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

AUGUST DEKKER, et al.,

Plaintiffs,

v.

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

JASON WEIDA, et al.,

Defendants.

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

- I, Johanna Olson-Kennedy, M.D., M.S., hereby state as follows:
- 1. I have been retained by counsel for Plaintiffs as an expert in connection with the above-captioned litigation.
 - 2. I am over the age of 18.
- 3. I have actual knowledge of the matters stated herein. If called to testify in this matter, I would testify truthfully and based on my expert opinion.
- 4. I previously submitted an expert witness report in this case ("Olson-Kennedy Report"). I submit this report to respond to points raised in the reports of Defendants' designated experts: Michael K. Laidlaw, M.D., Paul W. Hruz, M.D., and Michael Biggs, Ph.D., as well as those by Stephen B. Levine, M.D.,

Kristopher Kaliebe, M.D., Patrick Lappert, M.D., Joseph Zanga, M.D., Sophie Scott, Ph.D., and G. Kevin Donovan, M.D.

5. My background, qualifications, and compensation for my services in this case, and the bases for my opinions in this case are described in my original

report.

6. In preparing this report, I was provided with and reviewed the

reports from defendants' designated experts described above and the

accompanying exhibits, as well as the expert reports of Dr. Armand Antommaria,

Dr. Kellan Baker, Dr. Dan Karasic, Dr. Loren Schechter, and Dr. Daniel Shumer,

submitted by plaintiffs.

7. In preparing this rebuttal report, I have relied on my training and

years of research and clinical experience, as set out in my curriculum vitae

(attached as **Exhibit A** to my original report) and on the materials listed therein;

the materials listed in the bibliography attached as **Exhibit B** to my original

report; and the additional materials listed in the supplemental bibliography

attached as Exhibit C to this rebuttal report. The sources cited in each of these

are the same types of materials that experts in my field of study regularly rely

upon when forming opinions on the subject, which include authoritative,

scientific peer-reviewed publications.

8. I reserve the right to revise and supplement the opinions expressed in this report or the bases for them if any new information becomes available in the future, including as a result of new scientific research or publications or in response to statements and issues that may arise in my area of expertise. I may also further supplement these opinions in response to information produced by Defendants in discovery and in response to additional information from Defendants' designated experts.

EXPERT OPINIONS

- 9. Defendants' designated experts show a lack of familiarity and understanding regarding the existing research about gender identity and gender dysphoria, as well as the clinical experience surrounding the treatment of gender dysphoria, particularly regarding transgender youth.
- 10. This lack of familiarity and understanding makes sense. Dr. Laidlaw, Dr. Hruz, Dr. Kaliebe, Dr. Lappert, Dr. Donovan, and Dr. Scott have no experience working with transgender patients suffering from gender dysphoria or conducting original research regarding the safety and efficacy of genderaffirming care. Dr. Biggs has no experience whatsoever treating patients, as he is a sociologist, not a health care provider. Finally, Dr. Levine has very limited

experience working with transgender youth and has not been a member of WPATH for decades.

These doctors have critiqued and opposed the provision of gender-

affirming care as treatment for gender dysphoria for years, and in the case of Dr. Levine, decades. Yet, in all of these years, they have not undertaken the research they call for to answer the questions they raise. Rather, it seems their primary goal is opposing gender-affirming care for transgender people, instead of finding

answers to questions and providing the best care for transgender people suffering

from gender dysphoria.

11.

12. Below I outline more specific critiques regarding the reports of Dr.

Laidlaw, Dr. Hruz, and Dr. Biggs. Some of the specific critiques apply in equal

measure to more than one expert report, however.

Dr. Laidlaw's Report

13. Dr. Laidlaw has no peer-reviewed original publications regarding

transgender individuals, either adults or youth. While he is an adult

endocrinologist, he does not have any cited experience in the clinical care of

children, adolescents, or adults with gender dysphoria.

14. One of Dr. Laidlaw's major critiques of gender-affirming care is

that "[t]here are no laboratory, imaging, or other objective tests to diagnose a true

transgender child," (Laidlaw Report, at ¶24), as if this was a reason to deny coverage and access to medically necessary gender-affirming medical care as treatment for gender dysphoria. While it is true that there is no objective test to determine someone's gender identity yet, this does not mean there are no biological markers to prove someone has gender dysphoria. It also ignores that the lack of such "objective tests" is not uncommon for other medical conditions. Take chronic fatigue syndrome, for example. The CDC says this about chronic fatigue syndrome: "Myalgic encephalomyelitis/chronic fatigue syndrome (ME/CFS) is a serious, long-term illness that affects many body systems ... Researchers have not yet found what causes ME/CFS, and there are no specific laboratory tests to diagnose ME/CFS directly. Therefore, doctors need to consider the diagnosis of ME/CFS based on in-depth evaluation of a person's symptoms and medical history." (CDC, 2021).

15. In paragraph 26 of his report, Dr. Laidlaw further opines that "gender dysphoria is a purely psychological phenomenon and not an endocrine condition." Dr. Laidlaw provides no support for his assertion that gender dysphoria is a purely psychological condition. Indeed, there is no existing data to demonstrate that gender dysphoria is a psychological phenomenon. Human developmental trajectories that are not yet fully understood are often considered

psycho pathological, such as left handedness and homosexuality. Gender incongruence is such a developmental trajectory, likely related to the morphology and connectivity of the brain structures. Like many developmental trajectories, it Same sex attraction is also the non-dominant trajectory of is rare. romantic/sexual development and was similarly considered psychopathologic. Same sex attraction was viewed as such secondary to existing theories at the time that some posited, like Dr. Laidlaw does in his report, that "some internal defect or external pathogenic agent causes homosexuality and that such events can occur pre- or postnatally (i.e., intrauterine hormonal exposure, excessive mothering, inadequate or hostile fathering, sexual abuse, etc.)" (Drescher, 2015). But just as "homosexuality" was first pathologized and then depathologized within the DSM, ultimately being removed altogether, gender incongruence has been depathologized within the DSM, moving from "gender identity disorder" to "gender dysphoria." This change within the DSM-5 came about because "[t]he presence of gender variance is not the pathology but dysphoria is from the distress caused by the body and mind not aligning and/or societal marginalization of gender-variant people" (Yarbrough, et al., 2017).

16. In paragraph 35 of his report, Dr. Laidlaw takes issue with my discussion of desistance studies by stating that I "confused prepubertal (a medical

term) with preadolescence (a psychological designation)" and emphasizing that the studies "include children in the age range of 8-12 years old many of whom were going through puberty based on their age." But while the upper range of some of these studies might have included a few youth in Tanner stage 2 (i.e., children at the onset of puberty) or greater, the average age of the participants places them in a prepubertal age range and a review of the ages of the participants shows that most were in indeed pre-pubertal. What is more, consistently in these studies, the investigators specifically point out that older youth to which Dr. Laidlaw refers were more likely to continue experiencing gender incongruence. The question confronted in the GAPMS Memo and this case pertains to medical intervention, which is not even considered in pre-pubertal children. As Dr. Laidlaw himself asserts, Tanner stages are not reported in any of these early studies and it is therefore inappropriate for him to extrapolate data from studies looking at desistance rates of *primarily* pre-pubertal *gender diverse* children (not necessarily transgender children), as informing anything about the trajectory or likelihood of desistance among transgender adolescents who are peri-pubertal or pubertal. The studies simply cannot support that proposition.

17. In paragraph 92 of his report, Dr. Laidlaw purports to opine about infertility as a result of the use of GnRH analogs. However, it is well established

that GnRH analogs do not cause infertility. In a manuscript published in 2019 entitled "Use of Gonadotropin-Releasing Hormone Analogs in Children: Update by an International Consortium" the following statement regarding infertility and the use of GnRH analogs is asserted: "There is no substantiated evidence that GnRHa treatment for CPP impairs reproductive function or reduces fertility. In most girls, gonadal function is restored promptly after cessation of therapy, with subsequent menarche and regular ovulatory menstrual cycles" (Bangalore, et al., 2019). It is true that individuals who do not go through endogenous puberty as a result of using GNRH analogs directly followed by GAH will likely experience impacts on future fertility. It is for this reason that the SOC cautions clinicians to counsel patients and families about fertility when they use these medications so that they can make informed choices about future fertility and reproduction, which may include creating a window between GnRHa use and GAH in order to collect and preserve gametes. Indeed, there have been transgender patients who have discontinued GNRH analogs or GnRHa/GAH in order to progress through puberty and undergo fertility preservation. These individuals resumed menstruation and/or underwent fertility induction for harvesting of mature eggs. (Martin, et al., 2021; Rothenberg, et al., 2019).

18. Similarly, in paragraph 94 of his report, Dr. Laidlaw opines about sterility, particularly with regards to the minor plaintiffs (whom he appears to have neither met nor examined). However, Dr. Laidlaw disregards the despair that many transgender youth have about experiencing or anticipating going through endogenous puberty. It is a common perspective from those who do not work with youth experiencing gender dysphoria. The question posited to such youth is not "what do you think about not having biological children in your future" but rather "do you want to undergo the changes of puberty that are not aligned with your gender." The advantage of GnRH analogs is that they act as a bridge, so that cognition can develop but spare the development of misaligned secondary sex characteristics that will result in a patient being perceived as the wrong gender.

19. In paragraph 97, Dr. Laidlaw goes on to assert that "[t]here is the additional possibility that cytotoxic effects of high dose opposite sex hormones will damage the immature gonads leading to permanent sterility." However, Dr. Laidlaw provides no support for this assertion. In fact, as someone familiar with this care would know, viable follicles and sperm have been obtained from individuals who discontinue GnRH analogs and/or GAH for the purpose of fertility preservation.

20. In paragraphs 98 and 99 of his report, Dr. Laidlaw opines about sexual dysfunction as a result of the use of GnRH analogs. There is no evidence, however, to suggest that sexual dysfunction will occur. To the contrary, there is both existing evidence and clinical evidence that orgasm does occur both in prepubertal youth, as well as transgender youth who have utilized GnRH analogs to treat gender dysphoria. (Finkelstein, et al., 1996; Leung and Robson, 1993; Fleischer and Morrison, 1990). Leaning on one reality TV show to make a broad assertion about all transgender youth is what people do when they do not have clinical experience or research to substantiate their perspective.

21. In paragraphs 101 through 106 of his report, Dr. Laidlaw discusses the use of DEXA scans to evaluate changes in bone density. What Dr. Laidlaw does not explain is that DEXA scans compare bone density of **individuals of the same age**. It is expected that the bone density of someone who had their puberty delayed would demonstrate a lower bone density than their peers who had not had puberty delayed. However, as explained in paragraph 105 of my original report, following cessation of therapy with puberty-delaying medications, bone

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

¹ While these articles don't specifically state that the children had orgasms, the movements and physical responses described in them indicate as such.

mineral accrual appears to be within the normal range compared with population

norms. Dr. Laidlaw fails to disclose or respond to such studies.

22. In paragraph 109, Dr. Laidlaw then states that "Amenorrhea is

detrimental to bone health." But, while taking GnRH analogs, the body is not

producing sex steroids. If someone discontinues GnRH analogs, their body will

resume endogenous puberty (after some delay). If that individual has ovaries,

they will begin to secrete estrogen, which stimulates and supports bone density.

If that individual adds testosterone to their hormone regimen to undergo

masculinization, the testosterone will support accrual and maintenance of bone

density. Dr. Laidlaw is conflating amenorrheic women, who have little or no sex

steroids, to transmasculine individuals, who are taking testosterone that supports

bone density.

23. In paragraph 110, Dr. Laidlaw opines about "unknown, but likely

negative consequences to blocking normal puberty with respect to brain

development." Dr. Laidlaw's assertion has at least two foundational problems.

First, what is known about is the negative impact of untreated gender dysphoria

on cognition, which Dr. Laidlaw ignores, and which at best can be persistently

distressing and at worst, life threatening. Second, Dr. Laidlaw ignores that

suppression in transgender youth does not delay puberty beyond the typical

range. As explained in my original report, pubertal development has a very wide variation among individuals. Puberty in individuals assigned male at birth typically begins anywhere from age nine to age fourteen, and sometimes does not complete until a person's early twenties. For those individuals assigned female at birth, typically ranges from age eight to age seventeen (Wyshak and Frisch, 1982). Protocols used for transgender youth would tend to put them in the latter third of typical puberty but nothing outside of the typical range (Hembree, et al., 2017). As such there is no reason to assume, and no data to support, Dr. Laidlaw's assumption that slightly delaying puberty will have negative short- or long-term consequences.

24. In paragraph 111 of his report, Dr. Laidlaw again misrepresents the desistance literature to state that "a very high proportion of minors diagnosed with gender dysphoria will eventually desist or come to accept their physical sex." This is an inaccurate statement. Dr. Laidlaw is lumping together prepubertal children and adolescents. In the same paragraph, Dr. Laidlaw further argues that "Puberty blockers have been shown to dramatically alter natural desistance." However, this is an assumed causality with no support in the literature. Youth who are more gender dysphoric in childhood are more likely to persist with gender incongruence. They are also more likely to seek out a

mechanism to avoid the development of secondary sex characteristics that are not aligned with their gender. It is thus unsurprising that the youth whose gender dysphoria persisted until the onset of puberty and who presented for medical care were indeed the youth who are transgender. As stated in my original report, studies show that if gender dysphoria is present in adolescence, it usually persists. *See* Olson-Kennedy Report, at ¶52-57.

25. Dr. Laidlaw's claim that "puberty blockers, rather than being a 'pause' to consider aspects of mental health, are instead a pathway towards future sterilizing surgeries" (Laidlaw Report, at ¶ 112) is a wholly unsubstantiated claim. Again, youth with significant gender dysphoria pursue blockers because of that distress, they do not experience continued incongruence because of the intervention. Dr. Laidlaw's argument is akin to saying something like "youth who are treated with combined oral contraceptive pills for endometriosis in adolescence are more likely to undergo laparoscopic treatment for endometriosis because of the earlier OCP treatment." Youth who are prescribed GnRH analogs for gender incongruence have gender incongruence, and if it continues, they are likely to go on gender-affirming hormone therapy ("GAH"). Dr. Laidlaw and others who assert that GnRH analogs are a gateway drug to GAH and surgery

make an unsubstantiated and false claim that gender incongruence dissipates in

the majority of those who initiate care in adolescence.

26. In paragraph 113 of his report, Dr. Laidlaw states that "[t]he third

stage of gender affirmative therapy involves using hormones of the opposite sex

(also called cross sex hormones) at high doses to attempt to create secondary sex

characteristics in the person's body." The staging suggested by Dr. Laidlaw

assumes a linear progression through various available interventions. This

perspective is indicative of someone unfamiliar with the care, which is

individualized. Some youth who go on blockers do not continue GAH. Many

youth who utilize GAH do not pursue surgery. Some youth stop GAH after they

achieve their embodiment goals. Additionally, high doses of hormones are not

utilized. Treatment for gender dysphoria involves getting someone's hormones

to the same level as their cisgender counterparts of the same gender.

27. In paragraph 115, Dr. Laidlaw opines that "[t]he use of high dose

testosterone in females is experimental." The implication here is that testosterone

use in transgender males is new. The use of testosterone in transmasculine

individuals has been happening for close to 100 years. Also, as discussed above,

the treatment doses are not "high dose."

28. In paragraph 116, Dr. Laidlaw states that "[t]here have been reports of misuse by men taking higher doses of legally obtained testosterone than prescribed and continuing testosterone despite adverse events or against medical advice." Dr. Laidlaw cites to no evidence for this statement, and I am not aware of a single case report of a transgender man abusing testosterone. This is a phenomenon widely understood among cisgender men using higher doses of testosterone for sports and aesthetic enhancement. To equate these two things is improper, and is characteristic of someone who does not take care of transgender people. In any event, even Dr. Laidlaw's assertion notes that this occurs "against medical advice" so it is difficult to see how this unfounded assertion supports the denial of coverage of medical treatment prescribed and provided by medical professionals.

29. In paragraph 118 of his report, Dr. Laidlaw opines "that testosterone applied to the adolescent will cause premature closure of the growth plates, stopping further gains in height in the growing individual, and ultimately making the person shorter than they otherwise would have been." Professionals using GAH in youth with gender dysphoria understand the mechanism of epiphyseal plate fusion. Testosterone dosing is ramped up in a manner equivalent to that of

testosterone administration in youth with hypogonadal hypogonadism in order to

mimic a cisgender male pubertal process.

30. Dr. Laidlaw goes on to opine in paragraph 119 of his report that

"[1]ong-term clinical safety trials have not been conducted to assess the

cardiovascular outcomes of testosterone replacement therapy in men." This is

untrue, as there have been studies examining the metabolic effect of testosterone

in transgender men, including a review by Aranda et al. in 2021 titled

"Cardiovascular Risk Associated With Gender Affirming Hormone Therapy in

Transgender Population." This review and other studies have demonstrated that

transgender men using testosterone have a similar risk of myocardial infarction

to that of cisgender males, and higher than cisgender females.

31. In paragraph 120 of his report, Dr. Laidlaw cites a drug label insert

for the proposition that "[t]here have been postmarketing reports of venous

thromboembolic events [blood clots], including deep vein thrombosis (DVT)

[blood clot of the extremity such as the lef] and pulmonary embolism (PE) [blood

clot of the lung which may be deadly], in patients using testosterone products,

such as testosterone cypionate." However, in a meta-analysis of studies

examining the relationship between testosterone and venous thromboembolism

(VTE), the authors concluded: "Results: Six RCTs (n = 2236) and 5 observational

studies (n = 1,249,640) were included. Five RCTs were performed in men with documented hypogonadism. The observational studies included: 2 case-control studies, 2 retrospective cohorts, and 1 retrospective cohort with a nested case-control study. There was no evidence of a statistically significant association between VTE and testosterone (OR 1.41, 95%CI 0.96-2.07). Heterogeneity was high (I-squared = 84.4%). The association remained nonsignificant when the analysis was stratified by study design: RCTs (2.05, 95% CI 0.78-5.39); cohort (1.06, 95% CI 0.85-1.33); and case-control (1.34, 95% CI 0.78-2.28). The overall risk of bias was moderate." (Houghton, et al., 2018).

- 32. In paragraph 122, Dr. Laidlaw states that "Prolonged use of high doses of androgens ... has been associated with development of hepatic adenomas [benign tumors], hepatocellular carcinoma [cancer], and peliosis hepatis [generation of blood-filled cavities in the liver that may rupture] —all potentially life-threatening complications." However, the types of liver damage discussed by Dr. Laidlaw have not been reported in transgender men taking testosterone in the literature, nor in clinical professional spaces. Again, the levels of serum testosterone in transmasculine individuals mimics that of cisgender men.
- 33. In paragraph 138, Dr. Laidlaw appeals to common sense for the proposition "that changes of voice and hair growth could be psychologically

troubling should a patient decide to detranstition and attempt to reintegrate into society as female." However, Dr. Laidlaw ignores that someone who identifies as male would desire a lower voice and male pattern facial and body hair. The proportion of people who "detransition," which is very rare, is degrees of multitude lower than those who do not. There is no space in medicine where we prioritize a false positive by discontinuing care for all of the true positives.

- 34. Dr. Laidlaw states in paragraph 139 of his report that "[p]otential cancer risks from high dose testosterone include ovarian and breast cancer." However, there is no data substantiating increased ovarian or breast cancer in transgender men taking testosterone and, again, the levels of serum testosterone in transmasculine individuals mimics that of cisgender men.
- 35. In paragraph 140 of his report, Dr. Laidlaw cites a paper by Hall et al. in 2005 to argue that 23% of subjects with "medium steroid use (between 300 and 1000 mg/week of any AAS) and high use (more than 1000 mg/week of any AAS)" "met the DSM-III-R criteria for a major mood syndrome (mania, hypomania, and major depression) and that 3.4% 12% developed psychotic symptoms." However, dosage of 300 to 1000 mg/week is markedly higher than the doses prescribed for transgender men and transmasculine adolescents. The

dosing for the purposes of masculinization are usually between 20 and 100

mg/week. Thus, the Hall paper is irrelevant to the risk to this population.

36. In paragraph 149 of his report, Dr. Laidlaw asserts that "[t]he use of

estrogen to treat pediatric age males is experimental." The implication here is

that the use of estrogen in young transgender females is new and untested. Not

only has this care been shown to be safe and effective in numerous studies, but

Harry Benjamin's first patient in 1948 was a 14 y/o transgender girl, for whom

he prescribed estrogen. Additionally, female adolescent transgender patients

have been treated with estrogen for decades in this country and abroad.

37. In paragraph 154 of his report, Dr. Laidlaw seems to imply that the

growth of breast tissue in transgender females is akin to gynecomastia, but breast

development is a positive side effect of estrogen and indeed a desired effect for

transgender women. It is not gynecomastia as Dr. Laidlaw suggests. Likewise

in paragraph 155 of his report, Dr. Laidlaw states that other changes "such as

softening of the skin and changes in fat deposition and muscle development" may

occur as a result of feminizing GAH, but again those are also desirable effects of

estrogen in transgender women.

38. In paragraph 156 of his report, Dr. Laidlaw states "[t]here is strong

evidence that estrogen therapy for trans women increases their risk for venous

thromboembolism over 5 fold." But Dr. Laidlaw reveals his lack of familiarity with gender-affirming medical care by failing to explain that this risk is related to the use of ethinyl estradiol, a synthetic estrogen, and that when this risk was identified, practice changed to utilize only bioidentical estrogen (17 β estradiol),

reducing the risk.

- 39. In paragraph 157 of his report, Dr. Laidlaw speaks of the risk of breast cancer in transgender women after GAH, but as stated previously, it is not surprising that establishing a hormone milieu similar to that of a cisgender female would also increase risk related to that of a cisgender male. Moreover, in the study Dr. Laidlaw references, the risk was actually lower in transgender women than cisgender women. Moreover, the risk factor profile associated with hormone use is discussed during the consent process.
- 40. In paragraphs 180 and 181 of his report Dr. Laidlaw discusses his concerns about informed consent in this context. However, Dr. Laidlaw ignores that there is a relatively large body of evidence indicating that adolescents do have the capacity to make informed decisions in the context of medical care and provide assent, particularly at age 14 and above. Moreover, part of providing consent is knowledge of existing studies, and knowledge of what is not understood or poorly understood. This is discussed with patients and their

parents/guardians. Moreover, parents/guardians routinely consent to treatments in other areas of medicine that result in irreversible changes (including infertility) for their minor children, including chemotherapy and other cancer-related treatments like surgery and radiation.

41. In paragraph 191 of his report, Dr. Laidlaw argues that retrospective review of all of the Endocrine Society's guidelines by ECRI implies that the Endocrine Society Guidelines relating to gender dysphoria that "not all recommendations were 'based on verifiable systematic evidence review with explicit descriptions of search strategy, study selection, and evidence summaries." Dr. Laidlaw does not specify which recommendations within the Endocrine Society Guidelines do not meet this standard but also that the Endocrine Society has authored 29 clinical practice guidelines, including guidelines for cardiovascular endocrinology, Diabetes Mellitus and Glucose metabolism. Endocrine cancer and neoplasia, Female Reproductive Endocrinology, Male Reproductive Endocrinology, Neuroendocrinology Conditions, Obesity Management, and Pediatric Endocrinology with subcategories for each of these. Given that only the guidelines relating to osteoporosis met the standard Dr. Laidlaw articulates, one must wonder whether each of these 27 other guidelines (some of which Dr. Laidlaw and Dr. Hruz, as

endocrinologists, presumably rely on) would also be considered unreliable by Dr.

Laidlaw.

42. In paragraph 191 of his report, Dr. Laidlaw takes issue with the

overlap in authorship between the WPATH SOC and the Endocrine Society

Guidelines. But expertise within a field does not represent a conflict of interest.

This is akin to suggesting that a co-author of guidelines published by the

American Heart Association should not be able to co-author any

recommendations from the American College of Cardiology. The people that are

co-authors of the WPATH SOC and the Endocrine Society Guidelines are tasked

with this responsibility by the organizations because they have expertise and

experience in the field of transgender health care, unlike Defendants' designated

experts.

43. In paragraph 200 of his report, Dr. Laidlaw takes issue with my

example of the off-label use of antibiotics or anti-histamines being indicative of

the routineness with which medications are used off-label, particularly for the

pediatric population. Specifically, Dr. Laidlaw states that "[t]he health

consequences are categorically different and the lifelong potential for permanent

injury are extremely high in GAT." Of course, those are not the only examples.

Vincristine and procarbazine, medications commonly used off-label for cancer

treatment, are two other examples. These medications are not FDA-approved for use in breast cancer but are commonly used off-label for this purpose. Both medications have the potential to cause the development of other cancers, which could be life-altering, but this does not make their off-label use experimental or unsafe.

44. In paragraph 202 of his report, Dr. Laidlaw misrepresents and misuses the data from Djhene et al.'s study. The study found that suicide rates are higher among transgender people than the population as a whole. In her study, Dhejne did not compare treated vs. untreated transgender women. These data speak to the comparison of transgender people compared to the general population. The study itself warns against drawing any conclusions regarding the effectiveness of surgery as a treatment for gender dysphoria. To be clear, Dhejne's study states: "For the purpose of evaluating whether sex reassignment is an effective treatment for gender dysphoria, it is reasonable to compare reported gender dysphoria pre and post treatment. Such studies have been conducted either prospectively or retrospectively, and suggest that sex reassignment of transsexual persons improves quality of life and gender dysphoria."

45. Dr. Laidlaw criticizes my study pertaining to chest surgery in transgender adolescents as "flawed and unethical." Laidlaw Report, at ¶ 214. It was neither. While it is true that at the time of the study the Chest Dysphoria Scale was not yet formally validated, the individual elements of the scale are taken directly from ten years of experience caring for transmasculine young people seeking chest surgery. Additionally, the scale has now been demonstrated to correlate with depression and anxiety.

46. In a different study utilizing the scale we developed, entitled "Association of Chest Dysphoria with Anxiety and Depression in Transmasculine and Non-binary Adolescents Seeking Gender Affirming Care," the authors wrote: "One hundred fifty-six patients met inclusion criteria. Mean age was 15.3 years (standard deviation [SD] = 1.7). Most patients identified as transmasculine (n = 132); 18 identified as nonbinary and 6 as questioning. Mean (SD) YI-4 symptom severity scores were 10.67 (6.64) for anxiety and 11.99 (7.83) for depression. Mean (SD) Chest Dysphoria Measure composite score was 30.15 (9.95); range 2-49." (Sood, et al., 2021). The study concluded that "Chest dysphoria was positively correlated with anxiety (r = .146; p = .002) and depression (r = .207; p < .001). In multivariate linear regression models, chest dysphoria showed a significant, positive association with anxiety and depression,

after accounting for gender dysphoria, degree of appearance congruence, and

social transition status." Id.

47. In addition, within this same cohort, Ascha et al. demonstrated

similar findings in their study entitled "Top Surgery and Chest Dysphoria Among

Transmasculine and Non-Binary Adolescents and Young Adults." This study

demonstrated an improvement in chest dysphoria, transgender congruence and

body esteem after surgery. (Ascha, et al., 2022).

