-

[146] Tordoff DM, Wanta JW, Collin A, Stepney C, Inwards-Breland DJ, Ahrens K. Mental Health Outcomes in Transgender and Nonbinary Youths Receiving Gender-Affirming Care. JAMA Netw Open. 2022 Feb 1;5(2):e220978. doi: 10.1001/jamanetworkopen.2022.0978. Erratum in: JAMA Netw Open. 2022 Jul 1;5(7):e2229031.

[147] D'Angelo, R., Syrulnik, E., Ayad, S. *et al.* One Size Does Not Fit All: In Support of Psychotherapy for Gender Dysphoria. *Arch Sex Behav* **50**, 7–16 (2021). https://doi.org/10.1007/s10508-020-01844-2

[148] Tyrer S, Heyman B. Sampling in epidemiological research: issues, hazards and pitfalls. BJPsych Bull. 2016 Apr;40(2):57-60. doi: 10.1192/pb.bp.114.050203. PMID: 27087985; PMCID: PMC4817645.

[149] Coughlin SS. Recall bias in epidemiologic studies. J Clin Epidemiol. 1990;43(1):87-91. doi: 10.1016/0895-4356(90)90060-3. PMID: 2319285.

misses these concerns, by design, the study is not able to make any conclusions regarding a causal relationship between GAH access and mental health. Review of the data contained within the paper leads to conclusions that are far different than those stated by the study authors regarding mental health of the study participants. While the odds ratio for past year suicidal ideation was statistically different between those who did and those who did not get GAH, there was no difference in those who had a suicide plan, actually attempted suicide, or were hospitalized for a suicide attempt. This is important since the rationale for accepting the attendant risks of gender affirming hormones is to prevent suicide. Those with a suicide plan or attempt are far more likely to succumb to suicide than those who merely contemplated suicide. As pointed out by Michael Biggs in a commentary of this article,[150] the data presented in this study negate the purported significance of effects of puberty blocker access on mental health as reported in Turban's 2020 Pediatric article.

The 2022 Tordoff study is a prospective observational cohort study that assessed the mental health of patients presenting to the Seattle Children's gender clinic over a one year period of follow up. The authors claimed that access to gender affirming care had significantly improved mental health with lower odds ratios

[150] https://journals.plos.org/plosone/article/comment?id=10.1371/annotation/dcc6a58e-592a-49d4-9b65-ff65df2aa8f6

of depression and suicidality. This purported finding was widely publicized by the University of Washington and was featured on several news media sites. A detailed critique of the paper's data and flawed conclusions have been posted online.[151] Contrary to the claims, data contained in the paper did not show improvement in mental health over the one year study period. At entry into the study, 59% of the subjects had moderate to severe depression. At the end of the study, 56% had moderate to severe depression. Self-harm or suicidal thoughts were 45% and 37% at baseline and 12 months, respectively. These are alarmingly high numbers for an intervention that is touted to be lifesaving. The reported statistical difference in odds ratios were comparisons between those who started on puberty blockers and cross-sex hormones and those who did not receive hormones. Importantly, there was a marked difference in the number of dropout subjects in the treated and non-treated groups (17.5% versus 80%, respectively). It is reasonable to speculate that the small number of subjects who remained in the study but did not receive hormones had significant co-morbidities that prevented them from accessing this intervention. In any event, the actual data from this study demonstrates that access to puberty blockers and gender affirming hormones did not improve mental health over the first year of treatment. This is drastically different from what the authors and the media claimed.

[151] See https://jessesingal.substack.com/p/researchers-found-puberty-blockers?s=r

The 2022 Chen study[152] is a longitudinal observational study of patients receiving care at four gender centers in the United States. The primary conclusion made by the authors is that "GAH improved appearance congruence and psychosocial functioning." However, there are major limitations and weaknesses in the data that limit the conclusions that can be made. A revealing critique of the paper by de Vries and Hannema that was published alongside this article exposes some of these concerns.[153] The most glaring problem is that the study was observational and did not include a control group. Thus, there is no ability to draw causal conclusions. At best, the authors can find associations. Akin to many of the other papers in this field, there is no way to determine whether any of the changes were contributed by or due solely to psychiatric interventions. It is also notable that even though the study was designed to recruit only subjects in with good mental health at baseline, 48 of the 307 study subjects (15.6%) were described as having severe depression at this time point. At the end of the two year follow up, 30 of the 219 remaining subjects (13.7%) were reported to have major depression. Furthermore, two patients committed suicide during the time of observation. This is an outcome that in most

[152] Chen D, Berona J, Chan YM, Ehrensaft D, Garofalo R, Hidalgo MA, Rosenthal SM, Tishelman AC, Olson-Kennedy J. Psychosocial Functioning in Transgender Youth after 2 Years of Hormones. N Engl J Med. 2023 Jan 19;388(3):240-250. doi: 10.1056/NEJMoa2206297.
[153] de Vries ALC, Hannema SE. Growing Evidence and Remaining Questions in Adolescent Transgender Care. N Engl J Med. 2023 Jan 19;388(3):275-277. doi: 10.1056/NEJMe2216191

other situations would lead to a halt in study and detailed inquiry by an institutional review board.[154] The paper claims to present two year follow up data in this cohort. However, only half of the study participants were assessed at each study time point and 30% did not have 24 month data collected. Even if one accepted the follow up period, this is likely not long enough to make firm conclusions about long-term efficacy. Most of the measures are based upon subjective experience. There is no inclusion of more robust measures of psychological well-being such as the number on antidepressants and other psychotropic medications. The study effects for many of the measured parameters was very modest at best and, while statistically significant, do not have any meaningful clinical significance. For example, the depression scores, showed little change over two years in the highest severity group. There is also significant heterogeneity in responses with some subjects showing improvement, some no change, and others worsening. Despite the spin provided by the authors and media, these data do not alleviate the serious concerns raised regarding the safety and efficacy of gender affirming medical interventions.

121. Many conclusions in the above studies are drawn or characterized in fundamentally unscientific ways without apparent regard to the scientific process of disproving a null hypothesis. Instead, these studies suggest that the authors began with a conclusion and then looked for data to support that conclusion. That is

[154] https://grants.nih.gov/grants/guide/notice-files/NOT99-107.html

a vastly unsound way of doing science, and patients will not be aware of these methodological limitations and distortions when informed of these purported conclusions.

122. There remains a significant and unmet need to improve our understand of the biological, psychological, and environmental basis for the manifestation of patient reports of discordance of gender identity and biological sex in affected individuals, as well as the long-term effects of "affirming" interventions.[155] In particular, there is a concerning lack of randomized controlled trials or adequately controlled longitudinal studies comparing outcomes of youth with gender dysphoria who received psychological support, were encouraged to socially transition, or were put on medical interventions, and how these differential treatments affect the usual and natural progression to resolution of gender dysphoria and other variables. Such studies can be ethically designed and executed with provisions for other dignity affirming measures to all treatment groups.[156] But they have not been performed in the existing literature, leaving that literature in a state insufficient to enable sound conclusions about the efficacy of "affirming" treatments.

[155] Olson-Kennedy, J. et al. Research priorities for gender nonconforming/transgender youth: gender identity development and biopsychosocial outcomes. Current Opinion in Endocrinology, Diabetes and Obesity 23, 172-179, (2016).
[156] See Sugarman J. Ethics in the design and conduct of clinical trials. Epidemiol Rev. 2002;24(1):54-8. doi: 10.1093/epirev/24.1.54. PMID: 12119856; And https://clinicalcenter.nih.gov/recruit/ethics.html.

International Responses

123. Recognizing the paucity of evidence supporting "affirming" treatments, along with the proven risks of those treatments, other countries are increasingly limiting use of those treatments.

124. **Finland**: The National Science Review in Finland carefully examined all relevant science and suspended transition treatments for minors under age 16.[157] The review determined that "[t]he first-line treatment for gender dysphoria is psychosocial support and, as necessary, psychotherapy and treatment of possible comorbid psychiatric disorders." According to the review, "[c]ross-sex identification in childhood, even in extreme cases, generally disappears during puberty." The review also found: "Potential risks of GnRH therapy include disruption in bone mineralization and the as yet unknown effects on the central nervous system"; "there are no medical treatments (for transitioning) that can be considered evidence-based"; and, "[t]he reliability of the existing studies with no control groups is highly uncertain." Thus, "because of this uncertainty, no decisions should be made that can permanently alter a still-maturing minor's mental and physical development," and "[n]o gender confirmation surgeries are performed on

[157] See 2020 Recommendation of the Council for Choices in Health Care in Finland (PALKO / COHERE Finland) Medical Treatment Methods for Dysphoria Related to Gender Variance In Minors.

minors." "Since reduction of psychiatric symptoms cannot be achieved with hormonal and surgical interventions, it is not a valid justification for gender reassignment. A young person's identity and personality development must be stable so that they can genuinely face and discuss their gender dysphoria, the significance of their own feelings, and the need for various treatment options. For children and adolescents, these factors are key reasons for postponing any interventions until adulthood…. In light of available evidence, gender reassignment of minors is an experimental practice."

125. **Sweden**: The world-renowned Karolinska Hospital reviewed the current research and suspended pediatric gender transitions for patients under 16 outside of experimental, monitored clinical trials settings as of May 2021. Treatment will focus on psychotherapy and assessment[158]. The "Dutch protocol" for treating gender dysphoric minors has been discontinued over concerns of medical harm and uncertain benefits.

Moreover, in a national policy review, a report commissioned by the Swedish government concluded that:

- We have not found any scientific studies which explains the increase in incidence in children and adolescents who seek the heath care because of gender dysphoria.

[158] See Sweden's Karolinska Ends All Use of Puberty Blockers and Cross-Sex Hormones for Minors Outside of Clinical Studies. https://segm.org/Sweden_ends_use_of_Dutch_protocol. See also, Karolinska Policy Change K2021-3343 March 2021 (in English).pdf; Karolinska Hospital Ends the Use of Puberty Blockers for patients under 16: New policy statement from the Karolinska Hospital.

- We have not found any studies on changes in prevalence of gender dysphoria over calendar time, nor any studies on factors that can affect the societal acceptance of seeking for gender dysphoria. There are few studies on gender affirming surgery in general in children and adolescents and only single studies on gender affirming genital surgery.
- Studies on long-term effects of gender affirming treatment in children and adolescents are few, especially for the groups that have appeared during the recent decennium…
- No relevant randomized controlled trials in children and adolescents were found.[159]

From these findings, the Swedish National Board of Heath in December of 2022 issued updated guidelines for the care of adolescents and children with gender dysphoria.[160] This medical board concluded that "the risks of puberty blockers and gender-affirming treatment are likely to outweigh the expected benefits of these treatment". Noting that there is uncertainty about the cause for the rapid rise in number of people being diagnosed with gender dysphoria, documented evidence of detransitioning young adults with uncertainty regarding the prevalence of this outcome, and lack of uniformity in experience-based knowledge among providers, GnRH analogues, gender affirming hormones and mastectomy should be provided only in exceptional cases and ideally as part of an experimental trial.

.

[159] See Sweden Policy Review, Gender dysphoria in children and adolescents: an inventory of the literature, SBU Policy Support no 307, 2019 (https://www.sbu.se/307e).
[160] https://www.socialstyrelsen.se/globalassets/sharepoint-dokument/artikelkatalog/kunskapsstod/2023-1-8330.pdf

126. **United Kingdom**: The British official medical review office (National Institute of Health and Care Excellence, NICE) published reports on the use of both puberty blockers and hormones for transitioning purposes. The assessment of the evidence into the drugs was commissioned by NHS England. The review found that the evidence for using puberty blocking drugs to treat young people struggling with their gender identity is "very low certainty."[161] The review found that "all small, uncontrolled observational studies, which are subject to bias and confounding, and all the results are of very low certainty using modified GRADE. They all reported physical and mental health comorbidities and concomitant treatments very poorly."

NICE also reviewed the evidence base for cross-sex hormones.[162] The review found the evidence of clinical effectiveness and safety of cross-sex hormones was also of "very low" quality. The review concluded: "Any potential benefits of gender-affirming hormones must be weighed against the largely unknown long-term safety profile of these treatments in children and adolescents with gender dysphoria."

[161] https://cass.independent-review.uk/wp-content/uploads/2022/09/20220726_Evidence-review_GnRH-analogues_For-upload_Final.pdf
[162] https://cass.independent-review.uk/wp-content/uploads/2022/09/20220726_Evidence-review_Gender-affirming-hormones_For-upload_Final.pdf

A recent independent review of gender identity services in the United Kingdom, by Dr. Hillary Case, concluded that "Evidence on the appropriate management of children and young people with gender incongruence and dysphoria is inconclusive both nationally and internationally."[163] Dr. Cass notes that "[t]here is lack of consensus and open discussion about the nature of gender dysphoria and therefore about the appropriate clinical response."

Citing concerns from the Cass report that the Tavistok model of care placed affected youth at considerable risk of poor mental health, and is therefore "not a safe or viable long-term option," this clinic is being shut down. It will be replaced by a new regional hospital-based service where related services for mental health and autism can be provided by clinicians who have expertise in safeguarding, supporting looked-after children and children who have experienced trauma. Thus, gender-related distress will be addressed "within a broader child and adolescent health context."

This new model is in sharp contrast to recommendations made by WPATH in their "standards of care" (SOC8). Differences in approach include the prioritization of parent versus child expectations for care, recommendations against social

[163] https://cass.independent-review.uk/wp-content/uploads/2022/03/Cass-Review-Interim-Report-Final-Web-Accessible.pdf

affirmation of pre-pubertal youth, the provision of puberty blockers within the experimental setting, initial focus on exploration and treatment of mental health problems, and use of psychological support as a primary intervention.

Conclusions

127. There are no long-term, peer-reviewed published, reliable and valid research studies documenting the reliability and validity of assessing gender identity by relying solely upon the expressed desires of a patient.

128. There are no long-term, peer-reviewed published, reliable, and valid research studies documenting any valid and reliable biological, medical, surgical, radiological, psychological or other objective assessment of gender identity or gender dysphoria.

129. A large percentage of children (over 80% in some studies) who questioned their gender identity will, if left alone, develop an acceptance of their natal (biological) sex.

130. A currently unknown percentage and number of patients reporting gender dysphoria suffer from mental illness(es) that complicate and may distort their judgments and perceptions of gender identity.

131. A currently unknown percentage and number of patients reporting gender dysphoria may be manipulated by a social contagion and social pressure

processes, including peer group, social media, YouTube role modeling, and parental pressures.

132. There are no long-term, peer-reviewed published, reliable and valid research studies documenting the number or percentage of patients receiving gender affirming medical interventions who are helped by such procedures.

133. There are no long-term, peer-reviewed published, reliable and valid research studies documenting the number or percentage of patients receiving gender affirming medical interventions who are injured or harmed by such procedures.

134. "Affirming" treatments have no known, peer reviewed and published error rates.

135. The gender affirming approach has limited, very weak scientific support for short-term alleviation of dysphoria and no long-term outcomes data demonstrating superiority over the other approaches.

136. Because of the major methodological limitations and weaknesses of the extent published literature in the field of gender dysphoria, one cannot make a conclusion that "affirming" treatments are justified as a safe and effective long-term solution to gender dysphoria in consideration of the significant risks and unsubstantiated long-term benefits.

137. With the limited and poor-quality data currently available about the purported efficacy of blocking normally timed puberty, administering cross-sex

hormones, and gender affirming surgeries in alleviating psychological morbidity for youth who experience sex-discordant gender identity and the associated serious medical risks associated with these interventions, it cannot be concluded that this approach is "medically necessary." Use of such medical interventions remains a largely experimental approach.

138. Experimentation on gender discordant youths is especially likely to cause harm to patients from historically marginalized communities. That is because children in such communities are disproportionally affected by gender discordance. These include:

- children with a history of psychiatric illness;[164]
- children of color;[165]
- children with mental developmental disabilities;[166]
- children on the autistic spectrum;[167] and,

[164] See, e.g., Kaltiala-Heino, R., Sumia, M., Työläjärvi, M., & Lindberg, N. (2015). Two years of gender identity service for minors: overrepresentation of natal girls with severe problems in adolescent development. *Child and adolescent psychiatry and mental health*, *9*, 9. https://doi.org/10.1186/s13034-015-0042-y.

[165] See, e.g., G. Rider et al. (2018), Health and Care Utilization of Transgender/Gender Non-Conforming Youth: A Population Based Study, Pediatrics at 4, DOI: 10.1542/peds.2017-1683.

[166] See, e.g., Bedard, C., Zhang, H.L. & Zucker, K.J. Gender Identity and Sexual Orientation in People with Developmental Disabilities. *Sex Disabil* 28**,** 165–175 (2010). https://doi.org/10.1007/s11195-010-9155-7.

[167] See, e.g., de Vries, A. L., Noens, I. L., Cohen-Kettenis, P. T., van Berckelaer-Onnes, I. A. & Doreleijers, T. A. Autism spectrum disorders in gender dysphoric children and adolescents. *J Autism Dev Disord* 40, 930-936, doi:10.1007/s10803-010-0935-9 (2010).

- children residing in foster care homes and adopted children.[168]

139. Patients suffering from gender dysphoria or related issues have a right to be protected from experimental, potentially harmful treatments lacking reliable, valid, peer reviewed, published, long-term scientific evidence of safety and effectiveness.

140. The treatment protocols and recommendations of politically influenced, non-science associations like WPATH and the American Academy of Pediatrics that engage in consensus-seeking methodologies by vote rather than science are not based on competent, credible, methodologically sound science, and have no known or published error rate.

141. Administering hormones to a child whose gender dysphoria is highly likely to resolve is risky, unscientific, and unethical. Iatrogenic damages from these interventions, including infertility, stunted growth, increased heart attack risk, and many more, are often irreversible.

142. Because of these concerns about the safety, efficacy, and scientific validity of controversial, unproven, and experimental treatment paradigms, I have not personally engaged in the delivery of gender affirming medical interventions to children with gender dysphoria. Given the unproven long-term benefits and the

[168] See, e.g., See e.g., D. Shumer et al. (2017), Overrepresentation of Adopted Adolescents at a Hospital-Based Gender Dysphoria Clinic, Transgender Health Vol. 2(1).

well-documented risks and harms of "transitioning" children, I decline to participate in such experimental treatments until the science has proven that the relative risks and benefits of this approach warrant such procedures.

143. My decision is strengthened by the knowledge that the vast majority of children who report gender dysphoria will, if left untreated, grow out of the problem — a natural coping-developmental process — and willingly accept their biological sex. Since there are no reliable assessment methods for identifying the small percentage of children with persisting sex-gender identity discordance from the vast majority who will accept their biological sex, and since puberty blocking treatments, hormone transition treatments, and surgical transition treatments are all known to have potentially life-long devastating, negative effects on patients, I and many colleagues view it as unethical to treat children with an unknown future by using experimental, aggressive, and intrusive gender affirming medical interventions.

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

Executed on February 15, 2023.

Paul W. Hruz, M.D., Ph.D.

Exhibit "A"

Curriculum Vitae

Date: 2/15/2023
Name: Paul W. Hruz, M.D., Ph.D.

Contact Information

Office:	Phone: 314-286-2797 Fax: 314-286-2892
Mail:	Washington University in St. Louis School of Medicine Department of Pediatrics Endocrinology and Diabetes 660 South Euclid Avenue St Louis MO 63110
Email:	Office: hruz_p@wustl.edu

Present Position

Associate Professor of Pediatrics, Endocrinology and Diabetes
Associate Professor of Pediatrics, Cell Biology & Physiology

Education

1987	BS, Chemistry, Marquette University, Milwaukee, WI
1993	PhD, Biochemistry, Medical College of Wisconsin, Milwaukee, WI Elucidation of Structural, Mechanistic, and Regulatory Elements in 3-Hydroxy-3-Methlyglutaryl-Coenzyme A Lyase, Henry Miziorko
1994	MD, Medicine, Medical College of Wisconsin, Milwaukee, WI
1994 - 1997	Pediatric Residency, University of Washington, Seattle, Washington
1997 - 2000	Pediatric Endocrinology Fellowship, Washington University, Saint Louis, MO
2017	Certification in Healthcare Ethics, National Catholic Bioethics Center, Philadelphia, PA

Academic Positions / Employment

1996 - 1997	Locum Tenens Physician, Group Health of Puget Sound Eastside Hospital, Group Health of Puget Sound Eastside Hospital, Seattle , WA
2000 - 2003	Instructor in Pediatrics, Endocrinology and Diabetes, Washington University in St. Louis, St. Louis, MO
2003 - 2011	Assistant Professor of Pediatrics, Endocrinology and Diabetes, Washington University in St. Louis, St. Louis, MO
2004 - 2011	Assistant Professor of Pediatrics, Cell Biology & Physiology, Washington University in St. Louis, St. Louis, MO
2011 - Pres	Associate Professor of Pediatrics, Cell Biology & Physiology, Washington University in St. Louis, St. Louis, MO

2011 - Pres	Associate Professor of Pediatrics, Endocrinology and Diabetes, Washington University in St. Louis, St. Louis, MO
2012 - 2017	Division Chief, Endocrinology and Diabetes, Washington University in St. Louis, St. Louis, MO

Clinical Title and Responsibilities

	General Pediatrician, General Pediatric Ward Attending: 2-4 weeks per year, St. Louis Children's Hospital
2000 - Pres	Pediatric Endocrinologist, Endocrinology Night Telephone Consult Service: Average of 2-6 weeks/per yr, St. Louis Children's Hosptial
2000 - Pres	Pediatric Endocrinologist, Inpatient Endocrinology Consult Service: 3-6 weeks per year, St. Louis Children's Hospital
2000 - Pres	Pediatric Endocrinologist, Outpatient Endocrinology Clinic: Approximately 50 patient visits per month, St. Louis Children's Hospital

Teaching Title and Responsibilities

2009 - Pres	Lecturer, Markey Course-Diabetes Module
2020 - 2020	Facilitator, Reading Elective-Interdisciplinary/Miscellaneous Course #M80-800, Washington University School of Medicine

University, School of Medicine and Hospital Appointments and Committees

University

2012 - 2020	Disorders of Sexual Development Multidisciplinary Care Program

School of Medicine

2013 - 2020	Molecular Cell Biology Graduate Student Admissions Committee
2014 - Pres	Research Consultant, ICTS Research Forum - Child Health

Hospital

2000 - Pres	Attending Physician, St. Louis Children's Hospital

Medical Licensure and Certifications

1997 - Pres	Board Certified in General Pediatrics
2000 - Pres	MO Stae License #2000155004
2001 - Pres	Board Certified in Pediatric Endocrinology & Metabolism

Honors and Awards

1987	National Institute of Chemists Research and Recognition Award
1987	Phi Beta Kappa
1987	Phi Lambda Upsilon (Honorary Chemical Society)
1988	American Heart Association Predoctoral Fellowship Award
1994	Alpha Omega Alpha
1994	Armond J. Quick Award for Excellence in Biochemistry

1994	NIDDK/Diabetes Branch Most Outstanding Resident
1998	Pfizer Postdoctoral Fellowship Award
2002	Scholar, Child Health Research Center of Excellence in Developmental Biology at Washington University
2013	Julio V Santiago, M.D. Scholar in Pediatrics
2017	Redemptor Hominis Award for Outstanding Contributions to the Study of Bioethics
2018	Eli Lilly Outstanding Contribution to Drug Discovery: Emerging Biology Award
2018	Scholar-Innovator Award, Harrington Discovery Institute
2021	Linacre Award

Editorial Responsibilities

Editorial Ad Hoc Reviews

	AIDS
	AIDS Research and Human Retroviruses
	American Journal of Pathology
	American Journal of Physiology
	British Journal of Pharmacology
	Circulation Research
	Clinical Pharmacology & Therapeutics
	Comparative Biochemistry and Physiology
	Diabetes
	Experimental Biology and Medicine
	Future Virology
	Journal of Antimicrobial Chemotherapy
	Journal of Clinical Endocrinology & Metabolism
	Journal of Molecular and Cellular Cardiology
	Obesity Research
2000 - Pres	Journal of Biological Chemistry
2013 - Pres	PlosOne
2016 - Pres	Scientific Reports
2018 - Pres	Nutrients

Editorial Boards

2014 - 2015	Endocrinology and Metabolism Clinics of North America

National Panels, Committees

2017 - Pres	Consultant, Catholic Health Association
2021 - Pres	Consulting Fellow, National Catholic Bioethics Center

National Boards

2020 - Pres	WU ICTS Clinical and Translational Research Funding Program (CTRFP) Review Committee

Community Service Contributions

Professional Societies and Organizations

American Diabetes Association
Endocrine Society
Pediatric Endocrine Society

Major Invited Professorships and Lectures

2002	Pediatric Grand Rounds, St. Louis Children's Hospital, St Louis, MO
2004	National Disease Research Interchange, Human Islet Cell Research Conference, Philadelphia, PA
2004	NIDA-NIH Sponsored National Meeting on Hormones, Drug Abuse and Infections, Bethesda, MD
2005	Endocrine Grand Rounds, University of Indiana, Indianapolis, IN
2005	The Collaborative Institute of Virology, Complications Committee Meeting, Boston, MA
2006	Metabolic Syndrome Advisory Board Meeting, Bristol-Meyers Squibb, Pennington, NJ
2007	American Heart Association and American Academy of HIV Medicine State of the Science Conference: Initiative to Decrease Cardiovascular Risk and Increase Quality of Care for Patients Living with HIV/AIDS, Chicago, IL
2007	Minority Access to Research Careers Seminar, University of Arizona, Tucson, AZ
2007	MSTP Annual Visiting Alumnus Lecture, Medical College of Wisconsin , Milwaukee, WI
2007	Pediatric Grand Rounds, St Louis Children's Hospital, St Louis, MO
2008	Division of Endocrinology, Diabetes and Nutrition Grand Rounds, Boston University, Boston, MA
2009	Pediatric Grand Rounds, St Louis Children's Hospital, St. Louis, MO
2010	American Diabetes Association Scientific Sessions, Symposium Lecture Orlando, FL
2010	School of Biological Sciences Conference Series, University of Missouri Kansas City, Kansas City, MO
2011	Life Cycle Management Advisory Board Meeting, Bristol-Myers Squibb,, Chicago, IL
2013	Pediatric Grand Rounds, St Louis Children's Hospital, ST LOUIS, MO
2013	Clinical Practice Update Lecture, St Louis Children's Hospital, St Louis, MO
2014	Pediatric Academic Societies Meeting,, Vancouver, Canada
2014	American Diabetes Association 74th Scientific Sessions, , San Francisco, CA
2017	Division of Pediatric Endocrinology Metabolism Rounds, University of Michigan, Ann Arbor, MI
2017	Catholic Medical Association National Conference, Denver, CO
2018	Obstetrics, Gynecology & Women's Health Grand Rounds, Saint Louis University, St. Louis, MO
2018	Medical Grand Rounds, Sindicato Médico del Uruguay, Montevideo, Uraquay
2018	Internal Medicine Grand Rounds, Texas Tech , Lubbock, TX
2019	Veritas Center for Ethics in Public Life Conference, Franciscan University, Steubenville, OH
2019	MaterCare International Conference, Rome, Italy
2019	Child Health Policy Forum, Notre Dame University, South Bend , IN

2021	Obstetrics & Gynecology Grand Rounds, University of Tennessee, Knoxville , TN
2022	The World Federation of Catholic Medical Associations (*FIAMC*), Rome, Italy

Consulting Relationships and Board Memberships

1996 - 2012	Consultant, Bristol Myers Squibb
1997 - 2012	Consultant, Gilead Sciences

Research Support

Completed Governmental Support

2001 - 2006	K-08 A149747, NIH Mechanism of GLUT4 Inhibition by HIV Protease Inhibitors Role: Principal Investigator
2007 - 2012	R01 Mechanisms for Altered Glucose Homeostasis During HAART Role: Principal Investigator Total cost: $800,000.00
2009 - 2011	R01 Student Supp Mechanisms for Altered Glucose Homeostasis During HAART Role: Principal Investigator Total cost: $25,128.00
2009 - 2014	R01 Direct Effects of Antiretroviral Therapy on Cardiac Energy Homeostasis Role: Principal Investigator Total cost: $1,250,000.00
2017 - 2019	R-21 1R21AI130584 , National Institutes of Health SELECTIVE INHIBITION OF THE P. FALCIPARUM GLUCOSE TRANSPORTER PFHT Role: Principal Investigator Total cost: $228,750.00

Completed Non-Governmental Support

2015	Novel HIV Protease Inhibitors and GLUT4 Role: Principal Investigator
2008 - 2011	II Insulin Resistance and Myocardial Glucose Metabolism in Pediatric Heart Failure Role: Co-Investigator PI: Hruz Total cost: $249,999.00
2009 - 2012	Research Program Regulation of GLUT4 Intrinsic Activity Role: Principal Investigator Total cost: $268,262.00
2010 - 2011	Protective Effect of Saxagliptin on a Progressive Deterioration of Cardiovascular Function Role: Principal Investigator
2012 - 2015	II Solution-State NMR Structure and Dynamics of Facilitative Glucose Transport Proteins Role: Principal Investigator Total cost: $375,000.00

2017 - 2020 Prevention And Treatment Of Hepatic Steatosis Through Selective Targeting Of GLUT8
Role: Co-Principal Investigator
PI: DeBosch
Total cost: $450,000.00

2017 - 2021 Matching Micro Grant
Novel Treatment of Fatty Liver Disease (CDD/LEAP)
Role: Principal Investigator
Total cost: $68,500.00

2018 - 2021 LEAP Innovator Challenge
Novel Treatment of Fatty Liver Disease
Role: Principal Investigator
Total cost: $68,500.00

2019 - 2021 Scholar-Innovator Award HDI2019-SI-4555 , Harrington Foundation
Novel Treatment of Non-Alcoholic Fatty Liver Disease
Role: Principal Investigator
Total cost: $379,000.00

Current Governmental Support

2021 - 2025 R-01 DK126622 (Co-investigator), 8/25/2021-7/31/2025, NIH-NIDDK, , NIH
Leveraging glucose transport and the adaptive fasting response to modulate hepatic metabolism
Role: Co-Investigator
PI: DeBosch

Trainee/Mentee/Sponsorship Record

2002 - 2002 Nishant Raj- Undergraduate Student, Other
Study area: Researcher

2002 - 2010 Joseph Koster, PhD, Postdoctoral Fellow
Study area: Researcher

2003 - 2004 Johann Hertel, Medical Student
Study area: Research
Present position: Assistant Professor, University of North Carolina, Chapel Hill, NC

2003 - 2003 John Paul Shen, Medical Student
Study area: Research

2004 - 2005 Carl Cassel- High School Student, Other
Study area: Research

2004 - 2004 Christopher Hawkins- Undergraduate Student, Other
Study area: Researcher

2004 - 2004 Kaiming Wu- High School Student, Other
Study area: Research

2005 - 2005 Helena Johnson, Graduate Student

2005 - 2005 Jeremy Etzkorn, Medical Student
Study area: Researcher

2005 - 2005 Dominic Doran, DSc, Postdoctoral Fellow
Study area: HIV Protease Inhibitor Effects on Exercize Tolerance

2006 - 2006 Ramon Jin, Graduate Student
Study area: Research

2006 - 2006 Taekyung Kim, Graduate Student
Study area: Research

2007 - 2007 Jan Freiss- Undergraduate Student, Other
Study area: Researcher

2007 - 2008 Kai-Chien Yang, Graduate Student
Study area: Research
Present position: Postdoctoral Research Associate, University of Chicago

2007 - 2007 Paul Buske, Graduate Student
Study area: Research

2007 - 2007 Randy Colvin, Medical Student
Study area: Researcher

2008 - 2011 Arpita Vyas, MD, Clinical Fellow
Study area: Research
Present position: Assistant Professor, Michigan State University, Lansing MI

2008 - 2009 Candace Reno, Graduate Student
Study area: Research
Present position: Research Associate, University of Utah

2008 - 2012 Dennis Woo- Undergraduate Student, Other
Study area: Researcher
Present position: MSTP Student, USC, Los Angeles CA

2008 - 2008 Temitope Aiyejorun, Graduate Student
Study area: Research

2009 - 2009 Anne-Sophie Stolle- Undergraduate Student, Other
Study area: Research

2009 - 2009 Matthew Hruz- High School Student, Other
Study area: Research
Present position: Computer Programmer, Consumer Affairs, Tulsa OK

2009 - 2009 Stephanie Scherer, Graduate Student
Study area: Research

2010 - 2014 Lauren Flessner, PhD, Postdoctoral Fellow
Present position: Instructor, Syracuse University

2010 - 2010 Constance Haufe- Undergraduate Student, Other
Study area: Researcher

2010 - 2011 Corinna Wilde- Undergraduate Student, Other
Study area: Researcher

2010 - 2010 Samuel Lite- High School Student, Other
Study area: Research

2011 - 2016 Thomas Kraft, Graduate Student
Study area: Glucose transporter structure/function
Present position: Postdoctoral Fellow, Roche, Penzberg, Germany

2011 - 2011 Amanda Koenig- High School Student, Other
Study area: Research

2011 - 2012 Lisa Becker- Undergraduate Student, Other

2011 - 2011 Melissa Al-Jaoude- High School Students, Other

2019 Ava Suda, Other, Pre-med

Bibliography

A. Journal Articles

1. Hruz PW, Narasimhan C, Miziorko HM. 3-Hydroxy-3-methylglutaryl coenzyme A lyase: affinity labeling of the Pseudomonas mevalonii enzyme and assignment of cysteine-237 to the active site. *Biochemistry*. 1992;31(29):6842-7. PMID:1637819
2. Hruz PW, Miziorko HM. Avian 3-hydroxy-3-methylglutaryl-CoA lyase: sensitivity of enzyme activity to thiol/disulfide exchange and identification of proximal reactive cysteines. *Protein Sci*. 1992;1(9):1144-53. doi:10.1002/pro.5560010908 PMCID:PMC2142181 PMID:1304393
3. Mitchell GA, Robert MF, Hruz PW, Wang S, Fontaine G, Behnke CE, Mende-Mueller LM, Schappert K, Lee C, Gibson KM, Miziorko HM. 3-Hydroxy-3-methylglutaryl coenzyme A lyase (HL). Cloning of human and chicken liver HL cDNAs and characterization of a mutation causing human HL deficiency. *J Biol Chem*. 1993;268(6):4376-81. PMID:8440722
4. Hruz PW, Anderson VE, Miziorko HM. 3-Hydroxy-3-methylglutaryldithio-CoA: utility of an alternative substrate in elucidation of a role for HMG-CoA lyase's cation activator. *Biochim Biophys Acta*. 1993;1162(1-2):149-54. PMID:8095409
5. Roberts JR, Narasimhan C, Hruz PW, Mitchell GA, Miziorko HM. 3-Hydroxy-3-methylglutaryl-CoA lyase: expression and isolation of the recombinant human enzyme and investigation of a mechanism for regulation of enzyme activity. *J Biol Chem*. 1994;269(27):17841-6. PMID:8027038
6. Hruz PW, Mueckler MM. Cysteine-scanning mutagenesis of transmembrane segment 7 of the GLUT1 glucose transporter. *J Biol Chem*. 1999;274(51):36176-80. PMID:10593902
7. Murata H, Hruz PW, Mueckler M. The mechanism of insulin resistance caused by HIV protease inhibitor therapy. *J Biol Chem*. 2000;275(27):20251-4. doi:10.1074/jbc.C000228200 PMID:10806189
8. Hruz PW, Mueckler MM. Cysteine-scanning mutagenesis of transmembrane segment 11 of the GLUT1 facilitative glucose transporter. *Biochemistry*. 2000;39(31):9367-72. PMID:10924131
9. Hruz PW, Mueckler MM. Structural analysis of the GLUT1 facilitative glucose transporter (review). *Mol Membr Biol*. 2001;18(3):183-93. PMID:11681785
10. Murata H, Hruz PW, Mueckler M. Investigating the cellular targets of HIV protease inhibitors: implications for metabolic disorders and improvements in drug therapy. *Curr Drug Targets Infect Disord*. 2002;2(1):1-8. PMID:12462148
11. Hruz PW, Murata H, Qiu H, Mueckler M. Indinavir induces acute and reversible peripheral insulin resistance in rats. *Diabetes*. 2002;51(4):937-42. PMID:11916910
12. Murata H, Hruz PW, Mueckler M. Indinavir inhibits the glucose transporter isoform Glut4 at physiologic concentrations. *AIDS*. 2002;16(6):859-63. PMID:11919487
13. Koster JC, Remedi MS, Qiu H, Nichols CG, Hruz PW. HIV protease inhibitors acutely impair glucose-stimulated insulin release. *Diabetes*. 2003;52(7):1695-700. PMCID:PMC1403824 PMID:12829635
14. Liao Y, Shikapwashya ON, Shteyer E, Dieckgraefe BK, Hruz PW, Rudnick DA. Delayed hepatocellular mitotic progression and impaired liver regeneration in early growth response-1-deficient mice. *J Biol Chem*. 2004;279(41):43107-16. doi:10.1074/jbc.M407969200 PMID:15265859
15. Shteyer E, Liao Y, Muglia LJ, Hruz PW, Rudnick DA. Disruption of hepatic adipogenesis is associated with impaired liver regeneration in mice. *Hepatology*. 2004;40(6):1322-32. doi:10.1002/hep.20462 PMID:15565660
16. Hertel J, Struthers H, Horj CB, Hruz PW. A structural basis for the acute effects of HIV protease inhibitors on GLUT4 intrinsic activity. *J Biol Chem*. 2004;279(53):55147-52. doi:10.1074/jbc.M410826200 PMCID:PMC1403823 PMID:15496402

17. Yan Q, Hruz PW. Direct comparison of the acute in vivo effects of HIV protease inhibitors on peripheral glucose disposal. *J Acquir Immune Defic Syndr*. 2005;40(4):398-403. PMCID:PMC1360159 PMID:16280693
18. Hruz PW. Molecular Mechanisms for Altered Glucose Homeostasis in HIV Infection. *Am J Infect Dis*. 2006;2(3):187-192. PMCID:PMC1716153 PMID:17186064
19. Turmelle YP, Shikapwashya O, Tu S, Hruz PW, Yan Q, Rudnick DA. Rosiglitazone inhibits mouse liver regeneration. *FASEB J*. 2006;20(14):2609-11. doi:10.1096/fj.06-6511fje PMID:17077279
20. Hruz PW, Yan Q, Struthers H, Jay PY. HIV protease inhibitors that block GLUT4 precipitate acute, decompensated heart failure in a mouse model of dilated cardiomyopathy. *FASEB J*. 2008;22(7):2161-7. doi:10.1096/fj.07-102269 PMID:18256305
21. Hruz PW. HIV protease inhibitors and insulin resistance: lessons from in-vitro, rodent and healthy human volunteer models. *Curr Opin HIV AIDS*. 2008;3(6):660-5. doi:10.1097/COH.0b013e3283139134 PMCID:PMC2680222 PMID:19373039
22. Flint OP, Noor MA, Hruz PW, Hylemon PB, Yarasheski K, Kotler DP, Parker RA, Bellamine A. The role of protease inhibitors in the pathogenesis of HIV-associated lipodystrophy: cellular mechanisms and clinical implications. *Toxicol Pathol*. 2009;37(1):65-77. doi:10.1177/0192623308327119 PMCID:PMC3170409 PMID:19171928
23. Tu P, Bhasin S, Hruz PW, Herbst KL, Castellani LW, Hua N, Hamilton JA, Guo W. Genetic disruption of myostatin reduces the development of proatherogenic dyslipidemia and atherogenic lesions in Ldlr null mice. *Diabetes*. 2009;58(8):1739-48. doi:10.2337/db09-0349 PMCID:PMC2712781 PMID:19509018
24. Guo W, Wong S, Pudney J, Jasuja R, Hua N, Jiang L, Miller A, Hruz PW, Hamilton JA, Bhasin S. Acipimox, an inhibitor of lipolysis, attenuates atherogenesis in LDLR-null mice treated with HIV protease inhibitor ritonavir. *Arterioscler Thromb Vasc Biol*. 2009;29(12):2028-32. doi:10.1161/ATVBAHA.109.191304 PMCID:PMC2783673 PMID:19762785
25. Vyas AK, Koster JC, Tzekov A, Hruz PW. Effects of the HIV protease inhibitor ritonavir on GLUT4 knock-out mice. *J Biol Chem*. 2010;285(47):36395-400. doi:10.1074/jbc.M110.176321 PMCID:PMC2978568 PMID:20864532
26. Gazit V, Weymann A, Hartman E, Finck BN, Hruz PW, Tzekov A, Rudnick DA. Liver regeneration is impaired in lipodystrophic fatty liver dystrophy mice. *Hepatology*. 2010;52(6):2109-17. doi:10.1002/hep.23920 PMCID:PMC2991544 PMID:20967828
27. Hresko RC, Hruz PW. HIV protease inhibitors act as competitive inhibitors of the cytoplasmic glucose binding site of GLUTs with differing affinities for GLUT1 and GLUT4. *PLoS One*. 2011;6(9):e25237. doi:10.1371/journal.pone.0025237 PMCID:PMC3179492 PMID:21966466
28. Vyas AK, Yang KC, Woo D, Tzekov A, Kovacs A, Jay PY, Hruz PW. Exenatide improves glucose homeostasis and prolongs survival in a murine model of dilated cardiomyopathy. *PLoS One*. 2011;6(2):e17178. doi:10.1371/journal.pone.0017178 PMCID:PMC3040766 PMID:21359201
29. Hruz PW, Yan Q, Tsai L, Koster J, Xu L, Cihlar T, Callebaut C. GS-8374, a novel HIV protease inhibitor, does not alter glucose homeostasis in cultured adipocytes or in a healthy-rodent model system. *Antimicrob Agents Chemother*. 2011;55(4):1377-82. doi:10.1128/AAC.01184-10 PMCID:PMC3067185 PMID:21245443
30. Remedi MS, Agapova SE, Vyas AK, Hruz PW, Nichols CG. Acute sulfonylurea therapy at disease onset can cause permanent remission of KATP-induced diabetes. *Diabetes*. 2011;60(10):2515-22. doi:10.2337/db11-0538 PMCID:PMC3178299 PMID:21813803
31. Aerni-Flessner L, Abi-Jaoude M, Koenig A, Payne M, Hruz PW. GLUT4, GLUT1, and GLUT8 are the dominant GLUT transcripts expressed in the murine left ventricle. *Cardiovasc Diabetol*. 2012;11:63. doi:10.1186/1475-2840-11-63 PMCID:PMC3416696 PMID:22681646

32. Vyas AK, Aerni-Flessner LB, Payne MA, Kovacs A, Jay PY, Hruz PW. Saxagliptin Improves Glucose Tolerance but not Survival in a Murine Model of Dilated Cardiomyopathy. *Cardiovasc Endocrinol*. 2012;1(4):74-82. doi:10.1097/XCE.0b013e32835bfb24 PMCID:PMC3686315 PMID:23795310
33. Hresko RC, Kraft TE, Tzekov A, Wildman SA, Hruz PW. Isoform-selective inhibition of facilitative glucose transporters: elucidation of the molecular mechanism of HIV protease inhibitor binding. *J Biol Chem*. 2014;289(23):16100-16113. doi:10.1074/jbc.M113.528430 PMCID:PMC4047383 PMID:24706759
34. Mishra RK, Wei C, Hresko RC, Bajpai R, Heitmeier M, Matulis SM, Nooka AK, Rosen ST, Hruz PW, Schiltz GE, Shanmugam M. In Silico Modeling-based Identification of Glucose Transporter 4 (GLUT4)-selective Inhibitors for Cancer Therapy. *J Biol Chem*. 2015;290(23):14441-53. doi:10.1074/jbc.M114.628826 PMID:25847249
35. Kraft TE, Hresko RC, Hruz PW. Expression, purification, and functional characterization of the insulin-responsive facilitative glucose transporter GLUT4. *Protein Sci*. 2015. doi:10.1002/pro.2812 PMID:26402434
36. Kraft TE, Armstrong C, Heitmeier MR, Odom AR, Hruz PW. The Glucose Transporter PfHT1 Is an Antimalarial Target of the HIV Protease Inhibitor Lopinavir. *Antimicrob Agents Chemother*. 2015;59(10):6203-9. doi:10.1128/AAC.00899-15 PMCID:PMC4576095 PMID:26248369
37. DeBosch BJ, Heitmeier MR, Mayer AL, Higgins CB, Crowley JR, Kraft TE, Chi M, Newberry EP, Chen Z, Finck BN, Davidson NO, Yarasheski KE, Hruz PW, Moley KH. Trehalose inhibits solute carrier 2A (SLC2A) proteins to induce autophagy and prevent hepatic steatosis. *Sci Signal*. 2016;9(416):ra21. doi:10.1126/scisignal.aac5472 PMID:26905426
38. Hresko RC, Kraft TE, Quigley A, Carpenter EP, Hruz PW. Mammalian Glucose Transporter Activity is Dependent upon Anionic and Conical Phospholipids. *J Biol Chem*. 2016. doi:10.1074/jbc.M116.730168 PMID:27302065
39. Kraft TE, Heitmeier MR, Putanko M, Edwards RL, Ilagan MX, Payne MA, Autry JM, Thomas DD, Odom AR, Hruz PW. A Novel Fluorescence Resonance Energy Transfer-Based Screen in High-Throughput Format To Identify Inhibitors of Malarial and Human Glucose Transporters. *Antimicrob Agents Chemother*. 2016;60(12):7407-7414. PMCID:PMC5119023 PMID:27736766
40. Mayer AL, Higgins CB, Heitmeier MR, Kraft TE, Qian X, Crowley JR, Hyrc KL, Beatty WL, Yarasheski KE, Hruz PW, DeBosch BJ. SLC2A8 (GLUT8) is a mammalian trehalose transporter required for trehalose-induced autophagy. *Sci Rep*. 2016;6:38586. PMCID:PMC5138640 PMID:27922102
41. Edwards RL, Brothers RC, Wang X, Maron MI, Ziniel PD, Tsang PS, Kraft TE, Hruz PW, Williamson KC, Dowd CS, John ARO. MEPicides: potent antimalarial prodrugs targeting isoprenoid biosynthesis. *Sci Rep*. 2017;7(1):8400. PMCID:PMC5567135 PMID:28827774
42. Wei C, Bajpai R, Sharma H, Heitmeier M, Jain AD, Matulis SM, Nooka AK, Mishra RK, Hruz PW, Schiltz GE, Shanmugam M. Development of GLUT4-selective antagonists for multiple myeloma therapy. *Eur J Med Chem*. 2017;139:573-586. PMCID:PMC5603412 PMID:28837922
43. Wei C, Heitmeier M, Hruz PW, Shanmugam M. Evaluating the Efficacy of GLUT Inhibitors Using a Seahorse Extracellular Flux Analyzer. *Methods Mol Biol*. 2018;1713:69-75. PMID:29218518
44. Heitmeier MR, Payne MA, Weinheimer C, Kovacs A, Hresko RC, Jay PY, Hruz PW. Metabolic and Cardiac Adaptation to Chronic Pharmacologic Blockade of Facilitative Glucose Transport in Murine Dilated Cardiomyopathy and Myocardial Ischemia. *Sci Rep*. 2018;8(1):6475. PMID:29691457
45. Zhang Y, Higgins CB, Mayer AL, Mysorekar IU, Razani BB, Graham MJ, Hruz PW, DeBosch BJ. TFEB-dependent Induction of Thermogenesis by the Hepatocyte SLC2A Inhibitor Trehalose. *Autophagy*. 2018. PMID:29996716

46. Emfinger CH, Yan Z, Welscher A, Hung P, McAllister W, Hruz PW, Nichols CG, Remedi MS. Contribution of systemic inflammation to permanence of K_{ATP}-induced neonatal diabetes in mice. *Am J Physiol Endocrinol Metab*. 2018;315(6):E1121-E1132. PMCID:PMC6336961 PMID:30226997
47. Heitmeier MR, Hresko RC, Edwards RL, Prinsen MJ, Ilagan MXG, Odom John AR, Hruz PW. Identification of druggable small molecule antagonists of the Plasmodium falciparum hexose transporter PfHT and assessment of ligand access to the glucose permeation pathway via FLAG-mediated protein engineering. *PLoS One*. 2019;14(5):e0216457. PMCID:PMC6508677 PMID:31071153
48. Hruz PW. Deficiencies in Scientific Evidence for Medical Management of Gender Dysphoria. *Linacre Q*. 2020;87(1):34-42. PMCID:PMC7016442 PMID:32431446
49. Zhang Y, Shaikh N, Ferey JL, Wankhade UD, Chintapalli SV, Higgins CB, Crowley JR, Heitmeier MR, Stothard AI, Mihi B, Good M, Higashiyama T, Swarts BM, Hruz PW, Shankar K, Tarr PI, DeBosch BJ. Lactotrehalose, an Analog of Trehalose, Increases Energy Metabolism Without Promoting Clostridioides difficile Infection in Mice. *Gastroenterology*. 2020;158(5):1402-1416.e2. PMCID:PMC7103499 PMID:31838076
50. Malone WJ, Hruz PW, Mason JW, Beck S. Letter to the Editor from William J. Malone: "Proper Care of Transgender and Gender Diverse Persons in the Setting of Proposed Discrimination: A Policy Perspective". *J Clin Endocrinol Metab*. 2021. PMID:33772300
51. McMillin SL, Evans PL, Taylor WM, Weyrauch LA, Sermersheim TJ, Welc SS, Heitmeier MR, Hresko RC, Hruz PW, Koumanov F, Holman GD, Abel ED, Witczak CA. Muscle-Specific Ablation of Glucose Transporter 1 (GLUT1) Does Not Impair Basal or Overload-Stimulated Skeletal Muscle Glucose Uptake. *Biomolecules*. 2022;12(12):1734. PMID: 36551162; PMCID: PMC9776291.