48. Finally, there is no need for validation of the question "Do you regret

having chest surgery?" In my study, only one participant responded

"sometimes."

49. In paragraph 215 of his report, Dr. Laidlaw criticizes a study by

Mehringer et al. in 2021. But the Mehringer et al. study was a qualitative study

asking respondents specifically about chest distress. Attributing chest dysphoria

to a side effect of testosterone is outlandish, particularly given that the adverse

responses Dr. Laidlaw is referring to are related to "high doses" of testosterone,

which as discussed before is not what is used in GAH care.

50. In paragraph 219 of his report, Dr. Laidlaw makes the unfounded

accusation that both my study and the Mehringer study "appear[] to have been

designed, at least in part, to justify insurance companies paying for mastectomy

procedure for minors with GD, even though they have provided no long-term statistical evidence of benefit." This is false. Our study was undertaken to better understand the impact of chest surgery in transgender adolescents, as well as to document regret (if any). Additionally, we undertook the study to determine if the impact was different depending on the age of the individual undergoing surgery (it was not). Finally, we wanted to determine if time on testosterone was a useful benchmark and requirement for chest surgery. Clinically we understood that chest distress actually increases with time on testosterone, so it was important to test and see if this actually was the case (it was). There is no existing data that even suggests that chest masculinizing surgery is problematic for people. To suggest that this procedure is dubious is flatly unsubstantiated.

51. In paragraph 221 of his report, Dr. Laidlaw opines that "evidence of benefit is lacking and the risks and harms due to GAT are very high." To be sure, Dr. Laidlaw may believe that the body of evidence demonstrating the benefit of gender affirming treatment is inadequate, but that does not make it true and only represents his personal opinion. As discussed in my original report, there are many studies demonstrating the safety and efficacy of gender affirming hormones, as well as GnRH analogs, to treat gender dysphoria. *See* Olson-Kennedy Report, at ¶24-41. The same is true with regards to surgery. *See*

Olson-Kennedy Report, at ¶¶42-46. By contrast, it is clear that there is no evidence that such interventions are harmful, and Dr. Laidlaw cites to none.

52. In paragraph 223 of his report, Dr. Laidlaw alludes to and references to the case of *Bell v. Tavistock* in the United Kingdom. I do not disagree that gender-affirming care, like all of medicine, should be done with great care. What the final decision in *Bell v. Tavistock* made clear, however, is that the decision making in this context should lie with the patient, family and prescribing doctor.

Dr. Hruz's Report

- 53. Similar, to Dr. Laidlaw, Dr. Hruz has no peer-reviewed publications regarding transgender individuals, either adults or youth. While he appears to have experience in the care of intersex patients, he does not have any cited experience in the clinical care of children, adolescents or adults with gender dysphoria.
- 54. In paragraph 19 of his report, Dr. Hruz speaks of "gender" as "a term that had traditionally been reserved for grammatical purposes" and that it "exist[s] only in reference to subjective personal perceptions and feelings and societal expectations, not biology." But as early as 1910, Magnus Hirschfeld described gender as the sexual organs, the other physical characteristics, sex drive, and emotional characteristics. "Gender" is thus a concept that incorporates

chromosomes, sexual organs and respective gametes (sex) as well as identity such as male or female. More importantly, the arguments made by Dr. Hruz about language do not negate the necessity for medication intervention as treatment for gender dysphoria.

In paragraph 20 of his report, Dr. Hruz states that "[t]he term 'gender 55. identity' is controversial" and that "[t]here is no current worldwide definition of 'gender identity' accepted by the relevant clinical communities." This is false. It is remarkable that Dr. Hruz consistently positions the advancement of our understanding about gender and gender dysphoria as controversial, untested and unethical when he has little to no experience clinically with treating transgender youth or even communicating with transgender youth. The term gender identity was originally coined in 1964 by American psychiatrist Robert J. Stoller, a noted psychoanalyst who studied sexual orientation, gender identity, and differences in sexual development. Gender identity is defined as a personal conception of oneself as male or female (or rarely, both or neither). The concept of gender identity is contemporaneously understood both colloquially and within the domain of science and medicine to denote someone's gender. It is a concept wellunderstood and accepted in medicine and science. Indeed, gender identity

information is commonly collected and reported on within the context of scientific research (Clayton, et al., 2016).

56. In paragraphs 57 and 58 of his report, Dr. Hruz inaccurately suggests that diagnosis of gender dysphoria is done solely through a patient's self-report. His critique demonstrates a fundamental misunderstanding of how gender affirming care is provided. While we have continued to attain a greater understanding about the etiology of gender incongruence, patients do not "selfdiagnose." However, it is not unusual or extraordinary in medicine for a provider to consider patients' reports of their symptoms as part of the medical assessment. Much like the diagnosis of many clinical conditions, providers rely on self-report to ascertain accurate diagnoses. Again, consider the diagnosis of chronic fatigue. The diagnostic criteria for this diagnosis include the following: fatigue so severe that it interferes with the ability to engage in pre-illness activities; of new or definite onset (not lifelong); not substantially alleviated by rest; worsened by physical, mental or emotional exertion. Like gender dysphoria, these diagnostic criteria are a subjective telling of an individual's personal experience. It is incumbent upon providers of gender affirming care to acquire skills that help them ascertain many details about their patient's gender experience including but not limited to the history, developmental trajectory and expectations regarding

treatment options.

57. Moreover, the provision of gender-affirming care for adolescents

primarily occurs in multi-disciplinary settings, and indeed, the Standards of Care

recommend such an approach (Chen, et al., 2016; Coleman, et al., 2022). The

multiple health providers involved, from various fields, are well trained to

conduct clinical interviews and to assess a patient's report to determine whether

they meet the diagnostic criteria for gender dysphoria.

58. In paragraph 60 of his report, Dr. Hruz discusses so-called

"reparative therapy" as a modality of treatment. However, as discussed in my

original report, "reparative therapy is both ineffective and harmful for

transgender and gender diverse youth." See Olson-Kennedy Report, at ¶¶ 14-15.

Indeed, there are no studies that I know of in which reparative therapy has

successfully changed someone's gender identity in adolescence. To posit this

mechanism as a successful mechanism to manage gender dysphoria is

unsubstantiated and shows a clear lack of understanding of the literature and

clinical experience in this field.

59. In paragraphs 61 to 64 of his report, Dr. Hruz discusses and

misrepresents the "watchful waiting" model of treatment. I describe this model

of treatment in paragraph 17 of my original report. However, it is important to note that even under the "watchful waiting" model, gender-affirming medical care is recommended and appropriate for adolescents with gender dysphoria. That is so because studies show that if gender dysphoria is present in adolescence, it usually persists (de Vries, et al., 2011).

In paragraph 63 of his report, Dr. Hruz makes the unfounded 60. assertion that "very few gender dysphoric children still want to transition by the time they reach adulthood." Dr. Hruz not only seems to misapprehend the literature pertaining to desistance but he fails to distinguish between gender diverse children and transgender children, adolescents, and adults. I discuss the desistance literature and the misrepresentations and misunderstanding of it more fully in paragraphs 52-57 of my original report. However, it is worth adding that the studies upon which Dr. Hruz relies are of predominately *pre-pubertal* youth, based on ages of the children studied. While it is possible that some of the children were in early puberty, none of these studies report Tanner staging. Additionally, in a personal communication to me, one of the authors of the Wallien study reported that some of those youth categorized as desisters returned to the center for care related to phenotypic transition after the study had concluded. Finally, in the Wallien study specifically, all of the participants who

were not available were categorized as desisters. This data was deconstructed in the manuscript: A critical commentary on follow-up studies and "desistance" theories about transgender and gender-nonconforming children (Temple, et al.,

2018).

61. Dr. Hruz's suggestion in paragraph 64 that psychological treatment

alone is effective in treating gender dysphoria is not true. Moreover, the studies

he cites for this proposition employed modalities of treatment that have been

widely critiqued as unethical. For example, Dr. Zucker (in Canada) would

instruct the parents of gender non-conforming children to ignore or even punish

their children for exhibiting or showing interest in games, toys or clothing outside

of gender stereotypical behaviors.

62. In paragraph 65 of his report, Dr. Hruz misrepresents the "gender

affirming" care model by stating that it "encourages children to embrace

transgender identity with social transitioning followed by puberty blockage and

hormonal therapy (cross-sex hormones), and potential surgical interventions."

As explained in my original report, the gender affirmative model is defined as a

method of therapeutic care that includes allowing children to express their gender

identity without fear of shame or coercion to change it, and providing support for

them to evolve into their authentic gender selves regardless of age. Support is not

characterized by "encouraging" children or youth to be transgender or not. In any event, there is little relevance to Dr. Hruz's statement as no prepubertal children are provided with medical care, and the Challenged Exclusion and this case concern Medicaid coverage of gender-affirming medical care, which is not provided to any patient until *after* the onset of puberty.

- 63. Dr. Hruz goes on to argue in the following paragraph that "underlying biology is not changed by altering bodily features to appear as the opposite sex." Hruz Report, at ¶ 66. This perspective assumes that individuals undergoing phenotypic gender transition do not know this, and that the singular goal of all humans is reproduction. Transgender individuals, including adolescents, understand they will not be able to produce gametes in alignment with their gender. While this may be challenging for some individuals, most people will choose to be perceived and walk in the world as themselves over gamete production associated with their own genetic material.
- 64. In paragraph 69, Dr. Hruz states that gender dysphoria is "unique" because it would be "the only psychiatric condition to be treated by surgery." To be clear, not every transgender individual needs or requires gender-affirming surgery, and surgery is very rare for transgender adolescents, usually limited to chest surgery for older transgender adolescent males. Moreover, Dr. Hruz

appears to be operating under the assumption that gender dysphoria is a purely psychiatric illness. But gender incongruence is a developmental trajectory, likely related to the morphology and connectivity of the brain structures. Like many developmental trajectories, it is rare. So while the distress that results from such incongruence is part of the diagnostic criteria, and suffering is a psychological state, the condition is not purely psychological, as Dr. Hruz assumes. That said, Dr. Hruz ignores that there are indeed some surgeries that are performed to address psychological disorders, such as anterior cingulotomy, subcaudate tractotomy, limbic leucotomy, and anterior capsulotomy. And if surgeries are able to bring someone's physical body into better alignment with their gender and alleviate some of their distress so that their functioning improves (which decades of research and clinical experience shows that gender affirming surgery does), it is irrelevant if it is the first time or not that surgery is being utilized to address a psychiatric condition, as Dr. Hruz assumes gender dysphoria to be.

65. In paragraph 71 of his report, while discussing puberty-delaying medications, Dr. Hruz seems to argue that providing puberty-delaying medications interferes with an adolescent's ability to develop "a gender identity corresponding to his or her biological sex." Ignoring for purposes of this paragraph the assumptions built into the use of the term "biological sex" here,

Dr. Hruz seems to exhibit a willful ignorance of the devastation that may be

caused to transgender adolescents by undergoing an unaligned puberty.

66. The concept of passing within the transgender community refers to

the ability to walk in the world and be perceived as their gender, just as it would

be for a cisgender person (those who's sex designated at birth is aligned with

their gender). While passing is critiqued within the community, it remains a

common goal of many transgender individuals who are undergoing medical

interventions. In an article entitled "Your Picture Looks the Same as My Picture":

An Examination of Passing in Transgender Communities" written by Alecia

Anderson et al., the authors posit that passing for transgender individuals serves

two primary purposes. The first is to escape violence and discrimination based

on transphobia. The second is for affirmation of gender. While not all transgender

individuals identify passing as important; for some, passing can be lifesaving.

Transgender people are identifiable as transgender when they look, dress and

behave outside of our rigid societal expectations about how men and women

should do these things.

67. Physiologic changes that result from puberty for those designated

male at birth include deepening of the voice, development of male pattern facial

and body hair, laryngeal prominence (Adam's apple), larger hands and feet and

others. While gender affirming hormones can promote breast development, soften skin, redistribute body fat and slow down body and facial hair growth, they have no impact on voice, laryngeal prominence, stature, size of hands and feet or skeleton. For those designated female at birth, shorter stature, higher voice pitch, menstruation, predominance of hip and thigh development and breast development all provide clues for someone to be perceived as female. While hormones may lower the voice and stop menstruation, there are some body features that simply cannot be altered. The use of puberty-delaying medications in early puberty followed by gender affirming hormones not only helps eliminate much of the incongruence that leads to the distress that characterizes gender dysphoria, but it also radically increases the possibility of "passing" because the development of secondary sex characteristics is avoided. The introduction of puberty-delaying medications is perhaps the most significant event in the landscape of transgender medicine since the synthesizing of exogenous hormones. This intervention spares transgender individuals from the changes of endogenous puberty that lead to significant downstream issues.

68. Dr. Hruz's assumption that "normal pubertal development will influence the gender identity of the child by reducing the prospects for developing a gender identity corresponding to his or her biological sex" has no basis in fact.

Indeed, he cites to no authority for it. But for the sake of argument, if such assumption were true, there would be no individuals who ever transition after puberty, which is actually when the majority of transgender individuals transition. Everyone who has, in adulthood, sought or required medical treatment to bring about physical changes that would bring their body into more alignment with their gender experienced their "natural" puberty, and yet, their gender identity was not aligned with their sex assigned at birth.

- 69. With regards to paragraph 75 of Dr. Hruz's report, youth experiencing gender dysphoria related to going through an unaligned puberty have many challenges, including emergence or worsening of anxiety, depression, social isolation and suicidality. These symptoms impact cognitive development and should not be dismissed for a theoretical possibility. Puberty-delaying medications can alleviate the distress related to the development of permanent secondary sex characteristics that will eventually result in someone being perceived as the incorrect gender, and in the worst cases, victimized by violence and sometimes homicide.
- 70. In paragraph 77 of his report, Dr. Hruz asks, "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." I do

not disagree that investigating all outcomes is paramount. However, the fact that a very small percentage of youth who experience gender dysphoria in adolescence later identify with their birth assigned sex (indeed, it is a very small percentage of an already very small minority), it does not follow that the rest should be denied care that has been shown to be safe and effective to treat to gender dysphoria.

71. Dr. Hruz says that scientific studies in support of treatments for gender dysphoria are of low quality. The care of transgender individuals has a long history, and cannot be equated to the sorts of things that Dr. Hruz likens it to, however, including eugenics, the Tuskegee experiments, or the relatively short phase of unlocking "repressed memories." *See* Hruz Report, at ¶109. As I explain in my original report, the care of transgender individuals has a long history and, as with *all medical care*, there is a range of quality in the existing data regarding the treatment of gender dysphoria. *See* Olson-Kennedy Report, at ¶¶ 70-72. But not only are there dozens of interdisciplinary gender clinics associated with research institutions and teaching hospitals that have been providing gender affirming care for transgender youth and adults across the United States for years, but, in 2017, Dr. Hruz's own Washington University in St. Louis opened a

Transgender Center that provides gender affirming care for children, adolescents,

and adults.

72. As Dr. Hruz notes (Hruz Report, at ¶111), one of the intrinsic

elements of rating the quality of evidence is the study design. And while

randomized controlled studies are considered the highest quality in the grading

of evidence, as I explain on my original report (Olson-Kennedy Report, at ¶¶74-

75), it is well-established that utilizing an untreated control group is unethical in

this context, where gender-affirming medical interventions have been used for

decades, resulting in a vast amount of clinical knowledge about their efficacy.

That said, we have a large de facto group of untreated individuals with gender

dysphoria who experience significant psychiatric symptoms because of

widespread barriers to access to care.

73. In the end, the safety and efficacy in medicine is not and cannot be

measured by any single study. Indeed, every study has limitations. To determine

whether a treatment is safe and effective, and whether it is experimental or

investigational, we look at the whole body of research and clinical experience.

By this measure, gender-affirming medical care as treatment for gender

dysphoria has been shown to be safe, effective, and is not experimental or

investigational.

74. As discussed in my original report, there is a multitude studies

demonstrating the safety and efficacy of gender affirming hormones, as well as

of GnRH analogs, to treat gender dysphoria. See Olson-Kennedy Report, at ¶¶24-

41. The same is true with regards to surgery. See Olson-Kennedy Report, at

¶¶42-46.

75. In paragraphs 47 and 82 of his report, Dr. Hruz makes reference to

the concept of sexually dimorphic epigenetics in discussing how people with

different genetic makeup may respond to hormone therapy. However, none of

the articles Dr. Hruz cites in paragraph 47 mention or discuss the influence of sex

steroids on the sex differential expression. Nor does Dr. Hruz offer an example

or authority for his supposition that "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." But simply because there are sexually dimorphic genes does not mean

that there are negative consequences to having one's hormone milieu adjusted.

76. In addition, in paragraph 86 of his report, Dr. Hruz says he is not

aware of any reports that show that adolescents treated with puberty-delaying

medications followed with GAH was able to preserve their fertility. I am

surprised, however, that Dr. Hruz fails to discuss a case report originating from

his own hospital and division. Indeed, providers from Washington University in Saint Louis/St. Louis Children's Hospital published a case report in 2021 of a successful case of ovarian hyperstimulation and oocyte cryopreservation in a transgender male adolescent after suppression with a gonadotropin-releasing hormone (GnRH) agonist (Martin, et al., 2021). Given that this case report originates from Dr. Hruz's own institution, one can assume that he is familiar with it and would have expected him to discuss it.

77. In paragraph 90 of his report, Dr. Hruz argues, without any support, that providers are "compelled (sometimes under fear of employment termination or legal attacks) to adopt a patient's self-diagnosis and only support 'affirming' medical interventions" and are therefore "being pressured and/or compelled to commit the scientific and medical malpractice of confirmation bias." This is false. Providers are not pressured or compelled to commit confirmation bias nor are they required to provide gender-affirming medical services at all if they have reservations or concerns about the care based on their clinical judgment. However, this statement by Dr. Hruz highlights an overarching theme with the GAPMS Memo and the reports by Defendants' designated experts, that being the overlooking of the experience of the providers of gender-affirming care.

and judgment, as well as utilizing existing data, to help make recommendations

for patients and their families. However, this is completely ignored by

Defendants and their experts.

78. Without any citation or support, Dr. Hruz opines in paragraph 91 of

his report that "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." Not only is Dr. Hruz's offensive opinion unfounded, but

it is also false. There is so much clarity in the WPATH SOC 8 about the

qualifications of providers making a diagnosis of gender incongruence/gender

dysphoria. The recommendations from WPATH regarding the qualifications of

healthcare providers assessing adolescents are as follows:

Statements of Recommendations

6.1- We recommend health care professionals working with gender diverse

adolescents:

6.1.a- Are licensed by their statutory body and hold a postgraduate degree or

its equivalent in a clinical field relevant to this role granted by a

nationally accredited statutory institution.

- 6.1.b- Receive theoretical and evidenced-based training and develop expertise in general child, adolescent, and family mental health across the developmental spectrum.
- 6.1.c- Receive training and have expertise in gender identity development, gender diversity in children and adolescents, have the ability to assess capacity to assent/consent, and possess general knowledge of gender diversity across the life span.
- 6.1.d- Receive training and develop expertise in autism spectrum disorders and other neurodevelopmental presentations or collaborate with a developmental disability expert when working with autistic/neurodivergent gender diverse adolescents.
- 6.1.e- Continue engaging in professional development in all areas relevant to gender diverse children, adolescents, and families.
- 6.2- We recommend health care professionals working with gender diverse adolescents facilitate the exploration and expression of gender openly and respectfully so that no one particular identity is favored.
- 6.3- We recommend health care professionals working with gender diverse adolescents undertake a comprehensive biopsychosocial assessment of adolescents who present with gender identity-related concerns and seek medical/surgical transition-related care, and that this be accomplished in a collaborative and supportive manner.

- 6.4- We recommend health care professionals work with families, schools, and other relevant settings to promote acceptance of gender diverse expressions of behavior and identities of the adolescent.
- 6.5- We recommend against offering reparative and conversion therapy aimed at trying to change a person's gender and lived gender expression to become more congruent with the sex assigned at birth.
- 6.6- We suggest health care professionals provide transgender and gender diverse adolescents with health education on chest binding and genital tucking, including a review of the benefits and risks.
- 6.7- We recommend providers consider prescribing menstrual suppression agents for adolescents experiencing gender incongruence who may not desire testosterone therapy, who desire but have not yet begun testosterone therapy, or in conjunction with testosterone therapy for breakthrough bleeding.
- 6.8- We recommend health care professionals maintain an ongoing relationship with the gender diverse and transgender adolescent and any relevant caregivers to support the adolescent in their decision-making throughout the duration of puberty suppression treatment, hormonal treatment, and gender- related surgery until the transition is made to adult care.
- 6.9- We recommend health care professionals involve relevant disciplines, including mental health and medical professionals, to reach a decision about whether puberty suppression, hormone initiation, or gender-related surgery for gender

diverse and transgender adolescents are appropriate and remain indicated throughout the course of treatment until the transition is made to adult care.

- 6.10- We recommend health care professionals working with transgender and gender diverse adolescents requesting gender-affirming medical or surgical treatments inform them, prior to initiating treatment, of the reproductive effects including the potential loss of fertility and available options to preserve fertility within the context of the youth's stage of pubertal development.
- 6.11- We recommend when gender-affirming medical or surgical treatments are indicated for adolescents, health care professionals working with transgender and gender diverse adolescents involve parent(s)/guardian(s) in the assessment and treatment process, unless their involvement is determined to be harmful to the adolescent or not feasible.

The following recommendations are made regarding the requirements for gender-affirming medical and surgical treatment (All of them must be met):

- 6.12- We recommend health care professionals assessing transgender and gender diverse adolescents only recommend gender-affirming medical or surgical treatments requested by the patient when:
 - 6.12.a- The adolescent meets the diagnostic criteria of gender incongruence as per the ICD-11 in situations where a diagnosis is necessary to access health care. In countries that have not implemented the latest ICD, other taxonomies may be used although efforts should be undertaken to utilize the latest ICD as soon as practicable.

- 6.12.b- The experience of gender diversity/incongruence is marked and sustained over time.
- 6.12.c- The adolescent demonstrates the emotional and cognitive maturity required to provide informed consent/assent for the treatment.
- 6.12.d- The adolescent's mental health concerns (if any) that may interfere with diagnostic clarity, capacity to consent, and gender-affirming medical treatments have been addressed.
- 6.12.e- The adolescent has been informed of the reproductive effects, including the potential loss of fertility and the available options to preserve fertility, and these have been discussed in the context of the adolescent's stage of pubertal development.
- 6.12.f- The adolescent has reached Tanner stage 2 of puberty for pubertal suppression to be initiated.
- 6.12.g- The adolescent had at least 12 months of gender-affirming hormone therapy or longer, if required, to achieve the desired surgical result for gender-affirming procedures, including breast augmentation, orchiectomy, vaginoplasty, hysterectomy, phalloplasty, metoidioplasty, and facial surgery as part of gender-affirming treatment unless hormone therapy is either not desired or is medically contraindicated.

Dr. Hruz goes on to conclude his critique by stating that "[t]here is no biological test to verify the diagnosis," as if this was a reason not to cover this medically

necessary care. This is misguided for the same reasons articulated above with

regards to Dr. Laidlaw.

79. Finally, like Dr. Laidlaw, Dr. Hruz takes issue with the overlap in

authorship between the WPATH SOC and the Endocrine Society Guidelines. But

as noted above, expertise within a field does not represent a conflict of interest.

Dr. Biggs's Report

80. Dr. Biggs is a sociologist with absolutely no experience with the

provision gender-affirming care. While he appears to have published some letters

to the editor, he has not conducted any original research relating to gender

dysphoria nor published any peer-reviewed studies. Rather Dr. Biggs appears to

be an individual with no expertise, training, or experience in this field who has

made it his mission to stop transgender people from being able to access gender-

affirming medical care. Nonetheless, below I respond to some of the most

problematic aspects of Dr. Biggs's "expert" report.

81. In paragraph 7 of his report, Dr. Biggs states that "puberty

suppression for gender dysphoria entails stopping normal puberty in order to

prepare the child for taking hormones of the opposite sex." This is not the reason

for GnRHa use in this context. The use of GnRHa is to pause puberty for a variety

of reasons, including time for gender consolidation which may or may not be

followed by gender affirming hormone treatment, and in order to avoid having

the dysphoric adolescent from having to undergo a puberty incongruent with their

gender, which may lead to substantial distress and additional negative effects.

82. In paragraph 12 of his report, Dr. Biggs asserts, in reference to our

multi-site study, that "practitioners of gender medicine are curiously reluctant to

publish the outcomes of puberty suppression for psychological functioning and

gender dysphoria—even though those outcomes were the primary justification

for the treatment." This is patently false. We are not at all reluctant to publish

outcome data, analysis of data takes time and expertise. Our grant funding was

cut by 40% which left us with very limited biostatistical support. This is why the

publishing of data in our study has been slow. In fact, we just published a study

documenting the positive effects of GAH in adolescents and noted within that

paper what we are in the process of analyzing the data pertaining to the use of

GnRHa (Chen, et al., 2023).

83. In paragraph 14, Dr. Biggs asserts that "Children on the autistic

spectrum are more likely to face difficulties fitting in with their same-sex peers,

which makes a transgender identity obviously appealing as both an explanation

and a solution." Dr. Biggs cites to no authority in support of his statement. This

unsubstantiated claim is wild at best, and significantly damaging at worst. It is

equally likely that lack of societal pressure leaves individuals more room to express a gender not aligned with sex assigned at birth. The fact that there is a considerable overlap of autism spectrum disorder and gender dysphoria does not mean that assuming a transgender identity is a work around for difficulty fitting in with peers.

- 84. In paragraph 16 of his report, Dr. Biggs expounds about the distinction between suicidal ideation and suicide attempts. This distinction is known to all in adolescent work. Regardless of how the adolescent intends the suicidal thoughts to land (cry for help or intent to die) it is paramount to respond to this distress. I am not certain why Dr. Biggs is working so hard to convince the world that transgender youth are not really suicidal, while simultaneously criticizing the two suicide deaths in our own study as astronomical. Of course, suicidal ideation by an adolescent should be of concern to any provider and a clear sign of the intense distress experienced by the adolescent.
- 85. In paragraph 19 of his report, Dr. Biggs asserts that "[t]he elevated suicide rate of children who identify as transgender could be explained by some combination of gender dysphoria, accompanying psychological conditions, and ensuing social disadvantages such as bullying." Unfortunately, it seems Dr. Biggs has no comprehension of the level of transphobia that exists in our society

and the impact it has on transgender people, nor of the interconnectedness

between lack of access of gender-affirming care and some of these other stressors

(see discussion about passing above).

86. There is absolutely zero data to support Dr. Biggs's claim that "the

elevated suicide rate for transgender youth compared to their peers reflects the

higher incidence of ASC [(autism spectrum conditions)]." (Biggs Report, at

¶19). I am aware of no data linking the numbers of reported suicides being related

to ASD.