C2. Chapters

1. Henderson KE, Baranski TJ, Bickel PE, Clutter PE, Clutter WE, McGill JB. Endocrine Disorders in HIV/AIDS. In: *The Washington Manual Endocrinology Subspecialty Consult* Philadelphia, PA; 2008:321-328.
2. Paul W Hruz. Medical Approaches to Alleviating Gender Dysphoria In: Edward J Furton, eds. *Transgender Issues in Catholic Health Care* Philadelphia PA; 2021:1-42.
3. Cara Buskmiller and Paul Hruz. A Biological Understanding of Man and Woman In: John Finley, eds. *Sexual Identity: The Harmony of Philosophy, Science, and Revelation* Steubenville OH; 2022:Chapter 2, pp 65-103.

C4. Invited Publications

1. Grunfeld C, Kotler DP, Arnett DK, Falutz JM, Haffner SM, Hruz P, Masur H, Meigs JB, Mulligan K, Reiss P, Samaras K, Working Group 1. Contribution of metabolic and anthropometric abnormalities to cardiovascular disease risk factors. *Circulation*. 2008;118(2):e20-8. PMCID: PMC3170411 PMID: 18566314
2. Hruz PW. HIV protease inhibitors and insulin resistance: lessons from in-vitro, rodent and healthy human volunteer models. *Curr Opin HIV AIDS*. 2008;3(6):660-5. PMCID: PMC2680222 PMID: 19373039
3. Hruz PW. Molecular mechanisms for insulin resistance in treated HIV-infection. *Best Pract Res Clin Endocrinol Metab*. 2011;25(3):459-68. PMCID: PMC3115529 PMID: 21663839
4. Hruz PW. HIV and endocrine disorders. *Endocrinol Metab Clin North Am*. 2014;43(3): xvii–xviii. PMID: 25169571
5. Hruz PW. Commentary. *Clin Chem*. 2015;61(12):1444. PMID: 26614228

6. Hruz PW, Mayer LS, and McHugh PR. Growing Pains: Problems with Pubertal Suppression in Treating Gender Dysphoria *The New Atlantis*. 2017;52:3-36.
7. Hruz, PW. The Use of Cross-Sex Steroids in Treating Gender Dysphoria *Natl Cathol Bioeth Q*. 2018;17(4):1-11.
8. Hruz, PW. Experimental Approaches to Alleviating Gender Dysphoria in Children *Nat Cathol Bioeth Q*. 2019;19(1):89-104.

Expert Witness Testimony

2009 Rosas v. Astrazeneca

2012 O'Connor v. Stamford

2016 Carcaño et al. v. Patrick McCrory (United States District Court, M.D. North Carolina)

2016 Jane Doe v. Board of Education of the Highland School District (United States District Court For the Southern District of Ohio Eastern Division, Case No. 2:16-CV-, 524)

2017 Ward v. Janssen (Circuit Court of St Louis, Division 16, MO, Case No. 1522-CC00213-01)

2017 Adams v. St John's School Board (United States District Court For the Middle District of Florida, FL Civil Action No. 3:17-cv-00739-TJCJBT)

2017 Ashton Whitaker v. Kenosha Unified School District (United States District Court Eastern District of Wisconsin, Civ. Action No. 2:16-cv-00943)

2018 Terri Bruce v. State of South Dakota (The United States District Court District of South Dakota Western Division, Case No. 17-5080)

2019 Cause DF-15-09887-SD of the 255th Judicial Circuit of Dallas County, TX regarding the dispute between J.A. D.Y. and J.U. D.Y., Children

2021 Kadel vs. Falwell (The United States District Court For The Middle District Of North Carolina, Case No.: 1:19-cv-272-LCB-LPA)

2022 Brandt v Rutledge (The United States District Court Eastern District of Arkansas Central Division, Case No. 4:21-CV-00450-JM)

2022 Eknes-Tucker vs Ivey (United States District Court Middle District of Alabama Northern Division, Case 2:22-cv-00184-LCB-SRW)

2022 D.H. et al. v. Snyder (United States District Court For the District Court of Arizona, Case No. 4:20-cv-00335-SHR)

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

AUGUST DEKKER, et al., *Plaintiffs*, v. JASON WEIDA, et al., *Defendants*.	Case No. 4:22-cv-00325-RH-MAF

REBUTTAL EXPERT REPORT OF PAUL W. HRUZ, M.D, Ph.D.

Pursuant to 28 U.S.C. § 1746, I declare:

1. I have been retained by counsel for the Defendants as an expert witness in the above captioned litigation. On February 15, 2023, I submitted an expert report detailing my serious concerns about the safety, efficacy, and scientific validity of the controversial, unproven, and experimental treatment paradigm for the medical management of sex-gender identity discordance. My qualifications, publications, prior expert testimony, and compensation are discussed in that prior report.

2. I have read the declarations of Dr. Antommaria and Dr. Shumer, who are serving as witnesses for Plaintiffs. In these reports, Drs. Antommaria and Shumer make several assertions that are erroneous or highly misleading. This includes inaccurate or incomplete discussion of cited references, omission of key data, and demonstration of bias in the interpretation of published scientific literature in this controversial field of medicine. For several of the references cited in their reports, a summary of major study limitations and weaknesses was contained in my previously filed expert report. I provide here additional scientific evidence and discussion of key assertions made by the Plaintiffs' witnesses. This response is not exhaustive of all of my opinions. I reserve the right to supplement or amend this report based on any new future information that is provided to me.

3. The bases for my opinions expressed in this report are my review of the Antommaria and Shumer reports, my professional experience as a psychiatrist, and

my knowledge of the pertinent scientific literature, including those publications cited in this report.

Declaration of Dr. Shumer

4. Dr. Shumer's discussion of "conversion therapy" efforts in paragraph 28 of his declaration is heavily biased by inaccurate and unsupported claims regarding efforts to address gender dysphoria by means that do not include medical affirmation. Nearly all scientists and clinicians who participate in the care of individuals with gender dysphoria or who seek improved means to alleviate suffering in this patient population agree that coercive means to force an individual to accept their natal sex are unethical. However, a false dichotomy is made in equating medical practices or other efforts to address underlying psychological morbidity as conversion therapy if this results in reintegration of gender identity with biological sex. The major methodological flaws of the 2020 paper Turban et al. cited by Dr. Shumer as support for his claim have been discussed at length in a paper by D'Angelo and colleagues.[1] This includes "the use of a biased data sample, reliance on survey questions with poor validity, and the omission of a key control variable, namely subjects' baseline mental health status." The other report by Campbell et

[1] D'Angelo R, Syrulnik E, Ayad S, Marchiano L, Kenny DT, Clarke P. One Size Does Not Fit All: In Support of Psychotherapy for Gender Dysphoria. Arch Sex Behav. 2021 Jan;50(1):7-16. doi: 10.1007/s10508-020-01844-2.

al.[2] used the same biased data set as the Turban paper and has the same methodological flaws.

5. Dr. Shumer's attempt to establish a biological basis for sex-discordant gender identity by citing literature on brain anatomy, exposure to sex hormones during development, and twin studies fails to acknowledge the limitations of this type of evidence. Each of the studies he cites to support his opinion are insufficient to establish his conclusions, and many lead to questions about alternate hypotheses. In considering this evidence, as with all of the published data in this field, it is essential to distinguish between influencing factors and determining factors. Indeed, the very argument that gender identity can be fluid points strongly against a conclusion of biological determinism.

6. There have been a number of published reports examining brain anatomy and function that have attempted to demonstrate the "born in the wrong body" hypothesis for sex-discordant identity. In my first declaration, I discussed in general the limitations of small sample sizes, wide overlap in measured parameters, and the known phenomenon of neuronal plasticity in objectively assessing these data. Given Dr. Shumer's assertions, it is necessary to consider in greater depth the studies he cites to support his conclusions.

[2] Campbell, Travis and Rodgers, Yana van der Meulen, Conversion Therapy, Suicidality, and Running Away: An Analysis of Transgender Youth in the U.S. (November 15, 2022). Available at SSRN: https://ssrn.com/abstract=4180724 or http://dx.doi.org/10.2139/ssrn.4180724.

7. The 2009 study by Luders[3] compares brain MRI findings among 24 males who identify as women compared to 30 males who identify as men and 30 females who identity as women. The authors' main study result is an observation of "a significantly larger volume of regional gray matter in the right putamen [in males who identify as women] compared to men." Importantly, the authors themselves acknowledge that these data merely show an association, not a causal relationship between this finding and gender identity. They also acknowledge that there are multiple factors including psychosocial and environmental influences that could account for the differences observed.

8. The 2011 study by Rametti et al.[4] similarly compared structural brain differences in 18 females who identified as men compared to 24 males who identified as men and 19 females who identified as women. In general, control males had higher connectivity in specific brain regions than control females. Their primary study finding was that white matter brain connectivity in several of the measured brain regions of female transgender subjects was higher than control females (i.e. closer to the values seen in males). A strength of this study is that it investigated

[3] Luders E, Sánchez FJ, Gaser C, Toga AW, Narr KL, Hamilton LS, Vilain E. Regional gray matter variation in male-to-female transsexualism. Neuroimage. 2009 Jul 15;46(4):904-7. doi: 10.1016/j.neuroimage.2009.03.048

[4] Rametti G, Carrillo B, Gómez-Gil E, Junque C, Segovia S, Gomez Á, Guillamon A. White matter microstructure in female to male transsexuals before cross-sex hormonal treatment. A diffusion tensor imaging study. J Psychiatr Res. 2011 Feb;45(2):199-204. doi: 10.1016/j.jpsychires.2010.05.006.

subjects before exposure to cross-sex hormones. However, the study was cross-sectional and was unable to determine the extent to which neuronal plasticity from effects of social conditioning influenced the results. The study is also is limited by small samples size, preventing generalizability to the current demographic of individuals presenting to gender clinics for affirmative medical interventions.

9. The 2008 study by Berglund et al.[5] reported on measures of brain activation in response to smelling pheromone compounds in 12 males identifying as women. Observed activation of specific brain regions in response to these stimuli were compared to responses in control "heterosexual men" and "heterosexual women". The main study conclusion was that sex-discordant gender identity *may* be *associated* with differences in physiological responses to smells that are intermediate between those observed in males versus females. At best, this study provides preliminary data for hypothesis generation. It is an example of the highly speculative experimental status of research on potential causes of sex-discordant gender identity. It does not provide the level of evidence required to establish the biological basis for this condition that Dr. Shumer claims.

[5] Berglund H, Lindström P, Dhejne-Helmy C, Savic I. Male-to-female transsexuals show sex-atypical hypothalamus activation when smelling odorous steroids. Cereb Cortex. 2008 Aug;18(8):1900-8. doi: 10.1093/cercor/bhm216.

10. The 2011 study by Savic et al.[6] used magnetic resonance imaging (MRI) to compare the brain structures of 24 males identifying as female to 48 "heterosexual males and females". The investigators confirmed previously reported structural differences in the brains of males versus females. Yet they observed that the structures of the transgender subjects aligned with sex not gender identity. While this study is also limited by its small sample size similar to other brain studies, the observed results contradict the hypothesis of Dr. Shumer regarding an established biological basis for sex-discordant gender identity. The authors specifically state that "contrary to the primary hypothesis, no sex-atypical features with signs of 'feminization' were detected in the transsexual group." They conclude: "The present study does not support the dogma that MtF-TR [male to female transsexuals] have atypical sex dimorphism in the brain but confirms the previously reported sex differences in structural volumes, gray, and WM [white matter] fractions."

11. The 2002 study by Chung et al.[7] compares the size differences in an area of the brain previously shown to differ between males and females. Prior reports had shown that the size of this BST (bed nucleus of the stria terminalis) region in autopsy specimens from transgender subjects correlated with the lived

[6] Savic I, Arver S. Sex dimorphism of the brain in male-to-female transsexuals. Cereb Cortex. 2011 Nov;21(11):2525-33. doi: 10.1093/cercor/bhr032.
[7] Chung WC, De Vries GJ, Swaab DF. Sexual differentiation of the bed nucleus of the stria terminalis in humans may extend into adulthood. J Neurosci. 2002 Feb 1;22(3):1027-33. doi: 10.1523/JNEUROSCI.22-03-01027.2002.

gender of the individuals.[8] In addition to the problem of small sample size, there is lack of correlation between those subjects and the current demographic of people with gender dysphoria. The measured study parameter also has wide and overlapping distribution between males and females. In the 2002 Chung study, the authors report that the size of the BST increased with age and only became significantly different in adulthood. While the biological basis for this late developmental change remains speculative, the data suggest that environmental influences may be operative. Dr. Shumer fails to even consider that there exists fluidity in brain development throughout childhood and into early adult life.

12. To illustrate the problems with the above data, it is helpful to consider a more commonly understood physical difference between males and females. It is well established that on average, males are 5 inches taller than females. However, given the variability in heights among males and females with wide overlap in this measured parameter, it is impossible to determine the sex of an individual by measuring their height. Furthermore, the existence of mean differences in stature does not prove that height determines sex. Yet Dr. Shumer's argument about the biological basis of gender identity rests upon a similar logic.

[8] Zhou JN, Hofman MA, Gooren LJ, Swaab DF. A sex difference in the human brain and its relation to transsexuality. Nature. 1995 Nov 2;378(6552):68-70. doi: 10.1038/378068a0.

13. The 2012 study by Hyelens is a review of care reports of concordance or discordance of gender identity disorder among 29 identical (monozygotic) and non-identical (dizygotic) twin pairs. The concordance rate among identical twins was 39%. This means this trait was discordant in nearly two-thirds (61%) of monozygotic twin pairs. While this supports a potential genetic *influence* of gender dysphoria, it clearly demonstrates that this condition is **not** genetically *determined*. If it were, one would have seen 100% concordance among identical twins. The authors of this study acknowledge that the "etiology of GID is a complex process of biopsychosocial components with unexplained interaction." To put this data in proper perspective, there is a 50% concordance of alcoholism among identical twins.[9]

14. The 2005 study by Henningsson et al.[10] reports on DNA sequence variations in sex-steroid related genes among 29 males who identify as women and 29 males who identify as men. The main study conclusion was that differences (polymorphisms) could be found at a higher rate in one of the estrogen receptor genes between the two groups. Setting aside major concerns related to the rigor of

[9] Verhulst B, Neale MC, Kendler KS. The heritability of alcohol use disorders: a meta-analysis of twin and adoption studies. Psychol Med. 2015 Apr;45(5):1061-72. doi: 10.1017/S0033291714002165.

[10] Henningsson S, Westberg L, Nilsson S, Lundström B, Ekselius L, Bodlund O, Lindström E, Hellstrand M, Rosmond R, Eriksson E, Landén M. Sex steroid-related genes and male-to-female transsexualism. Psychoneuroendocrinology. 2005 Aug;30(7):657-64. doi: 10.1016/j.psyneuen.2005.02.006.

their statistical analyses, the authors themselves acknowledge that none of the studied variants can be considered the cause of sex-discordant gender identity. A basis for this limitation is that the genetic variations studies are common in the general population. Small sample size was another major limitation. Furthermore, there are no data on the functional consequences of the observed genetic differences. Thus, to cite this paper as evidence that sex-discordant gender identity is biologically determined is highly misleading and reflects Dr. Shumer's underlying bias in advocating for gender affirming medical interventions.

15. The 2005 study by Dessens et al.[11] reports on the observed frequency of male gender identity in females with congenital adrenal hyperplasia (CAH). In this study, 94.8% of the females were raised as girls and did not experience gender dysphoria. While it is possible that androgen exposure is a contributor to the small increase in the incidence of gender dysphoria in females with CAH compared to the background populations, there are a myriad other psychosocial factors that could be responsible for this effect. This includes differences in sex-stereotyped behavior that is misinterpreted as reflecting gender identity, resulting in gender exploration that might not otherwise be undertaken.

[11] Dessens AB, Slijper FM, Drop SL. Gender dysphoria and gender change in chromosomal females with congenital adrenal hyperplasia. Arch Sex Behav. 2005 Aug;34(4):389-97. doi: 10.1007/s10508-005-4338-5. PMID: 16010462.

16. Taken together, the evidence that Dr. Shumer provides in an attempt to support his assertion for a biological basis for sex-discordant gender identity reinforces the concerns that I raised in my declaration. Specifically, research in this area remains inconclusive with serious methodological limitations. Many alternative hypotheses for the development of this condition remain untested and are not even considered by Dr. Shumer in his declaration. Most glaring is the failure to address prior physical or psychological abuse, autism, and effect of social networking. At best, the existing data suggest that gender dysphoria is contributed to by several different influences that differ in both type and degree among affected individuals. Contributing factors for the current wave of adolescent females presenting with male gender identification without any antecedent gender dysphoria during childhood likely differ substantially from prior cohorts of predominately males presenting with sex-discordant gender identity prior to the onset of puberty.

17. To support Dr. Shumer's assertion that untreated gender dysphoria "can *result* in severe anxiety and depression, eating disorders, substance abuse, self-harm, and suicidality," he cites a 2015 study by Reisner et al.[12] In doing so, he further perpetuates the error of incorrectly making a causal conclusion where only

[12] Reisner SL, Vetters R, Leclerc M, Zaslow S, Wolfrum S, Shumer D, Mimiaga MJ. Mental health of transgender youth in care at an adolescent urban community health center: a matched retrospective cohort study. J Adolesc Health. 2015 Mar;56(3):274-9. doi: 10.1016/j.jadohealth.2014.10.264.

associations are possible. The Reisner study was a retrospective chart review that compared mental health diagnoses in patients listed in the charts as "transgender" in comparison to a sample of patients without sex-gender identity discordance at a Boston community health clinic. From this study, there is no basis to determine whether or not access to gender affirming medical interventions has any influence on adverse mental health.

18. Dr. Shumer attempts to minimize primary fertility concerns of affirmative hormonal interventions that include puberty blockers followed by cross-sex hormones by citing two studies of successful reproduction after receiving gender affirming hormones as adults. The study by Light et al.[13] is a retrospective survey that assessed pregnancy in females who had received testosterone starting at an average age of 25 years. While not directly discussed in the paper, at this age the initiation of testosterone almost certainly occurred after full ovarian maturation. The second reference cited by Dr. Shumer, the 2017 paper by Knudson and De Sutter, is an opinion piece devoid of actual study data. Within the discussion of the paper, the authors acknowledge that "should an adolescent pursue cross-gender hormones after pubertal suppression, it is unlikely that eggs or sperm can be retrieved, and therefore

[13] Light AD, Obedin-Maliver J, Sevelius JM, Kerns JL. Transgender men who experienced pregnancy after female-to-male gender transitioning. Obstet Gynecol. 2014 Dec;124(6):1120-1127. doi: 10.1097/AOG.0000000000000540.

conversations about fertility are being held with families of adolescents who are younger and younger."

19. In paragraph 84 of Dr. Shumer's report, he attempts to equate the relative risk versus benefit of sex-steroid hormones for adolescents with sex-discordant gender identity to that of giving these hormones to adolescents with hypogonadism, Turner Syndrome, Klinefelter Syndrome, premature ovarian failure, and disorders of sex development. The falsehoods of this claim include differences in sex-concordant versus sex-discordant hormonal effects and baseline differences in fertility. As discussed in my original declaration (¶ 47), due to systemic epigenetic differences between males and females, there are major sex-related differences in cellular responses to estrogen and testosterone. In contrast to individuals with sex-discordant gender identity who have normally formed and functioning sexual organs prior to the initiation of gender affirming medical interventions, for each of the above conditions, baseline fertility is absent or significantly reduced.

Declaration by Dr. Antommaria

20. Dr. Antommaria asserts that reliance on low quality evidence to recommend gender affirming medical interventions for adolescents who experience gender dysphoria is justified by comparison to other clinical practice guidelines issued by the Endocrine Society (Obesity and Congenital Adrenal Hyperplasia). In doing so, he fails to address fundamental differences in potential risk versus

purported benefit in these different conditions. The three recommendations in the Gender Dysphoria guidelines supported by moderate level evidence refer to the need to make an accurate diagnosis, the need to address medical conditions that could be exacerbated by hormonal treatment, and the need for fertility preservation efforts. In the Obesity Guidelines listed in Exhibit C, Table 1 of Dr. Antommaria's report, strong recommendations made with weak evidence is generally in reference to interventions such as reducing screen time, getting more exercise, or changing diet. The potential risks of these interventions are vastly different than recommendations for initiation of pubertal blockade with a GnRH analog or referral for gender affirming surgery, where interventions may permanently alter fertility, or increase the risk of serious morbidities (e.g. osteopenia, obesity, stroke, heart disease). All treatment recommendations in clinical practice guidelines require consideration of relative risk versus relative benefit. The greater the risk, the greater the need for higher quality evidence of proportionate benefit.

21. Contrary to the assertion of Dr. Antommaria, clinical equipoise does indeed exist in the field of transgender medicine. As summarized in my detailed critique of several published papers frequently used to justify gender affirming medical interventions in my first declaration for this case, there is a failure to assess whether any perceived benefit was due to psychological interventions independent of hormones, surgery, or other interventions. Given the low quality of scientific

evidence currently available regarding the relative risk versus benefit of gender affirming medical interventions, existing evidence that suicidality remains markedly elevated after engaging in this therapeutic approach, and a general failure to directly test the benefits of psychological intervention to alleviate suffering in people who experience sex-discordant gender identity, there is an ethical imperative to conduct clinical trials to assess the validity of alternate hypotheses for effective treatment.

22. Dr. Antommaria's dismissal of randomized controlled trials rests upon an erroneous portrayal of clinical trial design. While it may be true that potential research subjects would reject enrollment in a trial comparing affirmative care with no care, proper discussion of the inherent risk of gender affirming interventions, the lack of data showing long term resolution of suicidal ideation, and the goal of alleviating dysphoria through alternate means can provide reasonable expectation of enrolling a sufficient number of study subjects. There is no need to require such a study to be blinded. Both treatment arms would be identical except for the independent variable being tested. As in all clinical trials, close safety monitoring can and should occur. It is important to note that among the type of research that Dr. Antommaria asserts is ethical, adverse events can and do occur. For example, in the recently published study by Chen reporting on 2-year follow-up data from a

longitudinal study of adolescents with sex-discordant gender identity, two of the 315 study subjects committed suicide while enrolled in the study.[14]

23. In paragraphs 32 and 33 of his declaration, Dr. Antommaria asserts that the affirmative model for treating gender dysphoria is not experimental in nature. This claim is at odds with the official statement of the National Board of Health and Welfare in Sweden. In their "Updated recommendations for hormone therapy for gender dysphoria in young people" published on 02-22-2022, [15] the board concluded that "the risks of anti-pubertal and sex reassuring hormone therapy for those under 18 years of age currently outweigh the potential benefits for the group as a whole," and that hormone treatment should continue only *in the context of research*. Board spokesman Thomas Lindén stated "more knowledge is needed about the impact of treatments on gender dysphoria and the mental health and quality of life of minors, both in the short and long term."

24. Contrary to the apparent claim of Dr. Antommaria in paragraph 30 of his declaration that there is professional consensus on the best approach to managing gender dysphoria, growing concerns about the medical affirmation model for treating gender dysphoria have arisen among several international organizations and

[14] Chen D, Berona J, Chan YM, Ehrensaft D, Garofalo R, Hidalgo MA, Rosenthal SM, Tishelman AC, Olson-Kennedy J. Psychosocial Functioning in Transgender Youth after 2 Years of Hormones. N Engl J Med. 2023 Jan 19;388(3):240-250. doi: 10.1056/NEJMoa2206297.
[15] https://www.socialstyrelsen.se/om-socialstyrelsen/pressrum/press/uppdaterade-rekommendationer-for-hormonbehandling-vid-konsdysfori-hos-unga/.

healthcare professionals. I discussed many of these concerns in paragraphs 123 through 126 of my first declaration. Recently, these concerns were summarized in an article published in the highly respected BMJ, titled "Gender dysphoria in young people is rising-and so is professional disagreement."[16] In this article, Gordon Guyatt, distinguished professor in the Department of Health Research Methods, Evidence, and Impact at McMaster University, Ontario and co-founder of the GRADE system is quoted on his concern about making strong recommendations with low or very low quality evidence.

25. Dr. Antommaria's discussion of the ability of adolescents to provide informed consent fails to acknowledge the complexity of developmental processes that significantly impact decision making ability in gender dysphoric youth.[17] Contrary to his portrayal, there remains a lack of consensus among healthcare professionals as to whether and to what degree adolescents are capable of providing informed consent. Concerns are magnified by the co-occurrence of psychological distress, peer influences, and motivations of the affected adolescent.

26. In summary, contrary to the biased and inaccurate conclusions of Drs. Shumer and Antommaria as conveyed in their reports, serious questions

[16] Block J. Gender dysphoria in young people is rising-and so is professional disagreement. BMJ. 2023 Feb 23;380:p382. doi: 10.1136/bmj.p382.
[17] See Grootens-Wiegers P, Hein IM, van den Broek JM, de Vries MC. Medical decision-making in children and adolescents: developmental and neuroscientific aspects. BMC Pediatr. 2017 May 8;17(1):120. doi: 10.1186/s12887-017-0869-x.

remain regarding the best approach to care for individuals who express an understanding of their gender identity that is discordant with their biological sex to alleviate dysphoria and associated psychological morbidity.

I declare, pursuant to 28 U.S.C. § 1746, under penalty of perjury that the foregoing is true and correct.

Executed on March 10, 2023.

/s/ Paul W. Hruz

Paul W. Hruz, M.D., Ph.D.

REFERENCES

Berglund H, Lindström P, Dhejne-Helmy C, Savic I. Male-to-female transsexuals show sex-atypical hypothalamus activation when smelling odorous steroids. Cereb Cortex. 2008 Aug;18(8):1900-8. doi: 10.1093/cercor/bhm216.

Block J. Gender dysphoria in young people is rising-and so is professional disagreement. BMJ. 2023 Feb 23;380:p382. doi: 10.1136/bmj.p382

Campbell, Travis and Rodgers, Yana van der Meulen, Conversion Therapy, Suicidality, and Running Away: An Analysis of Transgender Youth in the U.S. (November 15, 2022). Available at SSRN: https://ssrn.com/abstract=4180724 or http://dx.doi.org/10.2139/ssrn.4180724

Chen D, Berona J, Chan YM, Ehrensaft D, Garofalo R, Hidalgo MA, Rosenthal SM, Tishelman AC, Olson-Kennedy J. Psychosocial Functioning in Transgender Youth after 2 Years of Hormones. N Engl J Med. 2023 Jan 19;388(3):240-250. doi: 10.1056/NEJMoa2206297.

Chung WC, De Vries GJ, Swaab DF. Sexual differentiation of the bed nucleus of the stria terminalis in humans may extend into adulthood. J Neurosci. 2002 Feb 1;22(3):1027-33. doi: 10.1523/JNEUROSCI.22-03-01027.2002.

D'Angelo R, Syrulnik E, Ayad S, Marchiano L, Kenny DT, Clarke P. One Size Does Not Fit All: In Support of Psychotherapy for Gender Dysphoria. Arch Sex Behav. 2021 Jan;50(1):7-16. doi: 10.1007/s10508-020-01844-2.

Dessens AB, Slijper FM, Drop SL. Gender dysphoria and gender change in chromosomal females with congenital adrenal hyperplasia. Arch Sex Behav. 2005 Aug;34(4):389-97. doi: 10.1007/s10508-005-4338-5. PMID: 16010462.

Grootens-Wiegers P, Hein IM, van den Broek JM, de Vries MC. Medical decision-making in children and adolescents: developmental and neuroscientific aspects. BMC Pediatr. 2017 May 8;17(1):120. doi: 10.1186/s12887-017-0869-x.

Henningsson S, Westberg L, Nilsson S, Lundström B, Ekselius L, Bodlund O, Lindström E, Hellstrand M, Rosmond R, Eriksson E, Landén M. Sex steroid-related genes and male-to-female transsexualism.

Light AD, Obedin-Maliver J, Sevelius JM, Kerns JL. Transgender men who experienced pregnancy after female-to-male gender transitioning. Obstet Gynecol. 2014 Dec;124(6):1120-1127. doi: 10.1097/AOG.0000000000000540.

Luders E, Sánchez FJ, Gaser C, Toga AW, Narr KL, Hamilton LS, Vilain E. Regional gray matter variation in male-to-female transsexualism. Neuroimage. 2009 Jul 15;46(4):904-7. doi: 10.1016/j.neuroimage.2009.03.048

Psychoneuroendocrinology. 2005 Aug;30(7):657-64. doi: 10.1016/j.psyneuen.2005.02.006.

Rametti G, Carrillo B, Gómez-Gil E, Junque C, Segovia S, Gomez Á, Guillamon A. White matter microstructure in female to male transsexuals before cross-sex hormonal treatment. A diffusion tensor imaging study. J Psychiatr Res. 2011 Feb;45(2):199-204. doi: 10.1016/j.jpsychires.2010.05.006.

Reisner SL, Vetters R, Leclerc M, Zaslow S, Wolfrum S, Shumer D, Mimiaga MJ. Mental health of transgender youth in care at an adolescent urban community health center: a matched retrospective cohort study. J Adolesc Health. 2015 Mar;56(3):274-9. doi: 10.1016/j.jadohealth.2014.10.264.

Savic I, Arver S. Sex dimorphism of the brain in male-to-female transsexuals. Cereb Cortex. 2011 Nov;21(11):2525-33. doi: 10.1093/cercor/bhr032.

National Board of Health and Welfare, Updated recommendations for hormone therapy for gender dysphoria in young people (Feb. 2, 2022), available at https://www.socialstyrelsen.se/om-socialstyrelsen/pressrum/press/uppdaterade-rekommendationer-for-hormonbehandling-vid-konsdysfori-hos-unga/.

Verhulst B, Neale MC, Kendler KS. The heritability of alcohol use disorders: a meta-analysis of twin and adoption studies. Psychol Med. 2015 Apr;45(5):1061-72. doi: 10.1017/S0033291714002165.

Zhou JN, Hofman MA, Gooren LJ, Swaab DF. A sex difference in the human brain and its relation to transsexuality. Nature. 1995 Nov 2;378(6552):68-70. doi: 10.1038/378068a0.

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

MAXWELL KADEL, et al.	)	
	)	
Plaintiffs	)	
	)	Cause No.
vs.	)	1:19-cv-00272-
	)	LCB-LPA
DALE FOLWELL, et al.	)	
	)	
Defendants	)	

VIDEO ZOOM DEPOSITION OF DR. PAUL W. HRUZ

Taken on behalf of the Plaintiffs

September 29, 2021

Sheryl A. Pautler, RPR,
MO-CCR 871, IL-CSR 084-004585

(The proceedings began at 9:31 a.m. Eastern.)

QUESTIONS BY: PAGE
Mr. Gonzalez-Pagan 8
Mr. Knepper 269
Mr. Gonzalez-Pagan 295

INDEX OF EXHIBITS

NO.		PAGE MKD.
Exhibit 1	(Expert report.)	11
Exhibit 2	(November 26, 2017, transcript.)	13
Exhibit 3	(July 16, 2018, transcript.)	15
Exhibit 4	(Publication of the National Catholic Bioethics Center.)	51
Exhibit 5	(Endocrine Society guidelines.)	86
Exhibit 6	(Press release.)	95
Exhibit 7	(Thomas Insel statement.)	115
Exhibit 8	(Article on adolescent health medicine and therapeutics.)	122
Exhibit 9	(Adolescent Health, Medicine Therapeutics article.)	123
Exhibit 10	(APA Official Actions.)	167
Exhibit 11	(Resolution by the American Psychological Association.)	168
Exhibit 12	(Understanding the Well Being of LGBTQI Plus Population.)	170
Exhibit 13	(Medical Treatment Methods for Dysphoria Related to Gender Variance in Minors.)	196

INDEX OF EXHIBITS CONTINUED

NO.		PAGE MKD.
Exhibit 14	(November 18, 1994, Food and Drug Administration notice.)	212
Exhibit 15	(Understanding and Approved Use of Approved Drugs Off-Label.)	214
Exhibit 16	(Off-Label, Investigational Use of Marketed Drugs, Biologics and Medical Devices.)	215
Exhibit 17	(Off-Label Use of Drugs in Children.)	217
Exhibit 18	(2019 Journal of the Endocrine Society article.)	230
Exhibit 19	(Declaration of Norm Spack in the Adams case.)	248
Exhibit 20	(The use of Cross-Sex Steroids in the Treatment of Gender Dysphoria article.)	255
Exhibit 21	(Doe v. Boyertown Area School District amicus brief.)	266
Exhibit 22	(Hisle-Gorman article.)	270
Exhibit 23	(2019 Goddings article)	288

(Exhibits attached to transcritp.)

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

MAXWELL KADEL, et al.	)	
	)	
Plaintiffs	)	
	)	Cause No.
vs.	)	1:19-cv-00272-
	)	LCB-LPA
DALE FOLWELL, et al.	)	
	)	
Defendants	)	

VIDEO ZOOM DEPOSITION OF WITNESS, DR. PAUL W. HRUZ, produced, sworn, and examined on the 29th day of September, 2021, between the hours of nine o'clock in the forenoon and eight o'clock in the afternoon of that day, via Veritext Zoom, before SHERYL A. PAUTLER, RPR, Certified Shorthand Reporter within and for the State of Illinois and Certified Court Reporter within and for the State of Missouri, in a certain cause now pending before the United States District Court for the Middle District of North Carolina, wherein MAXWELL KADEL, et al. are the Plaintiffs, and DALE FOLWELL, et al. are the Defendants.

A P P E A R A N C E S

For the Plaintiffs via Zoom:

Mr. Omar Gonzalez-Pagan
Ms. Tara Borelli
Lambda Legal Defense and
Education Fund, Inc.
120 Wall Street, 19th Floor
New York, New York 10005
212-809-0055
Ogonzalez-pagan@lambdalegal.orb

For the Defendants Dale Folwell, Dee Jones and North Carolina State Health Plan for Teachers and State Employees via Zoom:

Mr. John G. Knepper
Law Office of John G. Knepper
1720 Carey Avenue, Suite 590
Cheyenne, Wyoming 82002
307-632-2842
John@knepperllc.com

For the Defendant State of North Carolina Department of Public Safety via Zoom:

Mr. Alan D. McInnes
N.C. Department of Justice
114 West Edenton Street
Raleigh, North Carolina 27603
919-716-6529
Amcinnes@ncdoj.com

The Court Reporter:

Ms. Sheryl Pautler
Veritext Legal Solutions
701 Market Street, Suite 310
St. Louis, Missouri 63101
314-241-6750

Q. Okay. What is a wet lab?

A. A wet lab is really designating somebody that does hands-on research usually with either in-vitro or in-vivo studies, as opposed to a dry lab which mostly does literature searches or computer programming or things that do not involve experimentation with -- the reason the term comes, from wet reagents like buffers and solutions and bodily fluids.

Q. Is your research primarily conducted in a wet lab?

A. My -- until recently the vast majority of my research has been conducted in a wet lab. I have participated on a few occasions in clinical trials and have served as an adviser and consultant for colleagues in those types of studies.

Q. On how many occasions have you participated in clinical trials?

A. I never direct -- well, there was one trial at Washington University where I was more directly involved. But all of -- as far as principal investigator, all of my NIH funded research and service as a principal investigator has been done with my basic science research.

Q. Would you agree that clinical trials is

not your area of expertise?

MR. KNEPPER: Objection, form.

A. I would not agree with that statement. I would say that I -- in the course of the last decade that -- as I've been required to investigate the literature surrounding this particular issue of treatment of gender dysphoria, I have developed considerable expertise in clinical trials. And I also have previously served on institutional review boards. I did that while I was a medical student, where I reviewed the ethics of clinical trials and -- and in other ways as well. So I would say that covers my -- is included in my expertise as a physician scientist.

Q. (By Mr. Gonzalez-Pagan) Earlier you stated that the testimony you provided in the Bruce deposition was truthful; is that right?

A. To the best of my knowledge.

Q. In the Bruce deposition, you were asked: So clinical trials is in your area of expertise?

And you answered: That is correct.

MR. KNEPPER: Objection, form.

A. Can you please read that statement again? And it might even be helpful if we went to the area of that deposition so I can see the entire context.

But for now maybe you can just reread that just so I understand what that statement said.

Q. (By Mr. Gonzalez-Pagan) Well, let's -- my computer is not going to survive today. I apologize. It's on Page 39 of Exhibit 3.

A. Is there an easy way to navigate directly to a page without just scrolling down?

Q. Unfortunately I don't believe so. It's limitation of the medium. I apologize for that.

MR. KNEPPER: I will confirm that. Yeah. I haven't found one either.

A. Okay. So which line are you -- I'm on Page 39 right now.

Q. (By Mr. Gonzalez-Pagan) All right. So on line -- beginning on Line 23.

A. Okay.

Q. It says, Question: I see. So clinical trials isn't your area of expertise?

Answer: That is correct.

Did I read that correctly?

A. Well, if you read the preceding lines, it immediately followed a question about my direct participation in clinical trials where I clearly stated that there was only one clinical trial. That was the one I just mentioned to you at Washington

University. And similar to what I had in this deposition, my role in that project was relatively minor.

So in that sense, that does not mean that I do not have knowledge and experience in the context of clinical trials. It only means I have not directly participated in those clinical trials. Context is important.

Q. What is primary research?

A. I'm sorry. Primary research?

Q. Yeah.

A. Oh, so you're -- you're talking about the difference between conducting experimental -- directly conducting experiments versus systematic reviews and literature reviews of that nature. Is that the distinction you're trying to get at?

Q. Is that what you understand the distinction between primary and secondary research to be?

MR. KNEPPER: Objection, form.

A. That would be one definition that I would agree with, yes.

Q. (By Mr. Gonzalez-Pagan) Okay. Would it be okay if I were to adopt that definition, that primary research refers to conducting experiments --

experiments, etc. and not literature review or metanalysis of existing data?

A. For the purposes of this deposition, yes, that is fine.

Q. With that understanding, have you conducted any primary research relating to gender dysphoria?

MR. KNEPPER: Objection, form.

A. So if you're asking whether I have directly participated in clinical trials on gender dysphoria, the answer is no.

Q. (By Mr. Gonzalez-Pagan) Have you participated in cross-sectional studies related to gender dysphoria?

A. Again, I have not -- cross-sectional studies, you're meaning retrospective reviews?

Q. It could be longitudinal observational. It could be cohort studies. I guess my question is -- let me back up. Have you conducted any direct research relating to gender dysphoria that is not based on a literature review?

MR. KNEPPER: Objection, form.

A. It would depend on what your definition of conduct. I have not physically myself done those chart reviews or participated in the clinical

setting. My experience to what you had described as primary research is limited to my role as associate or assistant fellowship program director in supervising my fellows, two of whom are doing what we would -- what you would define as primary research.

I'm not the primary investigator, but I do have a role in directing my fellows in doing that research to make sure it's of the highest quality and standards that we expect of all of our fellows.

Q. (By Mr. Gonzalez-Pagan) When did you resume supervision of the fellowship program?

A. The official designation has happened since the time I filed my initial curriculum vitae. However, I have continually throughout my career been involved in the fellowship program.

One of the reasons I was reappointed as the assistant program director was that it was recognized that the area of scholarly research needed somebody with my background to be able to help the fellows to be able to select projects, select mentors and conduct research in the most rigorous manner. And that was a shortcoming that had developed since I had formally stepped away from

A. Okay.

Q. Well, actually, let me -- let me check. We've been going about an hour. Would you like to take a break right now or I can do this line of questioning? And we can --

A. I'm actually doing quite well. I'd be fine to keep pressing on.

MR. GONZALEZ-PAGAN: Sheryl, is that okay?

THE COURT REPORTER: That's fine.

Q. (By Mr. Gonzalez-Pagan) Okay. So if we go to the list of publications in your CV. Are you with me?

A. I am.

Q. In the category of journal articles, No. 48 is titled Deficiencies in Scientific Evidence for Medical Management of Gender Dysphoria. Did I read that correctly?

A. Yes. And I do see it here.

Q. Is that one of your publications relating to gender dysphoria?

A. Yes, it is. And it's probably one of the most highly cited of the papers that I provided.

Q. Sure. Is that a publication based on any primary research that you conducted?

MR. KNEPPER: Objection, form.

A. As which have defined it, no. It's a review of the literature and critical appraisal of the evidence.

Q. (By Mr. Gonzalez-Pagan) And that publication is -- that -- sorry. That -- that article was published in the Linacre Quarterly; is that right?

A. That is correct.

Q. Is the Linacre Quarterly a scientific publication?

A. It is an ethics journal. In fact, it's the longest standing continuously published ethics journal in the United States.

Q. Who publishes the Linacre Quarterly?

A. The NCBC.

Q. What does the NCBC stand for?

A. The National Catholic Bioethics Center.

Q. Turn to 50. Is this one of the other publications you have relating to gender dysphoria?

A. It's a letter to the editor.

Q. So it's not -- this is not a publication based on any primary research or scientific study you have conducted?

MR. KNEPPER: Objection, form.

A. As we have defined primary research, it is

merely a presentation of -- of concerns about the literature that has already been published.

Q. (By Mr. Gonzalez-Pagan) And as I understand this letter to the editor is a commentary on another publication, on another article; is that right?

MR. KNEPPER: Objection, form.

A. It includes more information than just the article itself. But, yes.

Q. (By Mr. Gonzalez-Pagan) And just pure curiosity, I don't know the answer to this, but are letters to the editor peer reviewed?

A. This particular one was. I recall when we were submitting this, that we were asked to make changes. And I interpret that as being peer reviewed.

Q. Well, I just want to clarify. There's peer review and then there's editorial review; is that right?

MR. KNEPPER: Objection, form.

A. There are numbers of different types of review; that's correct.

Q. (By Mr. Gonzalez-Pagan) Okay. As I understand peer review to mean, it is a process of objecting and circulating an author's work to the

scrutiny of others who are experts in the same field; is that right?

MR. KNEPPER: Objection.

A. That's how it's generally defined yes.

Q. Are you saying that the letter to the editor was circulated to experts in the field before it was published?

A. I don't know the details of how the letter was handled. I only can say that when we submitted it, we were asked to make revisions. It was reviewed by individuals with understanding of the area that was covered. I don't know any more details. And that's the way generally peer review occurs. One is not usually told who actually reviews the submission.

Q. The next publication, it's -- it's No. 2 under book chapter. It's titled Medical Approaches to Alleviating Gender Dysphoria. And it's a chapter in the book Transgender Issues in Catholic Healthcare; is that right?

A. That is correct.

Q. Who publishes the book, Transgender Issues in Catholic Healthcare?

A. That was also the NCBC.

Q. Is the book a peer-reviewed publication?

A. No.

Q. Going to the next page, there's a list of invited publications; is that right?

A. Yes.

Q. No. 6 is your article titled Growing Pains, Problems With Pubertal Supression in Treating Gender Dysphoria.

Did I read that correctly?

A. Yes, you did read it correctly.

Q. Is this a peer-reviewed publication?

A. It is not peer reviewed. It was editorially reviewed.

Q. The growing pains article was published in the New Atlantis; is that right?

A. That is correct.

Q. Is the New Atlantis a scientific journal?

A. It is not considered a scientific journal in the definition that we normally designate it. It was -- it's a journal that provides more broad readership to be able to distill topics of relevance at an understandable level to the lay public.

Q. At the time of the publication of the article, who published the New Atlantis?

A. Well, the New Atlantis.

Q. Was the new Atlantis a publication of the

ethics and public policy center?

MR. KNEPPER: Objection, form.

A. I believe that may be true. I didn't pay much attention to that.

Q. (By Mr. Gonzalez-Pagan) Let's turn to Exhibit No. 3, Page 44 -- sorry -- Page 46.

A. I went too far.

Q. You know what, it could probably be me. It's a few later. It's Page 49. I do apologize. Page 49.

A. I'm still scrolling, so. Okay. I'm there.

Q. Okay. Beginning on Line 13, it reads; Question: Okay. And the New Atlantis was founded by the Ethics and Public Policy Center; is that right?

Answer: I believe that that is correct.

Question: Okay. And that's a center dedicated to applying the Judeo-Christian moral tradition to critical issues of public policy; is that your understanding?

Answer: I believe that question came up at the last deposition. And I believe that that's an accurate statement.

Did I read that correctly?

A. You did read it correctly, yes.

Q. And you stand by that testimony?

A. Yes. I have no reason -- it's not something that I consider all that important. And I don't usually retain that. I've got so many other pieces of information for me to retain. But, yes.

Q. Going back to your CV, under invited publications.

A. I'm there.

Q. Okay. The next publication is an article titled The Use of Cross-Sex Steroids in Treating Gender Dysphoria; is that right?

A. That is correct.

Q. It was published in the National Catholic Bioethics Quarterly; is that right?

A. That is correct.

Q. Is this article, The Use of Cross-Sex Steroids, a peer-reviewed publication?

A. No, it is not.

Q. Is the National Catholic Bioethics Quarterly a peer-reviewed journal?

A. No.

Q. Is the National Catholic Bioethics Quarterly a scientific journal?

A. No. It is an ethics journal.

Q. All right. And the next publication, 8, under publications in your CV is Experimental Approaches to Alleviating Gender Dysphoria in Children; is that right?

A. Yes.

Q. And this is another one of your publications that relates to gender dysphoria?

A. Yes.

Q. Is this a peer-reviewed article?

A. It is published in the same journal as No. 7. And it is not a peer-reviewed journal.

Q. Okay. Do you have any other publications besides the ones that we just went through that relate to gender dysphoria?

MR. KNEPPER: Objection, form.

A. So there are -- I have no publications that have been added since the time I submitted this CV and it reflects my publications to date.

Q. (By Mr. Gonzalez-Pagan) Do you have any other publications besides the ones that we've discussed today relating to transgender people?

A. Not that I recall.

MR. GONZALEZ-PAGAN: All right. I actually do need to break. So if we can go off

scientific understanding of this condition. To my understanding, the transition from this definition as gender identity disorder to gender dysphoria was not based upon new scientific information.

It was more of a desire to alleviate the discomfort that one has in that label. So how we classify that really rests on the premises that one has about the underlying etiology. And I think that there are -- are more than one valid hypothesis or I should say premises that can be put forward, not necessarily all of equal weight.

Q. (By Mr. Gonzalez-Pagan) Okay. But what is your understanding of the condition of gender incongruent?

MR. KNEPPER: Objection, form, scope.

A. It's a very broad question. Could you narrow it down a little bit?

MR. GONZALEZ-PAGAN: John, what's the objection of the scope? I thought Dr. Hruz is here to testify about gender-affirming treatment for the condition of gender dysphoria and gender incongruent.

MR. KNEPPER: Hold on, Omar. You're free to ask the questions. I think the question I'm trying to understand is: Are you trying to ask

him to testify about -- as a psychiatrist or a psychologist? And it's not clear to me, you know, what the definition of gender incongruence -- are you -- it's not clear to me when you use that term, are you trying to say it's the ICD-11 definition or are you using something else?