87. In paragraph 20 of his report, Dr. Biggs opines that "[b]ecause the

risk of suicide increases greatly from prepubescence to late adolescence, halting

normal cognitive and emotional development with GnRHa could reduce the risk

of suicide by preventing the child from maturing." This ignores that most young

people who present for GnRHa as treatment for gender dysphoria have relatively

good mental health at baseline and by definition, have supportive parents or

guardians. The suicide rate in youth on GnRH analogs is very low, but this is

likely related to the fact that they are supported and are not anticipating

progressing through the wrong puberty. To assert that this is related to pausing

someone's endogenous puberty and therefore their cognitive age does not match

their chronologic age is the way someone might interpret this if they had no

experience in the field, like Dr. Biggs.

88. In paragraph 23 of his report, Dr. Biggs discusses some "drugs used

in Britain." But this is indicative of Dr. Biggs's lack of familiarity with this care,

particularly in the United States. In fact, the medications to which he refers are

not used in the United States, so this information is entirely irrelevant here.

89. In paragraph 26 of his report, Dr. Biggs asserts that "children given

GnRHa already have unusually low bone density, perhaps due to the high

prevalence of eating disorders." He cites no authority or source for this assertion

and I struggle to see why he is making this connection between GnRHa and eating

disorders, when there is no evidence or research linking the two.

90. In paragraph 27 of his report, Dr. Biggs cites a newspaper article as

anecdotal evidence that transgender adolescent "who started GnRHa at age 12

then experienced four broken bones by the age of 16." For one, Dr. Biggs

misgenders the young person in question. The young person described in this

media article is referred to as male, and clearly is not identifying as his sex

assigned at birth (female). And the young person bemoans not having a flat chest

and low voice. For another, the media article described here does not share many

important details about this young person's medical history. For example, what

was his bone density? Were his fractures traumatic? If one is to make a claim attributing broken bones to GnRH analogs, these data points are critical. Also interestingly, this young person suffered from not undergoing male puberty along with his peers. This is one of the primary reasons why we consider using genderaffirming hormones in patients who are in the adolescent age range.

91. In paragraph 28 of his report, Dr. Biggs makes reference to a statement by Dr. Marci Bowers. Dr. Bowers addressed this statement by her at WPATH's 2022 Conference. She acknowledged in a surgical workshop about vaginoplasties in girls who had received blockers that "I went back and counted. It was actually about half who had not achieved orgasm." The issues surrounding self-pleasure in girls who received puberty blockers in early in puberty are more complex than the idea put forth here by Dr. Biggs. I am wondering if he himself has ever had a conversation with a patient who had blockers in early puberty? I have had many such conversations. In fact, many of my patients have negative thoughts and feelings about experiencing sexual pleasure with the genitals they are born with. This is related to several factors. First, most transgender girls have been misgendered their whole lives because of their genitals. This has a proclivity to create an adversarial relationship with their genitals. Second, there are many transgender girls who feel like masturbation would make them "less of a girl." Some are simply reviled by their genitals. Some girls have heard incorrect information: that masturbation and ejaculation raise testosterone levels. It is incumbent upon professionals doing this work to be able to have sensitive conversations with patients about these issues. Dr. Biggs leans on two references here, the assertion of Dr. Bowers (which she significantly amended) and one article about one patient. His information simply is not representative of the literature or experience of clinicians who provide this care.

92. Finally, in paragraph 30 of his report, Dr. Biggs asserts that "[t]he suspicion is that puberty suppression reinforces gender dysphoria." Again, Dr. Biggs overlooks the fact that gender affirming hormones are a natural progression of care for adolescents with gender dysphoria. To suggest that GnRHa's are a "gateway drug" is completely unsubstantiated.

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

Executed this 9th day of March 2023.

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

Exhibit C Supplemental Bibliography

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

AUGUST DEKKER, et al.,

Plaintiffs,

v.

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

JASON WEIDA, et al.,

Defendants.

EXPERT REBUTTAL REPORT BY LOREN S. SCHECHTER, M.D.

Preliminary Statement

- 1. I have been retained by counsel for the Plaintiffs as an expert in the above-captioned lawsuit. I previously submitted an expert witness report ("Schechter Rep.") in connection with this case.
- 2. I submit this rebuttal report to respond to points raised in the reports of two of Defendants' retained experts, Patrick W. Lappert, M.D. and Michael K. Laidlaw, M.D.
- 3. My background, qualifications, and compensation for my services in this case are described in my original report. In my original report, I

inadvertently omitted that I also provided expert testimony in *C.P. v. Blue Cross Blue Shield*, W.D. Wash (deposition) within the last four years.

- 4. In preparing this rebuttal report, I reviewed the Expert Report of Patrick W. Lappert, M.D., with attachments, and the Expert Report of Michael K. Laidlaw, M.D., with attachments.
- 5. My opinions contained in this rebuttal report are based on: my professional experience, as set forth in my curriculum vitae (attached as Exhibit A to my original report); the materials included in the reference list attached as Exhibit B to my original report and the case-specific materials included in paragraph 18 of my original report; and the additional research and materials cited in the footnotes of this report and included in the supplemental reference list attached as Exhibit C.
- 6. Both Drs. Lappert and Laidlaw do not accept that gender dysphoria is a valid medical diagnosis. *See* Schechter Rep. ¶ 20. Because they do not accept gender dysphoria as a diagnosis, it is no surprise that Drs. Lappert and Laidlaw disagree that surgery is an appropriate reconstructive treatment. But their views on the appropriateness of surgery and other medical interventions to treat gender dysphoria fall far outside of the medical mainstream and are not supported by evidence.

Dr. Lappert

American Plastic Surgery Society Levels of Evidence

- 7. Dr. Lappert discusses the American Society of Plastic Surgeons Levels of Evidence, as well as the peer review process, extensively. *See* Lappert Rep. ¶¶ 24-28, 56-57. He suggests that with only Level IV and V peer-reviewed studies supporting gender affirming surgical procedures, these surgeries are not established as safe, effective, or accepted. *See* Lappert Rep. ¶¶ 55-67. This discussion has a number of flaws. First, Dr. Lappert ignores the Level III literature on gender affirming surgical care.¹
- 8. Second, as I described in my prior report, there are practical and ethical limitations on conducting studies in clinical medicine, especially in surgery. It is difficult, if not impossible, to conduct Level I or II studies in this context. *See* Schechter Rep. ¶¶ 52-53. But Dr. Lappert is wrong to contend that studies with lower levels of evidence are not useful to inform clinical decision making. In fact, Dr. Lappert has recognized the value of such studies. In 1998, he published a single case report (Level V) detailing the endoscopic repair of a

¹ See, e.g., Ascha, M. et al. (2022). Top Surgery and Chest Dysphoria Among Transmasculine and Nonbinary Adolescents and Young Adults. JAMA Pediatrics, 176(11): 1115-1122, doi:10.1001/jamapediatrics.2022.3424; Massie, J.P. et al. (2018). Predictors of Patient Satisfaction and Postoperative Complications in Penile Inversion Vaginoplasty. Plastic and Reconstructive Surgery, 141(6): 991e-921e, doi: 10.1097/PRS.00000000000004427.

frontal sinus fracture.² He stated: "This case demonstrates the safety, efficacy, and economy of the endoscopic technique in properly selected cases."³

- 9. Dr. Lappert focuses on the evolution of treatment for gastric ulcers to support his claims that using Level IV and V evidence to support surgical treatment "can result in grave missteps." Lappert Rep. ¶ 29. But as Dr. Lappert notes, once Level I and II studies demonstrated that gastric ulcers could be treated with medications, the standard of care changed. This is common in medicine. As the research and clinical evidence evolves, treatment evolves in turn. For example, we previously counseled patients that the only way to lose weight was through dietary changes. Now, we use surgical interventions, such as bariatric surgery, to treat obesity in certain situations.
- 10. Third, and relatedly, Dr. Lappert ignores that the quality of the evidence supporting gender affirming surgeries is similar to that supporting many common plastic surgeries, as I previously discussed. *See* Schechter Rep. ¶ 54. Outside the field of plastic surgery, many common and generally accepted

² Lappert, P.W. & Lee, J.W. (1996). Treatment of an Isolated Outer Table Frontal Sinus Fracture Using Endoscopic Reduction and Fixation. Plastic and Reconstructive Surgery, 102(5): 1642-5.

³ *Id.* at 1644.

⁴ See, e.g., Sugrue, C.M. et al. (2019). Levels of Evidence in Plastic and Reconstructive Surgery Research: Have We Improved Over the Past 10 Years? Plastic and Reconstructive Surgery Global Open, 7(9): e2408, doi: 10.1097/GOX.000000000002408.

medical treatments are not supported by higher level studies. One recent article concluded that "only a minority of outcomes for health care interventions are supported by high-quality evidence."⁵

based on their duration, *see* Lappert Rep. ¶¶ 101, 58 (claiming that a follow-up period of 4 to 7 years is insufficient), a three-year follow-up period is used and is sufficient to understand most acute surgical complications, and a five-year follow-up period is often used in studies of cancer treatments. And, as I previously described, the 2011 study by Dhejne et al., which Dr. Lappert holds up as a model long-term study, *see* Lappert Rep. ¶ 103, does not show that gender confirming surgeries are not effective. *See* Schechter Rep. ¶ 74. In fact, the authors of the article start from the premise that gender affirming surgery "has been practised for more than half a century and is the internationally recognized treatment to ease gender dysphoria."

⁵ Howick, J. et al., (2020). The quality of evidence for medical interventions does not improve or worsen: a metaepidemiological study of Cochrane reviews. J. Clin. Epidemiology, 126: 154-159, doi: 10.1016/j.jclinepi.2020.08.005.

⁶ Dhejne, C. et al. (2011). Long-Term Follow-Up of Transsexual Persons Undergoing Sex Reassignment Surgery: Cohort Study in Sweden; PLOS One, 6(2): e16885, doi: 10.1371/journal.pone.0016885 (noting that the design of the existing studies is reasonable given the nature of the surgery and that the studies suggest that surgery does improve quality of life and gender dysphoria).

Reconstructive Surgeries

- 12. Dr. Lappert goes to great pains to try to explain why gender affirming surgery is cosmetic, as opposed to reconstructive. However, none of his arguments is persuasive.
- 13. First, he contends that gender affirming surgery is cosmetic because it does not restore form or function that has been lost. *See* Lappert Rep. ¶ 44-45, 49-50. But, as I previously described, that distinction between reconstructive and cosmetic surgery simply does not hold up. *See* Schechter Rep. ¶¶ 35, 72.
- 14. Second, he wrongly suggests that gender confirming surgeries are cosmetic "because the patient is physically healthy before the surgery." Lappert Rep. ¶ 107. Of course, patients who have a genetic predisposition to cancer often undergo risk-reduction mastectomies and/or salpingo-oophorectomies even though the relevant tissue is "healthy." In addition, healthy individuals undergo surgery to donate a kidney or a portion of their liver to a person in need of a transplant. And again, Dr. Lappert misunderstands the condition of gender dysphoria. As I previously explained, it is the underlying diagnosis that distinguishes a reconstructive procedure from a cosmetic one. Schechter Rep. ¶¶ 31-32. Gender affirming surgery is considered medically necessary, reconstructive surgery when performed in accordance with the WPATH

Standards of Care because it is clinically indicated to treat the underlying diagnosis of gender dysphoria. While patients with gender dysphoria may be healthy in other respects, they have a real medical diagnosis for which surgery is indicated. This is no different from someone who is healthy but for their condition of appendicitis. The fact that they have no other ailments does not mean that an appendectomy is contraindicated. When a surgeon sees a patient for a particular condition, it is common for the surgeon to report that the patient "is otherwise healthy."

15. Third, Dr. Lappert incorrectly contends that gender affirming surgery must be cosmetic because studies of the treatment use "quality of life" as a measure of success. Lappert Rep. ¶¶ 48, 58. He ignores that studies of gender affirming surgery look at other outcomes as well.⁷ And, studies of procedures that Dr. Lappert would classify as reconstructive or medically necessary regularly use quality of life as a measure of success.⁸

⁷ See, e.g., Ascha, M. et al., *supra* note 1; Lane, M. et al. (2023). Gender Affirming Mastectomy Improves Quality of Life in Transmasculine Patients. Annals of Surgery, 277(3): e725-e729, doi:10.1097/SLA.000000000005158.

⁸ See, e.g., Fortunato, L. et al. (2021). Regret and Quality of Life After Mastectomy With or Without Reconstruction. Clinical Breast Cancer, 21(3): 162-169, doi: 10.1016/j.clbc.2019.11.005. ("Quality of life (QoL) issues are particularly relevant, currently, because breast cancer is a curable disease in most cases, and a long-term survival can be anticipated for the majority of the affected women."); Santosa, K.B. et al. (2018). Long-term Patient-Reported Outcomes in Postmastectomy Breast Reconstruction. JAMA Surgery, 153(10): 891-899, doi: 10.1001/jamasurge.2018.1677; Stavrou, D. et al. (2014). Health

16. Ultimately, Dr. Lappert classifies gender affirming procedures as cosmetic because he does not believe that gender dysphoria is a valid diagnosis for which surgery could ever be necessary, pointing to the lack of "objective" tests for the condition. Lappert Rep. ¶¶ 32, 53-55, 76, 107; see also id. ¶ 82 (stating that the condition of a cancer patient "is far more grievous" than the condition of a person with gender dysphoria). That belief conflicts with the consensus of the medical community. Schechter Rep. ¶¶ 24-27, 70. Moreover, despite Dr. Lappert's assertion that a "claim of consensus insists on an absence of important controversy surrounding the use of social, medical, and surgical gender affirmation, particularly with regard to the young," Lappert Rep. ¶ 33, he has not shown the existence of any such important controversy. The fact that a handful of doctors are opposed to providing any medical treatment for the condition does not mean that the treatment is not generally accepted. Rather, as I previously explained, the broader medical community has recognized that gender confirming surgeries are standard, appropriate, and often necessary treatments for adults and adolescents with gender dysphoria. See Schechter Rep. ¶ 27.

related quality of life in burn patients – a review of the literature. Burns, 40(5): 788-796, doi: 10.1016/j.burns.2013.11.014.

Informed Consent and Mental Health

17. It is not uncommon for patients needing surgery for a wide variety of conditions to have been diagnosed with mental health conditions; this includes transgender patients. Dr. Lappert claims that patients with mental health conditions that can "provoke the patient to acts of self-harm, or to suicidal ideation" cannot consent to surgery of any kind. Lappert Rep. ¶¶ 68-69. But patients with mental health conditions that can lead to self-harm or suicidal ideation regularly and appropriately consent (and assent, as described below) to surgical care. Generally, these conditions do not prevent patients from understanding the procedure, the risks and complications of the procedure, and the benefits that they can reasonably expect to achieve from surgery. Rather, in some cases, surgeons and their colleagues will work with patients in a capacity referred to as "prehabilitation" to address mental health conditions and psychosocial considerations that could impact surgical results. The WPATH Standards of Care are consistent with that approach. See Schechter Rep. ¶¶ 61-62.

⁹ See Durrand, J. et al. (2019). Prehabilitation. Clin. Med., 19(6): 458-64, doi: 10.7861/clinmed.2019-0257.

- 18. What is more, Dr. Lappert is wrong to suggest that if a patient is not engaging in self-harm or does not have suicidal ideation, then gender affirming surgery is not indicated or necessary. See Lappert Rep. ¶ 71. Surgery is indicated to alleviate gender dysphoria. The primary indication for gender affirming surgery is not a treatment for depression or anxiety, although these conditions may also improve following surgery. See Schechter Rep. ¶¶ 31-32. Certainly, if gender dysphoria is not adequately treated, it can lead to self-harm, suicide attempts, and suicide. However, it does not follow that providers withhold effective treatment for gender dysphoria until patients are experiencing these severe harms.
- 19. Dr. Lappert also misunderstands the informed consent process for minors, claiming they "by definition are not competent to consent." Lappert Rep. ¶ 70. When individuals under age 18 seek any surgery, including gender affirming surgery, it is their parent or guardian that must provide informed consent. Of course, the adolescent must also assent to gender confirming surgery. *See* Schechter Rep. ¶ 61.
- 20. In addition, Dr. Lappert misconstrues the process for determining if surgery is necessary for a particular patient, incorrectly suggesting that surgery is provided to young people on-demand. Lappert Rep. ¶ 76. To the contrary, the

Standards of Care recommend that health practitioners "undertake a comprehensive biopsychosocial assessment of adolescents who present with gender identity-related concerns and seek medical/surgical transition-related care." ¹⁰ In addition, the Standards of Care emphasize the importance of taking a multidisciplinary approach when determining if surgery is necessary for adolescents. ¹¹

21. Finally, Dr. Lappert ignores that once a diagnosis is established, treatment then depends on a discussion with the patient. For example, while Dr. Lappert references complex oropharyngeal reconstruction, *see* Lappert Rep. ¶ 78, he fails to acknowledge that there are other methods for treating and/or reconstructing this complex defect, as there are other techniques for reconstructing genitalia to treat gender dysphoria. Thus, while Dr. Lappert may be describing his preferred approach to patient care, that approach does not reflect the clinical reality of medicine in 2023.

¹⁰ Coleman, E. et al. (2022). Standards of Care for the Health of Transgender and Gender Diverse People, Version 8. Int'l J. of Transgender Health, 23: S1-S259, S50 doi: 10.1080/26895269.2022.2100644.

¹¹ *Id.* at S56-57, S133.

Dr. Laidlaw

- 22. Dr. Laidlaw is not a surgeon. Not only does he not perform gender affirming surgery, but he does not even refer transgender patients for gender affirming surgery. *See* Laidlaw Rep. ¶ 310. His report reveals his lack of expertise in this area of medicine.
- 23. Dr. Laidlaw makes several inaccurate or incomplete statements about "what any surgery can and cannot accomplish." Laidlaw Rep. ¶ 162. Dr. Laidlaw claims that "[i]n its basic form, surgery is subtractive." Laidlaw Rep. ¶ 163. Of course, that statement ignores the entire discipline of reconstructive surgery. *See* Schechter Rep. ¶¶ 35, 72.
- 24. While Dr. Laidlaw goes on to recognize the existence of reconstructive surgery, explaining that sometimes "a diseased tissue or organ is removed so that a foreign replacement part may be substituted for an unhealthy organ or tissue," Laidlaw Rep. ¶ 164, that statement is likewise far too simplistic. He ignores that surgeons often perform risk-reduction mastectomies and/or salpingo-oophorectomies in patients who do not have cancer, but have a genetic predisposition to cancer. In addition, some reconstructive surgeries do not involve the removal of tissue or an organ. For example, surgeons perform procedures to reconstruct structures that have been absent since birth.

- 25. Finally, Dr. Laidlaw claims that "surgery cannot de novo create new organs." Laidlaw Rep. ¶ 165. Here, Dr. Laidlaw ignores that surgeons regularly perform organ transplants, effectively giving the recipient a new organ, and that certain artificial organs, including artificial hearts and ventricular assist devices, have been used for decades.
- 26. His more specific claims about mastectomy and genital surgeries suffer from similar flaws. Dr. Laidlaw highlights the potential complications of mastectomy, vaginoplasty, and phalloplasty. Laidlaw Rep. ¶ 167, 171, 175. First, he fails to acknowledge that the risks he describes are equally present when the procedures are performed to treat conditions other than gender dysphoria. As I explained in my prior report, surgeons regularly perform mastectomies and genital reconstructive surgeries to treat a range of conditions. See Schechter Rep. ¶¶ 37-38. Second, some of what he describes as "complications" are not in fact seen as complications by surgery patients. For example, he emphasizes that mastectomy "results in a permanent loss of the ability to breastfeed." Laidlaw Rep. ¶ 167-168. While that is true, not every person with breasts can or wants to have a child, much less to breastfeed a child. Like Dr. Lappert, Dr. Laidlaw appears to have little regard for a patient's values, preferences, choices, and autonomy. See Schechter Rep. ¶ 71.

Conclusion

27. In sum, not all people with gender dysphoria need, want or are candidates for surgery. However, in appropriately-identified and prepared people, surgery is safe, effective, and medically necessary. See Schechter Rep. ¶ 81-82. As with all areas of medicine and surgery, clinicians and researchers continue to refine surgery, including techniques, timing, patient selection, and outcome measures. Such discussions are reasonable. However, a categorical exclusion of coverage for gender affirming surgery is clearly not supported by the evidence, professional medical consensus, or my professional experience.

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

Executed this ______day of March, 2023.

Loren-S. Schechter, M.D.

Exhibit C

Supplemental References

Supplemental References

- 1. Ascha, M. et al. (2022). Top Surgery and Chest Dysphoria Among Transmasculine and Nonbinary Adolescents and Young Adults. JAMA Pediatrics, 176(11): 1115-1122, doi:10.1001/jamapediatrics.2022.3424.
- 2. Coleman, E. et al. (2022). Standards of Care for the Health of Transgender and Gender Diverse People, Version 8. Int'l J. of Transgender Health, 23: S1-S259, S50 doi: 10.1080/26895269.2022.2100644.
- 3. Dhejne, C. et al. (2011). Long-Term Follow-Up of Transsexual Persons Undergoing Sex Reassignment Surgery: Cohort Study in Sweden; PLOS One, 6(2): e16885, doi: 10.1371/journal.pone.0016885.
- 4. Durrand, J. et al. (2019). Prehabilitation. Clin. Med., 19(6): 458-64, doi: 10.7861/clinmed.2019-0257.
- 5. Fortunato, L. et al. (2021). Regret and Quality of Life After Mastectomy With or Without Reconstruction. Clinical Breast Cancer, 21(3): 162-169, doi: 10.1016/j.clbc.2019.11.005.
- 6. Howick, J. et al., (2020). The quality of evidence for medical interventions does not improve or worsen: a metaepidemiological study of Cochrane reviews. J. Clin. Epidemiology, 126: 154-159, doi: 10.1016/j.jclinepi.2020.08.005.
- 7. Lane, M. et al. (2023). Gender Affirming Mastectomy Improves Quality of Life in Transmasculine Patients. Annals of Surgery, 277(3): e725-e729, doi:10.1097/SLA.000000000005158.
- 8. Lappert, P.W. & Lee, J.W. (1996). Treatment of an Isolated Outer Table Frontal Sinus Fracture Using Endoscopic Reduction and Fixation. Plastic and Reconstructive Surgery, 102(5): 1642-5.

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- 10. Santosa, K.B. et al. (2018). Long-term Patient-Reported Outcomes in Postmastectomy Breast Reconstruction. JAMA Surgery, 153(10): 891-899, doi: 10.1001/jamasurge.2018.1677
- 11. Stavrou, D. et al. (2014). Health related quality of life in burn patients a review of the literature. Burns, 40(5): 788-796, doi: 10.1016/j.burns.2013.11.014.
- 12. Sugrue, C.M. et al. (2019). Levels of Evidence in Plastic and Reconstructive Surgery Research: Have We Improved Over the Past 10 Years? Plastic and Reconstructive Surgery Global Open, 7(9): e2408, doi: 10.1097/GOX.000000000002408.

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

AUGUST DEKKER, et al.,

Plaintiffs,

v.

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

JASON WEIDA, et al.,

Defendants.

EXPERT REBUTTAL DECLARATION OF ARMAND H. MATHENY ANTOMMARIA, MD, PhD

- I, ARMAND H. MATHENY ANTOMMARIA, MD, PhD, have been retained by counsel for the plaintiffs in connection with the above-captioned litigation.
- 1. I have actual knowledge of the matters stated in this rebuttal report and declaration and have collected and cited relevant literature concerning the issues that arise in this litigation in the body of this report. I herein refer to my initial expert report and declaration in this matter as "Antommaria Report."
- 2. If called to testify in this matter, I would do so truthfully and based on my expert opinions.
- 3. I reviewed the reports of the defendants' experts Michael Biggs, PhD, G. Kevin Donovan, MD, MA, Paul W. Hruz, MD, PhD, Kristopher Kaliebe, MD, Michael K. Laidlaw, MD, Patrick W. Lappert, MD, Stephen B. Levine, MD, Sophie

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Scott, PhD, and Joseph Zanga, MD (referred to herein by the author's last name and "Report").

- 4. I respond in this report to some of those reports' the central points. I do not specifically address each study or article cited in putative support of the points. I instead explain the overall problems with the author's arguments and conclusions, and, in response, provide information showing why such conclusions are in error. I reserve the right to supplement my opinions, if necessary, as this matter proceeds.
- 5. In preparing this report, I reviewed again the text of General Medicaid Policy Rule 59G-1.050 at issue in this matter, as well as "Florida Medicaid: Generally Accepted Professional Medical Standards Determination on the Treatment of Gender Dysphoria" and all related attachments. I also relied on my education and training, my research experience, and my knowledge of the literature in the pertinent fields.
- 6. The materials I have relied on in preparing this rebuttal report are the kinds of materials that experts in my fields of study and practice regularly rely on when forming opinions on these subjects. I may wish to supplement these opinions or the bases for them because of new research or publications or in response to statements and issues that may arise in my areas of expertise.

INDIVIDUALS WHO PROVIDE GENDER-AFFIRMING MEDICAL CARE DO NOT HAVE INHERENT CONFLICTS OF INTEREST

- 7. Defendants' experts characterize Plaintiffs' experts and those who provide gender-affirming medical care as biased. They attempt to position themselves and those who never have or never will provide gender-affirming medical care as unbiased observers whose opinions are deserving of more credibility. Donovan Report p. 4; Kaliebe Report p. 66-67; Lappert Report p. 8.
- 8. Dr. Donovan, for example, states, "it is difficult for one whose professional reputation and financial compensation has depended heavily on a single diagnosis to maintain sufficient distance to render a completely unbiased opinion about it." Donovan Report p. 4.
- 9. Medical professionals performing research, developing clinical practice guidelines, or providing expert testimony within their clinical specialty is not unique to gender-affirming medical care. This assertion also ignores the various mechanisms within the medical profession to manage potential sources of bias.
- 10. Cardiologists (doctors who evaluate and treat patients for heart and blood vessel conditions) perform cardiology research and write cardiology clinical practice guidelines and oncologists (doctors who evaluate and treat patients for cancer) do the same in oncology. It is not clear who else the defendants' experts think would conduct the research or develop the clinical practice guidelines if not the professionals routinely evaluating and treating the relevant patient groups.

- 11. Medicine has multiple mechanisms to address potential bias and conflicts of interest. National Institutes of Health grant applications undergo peer review by scientific review groups and advisory councils or boards. Medical and scientific journals require authors to disclose potential conflicts of interest and submit manuscripts to peer review. Professional medical organizations also require those developing clinical practice guidelines and policy statements to disclose potential conflicts of interest and have processes for managing potential conflicts. In these ways potential biases are constrained.
- 12. Dr. Donovan characterizes himself as an unbiased observer stating, "none of my opinions are biased by my professional income being generated by these activities nor by my professional reputation relying primarily on these diagnoses." Donovan Report p. 4. Dr. Donovan, however, is not performing this work *pro bono* and is instead being compensated for his work at a rate of \$350 per hour. Donovan Report p. 4.

¹ NIH. Grants & funding: Peer Review. October 24, 2021. Accessed February 28, 2023. Available at https://grants.nih.gov/grants/peer-review.htm.