I'm happy -- happy to let you continue to pursue this. I'm just as interested as you are. But I want to make sure that as you go through this, we don't end up -- we don't end up down a path where you're trying to say, now, ah-ha, he's coming here pretending to be a psychologist which is outside the scope of what he said he's going to testify to.

MR. GONZALEZ-PAGAN: Well, I mean, we have a 90-page report that I'm happy to go through.

MR. KNEPPER: Please do.

Q. (By Mr. Gonzalez-Pagan) Dr. Hruz, in your report, you state a number of opinions about the validity of the diagnosis of gender dysphoria contained within the DSM; is that right?

MR. KNEPPER: Objection, form.

A. I would be much more comfortable looking at the specific areas that you're referring to.

Because I present many things in my report as hypotheses. And without making definitive statements. So it would be most helpful if we can look at specific areas that you're referring to.

Q. (By Mr. Gonzalez-Pagan) Okay. So I guess what I'm curious about is, do you have a particular as a physician scientist, do you have a particular belief as to whether gender dysphoria is a disorder?

A. I have multiple scientific premises that I have and continue to consider. Again not of equal weight or validity. One of those premises is that this condition arises from a disconnect between neuronal biology and the bodily from -- sex -- bodily form of the body.

Another scientific premise is that this condition is due to the number of environmental, social, hormonal and neuronal components. So how we understand this condition is markedly influenced by the premise that we come to address the hypotheses that we're going to need to consider to develop clinical trials to establish safety and efficacy of treatment that provides the greatest benefit to the affected patients.

Q. Would you agree there are transgender people in this world?

A. Again, we have to be very careful about the terminology that we're using, to acknowledge that the condition of sex discordant gender identity, and there are individuals that -- that express an identity that is not in agreement with their biology is a true statement. That's undeniable that these -- there are individuals that have this experience of discordance between their gender identity and their sex.

Q. Do you believe that the experience of discordance between their identity and what you term their biology, is a disorder?

MR. KNEPPER: Objection, form.

A. So, again, it depends on what premise you're operating under. As far as whether this is a normal experience of -- of a human condition or whether it falls outside of -- of the norm for us as sexed beings. And, again, as a physician scientist I'm obligated to be able to consider all possibilities to be able to do the proper science to get at the ultimate question here as to what we can do to alleviate the suffering.

Q. (By Mr. Gonzalez-Pagan) Dr. Hruz, I guess I'm a little confused as to what it is that is your opinion here. Can you briefly summarize for me what

more cautious approach by the recognition that the studies that have been done up to this point in time do not give us an answer as to whether this is the best or the only course of intervention to alleviate that suffering. Is that -- is that what you're looking for?

Q. Thank you. I appreciate that. In your -- as part of your opinions, do you provide -- let me back up.

Do you express an opinion as to which modality of care should be provided to people diagnosed with gender dysphoria?

A. I believe that it's an ongoing scientific question about what the most efficacious approach is to provide the greatest benefit with the least amount of risk. And that is why I'm participating as an expert witness in this case, to bring to light for the benefit of the court that this is something that needs to be very much investigated to be able to get an answer to that question.

Q. Do you express an opinion as to which modality of care should be provided to people experiencing gender dysphoria?

MR. KNEPPER: Objection, form.

A. I would say because it's an unsettled

scientific question, that I don't have a firm opinion as to which is the best approach. Yet as time has gone on, more and more information is being generated that calls into question the affirmation-only approach.

Q. (By Mr. Gonzalez-Pagan) And I don't want -- what I'm trying to do is get clarity here. So would it be fair to say that you do not provide an opinion as to which modality of care should be provided for people experiencing gender dysphoria?

MR. KNEPPER: Objection, form.

A. My opinion is that based upon the lack of evidence for the gender -- gender-affirmation approach, that if we are going to provide interventions for this population that it is best done under a carefully controlled clinical experimental setting.

Q. (By Mr. Gonzalez-Pagan) You express that there are ongoing questions as to the efficacy of the gender-affirmation approach; is that right?

A. That is correct.

Q. Again for clarity's sake, are you -- you're not expressing an opinion with -- with medical certainty as to whether the gender-affirmation approach is effective or not; is

anxiety?

A. I would say that the answer is yes.

Q. So for people who experience gender dysphoria and do not have any other co-morbidity, what would you do to address their gender dysphoria while the clinical trials are being conducted?

MR. KNEPPER: Objection, form.

A. That's a broad question. And it depends upon the individual characteristics of the patient, including their age and including all of the other factors that are associated with that gender dysphoria. Was it a child who is prepubertal? Is it a child who is an adolescent? Is it an adult? Is it a child or an adult that, you know, all of the social situations or circumstances that they're involved in?

Again, without having a formal diagnosis of depression or anxiety or these other co-morbidities, all of that is going to impact how one approaches that particular patient.

Q. (By Mr. Gonzalez-Pagan) I guess here we're talking about this case, you said it's a provision of coverage for treatment for gender dysphoria; is that right?

A. That is the nature of this case, correct.

had a new chairman that came on board from the one that recruited me to that position. We disagreed in more than one area.

There was also my research program had been rapidly expanding and was getting into the area of drug development. I would say that the role of chief of any division is a thankless job. It requires a tremendous amount of time and effort. And so, you know, the decision to -- to step down from that position was actually very advantageous to my further career development. But, you know, it was one of the -- the gender center was one among many disagreements that I had at that time.

Q. Does the Washington University Transgender Center offer pediatric and adolescent gender-affirming care?

A. Yes. In the definition that we're talking about here meaning the GnRH agonist or puberty blockers, cross-sex hormones.

Q. Does the Wash --

A. In addition to --

Q. Does the Washington University Transgender Center offer hormone therapy as treatment for gender dysphoria in adults?

A. Does the pediatric center -- your question

is does the pediatric center provide care for adults?

Q. Well, my -- the transgender center offers both care to pediatric and adult patients; is that right?

A. So in general, the care that's delivered at St. Louis Children's Hospital spans birth to the low -- early 20s. There are individuals that are adults that are cared for by the adult endocrine division. And there's a separate team of doctors that participate in that care.

Q. Are you a member of the Endocrine Society?

A. Yes.

Q. The Endocrine Society publishes clinical practice guidelines regarding the treatment of gender dysphoria; is that right?

A. That's correct. Their initial document came out in 2009 with lead author Hembree and then they had a revision that was done in 2017.

Q. Showing you what's been marked as Exhibit 5.

(Whereupon Exhibit 5 was introduced for identification.)

A. Okay. I see it.

Q. (By Mr. Gonzalez-Pagan) Do you recognize

THE COURT REPORTER: Thank you.

MR. GONZALEZ-PAGAN: Borrowing a word from you, John.

Q. (By Mr. Gonzalez-Pagan) What is WPATH?

A. It's an organization known as the World Association of Professional Transgender Health. It is -- again, this is the organization that came out with their version seven of the guidelines quite a long time ago to provide their perspective on what should be done for people that experience sex discordant gender identity.

Q. Does the Washington University Transgender Center follow the WPATH guidelines?

A. Again, I will say that I'm not directly involved in the gender center. My understanding based on conversations with the director of that center, he claims that they do.

Q. Do you, yourself, provide treatment for gender dysphoria?

A. I will state that I'm a pediatric endocrinologist charged with treating hormonal diseases. And because I have not seen the evidence that supports the proper risk/benefit to that intervention, I do not provide that care, as I don't in any other area where I have not determined

appropriate benefit versus risk.

Q. Have you ever diagnosed a person with gender dysphoria?

MR. KNEPPER: Objection, form.

A. I'm a pediatric endocrinologist and my charge is to treat hormone related diseases. And therefore, I've not been called upon to make that diagnosis.

Q. (By Mr. Gonzalez-Pagan) Would you agree you do not have any clinical experience providing care for people for gender dysphoria?

A. I would not agree with that.

Q. Do you provide treatment for people?

A. I provide -- I provide treatment for hormone-related conditions that includes people with gender dysphoria.

Q. But specifically in treating gender dysphoria, do you have any clinical experience with regards to the treatment of that condition?

A. Since I'm a pediatric endocrinologist, my experience is limited to the treating of hormone-related diseases.

Q. Is that a no?

A. I have not treated with hormones for the purpose of alleviating gender dysphoria. I have

however treated patients that have experienced side effects related to that hormonal treatment including obesity, diabetes, dyslipidemia. So in that respect I have treated them, but not to address dysphoria. But, rather, the complications that have occurred in association with that treatment.

Q. Clarify, you said association, yes?

A. That's correct.

Q. Do you have proof -- do you have proof that it was caused by the treatment for gender dysphoria?

A. If I thought I had enough evidence to say cause, I would have said caused. I said association.

Q. Thank you. You've given a number -- Strike that.

Have you given presentations regarding gender dysphoria?

A. Yes.

Q. Have any of these presentations been at medical conference -- conferences or settings?

A. Yes. I've -- well, I've delivered many lectures to major academic centers during medical grand rounds. And I'm happy to detail those for you. It includes University of Tennessee, Texas

Tech, Notre Dame, the University of Montevideo. And there are probably others. I can't remember. So -- and so as being a grand rounds presentation in major medical centers, yes.

Q. Aside from grand rounds, have you provided any presentations regarding gender dysphoria at any medical conferences or sites?

A. Well, I would consider grand rounds a conference.

Q. Grand rounds is when there's an invited lecturer at a particular hospital and everybody is invited to attend; is that right?

A. So you're asking about national meetings, like the Endocrine Society meetings or such?

Q. Well, let me just clarify what grand rounds are for the record. So what are grand rounds?

A. Grand rounds are usually a recurring series of talks given by experts in various fields to the relevant scientific community about topics of interest to those physicians. And generally, it involves the presentation of high quality scientific evidence for the conditions that those physicians in the audience would encounter.

Q. Okay. So you have not conducted any

studies for any gender dysphoria, right?

A. I believe we answered that question earlier when we went through my CV.

Q. Well, I'm just wondering what your presentation of the grand rounds are since you have not conducted any such study?

A. It was providing the same types of evidence that I presented in my expert declaration about the scientific studies that have been done or need to be done in this field. Presenting the various hypotheses for etiology and potential treatment. The various side effects that are known or potentially could occur. So it includes all of -- or very similar information regarding the scientific studies that I presented in my expert declaration.

Q. And now, to continue aside from grand rounds, have you provided any presentations regarding gender dysphoria in any other medical conferences or settings?

A. I would have to -- I'd have to think through my list. It's actually most of the major presentations that I've made are listed within my CV. So I'd have to look back as to what I listed there. But if you're asking about the Endocrine

Society or the pediatric Endocrine Society or those types of organizations, I have not presented at those conferences.

Q. Are you familiar with the gender and sex conference?

A. Yes. And are you referring to the one in Madrid.

Q. That was going to be my question. Did you participate in the gender and sex conference in Madrid in 2018?

A. I don't recall the exact date. But if it was 2018, yes, I did present there.

Q. Did you know that the conference was billed as, quote: A rebellion against the gender ideology and its freedom destroying damaging law, closed quote?

A. I -- I don't recall that language being presented to me when I agreed to present at that conference.

Q. Did you know that the conference was focused on opposing what it termed "gender ideology"?

A. You know, again, I was asked -- and this is true for -- if you're going to go through the list of all of the places that I've spoken at. When

I've been invited to present at any of these conferences, my desire is to provide the most accurate and up-to-date scientific information related to the condition of gender dysphoria.

I am willing to present to any audience that is willing to hear that information. I don't make judgment about what the motives are of the individuals organizing the conference. But merely serve with my area of expertise and my knowledge to be able to further that discussion in a productive manner. And that applies to that sex and gender conference in Madrid.

Q. Who organized the gender and sex conference in Madrid?

A. I do not recall the entity. I'm sure you'll tell me. But again that wasn't who invited me was not as important as whether I was going to be given the opportunity to present the information objectively on this particular condition within my area of expertise.

MR. GONZALEZ-PAGAN: Oh, shoot. John, I just published an exhibit without a label. Do you have any objection to me calling it Exhibit 6?

MR. KNEPPER: Having done that very same

thing, Omar, let me take a look at it. But, no, I -- I cannot imagine I will have an objection. Actually it labeled it as Exhibit 6 automatically, but there's no stamp.

MR. GONZALEZ-PAGAN: There's no stamp, yes.

MR. KNEPPER: Sheryl, you'll have to put the stamp on it. But I'm completely okay with calling that Exhibit 6.

MR. GONZALEZ-PAGAN: Thank you.

(Whereupon Exhibit 6 was introduced for identification.)

Q. (By Mr. Gonzalez-Pagan) Dr. Hruz, I'm showing you what's been marked as Exhibit 6.

A. I can see it.

Q. And I apologize for the formatting. Some pages don't print as well as others. This appears to be a press release following the conclusion of the gender and sex conference which you were talking about; is that right?

A. I've never seen this document before.

Q. Okay. If you go to the second page.

A. Okay. I think I'm there.

Q. It talks about the gender and sex -- in the paragraph beginning eight speakers, sort of --

A. Okay. I'm there. I've got it now.

Q. Okay. It speaks of the gender and sex conference as being organized by HazteOir.org and its international platform, CitizenGo; is that right?

A. That's what it says here, yes.

Q. And does that -- is that in keeping with your recollection about who organized the gender and sex conference?

A. Yes. I seem to recall now that you've jogged my memory. That is correct.

Q. Okay. And then on the third page in the middle, there's a paragraph beginning: The rest of the panel experts and lecturers was made up by Professor Glenn Stanton; Dr. Paul Hruz; the sociologist, Gabriella Kuby; and the former transsexual, Walt Heyer.

Did I read that correctly?

A. I see the paragraph that starts Stanton assured that and, in quotes, the gender theory is unscientific, is that what you're --

Q. Just above.

A. Oh.

Q. I skipped the links in reading those.

A. Ah, okay. I see that, yes.

Q. Okay. So it is your recollection then that you presented at this conference; is that right?

A. Oh, yes. I do recall the conference. I just didn't until you reminded me. I didn't know who organized it.

Q. You used the term "gender ideology" in your report; is that right?

A. I have used that term in the course of my investigation of this condition, yes.

Q. What is gender ideology?

A. I would define ideology is including statements that are made on a non -- a non-scientific basis with premises and goals that are outside of science.

Q. Do you consider any healthcare professional that subscribes to the gender-affirming treatment model to be a gender ideolog?

A. I think you're conflating different terms. You mentioned gender-affirming medical care and ideology; those are two separate --

Q. Well, that's my question. My question is, does somebody that provides or advocates for gender-affirming treatment, is that person a person who subscribes to the gender ideology?

turn to, to be able to define, you know, the condition and the treatment approach. And I --

Q. Isn't that true for many psychiatric conditions?

A. Absolutely. I would -- absolutely. It is not unique to the area of gender dysphoria. In fact, in talking, you know, to those that are engaged more in the field of psychiatry, they will acknowledge that the rudimentary nature of the discipline in comparison to the rest of the medical -- medical enterprise, it is a very known and serious shortcoming. And there is a desire certainly to -- to fill in those gaps.

And there's actually hope that as time moves forward with the advance in tools that one has, to study neurobiology and address some of these questions. But there will be an opportunity to provide clearer answers that are more evidenced based.

Q. Sure. But, I mean, isn't that the nature of science and medicine; we don't know everything, period?

A. We know far less of the psychiatric conditions that are listed in -- or many of the psychiatric conditions -- I wouldn't say all -- that

Q. But your practice is in the field of endocrinology, not psychiatry; is that right?

A. I think we've touched upon this earlier, but I'm happy to expound upon that. Is --

Q. Well, it's a yes or no.

A. I'm a physician scientist. So I'm very qualified to talk about deficiencies in scientific evidence that are present in this particular area.

Q. So you're not a psychiatrist?

A. I covered that earlier. That I'm a pediatric endocrinologist. Yes, that's correct.

Q. Are you aware that the revision of the DSM involves the establishment of a scientific review committee that evaluated and provided guidance on the strength of evidence of any proposed changes?

A. You know, that is how they describe the process. I again have asked for the evidence, scientific evidence for the change between gender identity disorder and gender dysphoria and then even the move to shift toward the ICD code of gender incongruence, that is based upon a scientific evidence, rather than something other than that.

Q. You also make reference in your report with statements by Thomas Insel, the then director of the National Institute of Mental Health, that it

field forward. So I think that's entirely consistent with my interpretation of the whole question.

Q. Were you aware that two weeks after the statement that you reference from Dr. Insel, Dr. Insel issued a joint statement with the American Psychiatric Association stating that, quote: The American Psychiatric Association Diagnostic and Statistical Manual of Mental Disorders, along with the International Classification of Diseases represents the best information currently available for clinical diagnosis of mental disorders.

Were you aware of that statement?

A. Yes. And that is completely in agreement with my opinion that I put forward here as well.

(Whereupon Exhibit 7 was introduced for identification.)

Q. (By Mr. Gonzalez-Pagan) Showing you what's been marked as Exhibit 7.

A. I have it.

Q. Okay. This is a statement issued by Thomas Insel, the then director of the National Institute of Mental Health, and Jeffrey Lieberman, the then president elect of the American Psychiatric Association; is that right?

A. Yes. I believe -- well, I don't know for sure, but I agree.

Q. Okay. Right below DSM-5 and RDoC, colon, shared interests, it states: The authors of this statement.

Do you see that?

A. I see the two authors, Thomas Insel and Jeffrey Lieberman, correct.

Q. All right. Going to the second paragraph, it reads: Today the American Psychiatric Association Diagnostic and Statistical Manual of Mental Disorders, along with the International Classification of Diseases represents the best information currently available for clinical diagnosis of mental disorders. Patients, families and insurers can be confident that effective treatments are available, and that the DSM is the key resource for delivering the best available care. The National Institute of Mental Health has not changed its position on DSM-5. As the National Institute of Mental Health research domain criteria project website states, the diagnostic categories represent that in the DSM-IV and the International Classification of Diseases 10, the main contemporary consensus standard for how mental disorders are

diagnosed and treated.

Did I read that correctly?

A. You read it correctly. Yet what follows in the next paragraph is more pertinent to the statement that I made in the declaration acknowledging the fact that the DSM is not sufficient for researchers and the statement was related to the basis for research funding. So, you know, taken in context, this document is completely in line with the statement that I made about the limitations of the DSM.

Q. But the DS -- the DSM -- this is a case about the treatment of gender dysphoria; is that right?

MR. KNEPPER: Objection form.

A. So as we've been talking about all morning, okay, the ability to have effective treatments is based upon quality research. And if the DSM is not sufficient for researchers to be able to conduct their scientific study, because of how the DSM generates their diagnostic codes, I think that that understanding is completely relevant to why one needs to be aware of that.

Q. (By Mr. Gonzalez-Pagan) All right. Going to what is the fifth paragraph, the second to last

sentence. It states: As research findings begin to emerge from the RDoC effort, this finding may be incorporated into future DSM revisions and clinical practice guidelines. But this is a long-term undertaking. It will take years to fulfill the promise that this research effort represents for transforming the diagnosis and treatment of mental disorders.

Did I read that correctly?

A. You did read it correctly.

Q. Is there a reason why you did not include this follow-up statement from Dr. Insel regarding the DSM views and reliability in your report?

A. You know, I could have put the entire document that you have here into the report. The point being made, I think, is one that I fully agree with. I think that as we be able to -- are able to incorporate science into the DSM, it is going to increase in its validity and its usefulness. But in its current state there is acknowledged in this statement itself by the fact that this research is needed. It acknowledges the deficiencies that currently exist. So there's a whole host of other things that I could have included in my declaration. The point that was intended, I think, was

sufficiently made and supported even by this document that you put forward as a new exhibit.

Q. Sure. But in clinical qualification to your statement is that that doesn't exist yet, and that the DSM is the best current available tool that we have according to this statement?

MR. KNEPPER: Objection, form.

A. The point I made is that there are deficiencies in how it was -- or limitations how the DSM has been put together. And that is relevant to the understanding of how we put forward hypotheses for efficacious treatments. And so I would say that, you know, that's -- the state of knowledge in this area is -- is what is of concern and how we are using the DSM beyond its capabilities without knowledge of molecular or physiologic mechanisms for most of the psychiatric diseases is a major limitation which is acknowledged by the authors of this document. That is what I believe is important for the court to recognize and to understand as we move forward in this conversation.

Q. (By Mr. Gonzalez-Pagan) In your report you speak of three modalities of treatment for gender dysphoria; is that right?

A. I would say three different categories

based upon different underlying scientific premises. I think the reality of interventions are much broader than that and not as easily demarcated into three categories. But indeed, I do present those in my declaration.

Q. And these modalities, are they reparative therapy, watchful waiting and the affirming approach?

A. That is how I presented it, correct. And, again, if it would be helpful, if we're going to talk about it, if we can direct ourselves to that part of my declaration.

Q. We'll get there. Are you familiar with Ken Zucker's work?

A. Yes, I am.

Q. In fact, you repeatedly cite Dr. Zucker throughout your report; is that right?

A. Yes, I do, among other people, yes.

Q. What do you understand to be the model of care that Dr. Zucker employed?

A. Broadly speaking prior to his clinic being shut down was to approach care in a way to understand the underlying basis for the sex discordant gender identity in that era was referred to as gender identity disorder.

And to -- one of the approaches that he used was to help facilitate an individual to realign their gender identity with their sex. And if that was not possible, would then advocate for moving forward with affirmative approaches.

Q. So under Dr. Zucker's model, affirming care would be provided if there was persistence of cross-gender identification into adolescence and adulthood?

A. Based upon the information that Dr. Zucker had at the time that he was engaged in that care, that was how he proceeded, yes. He was not privy to the information that has come forward in the last several years about outcomes with that affirmative approach.

Q. What is the watchful waiting model?

A. Again, all of these approaches are based upon different scientific premises and it is based upon the experience that the majority of prepubertal children that experience sex discordant gender identity, if merely left alone, will have spontaneous realignment of their gender identity with their sex.

And it is again, whether it's intended or not, perceived as to be a desirable

outcome. And that those individuals that have that experience will not be exposed to gender-affirming medical interventions with all the associated risks and questionable benefits that we -- that I mentioned already. And I certainly can share more information if you would like.

Q. Let me introduce you to what's been marked as Exhibit 8.

(Whereupon Exhibit 8 was introduced for identification.)

Q. (By Mr. Gonzalez-Pagan) Do you have access to the exhibit?

A. Yeah. I'm seeing it now, correct.

Q. This is a publication on -- it's an article on adolescent health medicine and therapeutics; is that right?

A. I'm seeing that here. Is this a peer-reviewed journal -- a peer-reviewed article, just so I know?

Q. I'll answer that question for you then. The answer is yes, but it's the next exhibit.

A. Okay. I'm sorry. Did you have a question for me?

Q. Not yet.

A. Okay.

Q. I will represent to you that this is a peer-reviewed journal, but -- and I'll come back to -- to another exhibit to discuss that with you. But turning --

A. The reason I ask that was because it's a review article. And even in peer-reviewed journals, not all reviewed articles are reviewed with the same rigor. So that's -- but thank you.

Q. Let's exit out of that exhibit. And if my computer will cooperate.

(Whereupon Exhibit 9 was introduced for identification.)

Q. (By Mr. Gonzalez-Pagan) All right. I'm introducing what's been marked as Exhibit 9.

A. I have the document, just so you know.

Q. Great. Do you see where it describes the journal as an international peer-reviewed, open access journal focusing on health, pathology and treatment issues specific to the adolescent age group?

A. That's true. Just below the ISSN number.

Q. Correct.

A. Yes, I see that.

Q. Okay. So you would agree that it is a peer-reviewed journal?

A. Yes. They're claiming it is. I would have no reason to doubt that.

Q. Okay. So going back to Exhibit 8. If you can turn to Page 61 of the document.

A. Okay. Are you referring to the highlighted area?

Q. Well, we're going to go to the bottom of the right-hand -- right-hand column.

A. Okay.

Q. Under the watchful waiting model.

MR. KNEPPER: And, Omar, let's identify on the record the highlighting is not in the underlying document, but it's been added.

MR. GONZALEZ-PAGAN: For the record, the highlighting in the exhibit has been added by me. Otherwise the document is unaltered.

Q. (By Mr. Gonzalez-Pagan) The highlighted portion states -- reads: In contrast to live in your own skin approach, a young child's demonstration of gender nonconformity, be it gender identity, expressions or both, is not to be manipulated in any way, but observed over time. If a child's cross-gender identification and affirmations are persistent over time, interventions are made available for a child to consolidate a

transgender identity, once it is assessed, through therapeutic intervention and psychometric assessment as in the best interest of the child. These interventions include social transition (the shift from one gender to another, including possible name change, gender marker change and gender pronoun changes), puberty blockers and, later, hormone and possible gender-affirming surgeries.

Did I read that correctly?

A. Yes.

Q. So under the watchful waiting model, gender-affirming care is provided for adolescents and adults if they persist in the cross-gender identification; is that right?

MR. KNEPPER: Objection to form.

A. That's correct according to this use of the model, yes.

Q. (By Mr. Gonzalez-Pagan) Well, the watchful waiting model was developed by -- it's the Dutch model. It was developed in the Amsterdam Center of Expertise on Gender Dysphoria; is that right?

A. That's my understanding.

Q. Under the gender-affirmative model, medical and -- no medical and surgical interventions are initiated until after the onset of puberty; is

that right?

A. If you're talking about there's no reason to block puberty that hasn't started yet or to intervene with cross-sex hormones until that age; that is correct.

Q. Did you disclose to the -- in your report that under Dr. Zucker's model, under the watchful waiting model, and under the gender-affirmative model, gender-affirming medical treatment is indicated if cross-gender identification persists into adolescence and adulthood?

A. I would challenge you on the assertion that it's indicated. I would say that the model itself bases itself on the next step of intervention. Whether there's a prudent approach is really what is of concern with the literature that we have available. So the models itself indeed -- and they actually differ in not only in the timing of when one engages.

The affirmative model actually begins earlier with social affirmation, not just medical intervention. And there's different scientific premises that are underlying -- underlie these two different approaches.

Q. But under each of the models of the three

models that we've discussed, medical and surgical care is provided as a mode of treatment?

MR. KNEPPER: Objection, form.

A. Under the model. So let me be clear. Okay. So the reason for the watch and wait approach is to know that in prepubertal children that present with gender dysphoria, that the vast majority of them will have that spontaneous realignment, other gender identity with their sex, by varying estimates ranging from 50 to 98 percent. I think 88 -- 85 percent is a good average based upon the published literature.

That means that this would apply to 15 -- at most 15 percent, maybe even less, that would have persistence. It also makes the assumption -- and this is certainly one that one considers with the current social environment as to whether the influence of the social affirmation component, you know, is -- is provided.

So the underlying premises are different in the two models. One has a premise that there are a number of factors that led to the gender dysphoria. And the vast majority of individuals, that they may differ from one patient to another. There is no biological test that one can do to

determine which of these individuals are going to have persistence or have that spontaneous realignment. And the safest course of action is to do nothing until things are sorted out.

The gender-affirmative model makes a scientific premise that when one experiences sex discordant gender identity, it reflects something that is innate and immutable. And, therefore, a prudent approach would be to immediately engage in social affirmation followed by these hormonal interventions. I hope that I've stated that clearly enough for you and for the court.

Q. (By Mr. Gonzalez-Pagan) Sure. But ultimately as to the question for transgender people who persist in their cross-gender identification by definition into adolescence and adulthood, medical care and surgical care if indicated under any of the three models, that being Zucker's model, the watchful waiting model or the gender-affirming model?

A. I don't know that I would distinguish what we were talking about earlier with the Zucker model being -- I think you're doing that more as the reparative therapy.

And this is based upon again the

issue at hand of the emerging scientific evidence that leads one to question whether this provides a long-term solution to the problem of dysphoria. And, again, I will state again that there are many concerns about the presumption in proceeding with affirmative care that can be challenged by the outcomes that one is observing about how well these individuals are doing after receiving the gender-affirmative care.

So this is -- these are statements in this particular paper by Dr. Ehrensaft that is based upon the presumption that those are -- who receive the affirmative approach are going to be completely cured of their difficulties that they experience. And my point is that when you say indicated, it fails to recognize the -- the challenges that are emerging for that outcome.

Q. Sure. But my last question wasn't whether it was indicated. My last question is whether under each of the three models -- and let me clarify something. You discuss a reparative therapy model in your report; is that right?

A. Yes. Can we again go to that part just so you can direct me just so we can be looking exactly at what I wrote.

Q. Sure. It's Page 49 going into Page 50.
A. Thank you very much. Okay. Very good.
Q. My point is --
A. I do remember what I wrote. I just want to make sure we're talking about the same thing.
Q. My point is that -- that I'm trying to distinguish actually there are four models, if you will. The Ken Zucker model is distinguished from reparative therapy in that -- in a significant way.

And let's go to Page 61 of Exhibit 8, the highlighted portion above the watchful waiting model. It states: If by the arrival of puberty a child is still exhibiting cross-gender identification and expressing a cross-gender identity, that child should be supported in transitioning to the affirmed gender including receiving puberty blockers and hormones once it is assessed from clinical interviews and psychometric testing that the affirmed gender identity is authentic.

Did I read that correctly?

A. Yes.
Q. Okay. So my question was whether you disclose in your report that under the watchful waiting model and/or Ken Zucker's approach,

gender-affirming medical care is provided after the onset of puberty?

A. I'm trying to -- let's go back again to my report and the context of the discussion that I'm putting forward. You said that was -- we were on page -- page or bullet point No. 59, I think you said.

Q. Page 49, going into 50.

A. 49. Okay. That's where I -- that's where I lost you. I was on 59. Sorry. So I would also add that the presentation of three broad categories -- and you've mentioned a variation of one of those categories saying there are four approaches. I would -- I would posit it that there's a number of other hypotheses that have been put forward about treatment approaches that --

Q. Did you disclose any of those other approaches in your report beyond the three that you listed in this paragraph?

A. Let me explain what I mean by that. Okay? As I repeatedly said in my declaration that there are multiple hypoth -- alternative hypotheses that can be put forward about the most prudent approach to care. These broad categories provide the foundation for understanding the design and

implementation of these various applications of these broad categories.

The point of dividing it up into three categories is to really -- and I think that that is still valid -- that the starting underlying scientific hypotheses or the scientific premise, I should say, varies in these three different approaches. How that scientific premise is translated into hypotheses that lead to care approaches is -- is at issue here. And that I think is the important point that I wanted to illustrate for the court. And make it very clear that what is put forward by the plaintiff experts, and they said this repeatedly, is that the affirmation-only approach is the only accepted intervention in the care of gender dysphoria youth. And in this paper here and in my declaration, you know, challenge that as far as the most prudent approach. And that's the point of why it was included in a benefit for the court.

The affirmation approach is not the sole approach. And there are alternative approaches that haven't been adequately investigated and that need to be investigated. And this is an area of unsettled controversial treatment that is going on

currently.

Q. Sure. But ultimately there's a distinction that they are different, right? Under all three of these models, gender medical care and surgical care is provided after the onset of puberty?

MR. KNEPPER: Objection, form.

A. I would say that is an important distinction because if the underlying --

Q. (By Mr. Gonzalez-Pagan) The modalities of treatment, are they different?

A. If the outcome of the affirmation approach is proven to be not effective it would change the way that one applies that model to the effected patients.

Q. But on the altering model, you're providing medical care after the onset of puberty. So the real difference has to do with prepubertal children and how they're treated; is that right?

A. Well, let's talk a little bit about the emerging demographic of what we are experiencing right now. Many of the people --

Q. But that's not my question, though. Like --

A. Okay. I don't think it applies

exclusively to the prepub -- medical care -- I would say the hormonal interventions apply only to people that have progressed at least to stage two puberty. Social affirmation applies across the board and would be relevant whether one presented during adolescence or in childhood.

Q. But social affirmation is not a medical or surgical treatment.

A. Many would argue that. And I would say in a technical sense, that is true. However, there are many concerns that are evidenced in the literature, that that influences the trajectory of the children as to whether they go on to medical care. So many can and have argued that it is the first step that is leading them on to the subsequent hormonal interventions. So I think it is relevant.

Q. In Paragraph 50 in discussing -- in describing the watchful waiting approach, you note that this approach may include the use of scientifically validated treatment, e.g., CBT, for the patient's anxiety, depression, social skill deficits or other issues.

But you do not note that gender-affirming medical care and surgical care are provided under this approach. I'm just wondering

why you did not provide that context in your report?

A. Because that's under the premise that the affirmative approach actually provides benefit, and throughout my declaration I have raised multiple concerns with existing published data that lead to a presumptive or tentative conclusion that at best we should have more caution to that approach.

Q. So at best your description of the watchful waiting approach in this paragraph is incomplete?

MR. KNEPPER: Objection.

A. Let's read through and we can even read it into the record if you'd like, the way that I present that. Because that's where I think it's important to look at this in context.

Q. (By Mr. Gonzalez-Pagan) Actually let's just -- let's just go to Paragraph 53 of your declaration. It states: Another controversy --

A. Hold on. I'm not there yet.

Q. Okay. I'll wait for you.

A. It's a long paragraph.

Q. Well, I'm right at the beginning of Paragraph 53.

A. It starts with "assistance"?

Q. Paragraph 53.

A. Paragraph 53 talking about another controversy, the watchful waiting treatment; is that what you're talking about?

Q. Sure.

A. Okay.

Q. I'll just read the heading: Another Controversy, the watchful waiting treatment modality involves no medical treatment and is currently the best specifically -- sorry -- is currently the best scientifically supported intervention for young children reporting gender dysphoria.

But the watchful waiting model does involve medical treatment; isn't that right?

A. Perhaps to clarify that statement when I say young children when we're referring to prepubertal children, that is true, and it is actually included in the Endocrine Society guidelines. As far as the concerns about intervening and the caution that should be expressed precisely because of the high rates of desistence.

So that statement, again, when we're talking about social affirmation and your contention as I'm hearing it as you're stating it is social affirmation is not technically a medical intervention. And I think we've already discussed

that. That it is relevant as far as the first step in influencing the trajectory of these individuals.

Q. This case --

A. And there's also --

Q. So this case involves gender-affirming care, right?

MR. KNEPPER: Object to form.

MR. GONZALEZ-PAGAN: I apologize, Sheryl.

A. So -- so -- okay. Let's -- let's also move on. So if -- if you then look at the first stage of medical intervention which involves the administration of an GnRH agonist or also known as a puberty blocker, significant concerns that that normal trajectory where you see the majority 50 to 98, I would say 85 percent have the desistence. That demographic or that statistic changes drastically in those individuals that have received that first step of pubertal blockade and that actually most of the studies that have been published thus far says the vast majority of -- it's not 100 percent. It's very close to that -- will go on cross-sex hormones. So again that is not -- that is more the affirmative model.

The watch and wait model would posit that as a child begins into their puberty, that

acknowledging that the bodily changes that occur may heighten the level of dysphoria that they experience. But as they go through that developmental process, that experience of puberty is actually critically important in the overall integration of one's identity with their sex. And that would be consistent with the watch and wait model. So that again, as being presented in this one review article by Dr. Ehrensaft -- much more I could say about that -- I think there's much more to be said about the way that these models are being presented.

Q. The study that you -- the study to which you refer regarding persistent cross-gender identification following the provision of GnRH analogue, is that the de Vries study?

A. That's the one that shows a hundred percent persistence or a hundred percent moving that across sex hormones. There's been subsequent ones where it's not been a hundred percent, but it's been the 90 percent range.

Q. You say that those studies pertain to the application of the gender-affirmation model, but the de Vries study is actually speaking to the watchful waiting model. It is the Dutch model.

A. We need to say a lot more about that if we want to flesh that out for you. I don't know that you've adequately characterized the Dutch model. And I will add that the Dutch model was presented a decade ago with a different patient population that is currently presenting at the gender clinics across the world. And even --

Q. But that's a different point than -- than the one that we're talking about, right? You indicated that the affirmation model -- studies show that the affirmation model leads into persistence, but you're relying on a study based on the Dutch model.

A. Well, I would qualify that statement. I didn't say that it leads to that model, because the way the study was conducted, you know, causal effect cannot be inferred. Okay? So I would moderate that. But I would say it's certainly of concern that that number is drastically different than the prior studies that have shown that rate of spontaneously -- spontaneous realignment with gender identity with sex.

Q. But those are different populations, right? I mean, we're talking about prepubertal and pubertal youth versus prepubertal youth?

A. Not necessary -- so, again, you know, it would be much more helpful to talk about specific studies. In the de Vries study, the whole basis of giving pubertal blockers applied only to pubertal patients.

Q. That's by definition any person who's receiving puberty blockers.

A. No necessarily.

Q. It has to happen at the onset of puberty.

A. Well, yes, onset of puberty, that would be the only indication for giving it in the area of pediatrics.

MR. GONZALEZ-PAGAN: All right. How about we break now for lunch?

MR. KNEPPER: Dr. Hruz?

MR. GONZALEZ-PAGAN: Well, I'm -- I'm hungry, so.

MR. KNEPPER: I know. This works with your diet?

THE WITNESS: Yeah. I think as we go through this, I'm going to be happy just plowing through. So it's going to have to come from your end if you want to take a break.

MR. GONZALEZ-PAGAN: Well, it's coming from my end. Because I -- I'm running on a

have to demonstrate a concept of what we call non-inferiority. So if that's the natural outcome, so if there's a realignment with gender identity with sex and that obviates the need for them to go on to receive hormonal treatment of any sort at all, that would be a desired outcome.

The challenge is that in those individuals, there is no reliable diagnostic test to predict which of those children are in the category of 85 percent, like we go to this realignment versus the subset that's going to persist in that sex discordant gender identity.

So that's the challenge. So I would say I wouldn't be so firm to make an absolute determination of the best course of action, but I wouldn't say that any alternate approach would have to prove that non-inferiority outcome.

Q. (By Mr. Gonzalez-Pagan) Okay. And the desistence study speaks to prepubertal youth who were diagnosed with gender identity disorder under the DSM-III or the DSM-IV; is that right?

A. So this is -- I'm very much aware of that critique, and the way that people have attempted to dismiss that desistence literature based upon that difference of gender identity disorder versus gender

dysphoria. It's very interesting that if you look in detail for example at that same paper the number of people based upon the criteria --

Q. I'm sorry, Doctor. I apologize for interrupting. But I guess -- I'm happy to go into a conversation about this. But I guess I have a predicate question, which is I want to establish whether it's true or not that the desistence studies are based on prepubertal children diagnosed with gender identity disorder as opposed to gender dysphoria under the DSM-5?

A. Well, older studies would certainly necessitate that they use the diagnostic criteria that was available at the time the study was conducted. And some of them -- and most of those studies were the era prior to the revision of the DSM-5 giving the gender dysphoria diagnosis.

Q. Are you aware of any studies looking into the desistence in prepubertal youth using the DSM-5 criteria?

A. You know, that is an outstanding question and I'm very happy to share with you the problems with that question. In the fact that because of what has happened in the approach to the care of these individuals, the opportunity because of the

widespread adoption of the affirmation only approach and the early adoption of social affirmation makes it very challenging to be able to even put forward as a hypothesis a study that would be able to operate under the current diagnosis of gender dysphoria.

And I think that's very problematic as we seek to understand the natural history of this disease, and we seek to find ways to alleviate the suffering that will be sustained long-term in these individuals. I think it's the fact that the discussion is not allowed to occur and the studies have not been proposed and conducted. And even if they were, there would be challenges in the current environment of really encouraging that social affirmation approach.

So the answer to the question is that there are many problems that currently exist as to why those studies have not been reported and would be very difficult to perform at this point in time, yet would be essential to providing the best care for these individuals.

Q. Okay. But you do not know of any studies documenting an 85 percent desistance rate for kids diagnosed -- prepubertal kids diagnosed with gender

dysphoria mode in the DSM-5?

A. I'm not aware the question has actually been investigated by a scientific trial. Not that there's data that says it doesn't exist, but that it has not been investigated. The only data that's available right now are people that have received that social affirmation which clearly shows that that demographic has changed. And, you know, if you ask this as a hypothesis --

Q. I appreciate that, Dr. Hruz. We'll get to the demographic changes later on. But I want to stay focused. So going back, the studies have to do -- the studies in desistance that you reference have to do with prepubertal children; is that right?

A. The ones that were done previously that I'm referring to dealt with prepubertal children. Now, there's another component of this, that of -- you divided this between prepubertal and adults. And it's very necessary if we're going to adequately address this question to consider what happens during the period of puberty.

Q. Okay. Are there studies that document desistence during the period of puberty?

A. There are case reports. There are not -- and there's a growing -- this gets at the --

Q. In your report you state that case reports are not valid scientific evidence.

A. They are useful for hypothesis generation. They're not useful for making definitive causal conclusions. That is correct.

Q. So are there any studies showing high desistence among adolescence diagnoses with gender identity disorder?

A. There are not. And the reason for that, again, is because in many of the studies where one looks at this, there's a very, very high dropout rate in many of the subjects where one can't conclude at all what the outcomes were. Based upon the available evidence, more by case reports of growing number of people experiencing this desistence, that did occur when it's experienced post pubertally would lead one to raise hypotheses to be investigated in a rigorous scientific manner to address that question.

Q. You believe that all medical treatment needs to be subjected to randomized clinical trial?

A. It depends on -- so every medical decision that is made is based upon consideration of the overall risk and the overall benefit. And I think that the greater the risk, the greater the scrutiny

are certainly --

Q. But that's just a hypothesis; is that right?

A. You know, all along here, I've been tell -- I've been stating, and I hope very clearly, that much of my opinion is based upon hypotheses and alternative hypotheses, because there is no definitive answer to this question. But the prevailing current hypothesis that's not presented as a hypothesis, it's presented as an established fact, is that gender-affirming interventions are the solution to gender dysphoria. And that is what I challenge. And that is what, I think, is very important for this court to understand, is that the scientific evidence does not support that as being a cure for all of the difficulties that these individuals are experiencing.

Q. Going back to the desistence studies. What is the error rate for the desistence studies that you rely on?

A. So the error rate is -- there's a number of factors. I'm glad that you brought this up as far as, you know, how we think about the reliability of studies. So this is a problem throughout the literature. And I've addressed this in my

Q. (By Mr. Gonzalez-Pagan) Are you aware that the American Psychiatric Association opposes reparative therapy efforts regarding gender identity?

A. Now we're into a new line of questioning about medical societies. But I'm aware of -- of the general recommendations for affirmation only. That is entirely consistent with what has been put forward by WPATH, American Psychological Association. There's a little bit more caveat in the Endocrine Society guidelines. I think they're a little bit more cautious in the prepubertal children, at least in the 2009 document cautioned against social affirmation in recognition of the same desistence literature that I'm referring to. Again, not just my opinion. This is the professional societies in the 2009 guidelines acknowledged those studies of being relevant to that consideration of treatment.

Q. Sorry. I just don't want us to go down a different path. I'm not talking about the general position statement about gender-affirming care. I am talking about the physician statements regarding conversion therapy. Are you aware that the American Psychiatric Association opposes conversion therapy

eff -- conversion therapy efforts?

A. The reason I answered in the way I did to your previous question was not to evade the question. It was merely to -- you began with a professional association. And so it's necessary to acknowledge what the basis of those statements are. The APA recommends the affirmative approach to care.

Q. Okay. But that's not my question. That is a different position statement. And I'm glad -- yeah, the APA does do that. But does the American Psychiatric Association also have a position statement regarding conversion therapy?

A. Okay. Thank you. Because you used the word "conversion therapy" for the first time. I think it's very important for us to acknowledge when we're talking about reparative therapy and what people talk about as far as conversion therapy. That's actually a pejorative term that actually is trying to equate these efforts to realign gender identify with sex to a completely different condition related to same sex attraction with methods that virtually everyone would recognize as being unethical.

And so I think it's an injustice to -- and the statements are often made in the

literature published talking about conversion therapy.

Q. All right. One second. Let's just go -- let's just go to Page 49 of your report, Paragraph 52.

A. Sorry. Paragraph 52?

Q. Yeah. So very last sentence going into the next page of your report states: The first approach often referred to as conversion or reparative -- reparative therapy --

A. Correct.

Q. -- is directed to or actively supporting and encouraging children to identify with their biological sex.

Did I read that correctly?

A. I could add often incorrectly referred to as conversion therapy. I think that's probably something I could have added to my declaration to indicate that. I think it's incorrect and an injustice to use that term to describe the approach to -- to addressing gender dysphoria.

Q. Are you aware that the American -- you know what, let's -- I apologize. I forgot the stamp again. It is marked Exhibit 10. Do you see that?

(Whereupon Exhibit 10 was

introduced for identification.)

A. Correct. I see this.

Q. (By Mr. Gonzalez-Pagan) Okay. Under the position heading at the bottom of the page, in Paragraph 2, it states: APA recommends that ethical practitioners respect the identity for those with gender diverse expression.

Did I read that correctly?

A. I'm in the wrong paragraph. You said the second paragraph?

Q. Under -- under the heading position at the bottom of the page?

MR. KNEPPER: Omar, I think you made -- I think you swapped gender and diverse. But it's just -- in other words, I think you read gender diverse expression and it's diverse gender expression.

Q. (By Mr. Gonzalez-Pagan) Sure. Let me just read that again. Are you there?

A. I'm here. Okay. I'm sorry. I was reading the introductory paragraph. Sorry.

Q. Okay. It states, Paragraph 2, quote: APA recommends that ethical practitioners respect the identity for those with diverse gender expressions.

Did I read that correctly?

A. Yes.

Q. Then just below that on Paragraph 3 on the next page, it states, quote: APA encourages psycho -- psychotherapies which affirm individual's sexual orientations and gender identities.

Did I read that correctly?

A. Yes.

(Whereupon Exhibit 11 was introduced for identification.)

Q. (By Mr. Knepper) Showing you what's been marked as Exhibit 11.

A. I see it.

Q. Okay. This is a resolution by the American Psychological Association on gender identity change efforts. Is that right?

A. That's the title of this document, correct.

Q. It's dated February 2021; is that correct?

A. That's correct.

Q. Go to the second page, third to last paragraph on the right-hand side column. And it's use of GICE as an acronym for gender identity change effort; is that right?

A. I see that, yes.

Q. It reads: Whereas, GICE has not been

shown to alleviate or resolve gender dysphoria (Bradley and Zucker, 1997; Cohen-Kettenis & Kuiper, 1984; Gelder and Marks, 1969; Greenson, 1964; Pauly, 1965; and SAMHSA, 2015).

Did I read that right?

A. You did.

Q. If you go to Page 3, the last two paragraphs, on the right-hand side column, it states: Be it therefore resolved, that consistent with the APA definition of evidenced-based practice (APA 2005), the APA affirms that scientific evidence and clinical experience indicates that GICE put individuals at significant risk of harm.

Be it further resolved that the APA opposes GICE because such efforts put individuals at significant risk of harm and encourages individuals, families, health professionals, organizations to avoid GICE.

Did I read that correctly?

A. You did.

Q. Okay. So the American Psychiatric Association and the American Psychological Association both oppose reparative therapy as a form of treatment; is that right?

A. Gender identity change efforts as stated

in the document, which again is different than what people generally equate with conversion therapy, in quotes.

Q. And the American Psychiatric Association and the American Psychological Association consider gender identity change efforts to be unethical and harmful; is that right?

A. That's what's stated in these documents.

Q. All right. I will apologize in advance, that exhibit is large and will make navigating it a little difficult. Hopefully it will take a little bit longer to upload.

(Whereupon Exhibit 12 was introduced for identification.)

Q. (By Mr. Gonzalez-Pagan) Showing you what's been marked as Exhibit 12. It's a document entitled Understanding the Well Being of LGBTQI Plus Population. Is that right?

A. That's the title in the document that I'm looking at, yes.

Q. It appears to have been published in 2010; is that right?

A. It says 2020.

Q. Sorry. 2020.

A. Okay.

correctly. And that many of the studies that are referenced here have major methodologic weaknesses and the strength of the statement based upon that evidence in light of the emerging evidence that is coming forward, for example, in the other studies that we've discussed already today --

Q. Well, let's --

A. -- this conclusion can be scrutinized.

Q. Let's move to the next page. The highlighted statement reads: The available evidence suggests that sexual orientation and gender identity conversion efforts were ineffective and dangerously detrimental to the health of SGD population, especially for minors who are unable to give informed consent.

Did I read that correctly?

A. I'll say again, you read it correctly. And the meaning of that statement and context of the whole paper is something that we can discuss later.

Q. Would you agree that it is the position of the National Academies of Sciences, Engineering and Medicine that conversion therapy is harmful?

MR. KNEPPER: Objection, form.

A. I don't know whether the small panel of people that were included in generating this

consensus statement represents the entire views of the entire membership of that society. I know from my own experience that for the other societies that I'm involved with these types of consensus statements are not brought to the entire membership of the organization. I can only conclude that the members that were present on this panel made those conclusions. I would not go as far as to say that it was supported by every member or even majority or even substantial number of the rest of that group.

Q. (By Mr. Gonzalez-Pagan) If you go to the fourth page of the PDF.

A. Back up to the top now? Okay.

Q. On the last sentence, the second clause, it states: It represents the position of the National Academies on the statement of facts; is that right?

A. That is what is stated here, and that is also stated by other organizations that have put forward similar statements. The same concern applies, that just because they put it forward, it does not mean that -- that the entire membership has been able to weigh into this question or those that wish to do so.

Q. Was the review that you referenced in

A. You know, again I don't have the answer. I don't know.

Q. Okay. Are you aware that in the United Kingdom, medical and surgical care is provided for transgender adolescents post puberty and for transgender adults?

MR. KNEPPER: Objection to form.

A. I guess I didn't understand the question there.

Q. (By Mr. Gonzalez-Pagan) Sure.

(Simultaneous speakers.)

Q. (By Mr. Gonzalez-Pagan) You talk about -- you talk about the reviews in the United Kingdom, in Finland and in Sweden. So I'm curious, are you aware -- are you aware whether in the national health system in the United Kingdom, they provide coverage and treatment for gender dysphoria in post prepubertal adolescents and adults?

A. So I think it's reflected in the recent Tavistock versus Bell decision. It is recognized that this is an area of controversy and that is an unsettled question about --

Q. Well, the Tavistock decision has to do with minors. I'm talking about adults and cross-sex hormones and surgery. Are you aware whether in the

United Kingdom they provide coverage and treatment of cross-sex hormones and surgery as a modality of treatment for gender dysphoria?

A. Yes, I do.

Q. Okay. Same question with regards to Sweden?

A. Sweden -- again, I'm a pediatric endocrinologist. And I think that the caution that is put forward in relegating this care to the setting of -- of an experimental setting is where it's been pulled back with concerns based upon the --

Q. The restrictions to which you speak all relate to the provision of puberty blockers; is that right?

A. No. I think it's more extensive than that. But it -- it acknowledges that based upon the literature that there's not very stong evidence and then instructs that this care be delivered with the safeguards exactly as I'm saying, you know, it should be done here in the United States. Recognizing that this is --

Q. That's in the context of minors, though; is that right?

MR. KNEPPER: Objection, form.

A. Again, that's what I've addressed in my declaration. And that is my --

Q. (By Mr. Gonzalez-Pagan) But with regards to transgender adults in Sweden, does the nationalized healthcare system in Sweden provide coverage and treatment for gender dysphoria in the form of hormones and surgical care?

A. You know, I would say this is outside the scope if we're getting into a discussion about insurance coverage. My expertise is in looking at the scientific data about the affirmation and other --

Q. Well, you rely on the national reviews of Sweden, Finland, and the United Kingdom. So --

A. Correct.

Q. -- I'm wondering if you rely on the national reviews, I think it's pertinent and relevant whether you disclose in your report that these countries provide for the treatment and coverage of this care?

MR. KNEPPER: Objection, form, scope.

A. As a pediatric endocrinologist and physician scientist, my service to this court is not to opine upon -- I know it's a big part about this case about insurance coverage. My role in this

gender-affirming treatment for adults?

A. Again, I would have to say for me to comment specifically about that, we would need to have the document in front of me to be able to look through all of the papers. It was a very extensive study. And there are a number of papers there.

And so I would have to look through the papers to specifically look at the inclusion criteria, whether it was exclusively in kids or included adults and, again, how he defined, you know, adulthood, whether it's post prepubertal, post 18, early 20s. You know, many people have different definitions of that. And so --

Q. All right. Same line of questioning with regards to Finland. Did you disclose that Finland provides through its national -- nationalized health care system gender-affirming treatment for gender dysphoria for adults?

MR. KNEPPER: Objection, form, scope.

A. I'm going to state again that for me to opine on that, I would need to look at, in those studies, what the inclusion -- inclusion criteria and whether it extended into adulthood.

Q. (By Mr. Gonzalez-Pagan) My -- my -- my question is not pertinent to the report. It's not a

question of whether they reviewed it. It's a question whether that care is provided in Finland.

MR. KNEPPER: Objection, form.

A. I will say again that this is a question related to insurance coverage. And I'm a pediatric endocrinologist, physician scientist opining on issues of science, not on medical coverage.

Q. (By Mr. Gonzalez-Pagan) One moment, please. Let's take a -- well, actually no. We'll come back. In your report you disclose the Bell v. Tavistock position; is that right?

A. That's correct.

Q. That was a decision from December 2020 in the United Kingdom?

A. Correct. And it was before the appeals court decision came out recently.

Q. And you submitted an expert report in Tavistock; is that right?

A. In that Bell versus Tavistock case, I did.

Q. Are you aware that the Bell v. Tavistock case dealt solely with the ability of a minor to provide informed consent on their own?

MR. KNEPPER: Objection to form.

A. So the decision was based on that. But that was not what I was opined [sic] to comment on.

there's no indication here that this was a peer-reviewed document. It wasn't published in a journal in the typical way that we do it. So it's a Council for Choices -- recommendations of the Council for Choices in Healthcare in Finland. So this is -- the council itself came to this conclusion to answer your question.

Q. Let's go back to Exhibit 12.

A. I'm there.

Q. All right. We're going to go to Page 12-10. It is Page 311 of the PDF.

A. I wish there was a way you could just type in the number and get to it.

Q. Don't we all.

A. Okay. This is with the section that's titled Guidelines and Policies Related to Gender-Affirmation?

Q. That's right.

A. Very good.

Q. The highlighted statement states: Clinicians who provide gender-affirming psychosocial and medical services in the United States are informed by expert evidence-based guidelines. In 2012, the World Professional Association for Transgender Health, WPATH, published Version 7 of

the Standards of Care for the Health of Transgender, Transsexual, and Gender-Nonconforming People, which have been continuously maintained since 1979, and revisions for Version 8 are currently underway (Coleman, et al., 2012). Two newer guidelines have also published -- have also been published by the Endocrine Society (Hembree, et al., 2017), and the Center of Excellence for Transgender Health (UCSF Transgender Care, 2016). Each set of guidelines is informed by the best available data and is intended to be flexible and holistic in application to individual people. All of the guidelines recommend psychosocial support in tandem with physical interventions and suggest timing interventions to optimize an individual's ability to give informed consent. Mental and physical health problems need not be resolved before a person can begin a process of medical gender-affirmation, but they should be managed sufficiently such that they do not interfere with treatment.

Did I read that correctly?

A. You indeed read that correctly.

Q. Okay. This is a consensus study report by the National Academies of Sciences, Engineering and Medicine of the United States; is that right?

record. This is Media Unit No. 5. The time is 4:05 Eastern time.

Q. (By Mr. Gonzalez-Pagan) Dr. Hruz, one of the critiques in your report is that puberty blockers have not been approved by the FDA as a treatment for gender dysphoria; is that right?

A. That is correct. Although it's important to understand why that is a relevant piece of information.

Q. Well, let's go to page 50 of your report.

A. I'm there.

Q. Okay. On the -- there's a number of statements that you bold and italicize, but on the third -- the sentence involving the third bold and italics.

A. Okay.

Q. It's like in the middle of the page. It states: The off-label prescription of this drug is legal but unethical outside the setting of a carefully controlled and supervised clinical trial.

Did I read that correctly?

A. You did.

Q. And why is that?

A. So, again, this relates to the statements that are made that these drugs are known to be safe

in this patient population. And we really don't have the scientific evidence to make that statement. Because it's unknown what the -- some of the effects are known, but many of the effects are unknown, to be able to expose people to this intervention, not only to expose them to that, but to make the statement that it is known to be safe with that absence of evidence, it really finds itself outside of what I'd consider ethical.

Q. Just for clarify, what do you understand "off-label" use to mean?

A. Oh, it's actually very common in the area of pediatrics. It's to prescribe a medication for something that it has not been FDA approved. So it could be for another -- a drug that's approved for one purpose and using it for another purpose. Most often that's how it's used.

Q. Have you personally ever prescribed any drugs on an off-label basis?

A. Very frequently do.

Q. Do you do so even in the absence of randomized clinical control trials?

A. Usually when I prescribe them off-label, there are randomized controlled trials in different populations that I turn to. I look at the relative

risk and -- but I don't make the statement that we know with definity [sic] about the safety of a medication in a way that we don't have that information.

Q. And you said usually. So there are times when you prescribe off-label drugs even in the absence of clinical controlled randomized trials?

MR. KNEPPER: Objection, form.

A. Usually when I'm prescribing it, what we would consider off-label most often, it is for a condition that is not markedly different for the use that it is being given only that it had been approved most often for adults rather than children.

Q. (By Mr. Gonzalez-Pagan) And clinical control trials are actually relatively rare in the pediatric population?

A. No. I would say that -- I mean, that's the standard that's accepted especially for medication use. The reason why they're not done in pediatrics is that usually there's a substantial cost associated with that. People are looking at market share and, you know, how much it's going to cost to be able to study that drug in that patient population. Yet it's already been studied in a randomized control trial in a similar population

without the same caveats that we consider when we look at this question of pubertal blockade.

Q. What is the FDA?

A. The Food and Drug Administration.

Q. Does the FDA regulate prescription drugs?

A. Yes.

Q. What is the FDA's decision with regards to a prescription of off-label use of drugs?

MR. KNEPPER: Objection, form, scope.

A. You know, I don't know that they have a statement that there is an ethical responsibility that all physicians who are prescribing off-label. It also applies both to the prescribing physician and it also applies to the pharmaceutical company that's making the medication.

If it's off-label, they cannot market it to a group of people that it wasn't approved for. Physicians that prescribe off-label medications accept the responsibility, you know, for the risks and benefits. And they're obligated to inform their patients of the evidence that they have, where it comes from, and the basis for recommending that medication.

That's true for all medications, but certainly when you're using it off-label, you know,

it involves consideration of the indication, how applicable the randomized control studies that have been done to approve the drug are applicable to the population that you're going to use it for.

(Whereupon Exhibit 14 was introduced for identification.)

Q. (By Mr. Gonzalez-Pagan) Showing you what's been marked as Exhibit 14. Do you have that in front of you?

A. I do.

Q. This appears to be a notice by the Food and Drug Administration in the Federal Register dated November 18, 1994, pertaining to a citizen petition regarding the Food and Drug Administration's policy on promotion of unapproved uses of approved drugs and devices, request for comments.

A. I see that.

Q. Did I -- did I describe the document correctly?

A. I've not read the entire document. But that section that you read was read correctly.

Q. Okay. Going on to the second page. It's a highlighted portion. I will represent any highlights in the document were done by me. And

there are no other alterations to the document.

The highlighted portion reads: Over a decade ago, the FDA Drug Bulletin informed the medical community that once a drug product has been approved for marketing, a physician may prescribe it for uses or in treatment regimens of patient populations that are not included in approved labeling.

The publication further stated unapproved, or more precisely unlabeled uses may be appropriate and rational in certain circumstances and may, in fact, reflect approaches to the drug therapy that have been extensively reported in medical literature. Valid new uses of drugs already on the market are often first discovered through serendipitous observations and therapeutic innovations, subsequently confirmed by well-planned and executed clinical investigations.

Did I read that correctly?

A. You did, indeed.

Q. Your report doesn't acknowledge that the long-standing position of the FDA has -- with regards to off-label use of drugs?

MR. KNEPPER: Objection, form.

A. I would say that this paragraph that you

read does not directly apply for the reason for my consideration of this use of GnRH agonist in pubertal adolescence for gender dysphoria is the same. And it's important to note in this paragraph, it says the word "may." It doesn't guarantee that it is. And it reflects the nature of the application that one is providing.

(Whereupon Exhibit 15 was introduced for identification.)

Q. (By Mr. Gonzalez-Pagan) Introducing what has been marked as Exhibit 15. Noted below, the creator of the document is a printout of a web page from the Food and Drug Administration's website. It is titled Understanding and Approved Use of Approved Drugs Off-Label.

Did I read the title of this web page correctly?

A. Yes, you did.

Q. Okay. Moving on to the second page, there's a highlighted portion. I will stipulate for the record that any highlights in this document were inserted by me and that there are no other alterations to the document.

The highlighted portion of the document states: From the FDA perspective, once the

FDA approves a drug, healthcare providers generally may prescribe the drug for an unapproved use when they judge that it is medically appropriate for their patient?

Did I read that correctly?

A. You indeed read it correctly.

Q. Before opining as to whether the use of off-label puberty blockers should be considered unethical, did you review the positions of the FDA with regards to off-label use?

A. Again, I'm very, very familiar with that. Maybe perhaps not these specific documents, but I -- this is entirely consistent with my understanding of the off-label use of drugs.

(Whereupon Exhibit 16 was introduced for identification.)

Q. (By Mr. Gonzalez-Pagan) Showing you what's been marked as Exhibit 16. I'll represent this is a guidance for institutional review board for clinical investigators published by the Food and Drug Administration dated January 1998. It is titled Off-Label, an Investigational Use of Marketed Drugs, Biologics and Medical Devices.

Did I represent the document correctly?

A. You correctly read the title of this document.

Q. There is a highlighted portion in the first page of the exhibit. I'll represent that all the highlights were added by me to that exhibit. And there are no other alterations to the document.

The highlighted statement reads: If physicians use a product for an indication not in the approved labeling, they have the responsibility to be well-informed about the product, to base its use on firm scientific rationale and on sound medical evidence, and to maintain records of the product's use and effects. Use of the marketed product in this manner when the intent is the practice of medicine does not require the submission of an Investigational New Drug Application, Investigational Device Exception or review by an Institutional Review Board.

Did I read that correctly?

A. You read that section correctly.

Q. Do you acknowledge this guidance of the FDA in your report?

A. You mean the statement that I made about the ethics of prescribing the medication and the need does not require that, but it does not mean

that it's not the approach that should be done. So that one -- for example, it's not malpractice and one's not going to lose their license by prescribing a medication off-label in this manner.

However, when we look at the use of this -- the GnRH agonist with a reference that I made to the FDA off-label use involves product use that is not the same as what it is used in the treatment of prepubertal children and the risks require -- and because of the risks of the intervention and the lack of knowledge, it's very different than many of the other times that I myself have used off-labeled use of medications.

So the statement itself is accurate. It is consistent with my understanding of the FDA guidelines for that. And I think my statement in my declaration fully reflects the reason why it is of ethical concern in this case.

(Whereupon Exhibit 17 was introduced for identification.)

Q. (By Mr. Gonzalez-Pagan) Showing you what's been marked as Exhibit 17. Are you familiar with the American Academy of Pediatrics?

A. I was a member of the American Academy of Pediatrics for over 20 years.

Q. This is a policy statement by that organization titled Off-Label Use of Drugs in Children; is that right?

A. That is the title of the statement, yes.

Q. I'll represent that there are highlights within this document. Those highlights have been added by me. And there are no other alterations in the document.

On the abstract in the highlighted portion, it states: However, off-label drug use remains an important public health issue for infants, children and adolescents, because an overwhelming number of drugs still have no information in the labeling for use in pediatrics. The purpose of off-label use is to benefit the individual patient. Practitioners use their professional judgment to determine these uses. As such, the term "off-label" does not imply an improper, illegal, contraindicated or investigational use. Therapeutic decision-making must always rely on best available evidence, the importance of the benefit for the individual patient.

Did I read that correctly?

A. You read it correctly. And I would

comment that the very last sentence is at the heart of my concern about how it's -- GnRH agonists are being used in the setting of gender dysphoria.

Q. So is your critique that the use of GnRH analogues [sic] for the treatment of gender dysphoria is unethical because it's not the best available evidence in your opinion?

A. There are many layers to the question. I would say that many of the people that are prescribing these drugs are not even aware of the emerging evidence that is coming forward about lack of efficacy and the risks of these medications. They're relying on their decision based upon statements made by many of the organizations that you mentioned earlier that -- that are not considering the relative risk-benefit analysis. And so a provider, unless they've had the opportunity like myself and others who have been familiar with the literature, are going to be misled with the assumption that this is the available evidence, supports its use.

Q. Well --

A. Many of the people that are prescribing these medications have not read those papers, not considered those papers, not considered the poor

Q. (By Mr. Gonzalez-Pagan) Dr. Hruz, how did you first come to be an expert in transgender litigation?

A. Well, I think it was a recognition of my knowledge of the -- of the subject area and -- that I had in a number of different settings including the grand rounds talks that I said previously and some of the things that I've been discussing for the last -- since almost ten years now.

Q. Do you know what the Alliance Defending Freedom is?

A. Yes.

Q. Have you met with staff from the Alliance Defending Freedom in order to discuss how to serve as an expert in cases involving transgender issues?

A. My involvement was mostly to tap into my knowledge and expertise in this area, to inform that organization of some of the relevant issues. I've never been coached on how to be an expert witness, nor have I necessarily been encouraged in any way. These requests have generally come from the litigating lawyers, how they received my name or to what extent and in what ways they became familiar with my knowledge and expertise in this area is not known to me.

Just like the other groups that I've spoken to, I've been more than willing to be -- to share the knowledge that I've accumulated over this last decade in this area.

Q. Did you attend a meeting at the Alliance Defending Freedom offices in Arizona in 2017?

A. I don't recall the exact date, but I did travel to Arizona to meet with other individuals that also had unique areas of expertise in the area, yes.

Q. Just to clarify, was that one or two meetings?

A. I think I've had two separate meetings. The first was much shorter. And the second one was much more of presentations with actual data.

Q. What was discussed in that first meeting?

A. Again, it was many years ago. But my recollection was just to understand what was going on. It was -- it was the same types of questions about the care that is being proposed and offered. But it was much less defined, I think, at that point in time. It was more of an informal type of meeting.

Q. Who was in attendance at that first meeting?

A. I suspected you were going to ask me. And, you know, honestly I don't remember the exact composition of the people that were there. If you happen to know, I can acknowledge or deny whether they were there or not. But I've met literally hundreds of people over the last ten years in various settings. I do know that at that first meeting, Allan Josephson was there. And I believe that Mark Ramirez was there as well.

Q. Was Jeff Shafer there?

A. Yes. He actually at that time was working for ADF.

Q. Was Gary McCaleb there?

A. Yes. And he was one of the first contacts I had from that group.

Q. When they invited you to this meeting, what was the invitation, what did they tell you it was going to be about?

A. They had desired to convene a group of people that had knowledge in this area and to be able to discuss that, is my recollection at that point in time.

Q. Was Ryan Anderson there?

A. He was at one of the meetings, the two meetings, I'm not sure which -- which one.

Q. About how many people were in that first meeting?

A. Probably about eight to ten if you include Jeff Shafer and Gary McCaleb. You know, no more than a dozen, probably less than that.

Q. And the second meeting, you indicated that it involved some presentations; is that right?

A. That's correct.

Q. Was it also in Arizona?

A. Yes.

Q. Who was present at the second meeting?

A. Similar to the first meeting. And, again, I may get mixed up, the first and second meetings. There were different people that were present. I know that Walt Heyer was at one of the meetings. Oxy Horvath was at one of the meetings as well. You'd have to give me the other names if there was any. I'm drawing a blank. It was a while ago.

Q. Was Mark Regnerus at the second meeting?

THE COURT REPORTER: I'm sorry. What was that name?

A. He was only at --

MR. GONZALEZ-PAGAN: Mark Regnerus, R-E-G-N-E-R-U-S.

A. I believe he was at one of the meetings.

I'm not sure which one.

Q. (By Mr. Gonzalez-Pagan) Was Patrick Lappert at one of these meetings?

A. He would have been likely at the second meeting.

Q. Was Paul McHugh at any of those meetings?

A. No.

Q. Was Michelle Cortella at any of these meetings?

A. I've encountered Michelle at a number of different settings. I'm trying to think back. I honestly -- I just can't remember. She may have been at one of them.

Q. Was Quinton Van Meter at any of these meetings?

A. I have met with him. I'm just trying to think of what the circumstances and when he was there. Again, you know, I've met so many people over many different years in many different venues. It's challenging for me to remember who was in what meeting.

Q. Did the ADF lawyers discuss the need to develop expert witnesses for litigation?

A. Again since it was several years ago, I'm trying to remember the exact content. I think the

main focus was -- was understanding what was going on to be able to understand from multiple different perspectives. One of the most helpful outcomes for myself was the opportunity to talk to the transitioners. These are adults that have had the experience of going through the affirmation approach only to discover eight to ten years after that, that it did not solve their problems.

It was similar to my efforts to connect with parents and -- that were experiencing this with their children as part of my understanding of the unique circumstances facing these individuals. That's what I walked away with more than anything else. Whether there was discussions about, you know, whether there were -- were litigation going on is -- I just don't recall.

Q. Were you aware that the Alliance Defending Freedom is a religious organization?

A. I think that's -- if you travel to their headquarters, that's hard to miss.

Q. Let's go back to your report, Exhibit 1. On the third page, Paragraph 7.

A. We're on my expert report. Okay.

Q. Page 3, Paragraph 7.

A. Thank you. I'm going to go to my clean

copy that I have printed out. Okay.

Q. Okay. It is mentioned that you also spoken with parents of children experiencing gender dysphoria and earlier you mentioned that you had spoken with Eli Coleman; is that right?

A. That is correct.

Q. And Eli Coleman is one the authors of the WPATH standards of the care; is that correct?

A. He's one of the lead authors, correct.

Q. In Paragraph 7 you state that you have met individually and consulted with several pediatric endocrinologists including Dr. Norman Spack, who had developed and led transgender programs in the United States; is that right?

A. That is correct.

Q. Who's Norman Spack?

A. Norman Spack was from Harvard. He was actually probably the first person to introduce the Dutch model of care to the United States. In the latter years of his career, he became a very outspoken advocate for that approach. In fact, Dr. Spack was invited to Washington University very early on when the question was being proposed to start the gender center at Washington University.

Q. And you discussed the treatment of gender

dysphoria and transgender people with Dr. Spack?

A. That's correct.

(Whereupon Exhibit 19 was introduced for identification.)

Q. (By Mr. Gonzalez-Pagan) Showing you what's been marked as Exhibit 19.

A. So this is the declaration for Norm Spack for the Drew Adams case, correct?

Q. That's correct, yes. Have you seen this document before?

A. I've heard of it. I believe I saw that during the -- my involvement in the Adams case.

Q. He mentions that on or about October 19, 2014 -- sorry. On Paragraph 8 of the declaration on Page 2, he mentions that on or about October 9, 2014, he gave a presentation at St. Louis Children's Hospital regarding the foundation of GeMS, the workings of a gender management program at a pediatric hospital, and in medical treatment and care of gender and nonconforming and transgender children and adolescents; is that right?

A. Other than the word "gender" is misspelled, yes.

Q. It goes on to say on Paragraph 9 on the next page that following the presentation, he met

privately with medical staff including endocrinologists at St. Louis Children's Hospital to answer their questions and share his knowledge and experience.

He then goes on to say that he also in that context met privately with you at St. Louis Children's Hospital when you approached him after the presentation.

Do you recall that?

A. I recall the meeting both with the faculty -- I don't specifically remember the private meeting afterwards. I do remember we had kind of a round table. We actually sat around a circle with other colleagues of mine and addressed questions. But I -- it certainly would be in agreement with where I was at that point in time in an understanding for the proposal for care involving affirmation.

Q. He goes on say that during his meeting with you, you directly expressed that you had, quote, a significant problem with the entire issue, closed quote, and, quote, whole idea of transgender, closed quote. He then states that you followed up these comments by stating, quote, for me it is a matter of my faith, closed quote.

Do you recall making these statements to Dr. Spack?

A. I do not.

Q. Do you deny making these statements to Dr. Spack?

A. I do not recall making those statements. And it really seems to be -- I'm not sure of the context of the conversation, where that came from. This was a time shortly after our institution was considering the adoption of the affirmative care model for starting their gender center. And very clearly at that point in time, I was very early in investigating the literature and I remember talking with my colleagues at that very same time about the questions that I had about the science, about some of the statements that were being made.

One of the questions that came up related to some of the assertions about more in the area of anthropology as far as a human being and whether it was possible for one to change one's sex. I recall that at that point in time, you know, the people were just starting to make the comments like in one of the other cases where Dr. Atkins would make the statements gender is sex. And I certainly challenged those assertions at that time.

So this is a period of discovery for me. And for me to make a definitive statement like that is not really even logical from where I was at that point in time.

Q. Are you familiar with the St. John Paul, II, Bioethics Center?

A. Yes.

Q. Is St. John Paul, II, Bioethics Center a religiously affiliated institution?

A. I believe it is, yes.

Q. Did you speak at the St. John Paul, II, Bioethics Center in November of 2017?

A. I'm not sure of the exact date. But I did deliver a talk to that group.

Q. During that talk, did you not state about being transgender that, quote, in fact, probably goes back to some of the early heresies in the church, closed quote?

MR. KNEPPER: Objection, form, scope.

A. You know, I'd have to see the context of when that statement was made and how it was being portrayed to that audience, whether it was in response to a question with context that is not included in your question.

Again, as you mentioned, this was a

UNITED STATES DISTRICT COURT
FOR THE
MIDDLE DISTRICT OF FLORIDA

DREW ADAMS, a minor,)
)
Plaintiff,)
)
vs.)Civil Action
)No.3:17-cv-00739-TJC-JBT
THE SCHOOL BOARD OF ST.)
JOHNS COUNTY, FLORIDA,)
)
Defendant.)

VIDEOTAPED DEPOSITION OF PAUL W. HRUZ, M.D., Ph.D
Taken on behalf of Plaintiff
November 20, 2017
(Starting time of the deposition: 8:58 a.m.)

Exhibit
0002
9/29/2021
Hruz

I N D E X O F E X A M I N A T I O N

	Page
Questions by Mr. Gonzalez-Pagan	7
Questions by Mr. Kostelnik	286
Further Questions by Mr. Gonzalez-Pagan	292

INDEX OF EXHIBITS

EXHIBIT	DESCRIPTION	PAGE
For the Plaintiff:		
Exhibit 1	Subpoena	11
Exhibit 2	Expert Declaration	29
Exhibit 3	Growing Pains Article	29
Exhibit 4	Letter	68
Exhibit 5	Article	163
Exhibit 6	Article	231
Exhibit 7	Article	246
Exhibit 8	Article	249

(The original exhibits were retained by the court reporter, to be attached to Mr. Gonzalez-Pagan's transcript.)

UNITED STATES DISTRICT COURT
FOR THE
MIDDLE DISTRICT OF FLORIDA

DREW ADAMS, a minor,)
)
Plaintiff,)
)
vs.)Civil Action
)No.3:17-cv-00739-TJC-JBT
THE SCHOOL BOARD OF ST.)
JOHNS COUNTY, FLORIDA,)
)
Defendants.)

VIDEOTAPED DEPOSITION OF WITNESS, PAUL W. HRUZ, M.D., Ph.D., produced, sworn, and examined on the 20th day of November, 2017, between the hours of nine o'clock in the forenoon and six o'clock in the evening of that day, at the offices of Veritext Legal Solutions, 515 Olive Street, Suite 300, St. Louis, Missouri before BRENDA ORSBORN, a Certified Court Reporter within and for the State of Missouri, in a certain cause now pending in the United States District Court for the Middle District of Florida, wherein Drew Adams, a minor, is the Plaintiff and The School Board of St. Johns County, Florida is the Defendant.

A P P E A R A N C E S

For the Plaintiff:
Mr. Omar Gonzalez-Pagan
Lambda Legal
120 Wall Street
New York, New York 10005
(212) 809-8585
ogonzalez-pagan@lambdalegal.org
and
Ms. Shani Rivaux
Pillsbury Winthrop Shaw Pittman LLP
600 Brickell Avenue, Suite 3100
Miami, Florida 33131
(786) 913-4882
shani.rivaux@pillsburylaw.com

For the Defendant:
Mr. Kevin Kostelnik
Mr. Terry Harmon (via phone)
Sniffen & Spellman, P.A.
123 North Monroe Street
Tallahassee, Florida 32301
(850) 205-1996
kkostelnik@sniffenlaw.com

The Court Reporter:
Ms. Brenda Orsborn, RPR/CSR/CCR
Missouri CCR No. 914
Illinois CSR No. 084-003460
Veritext Legal Solutions
515 Olive Street, Suite 300
St. Louis, Missouri 63101
(888) 391-3376

The Videographer: Ms. Kimberlee Lauer

Q. So is that a "yes" or a "no"?
A. That is a -- to make sure I understand the question again, please address it again.
Q. If Drew asked you to use male pronouns, would you use male pronouns?
A. Yes.
Q. In your practice -- and I take it you've been practicing for several years, so in your practice, how many transgender patients have you treated in the past five years?
A. As stated explicitly in my declaration, I intentionally do not treat transgender patients.
Q. At all?
A. That is correct.
Q. In any -- for any treatment?
A. Oh, the ones that I'm aware of, I have not encountered any patients that have presented to me as transgendered for any other conditions. I have certainly encountered many patients where that was something under consideration or something that I suspected, but nobody has ever mentioned directly to me that they were transgendered.
Q. Okay. So to your knowledge, you have not treated any person that you knew was transgender?
MR. KOSTELNIK: Form.

A. Well, again, if you would -- yeah, that is true for -- for the -- the patient -- somebody like Drew Adams that was biologically normal. I have certainly cared for hundreds of patients that have disorders of sexual development. Many practitioners will include those in that designation. I believe that they are a completely different patient population than Drew Adams.

Q. (By Mr. Gonzalez-Pagan) What is gender dysphoria?

A. Gender dysphoria is the discomfort that one experiences related to gender identity that does not conform with one's biological sex.

Q. Is that the definition in the DSM?

A. Yes.

Q. It uses the word "discomfort"?

A. I'd have to go look back at the exact wording of that. It's the difficulty that they experience, psychological difficulty with that, yes.

Q. Okay. And based on your testimony, would you agree that you have not treated any transgender patients for gender dysphoria?

A. Yes, I would agree.

Q. Would you agree that Drew's treating physicians have diagnosed him with gender dysphoria?

the person putting forward this clinic and trying to understand what care that was being proposed to be provided in the setting of that context in my role as the director of our -- or the chief of our division of endocrinology.

Q. Just to be clear, though, you have never sat in a meeting between a provider and a patient discussing their treatment options for gender dysphoria?

A. That is correct, I've never been in the room with a patient while that care is being discussed.

Q. All right. Would you agree that Drew Adams' doctors have concluded that gender-affirming treatment is appropriate treatment for him?

A. That is what they concluded, yes.

Q. Would you agree that Drew Adams' doctors have concluded that the gender-affirming treatment has been helpful to Drew?

A. I believe that that's what they claim, yes.

Q. Do you agree that Drew Adams' gender-affirming treatment has been beneficial for him?

A. It depends on what you mean by beneficial. I think that it is far too early to know what the long-term outcome -- outcomes are going to be from what is being provided for Drew Adams.

Q. As we stand here today, has the gender-affirming treatment been beneficial to Drew with regards to his gender dysphoria?

MR. KOSTELNIK: Object to form.

A. So similar to the literature that has already been published in this area, Drew, by the reports that I've read, is experiencing a -- a lessening of the dysphoria in relation to the gender discordance, and I would say that based on the information that I saw, the answer is yes.

Q. (By Mr. Gonzalez-Pagan) As we stand here today, do you agree that Drew Adams' gender-affirming treatment has improved his quality of life?

A. So again, I can't say with certainty what actually has improved his quality of life. I can say, based on the record, that he is better adjusted than previously.

Q. Dr. Hruz, you're an endocrinologist, correct?

A. That is correct.

Q. You're not a psychiatrist, correct?

A. That is correct.

Q. You're not a psychologist?

A. That is correct.

Q. Are you a licensed mental healthcare

provider of any kind?

A. I am not.

Q. Can you diagnose gender dysphoria?

A. I can -- I can diagnose gender dysphoria to the extent that my colleagues, as pediatric endocrinologists, follow the DSM-5 and look at the criteria and put the check boxes there. That is the extent of what my colleagues, as pediatric endocrinologists, do, and I'm just as capable of doing that as they are.

Q. As an endocrinologist, do you routinely diagnose conditions in the DSM-5?

A. I -- I do not -- well, let me -- I'm trying -- the reason I'm waiting is I'm trying to think as I put in my ICD9 codes in my visits, I do believe that I've actually added them, but I do not consider myself as a psychiatrist to making those diagnoses, no.

Q. Do you have any basis to know whether Drew Adams has suffered distress as a result of being denied access to the restroom consistent with his gender identity?

A. I can only evaluate what is contained within his patient chart and the literature -- or the information that was provided to me.

whether the person they're using right now is not specifically dedicated to the clinic, but there are many psychologists there at Children's Hospital, and I certainly could refer them to one of those psychologists, that's correct.

Q. Just to clarify, would you discourage them from using the transgender center at your university?

A. I would neither encourage nor discourage. I would merely state that I do not agree with the treatment that is being done in that clinic.

Q. And that treatment is the treatment that is in accordance with the Endocrine Society's clinical guidelines?

A. That is correct.

Q. And in accordance with the WPATH standards of care?

A. As I understand it.

Q. And the treatment that is being allowed by the Washington University at the clinic?

A. Yes.

Q. Would you tell the patient that?

A. Excuse me. Tell them what?

Q. That the care provide -- would you tell the patient that the care provided at the transgender center is in accordance with the Endocrine Society's

clinical guidelines?

A. I would let them know that the clinic was available, and I would let the people in that clinic, if they chose to attend that clinic, present all of the information for the basis for their treatment approach.

Q. So you wouldn't inform the patient that the treatment is in accordance with the clinical guidelines?

A. I'm envisioning the hypothetical situation that you're talking about, and the extent of my normal clinic visit and how much time I have to present all of the -- the important aspects of clinical care, and I'm envisioning that there would be a limit of the -- the length of that conversation if I was going to adequately address all of the other relevant issues that I was caring that patient for [sic].

Q. Would you suggest that the patient seek conversion therapy?

A. No.

Q. Is the treatment at the transgender center consistent with the position and recommendations of the American Medical Association?

A. I -- as I understand it, yes.

Q. Is the treatment at the transgender center

consistent with the position and recommendations of the American Academy of Pediatricians?

A. The AAP, yes.

Q. Is the treatment at the transgender center consistent with the position and recommendations of the American Psychiatric Association?

A. I don't follow those as closely, but I would assume yes.

Q. Is the treatment at the transgender center consistent with the position and clinical guidelines of the American Psychological Association?

A. The same as the last answer. To my knowledge, I don't know them specifically, but I would say yes.

Q. Okay. Let's go a little bit for some of your memberships. You're a member of the American Medical Association, right?

A. No.

Q. Were you a member of the American Medical Association?

A. I was in the past, yes.

Q. Are you a member of the American Academy of Pediatricians?

A. Yes.

Q. Is your position in your report and as you

sit -- sit here today consistent with the position of the American Academy of Pediatricians?

A. It is not consistent with the -- the opinion that is presented by the AAP. Again, I will note that is not a -- a position that has been voted upon by the entire membership of the AAP.

Q. Are the -- all the positions adopted by the AAP voted upon by the membership?

A. No. In fact, they're usually voted on by a very small select committee, a -- a very minority of the entire academy.

Q. So the position of the AAP on this subject has been adopted via its regular procedures?

A. Yes. Which -- which I would add do not involve membership of the entire academy.

Q. Are you a member of the Endocrine Society?

A. Yes, I am.

Q. Are your positions here today and in your report consistent with the clinical guidelines of the Endocrine Society?

A. They are at odds with the recommendations that are put forward, the guidelines that are put forward for the treatment of gender dysphoria.

Q. You're a member of the Pediatric Endocrine Society, correct?

A. Yes, I am.
Q. Are your positions here today and the positions in your report consistent with the positions adopted by the Pediatric Endocrine Society?
A. They are not, and I've actually written to the PES on more than one occasion with my opinions and invited them to dialogue about the -- the scientific evidence that I have in dispute from -- that are included per the recommendations.
Q. And we've requested those comments, right?
A. Yes. And everything I have on file, I gave you everything I have. I don't have records of anything that I did not send you.
Q. You have published a body of literature in your career, correct? Right?
A. That is correct.
Q. How many peer-reviewed articles have you written and published regarding gender identity?
A. I have not published peer-reviewed articles on gender identity.
Q. How many peer-reviewed articles have you written and published regarding transgender people?
A. I have not written peer -- peer-reviewed papers on that topic.
Q. How many peer-reviewed articles have you

written and published regarding the treatment of transgender children and adolescents?

A. Again, as peer-reviewed, I have not written any.

Q. How many peer-reviewed articles have you written and published regarding the treatment of gender dysphoria?

A. I have not written any.

Q. How many peer-reviewed articles have you written and published regarding the use of restrooms by transgender students?

A. I have not written any.

Q. How many studies have you conducted regarding gender identity?

A. Conducted, I have not conducted any, but I am in the process right now of responding to a research funding announcement by the NIH to be able to engage in that research.

Q. But just to be clear, you haven't conducted any as we stand here today?

A. That is correct.

Q. And you -- have you submitted that proposal to the NIH?

A. I -- I have not.

Q. How many studies have you conducted

regarding transgender people?

A. I have not.

Q. How many studies have you conducted regarding the treatment of transgender children and adolescents?

A. I have not.

Q. How many studies have you conducted regarding the treatment for gender dysphoria?

A. I have not.

Q. How many studies have you conducted regarding the use of restrooms by transgender students?

A. I have not.

Q. So you have no experience treating gender dysphoria, right?

A. Treating gender dysphoria?

Q. Yes.

A. I have not -- as I said earlier, I have not treated patients with gender dysphoria.

Q. And you have no experience conducting studies regarding transgender youth and adolescents, correct?

A. Conducting studies, I have not, as I said, have not participated in any studies to date.

Q. And you have no experience conducting

studies regarding gender dysphoria?

A. I have not conduct -- as I said, I have not conducted any studies on gender dysphoria.

Q. Nor have you published any literature regard -- regard -- peer-reviewed literature regarding gender dysphoria?

A. Peer-reviewed, no.

Q. So having no experience treating transgender patients for gender dysphoria, no experience conducting studies regarding transgender people, and no experience publishing peer-reviewed literature regarding transgender people, you consider -- do you consider yourself an expert on transgender issues?

MR. KOSTELNIK: Object to form.

A. I am a physician/scientist who has extensively read the literature for the merits, as I do in any other condition, and I believe I have expertise related to my role as a physician and a scientist and a pediatric endocrinologist to adequately assess the quality and quantity of the literature that's present on this area.

Q. (By Mr. Gonzalez-Pagan) And having no experience treating gender dysphoria, no experience conducting studies -- scratch that.

Let's talk a little bit about your article,

references that I provided, that it would not be sufficient.

Q. (By Mr. Gonzalez-Pagan) Okay. Can you please read for me the last paragraph?

A. "In summary, as researchers and clinicians with expertise in gender and sexuality, we affirm that the 'Sexuality and Gender' report does not represent prevailing expert consensus opinion about sexual orientation or gender identity, related research or clinical care."

Q. Do you agree with that statement?

A. To the extent that the paper, the "Sexuality and Gender" paper, addresses the issue of consensus, what we define by consensus -- so the -- there are many individuals that signed this letter that have an opinion that is not supported by the literature that's cited in the "Sexuality and Gender" paper. So if you look to the specific information contained within that paper and critically evaluate it, I think that it would be at odds with what these individuals that have signed this paper have put forward.

Q. Is the position of the American Medical -- Medical Association at odds with the position of this [sic] several hundreds of signatories?

A. So the American Medical Association, all of

the -- the organizations that we already mentioned earlier in this deposition have similar statements related to the treatment guidelines, and all of them are limited by the lack of scientific justification or evidence supporting those recommendations.

Q. Okay. And just to clarify, that's the American Medical Association, right?

A. That's one of the organizations, correct.

Q. And the American Academy of Pediatricians, right?

A. That is correct.

Q. And the American Psychological Association?

A. That is correct.

Q. And the American Psychiatric Association?

A. That is correct.

Q. And the Endocrine Society?

A. That is correct.

Q. And the Pediatric Endocrine Society?

A. That is correct.

Q. And the World Professional Association of Transgender Health?

A. That is correct.

Q. All right. Would you agree that your article, Growing Pains, similarly does not reflect current scientific or medical consensus about gender

with that, so --

Q. Is "Growing Pains" your only article on transgender people and gender dysphoria?

A. Yes.

Q. Are you familiar with the St. John Paul II Bioethics Center?

A. Absolutely.

Q. Is this St. John Paul II Bioethics Center a religiously affiliated institution?

A. Yes, it is.

Q. Is it part of the Holy Apostles College and Seminary?

A. Yes, it is.

Q. Did you speak at the St. John Paul II Bioethics Center just three days ago, on Friday, November 17th?

A. I did, yes.

Q. During your speech last Friday, did you -- you said, "The identity of the individual is interactively linked to the body and the soul of the person." Is that right?

MR. KOSTELNIK: Form.

A. Repeat that again, just so I make sure you said that accurately.

Q. (By Mr. Gonzalez-Pagan) During your speech

last Friday, you said, "The identity of the individual is interactively linked to the body and soul of a person." Is that correct?

MR. KOSTELNIK: Form.

A. That is correct.

Q. (By Mr. Gonzalez-Pagan) During your speech last Friday, you said about being transgender, that, in fact, it probably goes back to some of the early heresies in the church; is that correct?

A. The introduction that I was providing to that audience was trying to put the context of the discussion in the proper framework, and I specifically made the statement that I am not a philosopher, that I'm going to be talking about issues of science and medicine. And it was an introduction to that talk to -- for that audience.

Q. Okay. Do you know who Caitlyn Jenner is?

A. Yes, I do.

Q. Caitlyn Jenner is a transgender woman, correct?

MR. KOSTELNIK: Form.

A. Caitlyn Jenner, formerly known as Bruce Jenner, is somebody that has been widely advertised in -- in the media related to the gender transition that -- that Caitlyn underwent.

Q. (By Mr. Gonzalez-Pagan) Is Caitlyn Jenner transgender?

A. By definition, yes.

Q. In referring to a picture of Caitlyn Jenner, did you not say these pictures are often disturbing?

A. I did. And that was the slide -- specifically was the statement, not Caitlyn Jenner, but there were two other pictures presented in that talk of children saying I hate my body. That was what I was referring to.

Q. Just to be clear, when it comes to the treatment of transgender people and gender dysphoria, your only publication is in a religiously-affiliated journal and you've spoken to -- about the topic to religiously-affiliated institutions?

MR. KOSTELNIK: Form.

A. I have offered to speak at all institutions that have invited me. And to date, yes, that was -- that was the institute that -- that invited me to speak last Friday.

Q. (By Mr. Gonzalez-Pagan) When did you first become interested in the matter of transgender people and the treatment of -- for gender dysphoria?

A. It was about five to six years ago, as chief of our Division of Endocrinology, when the question

A. I provided everything that I have access to right now that I can recall. I'm only stating that there are likely other papers that I do not have access to, because I did not keep track of it at the time that I read them or looked at them.

Q. Okay. Have you spoken with Dr. Allan Josephson?

A. Yes, I have.

Q. When?

A. On multiple occasions.

Q. Can you please describe?

A. I met Dr. Josephson within the last year as -- it was probably in the spring at some point in time, the first time that I actually met him. We've had a number of conversations over this past year, specifically related to his expertise as -- as a psychiatrist and mine as an endocrinologist. I have drawn upon him for questions related to psychiatric issues that -- that I did not have expertise in, to gather his opinion.

Q. In what capacity did you first counter-interact with Dr. Josephson?

A. It was at a conference that was put together to bring experts from various disciplines to this question of -- of gender dysphoria.

Q. Who put that conference together?
A. The Alliance Defending Freedom.
Q. The Alliance Defending Freedom is a religiously-affiliated institution, isn't it?
A. If you say so. I don't pay attention to what their religious affiliation is.
Q. When was this conference?
A. It was in the -- I don't know the exact date, but it was in the spring.
Q. Where was this conference?
A. It was in Phoenix.
Q. Aside from you and Dr. Josephson, do you recall any other experts, physicians or clinicians that attended this conference?
A. Yes, there were -- there was several other psychiatrists and psychologists. I don't remember their specific names, unfortunately. There were people that are in the social sciences. There was one other endocrinologist. I'm trying to remember who else was there. There were several lawyers from the ADA.
Q. Do you have any documents pertaining to this conference?
A. Not that I saved, no.
Q. Just to clarify, is there anything you

university, they offer gender-affirming treatment for gender dysphoric youth?

A. Yes, they do.

Q. Do they offer reparative treatment as a treatment for gender dysphoria at Boston Children's Hospital?

MR. KOSTELNIK: Form.

A. The word reparative therapy covers a lot of connotation by different people but to my understanding, they do not make any specific effort in counseling to lead to the realignment of gender with sex, if that's what you mean by conversion therapy.

Q. Before you started researching the issues of dysphoria around five years ago, had you met with Dr. Spack then?

MR. KOSTELNIK: Form.

A. Prior to five years ago, I do not recall a specific encounter yet. I'm sure we interacted at some point at one of the international meetings.

Q. (By Mr. Gonzalez-Pagan) In Paragraph 7, you state that you have met with parents of children with gender dysphoria; is that correct?

A. That is correct.

Q. In what capacity have you met with the parents of transgender children?

A. Again, this was at the very early time frame when I was trying to investigate the claims for the treatment and care, and I wanted to get as comprehensive of a viewpoint as I could. The first encounter I had was with a mother of an organization called Trans Parent Child, and I sat down for lunch with her for an extended period of time, more to listen to the experience that she had in countering a transgender child that she had.

Q. With how many parents of transgender children have you met?

A. Met or spoken on the phone? I think lately many of them have been over the telephone. I would say it's less than a dozen, but it's quite a few, and it's actually increased certainly since the publication of the "New Atlantis" article.

Q. So in the last five years, you've spoken to less than a dozen parents of transgender children?

A. Yes.

Q. When you first met with the parent of the -- associated with the organization Trans Parent, was this before you dealt -- scratch that.

MR. GONZALEZ-PAGAN: You're going to object anyway.

Q. (By Mr. Gonzalez-Pagan) When you met with

the parent associated with the association Trans Parent, had you already delved into the literature regarding gender dysphoria?

A. I was starting the process. It was very early on, so I don't recall the exact timing. I had read some papers, but I was still in the very early investigative phase.

Q. You said you have been contacted by parents since the publishing of your article "Growing Pains." Is that correct?

A. That is correct.

Q. How many have contacted you since the publishing of the article "Growing Pains"?

A. I'm not keeping track of that.

Q. Less than 35?

A. It may be more than five. Probably less than a dozen.

Q. What did you discuss with the parents of the transgender children that have contacted you since the publishing of your article "Growing Pains"?

A. I specifically discussed the context of my "New Atlantis" article in my role as a physician, which I always take as being a teacher. I try to educate them on my understanding of the condition and the treatment paradigm that was being offered to their

outcome and one with no bias as to what the outcome is. The goal, my understanding, of the people that I would recommend for psychiatric care would be interested in the best interest of the child for their best psychosocial functioning moving forward. That is the goal.

Q. Are you aware that reparative therapy is considered harmful by the American Medical Association?

A. I find no scientific justification to support that statement, but they do say that, yes.

Q. Are you aware that the Department of Health and Human Services commissioned a study with regards to conversion therapy?

A. I am familiar with the evidence that's available that's put forward as the evidence that says that it's harmful, and it's by no means definitive information. There are problems with the studies that limit the ability to make those conclusions.

Q. Just to clarify, you believe reparative therapy is an appropriate option for treatment?

A. I don't believe there's enough evidence to make a definitive statement one way or the other, but I believe that there -- that the psychotherapy that I believe can be helpful, whether it leads to conversion

access the bathrooms as the cause of Drew's distress is not supported.