² See, for example, AAP Publications: Pediatrics: Author Instructions: Publication Ethics. March 11, 2022. Accessed February 28, 2023. Available at https://publications.aap.org/pediatrics/pages/author-instructions?autologincheck=redirected#publication ethics.

³ See, for example, American Academy of Pediatrics. Evidence-Based Clinical Practice Guidelines: Development and Implementation Manual. November 10, 2019. Accessed February 28, 2023. Available at https://downloads.aap.org/DOCCSA/CPGManual20190628.pdf.

GENDER DYSPHORIA IS A RELIABLE MEDICAL DIAGNOSIS

- 13. The defendants' experts assert that gender-dysphoria is an unreliable diagnosis because it is solely based on individuals' self-reported symptoms⁴ and cannot be confirmed by a diagnostic test.⁵
- 14. Dr. Hruz, for example, states "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." Hruz Report, p. 31.
- 15. As stated in my initial report, there are other common medical diagnoses, such as migraine headache, which rely on individuals' self-report of their symptoms and do not have confirmatory laboratory or radiographic tests. Antommaria Report p. 26-27. Dr. Laidlaw asserts that this comparison is "faulty" but he either misunderstands or misrepresents it. Laidlaw Report p. 66.
- 16. For, example, Dr. Laidlaw states that, "migraine headaches are a neurological condition with a potential vascular component and not a condition of the mind, nor found as a psychological diagnosis in the DSM-5." Laidlaw Report p. 66. This is exactly the point. Many psychiatric diagnoses, such as major depressive disorder and anxiety disorder, rely on individuals' self-reports of their symptoms

⁴ Hruz Report p. 31-33, 45-46, 52, 96; Kaliebe Report p. 64; Laidlaw Report p. 13; Lappert Report p. 16, 17, 26, 33, 46, 65; Levine Report p. 51.

⁵ Donovan Report p. 6; Hruz Report p. 31, 52, 96; Laidlaw Report p. 8, 13; Lappert Report p. 16, 17, 26, 33, 46, 65; Levine Report p. 9; Scott Report p. 3.

and do not have confirmatory laboratory or radiographic tests. This is not only true of psychiatric conditions but also of some "medical" conditions like migraine headache. Presumably Dr. Laidlaw does not question the reliability of the diagnosis of migraine headache. That migraine headache has a potential vascular component is irrelevant. Regional cerebral blood flow imaging is not a diagnostic test for migraine. His further claims about treatment of migraine and gender dysphoria are also irrelevant to this point about the credibility of the diagnosis.

- 17. Defendants' experts also falsely assert that health care providers rely on individuals with gender dysphoria's "self-diagnosis" for diagnosing patients.⁷ Again, as stated in my report, this claim is false. Antonmaria Report p. 27.
- 18. Individuals may suspect that they have gender dysphoria based on their symptoms, e.g., a strong desire to be rid of their facial hair because of a marked incongruence with their experienced female gender, in the same way that individuals may suspect that they have pneumonia based on their symptoms, e.g., fever, cough, and shortness of breath. Health care providers, however, evaluate patients and formulate their own diagnoses before beginning treatment. A health care provider would, to extend the analogy, take a history and perform a physical examination to

⁶ Steiner TJ, Jensen R, Katsarava Z, et al. Aids to management of headache disorders in primary care, 2nd edition. *J Headache Pain*. 2019;20(1):57; Headache Classification Committee of the International Headache Society (IHS). The international classification of headache disorders, 3rd edition. *Cephalalgia*. 2018;38(1):1-211.

⁷ Donovan Report Exhibit A p. 5; Hruz Report p. 51; Kaliebe Report p. 54, 64; Lappert Report p. 7, 33, 43, 45, 64.

determine whether a patient has pneumonia before prescribing antibiotics. The diagnostic criteria, clinical evaluation, and, if appropriate, subsequent treatment of gender dysphoria, are described in clinical practice guidelines.⁸

- 19. In contrast to the defendants' experts' claim that gender dysphoria is a subjective diagnosis, they assert that identifying an individuals' sex is an objective determination. Dr. Laidlaw, for example, states, "Biological sex is the objective physical condition having organs and body parts which correspond to a binary sex." Laidlaw Report at p. 13.
- 20. Dr. Laidlaw's assertion of the objectivity of sex is undermined by Dr. Hruz who states, "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." Hruz Report p. 11. If identifying an individual's sex was objective, psychologic outcomes and parental desires would be irrelevant. Note also that Dr. Hruz uses the term "assignment," which affirms the accepted understanding that physicians indeed "assign" sex to newborns.

⁸ Hembree WC, Cohen-Kettenis PT, Gooren L, et al. Endocrine treatment of gender-dysphoric/gender-incongruent persons: An Endocrine Society clinical practice guideline. *J Clin Endocrinol Metab*. 2017;102(11):3869-3903.

GENDER-AFFIRMING MEDICAL CARE IS NOT EXPERIMENTAL

- 21. Defendants' experts incorrectly characterize gender-affirming medical care as "experimental." Their reports do not generally define experimental, but, to the extent that they do, their definitions are inaccurate.
- 22. Dr. Donovan, for example, states, "In any medical condition where the cause is unknown, the treatments still uncertain, and the adverse effects of the interventions not fully elucidated, a proposed course of therapy would have to be seen as experimental." Donovan Report p. 7.
- 23. There are many medical conditions whose cause is not known but that nonetheless have well established treatments. Kawasaki disease, for example, is an acute febrile illness in children which causes inflammation of the blood vessels and, in some cases, ballooning of the blood vessels that supply the heart.
- 24. The American Heart Association's (AHA's) clinical practice guideline for the diagnosis, treatment, and long-term management of this condition states, "Kawasaki disease (KD) is an acute, self-limited febrile illness of unknown cause that predominantly affects children <5 years of age" and that "[d]espite 4 decades of investigation, the cause of KD remains unknown." The AHA nonetheless recommends individuals with Kawasaki disease be treated with intravenous

⁹ Donovan Report Exhibit A p. 1, 4; Hruz Report p. 56-57, 69, 98-100; Kaliebe Report p. 63; Laidlaw Report p. 22, 25, 39, 81-82; Lappert Report p. 10, 41; Levine Report p. 11, 65, 81; Zanga Report p. 9-10.

immunoglobulin (Class 1; Level of Evidence A).¹⁰ The American College of Cardiology Foundation and the AHA use different categories for the quality of evidence and the strength of recommendations¹¹ from the Grading of Recommendations Assessment, Development and Evaluation (GRADE) system described in my report. Antommaria Report p. 7-11. This treatment recommendation can, nonetheless, be interpreted as a strong recommendation based on high quality evidence.

- 25. The adverse effects of a treatment not being fully elucidated also does not make the treatment experimental.
- 26. Defendants' experts appear to accept that approval by the United States (US) Food and Drug Administration (FDA) is a sufficient criterion for a medication to not be experimental based on their discussion of off-label treatment analyzed below. But the FDA requires post-marketing surveillance of medications' adverse effects because the clinical trials on which the approvals are based cannot identity

Documents/Methodology/2014/Methodology-Practice-

Guidelines.pdf?la=en&hash=157B7835091CF7856B26528717BE14B33BE8226F.

¹⁰ McCrindle BW, Rowley AH, Newburger JW, et al. Diagnosis, treatment, and long-term management of Kawasaki disease: A scientific statement for health professionals from the American Heart Association. *Circulation*. 2017;135(17): e927-e999. The quotations appear on pages e928 and e931 respectively.

¹¹ American College of Cardiology Foundation, American Heart Association. Methodology manual and policies from the ACCF/AHA Task Force on practice guidelines. June 2010. Accessed March 5, 2023. Available at https://www.acc.org/-/media/Non-Clinical/Files-PDFs-Excel-MS-Word-etc/Guidelines/About-Guidelines-and-Clinical-

all possible side effects.¹² Defendants' experts appear to expect a level of certainty that is not always available in medicine, nor that even the FDA expects.

- 27. Defendants' expert reports also repeatedly note that puberty blockers, testosterone, and estrogen are prescribed off-label in their use to treat gender dysphoria as supposed further evidence that the treatment is experimental. Biggs Report p. 4; Donovan Report Exhibit A p. 4; Laidlaw Report p. 25, 29, 52, 59, 66, 81-82, 107.
- 28. Dr. Donovan's report, for example, states, "After close scrutiny, it can only be seen as off label experimentation, despite the fact that informed consent practices do not conform to this reality." Donovan Report Exhibit A p. 4.
- 29. My report, however, demonstrates that a medication being used offlabel does not mean it is either unsafe or ineffective. Antommaria Report p. 18-21.
- 30. A treatment not having been evaluated using a particular study design is also not an indication that the treatment is experimental, contrary to what Dr. Laidlaw states in his report. He claims, "[T]he use of [gonadotrophin releasing hormone (GnRH)] anolgue [sic] medication for this purpose in adolescents is experimental as there have been no randomized controlled trials for this specific use case." Laidlaw Report p. 25. Randomized controlled trials are not a necessary

¹² U.S. Food & Drug Administration. Postmarketing Surveillance Programs. April 2, 2020. Accessed February 26, 2023. Available at https://www.fda.gov/drugs/surveillance/postmarketing-surveillance-programs.

criterion for a medication to not be deemed experimental. GnRH analogues were approved by the FDA for treatment of central precocious puberty without randomized controlled trials.¹³

- 31. In general, defendants' experts' primary contention appears to be that there is inadequate evidence of gender-affirming medical care's safety and efficacy or, in other words, this care is unproven. My report demonstrates that there is sufficient evidence to recommend this medical care and that the evidence for this care is the same quality as used to make recommendations in other areas of medicine. Antommaria Report p. 7-13.
- 32. Several of the defendants' experts emphasize the lack of randomized trials, Biggs Report p. 5; Hruz Report p. 65, 69, 90; Laidlaw Report p. 25, 108, without addressing the methodological and ethical issues with such trials in genderaffirming medical care. Antommaria Report p. 13-15.
- 33. Dr. Hruz, for example, states "Such studies can be ethically designed and executed with provisions for other dignity affirming measures to all treatment groups." Hruz Report p. 156. Dr. Hruz does not, however, provide any additional explanation to substantiate this claim. His citation, Sugarman J., Ethics in the design and conduct of clinical trials. *Epidemiol Rev.* 2002;24(1):54-58, does not justify it.

¹³ HIGHLIGHTS OF PRESCRIBING INFORMATION. May 2017. Accessed February 26, 2023. Available at

https://www.accessdata.fda.gov/drugsatfda_docs/label/2017/020263s042lbl.pdf.

Dr. Sugarman's article is a general outline of ethical issues in designing and conducting clinical research and does not address the specific ethical issues in clinical research on gender-affirming medical care.

- 34. Some of the expert witnesses go even further to suggest that some individuals with gender dysphoria have been experimented on without their, or their parents' or legal guardian's consent.
- 35. Dr. Levine asserts that two individuals were correct to feel that they were treated like guinea pigs and Dr. Hruz compares gender-affirming medical care to the "infamous Tuskegee studies" and the "Nazi and Imperial Japanese wartime experiments." Levine Report p. 71; Hruz Report p. 62.
- 36. Such accusations are unfounded and irresponsible. Neither report provides evidence that individuals with gender dysphoria were treated without adequate informed consent.

PARENTS AND GUARDIANS CAN AND DO PROVIDE INFORMED CONSENT FOR GENDER-AFFIRMING MEDICAL CARE

- 37. Several of the defendants' experts emphasize minors' inability to provide informed consent for gender-affirming medical care.¹⁴
- 38. Dr. Hruz, for example, asserts, "For adolescent children seeking medical gender affirmation medical [sic], well established limitations in decision

¹⁴ Donovan Report Exhibit A p. 2; Hruz Report p. 58-59; Kaliebe Report p. 5-6; Laidlaw Report p. 59-60, 72, 79, 108-109; Lappert Report p. 44; Scott Report p. 11.

making ability raise serious concerns about their ability to consent to hormonals [sic] and surgical interventions." Hruz Report p. 58.

- 39. These claims ignore the fact that it is parents or legal guardians and not minors who provide informed consent for gender-affirming medical care. (The exception is adolescents who have been legally emancipated, but in this case their decision-making capacity has been verified.)
- 40. Dr. Laidlaw goes on to assert, "With respect to [gender affirmative therapy], in my opinion, it is not possible for the parent or guardian to make a true informed consent decision for the child because of the poor quality of the evidence of benefit, the known risks or harm, and the many unknown longterm [sic] risks of harm which could only truly be known after years and decades of gender affirmative therapy." ¹⁵ Laidlaw Report p. 59-60, see also p. 109.
- 41. To the contrary, parents and legal guardians are frequently asked to consent to interventions in which there is uncertainty about the nature or the frequency of the risks. There is, for example, substantial uncertainty in medical decisions in neonatology, especially for infants born between 22 and 25 weeks

¹⁵ Cf, Laidlaw Report p. 79 where he lists criteria for applying gender affirmative therapy to patients that suggest adult patients and parents and guardians can provide informed consent.

estimated gestational age. 16 Clinicians or investigators disclose this uncertainty, and parents or legal guardians weigh it in their decision making.

- 42. One component of informed consent is the disclosure of the potential benefits, risks, and alternatives to the proposed treatment.
- 43. The defendants' experts at times mischaracterize the potential benefits of gender-affirming medical care. Dr. Laidlaw, for example, bizarrely asserts that the Endocrine Society and World Professional Association for Transgender Health (WPATH) mislead patients and their families into believing that gender-affirming medical care will change transgender women's testicles into ovaries, permit them to develop uteruses, and allow them to conceive and carry a pregnancy to term. He provides no citation or evidence to support this assertion. Laidlaw Report p. 98.
- 44. The defendants' experts also, at times, overstate the potential risks of gender affirming medical care. Levine Report p. 60, 89. Cf., Hruz Report p. 48. For example, while gender-affirming medical care entails a risk of infertility, gender-affirming hormone treatment does not universally result in sterility. There are transgender men who became pregnant while on or after discontinuing testosterone therapy.¹⁷ Transgender men and women are also capable of producing eggs and

¹⁶ Crilly CJ, Haneuse S, Litt JS. Predicting the outcomes of preterm neonates beyond the neonatal intensive care unit: What are we missing? *Pediatr Res.* 2021;89(3):426-445.

¹⁷ Light AD, Obedin-Maliver J, Sevelius JM, Kerns JL. Transgender men who experienced pregnancy after female-to-male gender transitioning. *Obstet Gynecol*. 2014;124(6):1120-1127.

sperm respectively after the discontinuation of gender-affirming hormone treatment.¹⁸

- 45. Several of the defendants' experts propose mental health interventions alone as the alternative to gender-affirming medical care. Hruz Report p. 36-37; Kaliebe Report p. 57-61; Lappert Report p. 44. While some experts overstate the evidence base of this proposed alternative, others acknowledge its limitations. Dr. Levine, for example, states, "To my knowledge, there is no evidence beyond anecdotal reports that psychotherapy can enable a return to male identification for genetically male boys, adolescents, and men, or return to female identification for genetically female girls, adolescents, and women." Levine Report p. 26-27.
- 46. Defendants' experts assert that parents, guardians, and/or adolescent patients are provided inadequate information to make informed decisions, Donovan Report Exhibit A p. 3-4; Hruz Report p. 56-57, 59-62, or are coerced into decisions that are not voluntary. Hruz Report p. 60; Levine Report p. 76. They do not, however, provide empirical data to support these claims.
- 47. Dr. Hruz, for example, contends "Parents are often told by gender affirmation activists or providers that the failure to allow a gender dysphoric child

¹⁸ Leung A, Sakkas D, Pang S, Thornton K, Resetkova N. Assisted reproductive technology outcomes in female-to-male transgender patients compared with cisgender patients: A new frontier in reproductive medicine. *Fertil Steril*. 2019;112(5):858-865; de Nie I, van Mello NM, Vlahakis E, et al. Successful restoration of spermatogenesis following gender-affirming hormone therapy in transgender women. *Cell Rep Med*. 2023;4(1):100858.

to medically transition will result in suicide. These 'threats' ignore data that challenge this biased assumption." Hruz Report p. 60. Dr. Hruz does not, however, provide any empirical data regarding the frequency with which parents are told this or the effect this reported claim has on their ability to weigh the potential benefits and risks of treatment. The article that he cites, 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;50(1):7-16, also lacks such information.

WPATH, THE ENDOCRINE SOCIETY, AND THE AMERICAN ACADEMY OF PEDIATRICS (AAP) ARE MEDICAL PROFESSIONAL ORGANIZATIONS THAT DEVELOP CLINICAL PRACTICE GUIDELINES AND POLICY STATEMENTS USING ESTABLISHED METHODS

- 48. Defendants' expert reports make many misleading or inaccurate claims about medical professional organizations and the development of clinical practice guidelines and policy statements.
- 49. Dr. Levine, for example, argues that WPATH "can no longer be considered a purely professional organization" because it permits "trans individuals who are not licensed professionals" to attend its biennial meetings. Levine Report p. 37.

- 50. In fact, to be a full member of WPATH, with full voting rights, individuals must have relevant professional qualifications.¹⁹
- 51. An active member of the Endocrine Society must be "a physician or scientist whose training and interests promote the knowledge of hormones and other regulatory substances." Voting rights are limited to active, emeritus, and retired members and doctoral-level trainees.
- 52. The AAP similarly restricts voting to fellows, specialty fellows, post residency training members that are board certified, candidate members, and senior members.²¹
- 53. Others of defendants' experts characterize WPATH as an advocacy organization. Hruz Report p. 55; Kaliebe Report p. 3; Levine Report p. 35-36. This is an inappropriately narrow characterization of the association. WPATH describes its mission as follows: "To promote evidence-based care, education, research, public policy, and respect in transgender health."²²

¹⁹ The World Professional Association for Transgender Health, Inc. A Nonprofit Educational Organization: Bylaws. Accessed February 26, 2023. Available at https://www.wpath.org/media/cms/Documents/About/Bylaws%20APPROVED%20by%20Mem bers%201-22-2016.pdf.

²⁰ Endocrine Society. Bylaws. May 2019. Accessed March 5, 2023. Available at https://www.endocrine.org/-/media/endocrine/files/about/bylaws.pdf.

²¹ American Academy of Pediatrics. Constitution and Bylaws. Accessed February 27, 2023. Available at https://downloads.aap.org/AAP/PDF/Const-and-Bylaws-2020.pdf.

²² WPATH: World Professional Association for Transgender Health. Mission and Vision. Accessed February 26, 2023. Available at https://www.wpath.org/about/mission-and-vision.

- 54. It is common for medical professional organizations to have advocacy as a component of their mission as the welfare of the patients that the members of the association treat is contingent on the laws and regulations governing that medical care.
- 55. The Endocrine Society's bylaws emphasize the promotion of research and study in the science of endocrinology and the diffusion of information.²³ Its website also describes its advocacy efforts, stating, "We identify issues that will impact the profession of endocrinology and patients with endocrine conditions and pursue opportunities to impact relevant policy through our relationships with policymakers and by engaging you, their constituents."²⁴
- 56. The AAP articulates 13 scientific, social, and educational objectives including "function as an effective advocate for all children and youth in all matters pertaining to health and health care."²⁵
- 57. Some of the defendants' experts contend that small numbers of "activists" have been able to commandeer medical professional organizations' decision-making processes to advance a specific agenda. Kaliebe Report p. 3, 31, 32, 66; Lappert Report p. 46

²³ Endocrine Society. Bylaws. May 2019. Accessed March 5, 2023. Available at https://www.endocrine.org/-/media/endocrine/files/about/bylaws.pdf.

²⁴ Endocrine Society. Shaping public policy. September 6, 2022. Accessed March 5, 2023. Available at https://www.endocrine.org/our-community/shaping-healthcare-and-research-policy.

²⁵ American Academy of Pediatrics. Constitution and Bylaws. Accessed February 27, 2023. Available at https://downloads.aap.org/AAP/PDF/Const-and-Bylaws-2020.pdf.

- 58. Dr. Kaliebe, for example, asserts that, "Small numbers of advocate physicians within medical organizations have been able to leverage moralized claims and low-quality evidence in order to promote affirmative care for gender dysphoria." Kaliebe Report p. 3.
- 59. However, this is not true. In my report I describe the rigorous and transparent methods the Endocrine Society and WPATH use to develop their clinical practice guidelines. Antommaria Report p. 7-8, 15-16. Given guidelines are developed by a well-defined, reproducible, and transparent methods, it is not clear why they should be subject to the vote of medical professional organization's entire membership. Hruz Report p. 54; Lappert Report p. 46. Dr. Hruz confusingly both criticizes medical professional organizations for not submitting guidelines to their entire membership for approval and for engaging in "consensus-seeking methodologies by vote." Hruz Report p. 54, 99.
- 60. Defendants' experts also provide no evidence to support their assertion that membership in one medical professional organization constitutes a conflict of interest for their work in another medical professional organization. Hruz Report p. 54; Laidlaw Report p. 61, 63. Medical professionals are commonly members of multiple medical professional organizations which does not present an intrinsic conflict of interest of which I am aware. Dr. Donovan's curriculum vitae, for example, lists membership in 13 professional societies and concurrent membership

on the AAP Committee on Bioethics, the North American Society for Pediatric Gastroenterology, Hepatology, and Nutrition Ethics Committee, and the Oklahoma State Medical Association Bioethics Committee. Donovan Report Exhibit B p. 5-7.

- 61. Defendants' experts also draw attention to legal disclaimers in clinical practice guidelines. Laidlaw Report p. 61; Lappert Report p. 19, 21-22; Levine Report p. 44. Such disclaimers do not in fact undermine the credibility of the guidelines. They simply indicate that health care providers need to consider the characteristics of each individual patient and that such characteristics may justify deviating from the guideline's recommendations.
- 62. Here I will focus on the AAP's process for developing policy statements. Another of the defendant's expert's description of this process makes clear the erroneous nature of Dr. Kaliebe's claims. Zanga Report p. 4-5.
- 63. AAP policy statements are developed by its committees, sections, councils, and task forces. Committee members and chairpersons are not self-selected but are appointed by the Board of Directors. Board members are elected from specific geographic regions or nationally except for the Chief Executive Officer/Executive Vice President who is appointed by the Board. Entities proposing to develop or revise policy statements must submit an intent form which includes a preliminary literature search and a draft outline. Permission to develop potential policy statements must be given by the Board's Policy Committee and the Intent

Review Committee. Authors of policy statements are required to disclose potential conflicts of interest. Draft policy statements are reviewed by internal (e.g., other committees, sections, and councils) and external reviewers (e.g., other medical professional associations). After revisions are made, senior staff and the entire Board of Directors review proposed policy statements and final approval must be given by the Board's Executive Committee. ²⁶

- 64. The requirement that the elected Board approve policy statements prevents the process from being commandeered by a small group of individuals. Given the Board is elected by the members to represent them, it is unclear, and no evidence is provided, as to why defendant's expert suggested policy statements would need to be approved by a vote of the entire membership. Zanga Report, p. 5.
- 65. In addition to these robust methods to develop policy statements, the AAP has mechanisms for members of national leaderships entities to express disagreement with positions taken by the Board of Directors or its Executive Committee, and to facilitate communication from the membership to the Board of Directors.

²⁶ American Academy of Pediatrics. AAP Board of Directors policy and procedures manual.

^{2021.} Accessed February 27, 2023. Available at

https://collaborate.aap.org/Lead/Documents/PolicyManual-2021-

 $[\]underline{06.pdf\#search=AAP\%20Board\%20of\%20Directors\%20policy\%20and\%20procedures\%20manu}$

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Individual members of the AAP, chapters, committees, councils, 66. sections, and districts may submit resolutions to the Academy's Annual Leadership Forum. Resolutions are reviewed by the Chapter Forum Management Committee, the Senior Leadership Team, and the Manager of Chapter Programs who may request changes to improve clarity or meet formatting requirements. If the resolution is accepted, it is referred to the staff liaisons of entities within the Academy to provide background information. Members are permitted to review and comment on resolutions prior to the Forum. Resolutions likely to pass through the Forum are placed on a Consent Calendar and the others are assigned to Reference Committees that hold hearings on the resolutions. Resolutions from individual members that are not endorsed by a chapter, committee, council, section, or district requires a second by a Forum representative to be considered. The Forum may adopt, adopt as amended, defeat, refer, postpone, or table resolutions. The Senior Leadership Team and Board of Directors review all adopted resolutions and refer them to appropriate entities for their response.²⁷

67. The fact that the resolutions to which Dr. Zanga refers were not adopted by the Forum does not mean that they were treated undemocratically, or outside of the Academy's standard procedures. Zanga Report p. 6.

²⁷ American Academy of Pediatrics. Guidelines for Submitting Resolutions. October 30, 2020. Accessed February 27, 2023. Available at https://aapca2.org/wp-content/uploads/2021/02/Guidelines-for-Submitting-Resolutions-2021.pdf.

- 68. Dr. Kaliebe's report also contends that academic journals affiliated with medical professional organizations stifle debate. Kaliebe Report p. 3, 33-36. On the contrary, the AAP's journals have editorial independence from the Academy and regularly publish articles which question the Academy's clinical practice guidelines and policy statements.
- 69. The AAP, for example, produced a revised, clinical practice guideline for the diagnosis and management of the initial urinary tract infections (UTIs) in febrile infants and children 2 to 24 months of age that was published in September 2011.²⁸ The guideline recommended febrile infants with UTIs should undergo renal and bladder ultrasonography but not voiding cystourethrograms (VCUGs) unless the ultrasound revealed findings consistent with high-grade vesicular ureteral reflux or obstructive uropathy. *Pediatrics* published an accompanying commentary to the guideline in which the author made alternative recommendations that the author believed were supported by the available evidence.²⁹ In April 2012, the journal published another commentary, this time by the Executive Committee of the Section

²⁸ Subcommittee on Urinary Tract Infection, Steering Committee on Quality Improvement and Management, Roberts KB. Urinary tract infection: Clinical practice guideline for the diagnosis and management of the initial UTI in febrile infants and children 2 to 24 months. *Pediatrics*. 2011;128(3):595-610.

²⁹ Newman TB. The new American Academy of Pediatrics urinary tract infection guideline. *Pediatrics*. 2011;128(3):572-5.

on Urology, critical of the recommendation against performing VCUGs and a response by several authors of the guideline.³⁰

- 70. With respect to gender-affirming medical care, *Pediatrics* has published comments on its website and Letters to the Editor in the journal critical of articles on gender-affirming medical care. The journal solicits reader comments and posts selected comments on its website following editorial review. Comments may also be published in *Pediatrics* as Letters to the Editor.³¹
- 71. An example of such criticism is the response to the article by Turban et al. in which the authors argued that the sex assigned at birth ratio of transgender and gender diverse adolescents in the US does not favor individuals assigned female at birth based on their analysis of the Youth Risk Behavior Survey.³² The journal posted 4 critical comments on its website, including one by Lisa Littman,³³ and

³⁰ Wan J, Skoog SJ, Hulbert WC, et al. Section on Urology response to new guidelines for the diagnosis and management of UTI. *Pediatrics*. 2012;129(4):e1051-1053 and Roberts KB, Finnell SM, Downs SM. Response to the AAP Section on Urology concerns about the AAP urinary tract infection guideline. *Pediatrics*. 2012;129(4):e1054-1056. See also American Academy of Pediatrics. Committee on Bioethics. Children as hematopoietic stem cell donors. *Pediatrics*. 2010;125(2):392-404; Pentz RD, Alderfer MA, Pelletier W, et al. Unmet needs of siblings of pediatric stem cell transplant recipients. *Pediatrics*. 2014;133(5):e1156-1162; and Ross LF, Antommaria AH. The need to promote all pediatric stem cell donors' understanding and interests. *Pediatrics*. 2014;133(5):e1356-1357.

³¹ AAP Publications: Pediatrics. Author Instructions: Reader Comments. March 11, 2022. Accessed February 28, 2023. Available at https://publications.aap.org/pediatrics/pages/author-instructions#reader comments.

³² Turban JL, Dolotina B, King D, Keuroghlian AS. Sex assigned at birth ratio among transgender and gender diverse adolescents in the United States. *Pediatrics*. 2022;150(3):e2022056567.

³³ AAP Publications: Pediatrics. Sex assigned at birth ratio among transgender and gender diverse adolescents in the United States. Accessed February 28, 2023. Available at

subsequently published 1 of the comments as a Letter to the Editor. The Letter writers state that they "identified critical theoretical and methodological concerns specific to [the study's] conceptualization of social contagion and its data analysis."³⁴ A reply by Turban et al. includes additional analyses of the data in response to the commenters' criticisms.³⁵ *Pediatrics*' posting and publication of these criticisms belies Kaliebe's claims. Kaliebe Report p. 3, 33-36.

DOCUMENTS FROM OTHER COUNTRIES DO NOT SUPPORT BANS ON GENDER-AFFIRMING MEDICAL CARE

- 72. Defendants' experts reference documents from several other countries on the treatment of gender dysphoria, predominantly from Finland, Sweden, and the United Kingdom (UK), although they also mention documents from France, Australia, and New Zealand.³⁶
- 73. Before addressing the substance of these claims, several preliminary points should be made. Defendants' experts do not provide a comprehensive review of international practices, rather they selectively cite documents that they believe

https://publications.aap.org/pediatrics/article/150/3/e2022056567/188709/Sex-Assigned-at-Birth-Ratio-Among-Transgender-and?autologincheck=redirected.

³⁴ Lett E, Everhart A, Streed C, Restar A. Science and public health as a tool for social justice requires methodological rigor. *Pediatrics*. 2022;150(6):e2022059680.

³⁵ Turban JL, Dolotina B, King D, Keuroghlian AS. Author response to: Science and public health as a tool for social justice requires methodological rigor. *Pediatrics*.

^{2022;150(6):}e2022059680. See also Correction to Branstrom and Pachankis. *Am J Psychiatry*. 2020;177(8):734 that is discussed by Laidlaw Report p. 68.

³⁶ Donovan Report p. 6-7, Exhibit A p. 1, 3; Hruz Report p. 91-96; Kaliebe Report p. 18-24; Laidlaw Report p. 75; Lappert Report p. 2, 63; Levine Report 42-43; Zanga Report p. 11.

support their position. Hruz, for example, cites a document reportedly from the Astrid Lindgren Children's Hospital³⁷ without acknowledging that the 5 other children's hospitals in Sweden that provide gender-affirming medical care did not concurrently modify their practices.³⁸ Hruz Report p. 92.

- 74. Language differences also make it difficult to assess fully some of the material that the defendants' experts cite to as support for their claims. For example, the Swedish National Board of Health and Welfare's (NBHW's) guideline for the care of children and adolescents with gender dysphoria is not available in an official English translation; only a 6-page summary is available in an official English translation.³⁹
- 75. With respect to the content of these documents, none is a clinical practice guideline which rates the quality of the evidence and the strength of the recommendations. Some of the documents are systematic reviews of the literature

³⁷ It should also be noted that to support his assertion, Dr. Hruz cites a webpage of the "Society for Evidence Based Gender Medicine." Hruz Report p. 92. This webpage contains links to PDFs of documents that the webpage states were obtained from the Karolinska Hospital and links to the Society's unofficial translations of the documents. The webpage does not contain links to the documents on the Karolinska Hospital's own website or information regarding who performed the translation and their credentials. Society for Evidence Based Gender Medicine. Sweden's Karolinska ends all use of puberty blockers and cross-sex hormones on minors outside of clinical studies. February 2022. Accessed March 5, 2023. Available at https://segm.org/Sweden ends use of Dutch protocol.

³⁸ Mission Investigate/SVT. Transbarnen. 2021. Accessed March 10, 2023. Available at https://b2b.svt.se/svt-sales/programme-sales/trans-children.html.

³⁹ The National Board of Health and Welfare. Care of children and adolescents with gender dysphoria: Summary. 2022. Accessed February 27, 2023. Available at https://www.socialstyrelsen.se/globalassets/sharepoint-dokument/artikelkatalog/kunskapsstod/2022-3-7799.pdf.

that rate the quality of the evidence but do not make recommendations.⁴⁰ Direct inferences cannot be drawn from the quality of the evidence to the strength of recommendations; low quality evidence may be a sufficient basis for strong recommendations. Antonmaria Report p. 10-11. The French document referenced is in fact only a press release.⁴¹

76. Several of defendants' experts mischaracterize the conclusions of these documents. Kaliebe, for example, states "Sweden, England and Finland have all reviewed the evidence and pressed pause." Kaliebe Report p. 65. Similarly, Dr. Lappert asserts "The world literature demonstrates emphatically that early medical and surgical transitioning is in fact so controversial that medical leadership in multiple countries has put a stop to it." Lappert Report p. 64. None of the documents to which defendants' experts refer recommends banning gender-medical care and none, to the best of my knowledge, addresses insurance coverage.

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⁴⁰ National Institute for Health and Care Excellence (NICE). Evidence review: Gonadotrophin releasing hormone analogues for children and adolescents with gender dysphoria. October 2020. Accessed February 27, 2023. Available at https://cass.independent-review.uk/nice-evidence-reviews/. Available at https://cass.independent-review.uk/nice-evidence-reviews/. Accessed February 27, 2023. Available at https://cass.independent-review.uk/nice-evidence-reviews/. Académie Nationale de Médecine. Medicine and gender transidentity in children and adolescents. February 25, 2022. Accessed February 27, 2023. Available at https://www.academie-medecine.fr/la-medecine-face-a-la-transidentite-de-genre-chez-les-enfants-et-les-adolescents/?lang=en.

- 77. Finland, Sweden, and the UK are all moving to providing care through regional multidisciplinary clinics, the type of care commonly provided in the US.⁴² In Finland, for example, gender-affirming medical care is provided by Helsinki University Central Hospital and Tampere University Hospital. Puberty blockers and gender-affirming hormone treatment are provided to minors with persistent gender dysphoria on a case-by-case basis.⁴³
- 78. Sweden is restructuring care for gender dysphoria into 3 national specialized medical care units. While the Swedish recommendations state puberty blockers and gender-affirming hormone treatment "should be offered only in exceptional cases," they later state "an early (childhood) onset of gender incongruence, persistence of gender incongruence until puberty and a marked psychological strain in response to pubertal development is among the recommended criteria."

⁴² Hsieh S, Leininger J. Resource list: Clinical care programs for gender-nonconforming children and adolescents. *Pediatr Ann.* 2014;43(6):238-244.

⁴³ Council for Choices in Health Care in Finland. Medical treatment methods for dysphoria associated with variations in gender identity in minors – recommendation. June 16, 2020. Accessed February 27, 2023. Available at

https://palveluvalikoima.fi/documents/1237350/22895008/Summary minors en+(1).pdf/fa2054c 5-8c35-8492-59d6-b3de1c00de49/Summary minors en+(1).pdf?t=1631773838474.

The National Board of Health and Welfare. Care of children and adolescents with gender dysphoria: Summary. 2022. Accessed February 27, 2023. Available at https://www.socialstyrelsen.se/globalassets/sharepoint-dokument/artikelkatalog/kunskapsstod/2022-3-7799.pdf.

- 79. The UK is moving from a single specialist provider model to regional centers. The Cass Review does not provide definitive advice on the use of puberty blockers or gender-affirming hormone treatment in its interim report.⁴⁵
- 80. The documents all emphasize the importance of data collection. The Cass Review recommends, for example, "Existing and future services should have standardised data collection in order to audit standards and inform understanding of the epidemiology, assessment and treatment of this group of children and young people."⁴⁶
- 81. The Swedish NBHW, however, states, "To ensure that new knowledge is gathered, the NBHW further deems that treatment with GnRH-analogues and sex hormones for young people should be provided within a research context, which does not necessarily imply the use of randomized controlled trials (RCTs). As in other healthcare areas where it is difficult to conduct RCTs while retaining sufficient internal validity, it is also important that other prospective study designs are considered for ethical review and that register studies are made possible."⁴⁷

⁴⁵ The Cass Review. Independent review of gender identity services for children and young people: Interim report at p. 22. February 2022. Accessed February 27, 2023. Available at https://cass.independent-review.uk/publications/interim-report/.

⁴⁶ The Cass Review. Independent review of gender identity services for children and young people: Interim report. February 2022. p. 22. Accessed February 27, 2023. Available at https://cass.independent-review.uk/publications/interim-report/.

⁴⁷ The National Board of Health and Welfare. Care of children and adolescents with gender dysphoria: Summary at p. 4. 2022. Accessed February 27, 2023. Available at https://www.socialstyrelsen.se/globalassets/sharepoint-dokument/artikelkatalog/kunskapsstod/2022-3-7799.pdf.

82. This is inconsistent with the defendants' experts' emphasis on the use of randomized controlled trials discussed above.

GENDER DYSPHORIA AND GENDER-AFFIRMING MEDICAL CARE ARE NOT PROPERLY ANALOGIZED TO ANOREXIA NERVOSA, BODY INTEGRITY IDENTITY DISORDER, OR LOBOTOMIES

- 83. The treatment of gender dysphoria can be clearly differentiated from the treatment of anorexia nervosa and body integrity identity disorder. Cf., Donovan Report Exhibit A p. 7; Kaliebe Report p. 54; Zanga Report p. 8. Clinical studies have shown that gender-affirming medical care improves the clinical outcomes of individuals with gender dysphoria. This is not the case with endorsing individuals with anorexia nervosa's fear of gaining weight or becoming fat. Anorexia nervosa is treated with family-based therapy and weight restoration.⁴⁸
- 84. Body integrity identity disorder is not a diagnosis contained in the American Psychiatric Association's *Diagnostic and Statistical Manual*.⁴⁹ Evidence regarding the effects of amputation is limited to case reports⁵⁰ and cross-sectional studies⁵¹ as opposed to observational studies as in gender-affirming medical care.

⁴⁸ Society for Adolescent Health and Medicine. Medical management of restrictive eating disorders in adolescents and young adults. *J Adolesc Health*. 2022;71(5):648-654 and Bou Khalil R, Richa S. Apotemnophilia or body integrity identity disorder: A case report review. *Int J Low Extreme Wounds*. 2012;11(4):313-319.

⁴⁹ American Psychiatric Association. *Diagnostic and Statistical Manual of Mental Disorders*. 5th ed, Text Revision. American Psychiatric Publishing; 2022.

⁵⁰Bou Khalil R, Richa S. Apotemnophilia or body integrity identity disorder: A case report review. *Int J Low Extrem Wounds*. Dec 2012;11(4):313-319.

⁵¹ First MB. Desire for amputation of a limb: Paraphilia, psychosis, or a new type of identity disorder. *Psychol Med.* 2005;35(6):919-928.

85. The fact that some medical treatments, such as lobotomy, can be shown retrospectively to have been unsafe or ineffective or better alternatives were developed does not permit one to know prospectively when this will be the case.⁵² Cf., Donovan Report p. 9-10; Kaliebe Report p. 63.

RECONSTRUCTIVE AND AESTHETIC SURGERY

- 86. Dr. Lappert's putative distinction between reconstructive and aesthetic surgery does not provide a sound basis to support providing coverage for gynecomastia and breast reduction surgery and excluding coverage for genderaffirming surgeries.
- 87. Dr. Lappert defines reconstructive surgery as "the restoration of form and function for a person who has suffered a loss through genetic, in utero developmental accident, trauma, infection, or surgery for infectious events or cancer." Lappert Report p. 24-25. He contends that reconstructive breast reduction surgery is differentiated from cosmetic breast reduction surgery based on the weight of the breast tissue removed and that this criterion is based on the highest levels of

⁵² In this regard, Dr. Lappert misrepresents the history of the treatment of peptic ulcer disease and Profs. Seselja and Strasser's article. Lappert Report p. 15, 57. Profs. Seselja and Strasser argue that there were two rival hypotheses of the cause of peptic ulcer disease—that it was caused by gastric acid and that it was caused by bacteria. The bacterial hypothesis was perceived to be refuted by a large study which failed to demonstrate bacteria in the stomach using a particular stain until later investigators identified bacteria using a different staining technique. The authors argue that there were sound reasons not to abandon the bacterial hypothesis at the time the earlier study was published. Seselja D, Strasser C. Heuristic reevaluation of the bacterial hypothesis of peptic ulcer disease in the 1950s. *Acta Biotheor*. 2014;62(4):429-454.

scientific support. Lappert Report p. 31-33. He characterizes aesthetic surgery as beginning in the subjective life of the patient and research on aesthetic surgery as relying on purely subjective evaluations. Lappert Report p. 25, 47.

- 88. Clinical practice guidelines published by professional medical organizations characterize both gynecomastia and breast reduction surgery as aesthetic surgery according to Dr. Lappert's definitions. The European Academy of Andrology has published a clinical practice guideline for the evaluation and management of gynecomastia (GM) using the GRADE system, the same system used by the Endocrine Society in its guidelines, including its guideline for the endocrine treatment of gender-dysphoric/gender-incongruent persons.
- 89. The Academy's recommendation regarding surgical management, "We suggest surgical treatment only for patients with long-lasting GM, which does not regress spontaneously or following medical therapy" is a weak recommendation based on low quality evidence.⁵³
 - 90. The guideline's remarks regarding surgery state the following:

Persistent GM may have significant psychosocial and psychological consequences. Available literature suggests the association of GM with depression, anxiety, low self-esteem and body image concerns, issues that may lead patients to maladaptive coping mechanisms such as wrapping of the chest, walking with slumped shoulders and arms crossed, and eventually restriction of physical and social activities (Ordaz & Thompson, 2015). It should be noted though that most of the relevant data refer to adolescents, with

⁵³ Kanakis GA, Nordkap L, Bang AK, et al. EAA clinical practice guidelines-gynecomastia evaluation and management. *Andrology*. 2019;7(6):779.

other populations being less represented (Kinsella et al., 2012). In such cases of GM where the disease causes considerable cosmetic and psychological distress, surgical treatment is justified (Mathur & Braunstein, 1997; Kasielska & Antoszewski, 2011; Rew et al., 2015). Older studies suggest better psychological post-operative adjustment when surgery is combined with psychotherapy (Schonfeld, 1962); however, recent data are missing.

- 91. The analysis focuses exclusively on individuals' subjective experiences consistent with Dr. Lappert's characterization of aesthetic surgery.
- 92. The American Society of Plastic Surgeons has published a revised clinical practice guideline on reduction mammaplasty which also uses the GRADE approach.⁵⁴ It makes a strong recommendation that "post menarche female patients presenting with breast hypertrophy should be offered reduction mammaplasty surgery as first-line therapy over nonoperative therapy based solely on the presence

However, this guideline should not be construed as a rule, nor should it be deemed inclusive of all proper methods of care or exclusive of other methods of care reasonably directed at obtaining the appropriate results. It is anticipated that it will be necessary to approach some patients' needs in different ways. The ultimate judgment regarding the care of a particular patient must be made by the physician in light of all the circumstances presented by the patient, the available diagnostic and treatment options, and available resources.

This guideline is not intended to define or serve as a standard of medical care. Standards of medical care are determined on the basis of all the facts or circumstances involved in an individual case and are subject to change as scientific knowledge and technology advance. The recommendations in this guideline reflect the state of current knowledge at the time of publication. Given the inevitable changes in the state of scientific information and technology, this guideline will be considered relevant for a period of 5 years after publication, in accordance with the inclusion criteria of the ECRI Guidelines Trust (939e).

The guideline nonetheless goes on to state, "Reduction Mammaplasty surgery is considered standard of care for symptomatic breast hypertrophy (396e)." Perdikis G, Dillingham C, Boukovalas S, et al. American Society of Plastic Surgeons evidence-based clinical practice guideline revision: Reduction mammaplasty. *Plast Reconstr Surg.* 2022;149(3):392e-409e.

⁵⁴ I will note that the guideline includes a disclaimer that states in part:

of multiple symptoms rather than resection weight" based on high quality evidence. 55

- 93. In its discussion of the rationale for this recommendation, the guideline states, "The evidence demonstrates that resection weight does not accurately predict patient-oriented outcomes such as alleviation of pain and related symptoms, and should not be the primary determinant of medical necessity" citing 11 references. ⁵⁶ By multiple symptoms, it means two or more of the following symptoms: upper back pain, rashes, bra strap grooves, neck pain, shoulder pain, numbness, and arm pain. In its discussion of the outcomes of surgery, the guidelines mention reduction in depression and anxiety and increases in quality of life.
- 94. Again, based on Dr. Lappert's own definitions, reduction mammaplasty would be considered an aesthetic surgery. He therefore does not provide a sound basis for providing coverage of gynecomastia and breast reduction surgery but not coverage of gender-affirming surgery.

⁵⁵ Perdikis G, Dillingham C, Boukovalas S, et al. American Society of Plastic Surgeons evidence-based clinical practice guideline revision: Reduction mammaplasty. *Plast Reconstr Surg.* 2022;149(3):395e.

⁵⁶ Perdikis G, Dillingham C, Boukovalas S, et al. American Society of Plastic Surgeons evidence-based clinical practice guideline revision: Reduction mammaplasty. *Plast Reconstr Surg.* 2022;149(3):396e.

I declare under penalty of perjury under the laws of the United States of America that this foregoing is true and correct. Executed on this 10th day of March 2023.

ARMAND H. MATHENY ANTOMMARIA, MD, Phi

Exhibit A

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

Plaintiffs,

V.

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

JASON WEIDA, et al.,

Defendants.

CORRECTED EXPERT REBUTTAL REPORT OF E. KALE EDMISTON, PH.D.

- I, E. Kale Edmiston, Ph.D., hereby declare and state as follows:
- 1. I am over the age of eighteen and submit this expert rebuttal report based on my expert opinion.
- 2. I have been retained by counsel for plaintiffs as an expert in connection with the above referenced litigation. The opinions expressed herein are my own and do not express the views or opinions of my employer.
- 3. I have actual knowledge of the matters stated herein. If called to testify, I would testify truthfully based on my expert opinion.

Background and Qualifications

4. I am an Associate Professor of Psychiatry at the University of Massachusetts Chan Medical School. Prior to this appointment, I was an Assistant

Professor of Psychiatry at the University of Pittsburgh from 2019 to 2022. I have

more than 15 years of experience conducting psychiatric neuroimaging research,

with a focus on adolescence and young adulthood, mood and anxiety disorders, and

impulsivity and emotional regulation. My methodological expertise lies in

neuropsychological assessment, multimodal neuroimaging, psychophysiological

measures such as heart rate variability, and measures of neuroendocrine function

across adolescent development.

5. I completed a bachelor's degree from Hampshire College in 2007,

where I studied cognitive science. I received postbaccalaureate training in

psychiatric neuroimaging at the Yale School of Medicine. I earned a PhD in

neuroscience from Vanderbilt University in 2015, as well as a graduate certificate in

medical humanities, with a focus on bioethics and medical decision-making. I then

completed post-doctoral training at China Medical University and the University of

Pittsburgh.

6. In 2014, I co-founded the Trans Buddy Program at Vanderbilt

University Medical Center, a peer navigator and support program for transgender

people seeking healthcare. As a part of this program, my work primarily focused on

supporting transgender adolescents experiencing mental health crisis. At this time, I

also served as the Co-Director for the Vanderbilt University Program for LGBTI

Health. I later replicated the Trans Buddy Program at the University of Pittsburgh Department of Adolescent Medicine.

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7. From 2018-2022, I served as a chapter author for the Assessment

chapter of the World Professional Association for Transgender Health's Standards

of Care for the Health of Transgender and Gender Diverse People, Version 8.

8. I have authored over 100 peer-reviewed manuscripts, book chapters,

and conference proceedings in psychiatric neuroscience and transgender health.

9. Further information about my professional background and experience

is outlined in my curriculum vitae, a true and accurate copy of which is attached as

Exhibit A to this report.

Prior Testimony

10. I have not testified as an expert at trial or by deposition within the last

four years.

Compensation

11. I am being compensated for my time at a rate of \$175/hour. My

compensation is in no way contingent on the conclusions reached as a part of my

testimony or on the outcome of this case.

Basis for Opinions

12. In preparing this report, I have reviewed: the Complaint in this case;

Florida Administrative Code 59G-1.050(7) (the "Challenged Exclusion"); the

document titled "Florida Medicaid: Generally Accepted Professional Medical

Standards Determination on the Treatment of Gender Dysphoria," published by the

Florida Agency for Health Care Administration in June 2022, and its attachments;

the expert reports of Drs. Armand Antommaria, Dan Karasic, Johanna Olson-

Kennedy, Loren Schechter, and Dr. Daniel Shumer, submitted by plaintiffs; and the

expert reports Drs. Michael Biggs, G. Kevin Donovan, Paul Hruz, Kristopher

Kaliebe Michael Laidlaw, Patrick Lappert, Stephen Levine, Sophie Scott, and

Joseph Zanga, submitted by defendants.

13. My opinions are based on my years of research and academic

experience, as well as my professional knowledge, as set out in my curriculum vitae

(Exhibit A) and the materials listed therein; my knowledge of the peer-reviewed

literature relating to neuropsychological assessment and brain development; my

knowledge of the clinical practice guidelines for the treatment of gender dysphoria,

including my work as a contributing author of WPATH SOC 8; and my review of

any of the materials cited herein.

14. I have also reviewed the materials listed in the bibliography attached as

Exhibit B. I may rely on those documents as additional support for my opinions.

15. The materials I have relied upon in preparing this report are the same

types of materials that experts in my field of study regularly rely upon when forming

opinions on the subject. I may wish to supplement these opinions or the bases for

them as a result of new scientific research or publications or in response to

statements and issues that may arise in my area of expertise.

Adolescent Brain Development

16. Dr. Scott's report stating that adolescents are more likely to engage in

risky behaviors relative to adults fails to include the specific context in which this is

true. That is, the literature indicates that there are highly specific circumstances in

which adolescents are more likely to engage in risky or impulsive behavior. Indeed,

Dr. Scott lists some of these circumstances in her testimony: driving, drinking

alcohol, getting a tattoo. However, none of these examples are relevant to the issue

at hand: protracted medical decision-making made in the context of adult guidance

and consultation with a medical professional.

17. Dr. Scott fails to cite the large body of evidence indicating that

adolescents are capable of deliberative decision making in the presence of adults

(i.e., healthcare providers and caregivers) and when decision making occurs over a

protracted period. This is the exact context in question: decisions about accessing

gender-affirming medical care, such as gonadotropin releasing hormone agonists

(GnRHa) and hormone treatment, are made jointly among the adolescent patient, their caregiver(s), and medical professionals. These decisions are also made over time; data show that the typical time between an adolescent realizing they are transgender and coming out to an adult is three years (Bauer et al., 2022). Furthermore, once an adolescent discloses their identity to a supportive adult, they will then have to schedule a healthcare appointment and undergo assessment prior to accessing treatment. This process typically takes months and for some, even years.

18. Dr. Scott misrepresents the literature on adolescent decision making by generalizing findings made in "hot" contexts to those made in "cold" contexts. Indeed, the Blakemore and Robbins review from 2012 that she cites explicitly states that the literature concludes that adolescents demonstrate adult-typical decision-making abilities in cold contexts. It is not that adolescence is associated with a failure to engage cognitive control networks, but rather, that cognitive control networks are engaged with greater variability during this time than during adulthood. Decision-making is a multifactorial process that includes valuation of both risk and reward. While adolescents are more likely to overvalue reward and underestimate risk when peers are present or when decisions must be made quickly, they demonstrate deliberative and appropriate consideration of reward and risk valuation in the absence of peers, in the presence of adults, and when decisions are made over time.

This important difference in the contextual nature of decision-making in adolescence is an established finding that has been replicated across multiple studies (Chein et al., 2011; O'Brien et al., 2011; Simons-Morton et al., 2011; Smith et al., 2014; Weigard et al., 2014; Hartley & Somerville, 2015; Guassi Moreira & Telzer, 2018). Indeed, deliberative decision making in contexts without pressure to decide quickly has been repeatedly shown in adolescents (Byrnes, 2002; Figner et al., 2009; Wolff & Crockett, 2011; Icenogle & Cauffman, 2021).

19. Dr. Scott also states that "at 18yrs old, the connections to the frontal lobes are not myelinated¹ like a mature adult brain, and this is likely to affect frontal lobe functions." This is an oversimplification of an extremely complex literature. A study of over 10,000 participants has shown quite the opposite: that by the age of 18, adult-level cognition is established (Tervo-Clemmens et al., 2022), while other studies have shown mature integration of functional networks by late adolescence (Marek et al., 2015) and fractional anisotropy of prefrontal white matter (Lebel & Beaulieu, 2011, fractional anisotropy is an indirect measure of myelination). Even though, on average, there are developmental differences in prefrontal myelination,

¹ Myelin is a protein sheath that covers the axons of neurons. The axons comprise white matter in the brain, and bundles of these fibers transmit signals from region to region in the brain. When an axon is myelinated, the signal can travel faster down the axon.

there is not strong evidence that these differences are associated with an inability to make deliberative decisions with the support of caregivers and expert clinical

guidance.

20. Furthermore, there is a great deal of variation in the timing of

development between different prefrontal white matter tracts, as well as a great deal

of variation between individuals. Indeed, in Lebel & Beaulieu's longitudinal study

of over 100 individuals from childhood to young adulthood, many individuals

showed decreases or no changes in fractional anisotropy (FA) during adolescence,

and these differences also varied by prefrontal white matter tract (2011). This

literature represents differences in group averages and should not be used to predict

the behavior or development of an individual adolescent; we cannot draw

conclusions about all 18-year-olds from these studies. This is why the WPATH SOC

8 recommends an individualized approach to joint decision-making regarding

healthcare.

There is Little Evidence to Support Defendants' Designated Experts' Speculation about Negative Effects of GnRHas on Cognition

21. Dr. Scott cites a 2016 study by Wojniusz and colleagues as evidence of

the negative effects of GnRHas on emotional reactivity in a sample of girls with

central precocious puberty. This is puzzling because the authors of this paper

explicitly state the opposite interpretation: "Overall, our findings do not provide firm

Q

conclusions with regard to differences in emotional processing between the GnRHa

treated CPP girls and age-matched controls." (pp13).