Q. But you're not a mental health provider, right?

A. That is correct.

Q. And you've never met with Drew, right?

A. That is correct.

Q. Let's go back to the meetings with parents that you had when you were first delving into this topic?

A. Very good.

Q. You discussed that you met with a parent associated with an organization called Trans Parent; is that correct?

A. That is correct.

Q. What did you learn from that meeting?

A. I learned quite few things. The most important thing that I learned, and that was what I was actually seeking in the interaction, was to really understand the suffering that was going on in this family. I wanted to understand the dynamics of what was going on in the family, the approach that the parents had in dealing with the presentation of their child, what they had attempted to do to address this particular issue, and at that point in time, I was

approaching this in a purely investigative manner. I did more listening than anything else, asking questions about their lived experience.

Q. What did the parent tell you?

A. Well, that was many years ago, but I will try to summarize my recollection of that conversation. This was with the mother. And she shared that this child, who was a prepubertal in early grade school, told her, when the mother was talking -- they were combing hair or something of that nature -- that she would -- he, at that time, was a girl, so she was referring to him as a girl, and that the parents' reaction initially was shock, fear, trying to understand what was going on, trying to be able at that time -- this was early on in this resurgence -- or emergence, I should say of this discussion that's going on socially, so there wasn't, at that time, a lot of resources being published on the Internet.

So she shared her attempt to look at what experience people have had with this particular condition. And I saw at that time, certainly a parent that was desiring to do the best for their child, but having questions that were not answered, and at that time, with the information I had, I was certainly not able to provide any answers. And, in fact, at this

point in time, I don't think I would have been able to specifically answer the questions that she had as far as long-term outcomes, because we don't have that information. It was a very respectful conversation. It was very helpful. I think that it was mutually beneficial, but, again, the purpose was for me to understand this particular family and their experience with transgender identity.

Q. What is the organization Trans Parent?

A. All I know is it's a -- it's supposed to be a support group, and I think that the parents themselves, the woman I talked to at that time was trying to get out information so other people understood what they were experiencing.

Q. In that meeting with the parents of a transgender -- let me scratch that.

The next set of the questions I'm just going to be focusing on that one parent.

A. Okay.

Q. In that meeting with the parent of the transgender child, did you ever tell the parent that their child was not normal and would never be normal?

A. I did not, because I was still investigating and trying to understand what was going on.

Q. In that meeting with the parent of that

transgender child, did you ever tell that parent that their transgender son was a girl and would never be a boy?

A. I never said that, no.

Q. In that meeting with the parent of that transgender child, have you ever told -- scratch that.

In that meeting with the parent of a transgender child, did you ever tell the parent that surgeries attempting to change sex was wrong and went against God's plan for humanity?

A. No, not that I recall. That was many years ago, but I don't remember that, no.

Q. In that meeting with the parents of the transgender child, did you not urge them to read Pope John Paul II's writing on gender to fully understand God's plan regarding gender?

A. Thank you for reminding me. That was a long time ago, so this is bringing back some information. I believe that -- this was a personal conversation. This was a one-on-one conversation, and I think at the time that we began talking about that, she started relating her personal faith training, and I never back away from those conversations when people are asking me those questions, and I think that that's what led to that particular conversation.

Q. Are you aware that the AMA, quote, "opposes the use of reparative or conversion therapy for sexual orientation or gender identity"?

MR. KOSTELNIK: Form.

A. I'm aware of the WPATH saying that, and I -- I believe it may also be in the AMA statement as well.

Q. (By Mr. Gonzalez-Pagan) Are you aware that the American Academy of Pediatricians has stated that, quote, "In no situation is a referral for conversion or reparative therapy indicated"?

A. I'm aware of that statement, yes.

Q. Are you aware that a publication by the American Psychological Association and the U.S. Department of Health and Human Services states that interventions -- quote, "Interventions aimed at a fixed outcome, such as gender conformity or heterosexual orientation, including those aimed at changing gender identity, gender expression and sexual orientation are coercive, can be harmful and should not be part of the behavior health treatment"?

MR. KOSTELNIK: Form.

A. I am aware of that statement, but there is no scientific evidence to support that statement.

Q. (By Mr. Gonzalez-Pagan) On what basis do you disagree with that statement?

amount of experience that somebody who is a clinical -- a full-time clinician versus -- now, I -- I know from my own experience many people that are listed on those clinical studies were not the ones that designed the trial. They're not the ones analyzing the data. Their role usually in those studies, as clinical faculty, are usually in filling out and the protocols that are present for those. And now the specifics of the trial that she's involved with, I would have to look in more detail to assess that in -- in greater detail.

Q. Okay. Do you know what her role is?

A. You'll have to tell me what the study is and -- and give me more information to be able to do that.

Q. Did you review Dr. Ehrensaft's expert -- expert report in this case?

A. I did.

Q. Have you published any peer-reviewed literature regarding gender dysphoria or transgender youth?

A. These are questions that I've already answered, and the answer is no.

Q. Okay. Are you aware that Dr. Ehrensaft has published a number of peer-reviewed articles regarding

IN THE UNITED STATES DISTRICT COURT FOR
THE DISTRICT OF SOUTH DAKOTA

TERRI BRUCE,)
Plaintiff,)
vs.) No. 17-5080
STATE OF SOUTH DAKOTA and)
LAURIE GILL, in her official)
capacity as Commissioner of)
of the South Dakota Bureau)
of Human Resources,)
Defendants.)

DEPOSITION OF DR. PAUL W. HRUZ, M.D., Ph.D.
TAKEN ON BEHALF OF THE PLAINTIFF
JULY 16, 2018

(Starting time of the deposition: 8:49 a.m.)

Exhibit
0003
9/29/2021
Hruz

I N D E X

PAGE

QUESTIONS BY:

Ms. Cooper 5

E X H I B I T S

EXHIBIT	DESCRIPTION	PAGE
Exhibit 1	Dr. Hruz Expert Declaration	40
Exhibit 2	Cross Sex Steroids Article	51
Exhibit 3	International Conference/Madrid Document	56
Exhibit 4	About The National Catholic Bioethics Quarterly	69
Exhibit 5	Declaration of Dr. Spack	84
Exhibit 6	Endocrine Treatment of Gender Dysphoria; Clinical Practice Guideline	223
Exhibit 7	Expert Declaration of Dr. Paul Hruz - Adams Case	262
Exhibit 8	National Catholic Certification Program in Health Care Ethics	293

(Original exhibits retained by the court reporter to be copied and attached to the transcript.)

IN THE UNITED STATES DISTRICT COURT FOR
THE DISTRICT OF SOUTH DAKOTA

TERRI BRUCE,)
Plaintiff,)
vs.) No. 17-5080
STATE OF SOUTH DAKOTA and)
LAURIE GILL, in her official)
capacity as Commissioner of)
of the South Dakota Bureau)
of Human Resources,)
Defendants.)

Deposition of DR. PAUL W. HRUZ, M.D., Ph.D., produced, sworn and examined on the 16th Day of July, 2018 between the hours of 9:00 a.m. and 5:00 p.m. at the offices of Alaris Litigation Services, 711 N. 11th Street, in the City of St. Louis, State of Missouri, before Rebecca Brewer, Registered Professional Reporter, Certified Realtime Reporter, Missouri Certified Shorthand Reporter, and Notary Public within and for the State of Missouri.

A P P E A R A N C E S

FOR THE PLAINTIFF:

Ms. Leslie Cooper

Mr. Joshua A. Block

American Civil Liberties Union Foundation

125 Broad Street, 18th Floor

New York, New York, 10004

Lcooper@aclu.org

Jblock@aclu.org

FOR THE DEFENDANT:

Mr. Jerry D. Johnson

Jerry Johnson Law Office

909 St. Joseph Street, Suite 800

Rapid City, South Dakota, 57701

Jdjbjck@aol.com

Ms. Rebecca Brewer, RPR, CCR, CRR

Alaris Litigation Services

711 North Eleventh Street

St. Louis, Missouri, 63101

(314) 644-2191

clarify what you mean by formal education.

Q Well, I'll ask broadly; any kind of training of any sort that a doctor would get in the course of, you know, either their initial medical education or continuing education.

A So, working at a major academic institution, we're actually charged with providing medical education and so, to the extent that we've held journal clubs that we've had presentations with my colleagues where we've discussed the scientific evidence, where we've gone formally through the DSM Guidelines, where we've gone through the Endocrine Society Guidelines, that has been done at my institution. Have I sought out and gone to a separate conference related to gender dysphoria? The answer is no.

Q But, at your own institution, you've participated in these interactions, these journal clubs and other activities that address gender dysphoria and the treatment for gender dysphoria?

A That is a standard -- that is one of the components of what we do for all the conditions that endocrinologists are engaged in.

Q Okay. Have you conducted any research related to gender dysphoria or the treatment of

gender dysphoria?

A No formal trials, no.

Q Any other research?

A I've been in the area of HIV research for 20 years and conducted a number of scientific studies that -- but not directly related to gender dysphoria.

Q Yeah, I'm sorry if I was unclear. I didn't -- I know you've done research, but in the area of gender dysphoria, no research, is that right?

A I have not done any -- I'm not a clinical trials physician scientist. I'm a bench scientist.

Q What does that mean?

A I conduct laboratory research, so I'm engaged in hypothesis-driven research.

Q Okay. So, talking about research broadly, you haven't conducted any form of research relating to gender dysphoria, is that right?

A No, I have. I would consider research in looking at the extensive literature that's there is research. It's not a randomized controlled trial, it's not a formal study, but that would fit within the domain of research.

Q You mean reviewing research that was

published by other people? Is that what you mean?

A So, again, we can define research in many different ways. If you're asking the question about research, about gathering information, about the evidence that's available, I've done a considerable amount of research and that has consisted of looking at what published data is available supporting the recommendations that are being made. That I would consider research, but it is not a clinical trial.

Q Okay. And what people might call studies, scientific studies, have you done any scientific studies?

A Again, how you define studies, again, I have not done clinical trials.

Q Okay. When you were deposed in the Adams case, November, I believe it was, last year, you mentioned you were in the process of responding to a research funding announcement by the NIH to do research related to gender dysphoria or gender identity issues. Did I get that right?

A Yes.

Q Can you tell me the status of that?

A Yes. There are a number of logistical issues that are needing to be worked out. There is no funding for that particular study going on,

recruiting the people that are going to be necessary to conduct that study, again, I'm a pediatric endocrinologist. And to my knowledge, you know, that hasn't moved much beyond the initial planning stages. The proposal itself was a suggestion to address the question of -- a very particular question of the effects of pubertal blockade on the trajectory as far as the number of individuals that went on to cross hormone therapy and those that did not.

Q So, did you ever submit a proposal to NIH to do this research?

A No.

Q Okay. Did you ever respond to the funding announcement in any way?

A Depends on how you say "respond." I've already said I did not submit a proposal. I have taken that to colleagues. In fact, I've had very recent discussions with my colleague at Washington University that is interested in starting some sort of research effort. And I could speak at length of what I've recommended to him as far as how these studies should be conducted. I've been very disappointed that the rigor -- scientific rigor that's necessary for those studies is not currently

realignment of gender identity with sex that occurs when people do not get pubertal blockade, to the results of that particular -- again, it was a very small study -- would lead to that being asked as a hypothesis as to whether that intervention itself might have been influencing the outcome.

Q So, just to make sure I'm clear, it is still just a hypothesis that pubertal blockade could lead to persistence? That's not been proven?

A That is correct. And the opposite has not been proven as well.

Q I understand. Okay. Let's take your report from this case. Actually, before we turn to that, I forgot to ask one other question. Do you have experience conducting clinical trials on any topic?

A I've only been involved in one clinical trial. It's a very small study and my role was very minor.

Q And what was that topic?

A It was on the influence of insulin sensitivity on cardiac function.

Q I see. So clinical trials isn't your area of expertise?

A That is correct.

the meeting was?

A He was trying to convene a meeting so we could discuss the issues related to gender dysphoria. There was -- they were searching for somebody from the endocrine field that would be willing to talk over the issues that I had expertise in, that I had developed my understanding of what the literature showed, and he specifically said, You've got expertise in this area and we'd like to learn.

Q And did they talk about a need to develop expert witnesses for litigation?

A You know, I think that was implicit. I don't think that was -- I mean, I was not surprised when I was asked to serve as an expert. I'd actually submitted a declaration prior to that meeting. And I'm not sure exactly how that -- any of the details how I was asked to do that, but so I had already done some of the work there, so I made the assumption that that was one of the reasons why he invited me down.

Q Okay. So, the folks there were people who would potentially be expert witnesses in litigation?

A Not everyone that was there. I think there were people that explicitly said, I'm not

Adolescent Health, Medicine and Therapeutics

Dovepress
open access to scientific and medical research

Open Access Full Text Article

REVIEW

Gender nonconforming youth: current perspectives

This article was published in the following Dove Press journal:
Adolescent Health, Medicine and Therapeutics
25 May 2017
Number of times this article has been viewed

Diane Ehrensaft

Department of Pediatrics, University of California, San Francisco, CA, USA

Abstract: Beginning with a case vignette, a discussion follows of the reformulation of theories of gender development taking into consideration the recent upsurge of gender nonconforming and transgender youth presenting for gender services and also in the culture at large. The three predominant models of pediatric gender care are reviewed and critiqued, along with a presentation of the recently developed interdisciplinary model of gender care optimal in the treatment of gender nonconforming youth seeking either puberty blockers or cross-sex hormones.

Keywords: gender nonconforming, transgender, pediatric gender care, puberty blockers, cross-sex hormones

Introduction

The field of interdisciplinary treatment for gender nonconforming children and youth has not just expanded at an astronomically fast rate; to switch metaphors, it has rather been such as a tsunami, with a swell of children and families seeking support and services and stretching existing gender clinics and programs at their seams. This cohort of young people includes those who do not accept the sex assignment given to them at birth, those who do not accept their culture's expectations and rules about gender roles and gender behaviors, and those who present with a combination of both.

The case of Daniel is presented to launch this review of current perspectives on gender nonconforming youth. Daniel was 19 years old and in his first year of college (note: all identifying information has been changed to preserve confidentiality. In addition, the patient in the case vignette has provided written informed consent for the publication of the anonymized case details). Just a few months earlier he had announced to each of his parents, who were divorced, that he was transgender. For some years before that, he had been living as a girl, assuming that he was either a "butch dyke" or a masculine identified bisexual young woman. His father and stepmother's response was, "Yes, of course, it makes perfect sense. We'll support you in whatever you need". His mother's response was quite different, "God gave you a body, why would you want to go against God's will? I am so ashamed. What will I ever tell my family? I've always supported you, but I can't do this".

Taking a history, Daniel reported that by the end of his sophomore year in high school he discovered that he was transgender. Before that, he never had the language for who he was. Up until second grade, he, then she with the name Daisy, truly believed that when she reached puberty she would simply switch gears, grow a penis, get a beard,

Correspondence: Diane Ehrensaft
Department of Pediatrics, University of California, 445 Bellevue Avenue Suite 302 Oakland, CA 94610, USA
Email dehrensaft@earthlink.net

and become a man. From early childhood she dressed like a boy, insisted on wearing her hair short, and was perceived by all as the neighborhood tomboy. When she learned about the physical changes that accompanied female–menstruating, growing breasts, she responded, by her own report: "Whew, I'm so glad I'll never have to go through that". When an older youth disabused her of her misconception, informing her that she would receive no exemption and she would never grow to be a man because she was born a girl, she was temporarily devastated, coming to the realization that she was now doomed to walk the plank of female development. For her, this was a horrible thought. When she actually got her period in the sixth grade, she experienced, with trepidation, that her fate had been sealed – "I'm cooked, there's no turning back now".

In middle school, Daisy had her first girlfriend; she confided in her older brother about her new romance, and he promptly issued her a label, "You're a dyke". Except Daisy kept protesting, "I like boys, too". For high school, Daisy chose to go to a boarding school, the prime reason being that she was tired of going back and forth between two houses in her postdivorce family, and just wanted one place to settle into. It was a Catholic all-girls school and she got in trouble for having a romantic relationship with another girl at school. She persisted in dating girls, just not ones from her school, and through her peer connections first learned about the concept of transgender. She surfed the internet, joined chat rooms, and came to discover that "transgender would be me". Her then girlfriend, beginning to recognize who her partner really was, began referring to Daisy as D. and using male pronouns for D. D. never felt happier. But D. kept it a secret for 2 years, waiting out the end of high school and the opportunity to start a new life in college before affirming a male identity publicly. D. chose a liberal arts college far away from home and within weeks came out at school as Daniel. By Thanksgiving break, Daniel was ready to disclose to his parents, and that circles back to the beginning of the story.

After disclosing to his parents, Daniel then wanted hormones to align his body with his male identity, envisioning surgeries, including top and genital surgery, in his future, but not right then. Daniel's story is presented as an opener to highlight the two questions, "What is your gender?" and "What is to be done once discovered?" that underlie all existent adolescent gender care.

Daniel's case is not a unique one. One might even say that it is emblematic of the increasing number of youth who are seeking professional services, along with their parents, to sort out their authentic gender and discover ways to affirm that authenticity. In most Western cultures gender has historically been considered bedrock: one is assigned a sex at birth, either male or female, typically based on external appearance of genitalia, and this assignment determines one's gender for the duration of that individual's life. Upon entrance into the 21st century, that paradigm of gender bedrock has been hit with a sledge hammer; in its stead, we now have gender as moving boulders, with a sensibility of gender not coming in two boxes, but in infinite varieties, and not necessarily stable over the course of one's lifetime. As this has occurred, providers struggle to keep up with newly emerging theories of gender development and standards of care for the proper care of these youth. Just as an example, the World Professional Association for Transgender Health 7th Edition of the Standards of Care,[1] released in 2011, is already outdated and in the process of being revamped, with the section on children and adolescents in particular need of an update. The needed changes come most significantly in the area of social gender transitions for prepubertal youth, minimum ages for medical interventions, particularly puberty blockers and cross-sex hormones, but also surgeries for individuals before reaching the age of majority. Regarding numbers, the cohort of gender nonconforming youth seems to have expanded exponentially in the most recent decade, as reported by gender programs serving these children throughout North America and beyond.[2,3] In negotiating these phenomenal changes in the gender terrain, four major areas have needed to be addressed: the necessity of relearning gender so that health professionals can retool themselves to best serve this group of youth; the tensions between the three models of care; the importance of interdisciplinary collaboration in care; the introduction of medical interventions in the care of the youth.

Reformulate theories of gender development in light of gender nonconforming youth

Most professionals in the field of gender care have had to unlearn everything taught in training about gender and relearn a new model of gender development. To review the traditional model, children at birth are assigned a sex, male or female, typically based on appearance of external genitalia. If the genitalia were ambiguous in appearance, genital surgical procedures to establish a stable singular sex assignment with matching gender were to be performed as soon as possible, and no later than 18 months. The reasoning behind this, as propounded by Dr John Money and his associates,[4] was that after 18–24 months a child is firm in a core gender identity – I am male, I am female, and thereafter it becomes very difficult to change that identity as it is

already cognitively fixed. Once knowing one's gender label, which is both facilitated and mediated by parents' conscious and unconscious messages and reflections, a child's next developmental task is to learn how to "do" gender. Known as gender role socialization, this process is done in close relationship to one's mother and father, with the underlying assumption that all children will have both.[5,6] Within the psychoanalytic paradigm, during this same period a tumultuous drama unfolds, the Oedipal phase – children have intense erotic fantasies about their parents: boys will want to marry their mothers, girls their fathers. Through successful negotiation of these fantasies, facilitated by parents' empathy and boundary setting, children will emerge from the Oedipal phase relinquishing those infantile incestuous desires, firming their own heterosexual identities as they forestall gratification and await an opposite sex partner of their own when they reach adulthood.[7] Within that process they will establish a firm gender identity with a new understanding that one is and always will remain the sex listed on one's birth certificate or assigned early in life (for intersex children).[8] Throughout middle childhood youth will continue to internalize the gender norms of their culture, and learn to conform to them. With the advent of puberty and the entrance into adolescence, a new phase of gender consolidation occurs as youth awaken to their adult sexual urges and prepare for their gender-divided roles as men or women.

Within the traditional model of gender development, if this developmental trajectory takes a course other than that described above, there is cause for concern for the child, along with scrutiny of the parents, as parents are held accountable for the child's anomalies. To quote Robert Stoller, a pioneer in the treatment of gender disorders in youth in the 20th century,[9] speaking of "primary transsexual" boys (those nonintersex boys who have been feminine from the first year of life): "As an infant, such a boy usually has an excessively intimate, blissful, skin-to-skin closeness with his mother. This, unfortunately, is not interrupted by his father, a passive distant man who plays no significant part in bringing up his son" (p. 16). In family situations like the one inscribed above by Stoller, professional help was recommended to cure the youth's gender anomalies and to treat the parents so they cease veering their child's gender development in wrong directions because of their own internal conflicts.

For a theory of development to be robust, it should be evident in empirical observation or investigation. The traditional theory of gender development and disordered gender, which is still in use by many, fails that test, for the following reasons:[10]

- Many individuals continue renegotiating their gender throughout childhood or adulthood, with no observable detriment to their mental health;
- Youth may establish a gender identity in concordance with their assigned sex, be firm in that identity, yet not embrace a heterosexual identity, with no aspersion on their emotional well-being. Gender development and sexual identity development are two separate developmental tracks, albeit crossing at certain points.
- Whereas core gender identity is typically concordant with assigned sex based on observable external genitalia, for a minority of people this is not the case, with increasing evidence that gender identity lies not between our legs, in our genitalia and primary sex characteristics, but in our brains and minds.[11]
- Therefore, one's assigned sex at birth may differ from one's core gender identity, not because of poor parental handling or infantile confusions, but because of brain and mind gender messages overriding signals from genitalia, chromosomes, or parental expectations. Recently, this phenomenon of mind over matter has been referred to as "neurological sex", defined as a uniform standard of legal sex based on gender identity, in which brain messages are privileged over anatomy and chromosomes in determining an individual's authentic gender.[12]

In contemporary versions of gender development theory that take into account gender variations as a normal part of the human condition, the understanding is that the sex assigned at birth may match the gender a youth will eventually know themselves to be, but it might not. Each child is presented with a developmental task of weaving together threads of nature, nurture, and culture to establish their individual and unique authentic gender self. This self will be composed of both gender identity – who I know myself to be as male, female, or other, and gender expressions – how I choose to perform my gender, including clothing choices, activity preferences, friendship choices, and so forth. Recently, this transactional relationship between nature, nurture, and culture in gender development has been referred to as the gender web,[13] broken up into components that consist of the items in Table 1.

In this contemporary model of gender development, added to the three dimensions of nature, nurture, and culture is the fourth dimension: time. Each child alters their gender web as they weave together nature, nurture, and culture, "over time". In other words, gender is neither fixed by age 6, as in the traditional model, nor static throughout all stages of child and adult development, thus explaining how an individual

Table 1 Gender development: elements of the gender web

- Chromosomes
- Hormones
- Hormone receptors
- Gonads/primary sex characteristics
- Secondary sex characteristics
- Brain
- Mind
- Socialization: family, school, religious institutions, community
- Culture: values, ethics, laws, theories, and practices

at age 40 or 50 could come to the realization that the gender they had identified as being is no longer a good fit. It is also recognized that gender development is a discrete and separate track from development of one's sexual identity, and typically proceeds it in a youth's development.

In this model the role of parents and socialization agents is not to shape or reinforce a child's gender identity or expressions, but rather to facilitate it, mirroring back to the child the messages that the child communicates about their preferred gender expressions and articulated gender identity, which may or may not be in concordance with the sex assigned to the child at birth. With the advent of adolescence, it is recognized that some youth's gender trajectories may benefit from medical interventions, including puberty blockers (gonadotropin-releasing hormone [GnRh] agonist) and cross-sex hormones to bring the youth's body in better alignment with their affirmed gender identity.[14] To that end, the model of care that extends from this contemporary theory of gender development is one that strongly relies on interdisciplinary care, especially between mental health and medical providers as they address the holistic medical and psychosocial needs of the emergent cohort of gender nonconforming youth from the perspective of both their psychological and physical development.

Major mental health treatment models for gender nonconforming children and youth

As of the second decade of the 21st century, three major treatment models are available for addressing the needs of gender nonconforming children and their families, with overlapping premises based on the contemporary model of gender development outlined above but with distinct differences between them. The first model, represented in the work of Drs Susan Bradley and Ken Zucker, assumes that young children have malleable gender brains, so to speak, and that treatment goals can include helping a young child accept the gender that matches the sex assigned to them at birth. The second model, represented in the work of practitioners in the Netherlands, allows that a child may have knowledge of their gender identity at a young age, but should wait until the advent of adolescence before engaging in any full transition from one gender to another. The third model, represented in the work of an international consortium of gender affirmative theoreticians and practitioners, allows that a child of any age may be cognizant of their authentic identity and will benefit from a social transition at any stage of development. To situate and compare each of the three models, a typical referral that may come the way of a gender specialist, regardless of their orientation, is presented, with the assumption that this potential patient may be in need of services from a young age through adolescence:

> Hi Dr, I came across your information while I was researching for my son.
>
> He recently just turned 4 and wants to be a girl and is only drawn to girl toys/clothes for the past 2 years.
>
> We have not spoken with a professional doctor. But wanted to reach out early and find ways we as parents can support him.
>
> Please let me know if you could help.
>
> Thank you!

Dialing back a generation, if this child's name was Kyle and the same query came to a mental health professional participating in, for example, Dr Richard Green's clinic at the University of California Los Angeles, the treatment recommended and then implemented could very well have looked like this:

> When he was five, Kyle entered a behavior modification program. [...] Kyle received blue tokens for "desirable" behaviors […] red ones for "undesirable" behaviors […]. Blue tokens were redeemable for treats […]. Red tokens resulted in a loss of blue tokens, periods of isolation, or spanking by father.[15]

Setting a precedent for other clinicians of the time treating children who presented as gender nonconforming, Kyle's treatment at the UCLA program is emblematic of the model implemented during this era, with the goal of helping children accept the sex assigned to them at birth and adopt the culturally defined appropriate gender behaviors that would match that sex assignment, in alignment with the traditional model of gender development. Underlying the treatment was the intent of warding off a homosexual outcome for young effeminate boys. It should be mentioned

that this model is still practiced today, referred to by some as the reparative model.

Focusing now on contemporary approaches that stand in contrast to the above mode, all of which are to be differentiated from the UCLA program, the three major models, outlined earlier, are typically referred to, in order of presentation, as the following:

- The "live in your own skin" model
- The watchful waiting model
- The gender affirmative model

Below is a review of the manner in which each of these models would approach the treatment of a child or youth who is presenting as gender nonconforming, in their gender identity, gender expressions, or both.

The "live in your own skin" model

As mentioned earlier, this model was developed by Drs Susan Bradley and Ken Zucker at the Center for Alcoholism and Mental Health gender clinic in Toronto.[16] The treatment goal of facilitating a young child accepting the gender identity matching the sex assigned to that child at birth, based on the supposition that younger children, in contrast to older youth, have a malleable gender brain, is tied to a medical–social rationale. Specifically, being transgender is a harder way to live one's life, both because of social stigma and potential requested hormonal treatments and surgeries to align a youth's body with their transgender identity. Given the perceived plasticity of the young child's gender brain, best practice would be to introduce interventions to help a child accept the sex assigned to them at birth as their gender identity, with no harm done and indeed added benefit to their psychological and social well-being. As explained by Dr Zucker, employing this strategy results in lowering the odds that "as such a kid gets older, he or she will move into adolescence feeling so uncomfortable about their gender identity that they think that it would be better to live as the other gender and require treatment with hormones and sex reassignment surgery".[17] In addition to presuming gender identity malleability in young children, the model also assumes that parents' own conflicts or issues about gender likely contribute to a young child's gender dysphoria. With the parents' consent, the "live in your own skin" model employs a combination of behavior modification, ecological interventions, and family system restructuring to facilitate the child arriving at a place of accepting the gender matching their sex assigned at birth. Practices could include taking away cross-gender toys at home and replacing them with "gender-appropriate" toys, altering children's playmate choices to include more same-sex contacts, enrolling the children in "gender-appropriate" activities, encouraging the like-sex parent to become more actively involved and the opposite-sex parent to step back in relationship to the child, and offering psychotherapy to both the child and parents. The aim of treatment of the child is to explore the child's gender and solidify a "live in your own skin" outcome, and the treatment with the parents is aimed at investigating conflicts or psychological issues stemming from or contributing to the child's gender dysphoria. If by the arrival of puberty a child is still exhibiting cross-gender identifications and expressing a cross-gender identity, that child should be supported in transitioning to the affirmed gender, including receiving puberty blockers and hormones, once it is assessed through clinical interviews and psychometric testing that the affirmed gender identity is authentic. The reasoning behind this shift in adolescence is as follows: 1) by adolescence it is too late to intervene in facilitating a child living in their own skin, as the sensitive period of malleable brain development of gender has closed; 2) this individual can now be reliably identified as one of the small minority of youth who persist with a cross-gender identity from early childhood into adolescence, an indicator that this identification will most likely remain stable into adulthood. In the live in your own skin model, the parent reaching out for support of her 4-year-old son might be encouraged to engage in the treatment program outlined above, with the goal of helping her child accept that he is a boy, not a girl and with the intent of warding off a transgender outcome.

The watchful waiting model

The "watchful waiting" model was designed by the members of the interdisciplinary team at the Amsterdam Center of Expertise on Gender Dysphoria, VU University Medical Center, under the leadership of Dr Peggy Cohen-Kettenis. Borrowing from the medical use of GnRH agonists for children exhibiting precocious puberty, the Netherlands team is responsible for introducing the use of puberty blockers for gender purposes, to put a pause on pubertal growth and allow more time for a youth to explore their gender and consolidate their adolescent gender identity, with the future possibility of cross-sex hormone therapy to align their bodies with their affirmed gender identity. In contrast to the live in your own skin approach, a young child's demonstration of gender nonconformity, be it in identity, expressions, or both, is not to be manipulated in

any way, but observed over time. If a child's cross-gender identifications and affirmations are persistent over time, interventions are made available for a child to consolidate a transgender identity, once it is assessed, through therapeutic intervention and psychometric assessment, as in the best interests of the child. These interventions include social transitions (the shift from one gender to another, including possible name change, gender marker change, and gender pronoun changes), puberty blockers, and later hormones and possible gender-affirming surgeries. No attempts are made to alter a child's gender identity or expressions; yet it is postulated in this model that it would be better to hold off until puberty on any social transitions of a child from one gender to another, and instead give them safe spaces to fully express their gender as they prefer before facilitating any full gender transitions.[18,19] The rationale for holding off on any social transitions until adolescence is not to ward off a transgender identity but rather that 1) it would be advantageous that a child experiences the first stages of physical puberty for that child to best make a determination of the gender that feels most authentic to him/her; 2) given developmental stages of childhood, facilitating a social transition from one gender to another at a young age may create a form of cognitive constriction – the child may be prematurely blocked from considering any other possibilities once moved into a cross-gender status and socially constricted from further childhood gender exploration because now they know the cross-gender identity is what everyone has come to expect from them; 3) socially transitioning a child at a very young age may preclude the child from maintaining a realistic understanding of their body and historical status – as a penis-bodied (once a boy) or a vagina-bodied (once a girl) person. In informing their practices, this model, like the live in your own skin model, relies on the data gathered about "persisters" and "desisters", both at their own clinic in the Netherlands and in other international studies, particularly those conducted at the Centre for Addiction and Mental Health (CAMH) gender program in Toronto. In the most recent review of these studies, it was found that 63% of the children seeking services at a gender clinic at a young age, and diagnosed with gender dysphoria, no longer had that diagnosis at puberty, while 37% did have the diagnosis consistently from early childhood to adolescence.[20] Since a large majority of gender nonconforming young children seeking services at gender clinics desist in their gender dysphoria by adolescence, best practices would be to wait and see if the child persists into adolescence before making any significant changes in a child's gender identity.

During the preadolescent waiting period, the children are followed carefully by the clinical team in the watchful waiting model, with the support of outside therapists in the community (which is required before a child can receive medical services), to assure that the children are growing well and getting their emotional needs met, and in preparation for later transitioning and medical interventions if the child proves to be a good candidate. Like in the live in your own skin model, the children going through the program also receive a full battery of psychological tests, documenting not only their gender status but also their cognitive–social–emotional functioning. Some of these instruments are delivered to the children directly, some to their parents or teachers.

If the mother asking for help with her 4-year-old were to attend the Amsterdam clinic with her child, the team might do an assessment and advise that the 4-year-old be followed over time, with the understanding that if her son's declarations of wanting to be a girl persisted over time and if he continued to be drawn only to "girl" toys and activities, consideration of puberty blockers to buy more time to explore gender could certainly happen later, but for now it would be best to let her son continue to be a son free to explore whatever activities he enjoyed, with no corrections on his expressed desire to be a girl.

The gender affirmative model

The third model of care, the gender affirmative model, is closely aligned with the watchful waiting model but in opposition to the live in your own skin model. Where the gender affirmative model parts ways with the watchful waiting model is in the waiting part.

The gender affirmative model is defined as a method of therapeutic care that includes allowing children to speak for themselves about their self-experienced gender identity and expressions and providing support for them to evolve into their authentic gender selves, no matter at what age. Interventions include social transition from one gender to another and/or evolving gender nonconforming expressions and presentations, as well as later gender-affirming medical interventions (puberty blockers, cross-sex hormones, surgeries). A particular set of premises informs the model, as listed in Table 2.

The model is informed by the contemporary theory of gender development outlined above, with a recognition that although gender evolves over the course of a lifetime, gender identity appears to be a relatively more stable and consistent construct compared to gender expressions. Gender health is defined as a youth's opportunity to live in the gender that feels most real and/or comfortable, or, alternatively, a youth's

Table 2 Basic premises of the gender affirmative model

- Gender variations are not disorders.
- Gender presentations are diverse and varied across cultures, requiring cultural sensitivity.
- Gender involves an interweaving, over time, of biology; development and socialization; and culture and context.
- Gender may be fluid; it is not always binary.
- If present, individual psychological/psychiatric problems are more often than not secondary to negative interpersonal and cultural reactions to a child.
- Gender pathology lies more in the culture than in the child.

ability to express gender with freedom from restriction, aspersion, or rejection.[21] When considering a child's gender status, attention is paid to both gender identity and gender expressions, with the understanding that a child's gender identity may communicate something very different about the child than a child's gender expressions might.

Therapeutic goals in the gender affirmative model include:

- Facilitating an authentic gender self
- Alleviating gender stress or distress
- Building gender resilience
- Securing social supports

In contrast to the first two models, no assumption is made that every child exhibiting a gender nonconforming presentation is in need of mental health treatment. Because of the emphasis on social factors affecting the youth, interventions may be targeted at the surrounding environment, rather than the child's individual psyche. This might include interfacing with schools, social and religious institutions, and policy-making bodies to remove the "social" pathology impinging on the child, such as transphobic attitudes and responses, gender policing, or bullying and harassment. Relatedly, parent consultations often take precedence over individual treatment of the child,[22–24] with provision of services to help a parent make sense of their child's gender nonconformity, work through any extant conflicts and anxieties about their child's gender, and move toward acceptance of their child.

Individual treatment for the child is indicated for one of five reasons: 1) to assess a child's gender status; 2) to afford the child a "room of their own" to explore their gender; 3) to identify and attend to any co-occurring psychological issues; 4) to address and ameliorate a child's gender stress or distress; 5) to provide sustenance in the face of a nonaccepting or rejecting social milieu, which might include family, school, religious institution, or community. Some professionals working in this model will call on psychometric or projective measures to gather information about the child; others will rely on observation, play, interviewing, and dialog. If assessment instruments are employed, every effort is made to use protocols that do not rely on binary measures of gender (e.g., Are you a boy or a girl?) and are not pathology oriented, but instead assess strengths as well as weaknesses and differentiate between gender expressions and gender identity.

The basic therapeutic tenet of the gender affirmative model is quite simple: When it comes to knowing a child's gender, it is not for us to tell, but for the children to say. In contrast to the watchful waiting model, once information is gathered to assess a child's gender status, action is taken to allow that child to exercise that gender. Therefore, if after careful consideration, it becomes clear that a young child is affirmed in their gender, demonstrating that the gender they know themselves is different than or opposite to the gender that would match the sex assigned to them at birth, the gender affirmative model supports a social transition to allow that child to fully live in that gender, whether that child is 3, 7, or 17 years old. Such decision-making is governed by stages, rather than ages, both for social transitions and later for medical interventions. Once the child's gender comes into clear focus, which is posited as happening with a child of any age, no need is seen to hold off until adolescence to affirm that gender. This viewpoint is informed by data indicating the psychological harm that can be done, including heightened risk for generalized anxiety, social anxiety, oppositional behaviors, depression, compromised school performance, if a youth experiences themselves living in a gender that is inauthentic to them.[25]

In the gender affirmative model, the mother of the 4-year-old querying about her son's cross-gender interests would be invited in to the consultation room, along with any other parenting figure involved, to report more about what she had been observing in her child's behaviors from infancy to the present; to determine whether her son is showing any signs of stress or distress about his interest in all things girly things; to explore whether her child is indicating cross-gender expressions vs identity. If there was evidence of stress or distress, by parents' report, or if the parents desired to get a clearer picture of their child's gender status, the family would be invited to bring their son in for observation and play sessions. There would then be the opportunity to reflect, in collaboration with the parents or caregivers, on any evidence that this child was consistent in cross-gender declarations, as in "I'm a girl, not a boy", and that these declarations were persistent over time and not attributable to any other problems in life. If that evidence made clear that this child was communicating about a cross-gender identity rather than desired cross-

gender expressions, and if the parents were supportive of their child's gender identity affirmations, it would not be found necessary to recommend to this mother that she wait until puberty to take action regarding her child's gender identity. Instead, a present social transition to the gender that was more authentic for this child, in this case, female, would be considered. If, on the other hand, the child was happy as he was, if given the latitude to play with whatever he wanted and wear whatever he desired, as a boy, the recommendation to the mother might be to give her son the opportunity to express his gender freely, with the opportunity to return for services as requested. Along with this recommendation would be a reminder that all that can be known is the cross section of this child's gender as he presents it at age 4, a gender that may evolve into another configuration later in childhood, at which point a new assessment may be in order.

Critique of the three models

In brief, the live in your own skin model has been challenged as causing potential harm to gender nonconforming youth. A Canadian study conducted by Wallace and Russell assessed that in the living-in-your-own-skin model "there appears to be an enhanced risk of fostering proneness to shame, a shame-based identity and vulnerability to depression."[26] Major health organizations, including the World Professional Association for Transgender Health, the American Psychological Association, and the American Psychiatric Association, have issued statements stipulating that mental health professionals are not to engage in practices that attempt to alter the gender expressions or identity of an individual, including children and adolescents. The watchful waiting model is a highly respected model of care worldwide, offering careful and cautious procedures; but it has run into a snag: many contemporary families in the Netherlands are not content to hold their children back from social transitions until puberty, and have, through both local and international support networks of parents and professionals, proceeded to facilitate their children's social transitions without awaiting clinical approval or waiting until puberty arrives. Parents do this not because they dismiss professional care, but because evidence is accruing that young children thrive when given permission to live in the gender that is most authentic,[27,28] and are at risk for symptomatic behaviors if prevented from doing so. At the same time, the watchful waiting model is effective in its thorough attention and assessment of the child over time, integrating the services of mental health and medical professionals.

The gender affirmative model is questioned by some on the basis of the lack of evidence-based data that indicates that young children can reliably communicate and have self-knowledge of a transgender identity or benefit from a social transition. There is also concern that the model of listening to the children puts too much weight on a child's self-report. This is a valid concern, and to address it the self-report is embedded within a collaborative model with the child as subject and the collaborative team including the child, parents, and professionals. Together, the team will be making informed determinations about the most appropriate gender pathways to promote a child's gender health, be it a gender social transition, expanded opportunity to express gender in ways that feel authentic to the child, or deeper exploration of underlying issues that may be presenting as gender stress or distress. Such determinations typically involve extensive consultation and observation, but with no requirement for ongoing psychotherapy or psychometric testing, in comparison to the other two models.

Integration of medical and mental health care in adolescence

All of the three models of care referenced earlier share in common the administration of hormonal treatment in adolescence. The first category would be consideration of GnRH agonists (puberty blockers) to put a temporary pause on puberty, providing a youth with additional time to explore gender or, alternatively, warding off an unwanted puberty. The latter is particularly true for youth who socially transitioned early in life, living consistently in their affirmed gender from a young age; in those instances administration of puberty blockers could be considered a form of continuity of care, from social transitions to hormonal intervention. The second category includes feminizing or masculinizing hormones to bring a youth's body in better alignment with their affirmed gender identity. The minimal age for being eligible for such treatments may vary among approaches and indeed among clinics adopting the same approach, but there is common agreement that these treatments are in the best interests of the child who has a documented transgender identity.[29] It should be noted that there is probably no other aspect of adolescent care in which the medical and mental health professionals are so vitally interdependent in both assessment and treatment of the youth.[30] The reason for this is that each of the interventions has vital interconnected psychological and medical components, requiring an integration of medical evaluation and mental health assessment both to determine appropriateness, assess any medical or psychological impediments to treatment, and monitor follow-up, in terms of effects and supports over time as the youth is administered either the puberty blockers or hormones.

The role of the medical professional is first to assess the youth's level of puberty development, with an assessment of physical readiness for considerations for puberty blockers, which can be administered as soon as the youth enters Tanner Stage 2 of puberty. The medical professional will be responsible for ordering the lab work and bone density scans necessary to monitor a youth's progress and also to screen for any medical counter-indications to administering the blockers. As RnGH agonists are a completely reversible procedure regarding development of secondary sex characteristics, the medical provider will not need to worry about untoward permanent effects in that regard if the youth decides to go off blockers and return to the unfolding of a physical puberty in concordance with the sex assigned at birth. It should be noted, however, that the provider will need to alert the child and family about any side- or long-term effects of RnGH agonists, including effects on bone mineral density and overall bone health. If, on the other hand, the youth decides to proceed with cross-sex hormones to affirm a gender identity not in concordance with the sex assigned at birth, the medical provider will then be faced with the task of determining if the youth is a good candidate for this next step of treatment. Some youth will have already gone through full puberty before discovering or communicating to others a transgender identity, and the medical provider will be faced with the same task with these youth, with the added feature of explaining to the youth that certain of the developed features of the puberty they have already gone through will not disappear as they go through a second puberty on cross-sex hormones. In either case, cross-sex hormones involve a weightier decision than puberty blockers, as these interventions are only partially reversible in terms of secondary sex characteristics, so the provider will want to be cautious and judicious in determining if cross-sex hormones are appropriate for a particular youth.

This is where the mental health professional enters. In all of the models of gender care, the mental health professional is asked to weigh in as to 1) the authentic gender identity of the youth or level of gender dysphoria exhibited by the youth; 2) the youth's level of maturity and ability to assent to and follow through on the recommended hormonal treatment; 3) the evidence of any coexisting psychological conditions that might interfere with the hormone treatment or that alternatively might bear no weight on the requested treatments or even be alleviated by the hormonal interventions; and 4) the level of family support and willingness to consent to the treatment. In consultation with the medical professional, a decision will be made as to whether a youth is a good candidate for either puberty blockers or cross-sex hormones.

Another critical task for the medical-mental health team is the necessary discussion of fertility implications for each of these interventions. Although advances are being made in reproductive medicine to preserve immature gametes or reproductive tissues for later reproduction, at this point in history a child who begins puberty blockers at Tanner Stage 2 and proceeds directly to cross-sex hormones will be rendered infertile. Administration of testosterone or estrogen to a postpubertal adolescent may compromise a youth's later fertility, or might require going off the hormones for a period of time if a transgender youth who has not had gonad or genital surgeries later in life desires to have a genetically related child. Alternatively, a youth can bank gametes for the future before going on a course of cross-sex hormones, which is a medical possibility but also a psychological challenge for many transgender youth who find this antithetical to their affirmed gender status, requiring a transgender female to attend a fertility clinic and masturbate or a transgender male to undergo a gynecological vaginal ultrasound. Exploring fertility issues before making decisions about blockers or hormones are necessary but sensitive discussions to be had with both the youth and parents, and are best done with the presence of both a medical and a mental health professional who together can provide medical and psychological counsel to the family in this decision affecting later family-building.[31]

Not only is there no other aspect of adolescent care where the teamwork between medical and mental health provider is critical; there is no other domain of youth services in which a mental health provider is so actively involved in medical decision making. Where this has surfaced most recently is in the recent emergence of youth in gender clinics who present as neither male nor female, but rather gender nonbinary or "in the middle", adopting the platform of the multiplicity of gender. The challenge is when these youth ask for a particular medical intervention that achieves that goal of a middle ground – perhaps a touch of testosterone, or chest surgery with no other intervention and a chosen pronoun of "they" rather than "he" or "she". These are new horizons for both medical and mental health professionals today, and there is a mutuality, therefore, in the medical professional training the mental health professional while the mental health professional is in turn training the medical professional in order to integrate the biopsychosocial aspects of care to include the gamut of all the gender nonconforming youth presenting for care.[32]

With that said, it has proved to be critical that mental health professionals involved in this team work be trained gender specialists, with a basic understanding of the medical interventions involved in transgender care, expertise in

assessing gender dysphoria and identifying a youth's gender identity, and recognition of psychological issues other than gender that might drive a youth's request for a hormonal treatment. For example, a nurse practitioner on a gender team had administered a puberty blocker implant, Supprelin, which could stay in place for a year, after receiving a letter of support from a trained mental health expert recommending such treatment for this youth who presented as gender dysphoric and in need of further exploration of his gender before going forward with puberty. Over the course of the following year, he failed to return for follow up visits. A year had gone by and it was now time to replace the implant, which the nurse practitioner was prepared to do. The mental health member of the team first did a follow-up evaluation of the youth and discovered that he had made no efforts to explore his gender any further, with his motivation to continue on blockers driven by a desire to remain prepubertal for as long as possible. With the psychologist's guidance, the medical provider was able to recognize that the medical intervention as it stood was inappropriate for this youth. The interdisciplinary team informed the youth that he would be able to receive a new implant only if he was simultaneously working with a mental health gender specialist to further explore his gender identity. If that condition was met, once the twelve additional months on the puberty blockers was completed, the youth would then have to make a determination of which puberty path he would take – cross-sex hormones or the unfolding of his male, testosterone-producing puberty.

Conclusion

In the course of only two decades, sophisticated models for the care of gender nonconforming and transgender youth have evolved. There is an urgent need to provide more research data documenting the efficacy of these different programs, but the recent findings of the Amsterdam group provide hope that the care, particularly within the watchful waiting and gender affirmative models, is promoting gender health. In the Dutch authors' words, the treatment, including puberty suppression, cross-sex hormones, and then in adulthood gender affirmation surgery, "leads to improved psychological functioning of transgender adolescents. While enabling them to make important age-appropriate developmental transitions, it contributes to a satisfactory objective and subjective well-being in young adulthood".[33] The authors propose that not only early medical intervention, but also a comprehensive multidisciplinary approach contributes to the youth's gender health. Reflecting back on Daniel, the youth introduced at the opening of this review, the ability of professionals to aid youth such as Daniel in getting his authentic gender into focus and providing the appropriate treatments to bring that gender in alignment with his body is the key to overall well-being for all youth seeking professional gender care.

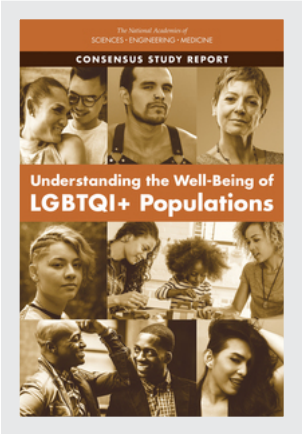
Disclosure

The author reports no conflicts of interest in this work.