22. Perhaps Dr. Scott has misinterpreted the nature of the emotional flanker

task. This task asks participants to determine if two simultaneously presented houses

are the same or different. The houses are presented at the center of a screen, and

emotional or neutral face distractors flank them. The outcome of interest is the

reaction time for the determination of whether the houses are the same or different.

The idea here is that people with poor emotional regulation will be more distracted

during the emotional face condition and therefore take longer to respond. This

interpretation can only be made when reaction times are increased in both the

emotional face conditions. In this study, the CPP girls showed longer reaction time

than controls during the emotional face condition only when the houses were

different, but not when the houses were the same. Thus, the findings do not indicate

an issue with emotional regulation. More likely, the results are incidental and due to

statistical issues regarding false discovery rate correction, an argument that the

authors of the paper themselves make.

23. The authors do find reduced heart rate and elevated heart rate variability

(HRV) during the emotional task. HRV is distinct from heart rate and is a measure

of cardiac vagal tone. HRV is a proxy for parasympathetic system or "rest and

digest" function. Thus, elevated HRV is associated with increased regulatory

capacity and is a marker of health. Thus, these findings are a sign of optimal

emotional regulation. Indeed, the authors state, "...the lower HR and higher HRV

could suggest that treated CPP girls have better emotion regulation capacity and

higher adaptability to changing contexts than controls" (pp13).

24. Dr. Scott then points out that, in a separate commentary on the article,

Dr. Hayes states that there were "notably" lower scores on IQ measures in the CPP

group relative to controls. However, Dr. Hayes's comment, and Dr. Scott's reliance

on it, is not supported by the findings of the study. Specifically, none of the

differences in IQ were statistically significant, and the mean IQ scores for both

groups were within the normal range. Furthermore, the mean difference between

groups in this study is within the realm of variation that may occur from repeated

administration of the WISC-III, i.e., although scores for an individual tend to remain

relatively stable over time, there is fluctuation that occurs even within an individual

and small differences in IQ (Watkins & Smith, 2013), as reported in this study, are

not only not statistically significant, they are not clinically significant. Dr. Scott has,

again, offered a misrepresentation of the literature.

25. Dr. Levine cites a single case study as evidence for an effect of GnRHa

treatment on IQ. Case studies are the lowest quality of evidence. Case studies can

provide important evidence for future areas of study or to provide an illustrative

example of a common clinical phenomenon, but they should not be used to make

general conclusions or policy positions. Putting aside the low quality of evidence

typical of case studies in general, this case study does not even provide sufficient

support for Dr. Levine's opinion as it describes a transgender girl who, prior to

initiation of treatment, already had below average IQ. While Dr. Levine highlights

the lack of change in fractional anisotropy values over the course of the study in this

case, this could be due to developmental delays that are independent of treatment

and are instead related to her low IQ. Therefore, the findings of this case study are

simply not generalizable to the broader population.

26. Dr. Michael Biggs, a sociologist, also offers speculation regarding

cognitive effects of GnRHa treatment as well, describing it as "...stopping normal

sexual and cognitive development..." This statement regarding cognitive

development appears to be pure speculation as he offers no citation regarding

evidence for deleterious effects of GnRHa treatment on cognition. In reviewing the

literature, including through specific searches, I have been unable to find compelling

evidence of this. I was able to identify two studies that showed no effect of GnRHa

treatment on executive function (Soleman et al., 2016; Staphorsius et al., 2015). The

lack of evidence for these effects is itself compelling, given that these medications

have been used in adolescents with central precocious puberty for decades.

Evidence for Effects of GnRHa treatment on the Brain

27. Both Dr. Levine and Dr. Laidlaw state that the effects of GnRHa

treatment on the brain are both "unknown" and "likely negative." They do not cite

any original research that supports this conclusion and thus it is unclear to me how

they concluded that the effects are likely negative in the absence of evidence. Dr.

Laidlaw even goes so far as to speculate on the individual brain maturation of three

specific transgender individuals. Both Levine and Laidlaw admit that there is no

evidence from the neuroimaging literature on negative effects of these treatments on

brain development, but even if there was, any neuroimaging study that compares

group averages would not support an inference about the brains of individual people.

There is a great deal of variation between and within individuals in many commonly

used neuroimaging measures. For this reason, neuroimaging methods commonly

used in research, such as fMRI, cannot be used diagnostically for individual people

in the absence of organic brain disease (Schleim & Roise, 2019).

28. Dr. Hruz also speculates in his testimony that there are negative effects

of GnRHa treatment on the brain: "A possible effect of blocking normally timed

puberty is alteration of normal adolescent brain maturation". Dr. Hruz then cites a

2013 review paper that describes typical adolescent brain maturation but does not

mention or describe any effects of blocking or delaying puberty on the brain (Arain

et al., 2013). Dr. Hruz therefore has not cited any support for his conclusion, and I

have not identified any studies relating to the evidence of negative longitudinal

effects on brain development related to GnRHa treatment in central precocious

puberty or in transgender adolescents, even after targeted searches for it.

29. There is not a large literature on the effects of GnRHa treatment on the

brain in humans, but this does not render such care experimental. GnRHa treatments

have been in used for decades, including for the treatment of gender dysphoria. That

said, there are a few cross-sectional studies on this issue, and it is significant that

none of the experts (nor the GAPMS memo) cited this literature in their testimonies.

In a study that compared transgender adolescent boys and girls taking GnRH

agonists to cisgender boys and girls, there were differences in brain function in some

brain regions that would indicate congruence with gender identity and other

differences that would indicate congruence with sex assigned at birth. However,

there were no between-group differences in network function on the basis of GnRHa

treatment. Furthermore, the authors searched for relationships between duration of

GnRHa treatment in the transgender adolescents and brain function and were unable

to find any effects. In a diffusion tensor imaging study of fractional anisotropy

values, an index of white matter myelination, again there was no significant

association between fractional anisotropy values and GnRHa treatment (van

Heesewijk et al., 2022). Similarly, in an fMRI study comparing cisgender boys and

girls to transgender boys and girls, there were no significant differences in brain

activity between transgender and cisgender adolescents during a verbal fluency task,

and no deficits in verbal ability in transgender youth (Soleman et al., 2013). In a

study of transgender individuals receiving GnRHa treatment and cisgender people,

there were differences in brain activity between groups, but these differences were

not associated with hormone levels, leading the authors to conclude that these

differences are associated with group differences that predate GnRHa treatment

(Soleman et al., 2016). In summary, to my knowledge, there have been three studies

of brain structure and function of transgender adolescents receiving GnRHa

treatment, and none of them have found any significant effects of treatment on the

brain.

30. A recent primate study provides evidence for some regional

neuroprotective effects of GnRHa treatment, although the results are complex

(Godfrey et al., 2023). In this study, the authors compared dominant and subordinate

adolescent rhesus monkeys. These monkeys form social hierarchies much like

human adolescents, and subordinate monkeys are subjected to aggression from the

more dominant monkeys. Both dominant and subordinate monkeys were randomly assigned to a GnRHa treatment or control group and then followed longitudinally. In the primates exposed to chronic social subordination stress, GnRHa treatment rescued the negative effect of stress on regional brain volume over time. These differences were seen in brain regions such as the amygdala that are well-established in the pathophysiology of depression and anxiety. There were also effects of GnRHa treatment in general; treatment in both social groups was associated with smaller hippocampal volume than control animals. Regarding the prefrontal cortex, a critical region during adolescent development, GnRHa treatment was associated with greater prefrontal grey matter volume prepubertally but this difference decreased by adolescence. There was an effect of GnRHa treatment early in puberty on prefrontal white matter volume; however, this difference was no longer present by the end of the study. Importantly, there are species-specific differences in prefrontal volume changes across puberty; the generalizability of the prefrontal findings to humans should be made with caution. Finally, the authors also assessed social behavior in both submissive and dominant primates over time and were able to determine that, at prepuberty, submissive primates were more socially isolated, but that GnRHatreated subordinate animals had normalized social behavior (reduced time spent alone) and normalized cortisol response to threat (cortisol is a stress hormone

associated with the hypothalamic pituitary adrenal axis). The authors conclude that

"...delayed puberty and estrogen suppression may be protective against the impact

of social stress" (pp12). This study provides strong evidence that GnRHa treatment

normalizes brain structure, physiological stress reactivity, and social behavior in

adolescent primates subjected to social subordination, an ecologically valid non-

human primate model of the psychosocial environment for transgender youth.

31. There is a small body of literature on the effects of gender affirming

hormone care on the brain in transgender adolescents. In a study comparing

transgender boys receiving testosterone therapy and those who were not,

testosterone treatment was associated with reductions in mood and anxiety

symptoms, as well as reductions in body image dissatisfaction. Gender affirming

hormone care was associated with an increase of functional coupling between the

amygdala and prefrontal cortex while research participants viewed threatening

emotional faces, likely indicating improved emotional regulation of the amygdala in

the boys who were treated with testosterone. Indeed, in the boys who were treated

with testosterone, greater coupling between these two regions was associated with

lower anxiety symptom severity (Grannis et al., 2021). Another study of transgender

boys receiving testosterone found that testosterone caused a shift in amygdala

activation, such that it became more typical of cisgender boys than cisgender girls (Beking et al., 2020).

32. 17. Both Dr. Scott and Dr. Biggs cite studies from the animal

literature regarding the "side effects" of GnRHa treatment on the brain and behavior.

However, they misinterpret or misrepresent the meaning of the term "side effect" in

this context. Pharmacological agents have effects. The determination of what is a

side effect and what is a desired effect is contextual. For example, Scott cites a 2021

rodent study of GnRHa treatment as an example of the "side effects" associated with

GnRHa treatment (Anacker, et al., 2021). If one were to read the abstract of the study

and not the full text, it may lead some to come to such a conclusion. However, what

the study shows is that, prior to GnRHa treatment, there are sex differences in rodent

behavior. Following GnRHa treatment, those sex differences are no longer present.

This is the expected and desired outcome of GnRHa treatment, not a side effect. For

example, female mice show greater locomotion behavior than male mice. Following

GnRHa treatment, male mice show greater locomotion behavior than untreated male

mice. Similarly, in a test of social interaction, GnRHa-treated males showed

differences in the time spent with male versus female mice relative to untreated male

mice, but not relative to untreated female mice. In both force-swim tests and a test

of feeding behavior, female GnRHa-treated mice differed from control female mice,

but not from male mice. This is a consistent pattern across behavioral assays performed in the study, and this pattern was present in biological assays as well. GnRHa-treated male mice showed greater corticosterone stress response to novelty than control male mice but did not differ from female mice. GnRHa treatment increased neural activity in the hippocampus of female mice, but this activity increase did not differ from male mice. This is not a compelling study of the side effects of GnRHa treatment, but rather, a study that shows us exactly what we would expect: that blocking sex hormones decreases sex differences, the intended outcome for transgender youth.

33. Dr. Scott and Dr. Biggs cite a series of studies of GnRHa effects on sheep from a specific laboratory. One study from this group did show sex-specific changes in feeding behavior and HRV following GnRHa treatment. While Dr. Biggs opts to highlight changes in behavior in the female sheep that could be interpreted as an increase in anxiety-like behavior, he fails to mention that GnRHa treatment was associated with *improvements* in these behaviors in the treated male sheep (Wojniusz et al., 2011). They also fail to mention that other studies from this group show no effects of GnRHa treatment on cognition (Nuruddin et al., 2013; Wojniusz et al., 2013), and, like the Anacker study, brain differences are best explained by an expected reduction of sex differences following treatment (Nuruddin et al., 2013).

This issue of inappropriate reference group is a common problem in the GnRHa animal literature and its extrapolation to transgender youth (Edmiston & Juster, 2022). While the literature regarding the effects of GnRHa treatment on sheep behavior from this research group is complex, it by no means offers compelling evidence of negative effects of GnRHa treatment. Furthermore, Dr. Biggs highlights a negative effect from one study- an increase in anxiety-like behavior in female sheep only. However, we know from studies of transgender youth and young adults that anxiety and depression symptoms decrease with treatment (de Vries et al., 2014; Dhejne et al., 2016; Aldridge et al., 2021; Chen et al., 2023). This is more compelling evidence than a single animal study, as sheep do not have the complex psychosocial identities that humans do.

Evidence for Negative Consequences of Depression and Anxiety on the Developing Brain

34. The brain is more plastic during adolescence than during adulthood. This means that adolescents are particularly vulnerable and at increased risk for the onset of mood and anxiety disorders, and, if untreated, that the onset of mood and anxiety symptoms can permanently alter the developmental trajectory of the brain into adulthood (Holder & Blaustein, 2014). Termed the "kindling effect", the concept here is that, as the efficiency of neural circuits is reinforced over time (i.e., "neurons that fire together wire together"), each depressive episode or

environmental stressor increases the risk for later depressive episodes. This effect

may be amplified during adolescence because of the greater plasticity of the brain.

35. There are well-documented disparities in mental health outcomes in

transgender youth that are caused by minority stress (for review, see White Hughto

et al., 2015). This includes evidence that transgender people who live in areas with

more accepting political climates show reduced biological stress markers and fewer

mental health symptoms than transgender people who live in less accepting areas

(DuBois & Juster, 2022). Others have shown an association between decreased

social support and biological markers of stress in transgender adolescents

(McQuillan et al., 2021). Given that transgender adolescents report high chronic

stress and high rates of depression, anxiety, and suicidality, transgender adolescents

are particularly vulnerable to the effects of stress on brain development, stress

system regulation, and long-term mental health outcomes (DuBois et al., 2021;

Potter et al., 2021; Randall et al., 2022).

36. In Dr. Levine's testimony, he quotes the Hippocratic Oath, "Above All

Do No Harm". He makes this argument on the assumption that GnRHa treatment

must necessarily cause harm because it is an intervention. This assumes that the

psychosocial environment and biology of transgender youth is like that of cisgender

youth. There is a great deal of evidence that this is not the case. Instead, in my

opinion not offering an intervention to transgender individuals that require treatment

actually does harm.

37. In this case, puberty blockers have demonstrated efficacy in reducing

symptoms of depression in transgender adolescents (de Vries et al., 2011), and

therefore may in fact be neuroprotective to the cumulative effects of stress caused

by gender dysphoria.

Conclusion

38. There is little to support the Defendants' designated experts'

speculation about the negative effects of GnRHa treatment on the brain. In contrast,

there is a great deal of evidence supporting the mental health benefits of GnRHa

treatment for transgender adolescents. Furthermore, it is well-known that

transgender adolescents face higher rates of psychosocial stress than their cisgender

peers, and there is clear evidence for the negative effects of psychosocial stress and

poor mental health on brain development. While the effects of GnRHa treatment on

the brain are an important area for future research, this does not render such care

experimental. To the contrary, this is treatment that has existed for decades and

arguments that a purported lack of evidence is equivalent to known harm are

spurious, particularly when there is a large literature indicating benefits of treatment

and harm of withholding treatment.

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

Executed this 22 day of March 2023.

E. Kale Edmiston, Ph.D.

Exhibit A Curriculum Vitae

EXPERT REPORT OF E. KALE EDMISTON, Ph.D. Case No. 4:22-cv-00325-RH-MAF

E. Kale Edmiston, PhD

Associate Professor
Department of Psychiatry
University of Massachusetts Chan Medical School
kale.edmiston@umassmed.edu

ACADEMIC APPOINTMENTS

Associate Professor of Psychiatry 2022-present
University of Massachusetts Chan Medical School Worcester, MA

Assistant Professor of Psychiatry 2019-2022
University of Pittsburgh School of Medicine Pittsburgh, PA

Postdoctoral Scholar 2016-2019 University of Pittsburgh Medical Center Pittsburgh, PA

PI: Mary L. Phillips, MD, MD (CANTAB)

Postdoctoral Fellow 2016

China Medical University Shenyang, China

PI: Fei Wang, MD, PhD

Research Assistant 2007-2010
Yale University School of Medicine New Haven, CT

PI: Hilary P. Blumberg, MD

EDUCATION

PhD, Neuroscience 2010-2015 Vanderbilt University Nashville, TN

Graduate Certificate 2015

Medicine, Health and Society

Nashville, TN

Vanderbilt University

BA, Cognitive Science 2005-2007 Hampshire College Amherst, MA

RESEARCH

CITATION METRICS (03/23):

Citations: 2087 H-Index: 25 i10 Index: 34

RESEARCH INTERESTS:

social and affective neuroscience, visual processing, anxiety disorders, multimodal MRI, neuromodulation

AWARDED GRANTS:

American Foundation for Suicide Prevention Award 2022

Title: Real-time study of psychotherapy, suicide risk, and resilience in transgender and non-

binary adults
PI: Sarah Victor

Co-I: **E. Kale Edmiston** Award amount: \$90,000.00

K01 MH117290 Mentored Scientist Career Development Award 2019-2024

Title: Feed forward visual system function in high trait anxiety

PI: E. Kale Edmiston

Award amount: \$868,978.00

Brain and Behavior Research Foundation Early Career Award 2019-2021

Title: Neuromodulation of visual cortex BOLD in high trait anxiety

PI: **E. Kale Edmiston** Award amount: \$69,401.00

The Opportunity Fund 2019

Title: Trans Buddy PGH: Peer healthcare support program

PI: Gerald Montano Co-I: **E. Kale Edmiston** Award amount: \$15,000

Center for Interventional Psychiatry 2018

Title: Neuromodulation of visual cortex and threat sensitivity in high anxiety

PI: **E. Kale Edmiston** Award amount: \$9,900.00

Campaign for Southern Equality 2017

Title: The Trans Buddy Program: Mental health advocacy for trans communities

PI: **E. Kale Edmiston** Award amount: \$1,000.00

University of Pittsburgh Office of Diversity and Inclusion Mini-Grant 2017

Title: Developing health promotion materials for the transgender community

PI: **E. Kale Edmiston** Award amount: \$1,000.00

Trans Justice Funding Project 2017

Title: The Trans Buddy Program: Peer advocacy solutions for mental health care access

PI: **E. Kale Edmiston** Award amount: \$2,500.00

The Pollination Project 2016

Title: The Trans Buddy Program: An innovative solution to transgender mental health disparity

PI: **E. Kale Edmiston** Award Amount: \$1,500.00

Culture, Brain, and Development Grant 2006

Title: Brain sex differences in mood disorders

PI: **E. Kale Edmiston** Award amount: \$3,000.00

PEER-REVIEWED PUBLICATIONS (https://orcid.org/0000-0002-3548-6026): 2023:

- 48. Hoelscher EC, Victor SE, **Edmiston EK**. Gender minority resilience and suicidal ideation: a longitudinal and daily examination of transgender and non-binary adults. Behavior Therapist. (In Press).
- 47. Schroth-Erickson L, Levin R, Mak K, **Edmiston EK**. A review of the neurobiobehavioral literature of transgender identity. J Gay and Lesbian Mental Health. (In Press). **2022:**
- 46. Coleman E, Radix AE, Bouman WP...**Edmiston EK**...Arcelus J. Standards of care for the health of transgender and gender diverse people, version 8. International Journal of Transgender Health. 2022; 23:1-258.
- 45. Juster RP, **Edmiston EK**. Refining research and representation of sexual and gender diversity in neuroscience. Biological Psychiatry: CNNI. 2022; 7(21):1251-7.
- 44. Colic L, Clark A, Sankar A, Rathi D, Goldman D, Kim JA, Villa LM, **Edmiston EK**, Lippard ETC, Mazure CM, Blumberg HP. Gender-related associations among childhood maltreatment on brain circuitry and clinical features of bipolar disorder. European Neuropsychopharmacology. 2022; 63:35-46.
- 43. **Edmiston EK**, Fournier JC, Chase HW, Aslam H, Lockovich J, Graur S, Bebko G, Bertocci M, Rozovsky R, Mak K, Forbes EE, Stiffler R, Phillips ML. Left ventrolateral prefrontal cortical activity during reward expectancy predicts mania risk up to one year post scan. J Affective Disorders. 2022; 319:325-8.

2021:

- 42. Bertocci MA, Chase HW, Graur S, Stiffler R, **Edmiston EK**, Coffman B, Greenberg T, Phillips ML. Reward circuitry-targeted cathodal transcranial direct current stimulation impacts reward circuitry and affect in bipolar disorder. Molecular Psychiatry. 2021; 26(8):4137-45. **2020:**
- 41. Feng R, Womer FY, **Edmiston EK**, Chen Y, Wang Y, Chang M, Yin Z, Wei Y, Duan J, Ren S, Li C, Liu Z, Jiang X, Wei S, Li S, Zhang X, Nuo X, Tang Y, Wang F. Antipsychotic effects on cortical morphology in schizophrenia and bipolar disorders. Frontiers Neuroscience. 2020; 14:579139.
- 40. Wang L, Zhao Y, **Edmiston EK**, Womer FY, Zhang R, Zhao P, Jiang X, Wu F, Kong L, Zhou Y, Tang Y, Wei S, Wang F. Structural and functional abnormalities of amygdala and prefrontal cortex in major depressive disorder with suicide attempts. Frontiers Psychiatry. 2020; 10:923.
- 39. Wang Y, Wei Y, **Edmiston EK**, Womer FY, Zhang X, Duan J, Zhu Y, Zhang R, Zhang Y, Jiang X, Wei S, Liu Z, Zhang Y, Tang Y, Wang F. Altered structural connectivity and cytokines levels in schizophrenia and genetically high-risk individuals: associations with disease state and vulnerability. Schizophrenia Research. 2020; 223:158-165.
- 38. **Edmiston EK**, Fournier JC, Chase HW, Bertocci MA, Greenberg T, Aslam HA, Lockovich JC, Graur S, Bebko G, Forbes EE, Stiffler R, Phillips ML. Assessing relationships

- among impulsive sensation-seeking, reward circuitry activity, and risk for psychopathology: an fMRI replication and extension study. Biological Psychiatry: CNNI. 2020; 5(7):660-68.
- 37. Sha Z, Versace A, **Edmiston EK**, Fournier JC, Graur S, Greenberg T, Lima Santos JP, Chase HW, Stiffler R, Bonar L, Hudak R, Yendiki A, Greenberg BD, Rasmussen S, Liu H, Quirk G, Haber S, Phillips ML. Functional disruption in prefrontal-striatal network in obsessive compulsive disorder. Psychiatry Research: Neuroimaging. 2020; 300:111081.
- 36. **Edmiston EK,** Song Y, Chang M, Yin Z, Zhou Q, Zhou Y, Jiang X, Wei S, Xu K, Tang Y, Wang F. Hippocampal functional connectivity in patients with schizophrenia and unaffected family members. Frontiers in Psychiatry. 2020; 11:278.
- 35. Wei S, Womer F, **Edmiston EK**, Zhang R, Jiang X, Wu F, Kong L, Zhou Y, Tang Y. Structural alterations associated with suicide attempts in major depressive disorder and bipolar disorder: a diffusion tensor imaging study. Progress in Neuropsychopharmacology & Biological Psychiatry. 2020; 98.
- 34. Beach L, Eckstrand K, Ehrenfeld J, **Edmiston EK**, Ding J. A model for improving transgender healthcare quality. The Joint Commission Journal on Quality and Patient Safety. 2020; 46:37-43.

2019:

- 33. Sha Z*, **Edmiston EK***, Versace A, Fournier JC, Graur S, Greenberg T, Lima Santos JP, Chase HW, Stiffler RS, Bonar L, Hudak R, Yendiki A, Greenberg BD, Rasmussen S, Liu H, Buckner R, Quick G, Haber S, Phillips ML. Multimodal disruption of cerbello-thalamo-motor circuit in obsessive compulsive disorder. Biological Psychiatry: CNNI. 2019; 5(4):438-47. *co-first authors
- 32. Wang L, Zhao Y, **Edmiston EK**, Womer FY, Zhang R, Zhao P, Jiang X, Wu F, Kong L, Zhou Y, Tang Y, Wei S. Structural and functional abnormalities of amygdala and prefrontal cortex in major depressive disorder with suicide attempts. Frontiers Psychiatry. 2019; 10:923.
- 30. Chang M, **Edmiston EK**, Womer F, Zhou Q, Shengnan W, Jiang X, Zhou Y, Ye Y, Huang H, Zui X, Xu K, Tang Y, Wang F. Spontaneous low-frequency fluctuations in the neural system for emotional perception in major psychiatric disorders: amplitude similarities and differences across frequency bands. Journal of Psychiatry and Neuroscience. 2019; 44:132-41.
- 29. Xia M, Womer FY, Chang M, Zhu Y, **Edmiston EK**, Jiang X, Wei S, Duan J, Xu K, Tang Y, He Y, Wang F. Shared and distinct functional architecture of brain networks across psychiatric disorders. Schizophr Bulletin. 2019; 47:450-63.

2018:

- 28. Li J, **Edmiston EK**, Tang Y, Fan G, Xu K, Wang F, Xu J. Shared facial emotion processing in medication-naive major depressive disorder and healthy individuals: detection by sICA. BMC Psychiatry, 2018; 18:96.
- 27. Chang M, Womer FY, **Edmiston EK**, Bai C, Zhou Q, Jiang X, Wei S, Wei Y, Ye Y, Huang H, He Y, Xu K, Tang Y, Wang F. Neurobiological commonalities among three major psychiatric diagnostic categories: a structural MRI study. Schizophrenia Bulletin. 2018; 44:65-74.

2017:

26. Wang N, **Edmiston EK**, Luo X, Yang H, Chang M, Wang F, Fan G. Comparing amplitude of low-frequency fluctuations in multiple system atrophy and idiopathic Parkinson's disease. Psychiatry Research Neuroimaging, 2017; 269:73-81.

- 25. Jiang X, **Edmiston EK**, Zhou Q, Xu K, Zhou Y, Wu F, Kong L, Wei S, Zhou Y, Chang M, Geng H, Wang D, Wang Y, Cui W, Tang Y, Wang F. Alteration of a cortico-striatal-limbic neural system in major depressive disorder and bipolar disorder. Journal of Affective Disorders, 2017; 221:297-303.
- 24. Corbett BA, Blain S, **Edmiston EK**. The role of context in psychosocial stress among adolescents with Autism Spectrum Disorder: piloting a semi-structured, video game-based paradigm. Journal of Intellectual & Developmental Disability. 2017; 43:20-8.
- 23. **Edmiston EK**, Muscatello RA, Corbett BA. Altered pre-ejection period response to social evaluative threat in adolescents with autism spectrum disorder. Research in Autism Spectrum Disorders. 2017; 36:57-65.

2016:

- 22. **Edmiston EK**, Donald CA, Sattler AR, Peebles JK, Ehrenfeld JM, Eckstrand KL. Opportunities and gaps in transgender primary healthcare: a systematic review. Transgender Health. 2016; 1(1):216-30.
- 21. **Edmiston EK**, Jones RM, Corbett BA. Physiological response to social evaluative threat in adolescents with autism spectrum disorder. Journal of Autism Developmental Disorders. 2016; 46(9):2992-3005.
- 20. **Edmiston EK**, Blain S, Corbett BA. Salivary cortisol and behavioral response to social evaluative threat in adolescents with autism spectrum disorder. Autism Research. 2016; Epub ahead of print.

2015:

- 19. Tang Y, Chen K, Zhou Y, Wang Y, Driesen N, **Edmiston EK**, Chen X, Jiang X, Kong L, Zhou Q, Li H, Wu F, Xu K, Wang Z, Tang Y, Wang F. Neural activity changes in unaffected children of patients with schizophrenia: a resting-state fMRI study. Schizophrenia Research. 2015; 168(1-2):360-5.
- 18. **Edmiston EK**, Merkle K, Corbett BA. Neural and cortisol responses during play with human and computer partners in children with autism. Social Cognitive Affective Neuroscience. 2015; 10(8):1074-83.

2014:

- 17. Corbett BA, Newsom C, Key AP, Qualls L, **Edmiston EK**. Examining the relationship between face processing and social interaction behavior in children with and without autism spectrum disorder. J Neurodevelopmental Disorders, 2014; 6(1):35.
- 16. Li J*, **Edmiston EK**,* Chen B, Tang Y, Ouyang X, Jiang Y, Fan G, Ren L, Liu J, Zhou Y, Jiang W, Liu Z, Xu K, Wang F. A comparative diffusion tensor imaging study of corpus callosum subregion integrity in bipolar disorder and schizophrenia. Psychiatry Res. 2014; 221(1):58-62.*co-first authors

2013:

- 15. **Edmiston EK***, McHugo M*, Dukic MS, Smith SD, Abou-Khalil B, Zald DH. Enhanced visual cortical activation for emotional stimuli is preserved in patients with unilateral amygdala resection. J Neuroscience, 2013; 33(27):11023-11031. *co-first authors
- 14. Liu H, **Edmiston EK**, Fan G, Ku X, Zhao B, Shang X, Wang F. Altered resting-state functional connectivity of the dentate nucleus in Parkinson's disease. Psychiatry Research: Neuroimaging. 2013; 211(1):64-71.

13. **Edmiston EK**, Blackford JU. Childhood maltreatment and response to novel face stimuli presented during functional magnetic resonance imaging in adults. Psychiatry Research: Neuroimaging. 2013; 212(1):36-42.

2012:

- 12. Fengrong O, Kai L, Qian G, Dan L, Jinghai L, Liwen H, Xian W, **Edmiston EK**; Yang L. An urban neo-poverty population-based quality of life and related social characteristics investigation from northeast china. PLoS One. 2012; 7(6):e38861.
- 11. Chepenik LG, Wang F, Spencer L, Spann MN, Kalmar JH, Womer F, **Edmiston EK**, Pittman B, Blumberg HP. Structure-function associations in hippocampus in bipolar disorder. Biological Psychiatry. 2012; 90(1):18-22.

2011:

- 10. Wang F, Kalmar JH, Womer FY, **Edmiston EK**, Chepenik LG, Chen R, Spencer L, Blumberg HP. Olfactocentric paralimbic cortex morphology in adolescents with bipolar disorder. Brain. 2011; 134(7):2005-12.
- 9. **Edmiston E**, Wang F, Mazure CM, Sinha R, Mayes LC, Blumberg HP. Cortico-striatal limbic gray matter morphology in adolescents reporting exposure to childhood maltreatment. Archives of Pediatric and Adolescent Med. 2011; 165(12):1069-77.
- 8. **Edmiston E**, Wang F, Kalmar JH, Womer FY, Chepenik LG, Pittman B, Gueorguieva R, Hur E, Spencer L, Staib LH, Constable RT, Fulbright RK, Papademetris X, Blumberg HP. Lateral ventricle volume and psychotic features in adolescents and adults with bipolar disorder. Psychiatry Research. 2011; 194(3):400-2.

2009:

- 7. Womer FY, Wang F, Chepenik LG, Kalmar JH, Spencer L, **Edmiston E**, Constable RT, Papademetris X, Blumberg HP. Sexually dimorphic features of vermis morphology in bipolar disorder. Bipolar Disord 2009; 11(7):753-8.
- 6. Jiang Y, **Edmiston E**, Wang F, Blumberg HP, Papademetris X, Staib, LH. Improving the reliability of shape comparison by perturbation. IEEE Biomedical Imaging 2009; 1:686-9.
- 5. Jiang Y, **Edmiston E**, Wang F, Blumberg HP, Staib LH and Papademetris X. Shape comparison using perturbing shape registration. IEEE Computer Vision Pattern Recognition 2009;683-90.
- 4. Wang F, Kalmar JH, He Y, Jackowski M, Chepenik LG, **Edmiston E**, Tie K, Gong G, Shah MP, Jones M, Uderman J, Constable RT, Blumberg HP. Functional and structural connectivity between the perigenual anterior cingulate and amygdala in bipolar disorder. Biological Psychiatry 2009; 66(5):516-21.
- 3. Kalmar JH, Wang F, Spencer L, **Edmiston E**, Lacadie CM, Martin A, Constable RT, Duncan JS, Staib LH, Papademetris X, Blumberg HP. Preliminary evidence for progressive prefrontal abnormalities in adolescents and young adults with bipolar disorder. J Int Neuropsychol Soc. 2009; 15(3):476-81.

2008:

- 2. Blumberg HP, Wang F, Chepenik LG, Kalmar JH, **Edmiston E**, Duman RS, Gelernter J. Influence of vascular endothelial growth factor variation on human hippocampus morphology. Biological Psychiatry 2008; 64(10):901-3.
- 1. Wang F, Kalmar JH, **Edmiston E**, Chepenik LG, Bhagwagar Z, Spencer L, Pittman B, Jackowski M, Papademetris X, Constable RT, Blumberg HP. Abnormal corpus callosum

integrity in bipolar disorder: A diffusion tensor imaging study. Biological Psychiatry 2008; 64(8):730-3.

MANUSCRIPTS (IN PROGRESS):

Ravindranath O, Perica MI, Parr AC, Pjha A, McKeon SD, Montano G, Ullendorf N, Luna B, **Edmiston EK**. Adolescent neurocognitive development and decision-making regarding gender affirming care. (Submitted).

Soehner AM, **Edmiston EK**, Wallace M, Chase HW, Lockovich J, Aslam H, Stiffler R, Graur S, Skeba A, Bebko G, Benjamin OE, Wang Y, Phillips ML. Neurobehavioral reward and sleep-circadian phenotypes predict present and next-year mania/hypomania risk. (Submitted).

Sequiera S, Tervo-Clemmens B, Carmel T, **Edmiston EK.** Towards a biopsychosocial model for neurodevelopment in transgender and gender diverse adolescents: understanding risk and resilience for mood disorders. (Submitted).

POSTERS, ABSTRACTS, AND CONFERENCE PROCEEDINGS:

- 53. Victor SE, **Edmiston EK**. Ecological momentary assessment of gender-relevant versus other interpersonal stressors predicting self-injurious thoughts and behaviors among transgender and non-binary adults. *Association for Behavioral and Cognitive Therapy Annual Convention. Submitted.*
- 52. **Edmiston EK**, Fournier JC, Chase HW, Phillips ML. Ventral visual stream functional coupling during implicit emotional face perception is associated with internalizing symptoms: a double dissociation by face valence at baseline and six months post-scan. *American College of Neuropsychopharmacology*. 2023.
- 51. Victor SE, Hoelscher E, Sandel D, Trieu T, **Edmiston EK.** Interpersonal and intrapersonal gender minority stressors as contribution to suicidal ideation among transgender and non-binary adults. *Suicide Research Symposium*. 2022.
- 50. Aslam MA, Mak K, **Edmiston EK.** Piloting transcranial direct current stimulation to reduce threat sensitivity in high trait anxiety. *University of Pittsburgh Department of Psychology Undergraduate Directed Experiences in Research Poster Day.* 2022.
- 49. **Edmiston EK** & Strakowski S. Understanding diagnosis and assessment disparities in transgender populations. *Society of Biological Psychiatry Annual Meeting.* 2022. Discussant, Lunchtime "Fireside Chat" Series.
- 48. Bertocci M, Afriyie-Agyemang Y, Rosovsky R, Aslam H, Graur S, **Edmiston EK**, Chase HW, Bebko G, Stiffler R, Phillips ML. Network interference during emotion regulation in distressed adults consistently predicts depression symptoms. *Society of Biological Psychiatry Annual Meeting*. 2022.
- 47. Afriyie-Agyemang Y, Bertocci M, Rozovsky R, Aslam H, Graur S, **Edmiston EK**, Chase HW, Bebko G, Stiffler R, Phillips ML. Overcompensation of the central executive network during working memory may be a neural marker for youth at risk for bipolar disorder. *Society of Biological Psychiatry Annual Meeting*. 2022.

- 46. Schumer MC, Bertocci MA, Bebko G, Stiffler RS, Lockovich JC, Aslam HA, Graur S, **Edmiston EK**, Chase HW, Johnson SL, Phillips ML. Trait urgency mediates associations between neural emotion-processing markers of emotion-triggered impulsivity and mania in young adults at-risk for bipolar disorder. *Society of Biological Psychiatry Annual Meeting*. 2022.
- 45. Young J, Roepke T, Anacker C, Ehrensaft D, **Edmiston EK**, Guthman EM, Eshel N, Marrocco J. Challenges and opportunities for translational research and clinical strategies within the LGBTQIA2S+ community. *American College of Neuropsychopharmacology Annual Meeting*. 2021. Discussant, Study Group.
- 44. Phillips ML, Bertocci M, Chase HW, Graur S, Stiffler R, **Edmiston EK**, Coffman BA. Targeted non-invasive neuromodulation impacts reward expectancy-related reward circuitry activity and affect in bipolar disorder and healthy adults. *Society of Biological Psychiatry Annual Meeting.* 2021.
- 43. **Edmiston EK**, Fournier JC, Rozovsky R, Chase HW, Bertocci MA, Aslam HA, Lockovich J, Graur S, Bebko G, Forbes EE, Stiffler R, Phillips ML. Left ventrolateral prefrontal cortex structure and reward-expectancy related activity predict manic symptom changes one year later. *American College of Neuropsychopharmacology Annual Meeting*. 2021.
- 42. **Edmiston EK**, Phillips ML, Mak K, Chase HW, Fournier JC. Visual cortex coupling and childhood maltreatment: associations with major depression and a compensatory mechanism. *Society of Biological Psychiatry Annual Meeting.* 2021.
- 41. Marrocco J, **Edmiston EK**, Anacker C, Bangasser D. The study of sex differences and gender bias, and trans inclusive research practices. *American College of Neuropsychopharmacology Annual Meeting.* 2020. Panelist, Networking Session.
- 40. Chase HW, Fournier JC, Bertocci MA, **Edmiston EK**, Lockovich JC, Aslam H, Stiffler RS, Graur S, Bebko G, Phillips ML. Decision-making variability in mood disorders: new insights for a replication attempt. *Society of Biological Psychiatry Annual Meeting*. 2020 (Submitted, meeting canceled due to COVID-19).
- 39. **Edmiston EK,** Fournier J, Greenberg T, Chase HW, Stiffler R, Lockovich J, Aslam H, Graur S, Bebko G, Phillips ML. A double dissociation between anxiety and depression symptom improvement and fusiform coupling and positive and negative emotional face processing. *Society of Biological Psychiatry Annual Meeting.* 2020 (Submitted, meeting canceled due to COVID-19).
- 38. **Edmiston EK**, Fournier JC, Chase HW, Bertocci MA, Greenberg T, Aslam HA, Lockovich JC, Graur S, Bebko G, Forbes EE, Stiffler R, Phillips ML. Assessing relationships among impulsive sensation-seeking, reward circuitry activity, and predisposition to bipolar disorder: an fMRI replication and extension study. *American College of Neuropsychopharmacology Annual Meeting. 2019.*
- 37. Paglisotti T, Montano G, Simpson A, **Edmiston EK**. Preliminary implementation of Trans Buddy PGH: establishing trust among transgender patients and healthcare providers. *University of Pittsburgh Medical Center Department of Psychiatry 19th Annual Research Day.* 2019.

- 36. **Edmiston EK**, Fournier JC, Chase HW, Bertocci MA, Greenberg T, Aslam H, Stiffler R, Lockovich J, Graur S, Bebko G, Phillips ML. Left ventrolateral prefrontal cortical BOLD signal during reward expectancy and impulsive sensation seeking: a replication study. *University of Pittsburgh Medical Center Department of Psychiatry 19th Annual Research Day. 2019.*
- 35. Chase HW, **Edmiston EK**, Bertocci M, Fournier JC, Greenberg T, Aslam H, Stiffler R, Lockovich J, Graur S, Bebko G, Forbes EE, Phillips ML. Similar neural representation of appetitive and loss avoidance prediction errors across distressed and healthy individuals. *Society of Biological Psychiatry Annual Meeting.* 2019.
- 34. **Edmiston EK**, Simpson A. Progress report: Quality improvement programming for transgender mental health. Symposium. *TransPride PGH Professional Conference*. 2018.
- 33. Schroth-Erickson L, Levin R, **Edmiston EK**. Talking to your patients about the biological basis of transgender identity. *Philadelphia Trans Wellness Conference Professional Track*. 2018.
- 32. **Edmiston EK**, Fournier J, Greenberg T, Chase HW, Stiffler R, Lockovich J, Aslam H, Graur S, Bebko G, Phillips ML. Fusiform gyrus-salience network coupling during emotion processing predicts anxiety and depression symptom change. *University of Pittsburgh Medical Center Department of Psychiatry 18th Annual Research Day.* 2018.
- 31. **Edmiston EK**, Fournier J, Greenberg T, Chase HW, Stiffler R, Lockovich J, Aslam H, Graur S, Bebko G, Phillips ML. Salience network BOLD response to emotional faces predicts anxiety and depression symptom outcomes. *Society of Biological Psychiatry Annual Meeting*. 2018.
- 30. Chase HW, Qiu H, Kerestes R, Shah N, Alkhar H, **Edmiston EK**, Soehner A, Greenberg T, Aslam H, Stiffler R, Lockovich J, Graur S, Bebko G, Pan L, Eickhoff SB, Phillips ML. Implication of the visual cortex in resting state fMRI studies of mood and anxiety disorders may relate to the propensity for within-scanner sleep. *Society of Biological Psychiatry Annual Meeting.* 2018.
- 29. Ding J, Ehrenfeld J, Raynor L, **Edmiston EK**, Eckstrand K, Beach L. A proposed systems level quality improvement model for transgender healthcare delivery. *The National Transgender Health Summit*. 2017.
- 28. **Edmiston EK.** Setting the agenda for transgender neuroimaging: a critical review and future directions. Symposium. *The National Transgender Health Summit.* 2017.
- 27. **Edmiston EK**, Fournier J, Greenberg T, Bertocci M, Stiffler R, Aslam H, Lockovich J, Phillips ML. Trait anxiety predicts visual system response to emotional faces. *Developmental Affective Neuroscience Symposium*. 2017.
- 26. **Edmiston EK.** The Trans Buddy Program: an innovative intervention for increasing health care utilization. Symposium. *TransPride PGH Professional Conference*. 2017.

- 25. Buchanan K, Richmond M, Sattler AR, **Edmiston EK**. Red state solutions for transgender health care access: provision in low resource areas. Symposium. *Philadelphia Transgender Health Conference*. 2017.
- 24. **Edmiston EK**, Chase H, Stiffler R, Lockovich J, Aslam H, Graur S, Bebko G, Phillips ML. Predicting quality of life in distressed youth: Cortico-thalamic BOLD signal and reward processing. *University of Pittsburgh Medical Center Department of Psychiatry 17th Annual Research Day.* 2017.
- 23. **Edmiston EK**, Chase H, Stiffler R, Lockovich J, Aslam H, Graur S, Bebko G, Phillips ML. Cortico-thalamic BOLD signal during reward processing predicts quality of life at follow up in distressed young adults. *Society of Biological Psychiatry Annual Meeting*. 2017.
- 22. Eckstrand KL, Mitchell L, **Edmiston EK.** The Trans Buddy Program: Transgender Leadership and peer advocacy for reducing health disparities. *University of Pittsburgh Health Sciences Health Disparity Poster Competition*. 2017.
- 21. **Edmiston EK.** Reframing the search for transgender neuroimaging biomarkers. *New Materialisms Annual Meeting* Warsaw, Poland. 2016.
- 20. Corbett BA, Muscatello R, **Edmiston EK**, Muse I. Examining the Diurnal Profile of Children and Adolescents with Autism Spectrum Disorder (ASD) and Typical Development between 8 to 17 years of age. *International Society for Psychoneuroendocrinology*. 2016.
- 19. Corbett BA, Muse I, **Edmiston EK**, Muscatello R. Diurnal and Stress Hormonal Profiles of Testosterone and Cortisol in Adolescents with Autism Spectrum Disorder (ASD) and Typical Development (TD). *International Society for Psychoneuroendocrinology*. 2016.
- 18. **Edmiston EK**. Psychophysiological characterization of adolescents with Autism Spectrum Disorder. Presentation, *Chinese Psychiatric Association Annual Meeting*. 2016.
- 17. **Edmiston EK**, Jones RM, Blain S, Corbett BA. Neuroendocrine and physiological responsivity during social stress in adolescents with and without autism spectrum disorder. *Vanderbilt Kennedy Center Science Day.* 2015.
- 16. **Edmiston EK**, Valencia B, Corbett BA. Autonomic nervous system function in response to social judgment in adolescents with and without autism spectrum disorder. *International Meeting for Autism Research.* 2015.
- 15. Corbett BA, Newsom C, Key S, Qualls L, **Edmiston EK**. A randomized wait-list control trial of a peer-mediated, theatre-based intervention to improve social ability in children with autism spectrum disorder. *International Meeting for Autism Research*. 2015.
- 14. Singer B, Eckstrand K, Ehrenfeld J, **Edmiston EK**. Transgender health and advocacy in academic medicine: an empowerment model. Workshop; *Gay and Lesbian Medical Association Annual Meeting*. 2014.
- 13. **Edmiston EK**, Corbett BA. Behavioral and endocrine alterations in adolescents with autism spectrum disorder. Selected presentation; *Vanderbilt Kennedy Center Science Day*. 2014.

- 12. **Edmiston EK.** Effects of a neurobiological explanation of sexual orientation on student attitudes towards lesbian, gay and transgender people. *Society for Neuroscience*. 2013.
- 11. Corbett BA, **Edmiston EK**, Zald DH. Neural and physiological responses during play with human and computer partners in children with autism. *Society for Neuroscience*. 2013.
- 10. **Edmiston EK,** McHugo M, Dukic MS, Eggers E, Zald DH. Visuocortical BOLD response to emotional stimuli in the absence of a functional amygdala. *Society for Neuroscience*. 2012.
- 9. **Edmiston EK.** Pelvic and chest exams in transgender men. Workshop; *Philadelphia Trans Health*. 2011.
- 8. **Edmiston EK**, Blackford JU. Childhood maltreatment affects face processing. *Biology of Prosocial Behavior*. 2011.
- 7. **Edmiston E,** Wang F, Mazure CM, Sinha R, Mayes LC, Blumberg HP. Cortico-striatal limbic gray matter morphology in adolescents reporting exposure to childhood maltreatment. *Vanderbilt Kennedy Center Science Day.* 2011.
- 6. Wang F, **Edmiston E**, Hur E, Kalmar JH, Womer FY, Chepenik LG, Blumberg HP. An Altered Developmental Trajectory of Frontotemporal Connectivity in Bipolar Disorder. *Biological Psychiatry* 2010; 67 (Supplement 9): 107.
- 5. Wang F, Chepenik LG, Shah MP, Kalmar JH, **Edmiston E**, Spencer L, Duman R, Gelernter J, Blumberg HP. Genes Regulating Neurotrophic Factors that Influence the Corticolimbic Connectivity in Mood Disorders: Treatment Implications. *Biological Psychiatry* 2009; 65 (Supplement 1): 174.
- 4. Kalmar JH, Wang F, Chepenik LG, Shah MP, McDonough A, **Edmiston E**, Blumberg HP. Amygdala functioning during emotional processing in adolescents with bipolar disorder or ADHD. *Biological Psychiatry* 2008; 63 (Supplement 1): 184.
- 3. Womer F, Wang F, Chepenik LG, Kalmar JH, **Edmiston E**, Spencer L, Constable RT, Papademetris X, Blumberg HP. Structural abnormalities of the cerebellar vermis in bipolar disorder. *Biological Psychiatry* 2008; 63 (Supplement 1): 141.
- 2. Wang F, Kalmar JK, Womer F, He Y, Chepenik L, **Edmiston E**, Blumberg HP. Abnormal morphological correlations within a cortico-limbic neural system in adolescents with bipolar disorder. *American Academy of Childhood and Adolescent Psychiatry*.
- 1. Wang F, Kalmar JH, **Edmiston E**, Chepenik LG, Tie K, Spencer L, Jackowski M, Papademetris X, Constable RT & Blumberg HP. Abnormal callosal integrity in bipolar disorder determined from diffusion tensor imaging. *Biological Psychiatry* 2008; 63 (Supplement 1): 43.

BOOK CHAPTERS:

Edmiston EK, Bertocci M, Phillips ML. Neuroimaging and Circuit Mechanisms of Bipolar Disorder. In *Neurobiology of Mental Illness*. 6th Ed. Eds: Eric Nestler & Alexander Charney. Oxford University Press. (In Press).

Tomson A & **Edmiston EK**. Understanding the basis of gender identity development: biological and psychosocial models. In *Trans Bodies, Trans Selves*. 2nd Ed. Ed: Sand Chang. Oxford University Press. 2022.

Edmiston EK. Community-led peer advocacy for transgender health care access in the southeastern United States: The Trans Buddy Program. In *Healthcare in Motion: Mobility forms in health service delivery and accessibility.* Berghahn Books. 2017.

Robles RJ & **Edmiston EK**. Community Responses to Trauma. In *Trauma, Resilience, and Health Promotion for LGBT Patients*. Springer Press. 2017.

Edmiston EK & Mitchell L. Trans Buddy: Innovation Profile. In *The Remedy: Queer and Trans Voices on Health and Health Care.** Arsenal Press. 2016. *Lambda Literary Award Winner, Non-Fiction Anthology

Eckstrand KL, **Edmiston EK**, Potter J. Obstetric and Gynecologic Care to LGBT Individuals. In *Lesbian, Gay, Bisexual, Transgender, and Intersex Healthcare: A Clinical Guide to Preventative, Primary, and Specialist Care*. Springer Press. 2015.

ADDITIONAL SCHOLARSHIP:

Edmiston EK. Letter to the Editor: The legacy of transgender surgery access is complex. *Annals of Plastic Surgery.* 2019.

Edmiston EK. Invited Commentary: Transgender health research must serve transgender people. *BJOG.* 2018.

Edmiston EK. Feminist bioethics and intersex medical interventions: A review of *Making Sense of Intersex*. *Catalyst: Feminism, Theory, Technoscience*. 2016; 2(1).

Jann JT, **Edmiston EK**, Ehrenfeld J. Letter to the Editor: Important considerations for addressing LGBT health care competency. *American J of Public Health* 2015; e1.

HONORS, AWARDS, AND FELLOWSHIPS:

American College of Neuropsychopharmacology Travel Award	2021
Society of Biological Psychiatry Early Career Investigator Travel Award	2019
NYC tDCS Fellowship City University of New York, New York, NY	2018
Trainee, T32 MH018951 Child and Adolescent Mental Health Research University of Plttsburgh, Pittsburgh, PA	2018-2019
Research Day Department of Psychiatry Outstanding Poster Award	2018
PLOS One Travel Award	2017
Fellow, Winter School in the Neuroscience of Consciousness Canadian Institute For Advanced Research	2017
Trainee, T32 MH16804 Transformative Discovery in Psychiatry	2016-2018

University of Pittsburgh, Pittsburgh, PA WPATH Outstanding Student Award 2015 International honor for contributions to transgender health research The Trans 100 2015 National honor for excellence in the transgender community Point Foundation Scholar 2014-2015 One of 20 selected nationally for program that funds education of LGBT students Vanderbilt Brain Institute Student Leadership and Service Award 2014 Graduate Student Travel Grant, Vanderbilt University 2013 Fellow, Summer Program in Neuroscience Ethics and Success 2013 Marine Biology Laboratory, Woods Hole, MA Clinical Neuroscience Scholar for Translational Research 2012-2015 Dan Marino Foundation Neurobiology of Social Behavior Travel Award 2011 Emory University, Atlanta, GA President's Scholarship 2003-2005 Case Western Reserve University, Cleveland, OH TEACHING AND MENTORSHIP **SELECTED TALKS:** Invited Speaker: Neuroscience in Service of Our Community: 2023 How Research Rooted in Empathy and Humility Makes Us Better Scientists Neuroscience Diversity Seminar University of Maryland School of Medicine Invited Speaker: Visual Cortex Distinguishes Anxiety and Depression 2023 Fournier Group Lab Meeting The Ohio State Medical School Presenter: Assessing Visual Perception in Depression and Anxiety 2023 Department of Psychiatry Faculty Meeting **UMass Chan Medical School** Invited Speaker: Neuroimaging Studies of Transgender People 2022

The Friedman Brain Institute and oSTEM
The Icahn School of Medicine at Mount Sinai

A Stable Marker for Bipolar Disorder risk

STEP Seminar

Truman State University

Invited Speaker: Impulsivity and Reward-related Activity:

Invited Speaker: Assessing Relationships Among impulsivity, Reward Circuitry, and Risk for Psychopathology Magnetic Resonance Research Center Forum Yale School of Medicine	2019
Presenter: Fusiform Gyrus Alterations During Emotion Processing: Predicting the Future in Anxiety Disorders Center for the Neural Basis of Cognition Seminar University of Pittsburgh and Carnegie Mellon University	2018
Panelist: Setting the Research Agenda in Transgender Health 27 th Annual Issues in Medical Ethics Conference The Icahn School of Medicine at Mount Sinai	2017
Panelist: Neuroimaging in Child and Adolescent Mental Disorders Chinese Society of Psychiatry 14 th Annual Meeting	2016
The Trans Buddy Program: An Innovative Model for Healthcare Access Medicine Health and Society Colloquium Series Vanderbilt University	2015
Panel Organizer: Intra-community Stigma in LGBT Populations 615Thrive Conference Tennessee Department of Health	2015
Transgender Health: Provider Considerations Department of Hearing and Speech Sciences Grand Rounds Vanderbilt University	2014
Sexual and Reproductive Health in LGBT Populations Sarah Fogel, PhD Department of Nurse Midwifery Vanderbilt University School of Nursing	2014, 2015
Panelist: (Im)Possible Politics: Intersectional Trans Organizing Ben Singer, PhD; Dean Spade, JD; Lisa Guenther PhD Department of Women and Gender Studies Vanderbilt University	2014
Plenary Speaker: Creating Change for LGBTI Health Gay and Lesbian Medical Association Annual Meeting	2013
Invited Speaker: <i>Threat Detection, Visual Cortex, and Anxiety</i> Department of Radiology Beijing Normal University	2013
Invited Speaker: <i>Threat Detection, Visual Cortex, and Anxiety</i> Department of Psychiatry China Medical University	2013