References

1. World Professional Association for Transgender Health. *Standards of Care for the Health of Transsexual, Transgender, and Gender Nonconforming People*. WPATH; 2011.
2. Hidalgo MA, Ehrensaft D, Tishelman AC, et al. The Gender affirmative model: what we know and what we aim to learn. *Hum Dev.* 2013;56:285–290.
3. Zucker KJ, Wood H, VanderLaan, DP. Models of psycho-pathology in children and adolescents with gender dysphoria. In: Kreukels BPC, T. Steensma TD, de Vries ALC, editors. *Gender Dysphoria and Disorders of Sex Development: Progress in Care and Knowledge*. New York, NY: Springer; 2014:171–192.
4. Money J, Ehrhardt A. *Man & Woman, Boy & Girl: Gender Identity from Conception to Maturity*. Northvale, NJ: Jason Aronson; 1996.
5. Diamond M. Sex, gender, and identity over the years: a changing perspective. *Child Adolesc Psychiatr Clin N Am*. 2004;13(3):591–607.
6. Tyson P. A Developmental line of gender identity, gender role, and choice of love object. *J Am Psychoanal Assoc.* 1982;30(1):61–86.
7. Freud S. *Three Contributions to the Theory of Sex*. New York, NY: E.P. Dutton; 1962.
8. Fast I. Aspects of core gender identity. *Psychoanal Dial*. 1999;9(5): 633–661.
9. Stoller R. *Presentations of Gender*. New Haven, CT: Yale University Press; 1985.
10. Ehrensaft D. *Gender Born, Gender Made.* New York, NY: The Experiment Press; 2011.
11. Diamond M. Sex and gender: same or different? *Feminism Psychol.* 2000;10(1):46–54.
12. Vanderhorst B. Whither lies the self: intersex and transgender individuals and a proposal for brain-based legal sex. *Harvard Law & Policy Review.* 2015;9:241–274.
13. Ehrensaft D. From gender identity disorder to gender identity creativity: true gender self child therapy. *J Homosex.* 2012;59(3):337–356.
14. Sherer I, Rosenthal S, Ehrensaft D, Baum J. Child and adolescent gender center: a multidisciplinary collaboration to improve the lives of gender nonconforming children and teens. *Pediatr Rev.* 2012;33(6): 273–276.
15. Green R. *The 'Sissy boy' Syndrome and the Development of Homosexuality.* New Haven, CT: Yale University Press; 1987:295.
16. Zucker K, Bradley S. *Gender Identity Disorder and Psychosexual Problems in Children and Adolescents.* New York, NY: The Guilford Press; 1995.
17. Cross JM. Outcry prompts CAMH to review its controversial treatment of trans youth. *Metro News*, Toronto; 2015, March 18; online. Available from: http://metronews.ca/news/toronto/1315743/outcry-prompts-camh-to-review-its-controversial-treatment-of-trans-youth
18. Cohen-Kettenis PT, Pfäfflin F. *Transgenderism and Intersexuality in Childhood and Adolescence*. Thousand Oaks, CA: Sage Publications; 2003.
19. Steensma TD, McGuire J, Kreukels BP, Beekman AJ, Cohen-Kettenis PT. Factors associated with desistence and persistence of childhood gender dysphoria: a quantitative follow-up study. *J Am Acad Child Adolesc Psychiatry.* 2013;52(6):582–590.

20. Steensma TD, Biemond R, de Boer F, Cohen-Kettenis PT. Desisting and persisting gender dysphoria after childhood: a qualitative follow-up study. *Clin Child Psychol Psychiatry.* 2011;16(4):499–516.
21. Ehrensaft D. *The Gender Creative Child.* New York, NY: The Experiment; 2016.
22. Ehrensaft D. Boys will be girls, girls will be boys. *Psychoanalytic Psychol.* 2011;28(4):528–548.
23. Ehrensaft D. From gender Identity disorder to gender identity creativity: true gender self child therapy. *J Homosex.* 2012;59(3):337–356.
24. Malpas J. Between pink and blue: a multi-dimensional family approach to gender non-conforming children and their families. *Fam Process.* 2011;50(4):453–470.
25. Roberts L, Rosario M, Corliss HL, et al. Childhood gender nonconformity: a risk indicator for childhood abuse and post-traumatic stress in youth. *Pediatrics.* 2012;129:410–417.
26. Wallace R, Russell H. Attachment and shame in gender-nonconforming children and their families: toward a theoretical framework for evaluating clinical interventions. *Int J Transgenderism.* 2013;14(3):113–126.
27. Olson KR, Key AC, Eaton NR. Gender cognition in transgender children. *Psychol Sci.* 2015;26(4):467–474.
28. Durwood L, McLaughlin KA, Olson KR. Mental health and self-worth in socially transitioned transgender youth. *J Am Acad Child Adolesc Psychiatry.* 2017;56(2):116–123.
29. Rosenthal SM. Approach to the patient: transgender youth: endocrine considerations. *J Clin Endocrinol Metab*. 2014;99(12):4379–4389.
30. Vance SR, Ehrensaft D, Rosenthal SM. Psychological and medical care of gender nonconforming youth. *Pediatrics.* 2014;134(6):1184–1192.
31. Ehrensaft D, Hastings J, Hsaio K. Ferility issues for youth: puberty blockers, hormones. Decision-making through the lens of family building options. World Professional Association for Transgender Health Symposia. Amsterdam, June 20, 2016.
32. Harris A. *Gender as Soft Assembly*. New York, NY: The Analytic Press; 2005.
33. deVries ALC, McGuire JK, Steensma TD, Wagenaar EC, Doreleijers TA, Cohen-Kettenis PT. Young adult psychological outcome after puberty suppression and gender reassignment. *Pediatrics.* 2014;134(4):696–704.



Understanding the Well-Being of LGBTQI+ Populations (2020)

DETAILS

436 pages | 6 x 9 | PAPERBACK

ISBN 978-0-309-68081-3 | DOI 10.17226/25877

CONTRIBUTORS

Charlotte J. Patterson, Mart n-Jos Sep lveda, and Jordyn White, Editors; Committee on Understanding the Well-Being of Sexual and Gender Diverse Populations; Committee on Population; Division of Behavioral and Social Sciences and Education; National Academies of Sciences, Engineering, and Medicine

SUGGESTED CITATION

National Academies of Sciences, Engineering, and Medicine. 2020. *Understanding the Well-Being of LGBTQI+ Populations*. Washington, DC: The National Academies Press. https://doi.org/10.17226/25877.

Understanding the Well-Being of LGBTQI+ Populations

Committee on Understanding the Well-Being of Sexual and Gender Diverse Populations

Charlotte J. Patterson, Martín-José Sepúlveda, and Jordyn White, *Editors*

Committee on Population

Division of Behavioral and Social Sciences and Education

A Consensus Study Report of

The National Academies of
SCIENCES • ENGINEERING • MEDICINE

THE NATIONAL ACADEMIES PRESS
Washington, DC
www.nap.edu

THE NATIONAL ACADEMIES PRESS 500 Fifth Street, NW Washington, DC 20001

This activity was supported by contracts between the National Academy of Sciences and Gilead Sciences (award no. 05352), the Sexual and Gender Minority Research Office of the National Institutes of Health (award no. 75N98019F00850), the Robert Wood Johnson Foundation (award no. 75874), the TAWANI Foundation (unnumbered), and the Tegan and Sara Foundation (unnumbered). Any opinions, findings, conclusions, or recommendations expressed in this publication do not necessarily reflect the views of any organization or agency that provided support for the project.

International Standard Book Number-13: 978-0-309-68081-3
International Standard Book Number-10: 0-309-68081-6
Digital Object Identifier: https://doi.org/10.17226/25877
Library of Congress Control Number: 2020949996

Additional copies of this publication are available from the National Academies Press, 500 Fifth Street, NW, Keck 360, Washington, DC 20001; (800) 624-6242 or (202) 334-3313; http://www.nap.edu.

Printed in the United States of America

Suggested citation: National Academies of Sciences, Engineering, and Medicine. (2020). *Understanding the Well-Being of LGBTQI+ Populations*. Washington, DC: The National Academies Press. https://doi.org/10.17226/25877.

The National Academies of
SCIENCES • ENGINEERING • MEDICINE

The **National Academy of Sciences** was established in 1863 by an Act of Congress, signed by President Lincoln, as a private, nongovernmental institution to advise the nation on issues related to science and technology. Members are elected by their peers for outstanding contributions to research. Dr. Marcia McNutt is president.

The **National Academy of Engineering** was established in 1964 under the charter of the National Academy of Sciences to bring the practices of engineering to advising the nation. Members are elected by their peers for extraordinary contributions to engineering. Dr. John L. Anderson is president.

The **National Academy of Medicine** (formerly the Institute of Medicine) was established in 1970 under the charter of the National Academy of Sciences to advise the nation on medical and health issues. Members are elected by their peers for distinguished contributions to medicine and health. Dr. Victor J. Dzau is president.

The three Academies work together as the **National Academies of Sciences, Engineering, and Medicine** to provide independent, objective analysis and advice to the nation and conduct other activities to solve complex problems and inform public policy decisions. The National Academies also encourage education and research, recognize outstanding contributions to knowledge, and increase public understanding in matters of science, engineering, and medicine.

Learn more about the **National Academies of Sciences, Engineering, and Medicine** at **www.nationalacademies.org**.

The National Academies of
SCIENCES • ENGINEERING • MEDICINE

Consensus Study Reports published by the National Academies of Sciences, Engineering, and Medicine document the evidence-based consensus on the study's statement of task by an authoring committee of experts. Reports typically include findings, conclusions, and recommendations based on information gathered by the committee and the committee's deliberations. Each report has been subjected to a rigorous and independent peer-review process and it represents the position of the National Academies on the statement of task.

Proceedings published by the National Academies of Sciences, Engineering, and Medicine chronicle the presentations and discussions at a workshop, symposium, or other event convened by the National Academies. The statements and opinions contained in proceedings are those of the participants and are not endorsed by other participants, the planning committee, or the National Academies.

For information about other products and activities of the National Academies, please visit www.nationalacademies.org/about/whatwedo.

SGD populations[16] (see Chapter 4 for a more detailed discussion of data collection).

GENDER-AFFIRMING CARE FOR TRANSGENDER PEOPLE

The first U.S. clinics providing gender-affirming care to transgender individuals opened in the 1960s and 1970s. Practice and research in the field of transgender health, however, was stymied in the 1980s and 1990s by the spread of public and private insurance exclusions for gender-affirming care. As these exclusions have begun to be removed, there has been exponential growth in evidence regarding the medical necessity of this care, and gender affirmation has emerged as a core intervention to improve the health and well-being of transgender people. This section reviews the components of and clinical and population evidence concerning gender affirmation.

Components of Gender Affirmation

Broadly speaking, gender affirmation is a process by which people who identify as transgender, non-binary, or gender diverse take steps to fully express their true gender. (An older but still common term for the process of gender affirmation is gender transition.) Gender affirmation may have social, legal, and medical components. Socially, people may use a name or pronoun different from those they were assigned at birth, or they may change aspects of their gender expression, such as hairstyle and clothing. Legal affirmation may include name or gender marker changes on identification documents—such as passports, driver's licenses, and birth certificates—which are affected by state and federal laws and policies. Gender-affirming clinical care may include psychosocial support, hormone therapy, and surgeries.

Psychosocial support for gender affirmation typically focuses on reducing emotional distress and supporting decision making regarding social, legal, and medical steps. Some young transgender people and their families opt for medication to delay the onset of puberty. Adults and some adolescents may take feminizing or masculinizing hormones to achieve gender-congruent secondary sex traits, often in conjunction with medications that suppress menses or block androgens. Many transgender adults and older adolescents undergo surgery to align the appearance of their face, chest or breasts, body shape, and genitals with their gender, and some may also pursue speech therapy or hair removal. Gender affirmation is different for every person: some people may take only social or legal steps, while others may need gender-affirming prescriptions or medical procedures. Regardless

[16] See https://dpcpsi.nih.gov/sgmro.

of an individual's path in relation to gender affirmation, social support and integrated, multidisciplinary care are essential for all transgender people, especially youth, and are consistently associated with improved mental health, social involvement, and self-esteem (Rafferty, Committee on Psychosocial Aspects of Child and Family Health, and Committee on Adolescence, 2018).

Guidelines and Policies Related to Gender Affirmation

Clinicians who provide gender-affirming psychosocial and medical services in the United States are informed by expert evidence-based guidelines. In 2012, the World Professional Association for Transgender Health (WPATH) published version 7 of the *Standards of Care for the Health of Transgender, Transsexual, and Gender-Nonconforming People*, which have been continuously maintained since 1979, and revisions for version 8 are currently under way (Coleman et al., 2012). Two newer guidelines have also been published by the Endocrine Society (Hembree et al., 2017) and the Center of Excellence for Transgender Health (UCSF Transgender Care, 2016). Each set of guidelines is informed by the best available data and is intended to be flexible and holistic in application to individual people. All of the guidelines recommend psychosocial support in tandem with physical interventions and suggest timing interventions to optimize an individual's ability to give informed consent. Mental and physical health problems need not be resolved before a person can begin a process of medical gender affirmation, but they should be managed sufficiently such that they do not interfere with treatment.

A major success of these guidelines has been identifying evidence and establishing expert consensus that gender-affirming care is medically necessary and, further, that withholding this care is not a neutral option (World Professional Association for Transgender Health, 2016). A number of professional medical organizations have joined WPATH in recognizing that gender-affirming care is medically necessary for transgender people because it reduces distress and promotes well-being, while withholding care increases distress and decreases well-being (American Academy of Family Physicians, 2012; American Academy of Pediatrics, 2018; American College of Nurse Midwives, 2012; American College of Obstetricians and Gynecologists, 2011; AMA, 2008; American Psychiatric Association, 2018; American Psychological Association (APA), 2008, 2015; Endocrine Society, 2017). Accordingly, public and private insurers have expanded access to gender-affirming care; some have done so proactively, while others have been required by state and federal nondiscrimination laws to remove coverage exclusions (Baker, 2017).

Coverage requirements for gender-affirming care typically rely on an overarching principle of parity between medically necessary services for transgender and cisgender people. Treatments that are gender affirming for transgender patients are covered by public and private insurers for

intersex and cisgender people for a variety of conditions, including genital difference, endocrine disorders, cancer prevention or treatment, and reconstructive surgeries following an injury. Examples of these services include testosterone or estrogen replacement therapy after surgery or menopause, vaginoplasty after pelvic surgery or for women with vaginal agenesis in the context of an intersex condition, and phalloplasty for cisgender male service members injured in war (Baker et al., 2012; Balzano and Hudak, 2018; Spade et al., 2009).

As this report goes to press, 24 states and the District of Columbia have enacted laws or made administrative changes prohibiting transgender-specific insurance exclusions in private coverage (Movement Advancement Project, 2020a). However, Medicaid programs in 10 states continue to explicitly exclude gender-affirming care for transgender individuals, and many states do not address the issue of this coverage in Medicaid (Mallory and Tentindo, 2019). At the federal level, the Medicare program removed its exclusion for "transsexual surgery" in 2014 (HHS, 2014), though coverage decisions related to gender-affirming surgeries are still made on a case-by-case basis (CMS, 2016). As discussed above, Section 1557 of the Affordable Care Act also has substantial ramifications for coverage of gender-affirming care: the 2016 HHS regulation embraced the principle of parity and prohibited categorical exclusions of gender-affirming care under the rubric of sex nondiscrimination. This aspect of the regulation remains contested in court, but it is expected that the original regulation's specific protections for transgender people will be found to be well within the scope of federal law and the agency's authority (Keith, 2020).

In order to justify coverage for gender-affirming care, insurance providers in the United States and most other countries require a supporting diagnosis. In 2013, the *Diagnostic and Statistical Manual of Mental Disorders* (DSM), 5th edition (American Psychiatric Association, 2013) replaced the diagnosis of gender identity disorder with gender dysphoria. Whereas gender identity disorder was perceived as pathologizing a person's gender identity, gender dysphoria emphasizes the clinically significant distress and impairment that can accompany incongruence between assigned sex and gender identity (Robles et al., 2016). A person who experiences no distress or impairment due to this incongruence will not meet diagnostic criteria for gender dysphoria. More recently, the *International Classification of Diseases*, 11th revision (WHO, n.d.) has replaced transsexualism and gender identity disorder with gender incongruence and moved the diagnosis out of the mental and behavioral disorders chapter and into a new chapter on sexual health.

Many insurers and some health care providers require documentation that an individual meets guideline requirements, including diagnostic criteria for gender dysphoria, as a prerequisite for hormonal or surgical

treatment. Because of the power differential inherent in this construct, this practice has been described as "gatekeeping" and can function as a significant barrier to accessing care. In a survey of transgender adolescents, for instance, participants described distress at having to prove to a mental health provider that they were "trans enough," having to wait for approval for treatment, and perceiving that their therapist feared legal liability should a person later regret the treatment (Gridley et al., 2016). Even transgender people with insurance coverage and access to providers report difficulty in navigating diagnosis-based requirements imposed by providers and insurers (James et al., 2016). Over the past 10 years, some U.S. medical professional organizations have increasingly moved to reduce psychiatric gatekeeping by shifting toward an informed consent and shared decision-making model, especially for adults (Schulz, 2018). Some countries have further underscored that transgender identity is not a pathology by recognizing gender affirmation as fundamental to the human right to self-definition and removing requirements that transgender people seeking gender-affirming medical care present with a diagnosis such as gender dysphoria (Arístegui et al., 2017).

Outcomes of Gender-Affirming Interventions

The evidence base for gender affirmation across age groups has grown rapidly over the last decade. For transgender youth who have not yet reached puberty, social affirmation and support are primary interventions. Using data from electronic records from the Kaiser Permanente system, recent work has suggested that prepubescent transgender children experience increased rates of mental health problems, especially anxiety, depression, and attention deficit disorders, relative to cisgender children (Becerra-Culqui et al., 2018). However, research also shows that, when transgender children in this age group are socially affirmed and supported by their families, their rates of depression are much nearer to those of cisgender children (Durwood, McLaughlin, and Olson, 2017). In one study, transgender youth who were socially affirmed had elevated rates of anxiety relative to their cisgender peers, but this difference was not clinically significant and may have reflected ongoing social stigma and minority stress (Olson et al., 2016). Another study found that using transgender youths' chosen names in home and at school was associated with reduced depression, suicidal ideation, and suicidal behavior (Russell et al., 2018).

Puberty blockers, typically gonadotropin-releasing hormone analogs, have been used since at least the late 1990s to prevent development of irreversible secondary sex traits and to give youth more time to explore their gender identity (Cohen-Kettenis and Van Goozen, 1998). In 2014, a landmark paper provided longitudinal data from a cohort of youth in the Netherlands: among this group, puberty suppression, followed several years

later by gender-affirming hormones and surgery, was effective in reducing gender dysphoria and restoring well-being equal to or better than same-age cisgender young adults (de Vries et al., 2014). Though most data on puberty suppression are limited and drawn from convenience samples in European clinics, this fully reversible gender-affirming intervention appears to confer improved psychological functioning and may reduce gender dysphoria (Mahfouda et al., 2017).

There is inconsistent and limited evidence regarding risks of irreversible low bone density and infertility (Chew et al., 2018; Mahfouda et al., 2017; Rafferty, Committee on Psychosocial Aspects of Child and Family Health, and Committee on Adolescence, 2018). In recognition of these risks, guidelines recommend monitoring bone density and counseling on fertility preservation prior to treatment (Hembree et al., 2017). Of note, while evidence indicates that social affirmation and puberty suppression are low risk and effective interventions for young transgender youth, there may be a significant delay between recognition and disclosure of gender incongruence: in one cohort, participants reported identification of gender incongruence on average at age 8 and disclosure to caregivers on average at age 17 (Olson et al., 2015). Support from parents and affirmation of gender diversity are critical to creating safe opportunities for young people to access the psychosocial and medical care that they need in a timely manner.

Hormone therapy with testosterone or estrogen is a common gender-affirming treatment for transgender adults and older adolescents. Though limited by heterogeneity of methodology, regimen, and outcomes measures, systematic reviews and meta-analyses consistently find that gender-affirming hormone treatment is associated with significant reductions in gender dysphoria, psychological symptoms, and psychiatric diagnoses and with improved markers of well-being, including quality of life, interpersonal functioning, psychological adjustment, sexual function, body satisfaction, and self-esteem (Costa and Colizzi, 2016; Dhejne et al., 2016; Keo-Meier et al., 2015; Murad et al., 2010; Nguyen et al., 2018; Rowniak, Bolt, and Sharifi, 2019; White Hughto and Reisner, 2016).

Both the WPATH and Endocrine Society guidelines identify age 16 as a general starting point for gender-affirming hormones, with the recognition that some adolescents benefit from earlier treatment (Coleman et al., 2012; Hembree et al., 2017). Evidence for hormone therapy in adolescents comes largely from outside of the United States and inconsistently tracks outcomes (Chew et al., 2018; Olson-Kennedy et al., 2016). The data available suggest that hormone therapy in adolescents likely yields reductions in dysphoria and distress and improvements in well-being similar to those in adults (Mahfouda et al., 2019). Gender-affirming hormone therapy can be managed for most patients by primary care providers,

as it typically involves long-term maintenance on doses similar to those used for cisgender patients with conditions such as hypogonadism (Wylie et al., 2016).

Surgeries involving the genitals or secondary sex characteristics can also improve health and well-being among transgender people and are an important and medically necessary aspect of gender-affirming care (Bailey, Ellis, and McNeil, 2014; Castellano et al., 2015; Murad et al., 2010; Passos et al., 2020; Wernick et al., 2019). Many factors affect an individual's need for and access to gender-affirming surgeries. In the 2015 USTS, only 25 percent of respondents had undergone some form of gender-affirming surgery, such as genital reconstruction or chest reconstruction, and having surgery was correlated with higher incomes (James et al., 2016). Respondents also reported varying degrees of experience with or need for specific procedures: 97 percent of transgender men had or needed chest reconstruction surgery, and 22 percent of transgender men had or needed phalloplasty. Similarly, 95 percent of transgender women had or needed hair removal procedures, and 76 percent had or needed vaginoplasty. Non-binary individuals generally had and needed fewer surgeries than their binary-identified counterparts: 48 percent of non-binary individuals assigned female at birth had or needed chest surgery, and 12 percent of non-binary individuals assigned male at birth had or needed vaginoplasty.

Surgeries for transgender men and other trans-masculine people may include bilateral chest reconstruction, salpingo-oophrectomy (removal of the ovaries and fallopian tubes), hysterectomy, genital reconstruction (metoidioplasty or phalloplasty with or without prosthesis), and, rarely, vocal surgery. Chest reconstruction, which involves removal of breast tissue and nipple preservation, is associated with significant improvements in mental health and well-being among trans-masculine adolescents and adults (Agarwal et al., 2018; Mahfouda et al., 2019; Van Boerum et al., 2019). A systematic review of studies of genital surgeries that included metoidioplasty indicated that 93 percent of patients were satisfied with the outcome, including preserved erogenous sensitivity, despite significant rates of postoperative complications (Morrison et al., 2016). A systematic review of penile prosthetic outcomes for 792 transgender men over a mean follow-up period of three years found inconsistent reporting of sensory, urinary, satisfaction, and sexual outcomes after surgery, with 36 percent reporting prosthesis complications (Rooker et al., 2019).

Surgeries for transgender women and other trans-feminine people may include breast augmentation, facial feminization, vocal surgery, orchiectomy, and vaginoplasty. Some studies have shown improvements in quality of life and high patient satisfaction following facial feminization procedures for trans-feminine individuals, including reshaping the contours of the face and larynx (Ainsworth and Spiegel, 2010; Van Boerum et al., 2019). A

systematic review of vaginoplasty for transfeminine individuals identified 26 studies with a total of 1,563 patients; although measures used to track outcomes varied between studies, and complications were frequent, with neovaginal stenosis the most common, patients tended to report high ratings in both sexual function and satisfaction after surgery (Horbach et al., 2015).

The research regarding outcomes for surgery in youth under 18 is sparse, in part because it is generally not clinically recommended for legal minors, though there is only a small amount of low-quality evidence that supports this limitation (Hembree et al., 2017). Chest masculinization is sometimes appropriate for youth 16 or older (Coleman et al., 2012), and some surgeons perform vaginoplasty on minors under specific circumstances (Milrod and Karasic, 2017). Several studies provide positive evidence regarding the benefits of chest reconstruction in minors, with reduced depressive and anxious symptoms and improved chest dysphoria; the most common complications were changes in sensation and scar cosmesis (Mahfouda et al., 2019). There are very few data regarding genitoplasty for minors.

As noted above, available evidence generally indicates that gender-affirming medical interventions, including surgeries, are associated with improvements in gender dysphoria, mental health, and quality of life for transgender people. Evidence also suggests, however, that mental health conditions can persist after treatment: for instance, a 2011 Swedish registry study of 324 patients who had undergone gender-affirming surgeries between 1973 and 2003 found increased rates of suicide attempts and psychiatric hospitalizations relative to population controls (Dhejne et al., 2011). The study notes that surgeries did alleviate gender dysphoria, and the study was unable to determine how patients might have fared without surgery. When a more recent Swedish registry study tracked mental health treatment utilization among people with a gender incongruence diagnosis relative to people without gender incongruence between 2005 and 2015 (N = 2,679), time since gender-affirming surgery was associated with reduced need for mental health services (aOR: 0.92; 95% CI: 0.87, 0.98) (Bränström and Pachankis, 2019). A reanalysis of these data compared individuals with gender incongruence who had gender-affirming surgery with those who did not and found comparable rates of reduced need for treatment for mood disorders between the groups, but higher rates of treatment for anxiety disorders among the group who did have surgery (aOR: 1.40; 95% CI: 1.00, 1.97) (Bränström and Pachankis, 2020). The authors note that the comparator nonsurgical group is heterogeneous, including a mixture of patients who both did and did not want surgery. Furthermore, as was discussed in detail in Chapter 11, transgender people have significantly elevated rates of mental health problems due not just to the experience of

gender dysphoria but also because of minority stress and stigma. While social and medical affirmation reduce gender dysphoria and can mitigate the impact of social factors, such as discrimination and family rejection, medical affirmation may not fully resolve or protect from experiences of stigma and stress. Future studies examining outcomes of gender affirmation should assess and control for these factors. Related research needs include exploration of factors that can promote resilience in different family and community settings and across the life course (Bockting et al., 2016).

Another major limitation in research on postsurgical outcomes is the absence of patient-reported outcome measures that have been validated in transgender and non-binary post-operative patient populations (Andréasson et al., 2018; Barone et al., 2017; Dy et al., 2019). Recent data overall suggest that satisfaction after gender-affirming surgeries is high and risk of regret is very low. For example, the Center of Expertise on Gender Dysphoria at the Free University Medical Center in Amsterdam published results from 43 years of clinical care in which regret was reported in only 14 patients (0.5%) of the more than 5,300 patients who underwent gonadectomy as part of gender affirmation (Wiepjes et al., 2018). A smaller study found that only 1 of 68 patients who received chest masculinization surgery experienced regret "sometimes" (Olson-Kennedy et al., 2018), consistent with findings from older research (Gijs and Brewaeys, 2007). Similarly, a 2018 systematic review and meta-analysis of 46 articles with 3,716 cases of vaginoplasty for transgender women reported a cumulative rate of regret of 1 percent, compared with an overall satisfaction rate of 92 percent across different surgical techniques (Manrique et al., 2018). While many studies do not qualitatively assess degree and reasons for regret, in one study patients who reported regret with surgeries reported mild regret and attributed this to cosmetic or functional outcomes rather than the decision to have surgery (van de Grift et al., 2017).

Substantial progress has been made over the past decade in research on outcomes of gender-affirming interventions, and there are ample opportunities for improvement. To address the scarcity of data and difficulties extrapolating findings from relatively homogeneous European samples, a United States-based comprehensive registry that tracks patient-centered outcomes for both youth and adults could lead to valuable insights on the benefits of medically supervised gender affirmation (Kimberly et al., 2018). Much remains to be learned regarding optimal timing and risk profiles for surgeries and other medical interventions, aided by standardized and validated tools for body satisfaction, gender-related quality of life, gender dysphoria, and mental health (Olson et al., 2016). Standardized assessment and reporting of outcomes are particularly essential for helping clinicians and patients understand surgical options. In this area, too, more attention is needed to populations that tend to be invisible or underrepresented in

clinical research, especially transgender people of color and non-binary individuals. Very little is known about the experiences and options for treatment for transgender individuals with intersex traits, especially those who had irreversible treatments as children. Overall, however, the evidence indicates that gender-affirming interventions, including social affirmation, hormonal treatment, and surgeries, are medically necessary for reducing distress and improving the health and well-being of transgender people.

CONVERSION THERAPY

Efforts to change sexual orientation or gender identity, which initially gained traction in the 1960s and which are often referred to as conversion or reparative therapies, assume that non-cisgender and non-heterosexual identities are abnormal. In 2009 the APA produced a landmark report that systematically reviewed the evidence of efficacy for sexual orientation change efforts (APA, 2009). Most of this research was conducted prior to 1981, and very few studies were experimental in design. The task force found that some people sought sexual orientation change efforts due to distress over their sexual orientation but that the treatments were unable to reduce same-sex attractions or increase other-sex attractions. Furthermore, there was evidence that individuals experienced harm from these treatments, including sexual dysfunction, depression, anxiety, and suicidality. With regard to gender identity, while interest in the so-called "desistence" of transgender identity has been informed by studies suggesting that as high as 80 percent of prepubertal youth presenting to pediatric gender clinics ultimately do not identify as transgender, many of the youth included in these studies did not meet full DSM criteria for a gender incongruence diagnosis (Olson, 2009). Recent evidence supports that early social affirmation of transgender identity is associated with good outcomes (Olson et al., 2016; Durwood, McLaughlin, and Olson, 2017) and that lack of social affirmation correlates with depression, anxiety, and suicidality (de Vries et al., 2016; James et al., 2016).

Consequently, sexual orientation and gender identity conversion efforts have fallen out of favor in mainstream psychological and psychiatric practice. By the time of the 2011 Institute of Medicine report, many medical organizations had issued statements condemning sexual orientation change efforts based on the lack of efficacy and evidence of harm. Many of these organizations have since updated their positions to decry conversion therapy for both sexual orientation and gender identity (AMA and GLMA: Medical Professionals Advancing LGBTQ Equality, 2018; American Academy of Child and Adolescent Psychiatry, 2018; Rafferty, Committee on Psychosocial Aspects of Child and Family Health, and Committee on Adolescence, 2018; SAMHSA, 2015; Streed et al., 2019a).

However, there is recent evidence that LGBTQ youth and adults continue to be exposed to conversion therapy. A 2019 report from Williams Institute estimated that 698,000 adults between ages 18 and 59 have undergone conversion therapy from a licensed professional or religious advisor, of whom 350,000 were adolescents when treated (Mallory, Brown, and Conron, 2019). The same study estimated that an additional 57,000 youth will receive conversion therapy from a health care or religious provider before 18 years of age. Among 25,000 LGBTQ youth respondents to a 2019 national survey, 67 percent reported that someone attempted to convince them to change their gender identity or sexual orientation (Trevor Project, 2019). A survey of 762 marriage and family therapists and members of the American Academy of Marriage and Family Therapists, which has a position statement against conversion therapy, found that 19.4 percent of respondents believed it was ethical to practice sexual orientation change therapy, and 3.5 percent of respondents had done so. This belief was associated with higher levels of negative beliefs about LGB clients than those of other therapists (McGeorge, Carlson, and Toomey, 2015).

A recent survey was among the first to evaluate the link between sexual orientation change therapy and the health of young people: among 245 white and Latinx LGBT individuals between the ages of 21 and 25, exposure to conversion efforts within or outside of their families during adolescence was associated with higher family religiosity, lower family socioeconomic status, and higher individual gender nonconformity (Ryan et al., 2018). In addition, exposure to conversion efforts during adolescence was significantly associated with increased suicidal ideation, suicide attempts, and depression, as well as diminished life satisfaction, self-esteem, social support, educational attainment, and lower income in young adulthood.

A systematic narrative review of gender identity conversion efforts found few data and a notable absence of research about their effects on both adolescents and adults (Wright, Candy, and King, 2018). However, a recent study using data from the 2015 USTS found that 14 percent of respondents had been exposed to gender identity conversion therapy during their lifetimes; exposure was associated with significantly higher rates of past-month severe psychological distress and lifetime suicide attempts compared with respondents who had not been exposed to such therapy (Turban et al., 2019). Exposure to gender identity conversion therapy before age 10 was associated with nearly twice the rate of lifetime suicide attempts.

The available evidence suggests that sexual orientation and gender identity conversion efforts are ineffective and dangerously detrimental to the health of SGD populations, especially for minors who are unable to give informed consent. As of early 2020, 20 states, the District of Columbia, Puerto Rico, and a number of municipalities had outlawed sexual orientation and gender identity conversion therapy for minors (Move-

ment Advancement Project, 2020b). As growing numbers of professional organizations and governments call for or legislate an end to conversion therapy, particularly for minors, it is important for clinicians working with SGD populations to understand the effects that these experiences can have on individuals, even many years later. Research on strategies for helping individuals who have experienced conversion therapy to heal and recover is essential. In order to end the practice of conversion therapy, it is not sufficient for professional organizations to recommend against conversion therapy; rather, professionals may require dedicated and specific training on the inefficacy and danger of conversion treatments, and insurance providers should consider limiting coverage for these non-evidence-based practices.

INTERSEX GENITAL SURGERY

The most expansive estimations of the prevalence of intersex traits, including any variation in any marker of sex (chromosomes, internal reproductive anatomy, external genital shape, and secondary sex traits), concludes that up to 1.7 percent of the population has an intersex trait (Fausto-Sterling, 2000). Estimates based on the number of people with clinically identifiable sexual or reproductive anatomic variations are closer to 0.5 percent (Nordenvall et al., 2014). Estimates for prevalence of infants born with obvious genital diversity, sometimes known as ambiguous genitalia, range from 0.03 percent to 0.1 percent (Blackless et al., 2000; Hughes et al., 2007; Thyen et al., 2006). Such variations can include differences in the length of the genital tubercule or glans (as in a shorter penis or longer clitoris), a narrow or absent vaginal opening, or presence of partially fused labia or a partially separated scrotum. This section focuses primarily on early genital surgery for children born with obvious genital diversity, which remains the most contentious area of clinical care—and increasingly, health law and policy—for persons with intersex traits (Dalke et al., 2020).

Genital Diversity and Early Genital Surgeries

Although some infants with genital diversity require urgent surgery to address urinary obstruction or exposed pelvic organs (Woo, Thomas, and Brock, 2010), many have no immediate medical concerns and do not require urgent medical treatment (Romao and Pippi Salle, 2017). Because the appearance of the external genitals is typically the primary datum for the sex assigned to infants at birth, genital diversity can lead to uncertainty about which sex a child with intersex traits should be assigned. Similarly, eventual gender identity cannot be readily predicted for many people with intersex traits based on the appearance of their genitals at birth (see more

Understanding Unapproved Use of Approved Drugs "Off Label"

Exhibit
0015
9/29/2021
Hruz

Has your healthcare provider ever talked to you about using an FDA-approved drug for an unapproved use (sometimes called an “off-label” use) to treat your disease or medical condition?

It is important to know that before a drug can be approved, a company must submit clinical data and other information to FDA for review. The company must show that the drug is safe and effective for its intended uses. "Safe" does not mean that the drug has no side effects. Instead, it means the FDA has determined the benefits of using the drug for a particular use outweigh the potential risks.

When you are prescribed a drug for its approved use, you can be sure:

- That FDA has conducted a careful evaluation of its benefits and risks for that use.
- The decision to use the drug is supported by strong scientific data.
- There is approved drug labeling for healthcare providers on how to use the drug safely and effectively for that use.

The approved drug labeling for healthcare providers gives key information about the drug that includes:

- The specific diseases and conditions that the drug is approved to treat.
- How to use the drug to treat those specific diseases and conditions.
- Information about the risks of the drug.
- Information that healthcare providers should discuss with patients before they take a drug.

Some drugs may also have labeling information for patients such as Medication Guides, Patient Package Inserts and Instructions for Use.

Why might an approved drug be used for an unapproved use?

From the FDA perspective, once the FDA approves a drug, healthcare providers generally may prescribe the drug for an unapproved use when they judge that it is medically appropriate for their patient.

You may be asking yourself why your healthcare provider would want to prescribe a drug to treat a disease or medical condition that the drug is not approved for. One reason is that there might not be an approved drug to treat your disease or medical condition. Another is that you may have tried all approved treatments without seeing any benefits. In situations like these, you and your healthcare provider may talk about using an approved drug for an unapproved use to treat your disease or medical condition.

What are examples of unapproved uses of approved drugs?

Unapproved use of an approved drug is often called "off-label" use. This term can mean that the drug is:

- Used for a disease or medical condition that it is not approved to treat, such as when a chemotherapy is approved to treat one type of cancer, but healthcare providers use it to treat a different type of cancer.
- Given in a different way, such as when a drug is approved as a capsule, but it is given instead in an oral solution.
- Given in a different dose, such as when a drug is approved at a dose of one tablet every day, but a patient is told by their healthcare provider to take two tablets every day.

If you and your healthcare provider decide to use an approved drug for an unapproved use to treat your disease or medical condition, remember that FDA has not determined that the drug is safe and effective for the unapproved use.

Questions you may want to consider

If your healthcare provider is thinking about using an approved drug for an unapproved use, you may want to ask your healthcare provider questions like these:

- What is the drug approved for?
- Are there other drugs or therapies that are approved to treat my disease or medical condition?
- What scientific studies are available to support the use of this drug to treat my disease or medical condition?
- Is it likely that this drug will work better to treat my disease or medical condition than using an approved treatment?
- What are the potential benefits and risks of treating my disease or medical condition with this drug?
- Will my health insurance cover treatment of my disease or medical condition with this drug?
- Are there any clinical trials studying the use of this drug for my disease or medical condition that I could enroll in?

Resources For You

- FDA Approved Medication Guides (/drugs/drug-safety-and-availability/medication-guides)
- Drugs@FDA Database (http://www.accessdata.fda.gov/scripts/cder/daf/index.cfm)
- DailyMed (https://dailymed.nlm.nih.gov/dailymed/index.cfm)

American Academy of Pediatrics
DEDICATED TO THE HEALTH OF ALL CHILDREN™

FROM THE AMERICAN ACADEMY OF PEDIATRICS

Organizational Principles to Guide and Define the Child Health Care System and/or Improve the Health of all Children

POLICY STATEMENT

Off-Label Use of Drugs in Children

Policy Statement–Reaffirmed with Reference & Data Updates

This policy statement has been reaffirmed with reference and data updates. New or updated references or datapoints are indicated in bold typeface. No other changes have been made to the text or content of the policy.

The AAP would like to acknowledge Jennifer Foster, MD, MPH, for these updates.

COMMITTEE ON DRUGS

KEY WORDS

off-label drug use, pharmaceuticals, pediatrics, infants, children, adolescents, prescribing

ABBREVIATIONS

BPCA—Best Pharmaceuticals for Children Act
FDA—US Food and Drug Administration
PREA—Pediatric Research Equity Act

www.pediatrics.org/cgi/doi/10.1542/peds.2013-4060

doi:10.1542/peds.2013-4060

PEDIATRICS (ISSN Numbers: Print, 0031-4005; Online, 1098-4275).

abstract

FREE

The passage of the Best Pharmaceuticals for Children Act and the Pediatric Research Equity Act has collectively resulted in an improvement in rational prescribing for children, including more than **800** labeling changes. However, off-label drug use remains an important public health issue for infants, children, and adolescents, because an overwhelming number of drugs still have no information in the labeling for use in pediatrics. The purpose of off-label use is to benefit the individual patient. Practitioners use their professional judgment to determine these uses. As such, the term "off-label" does not imply an improper, illegal, contraindicated, or investigational use. Therapeutic decision-making must always rely on the best available evidence and the importance of the benefit for the individual patient. *Pediatrics* 2014;133:563–567

INTRODUCTION

The purpose of this statement is to further define and discuss the status of off-label use of medications in children. Since publication of the 2002 statement from the American Academy of Pediatrics on the off-label use of drugs,[1] the number of drugs approved by the US Food and Drug Administration (FDA) with pediatric indications or expanded labeling that informs drug use in pediatric patients (eg, pharmacokinetic/pharmacodynamic data, safety data) has substantially increased. The passage of the Best Pharmaceuticals for Children Act[2] (BPCA) and the Pediatric Research Equity Act[3] (PREA) has resulted in more than **800** pediatric labeling changes. However, despite this success and advances in both basic science and clinical trials in pediatrics, off-label drug use remains a common and important issue for children and adolescents. Moreover, off-label use of drugs presents an even larger and more complex issue in preterm and full-term neonates, infants and in children younger than 2 years,[4] and children with chronic and/or rare diseases.[5,6]

DEFINING OFF-LABEL USE

The term "off-label" use refers to use of a drug that is not included in the package insert (approved labeling) for that drug. The purpose of off-label use is to benefit an individual patient. It is important to note that the term "off-label" does not imply an improper, illegal, contraindicated, or investigational use. To approve a drug for sale and marketing within the United States, the FDA requires substantial

evidence for efficacy and safety, usually in the form of 2 well-controlled trials. Subsequent requests by a sponsor to add a new indication to drug labeling must also be accompanied by additional evidence in support of that indication. If the FDA finds that such evidence supports approval, the new indication is added to the product labeling. If the evidence is deemed insufficient or if the sponsor chooses not to submit evidence, the indication is not added.

According to the Code of Federal Regulations,[7] a sponsor is the entity that holds an investigational new drug application and that both takes responsibility for and initiates a clinical investigation. The sponsor may be an individual or pharmaceutical company, governmental agency, academic institution, private organization, or other organization. A sponsor does not actually conduct the investigation unless the sponsor is a sponsor-investigator. A person other than an individual who uses 1 or more of his or her own employees to conduct an investigation that he or she has initiated is considered to be a sponsor, not a sponsor-investigator. In this case, the employees are investigators. Sponsor-investigators both initiate and conduct an investigation and direct the administration or dispensing of the investigational drug. The requirements applicable to a sponsor-investigator include both those applicable to an investigator and a sponsor. It is important to note that sponsors are not allowed to promote or even speak to off-label use. If a physician speaks on behalf of a sponsor, the same rule applies. It is acceptable to use drugs off label and to publish results related to off-label use, but it is not acceptable to receive remuneration from the sponsor for these uses.

The absence of labeling for a specific age group or for a specific disorder does not necessarily mean that the drug's use is improper for that age or disorder. Rather, it only means that the evidence required by law to allow inclusion in the label has not been approved by the FDA. Additionally, in no way does a lack of labeling signify that therapy is unsupported by clinical experience or data in children. Instead, it specifically means that evidence for drug efficacy and safety in the pediatric population has not been submitted to FDA for review or has not met the regulatory standards of "substantial evidence" for FDA approval. In contrast to the absence of pediatric-specific information on some medications, other drug labels contain statements such as "the safety and efficacy in pediatric patients have not been established," and explicit evidence-based warnings and contraindications are included on the label where indicated. Understanding the distinction between the lack of FDA approval for a particular use or dosing regimen in the former case versus explicit warnings or contraindications against use in the latter is essential for the pediatric practitioner. In addition, when considering best practices for therapeutic decision-making, it is essential to understand that the FDA does not regulate the use of drugs as they pertain to the practice of medicine.[8]

THE ROLE OF THE FDA

The FDA is the federal government agency charged with oversight responsibility for the manufacturing, labeling, advertisement, and safety of therapeutic drugs and biological products. The Food, Drug, and Cosmetic Act[9] requires that "substantial evidence," resulting from "adequate and well-controlled investigations" demonstrating that a new drug "will have the effect it purports or is represented to have under the conditions of use prescribed, recommended, or suggested in the proposed labeling," be submitted to and reviewed and approved by the FDA before the drug is marketed in interstate commerce. For drugs and biological agents (eg, vaccines, antibodies), proof of effectiveness consists of "adequate and well-controlled studies" as defined for new drugs in the Code of Federal Regulations.[10] Biological agents are approved under the Public Health Service Act.[11] Given these requirements as well as the rapid pace of medical discovery, it is not surprising that labeling does not reflect all possible uses of an agent. Off-label use of drugs in children is not overseen by the FDA, because the FDA does not regulate the prescription practices of individual practitioners.

The FDA maintains a system for postmarketing drug surveillance, compiling and analyzing information about the incidence and severity of adverse events reported by practitioners, sponsors, hospitals, and other health care facilities. It is important to note that this postmarket surveillance system is passive and that the total number of adverse event reports in pediatrics relative to adults is small. To address this issue, the BPCA provides for a systematized review of adverse event reports in pediatric patients through the FDA Pediatric Advisory Committee. When the FDA notes an apparent association between use of a drug and an adverse event, the FDA may choose from several actions: to request further focused study of the drug, to add a contraindication or warning to the drug labeling, to issue a warning about use of the drug, or to seek voluntary or compulsory removal of the drug from the market. Therefore, although the FDA does not regulate the practice of medicine, practitioners should be aware of new information brought forward by the FDA, because it can serve as a valuable resource for information regarding the potential or proven adverse effects of drugs (see www.fda.gov).

THERAPEUTIC DECISION-MAKING

Therapeutic decision-making should always be guided by the best available evidence and the importance of the benefit for the individual patient. Practitioners are in agreement regarding the importance of practicing evidence-based medicine. However, for the pediatric population, gold standard clinical trials are often not available, so practitioners must rely on either less definitive information, such as expert opinion for the age group that they are treating, or use evidence from a different population to guide practice. There are now many resources available to help assess the quality of evidence-based medicine, including but not restricted to articles in peer-reviewed journals, American Academy of Pediatrics practice guidelines and policy statements, consensus statements, and handbooks and databases (ie, Cochrane, Lexicomp, and Harriet Lane). At times, there may be little or no published information to guide therapy. This situation is especially true when treating rare diseases or sparse populations such as neonates. In such situations, the practicing physician can play an important role in adding to therapeutic information by publishing his or her experience with off-label uses of drugs. These reports can serve as the basis of more formal efficacy and safety studies and can serve as a therapeutic decision-making resource for other physicians. The practicing physician also has a responsibility to report adverse events to the FDA through the Medwatch program (www.fda.gov/Safety/MedWatch).

In most situations, off-label use of medications is neither experimentation nor research. The administration of an approved drug for a use that is not approved by the FDA is not considered research and does not warrant special consent or review if it is deemed to be in the individual patient's best interest.[8]

In general, if existing evidence supports the use of a drug for a specific indication in a particular patient, the usual informed-consent conversations should be conducted, including anticipated risks, benefits, and alternatives. If the off-label use is based on sound medical evidence, no additional informed consent beyond that routinely used in therapeutic decision-making is needed.[12,13] However, if the off-label use is experimental, then the patient (or parent) should be informed of its experimental status.[14] It would be prudent for pediatricians to know and abide by the appropriate informed consent laws in their respective states. In addition, particular risk-benefit ratios presented by the unproven therapies must be carefully considered and disclosed, and standard of care practices should be reviewed. When use of a drug is truly investigational, drug use should be performed in conjunction with a well-designed clinical trial whenever possible. This is especially true when the physician proposes to treat a group of patients rather than a single individual. Patients and/or their legal guardians should be specifically informed that the proposed therapy is investigational, and their consent to proceed despite the risks of investigational therapy should be carefully documented. Whether institutional review, consultation, or written consent are required for a given intervention depends on the degree of risk or departure from standard practices and the extent to which research, rather than individual patient care, is involved.

Practitioners may be concerned that the off-label use of an approved drug may invite a variety of legal actions. To conform to accepted professional standards, the off-label use of a drug should be done in good faith, in the best interest of the patient, and without fraudulent intent. A practitioner may be accountable for the negligent use of any drug in a civil action, regardless of whether the FDA has approved the use of that drug. Labeling is not intended to preclude the practitioner from using his or her best medical judgment in the interest of patients or to impose liability for off-label use. Indeed, the practice of medicine will more than likely require a practitioner to use drugs off label to provide the most appropriate treatment of a patient. However, because the use of drugs in an off-label capacity can increase the liability risk for a practitioner should an adverse event or poor outcome ensue, it is essential that practitioners document the decision-making process to use a drug off label in the patient's medical record.

FEDERAL LEGISLATION TO INCREASE DRUG TESTING IN CHILDREN

The BPCA and the PREA are 2 complementary federal laws that have substantially increased clinical evaluation and labeling of drugs in children both by the pharmaceutical industry and through government-sponsored trials.[10] The PREA mandates that almost all new drugs and certain approved drugs must be studied in children for approved uses of the product if there is potential for use of that drug in children and that the application for new drug approval include the results of adequate pediatric studies unless the studies are deferred or waived by the FDA. The BPCA allows sponsors to qualify for an additional 6 months of market exclusivity if the sponsor completes and submits pediatric studies to the FDA, as outlined in an FDA-issued written request. A written request may include off-label as well as approved uses of a drug. In addition, the BPCA authorizes the National Institutes of Health, in conjunction with the FDA

and physicians from clinical disciplines, to work together to assign priority for testing of specific drugs in children. The National Institutes of Health, acting through the Eunice Kennedy Shriver National Institute of Child Health and Human Development, then solicits proposals for pediatric drug testing concordant with the drug prioritization recommendations and funds clinical studies that are judged meritorious by external review. The ratification of these 2 laws has been considered a significant success, because there have been more than **600** pediatriclabeling changes. Also as a result of these laws, increased prospective pediatric drug testing has occurred via industry-sponsored studies, investigator-initiated studies, and consortia, such as the National Institute of Child Health and Human Development–funded Pediatric Trials Network. The net result has been an expansion of both pediatric labeling information and the knowledge base from which practitioners can draw to make informed therapeutic decisions.[15,16]

In 2012, Congress passed the Food and Drug Administration Safety and Innovation Act,[17] reauthorizing and strengthening the BPCA and PREA. The legislation aims to ensure that pediatric evaluations under PREA are conducted earlier in the drug development process to improve the quality of and accountability for completion of such studies and to advance the neonatal drug studies under the BPCA and PREA. The legislation also makes both the BPCA and PREA permanent law.

CONCLUSIONS

Off-label drug use remains an important public health issue, especially for infants, young children, and children with rare diseases. Evidence, not label indication, remains the gold standard from which practitioners should draw when making therapeutic decisions for their patients. The PREA and BPCA have been extremely successful and represent an essential first step in expanding this evidence as a means of achieving the ultimate goal that any and all drugs used to treat children will have age-appropriate evidence sufficient to provide information for labeling. However, labeling with pediatric information still exists in less than 50% of products,[18] such that much work remains to be done to ensure the best possible practice for therapeutic decision-making in pediatrics.

RECOMMENDATIONS

1. The practitioner who prescribes a drug is responsible for deciding which drug and dosing regimen the patient will receive and for what purpose.
   a. This decision should be made on the basis of the information contained in the drug's labeling (when available) or other data available to the prescriber.
   b. The use of a drug, whether off or on label, should be based on sound scientific evidence, expert medical judgment, or published literature whenever possible.
   c. Off-label use is neither incorrect nor investigational if based on sound scientific evidence, expert medical judgment, or published literature.
2. Pediatricians should continue to advocate for necessary incentives and requirements to promote the study of drugs in children.
3. Physician researchers are encouraged to continue the rational and critical study of drugs in children through conducting and/or collaborating in well-designed pediatric drug studies, including national consortium studies.
4. Journals should be encouraged to publish the results of all well-designed investigations, including negative studies.
5. Institutions and payers should not use labeling status as the sole criterion that determines the availability on formulary or reimbursement status for medications in children. Similarly, less expensive therapeutic alternatives considered appropriate for adults should not automatically be considered appropriate first-line treatment in children. Finally, off-label uses of drugs should be considered when addressing various drug-related concerns, such as drug shortages.

LEAD AUTHOR

Kathleen A. Neville, MD, MS

COMMITTEE ON DRUGS, 2019–2020

Bridgette Jones, MD, Chairperson
Jennifer Foster, MD, MPH
Constance S. Houck, MD
Matthew M. Laughon, MD
J. Routt Reigart, MD
Rohit Shenoi, MD
Janice E. Sullivan, MD

LIAISONS

John J. Alexander, MD – Food and Drug Administration
Janet D. Cragan, MD, MPH – Centers for Disease Control and Prevention
Hari Cheryl Sachs, MD – Food and Drug Administration
Perdita Taylor-Zapata, MD – National Institutes of Health
Geert W t'Jong, MD, PhD – Canadian Paediatric Society
Timothy Wilens, MD – American Academy of Child and Adolescent Psychiatry

STAFF

James Baumberger, MPP
Raymond J. Koteras, MHA
Tamar Haro

ACKNOWLEDGMENT

The 2020 data and reference update were completed by Jennifer Foster, MD, MPH.

REFERENCES

1. American Academy of Pediatrics Committee on Drugs. Uses of drugs not described in the package insert (off-label uses). *Pediatrics*. 2002;110(1 pt 1):181–183
2. Best Pharmaceuticals for Children Act. Pub L No. 107-109 (2002)
3. Pediatric Research Equity Act. Pub L No. 108-155 (2003)
4. Shah SS, Hall M, Goodman DM, et al. Off-label drug use in hospitalized children. *Arch Pediatr Adolesc Med*. 2007;161(3):282–290
5. **Czaja AS, Fiks AG, Wasserman RC, Valuck RJ; Comparative Effectiveness Research Through Collaborative Electronic Reporting (CER2) Consortium. Beyond the label: steering the focus toward safe and effective prescribing. *Pediatrics*. 2017;139(5): e20163518**
6. **Palmaro A, Bissuel R, Renaud N, et al. Off-label prescribing in pediatric outpatients. *Pediatrics*. 2015;135(1):49-58**
7. US Food and Drug Administration. Code of Federal Regulations Title 21. Available at: http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfcfr/CFRSearch.cfm?fr=312.3. Accessed November 20, 2012
8. US Food and Drug Administration. "Off-label" and investigational use of marketed drugs, biologics, and medical devices: information sheet. Available at: http://www.fda.gov/RegulatoryInformation/Guidances/ucm126486.htm. Accessed January 19, 2014
9. Drug Amendments of 1962. Part A: amendments to assure safety, effectiveness, and reliability. Pub L No. 87-781, §101-308
10. Applications for FDA approval to market a new drug. Adequate and well-controlled studies. (2000) (codified at 21 CFR §314.126)
11. Public Health Service Act. 42 USC §262 (1999)
12. *Blazoski v Cook,* 346 NJ Super 256, 787 A2d 910 (2002)
13. **Sharma AN, Arango C, Coghill D, et al. BAP position statement: Off-label prescribing of psychotropic medication to children and adolescents. *J Psychopharmacol*. 2016;30(5):416-421**
14. *Shadrick v Coker,* 963 SW2d 726, 733 (Tenn 1998)
15. Roberts R, Rodriguez W, Murphy D, Crescenzi T. Pediatric drug labeling: improving the safety and efficacy of pediatric therapies. *JAMA*. 2003;290(7):905–911
16. Steinbrook R. Testing medications in children. *N Engl J Med*. 2002;347(18):1462–1470
17. Food and Drug Administration Safety and Innovation Act. Pub L No. 112-144 (2012)
18. Sachs AN, Avant D, Lee CS, Rodriguez W, Murphy MD. Pediatric information in drug product labeling. *JAMA*. 2012;307(18):1914–1915

Off-Label Use of Drugs in Children

COMMITTEE ON DRUGS

Pediatrics 2014;133;563
DOI: 10.1542/peds.2013-4060 originally published online February 24, 2014;

PEDIATRICS®
OFFICIAL JOURNAL OF THE AMERICAN ACADEMY OF PEDIATRICS

Off-Label Use of Drugs in Children

COMMITTEE ON DRUGS

Pediatrics 2014;133;563
DOI: 10.1542/peds.2013-4060 originally published online February 24, 2014;

UNITED STATES DISTRICT COURT
FOR THE MIDDLE DISTRICT OF FLORIDA
JACKSONVILLE DIVISION

DREW ADAMS, et al.,

Plaintiff,

v.

THE SCHOOL BOARD OF ST. JOHNS COUNTY, FLORIDA,

Defendant.

No. 3:17-cv-00739-TJC-JBT

DECLARATION OF DR. NORMAN P. SPACK, M.D.

I, Norman P. Spack, pursuant to 28 U.S.C. § 1746, hereby declare as follows:

1. I am over the age of eighteen and submit this declaration based on my personal knowledge.

2. If called to testify, I would testify truthfully based on my own experience and knowledge regarding the matters discussed herein.

3. I am a pediatric endocrinologist. I began practicing pediatric endocrinology in 1976 at Boston Children's Hospital. I have an undergraduate degree from Williams College, a medical degree from the University of Rochester, and completed my pediatrics residency and fellowship in Pediatric Endocrinology and Adolescent Medicine at Boston Children's Hospital.

4. I am an Associate Physician in Medicine at Boston Children's Hospital, the Co-Founder and Co-Director *Emeritus* of the Gender Management Service (GeMS) Program at Boston Children's Hospital, and an Associate Clinical Professor of Pediatrics at Harvard Medical School in Massachusetts.

5. In 2007, I co-founded the GeMS Program at Boston Children's Hospital. The first-of-its-kind program in the United States, GeMS provides comprehensive care to the unique group of gender nonconforming and transgender children and adolescents. The GeMS team consists of providers from Endocrinology, Psychology, and Social Work, and works closely with specialists in other departments in the hospital such as Adolescent Medicine, Urology, and Plastic Surgery to develop individual care plans that meet every child's medical and emotional needs, as well as the family's need for information and support.

6. Since its founding, the GeMS Program has been replicated by over 60 similar programs at pediatric academic centers in North America, including the now Transgender Center at St. Louis Children's Hospital.

7. In 2012, I was awarded a Bicentennial Medal by Williams College in recognition for distinguished achievement in the field of pediatric endocrinology and for helping reduce the suicide rate among transgender adolescents through my work with GeMS.

8. On or about October 9, 2013, I gave a presentation at St. Louis Children's Hospital regarding the founding of GeMS, the workings of a gender management program at pediatric hospital, and the medical treatment and care of ender nonconforming and transgender children and adolescents.

9. Following my presentation, I privately met with medical staff, including endocrinologists, at St. Louis Children's Hospital to answer their questions and share my knowledge and experience.

10. It was in the aforementioned context that I also met privately with Dr. Paul W. Hruz at St. Louis Children's Hospital when he approached me after my presentation.

11. During my private meeting with Dr. Hruz, Dr. Hruz directly expressed that he had "a significant problem with the entire issue" and "whole idea of transgender."

12. Dr. Hruz followed up his comments by stating, "For me, it is a matter of my faith."

13. During our conversation, Dr. Hruz did not discuss or mention that his issues or concerns were based on science.

14. In my experience, someone who acts out of science would go and see how gender management clinics work in order to form their opinions.

This declaration was executed on this ___ day of December, 2017 in Boston, Massachusetts.

Pursuant to 28 U.S.C. § 1746, I declare under penalty of perjury that the foregoing is true and correct.

_____
Norman P. Spack, M.D.

9. Following my presentation, I privately met with medical staff, including endocrinologists, at St. Louis Children's Hospital to answer their questions and share my knowledge and experience.

10. It was in the aforementioned context that I also met privately with Dr. Paul W. Hruz at St. Louis Children's Hospital when he approached me after my presentation.

11. During my private meeting with Dr. Hruz, Dr. Hruz directly expressed that he had "a significant problem with the entire issue" and "whole idea of transgender."

12. Dr. Hruz followed up his comments by stating, "For me, it is a matter of my faith."

13. During our conversation, Dr. Hruz did not discuss or mention that his issues or concerns were based on science.

14. In my experience, someone who acts out of science would go and see how gender management clinics work in order to form their opinions.

This declaration was executed on this 5 day of December, 2017 in Boston, Massachusetts.

Pursuant to 28 U.S.C. § 1746, I declare under penalty of perjury that the foregoing is true and correct.

Norman P. Spack, M.D.

UNITED STATES DISTRICT COURT
FOR THE
MIDDLE DISTRICT OF FLORIDA

DREW ADAMS, a minor,)
)
Plaintiff,)
)
vs.)Civil Action
)No.3:17-cv-00739-TJC-JBT
THE SCHOOL BOARD OF ST.)
JOHNS COUNTY, FLORIDA,)
)
Defendant.)

TELEPHONIC DEPOSITION OF KIM G. HUTTON
Taken on behalf of Defendant
December 5, 2017
(Starting time of the deposition: 3:00 p.m.)

I N D E X O F E X A M I N A T I O N

Page

Questions by Mr. Harmon 5

Questions by Mr. Gonzalez-Pagan 49

(No exhibits were marked.)

UNITED STATES DISTRICT COURT
FOR THE
MIDDLE DISTRICT OF FLORIDA

DREW ADAMS, a minor,)
)
Plaintiff,)
)
vs.)Civil Action
)No.3:17-cv-00739-TJC-JBT
THE SCHOOL BOARD OF ST.)
JOHNS COUNTY, FLORIDA,)
)
Defendants.)

TELEPHONIC DEPOSITION OF WITNESS, KIM G. HUTTON, produced, sworn, and examined on the 5th day of December, 2017, between the hours of nine o'clock in the forenoon and six o'clock in the evening of that day, at the offices of Veritext Legal Solutions, 515 Olive Street, Suite 300, St. Louis, Missouri before BRENDA ORSBORN, a Certified Court Reporter within and for the State of Missouri, in a certain cause now pending in the United States District Court for the Middle District of Florida, wherein Drew Adams, a minor, is the Plaintiff and The School Board of St. Johns County, Florida is the Defendant.

A P P E A R A N C E S

For the Plaintiff:
Mr. Omar Gonzalez-Pagan
Lambda Legal
120 Wall Street
New York, New York 10005
(212) 809-8585
ogonzalez-pagan@lambdalegal.org

For the Defendant:
Mr. Terry Harmon (via phone)
Sniffen & Spellman, P.A.
123 North Monroe Street
Tallahassee, Florida 32301
(850) 205-1996
tharmon@sniffenlaw.com

The Court Reporter:
Ms. Brenda Orsborn, RPR/CSR/CCR
Missouri CCR No. 914
Illinois CSR No. 084-003460
Veritext Legal Solutions
515 Olive Street, Suite 300
St. Louis, Missouri 63101
(888) 391-3376

center in St. Louis.

And that's how that happened. Dr. Hruz e-mailed me -- it's either the same day or the next day, and invited me to lunch.

Q. Where did you go -- did you end up going to lunch?

A. We did.

Q. Where did you go?

A. At the Wild Flower in the Central West End.

Q. And what -- you said it was in 2013?

A. Yes.

Q. Do you recall what month?

A. October.

Q. Okay. Was anybody else at the lunch?

A. No.

Q. Do you recall approximately how long the lunch was?

A. Maybe 45 minutes.

Q. Was your conversation recorded?

A. No.

Q. I guess, to your knowledge, you may not know, right?

A. To my knowledge. I did not record it.

Q. Okay. What -- what did you -- when you were going to have that lunch with Dr. Hruz, what was the

purpose of it, in your mind?

A. Well, the e-mail that he sent me stated that he wanted to meet to -- I think he kind of positioned it as wanting to learn more about this experience, and he shared that he -- he was well aware that Dr. Abby Hollander was working with me, or that I had approached her about starting a pediatric gender center inside the hospital, and that he was having great difficulty being open to that concept based on his morals.

He said that he did not -- part of the note I remember said something about he did not agree with the -- the recommended standards of care, or something like that, for our children, that he didn't believe that it was appropriate medically or spirit -- or that it -- or that it wouldn't meet their spiritual needs, or something like that.

And so I realized -- I realized -- I felt like it was going to be not a great meeting, but I was still willing to meet with him because I felt that maybe, you know, the parent perspective could be helpful to him.

Q. Now, was that document, was that in an e-mail that he conveyed that information to you?

A. Yes.

Q. Do you still have that e-mail?
A. I do.
Q. Okay. Have you shown that e-mail to counsel in the room?
A. I did.
Q. Do you have it with you now?
A. I don't.
Q. Okay. To the best of your knowledge, can you tell me everything, aside from what you've already told me, that that e-mail says in it?
A. Those -- those were the sticking points for me, because I found it very odd that he would be talking about faith or morals or spiritual needs in the context of this conversation. It was not -- I talk to many medical professionals in my work with TransParent, and it's the first time that somebody was so overtly upfront that it was problematic due to their faith on some -- at least on some level. So I can't remember it. It wasn't -- it was longer -- the -- the note was longer than that, but those were the points that have stuck out with me.
Q. Okay. Other than that e-mail, do you have any other document that reflects communication you have had with Dr. Hruz?
A. There's -- I mean, after he e-mailed me, I

e-mailed him and told him that I, you know, was very excited to meet with him, although I was -- you know, I think I expressed some disappointment because Dr. Spack had shared that he was, you know, I guess against a pediatric gender center at St. Louis Children's Hospital and -- but that, you know, I was -- I would be very happy to have the conversation or something like that. And then he e-mailed me back and said, "Thank you for responding so quickly," and he would have his secretary reach out to me to set a date and time.

Q. Okay. So this meeting that you were going to have with him that ended up being a lunch, was any part of that meeting in the context of receiving medical care, opinions or services?

A. No.

Q. Okay. Were you going to learn anything from Dr. Hruz you would personally use with you or your family members when it comes to treatment for any type of disorders?

A. No.

Q. Was it just to learn about Dr. Hruz's position on the pediatric gender center at the Washington University?

A. Well, he called the meeting, so I -- I --

again, I really wanted to go, because I understood that he had a lot of influence on whether or not the center moved forward. And I had been talking with other doctors and people on their DSD team at St. Louis Children's Hospital about moving this forward, but it really had stalled.

And so I -- I just felt like being the head of Endocrine, that he would have a lot of influence over that decision. And so for me, that is why I wanted to go and meet with him, to see if I could say anything that would might make -- that might make him more interested in doing something like that.

Q. So would you characterize this as a business meeting?

A. Not really. I'm -- not really. I guess -- I guess --

Q. Were you hoping to come away from that meeting with some type of support from Dr. Hruz for the establishment of the pediatric gender center?

A. I guess I just felt like all of the treatment for our kids was going through a person that reported to Dr. Hruz. And so I guess I felt like he may not have enough information to support it or not support it. He wasn't seeing any of our kids. There -- there were only a handful of our kids at the

time.

You know, this is four years ago before everything really opened up in St. Louis as far as treatment and care for kids. But I just understood that he -- and especially since he had already said in his e-mail that he didn't support the center, I guess I was hopeful that the parent perspective might be helpful.

Q. Okay. Now, did I understand you to say that you were aware that Dr. Hruz was providing treatment to your -- when you say "our kids," are you referring to TransParent --

A. Yes.

Q. -- members' kids?

A. Yes.

Q. Okay. So to your knowledge, as of 2013, to your knowledge, was Dr. Hruz treating transgender children?

A. He was not, that I -- to my knowledge.

Q. Okay. So in terms of that -- that lunch meeting, can you tell me everything you can remember from the meeting?

A. Yes.

MR. GONZALEZ-PAGAN: Form.

Q. (By Mr. Harmon) Well, let me ask it a

different way. Can you tell me, to the best of your recollection, everything Dr. Hruz said to you during the lunch meeting?

MR. GONZALEZ-PAGAN: Form. You can answer.

THE WITNESS: Oh.

Q. (By Mr. Harmon) Yeah, you can answer.

A. Yeah. So after, you know, introducing ourselves I started off with trying to tell him a little bit about my family and our experience, but I -- I really didn't get very far. He interrupted me fairly quickly, probably within a minute or so, two minutes tops, and said that he had reviewed my brochure from TransParent and that he knew that my aim was to normalize the transgender experience, but that it would never be a normal experience. It was not a normal experience, and it would never be normal.

We went on to talk more about, you know, his -- he -- he actually started talking about Pope John Paul II's writings on gender and -- and how they explain God's plan for gender, and that I should consider reading them. And he said, you know, this idea that -- the idea of doing surgeries on transgender people is -- is wrong, that, you know, we should not be, you know, changing bodies.

And I said -- I -- I argued with him on that

point that, you know, there are men that have man boobs, and I said they have theirs surgically removed or altered. And I said wouldn't that be the same thing, and -- and why is that okay, but not removing the breast for a transgender boy, and he said, "Because male breasts aren't used for anything, but female breasts lactate and provide nourishment to babies. So, therefore, it would be -- it would go against, you know, God's plan to remove breasts from women." Something -- something very close that.

He said several times during this conversation, as I tried to tell him, you know, how hard it was for my child living a transgender life, you know, but that -- but what a great -- what a great son I've had since I allowed him to transition, how happy he was. And he said that, you know, what a -- I kept saying, "What a normal life -- like if you met my son, you would never know. He's a very normal little boy."

And he kept saying, he kept insisting that my child was not normal and would never be normal. And he said that to me at least three or four times during our conversation.

He said -- and -- and at the same time he just kept saying, "If only you would read Pope John

Paul II's writings. If only you would read them, you would understand everything." And I said, "Well, you know, the Bible tells a story about, you know, man was -- woman was created from the rib of man," and I said, "You know, maybe this all started with Adam and Eve because God took a rib from a woman -- or from a man and put it into women, and maybe he crossed that DNA, you know, at the very beginning, and maybe that's why we have transgender people."

He said -- he got very irritated with me, and he said, "Not all the stories in the Bible are true."

And I said, "Well, then how do you decide which ones you're going to believe and which ones you're not? How do you determine that, like, which ones you follow and which ones you don't follow?"

And he -- he reverted right back to -- he goes, "You just need to read Pope John Paul II's writings on gender. It will -- it will explain it all to you."

And I said, "Do you realize that kids like mine are at a 41 percent risk of suicide if they don't have acceptance and -- and care from their parents and -- and if they don't get their medical needs met?"

And he said, "Some children are born in this

world to suffer and die." And he said, "Do you think I don't ask myself all the time why some people get cancer?" He goes, "I -- I ask myself that all the time."

And I said, "Well, people with cancer, at least we try to help them. At least we give them care." And I think the conversation ended shortly after that, and he stood up, and he said, "I -- I have to tell you there will never be a pediatric gender center at St. Louis Children's Hospital. I won't allow it." And I --

Q. Did he say why?

A. Pardon me?

Q. Did he say why he would not allow it?

A. Well, based on every -- no, he did not say why. That's how he ended the conversation, but my interpretation would have been based on everything we -- he had just shared with me that he was in disagreement from -- based on his faith.

Q. Did he ever say that he would not allow a gender center because of his faith?

A. He did not.

Q. Okay. That was your interpretation of --

A. Yes.

Q. -- what the conversation was?

A. I am.
Q. How are you aware of what his position is now?
A. I saw a -- some papers that he's publishing, and I understand that he is involved in other cases involving students, so Internet searches.
Q. Did your conversation with Dr. Hruz anger you?
A. My conversation?
Q. Yes.
A. It -- it perplexed me. I found --
Q. Why did it perplex you?
A. Again, because it was so religious-based. I -- I was very taken off guard by the religious tone of the conversation, because I -- I figured it would at least be based on science. He would have some science behind his feelings over children like mine, but that is not what I heard in our conversation at all.
Q. So your conversation with Dr. Hruz, is it fair to say that it was based on religion and moral viewpoints as opposed to science?
A. Yes.
MR. GONZALEZ-PAGAN: Form.
Q. (By Mr. Harmon) What was the answer?

(https://thegenderandsexconference.org)

I International Conference on Gender, Sex and Education in Madrid against the LGBTI doctrine which is taking hold of Western countries is a resounding success

I International Conference on Gender, Sex and Education in Madrid against the LGBTI doctrine which is taking hold of Western countries is a resounding success (https://thegenderandsexconference.org/i-international-conference-on-gender-sex-and-

education-in-madrid-against-the-lgbti-doctrine-which-is-taking-hold-of-western-countries-is-a-resounding-success/)

Prensa HO (https://thegenderandsexconference.org/author/prensa/)

Nota de Prensa (https://thegenderandsexconference.org/category/nota-de-prensa/) Feb 28, 2018

53 ORGANIZATIONS FROM 17 COUNTRIES SUPPORT THE MADRID DECLARATION OF UNDERSTANDING, RESPECT AND FREEDOM

- *At the #GenderAndSex Conference, organized by HazteOir.org and its international platform CitizenGO, eight speakers from four countries participated and more than 250 people attended. At some point over 5,000 people connected to follow the conference online.*
- *Ignacio Arsuaga: "This conference is a rebellion against the gender ideology and its freedom-destroying, damaging laws – laws that mustn't and cannot succeed. At HazteOir.org and CitizenGO we will keep on fighting to stop the LGBTI agenda from being forced upon citizens".*

MADRID, 28. FEBRUARY 2018.– Ignacio Arsuaga, President of HazteOir.org and CitizenGO, sums up the success of the I **International Conference on Gender, Sex and Education** (http://thegenderandsexconference.org) **#GenderAndSex** which took place in Madrid last week Friday, with the following words: "This conference was **the world's first great public objection to totalitarian LGTBI laws**. We have now marked a "before" and an "after" (the conference), because we have made known the essential lie that hides behind the ideology of gender, contrary to the foundations of science, biology, reason and the anthropological truth of the human being".

Eight speakers from four countries took part in the #GenderAndSex Conference, organized by HazteOir.org and its international platform CitizenGO, **and over 250 people attended**. **At some point over 5000 people connected via the internet to follow the conference online**.

What's more, **53 organizations from 17 countries supported the Madrid Declaration for Understanding, Respect and Freedom** (https://drive.google.com/file/d/10fDoT_wlOu2npgzkli4pKErfLpyBaqT9/view?usp=sharing)**, which defends rights in the face of the "gender lie" .**

A conference to oppose gender ideology

In his keynote address, **Arsuaga** urged attendees not to allow "**damage made to children**" and **called on politicians** to "**leave the children in peace**".

Apart from the President of HazteOir.org and CitizenGO, **Miriam Ben-Shalom,** (http://thegenderandsexconference.org/speaker/miriam-ben-shalom-2/)US Lesbian activist, also spoke at the **I International Conference on Gender, Sex and Education**, saying that she feels "**very**

uncomfortable in showers or changing rooms for transgender women".

Agustín Laje (http://thegenderandsexconference.org/speaker/agustin-laje/), political science expert, called his listeners to speak out against the LGBTI offensive, saying: **"We need to bring the masses into the streets against gender ideology".** Laje believes that the left has adopted **the issue of sex and the gender ideology as a sort of "political strategy,** in order to keep their beliefs in the public domain."

The third presentation came from **Rubén Navarro,** (http://thegenderandsexconference.org/speaker/mr-ruben-navarro/)who condemned the fact that the **"LGTBI agenda has infiltrated the United Nations".** As an example of how pressure groups push their agenda, Navarro referred to legislation known as **"LGBTI gag law"** which the leftist group Podemos is promoting in Spain.

Michelle Cretella (http://thegenderandsexconference.org/speaker/mrs-michelle-cretella/), President of the American College of Pediatricians, also took part in the conference, explaining that **"schools need to avoid gender ideology because it is contrary to science and harmful to all children".**

The rest of the panel of experts and lecturers was made up by Professor **Glenn Stanton,** (http://thegenderandsexconference.org/speaker/mr-glenn-stanton/)Doctor **Paul Hruz** (http://thegenderandsexconference.org/speaker/mr-paul-hruz/), the sociologist **Gabriele Kuby** (http://thegenderandsexconference.org/speaker/mrs-gabriele-kuby/) and the former transexual **Walt Heyer.** (http://thegenderandsexconference.org/speaker/walt-heyer-2/)

Stanton assured that **" the gender theory is unscientific and full of contradictions".** Doctor **Hruz for his part** warned: **"Sex change is impossible. You cannot change your sex, the only thing you can change is the appearance".** In her explanations, **Kuby** affirmed that **"the sexual revolution has one objective only: to destroy the fertility, procreation and the family".**

The **I International Conference on Gender, Sex and Education** (#GenderAndSex Conference) was brought to a close by the testimony of **Heyer,** who had undergone gender reassignment surgery at the age of 42 years. He affirmed that **"there is nothing real in gender ideology".**

He added: **"I speak about this because I receive hundreds of letters from people all over the world who experienced the same as I did and this is a tragedy.** Will they get paid again for trying to put back that which they previously removed?"

53 organizations sign the Declaration of Madrid

The **I International Conference on Gender, Sex and Education** closed with a reading of the **Madrid Declaration for Understanding, Respect and Freedom** (https://drive.google.com/file/d/1cMpObKRmsbbRdDlHpuvpHXjFuants023/view?usp=sharing) which was joined, among others, by the **Foundation of Values and Society**, the **Association of Researchers and Professionals CiViCa,** and the **European Association of Family Lawyers –** all Spanish

institutions. The declaration was also supported by European organizations: **Generation Family** (Italy), **Free Society Institute** (Lithuania), **Family Alliance** (Austria) and **Femina Europa** (France). Among North and South American institutions who gave their support, were **Real Women of Canada** and **Population Research Institute** (United States), **National Family Forum** (Columbia), **National Union of Parents** (Mexico), **Center for Civic Studies** (Chile), **Argentinians Alert** and **Institute for Civic Action** (Peru). **A list of all organizations supporting the declaration can be found here.** (http://thegenderandsexconference.org/asociaciones-adheridas/)

I International Conference on Gender, Sex and Education Resources:

Vídeos:

All videos from the #GenderAndSex Conference: https://www.youtube.com/playlist?list=PL4bbuT69ULV_LIymyK7jh7PNEBkxSUPEJ (https://www.youtube.com/playlist?list=PL4bbuT69ULV_LIymyK7jh7PNEBkxSUPEJ)

Ignacio Arsuaga intervention: https://youtu.be/Dq-LwrPRoRo (https://youtu.be/Dq-LwrPRoRo)

Miriam Ben-Shalom intervention: https://youtu.be/f7vY1g-xK7w (https://youtu.be/f7vY1g-xK7w)

Agustín Laje intervention: https://youtu.be/w4PmcFf6Iw4– (https://youtu.be/w4PmcFf6Iw4--)

Ruben Navarro intervention: https://youtu.be/6MLSiiw11ac (https://youtu.be/6MLSiiw11ac)

Michelle Cretella intervention: https://youtu.be/3dzgFaE-dXo (https://youtu.be/3dzgFaE-dXo)

Glenn Stanton speech intervention: https://youtu.be/oHdM89IA4f8 (https://youtu.be/oHdM89IA4f8)

Paul Hruz intervention: https://youtu.be/-kUB4o5XFz8 (https://youtu.be/-kUB4o5XFz8)

Gabriele Kuby intervention: https://youtu.be/LxiXHYiAI4E (https://youtu.be/LxiXHYiAI4E)

Walt Heyer: https://youtu.be/OYvkiq8EEJc (https://youtu.be/OYvkiq8EEJc)

Madrid Declaration: https://youtu.be/X17JpYrEIRA (https://youtu.be/X17JpYrEIRA)

Reading of the Madrid Declaration: https://youtu.be/Gd526vRnnsI (https://youtu.be/Gd526vRnnsI)

Images from the I International Conference on Gender, Sex and Education:

https://www.flickr.com/photos/hazteoir/albums/72157693183146195 (https://www.flickr.com/photos/hazteoir/albums/72157693183146195)

I International Conference on Gender, Sex and Education Website: http://thegenderandsexconference.org/ (http://thegenderandsexconference.org/)

(http://twitter.com/share?url=https://thegenderandsexconference.org/i-international-conference-on-gender-sex-and-

-
edu
cati
on-
in-
ma
drid
-
agai
nst-
the-
lgbt
i-
doc
trin
e-
whi
ch-
is-
taki
ng-
hol
d-
of-
wes
tern
-
cou
ntri
es-
is-a-
res
oun

in
(htt
p://
ww
w.li
nke
din.

p:// din (htt co
ww g- ps:/ m/s
w.fa suc /plu har
ceb ces s.go eArt
ook. s/&t ogle icle
co ext .co ?
m/s =I% m/s min
har 20I har i=tr
er.p nter e? ue&
hp? nati url= url=
u=h onal http http
ttps %20 s://t s://t
://th Con heg heg
ege fere end end
nde nce era era
ran %20 nds nds
dse on% exc exc
xco 20G onf onf
nfer end ere ere
enc er,% nce. nce.
e.or 20S org/ org/
g/i- ex% i- i-
inte 20a inte inte
rnat nd% rnat rnat
iona 20E iona iona
l- duc l- l-
con atio con con
fere n%2 fere fere
nce- 0in nce- nce-
on- %20 on- on-
gen Ma gen gen
der- drid der- der-
sex- %20 sex- sex-

and agai and and
- nst - -
edu %20 edu edu
cati the cati cati
on- %20 on- on-
in- LGB in- in-
ma TI% ma ma
drid 20d drid drid
- octr - -
agai ine agai agai
nst- %20 nst- nst-
the- whi the- the-
lgbt ch% lgbt lgbt
i- 20is i- i-
doc %20 doc doc
trin taki trin trin
e- ng% e- e-
whi 20h whi whi
ch- old ch- ch-
is- %20 is- is-
taki of% taki taki
ng- 20 ng- ng-
hol We hol hol
d- ster d- d-
of- n%2 of- of-
wes 0co wes wes
tern untr tern tern
- ies - -
cou %20 cou cou
ntri is% ntri ntri
es- 20a es- es-
is-a- %20 is-a- is-a-
res res res res

res	res	res	res
oun	oun	oun	oun
din	din	din	din
g-	g%2	g-	g-
suc	0su	suc	suc
ces	cce	ces	ces
s/)	ss)	s/)	s/)

← previous article (https://thegenderandsexconference.org/exito-rotundo-del-i-congreso-internacional-sobre-genero-sexo-y-educacion-en-madrid-en-el-que-se-denuncio-como-los-dogmas-lgtbi-se-estan-imponiendo-en-occidente/)

SEARCH

Search . . . . .

PUBLICACIONES RECIENTES

I International Conference on Gender, Sex and Education in Madrid against the LGBTI doctrine which is taking hold of Western countries is a resounding success (https://thegenderandsexconference.org/i-international-conference-on-gender-sex-and-education-in-madrid-against-the-lgbti-doctrine-which-is-taking-hold-of-western-countries-is-a-resounding-success/)

Éxito rotundo del I Congreso Internacional sobre Género, Sexo y Educación en Madrid en el que se denunció cómo los dogmas LGTBI se están imponiendo en Occidente (https://thegenderandsexconference.org/exito-rotundo-del-i-congreso-internacional-sobre-genero-sexo-y-educacion-en-madrid-en-el-que-se-denuncio-como-los-dogmas-lgtbi-se-estan-imponiendo-en-occidente/)

Cincuenta asociaciones de diecisiete países apoyan la Declaración de Madrid por la Comprensión, el Respeto y la Libertad frente al "engaño del género" (https://thegenderandsexconference.org/cincuenta-asociaciones-de-diecisiete-paises-apoyan-la-declaracion-de-madrid-por-la-comprension-el-respeto-y-la-libertad-que-defiende-los-derechos-frente-al-engano-del-genero/)

COMENTARIOS RECIENTES

ARCHIVOS

febrero 2018 (https://thegenderandsexconference.org/2018/02/)

enero 2018 (https://thegenderandsexconference.org/2018/01/)

COMUNÍCATE CON NOSOTROS

Teléfono

+34 915547189

Dirección

Paseo de la Habana 200, Bj izq, 28036, Madrid, España

(https://thegenderandsexconference.org)

(https://twitter.com/@thegenderandsex) (https://www.instagram.com/thegenderandsex/)

Journal Pre-proof

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

PII: S0022-3476(21)01085-4

DOI: https://doi.org/10.1016/j.jpeds.2021.11.020

Reference: YMPD 12679

To appear in: *The Journal of Pediatrics*

Received Date: 31 August 2021

Revised Date: 8 October 2021

Accepted Date: 10 November 2021

Please cite this article as: 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"?, *The Journal of Pediatrics* (2021), doi: https://doi.org/10.1016/j.jpeds.2021.11.020.

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

Authors: Greta R. Bauer[a], PhD, MPH; Margaret L. Lawson[b], MD, MSc, FRCPC; Daniel L. Metzger[c], MD, FAAP, FRCPC, for the Trans Youth CAN! Research Team*

Affiliations: [a]Epidemiology and Biostatistics, Schulich School of Medicine & Dentistry, Western University, London, Canada; [b]Division of Endocrinology and Metabolism, Department of Pediatrics, Children's Hospital of Eastern Ontario, University of Ottawa, Ottawa, Canada; [c]Division of Endocrinology, Department of Pediatrics, BC Children's Hospital, University of British Columbia, Vancouver, Canada

*List of additional members of the Trans Youth CAN! Study Group is available at www.jpeds.com (Appendix)

Correspondence: Greta Bauer, Epidemiology and Biostatistics, Western Centre for Public Health and Family Medicine, 1465 Richmond St. N., London, ON N6G 2M1, [gbauer@uwo.ca], 519-661-2111 x86262

Funded by the Canadian Institutes for Health Research (MOP-148641 [to G.B.]). CIHR played no role in the design, conduct, writing, or submission decisions for this study. The authors declare no conflicts of interest.

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.

References

1. World Professional Association for Transgender Health. Standards of Care for the Health of Transsexual, Transgender, and Gender Nonconforming People (7th version) [Internet]. 2012 [cited 2021 May 30]. Available from: https://www.wpath.org/publications/soc
2. Scheim AI, Bauer GR. Sex and gender diversity among transgender persons in Ontario, Canada: results from a respondent-driven sampling survey. J Sex Res 2015;52:1–14.
3. Rafferty J, AAP Committee on Psychosocial Aspects of Child and Family Health, AAP Committee on Adolescence, AAP Section on Lesbian, Gay, Bisexual, and Transgender Health and Wellness. Ensuring comprehensive care and support for transgender and gender-diverse children and adolescents. Pediatrics 2018;142:e20182162.
4. Lopez X, Marinkovic M, Eimicke T, Rosenthal SM, Olshan JS. Statement on gender-affirmative approach to care from the Pediatric Endocrine Society Special Interest Group on Transgender Health. Curr Opin Pediatr 2017;29:475–80.
5. Hembree WC, Cohen-Kettenis PT, Gooren L, Hannema SE, Meyer WJ, Murad MH, et al. Endocrine treatment of gender-dysphoric/gender-incongruent persons: an Endocrine Society Clinical Practice Guideline. J Clin Endocrinol Metab 2017;102:3869–903.
6. Spack NP, Edwards-Leeper L, Feldman HA, Leibowitz S, Mandel F, Diamond DA, et al. Children and adolescents with gender identity disorder referred to a pediatric medical center. Pediatrics 2012;129:418–25.
7. Chen M, Fuqua J, Eugster EA. Characteristics of referrals for gender dysphoria over a 13-year period. J Adolesc Health 2016;58:369–71.

8. Wiepjes CM, Nota NM, de Blok CJM, Klaver M, de Vries ALC, Wensing-Kruger SA, et al. The Amsterdam Cohort of Gender Dysphoria Study (1972–2015): trends in prevalence, treatment, and regrets. J Sex Med 2018;15:582–90.
9. Aitken M, Steensma TD, Blanchard R, VanderLaan DP, Wood H, Fuentes A, et al. Evidence for an altered sex ratio in clinic- referred adolescents with gender dysphoria. J Sex Med 2015;12:756–63.
10. Littman L. Parent reports of adolescents and young adults perceived to show signs of a rapid onset of gender dysphoria. Romer D, editor. PLOS ONE 2018;13:e0202330.
11. Littman L. Correction: Parent reports of adolescents and young adults perceived to show signs of a rapid onset of gender dysphoria. PLOS ONE 2019;14:e0214157.
12. Costa AB. Formal comment on: Parent reports of adolescents and young adults perceived to show signs of a rapid onset of gender dysphoria. PLOS ONE 2019;14:e0212578.
13. Wadman M. 'Rapid onset' of transgender identity ignites storm. Science 2018;361:958–9.
14. Ashley F. A critical commentary on 'rapid-onset gender dysphoria.' Sociol Rev 2020;68:779–99.
15. Restar AJ. Methodological critique of Littman's (2018) parental-respondents accounts of "rapid-onset gender dysphoria." Arch Sex Behav 2020;49:61–6.
16. Hutchinson A, Midgen M, Spiliadis A. In support of research into rapid-onset gender dysphoria. Arch Sex Behav 2020;49:79–80.
17. Zucker KJ. Adolescents with gender dysphoria: Reflections on some contemporary clinical and research issues. Arch Sex Behav 2019;48:1983–92.

18. Bauer GR, Pacaud D, Couch R, Metzger DL, Gale L, Gotovac S, et al. Transgender youth referred to clinics for gender-affirming medical care in Canada. Pediatrics 2021;148: e2020047266.

19. Trans Youth CAN! Research Team. Trans Youth CAN! Baseline Youth Survey (English) [Internet]. 2017 [cited 2020 Jun 30]. Available from: https://transyouthcan.ca/wp-content/uploads/2018/04/Youth-Baseline-Survey.pdf

20. Trans Youth CAN! Baseline Case Report Form [Internet]. 2017 [cited 2020 Jun 30]. Available from: https://transyouthcan.ca/wp-content/uploads/2019/03/Case-Report-Form-COMBINED-Baseline-Clean-Jan22.2018.pdf

21. Campbell-Sills L, Norman SB, Craske MG, Sullivan G, Lang AJ, Chavira DA, et al. Validation of a brief measure of anxiety-related severity and impairment: the Overall Anxiety Severity and Impairment Scale (OASIS). J Affect Disord 2009;112:92–101.

22. Dunn EC, Johnson RM, Green JG. The Modified Depression Scale (MDS): A brief, no-cost assessment tool to estimate the level of depressive symptoms in students and schools. School Ment Health 2012;4:34–45.

23. Kessler RC, Andrews G, Colpe LJ, Hiripi E, Mroczek DK, Normand S-LT, et al. Short screening scales to monitor population prevalences and trends in non-specific psychological distress. Psychol Med 2002;32:959–76.

24. Bauer G, Churchill S, Ducharme J, Feder S, Gillis L, Gotovac S, et al. Trans Youth CAN! Gender Distress Scale (TYC-GDS) [Internet]. 2021. Available from: https://transyouthcan.ca/wp-content/uploads/2021/04/Gender-Distress-Scale-vSHARE_EN-2021.pdf

25. Zou G. A modified Poisson regression approach to prospective studies with binary data. Am J Epidemiol 2004;159:702–6.

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)

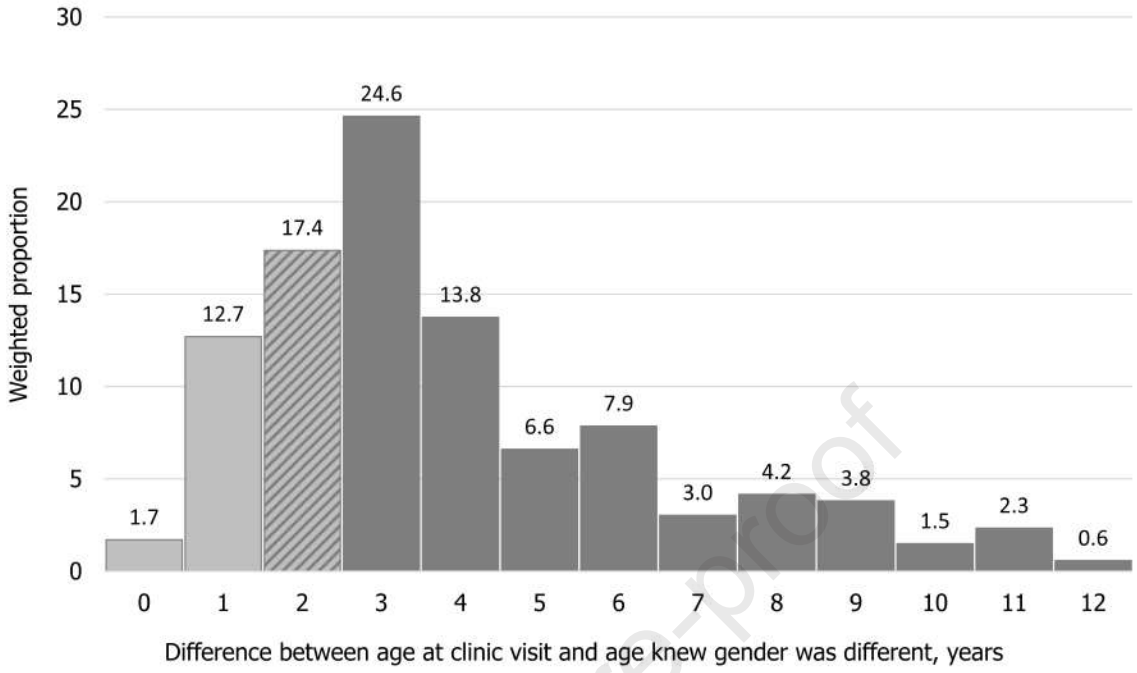
a. Estimates adjusted for age in years and sex assigned at birth. B = beta, regression parameter estimate; PR = prevalence ratio.

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

Additional members of the Trans Youth CAN! Study Group:

Joseph Bonifacio, MD, FRCPC, Adolescent Medicine, St. Michael's Hospital, Unity Health Toronto, Toronto, Ontario

Robert Couch, MSc, MD, FRCPC, Division of Pediatric Endocrinology, Department of Pediatrics, Stollery Children's Hospital, University of Alberta, Edmonton, Alberta

Jennifer Ducharme, PhD, C.Psych, Department of Clinical Health Psychology, Max Rady College of Medicine, Rady Faculty of Health Sciences, University of Manitoba, Winnipeg, Manitoba

Stephen Feder, MDCM, MPH, CCFP, Division of Adolescent Medicine, Department of Pediatrics, Children's Hospital of Eastern Ontario, University of Ottawa, Ottawa, Ontario

Lorraine Gale, MSW, Trans Youth CAN! Study Team, Toronto, Ontario

Shuvo Ghosh, MD, FAAP, Department of Pediatrics, Montreal Children's Hospital, McGill University Health Centre, Montreal, Quebec

Sandra Gotovac, PhD, Epidemiology and Biostatistics, Schulich School of Medicine & Dentistry, Western University, London, Ontario

Natasha Johnson, MD, FRCPC, Division of Adolescent Medicine, Department of Pediatrics, McMaster University, McMaster Children's Hospital, Hamilton, Ontario

Carys Massarella, MD, FRCPC, St. Joseph's Healthcare, Hamilton, Ontario

Arati Mokashi, MD, FRCPC, Department of Pediatrics, Division of Endocrinology, Dalhousie University; IWK Health Centre, Halifax, Nova Scotia

Danièle Pacaud, MD, FRCPC, Alberta Children's Hospital, Department of Pediatrics, Cumming School of Medicine, University of Calgary, Calgary, Alberta

Mark Palmert, MD, PhD, Division of Endocrinology, The Hospital for Sick Children, Departments of Pediatrics and Physiology, University of Toronto, Toronto, Ontario

Joe Raiche, MD, FRCPC, Foothills Medical Centre, Department of Psychiatry, Cumming School of Medicine, University of Calgary, Calgary, Alberta

Annie Pullen Sansfaçon, PhD, School of Social Work, University of Montreal, Montreal, Quebec

Elizabeth Saewyc, PhD, RN, jFSAHM, FCAHS, FAAN, FCAN, School of Nursing, University of British Columbia, Vancover, British Columbia

Kathy Nixon Speechley, PhD, Departments of Paediatrics and Epidemiology and Biostatistics. Schulich School of Medicine & Dentistry, Western University, London, Ontario

Robert Stein, MDCM, FRCPC, Division of Pediatric Endocrinology, London Health Sciences Centre, Schulich School of Medicine & Dentistry, London, Ontario

Françoise Susset, PsyD, Meraki Health Centre, Montreal, Quebec

Julia Temple Newhook, PhD, Department of Gender Studies, Memorial University, St. John's, Newfoundland and Labrador

Ashley Vandermorris, MD, MSc, FRCPC, Division of Adolescent Medicine, Department of Paediatrics, The Hospital for Sick Children, Toronto, Ontario

John Vandermeulen, MD, FRCPC, Division of Adolescent Medicine, Department of Pediatrics, McMaster University, McMaster Children's Hospital, Hamilton, Ontario

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)

References

1. Government of Canada SC. Visible minority of person [Internet]. 2015 [cited 2021 May 29]. Available from: https://www23.statcan.gc.ca/imdb/p3Var.pl?Function=DEC&Id=45152

2. Littman L. Parent reports of adolescents and young adults perceived to show signs of a rapid onset of gender dysphoria. PLOS ONE. 2018;13:e0202330.

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

CIVIL ACTION NO.: 1:19-cv-272-LCB-LPA

MAXWELL KADEL, et al.
Plaintiffs

v.

DALE FOLWELL, et al.
Defendants

REMOTE VIDEOTAPED VIDEOCONFERENCE
DEPOSITION TESTIMONY OF:
PATRICK LAPPERT, M.D.
September 30, 2021

A P P E A R A N C E S

FOR THE PLAINTIFFS (via remote videoconference):

Dmitriy Tishyevich, Esq.
MCDERMOTT, WILL & EMERY
One Vanderbilt Avenue
New York, New York 10017
dtishyevich@mwe.com

Tara L. Borelli, Esq.
LAMBDA LEGAL DEFENSE AND EDUCATION FUND
158 West Ponce de Leon Avenue, Suite 105
Decatur, Georgia 30030
tborelli@lambdalegal.com

Omar Gonzalez-Pagan, Esq.
LAMBDA LEGAL DEFENSE AND EDUCATION FUND
120 Wall Street, 19th Floor
New York, New York 1005
ogonzalez-pagan@lambdalegal.com

FOR THE DEFENDANTS (via remote videoconference):

John G. Knepper, Esq.
LAW OFFICE OF JOHN G. KNEPPER LLC
1720 Carey Avenue, Suite 590
Cheyenne, Wyoming 82001
john@knepperllc.com

Kevin G. Williams, Esq.
BELL, DAVIS & PITT
100 North Cherry Street, Suite 600
Winston-Salem, North Carolina 27101
kwilliams@belldavispitt.com

ALSO PRESENT (via remote videoconference):

Andrew Baker, Videographer

these meetings in more detail. So, how many -- strike that.

You've been to two meetings organized by ADF?

A. That's my recoll- -- yeah, two meetings. I think that's right.

Q. All right. Let's start with the first one. This was in 2017?

A. That sounds about right, yeah.

Q. What --

A. I think it was 2017, yeah.

Q. What month roughly?

A. I don't remember now.

Q. Do you know how they came to invite you to that first meeting?

A. I do not.

Q. Before that meeting, you had not published anything about gender dysphoria, had you?

A. No.

Q. Before that meeting, you had not published anything about the risks of use of hormone blockers in minors; right?

A. No. I've given -- I gave some -- some -- I think they may have heard of me not through publications, but through public speaking.

Q. How long have you been doing public speaking on the issues related to gender dysphoria?

A. Since 2014.

Q. Let's start with the first meeting. So, Dr. Hruz was also present at that meeting?

A. Yes.

Q. Was Dr. Levine present at that meeting?

A. I don't think I've ever met Dr. Levine, so I don't -- he couldn't have been there because I would have remembered meeting him, and I don't remember ever having met him.

Q. How about Dr. McHugh?

A. No. I would have remembered him. He's a very famous person.

Q. How many people were present at

heart of the presentation was what's the state of the science and where is the reliable science coming from and what is it -- what is it showing us, so. But they also -- the audience wanted to have an understanding of what these plastic surgery interventions were. So there was an extensive discussion of the particulars of the surgeries, the details about the surgeries, the typical outcomes of the surgeries, so.

Q. I want to -- strike that.

One of the topics of discussion at that meeting was about the need to have expert witnesses for litigation; right?

MR. KNEPPER: Objection, form, scope.

A. I remember -- I remember a fairly long discussion about the poverty of people who are willing to testify because of the risk that they take in testifying. That was a -- that was a

fairly long discussion. And the difficulty that that -- that people have in finding expert witnesses because of the risks they place themselves in, in testifying.

Q. And people at that meeting were asked whether they would be willing to participate as expert witnesses; right?

A. Yes.

Q. Before that meeting, you had never testified as an expert witness?

A. Before this moment, I never testified as an expert witness.

Q. Who made the introductory remarks at the beginning of this meeting?

MR. KNEPPER: Objection, form, scope.

A. I'm trying to remember. It was a -- it was an attorney whose first name is Jeff, and I'm trying to remember what his last name was. But he seemed to be the -- the -- kind of the emcee, if you will. Yeah, Jeff. I'll see if, in the

Omar Gonzalez-Pagan

From: Publications <publications@endocrine.org>
Sent: Tuesday, April 4, 2023 8:22 AM
To: Omar Gonzalez-Pagan
Subject: RE: Question re peer-review process at JCEM

Dear Dr. Gonzalez-Pagan,

Thank you for your email. Usually the handling editor with make a decision on a Letter to the Editor without peer review, but occasionally an external reviewer will be invited. It is at the editor's discretion.

If a Letter to the Editor is accepted, the authors of the original article the letter is regarding will be invited to submit a response.

Please let me know if you have any other questions.

Best regards,
Lisa Tetrault
JCEM Editorial Office

ENDOCRINE SOCIETY

PUBLICATIONS

2055 L STREET NW, SUITE 600, WASHINGTON, DC 20036
T. 202.971.3636 F. 202.736.9705 D. 202.971.3636
publications@endocrine.org endocrine.org

From: Omar Gonzalez-Pagan <ogonzalez-pagan@lambdalegal.org>
Sent: Monday, April 3, 2023 4:58 PM
To: Publications <publications@endocrine.org>
Subject: Question re peer-review process at JCEM

Good afternoon,

I am writing to inquire about the review process for letters to the editor published in JCEM. Are these letters externally peer-reviewed?

Thank you in advance for your attention to this matter.

Regards,

Omar Gonzalez-Pagan
Counsel and Health Care Strategist*
Pronouns: He/Him/His
Lambda Legal
120 Wall Street, 19th Floor
New York, New York 10005-3919
Work: 212-809-8585, ext. 2211 | Mobile: (617) 686-3464

Email: ogonzalez-pagan@lambdalegal.org | Fax: (212) 658-9721
http://www.lambdalegal.org
* *Admitted in Massachusetts and New York.*

To become a member or make a donation, visit http://www.lambdalegal.org/join

UNITED STATES DISTRICT COURT
NORTHERN DISTRICT OF FLORIDA

AUGUST DEKKER, et al.,
Plaintiffs,
vs.
JASON WEIDA, et al.,
Defendants.

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

March 17, 2023 10:03 am Zoom

DEPOSITION OF: Dr. Quentin Van Meter

This deposition was taken remotely via Zoom.

Signature of this deposition is reserved.

SHARON F. MCCLAIN
C.C.R. - B-2243
P.O. Box 1036
Gainesville, GA 30503
(770) 718-5145

ADF members as long ago perhaps as six or seven years ago. I have helped in providing input for patients and have been asked by them to be an expert witness in cases of child custody.

MR. GONZALEZ-PAGAN: Let's take if it's all right, and I do believe that with the next set of questions we should be over. So, I truly hope that we can be out of here probably by 4:30-ish. Let's take a five-minute break and go off the record.

DR. VAN METER: That's fine with me.

COURT REPORTER: We are off the record at 3:44 pm.

(Off the record for a short break.)

(Back on the record.)

COURT REPORTER: We are back on the record at 3:51 pm.

BY MR. GONZALEZ-PAGAN:

Q. Mr. Van Meter, I'm going to show you what's been marked as Exhibit 28. Well before I do that, we left off with you letting me know your communications with the Alliance Defending Freedom, is that right?

A. Yes.

Q. You said that they go back maybe five, six years or so?

A. Yes.

Q. In 2017 the Alliance Defending Freedom hosted a meeting in Arizona regarding transgender issues. Were you present at this meeting?

A. I was present at one of their meetings. I think there was a meeting the year before, that the 2017 would have been the second or the first. I did go to a meeting. That was the subject, but I believe it was the second such meeting that they had had.

Q. Andre Van Mol was present at that meeting as well, correct?

A. He was.

Q. Paul Hruz was present at that meeting as well, correct?

A. He was.

Q. So was Patrick Lappert?

A. Yes, he was. That's when he reminded me I knew him from the Navy days.

Q. Patrick Lappert actually has testified that one of the topics discussed at that meeting was the need for expert witnesses to support ADF's litigation efforts. Was that a topic that was discussed?

A. I'm sure it was. I can't state exactly, but I would have come away with the feeling that they wanted to get to know who we were and get to know about us.

Q. You have not provided expert testimony. We

went through your expert testimony before. You did not provide any expert testimony regarding transgender issues until 2017, is that right?

A. Let me think back. I think that's correct.

Q. I'm going to show you now what's been marked as Exhibit 28. Do you see this email?

A. I do.

Q. It is subject line Medicaid coverage for gender affirming care, privileged and confidential. Then it has a Bates stamp of Grossman0054, is that right?

A. That's correct.

Q. The first email is dated July 9, 2022. This is after the hearing, is that right?

A. Yes, it would have been after the hearing.

Q. The last couple of sentences from this email from Miriam Grossman -- well actually before I get to that, you're a recipient of this email, is that right?

A. I'm sorry. I was what?

Q. You're one of the recipients of this email, is that correct?

A. Yes.

(Plaintiff's Exhibit No. 28 was marked for identification.)

BY MR. GONZALEZ-PAGAN:

Q. In the last few sentences Miriam Grossman

Statement on Dr. Kenneth Zucker and Gender Identity Disorder (5/23/2008)

Kenneth J. Zucker, Ph.D., C.Psych., the Chair of the DSM-V Sexual and Gender Identity Disorders work group, is a widely respected and pre-eminent scholar in the world of academic sexology research. As Chair of the work group for Sexual and Gender Identity Disorders, Dr. Zucker's role is to coordinate and facilitate the work of the three sub-work groups addressing Sexual Dysfunctions, Paraphilias, and Gender Identity Disorders. Further information on the DSM-V development process can be found at:
http://www.psych.org/MainMenu/Research/DSMIV/DSMV/APAStatements/APAStatementonGIDandTheDSMV.aspx

Dr. Zucker has published 97 peer-reviewed journal articles, 48 book chapters, and a landmark textbook. His published work addresses psychosexual differentiation and its disorders, based on a wide range of empirical research studies on children and adolescents with gender identity disorder, with a focus on diagnosis and assessment, and their associated behavioral and psychological distress. As the current Editor of *Archives of Sexual Behavior*, the premier human sexuality research journal, he also has a wide familiarity with the disparate areas of sexual dysfunctions and paraphilias. Since 2001, he has been the Psychologist-in-Chief at the Centre for Addiction and Mental Health (CAMH), is a Professor in the Departments of Psychiatry and Psychology at the University of Toronto, and is on the Scientific Staff (Division of Child Psychiatry) at the Hospital for Sick Children. He was the President of the International Academy of Sex Research in 2005-2006.

Dr. Zucker and his service team at CAMH in Toronto have the longest standing research-clinical service for children and youth with gender identity problems in North America. Since the mid-1970s, Dr. Zucker and his team have evaluated over 900 children and youth with gender identity issues. Dr. Zucker is one of the few researchers who is doing long-term follow-up of the patients he has treated.

The philosophy of Dr. Zucker's team is to provide client-centered care that maximizes benefit and minimizes harm to each child or youth. The goal of treatment is a well-adjusted youth, regardless of ultimate gender identity or sexual orientation, who feels she or he has been genuinely helped by her or his healthcare providers. Dr. Zucker has offered a variety of treatment options, understanding that options may vary greatly with the age of the client. For younger clients, therapy options include helping the child to overcome discomfort with his or her body, i.e., helping clients learn to live comfortably in their natal sex. Diagnosis and treatment of other problems that may be present, such as anxiety, depression, or substance abuse are also available, as are services for family members.

For adolescent patients (including those who first came to the clinic as young children), Dr. Zucker follows the Standards of Care Guidelines of the World Professional Association for Transgender Health. The treatment options include helping patients make a satisfactory transition to the opposite sex, including the institution of hormonal treatment to facilitate transition. In some cases, treatment may include helping an interested adolescent obtain sex-reassignment surgery.

For all patients, regardless of age, the focus of therapy is the patient's gender identity, not the patient's sexual orientation. Dr. Zucker's therapeutic approach has no relationship to so-called reparative or sexual conversion therapies that attempt to change homosexual orientations to heterosexual ones. The goal of his therapy is the opposite of conversion therapy in that he considers well-adjusted transsexual, gay, lesbian or bisexual youth to be therapy successes, not failures.

AMERICAN PSYCHOLOGICAL ASSOCIATION

APA RESOLUTION on Gender Identity Change Efforts

FEBRUARY 2021

The foundational professional guideline for working with gender diverse persons acknowledges that, "Psychologists understand that gender is a nonbinary construct that allows for a range of gender identities and that a person's gender identity may not align with sex assigned at birth." (APA, 2015, p. 834). Gender identity refers to "a person's deep felt, inherent sense of being a girl, woman, or female; a boy, a man, or male; a blend of male or female; [or another] gender" (APA, 2015, p. 862). While gender refers to the trait characteristics and behaviors culturally associated with one's sex assigned at birth, in some cases, gender may be distinct from the physical markers of biological sex (e.g., genitals, chromosomes). Gender identity is also distinct from gender expression, which refers to "the presentation of an individual including physical appearance, clothing choice and accessories, and behaviors that express aspects of gender identity" (APA, 2015, p. 861). Cisgender refers to "a person whose gender identity aligns with sex assigned at birth" (e.g., an individual assigned female at birth who identifies as a woman/girl; APA, 2015, p. 861). Transgender is "an umbrella term used to describe the full range of people whose gender identity and/or gender role do not conform to what is typically associated with their sex assigned at birth" (APA, 2015, p. 863). For the purpose of this resolution, we are using a broad definition of transgender to include transgender women/girls, transgender men/boys, nonbinary individuals (i.e., people who may identify as a gender other than a woman/girl or a man/boy), and any individual who articulates a gender identity different from societal expectations based on their sex assigned at birth.

Some transgender and gender nonbinary individuals seek gender-affirming medical care (e.g., hormone therapy, surgery) while others do not. Similarly, some transgender and gender nonbinary individuals seek to change their gender marker and/or their name on legal documents, while others do not. In this resolution, we strive to be inclusive of all gender diversity regardless of a person's pursuance of social, medical, or legal transition.

The fields of psychiatry and psychology have a long history of pathologizing individuals and those who question their gender identity (Barkai, 2017; Benson, 2013; Bouman et al, 2014; Burke, 2011; Drescher, 2010; Nadal et al., 2010; Riggs et al. 2019). This history is informed by, and parallels, the larger Western and United States-based, medical-model, narratives that 1) define gender as binary and conflate it with physical markers, 2) define masculinity, and characteristics historically attributed to men/boys, as superior to femininity and characteristics historically attributed to women/girls, 3) create systems that confer privilege to cisgender people and label cisgender identities and expressions as normative, 4) discriminate against transgender and gender nonbinary individuals (Stryker, 2017).

Gender identity change efforts (GICE) refer to a range of techniques used by mental health professionals and non-professionals with the goal of changing gender identity, gender expression, or associated components of these to be in alignment with gender role behaviors that are stereotypically associated with sex assigned at birth, (Hill et al., 2010; SAMHSA, 2015). In addition to explicit attempts to change individuals' gender according to cisnormative pressures, GICE has also been a component of sexual orientation change efforts (SOCE). As intense focus on cisnormative conformity is a frequent characteristic of SOCE it is possible that authors in the literature describing sexual orientation change efforts misgendered their participants (Hipp et al., 2019). Moreover, "ex-gay" literature and discourse conceptualize gender diversity as a sin, a mental illness, and harmful, perpetuating cisgenderism and transmisogyny (Robinson & Spivey, 2019). Finally, Hipp et al. (2019) identified forms of GICE that are often not discussed in the psychological literature but that appear to disproportionately affect Black transgender and gender nonbinary individuals including violence, "church hurt" (i.e., religious or faith-based trauma), and gatekeeping from gender affirming care. These efforts may be referred to as "conversion therapies", "corrective" treatments, or "normalizing" therapies (Hill et al., 2010). However, to consider these techniques as therapies or treatments is inaccurate and inappropriate because, the incongruence between sex and gender in and of itself is not a mental disorder (World Health Organization, n.d.) so, any behavioral health or GICE technique or treatment that seeks to change an individual's gender identity or expression is not indicated; thus, any behavioral health or GICE effort that attempt to change an individual's gender identity or expression is inappropriate (Hill et al. 2010; SAMHSA, 2015).

With roots in this history, GICE are founded on the notion that any gender identity that is not concordant with sex assigned at birth is disordered, and that a cisgender identity is healthier, preferable, and superior to a transgender or gender nonbinary identity (Ansara & Hegarty, 2011; Hill et al., 2010; Robinson & Spivey, 2019).

GICE cause harm by reinforcing anti-transgender and anti-gender nonbinary stigma and discrimination (Turban et al., 2020); and by creating social pressure on an individual to conform to an

identity and/or presentation that may not be consistent with their sense of self (e.g., Bockting et al., 2013; Egan & Perry, 2001; Meyer, 2003; Nadal et al., 2012; Russell et al., 2012; Toomey et al., 2010; Sandfort et al., 2007). Furthermore, GICE are not supported by empirical evidence as effective practices for changing gender identity and are associated with psychological and social harm (Brinkman et al., 2014; Carr, 1998; Gagné & Tewksbury, 1998; Horn, 2007; Price et al., 2019; Smith & Leaper, 2006). The American Psychological Association (APA), as well as other healthcare organizations, (e.g., American Counseling Association, World Professional Association for Transgender Health) have established empirically-supported practice guidelines that encourage clinicians to use gender-affirming practices when addressing gender identity issues (ACA, 2010; APA, 2015; Coleman et al., 2012). Additionally, a number of national and international professional healthcare organizations have publicly warned against the harmful effects of GICE and SOCE (Sexual Orientation Change Efforts) by endorsing the United States Joint Statement Against Conversion Efforts (USJS, n.d.), including the American Academy of Family Physicians, American Academy of Nursing, American Association of Sexual Educators, Counselors and Therapists, American Counseling Association, American Medical Association, American Medical Student Association, American Psychoanalytic Association, The Association of LGBTQ Psychiatrists, Society for Affectional, Intersex, and Gender Expansive Identities, Clinical Social Work Association, GLMA: Health Professionals Advancing LGBTQ Equality, The Association of Lesbian, Gay, Bisexual, Transgender Addiction Professionals and their Allies, and the World Professional Association for Transgender Health. A growing number of states and municipalities have enacted laws that prohibit licensed mental health professionals from engaging in sexual orientation and gender identity change efforts with minors (Movement Advancement Project, n.d.)

GENDER DIVERSITY, STIGMA, AND DISCRIMINATION

WHEREAS diversity in gender identity and expression is part of the human experience and transgender and gender nonbinary identities and expressions are healthy, incongruence between one's sex and gender is neither pathological nor a mental health disorder (APA, 2009, 2015; SAMHSA, 2015);

WHEREAS gender diverse individuals experience cissexist discrimination and prejudice throughout the lifespan and life domains (APA, 2009) including significant discrimination in healthcare settings (Burnes et al., 2016; Fredriksen-Goldsen et al., 2014; Grant et al., 2011; James et al., 2016; Johns et al, 2019; Lambda Legal, 2010; Macapagal et al., 2016; Reisner et al., 2015; White Hughto et al., 2015);

WHEREAS the practice of GICE reinforces stigma and discrimination against transgender and gender diverse people (Turban et al., 2020);

WHEREAS gender-related bias, victimization, discrimination, criminalization, and forced-gender conformity experienced by transgender and gender nonbinary people are associated with poor psychosocial outcomes, such as heightened psychological distress, compromised overall wellbeing, and disparities across various contexts (e.g., healthcare, schools/education, workplace, law) (Bockting et al., 2013; dickey et al., 2016; Egan & Perry, 2001; Meyer, 2003; Nadal et al., 2012; Russell et al., 2012; Hendricks & Testa, 2012; Toomey et al., 2010; Sandfort et al., 2007);

WHEREAS invalidation and rejection of transgender and gender nonbinary identities and diverse gender expressions by others (e.g., families, therapists, school personnel) are forms of discrimination, stigma, and victimization, which result in psychological distress (Bockting et al., 2013; D'Augelli et al., 2006; Egan & Perry, 2001; Hendricks & Testa, 2012; Hidalgo et al., 2015; Landolt et al., 2004; Meyer, 2003; Nadal et al., 2012; Price, et al., 2019; Roberts et al., 2012; Sandfort et al., 2007; Stotzer, 2012; Russell et al., 2012; Toomey et al., 2010; Truong et al., 2020a, 2020b; Zongrone et al., 2020);

GICE AND RISKS OF HARM

WHEREAS individuals who have experienced pressure or coercion to conform to their sex assigned at birth or therapy that was biased toward conformity to one's assigned sex at birth have reported harm resulting from these experience such as emotional distress, loss of relationships, and low self-worth (Brinkman et al., 2014; Carr, 1998; Gagné & Tewksbury, 1998; Horn, 2007; Price et al., 2019; Smith & Leaper, 2006);

WHEREAS in one study of a large online sample of LGBTQ young people, those who reported experiencing change efforts were more than twice as likely to report having attempted suicide and having multiple suicide attempts as those who did not experience change efforts, (Green et al., 2020);

WHEREAS GICE have not been shown to alleviate or resolve gender dysphoria (Bradley & Zucker, 1997; Cohen-Kettenis & Kuiper, 1984; Gelder & Marks, 1969; Greenson, 1964; Pauly, 1965, SAMHSA, 2015);

WHEREAS GICE can cause undue stress and suffering and interfere with healthy sexual and gender identity development (Hiestand & Levitt, 2005; SAMHSA, 2015);

WHEREAS GICE can reduce one's willingness to pursue future mental health treatment (Craig et al., 2017);

WHEREAS GICE often involves the promotion of stereotyped gender behaviors consistent with cultural expectations (Coleman et al., 2012; Hill et al., 2010);

WHEREAS GICE are associated with harmful social and emotional effects for many individuals, including but not limited to, the onset or increase of depression, anxiety, suicidality, loss of sexual feeling, impotence, deteriorated family relationships, a range of post-traumatic responses, and substance abuse (c.f. Burnes et al., 2016; Green et al., 2020; SAMHSA 2015 for a review; Turban et al., 2019);

WHEREAS diverse gender expressions and transgender and gender nonbinary identities are not mental disorders (American Psychiatric Association, 2013) and many transgender and gender nonbinary individuals lead satisfying lives and have healthy relationships (APA, 2015; SAMHSA, 2015);

GENDER AFFIRMING PRACTICES

WHEREAS transgender and gender nonbinary people whose gender has been affirmed report increased quality of life (Ainsworth & Spiegel, 2010; APA, 2015; Gerhardstein & Anderson, 2010; Kraemer et al., 2008; Newfield et al., 2006);

WHEREAS self-determination in defining one's gender identity is a source of resilience for transgender and gender nonbinary people and associated with improvements in wellbeing and reductions in psychological distress (Menvielle & Tuerk, 2002; Pickstone-Taylor, 2003; Rosenburg, 2002; Singh et al., 2011; Singh et al., 2014);

WHEREAS individuals who have experienced gender-affirming psychological and medical practices report improved psychological functioning, quality of life, treatment retention and engagement, and reductions in psychological distress, gender dysphoria, and maladaptive coping mechanisms (Austin & Craig, 2015; de Vries et al., 2014; Haas et al., 2011; Sevelius, 2013; White Hughto & Reisner, 2016);

WHEREAS professional consensus recommends affirming therapeutic interventions for transgender and gender nonbinary adults who request that a therapist engage in GICE, and for trans youth whose parents/guardians or other custodians (e.g., state, foster care) request that a therapist engage in GICE (American Counseling Association, 2009; APA, 2012; 2015; American Psychiatric Association, 2018; Byne et al., 2012; Edwards-Leeper et al., 2016);

WHEREAS affirming therapeutic practices and guidelines recommend that the therapist should remain objective and nonjudgmental to the outcome, focusing on empowering the client to be active in exploring, discovering, and understanding their own identity (American Counseling Association, 2009; APA, 2012; 2015; American Psychiatric Association, 2018; Byne et al., 2012; Edwards-Leeper et al., 2016);

APA POLICY

WHEREAS APA opposes discrimination on the basis of gender identity, gender expression, and transgender and gender nonbinary identities, and actively opposes the adoption of discriminatory legislation (APA, 2008);

WHEREAS APA supports the passage of laws and policies protecting the legal rights and freedoms of transgender and gender nonbinary people, regardless of gender identity or expression (APA, 2008);

WHEREAS Psychologists' work is based upon established scientific and professional knowledge of the discipline. (APA, 2017b, p. 5);

WHEREAS APA recognizes that psychologists work is based upon Respect for People's Rights and Dignity (Principle E), Avoiding Harm (3.04), and Unfair Discrimination (3.01; APA, 2017b);

WHEREAS gender affirming psychotherapy is founded in clinical practice guidelines, and harm has not been identified for any of these gender-affirming treatment practices (APA, 2015, 2017b; Byne et al., 2012);

WHEREAS the APA policy and practice guidelines (e.g., Multicultural Guidelines: An Ecological Approach to Context, Identity, and Intersectionality; Guidelines for Psychological Practice with Transgender and Gender Nonconforming People) affirm that psychologists do not engage in discriminatory or biased practices and urge psychologists to take a leadership role in preventing discrimination towards transgender and gender diverse people (APA, 2009, 2015, 2017a);

WHEREAS APA's 2005 Policy Statement on Evidence-Based Practice in Psychology defines evidence-based practice as the integration of the best available research with clinical expertise in the context of patient characteristics, culture**,** and preferences (APA, 2005);

BE IT THEREFORE RESOLVED that consistent with the APA definition of evidence-based practice (APA, 2005), the APA affirms that scientific evidence and clinical experience indicate that GICE put individuals at significant risk of harm;

BE IT FURTHER RESOLVED that the APA opposes GICE because such efforts put individuals at significant risk of harm and encourages individuals, families, health professionals, and organizations to avoid GICE;

BE IT FURTHER RESOLVED that APA opposes the idea that incongruence between sex and gender is a mental disorder (Hill et al., 2010; SAMHSA, 2015; WHO).

BE IT FURTHER RESOLVED that after reviewing scientific evidence on GICE harm, affirmative treatments, and professional practice guidelines, the APA affirms GICE are associated with reported harm.

BE IT FURTHER RESOLVED that the APA opposes GICE because of their association with harm.

BE IT FURTHER RESOLVED that Transgender and gender nonbinary identities, as well as other gender identities that transcend culturally prescriptive binary notions of gender, represent normal variations in human expression of gender.

BE IT FURTHER RESOLVEDthat neither transgender or gender nonbinary identities nor the pursuit of gender-affirming medical care constitutes evidence of a mental disorder.

BE IT FURTHER RESOLVED that APA opposes portrayals of transgender and gender nonbinary people as mentally ill because of their gender identities and expressions.

BE IT FURTHER RESOLVED that evidence supports psychologists in their professional roles to use affirming and culturally relevant approaches with individuals of diverse gender expressions and identities.

BE IT FURTHER RESOLVED that APA is committed to promoting accurate scientific data regarding gender identity and expression in its own policy, public advocacy, judicial proceedings, media, and public opinion;

BE IT FURTHER RESOLVED that APA encourages collaboration between and among individuals and organizations to promote the wellbeing of transgender and gender nonbinary people;

BE IT FURTHER RESOLVED that the APA encourages psychologists to be aware of multiple and intersecting factors in identity, such as sex assigned at birth, gender expression, gender identity, age, race, ethnicity, religion, spirituality, socioeconomic status, disability, national origin, and sexual orientation in conceptualization, treatment, research, and teaching about transgender and gender nonbinary people;

BE IT FURTHER RESOLVED that the APA opposes the dissemination of inaccurate information about gender identity, gender expression, and the efficacy of GICE, including the claim that gender identity can be changed through treatment, the characterization of transgender or gender nonbinary identity as a mental disorder and the promotion of treatments that prescribe gender identity or expression consistent with one's birth-assigned sex as effective for clients with gender dysphoria;

BE IT FURTHER RESOLVED that APA encourages the development and dissemination of evidence-based, multiculturally-informed, and gender affirmative educational resources that inform psychologists, the community and education and mental health institutions about the harms of GICE;

BE IT FURTHER RESOLVED that APA re-affirms that APA (2015) encourages psychologists to:

- Acknowledge the diversity and complexity of identities and experiences and recognize transgender and gender nonbinary identities as healthy expressions of gender
- Recognize that descriptions of any gender identity or expression as unnatural, abhorrent, or unhealthy perpetuate stigma for sexual and gender minorities, and have negative mental health and social consequences
- Assist clients in a developmentally appropriate manner to explore and understand the cultural and familial influence on gender roles and expression. Psychologists are urged to help clients in a developmentally appropriate manner understand the societal contexts of sexism, heterosexism, transphobia, racism and other forms of social oppression, and to use a developmental multicultural- and gender-affirmative framework in research, teaching, training, and supervision;

BE IT FURTHER RESOLVED that the American Psychological Association opposes GICE because there is evidence of former participants reporting harm resulting from their experiences of GICE and the contribution that such efforts make to social stigma, injustice, and prejudice directed at gender diverse individuals, consistent with other major professional mental health associations, including the American Psychiatric Association (2018); American Counseling Association (2017), SAMHSA (2015), American Academy of Child & Adolescent Psychiatry (2018), World Health Organization (n.d.) and World Psychiatric Association (2016);

BE IT FURTHER RESOLVED that the APA, because of evidence of harm and lack of evidence of efficacy, supports public policies and legislation that prohibit, or aim to reduce GICE, cissexism, and anti-transgender and anti-gender nonbinary bias and that increase support for gender diversity;

BE IT FURTHER RESOLVED that the APA supports collaboration and partnerships with global, national and state and local partners to achieve the aims of this resolution;

BE IT FURTHER RESOLVED that the APA promotes professional training in gender-affirming practices and opposes professional training in GICE in any stage of the education of psychologists, including graduate training, continuing education, and professional development.

REFERENCES

Ainsworth, T. A., & Spiegel, J. H. (2010). Quality of life of individuals with and without facial feminization surgery or gender reassignment surgery. Quality of Life Research, 19(7), 1019-1024.

American Academy of Child and Adolescent Psychiatry. (2018, February). Conversion Therapy. Retrieved from: https://www.aacap.org/AACAP/Policy_Statements/2018/Conversion_Therapy.aspx

American Counseling Association. (2010). American Counseling Association competencies for counseling with transgender clients. *Journal of LGBT Issues in Counseling, 4*, 135-159. doi:10.1080/15538605.2010.524839

American Psychiatric Association. (2018). Position Statement on Conversion Therapy and LGBTQ Patients. Retrieved from: https://www.psychiatry.org/home/policy-finder?k=conversion%20therapy

American Psychological Association (2005). Policy Statement on Evidence-Based Practice in Psychology. Retrieved from: https://www.apa.org/practice/guidelines/evidence-based-statement

American Psychological Association (2009). Report of the American Psychological Association Task Force on Appropriate Affirmative Responses to Sexual Orientation. Retrieved from: https://www.apa.org/pi/lgbt/resources/therapeutic-response.pdf

American Psychological Association (2012). Recognition of psychotherapy effectiveness. Retrieved from: http://www.apa.org/about/policy/resolution-psychotherapy.aspx

American Psychological Association. (2015). Guidelines for psychological practice with transgender and gender nonconforming people. *American Psychologist, 70*(9), 832–864.

American Psychological Association. (2017). Multicultural Guidelines: An Ecological Approach to Context, Identity, and Intersectionality. Retrieved from: http://www.apa.org/about/policy/multicultural-guidelines.pdf

Austin, A., & Craig, S. L. (2015). Transgender affirmative cognitive behavioral therapy: Clinical considerations and applications. *Professional Psychology: Research and Practice, 46*(1), 21.

Barkai, A. R. (2017). Troubling Gender or Engendering Trouble? The Problem With Gender Dysphoria in Psychoanalysis. *The Psychoanalytic Review, 104*(1), 1-32.

Benson, K. E. (2013). Seeking support: Transgender client experiences with mental health services. *Journal of Feminist Family Therapy: An International Forum, 25*, 17–40.

Bockting, W. O., Miner, M. H., Swinburne Romine, R. E., Hamilton, A., & Coleman, E. (2013). Stigma, mental health, and resilience in an online sample of the US transgender population. *American Journal of Public Health, 103*(5), 943-951.

Bouman, W. P., Richards, C., Addinall, R. M., Arango de Montis, I., Arcelus, J., Duisin, D., Esteva, A., Fisher, F., Harte, B., Khaury, Z., Lu, A., Marais, A., Mattila, D., Nayarana Reddy, D., Nieder, T.O., Robles Garcia, R., Rodrigues, Jr., O.M., Roque Guerra, A., Tereshkevich, G., T'Sjoen, G., & Wilson, D. (2014). Yes and yes again: Are standards of care which require two referrals for genital reconstructive surgery ethical? *Sexual and Relationship Therapy, 29*, 377–389.

Bradley, S. J., & Zucker, K. J. (1997). Gender Identity Disorder: A Review of the Past 10 Years. *Journal of the American Academy of Child & Adolescent Psychiatry, 36*(7), 872-880.

Brinkman, B. G., Rabenstein, K. L., Rosén, L. A., & Zimmerman, T. S. (2014). Children's gender identity development: The dynamic negotiation process between conformity and authenticity. *Youth & Society, 46*(6), 835-852

Burke, M.C. (2011), Resisting Pathology: GID and the Contested Terrain of Diagnosis in the Transgender Rights Movement. In P. McGann & D.J. Hutson (Eds.) *Sociology of Diagnosis (Advances in Medical Sociology, Vol. 12)*, Emerald Group Publishing Limited, Bingley, pp. 183-210.

Burnes, T. R., Dexter, M. M., Richmond, K., Singh, A. A., & Cherrington, A. (2016). The experiences of transgender survivors of trauma who undergo social and medical transition. *Traumatology, 22*(1), 75-84.

Byne, W., Bradley, S. J., Coleman, E., Eyler, A. E., Green, R., Menvielle, E. J., Meyer-Bahlburg, H. F. L., Pleak, R. R., Tompkins, D. A., & American Psychiatric Association Task Force on Treatment of Gender Identity Disorder. (2012). Report of the American Psychiatric Association Task Force on Treatment of Gender Identity Disorder. *Archives of Sexual Behavior, 41*(4), 759–796. https://doi.org/10.1007/s10508-012-9975-x

Carr, C. L. (1998). Tomboy resistance and conformity: Agency in social psychological gender theory. *Gender & Society, 12*(5), 528-553.

Cohen-Kettenis, P. T., & Kuiper, A. J. (1984). Transseksualiteit en psychothérapie. *Tijdschrift Voor Psychotherapie, 10*, 153-166. (In Dutch)

Coleman, E., Bockting, W., Botzer, M., Cohen-Kettenis, P., DeCuypere, G., Feldman, J., ... & Monstrey, S. (2012). Standards of care for the health of transsexual, transgender, and gender-nonconforming people, version 7. *International journal of transgenderism, 13*(4), 165-232.

Craig, S. L., Austin, A., Rashidi, M., & Adams, M. (2017). Fighting for survival: The experiences of lesbian, gay, bisexual, transgender, and questioning students in religious colleges and universities. *Journal of Gay & Lesbian Social Services, 29*(1), 1-24.

D'Augelli, A. R., Grossman, A. H., & Starks, M. T. (2006). Childhood gender atypicality, victimization, and PTSD among lesbian, gay, and bisexual youth. *Journal of interpersonal violence, 21*(11), 1462-1482.

De Vries, A. L., McGuire, J. K., Steensma, T. D., Wagenaar, E. C., Doreleijers, T. A., & Cohen-Kettenis, P. T. (2014). Young adult psychological outcome after puberty suppression and gender reassignment. *Pediatrics, 134*(4), 696-704.

dickey, l. m., Budge, S. L., Katz-Wise, S. L., & Garza, M. V. (2016). Health disparities in the transgender community: Exploring differences in insurance coverage. *Psychology of Sexual Orientation and Gender Diversity, 3*(3), 275-282.

Drescher, J. (2010). Queer diagnoses: Parallels and contrasts in the history of homosexuality, gender variance, and the Diagnostic and Statistical Manual. *Archives of Sexual Behavior, 39*(2), 427-460.

Edwards-Leeper, L., Leibowitz, S., & Sangganjanavanich, V. F. (2016). Affirmative practice with transgender and gender nonconforming youth: Expanding the model. *Psychology of Sexual Orientation and Gender Diversity, 3*(2), 165.

Egan, S. K., & Perry, D. G. (2001). Gender identity: a multidimensional analysis with implications for psychosocial adjustment. *Developmental psychology, 37*(4), 451.

Fish, J. N., & Russell, S. T. (2020). Sexual Orientation and Gender Identity Change Efforts are Unethical and Harmful. *American Journal of Public Health, 110*(8), 1113-1114.

Fredriksen-Goldsen, K. I., Cook-Daniels, L., Kim, H. J., Erosheva, E. A., Emlet, C. A., Hoy-Ellis, C. P., Goldsen, J., & Muraco, A. (2013). Physical and mental health of transgender older adults: An at-risk and underserved population. *The Gerontologist, 54*(3), 488-500.

Gagné, P., & Tewksbury, R. (1998). Conformity pressures and gender resistance among transgendered individuals. *Social Problems, 45*(1), 81-101.

Gelder, M. G., & Marks, I. M. (1969). Aversion treatment in transvestism and transsexualism. Transsexualism and sex reassignment, 383-413.

Gerhardstein, K. R., & Anderson, V. N. (2010). There's more than meets the eye: Facial appearance and evaluations of transsexual people. *Sex roles, 62*(5-6), 361-373.

Green, A. E., Price-Feeney, M., Dorison, S. H., & Pick, C. J. (2020). Self-reported conversion efforts and suicidality among US LGBTQ youths and young adults, 2018. *American journal of public health, 110*(8), 1221-1227.

Grant, J., Mottet, L., Tanis, J., Harrison, J., Herman, J., & Keisling, M. (2011). Injustice at every turn: A report of the national transgender discrimination survey. National Center for Transgender Equality and National Gay and Lesbian Task Force. https://www.transequality.org/sites/default/files/docs/resources/NTDS_Report.pdf

Greenson, R. (1964). On homosexuality and gender identity. *International Journal of Psychoanalysis, 45*, 217-219. (In Japanese)

Haas, A. P., Eliason, M., Mays, V. M., Mathy, R. M., Cochran, S. D., D'Augelli, A. R., Silverman, M. M., Fisher, P. W., Hughes, T., Rosario, M., Russell, S. T., Malley, E., Reed, J., Litts, D. A., Haller, E., Sell, R. L., Remafedi, G., Bradford, J., Beautrais, A. L., Brown, G. K., Diamond, G. M., Friedman, M. S., Garofalo, R., Turner, M. S., Hollibaugh, A., & Clayton, P. J. (2011). Suicide and suicide risk in lesbian, gay, bisexual, and transgender populations: review and recommendations. *Journal of Homosexuality, 58*(1), 10-51.

Hendricks, M. L., & Testa, R. J. (2012). A conceptual framework for clinical work with transgender and gender nonconforming clients: An adaptation of the minority stress model. Professional Psychology: *Research and Practice, 43*, 460-467.

Hidalgo, M. A., Kuhns, L. M., Kwon, S., Mustanski, B., & Garofalo, R. (2015). The impact of childhood gender expression on childhood sexual abuse and psychopathology among young men who have sex with men. *Child Abuse & Neglect, 46*, 103-112.

Hiestand, K. R., & Levitt, H. M. (2005). Butch identity development: The formation of an authentic gender. *Feminism & Psychology, 15*(1), 61-85.

Hill, D. B., Menvielle, E., Sica, K. M., & Johnson, A. (2010). An affirmative intervention for families with gender variant children: Parental ratings of child mental health and gender. *Journal of Sex & Marital Therapy, 36*(1), 6-23.

Hipp, T. N., Gore, K. R., Toumayan, A. C., Anderson, M. B., & Thurston, I. B. (2019). From conversion toward affirmation: Psychology, civil rights, and experiences of gender-diverse communities in Memphis. *American Psychologist, 74*(8), 882–897

Horn, S. S. (2007). Adolescents' acceptance of same-sex peers based on sexual orientation and gender expression. *Journal of Youth and Adolescence, 36*(3), 363-371.

James, S. E., Herman, J. L., Rankin, S., Keisling, M., & Anafi, M. (2016). *The report of the 2015 U.S. transgender survey* (pp. 1–297). National Center for Transgender Equality.

Johns, M. M., Lowry, R., Andrzejewski, J., Barrios, L. C., Demissie, Z., McManus, T., Rasberry, C. N., Robin, L., & Underwood, J. M. (2019). *Transgender identity and experiences of violence victimization, substance use, suicide risk, and sexual risk behaviors among high school students—19 states and large urban school districts, 2017. 68*(3), 67–71. https://doi.org/10.15585/mmwr.mm6803a3

Kraemer, B., Delsignore, A., Schnyder, U., & Hepp, U. (2008). Body image and transsexualism. *Psychopathology, 41*(2), 96-100.

Lamda Legal (2010). *When Health Care Isn't Caring: Lambda Legal's Survey of Discrimination Against LGBT People and People with HIV.* New York: Lambda Legal.

Landolt, M. A., Bartholomew, K., Saffrey, C., Oram, D., & Perlman, D. (2004). Gender nonconformity, childhood rejection, and adult attachment: A study of gay men. *Archives of Sexual Behavior, 33*(2), 117-128.

Macapagal, K., Bhatia, R., & Greene, G. J. (2016). Differences in healthcare access, use, and experiences within a community sample of racially diverse lesbian, gay, bisexual, transgender, and questioning emerging adults. *LGBT Health, 3*(6), 434-442.

Menvielle, E. J., Tuerk, C., & Jellinek, M. S. (2002). A support group for parents of gender-nonconforming boys. *Journal of the American Academy of Child & Adolescent Psychiatry, 41*(8), 1010-1013.

Meyer I. H. (2003). Prejudice, social stress, and mental health in lesbian, gay, and bisexual populations: conceptual issues and research evidence. *Psychological Bulletin, 129*(5), 674-97.

Movement Advancement Project. (n.d.). *Conversion "therapy" laws.* https://www.lgbtmap.org/equality-maps/conversion_therapy

Nadal, K. L., Rivera, D. P., & Corpus, M. J. H. (2010). Sexual orientation and transgender microaggressions in everyday life: Experiences of lesbians, gays, bisexuals, and transgender individuals. In D. W. Sue (Ed.), *Microaggressions and marginality: Manifestation, dynamics and impact* (pp. 217–240). New York: Wiley.

Nadal, K. L., Skolnik, A., & Wong, Y. (2012). Interpersonal and systemic microaggressions toward transgender people: Implications for counseling. *Journal of LGBT Issues in Counseling, 6*(1), 55-82.

Newfield, E., Hart, S., Dibble, S., & Kohler, L. (2006). Female-to-male transgender quality of life. *Quality of Life Research, 15*(9), 1447-1457.

Pauly, I. B. (1965). Male psychosexual inversion: Transsexualism: A review of 100 cases. *Archives of General Psychiatry, 13*(2), 172-181.

Pickstone-Taylor, S. D. (2003). Letter to the editor. Children with gender nonconformity. *Journal of the American Academy Child & Adolescent Psychiatry, 42*, 266.

Price, M., Olezeski, C., McMahon, T., & Hill, N. (2019). A developmental perspective on victimization faced by gender-nonconforming youth. In H. Fitzgerald (Ed.), *Handbook of Children and Prejudice: Integrating Research, Practice, and Policy.* New York, NY: Springer Press.

Reisner, S. L., Vetters, R., Leclerc, M., Zaslow, S., Wolfrum, S., Shumer, D., & Mimiaga, M. J. (2015). Mental health of transgender youth in care at an adolescent urban community health center: a matched retrospective cohort study. *Journal of Adolescent Health, 56*(3), 274-279.

Riggs, D. W., Pearce, R., Pfeffer, C. A., Hines, S., White, F., & Ruspini, E. (2019). Transnormativity in the psy disciplines: Constructing pathology in the Diagnostic and Statistical Manual of Mental Disorders and Standards of Care. *American Psychologist, 74*(8), 912.

Roberts, A. L., Rosario, M., Corliss, H. L., Koenen, K. C., & Austin, S. B. (2012). Childhood gender nonconformity: A risk indicator for childhood abuse and posttraumatic stress in youth. *Pediatrics, 129*(3), 410-417.

Robinson, C. M., & Spivey, S. E. (2019). Ungodly Genders: Deconstructing Ex-Gay Movement Discourses of "Transgenderism" in the US. *Social Sciences, 8*(6), 191-218.

Rosenberg, M., & Jellinek, M. S. (2002). Children with gender identity issues and their parents in individual and group treatment. *Journal of the American Academy of Child & Adolescent Psychiatry, 41*(5), 619-621.

Russell, S. T., Sinclair, K. O., Poteat, V. P., & Koenig, B. W. (2012). Adolescent health and harassment based on discriminatory bias. *American Journal of Public Health, 102*(3), 493-495.

Substance Abuse and Mental Health Services Administration. (2015). Ending conversion therapy: Supporting and affirming LGBTQ youth. *HHS Publication No.(SMA) 15-4928.*

Sandfort, T. G., Melendez, R. M., & Diaz, R. M. (2007). Gender nonconformity, homophobia, and mental distress in Latino gay and bisexual men. *Journal of Sex Research, 44*(2), 181-189.

Sevelius, J. M. (2013). Gender affirmation: A framework for conceptualizing risk behavior among transgender women of color. *Sex Roles, 68*(11-12), 675-689

Singh, A. A., Hays, D. G., & Watson, L. S. (2011). Strength in the face of adversity: Resilience strategies of transgender individuals. *Journal of Counseling & Development, 89*(1), 20-27.

Singh, A. A., Meng, S. E., & Hansen, A. W. (2014). "I am my own gender": Resilience strategies of trans youth. *Journal of Counseling & Development, 92*(2), 208-218.

Smith, T. E., & Leaper, C. (2006). Self perceived gender typicality and the peer context during adolescence. *Journal of Research on Adolescence, 16*(1), 91-104.

Stotzer, R. L. (2012). *Comparison of Hate Crime Rates across Protected and Unprotected Groups - An Update.* Williams Institute on Sexual Orientation Law and Public Policy: Los Angeles, CA.

Stryker, S. (2017). *Transgender history: The roots of today's revolution.* Seal Press: New York.

Toomey, R. B., Ryan, C., Diaz, R. M., Card, N. A., & Russell, S. T. (2013). Gender-nonconforming lesbian, gay, bisexual, and transgender youth: school victimization and young adult psychosocial adjustment. *Developmental Psychology, 46*(6), 1580-1589.

Truong, N. L., Zongrone, A. D., & Kosciw, J. G. (2020a). Erasure and Resilience: The Experiences of LGBTQ Students of Color. Asian American and Pacific Islander LGBTQ Youth in US Schools. *Gay, Lesbian and Straight Education Network (GLSEN).*

Truong, N. L., Zongrone, A. D., & Kosciw, J. G. (2020b). Erasure and resilience: The experiences of LGBTQ students of color, Black LGBTQ youth in U.S. schools. New York: GLSEN.

Turban, J. L., Beckwith, N., Reisner, S. L., & Keuroghlian, A. S. (2020). Association between recalled exposure to gender identity conversion efforts and psychological distress and suicide attempts among transgender adults. *JAMA Psychiatry, 77*(1), 68. https://doi.org/10.1001/jamapsychiatry.2019.2285

United States Joint Statement Against Conversion Efforts (n.d.). https://usjs.org/

White Hughto, J. M., & Reisner, S. L. (2016). A systematic review of the effects of hormone therapy on psychological functioning and quality of life in transgender individuals. *Transgender Health, 1*(1), 21-31.

Hughto, J. M. W., Reisner, S. L., & Pachankis, J. E. (2015). Transgender stigma and health: A critical review of stigma determinants, mechanisms, and interventions. *Social Science & Medicine, 147,* 222-231. https://doi.org/10.1016/j.socscimed.2015.11.010

World Health Organization (n.d.) *Europe brief – transgender health in the context of ICD-11.* (2020, August 03). Retrieved August 03, 2020, from https://www.euro.who.int/en/health-topics/health-determinants/gender/gender-definitions/whoeurope-brief-transgender-health-in-the-context-of-icd-11

World Psychiatric Association (2016). *WPA Position Statement on Gender Identity and Same-Sex Orientation, Attraction, and Behaviours.* Retrieved from: http://www.wpanet.org/detail.php?section_id=7&content_id=1807

Zongrone, A. D., Truong, N. L., & Kosciw, J. G. (2020). Erasure and Resilience: The Experiences of LGBTQ Students of Color. Latinx LGBTQ Youth in US Schools. *Gay, Lesbian and Straight Education Network (GLSEN)*