MEDICAL STUDENT TEACHING EXPERIENCE: Guest Lecturer: Neuromodulatory Interventions in Mood Disorders Neuroscience Area of Concentration Seminar Series University of Pittsburgh School of Medicine	2022
Guest Lecturer: Building Trust with your Transgender Patients Texas Christian University School of Medicine	2021,2022
Instructor of Record: Introduction to Scientific Writing China Medical University	2016
Guest Lecturer: Clinical and Biobehavioral Features of Autism Clinical Medicine 400 China Medical University	2016
Guest Lecturer: Building an Inclusive Practice for LGB and T Patients First Year Seminar Meharry Medical College	2015
Guest Lecturer: Community Models for Improving Trans Healthcare Intercession Course Meharry Medical College	2015
Guest Lecturer: Providing Excellent Care for LGBT People Capstone Series Meharry Medical College	2015
GRADUATE AND UNDERGRADUATE TEACHING EXPERIENCE: Guest Lecturer: Neuromodulation interventions for threat sensitivity Biomedical Sciences First Year Seminar Graduate School of Biomedical Sciences UMass Chan Medical School	2022
Guest Lecturer: Impulsivity and reward-related activity: Predicting mania Undergraduate Research Methods Department of Psychology University of California San Diego	2021
Guest Lecturer: <i>Transgender people and neuroimaging: a critical review</i> Department of Psychology Mount Holyoke College	2021
Instructor of Record: PSY0205 Psychopathology Department of Psychology University of Pittsburgh	2021
Guest Lecturer: <i>Transgender People and Healthcare Systems</i> MHS 2110: American Medicine and the World	2015

Laura Stark, PhD, Vanderbilt University	
Guest Lecturer: <i>Transgender People and Healthcare Systems</i> MHS 3890: Documenting the Body Odie Lindsey, PhD, Vanderbilt University	2015
Guest Lecturer: Introduction to Social Neuroscience PSY3609: Educational Cognitive Neuroscience Sasha Key, PhD, Vanderbilt University	2014
Guest Lecturer: <i>Imagining Transgender Bodies in Healthcare</i> WGS 290: Theories of the Body Aimi Hamraie, PhD, Vanderbilt University	2013
Introduction to Cognitive Neuroscience Vanderbilt Neuroscience Graduate Program Boot Camp	2013-2014
The Center for Teaching, Vanderbilt University Scholarship of Teaching and Learning Certificate	2013
Teaching Assistant: NSC201 Introduction to Neuroscience Department of Neuroscience, Vanderbilt University	2011
TRAINEE MENTORSHIP, CERTIFICATION, AND SUPERVISION: Culturally Aware Mentorship Workshop University of Wisconsin Madison School of Medicine	2022
Tiffany Nhan (post bac lab assistant)	2022-present
M. Ali Aslam (undergraduate lab assistant)	2022
Paloma Rueda (undergraduate lab assistant)	2020-2021
Paloma Rueda (undergraduate lab assistant) Shelby Gardner (undergraduate lab assistant)	2020-2021 2020
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Shelby Gardner (undergraduate lab assistant)	2020
Shelby Gardner (undergraduate lab assistant) Kristie Mak (undergraduate lab assistant)	2020 2019-2020
Shelby Gardner (undergraduate lab assistant) Kristie Mak (undergraduate lab assistant) Taylor Pagliosotti, BA (graduate student, Department of Public Health)	2020 2019-2020 2018-2019
Shelby Gardner (undergraduate lab assistant) Kristie Mak (undergraduate lab assistant) Taylor Pagliosotti, BA (graduate student, Department of Public Health) Zhiqiang Sha, PhD (post doc, Mood and Brain Laboratory, PI: Phillips)	2020 2019-2020 2018-2019 2019
Shelby Gardner (undergraduate lab assistant) Kristie Mak (undergraduate lab assistant) Taylor Pagliosotti, BA (graduate student, Department of Public Health) Zhiqiang Sha, PhD (post doc, Mood and Brain Laboratory, PI: Phillips) Alicyn Simpson, BA (research assistant, Adolescent Medicine)	2020 2019-2020 2018-2019 2019 2018-2019
Shelby Gardner (undergraduate lab assistant) Kristie Mak (undergraduate lab assistant) Taylor Pagliosotti, BA (graduate student, Department of Public Health) Zhiqiang Sha, PhD (post doc, Mood and Brain Laboratory, PI: Phillips) Alicyn Simpson, BA (research assistant, Adolescent Medicine) Hana Choi, BA (intern, The Trans Buddy Program)	2020 2019-2020 2018-2019 2019 2018-2019 2016
Shelby Gardner (undergraduate lab assistant) Kristie Mak (undergraduate lab assistant) Taylor Pagliosotti, BA (graduate student, Department of Public Health) Zhiqiang Sha, PhD (post doc, Mood and Brain Laboratory, PI: Phillips) Alicyn Simpson, BA (research assistant, Adolescent Medicine) Hana Choi, BA (intern, The Trans Buddy Program) William Horn, BA (intern, The Trans Buddy Program)	2020 2019-2020 2018-2019 2019 2018-2019 2016 2015

Jamieson Jann, BA (summer intern, Program for LGBTI Health)	2014
SERVICE	

CURRENT MEMBERSHIPS:

Society of Biological Psychiatry	
DEPARTMENTAL, INSTITUTIONAL, AND DISCIPLINARY SERVICE: Editorial Board, <i>Journal of Mood and Anxiety Disorders</i>	2023-present
Member, Grand Rounds Committee Department of Psychiatry, UMass Chan Medical School	2023-present
Interviewer, Graduate School of Biomedical Sciences UMass Chan Medical School	2023-present
Co-Director, NeuroNexus Institute UMass Chan Medical School	2022-present
Co-chair, Diversity, Equity and Inclusion Committee Society of Biological Psychiatry	2021-present
Member, LGBTQIA+ Task Force American College of Neuropsychopharmacology	2021-present
Editorial Board, Bulletin of Applied Transgender Studies	2021-present
Grant Reviewer, Lesbian Health Fund, GLMA	2021
Member, Diversity, Equity, and Inclusion Committee	2019-2021
Department of Psychiatry University of Pittsburgh School of Medicine	
Chapter Author, Assessment of Adults with Gender Dysphoria WPATH Standards of Care 8 Committee	2018-2022
Chapter Author, Assessment of Adults with Gender Dysphoria	2018-2022 2018-2021
Chapter Author, Assessment of Adults with Gender Dysphoria WPATH Standards of Care 8 Committee Member, Diversity and Inclusion Committee	
Chapter Author, Assessment of Adults with Gender Dysphoria WPATH Standards of Care 8 Committee Member, Diversity and Inclusion Committee Society of Biological Psychiatry Ad Hoc Member, Diversity and Inclusion Task Force	2018-2021
Chapter Author, Assessment of Adults with Gender Dysphoria WPATH Standards of Care 8 Committee Member, Diversity and Inclusion Committee Society of Biological Psychiatry Ad Hoc Member, Diversity and Inclusion Task Force American College of Neuropsychopharmacology Member, Cross-Network Transgender Working Group,	2018-2021 2020-2021
Chapter Author, Assessment of Adults with Gender Dysphoria WPATH Standards of Care 8 Committee Member, Diversity and Inclusion Committee Society of Biological Psychiatry Ad Hoc Member, Diversity and Inclusion Task Force American College of Neuropsychopharmacology Member, Cross-Network Transgender Working Group, NIH Office of HIV/AIDS Network Coordination	2018-2021 2020-2021 2017-2019
Chapter Author, Assessment of Adults with Gender Dysphoria WPATH Standards of Care 8 Committee Member, Diversity and Inclusion Committee Society of Biological Psychiatry Ad Hoc Member, Diversity and Inclusion Task Force American College of Neuropsychopharmacology Member, Cross-Network Transgender Working Group, NIH Office of HIV/AIDS Network Coordination Co-Founder, Trans Buddy Pittsburgh	2018-2021 2020-2021 2017-2019 2016-2018
Chapter Author, Assessment of Adults with Gender Dysphoria WPATH Standards of Care 8 Committee Member, Diversity and Inclusion Committee Society of Biological Psychiatry Ad Hoc Member, Diversity and Inclusion Task Force American College of Neuropsychopharmacology Member, Cross-Network Transgender Working Group, NIH Office of HIV/AIDS Network Coordination Co-Founder, Trans Buddy Pittsburgh Student Representative, Vanderbilt Brain Institute Diversity Committee	2018-2021 2020-2021 2017-2019 2016-2018 2015-2016

Assoc. Director, Vanderbilt School of Medicine Program for LGBTI Health 2013-2014

Associate Editor, *Vanderbilt Reviews Neuroscience* 2013-2014

President, Vanderbilt Neuroscience Student Organization 2013-2014

Member, Vanderbilt Neuroscience Organization Academic Committee 2012-2013

Board Member, Vanderbilt School of Medicine Program for LGBTI Health 2012-2013

Affiliate, Vanderbilt Kennedy Center 2011-2016

AD HOC PEER REVIEW:

Acta Psychologica; American Journal of Psychiatry; American Journal of Sexuality Education; Annals of Internal Medicine; Biological Psychiatry: Cognitive Neuroscience Neuroimaging; BJOG: An International Journal of Obstetrics and Gynaecology; Bipolar Disorder; Brain and Behavior; Child Abuse & Neglect; Development and Psychopathology; Developmental Cognitive Neuroscience; Frontiers in Neuroscience; Frontiers in Sociology; Human Brain Mapping; Journal of Affective Disorders; Journal of Autism and Developmental Disorders; Journal of Homosexuality; Journal of Medical Systems; Journal of Neuroscience Research; Journal of Psychiatry, Depression, and Anxiety; LGBT Health; Molecular Autism; NeuroImage; Neuropsychologia; Neuropsychopharmacology; Neuroscience Letters; Psychiatry Research: Neuroimaging; PLOS One; Psychological Medicine; Psychology of Violence; Psychoneuroendocrinology; Scientific Reports; Schizophrenia Research; Transgender Health

REFERENCES

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Exhibit B Bibliography

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

AUGUST DEKKER, et al.,

Plaintiffs,

v.

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

JASON WEIDA, et al.,

Defendants.

REBUTTAL REPORT OF DANIEL SHUMER, M.D.

- I, Daniel Shumer, M.D., hereby declare and state as follows:
- 1. I have been retained by counsel for Plaintiffs as an expert in connection with the above-captioned litigation.
- 2. I have actual knowledge of the matters stated herein. If called to testify in this matter, I would testify truthfully and based on my expert opinion.
- 3. My background and qualifications, review of prior testimony, and compensation have been previously provided in my expert report ("Shumer Rep."). The curriculum vitae attached to my initial expert report remains true, correct and up to date.
- 4. I hereby provide a rebuttal report to respond to the expert reports provided by the Defendants. This report is provided after my review of reports

submitted by Dr. Michael Laidlaw, Dr. Paul Hruz, Dr. Stephen Levine, Dr.

Kristopher Kaliebe, Dr. Sophie Scott, Dr. Michael Biggs, and Dr. Joseph Zanga, as

well as my review of plaintiffs' medical records.

5. In preparing this rebuttal report, I have relied on my training and years

of research and clinical experience, as set out in my curriculum vitae (attached as

Exhibit A to my original report) and on the materials listed therein; the materials

listed in the bibliography attached as Exhibit B to my original report; and the

additional materials listed in the supplemental bibliography attached as Exhibit C

to this rebuttal report. The sources cited in each of these are the same types of

materials that experts in my field of study regularly rely upon when forming opinions

on the subject, which include authoritative, scientific peer-reviewed publications.

6. I reserve the right to revise and supplement the opinions expressed in

this report or the bases for them if any new information becomes available in the

future, including as a result of new scientific research or publications or in response

to statements and issues that may arise in my area of expertise. I may also further

supplement these opinions in response to information produced by Defendants in

discovery and in response to additional information from Defendants' designated

experts.

EXPERT OPINIONS

7. These expert reports all demonstrate a basic lack of understanding of the nature, evaluation, and treatment of gender dysphoria, the serious consequences of the condition if left untreated, and the strength of the evidence in support of medical management of gender dysphoria, including the efficacy and safety of these treatments. Defendants' experts have limited or no experience with diagnosis and treatment of gender dysphoria. Their opinions are not consistent with current evidence-based standards of care or the general medical consensus – they run counter to recommendations made by leading and well-respected medical bodies.

8. Some of the specific critiques apply in equal measure to more than one expert report.

I. <u>Efficacy of Gender-Affirming Care</u>

9. Dr. Laidlaw and Dr. Hruz are both endocrinologists not involved in the medical treatment of gender dysphoria. Dr. Laidlaw states, "treatment interventions on behalf of children and adults diagnosed with gender dysphoria must be held to the same scientific standards as other medical treatments. These interventions must be optimal, efficacious, and safe." (Laidlaw Rep. ¶ 12). I agree with Dr. Laidlaw's statement; all medical interventions, including treatment for gender dysphoria, require rigorous study and high-quality evidence. The responsibility of all medical

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providers is to provide care for patients with a goal of promoting health and wellness

while minimizing risk; this can only be done with a thorough knowledge of the

patient, their disease process, and the relevant scientific literature.

10. As a pediatric endocrinologist with vast experience in assessing and

treating transgender patients, I rely on extremely strong and compelling evidence

that hormonal treatments, including pubertal suppression and gender-affirming

hormonal care, are efficacious, safe, and promote optimal health outcomes.

11. In my expert report, I referenced several studies which demonstrate the

efficacy and safety of gender-affirming care. (Shumer Rep. ¶ 35 (citing de Vries, et

al., 2014; de Vries, et al., 2011; Green, et al., 2022; Smith, et al., 2005; Turban, et

al., 2022)). These articles represent a small percentage of the full body of literature

that was utilized to create evidence-based clinical practice guidelines for the

treatment of gender dysphoria in children, adolescents, and adults.

12. The guidelines were published by long-standing and well-respected

bodies: the World Professional Association for Transgender Health (WPATH) and

the Endocrine Society (Coleman, et al., 2022; Coleman, et al., 2012; Hembree, et al.,

2017; Hembree, et al., 2009). Other leading medical bodies including the American

Association of Pediatrics, the American Medical Association, the American

Psychological Association, the American Psychiatric Association, and American

Academy of Family Physicians all support the tenants of these guidelines due to the

rigorous nature of their review of scientific evidence in the field (Rafferty, et al.,

2018 (AAP), AMA, 2019; American Psychological Association, 2015; Drescher, et

al., 2018 (American Psychiatric Association); Klein, et al., 2018 (AAFP)).

13. Dr. Laidlaw and Dr. Hruz attempt to undermine the WPATH standards

of care by characterizing WPATH as an "advocacy organization" (Laidlaw Rep. ¶

185; Hruz Rep. ¶ 96). WPATH is a longstanding and well-respected standard-setting

organization whose mission is "to promote evidence-based care, education, research,

public policy, and respect in transgender health" (WAPTH Mission and Vision,

2023). Dr. Laidlaw takes issue with WPATH SOC 7's lack of description of the

grading system used. WPATH SOC 8 (the current version) clearly and transparently

outlines the grading system used, yet Dr. Laidlaw is still not satisfied, as he would

have preferred they presented this information differently (Laidlaw Rep. ¶¶ 196-

197). Yet his preference does not undermine the substance of the WPATH standards

of care or the evidence on which they rely.

14. Dr. Laidlaw and Dr. Hruz also criticize the Endocrine Society

guidelines, pointing to the makeup of the committee and the quality of the data (as

existed in 2017). Yet, they fail to provide guidelines published by any well-respected

medical body, which, after reviewing the evidence, came to opposite conclusions.

Instead, Dr. Laidlaw references other endocrinologists (one of whom is Dr. Hruz)

who form a small group of professionals outside of the mainstream on this topic.

15. Dr. Lappert, who is a retired surgeon – not an endocrinologist – claims

that a 2019 article jointly published by the Endocrine Society and other medical

bodies on the use of testosterone therapy for women contradicts the Endocrine

Society guidelines. But it does not. Adult women sometimes ask endocrinologists

for low-dose testosterone because they believe it will help with a variety of concerns

including low libido, sexual arousal, wellbeing, mood, or osteoporosis. The

consensus report was evaluating those questions. It was not reviewing evidence

related to gender dysphoria or making *any* statement for or against gender-affirming

care. The words gender, gender dysphoria, and transgender are not contained in the

document. The Endocrine Society likely assumed that readers would understand that

by use of a title including the word women they were talking about women and not

transgender men. Dr. Lappert's confusion here may be related to his refusal to

respect transgender men by using any other terminology to refer to them besides

"women."

16. Dr. Zanga appears to take issue with the decision of the American

Academy of Pediatrics to support the current standards of care related to assessment

and management of gender dysphoria (Zanga Rep. ¶¶ 8-18). Dr. Zanga claims that

the AAP ignored potential harms of gender-affirming care (Zanga Rep. ¶ 18). He is

wrong. The relevant AAP document very clearly and fairly outlines risks and

benefits related to gender-affirming care (Rafferty, et al., 2018). The AAP

recommends a "'gender-affirming,' nonjudgemental approach that helps children

feel safe in a society that too often marginalizes or stigmatizes those seen as

different" (AAP News Release, 2018). This is consistent with the approaches taken

by WPATH and the Endocrine Society.

17. Dr. Hruz argues that the outcomes of gender-affirming care are

unknown in part because no randomized control trials have been performed (Hruz

Rep. ¶ 112). While randomized control trials are an excellent study design in many

contexts, management of gender dysphoria is not amenable to this type of study. Due

to the current evidence supporting gender-affirming care, it would be unethical to

propose a study randomly assigning patients, for example, to GnRHa treatment or

placebo. Additionally, the study could not be blinded since patients and families

would immediately ascertain which group they were randomized to based on the

progression or non-progression of puberty. What is more, patients/families desiring

treatment with GnRHa would be unlikely to consent to such a study for fear of being

placed in the placebo group. Therefore, researchers in this field must rely on other

types of study design, such as longitudinal cohort studies, which monitor change in

symptoms over the course of treatment (de Vries ALC, 2014), or cross-sectional

studies comparing treated and untreated persons (Turban, 2022).

18. Dr. Laidlaw chooses to highlight several studies as examples of lack of

evidence of effectiveness of gender-affirming treatments (Laidlaw Rep. ¶¶ 201-227).

He leads with a review of Dhejne et al.'s study published in 2011. While Dr. Laidlaw

is correct that, among other things, this study demonstrates that even after receiving

appropriate gender-affirming care, transgender individuals are still at higher risk for

negative mental health outcomes than the general population, Dr. Laidlaw ignores

that stigma around transgender identity, both 12 years ago in Sweden and in Florida

today, makes life more challenging for transgender individuals. What this study did

not measure, however, is the difference in mental health between transgender

individuals who received evidence-based care, and those who were unable to receive

this care. In fact, the conclusion of Dhejne is not that gender-affirming care is

inappropriate, but rather that transgender people require additional support during

and after the process of transition.

19. Dr. Laidlaw also describes the efforts undertaken by himself and

colleagues to discredit the results of a Swedish study which aimed to investigate

rates of mood and anxiety disorder health care visits and antidepressant and

anxiolytic prescriptions in patients receiving hormonal or surgical interventions.

Ultimately, while the authors conceded in a letter to the editor that their conclusions

were "too strong," they maintained that the study "serves an important purpose and

fills an important knowledge gap." The study "lends support for expecting a

reduction in mental health treatment as a function of time since completing such

treatment" (Branstrom & Pachankis, 2019).

20. Dr. Laidlaw also unfairly discounts the 2015 US Transgender Survey

(2015 USTS) and studies based on data from this survey (Laidlaw \P 210-11). The

2015 USTS serves as the largest survey examining the experiences of transgender

people in the United States with 27,715 respondents from all fifty states, DC,

American Samoa, Puerto Rico, and U.S. military bases overseas. While extremely

large population studies are logistically challenging, the USTS clearly and

transparently outlines the recruitment methodology in Chapter 2 of its full report. Its

main outreach objective was to provide opportunities to access the survey for as

many transgender individuals as possible in different communities across the U.S.

and its territories (James, 2016). Thus, it was appropriate for the survey to use

convenience sampling to achieve its goals. While there are inherent limitations to

studies that use this method to reach a large sample, in reviewing any data derived

from the 2015 USTS, it is important to consider not only limitations of population-

based survey data, but also the significant strengths of being able to capture data

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from such a large cohort of individuals. Importantly, Dr. Laidlaw does not point to

any studies that contradict the findings of the 2015 USTS.

21. Dr. Hruz takes a similar approach, arguing that studies of gender-

affirming care have "major methodological limitations" and attempting to discredit

individual studies (Hruz Rep. ¶ 119). What Dr. Hruz ignores is that all scientific

studies have limitations. In fact, including a limitation section is required when

publishing any manuscript in scientific journals (Lancet, Information for Authors,

2023). That a study has limitations does not mean that the study is dismissed out of

hand. To the contrary, each study contributes to the collective knowledge base and

health care providers look at the entire body of evidence – as well as their own

clinical experience and that of their colleagues – to inform their approach to

treatment.

22. For example, Dr. Hruz critiques 2011 and 2014 studies by de Vries et

al., which demonstrated that patients with gender dysphoria had improved

behavioral and emotional outcomes and depressive symptoms after receiving

medical treatment for their gender dysphoria. Dr. Hruz suggests that because the

participants were also receiving psychological support, it is not possible to know if

it was medical treatment or psychological support which caused the improvement in

mental health symptoms (Hruz Rep. ¶ 120). He misunderstands that gender-

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affirming care does not mean drugs alone, but rather a constellation of medical

treatment and psychosocial support. Separating these aspects of care does not make

sense clinically. In my view, the findings in these two studies provide strong

evidence in favor of gender-affirming treatment.

23. Dr. Hruz also wrongly claims that the 2020 Turban et al. study is cited

as "proof that pubertal blockade prevents suicide in transgender youth" (Hruz Rep.

¶ 120). As I described in my prior report, that study is one of a number of studies

supporting the benefits of GnRHa treatment (Shumer ¶ 82). While Dr. Hruz points

out that the rate of suicidality is high in both the group treated with GnRHa and the

group that did not receive the treatment, that does not mean that the treatment was

not helpful. A reduction in suicidality is a significant finding. His critique of the

2022 Tordoff et al. study suffers from the same flawed reasoning.

24. Notably, Dr. Biggs significantly downplays the suffering of transgender

adolescents experiencing suicidality by arguing that most suicide attempts are not

fatal (Biggs Rep. ¶¶ 15-19). This rhetoric is not only dangerous, but overlooks the

fact that reduction in both completed suicide and suicidality are both worthy goals

of treatment.

25. While previously faulting studies due to lack of a control group, Dr.

Hruz discounts the findings of a study with a control group (van der Miesen, et al.,

2020) on the basis that the group of patients assessed before treatment with GnRHa are younger than the group of patients assessed after treatment. But of course, any pre-GnRHa group will be younger than a post-GnRHa group since GnRHa treatment is started in early puberty and discontinued in later adolescence. Again, Dr. Hruz ignores the inherent limitations of conducting research in clinical medicine.

II. Sex, Gender Identity, and Gender Dysphoria

26. Dr. Biggs's review of the natural history of gender identity differences in children and adolescents is inaccurate (Biggs Rep. ¶ 13). As reviewed in my report (Shumer Rep. ¶ 60), it appears true that the majority of prepubertal *gender diverse* children who are exploring their gender do not develop gender dysphoria and are not expected to become transgender adolescents or adults. But not all *gender diverse* children are *transgender* children. As Dr. Biggs points out, some of these young individuals may have same-sex attraction. They also may simply be gender nonconforming. In contrast, however, children whose gender dysphoria persists into adolescence are highly likely to be transgender (van der Loos, et al., 2022). Dr. Biggs is misinterpreting older studies showing that a large percentage of children diagnosed with gender identity disorder did not grow up to be transgender (e.g., GAPMS Memo at 14; Attachment D (Cantor) to GAPMS Memo at 6-9). Those studies include children who would not fulfill the current diagnostic criteria for

gender dysphoria and, in any case, have no relevance to this case because no

medications are prescribed to prepubertal children.

27. Dr. Biggs alludes to the higher rate of autism spectrum disorder (ASD)

among children presenting for care at adolescent gender clinics (Shumer et al.,

(2016); Strang et al., (2018)), apparently suggesting ASD as a cause of gender

dysphoria. Dr. Biggs claims that children "on the autistic spectrum are more likely

to face difficulties fitting in with same-sex peers, which makes a transgender identity

obviously appealing as both an explanation and a solution" (Biggs Rep. ¶14). This

is a conjecture by Dr. Biggs, a sociologist, that is not supported by any evidence. It

also ignores more plausible explanations. For example, children with ASD may be

less aware of social bias or social expectations and therefore be less worried about

how others may react to their transition, increasing the likelihood of coming out

(Strang, et al., 2016). In any event, there is no research suggesting that treatment for

ASD alleviates symptoms of gender dysphoria. Thus, any relationship between the

two conditions is irrelevant for the purposes of determining what treatment is

effective for gender dysphoria.

28. Similarly, in describing sex and gender, Dr. Hruz completely ignores

the role of gender identity (Hruz Rep. ¶¶ 13-21; see also Lappert Rep. ¶¶ 31-32).

Despite his assertion that sex is not "assigned at birth," it is a fact that the majority

of infants leave the hospital classified as either male or female based on the appearance of their sexual anatomy. Whether or not this assignment or classification will match future gender identity is uncertain. While Dr. Hruz acknowledges that when the sexual anatomy is ambiguous, other elements of sex including chromosomes, hormones, and internal organs can be evaluated to better understand the infant's sex, he fails to recognize that gender identity is another component of sex with biological underpinnings (see Shumer Rep. ¶¶ 29-33). Thus, Dr. Hruz correctly explains that in cases of ambiguity, "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 biological and psychologic outcomes" (Hruz Rep. ¶ 18). What does Dr. Hruz mean by this? My interpretation is that when there is discordance is some elements of sex (anatomic, hormonal, chromosomal), the best practice is to delay sex assignment until we feel we can choose a sex for the infant with the highest likelihood of promoting a happy and healthy life, which includes attempting to match sex assignment with future gender identity. Implicit in his statement is that sometimes we are wrong; the sex assigned at birth does not match future gender identity. In children with differences in sex development (DSD), one may then state, "we tried our best to assign sex, but we were wrong; now that the child can express themselves, the other sex assignment would have been correct."

When considering children with gender dysphoria *not* born with a DSD, this same

statement would be appropriate. The difference is that there were no clues at birth

alerting us to discordant elements of sex. Herein lies the reason that I so thoroughly

outlined the biological underpinnings of gender identity (see Shumer Rep. ¶¶ 29-

33): while not as obvious as in cases of DSD, a transgender person's sex assigned at

birth was equally not correct.

29. Dr. Lappert discounts gender identity on the basis that there is not an

"objective, repeatable test, with known error rates, that can be used to detect gender"

(Lappert Rep. ¶ 32). There actually is a test which can be used to discover someone's

gender identity: simply ask them. It is a human characteristic that is ascertained

through a conversation rather than a lab test. Gender identity is a real human

characteristic, and it is rooted in biology.

30. Further, I do not agree that providers providing this care (me included)

feel compelled to adopt a patient's self-diagnosis and feel that his characterization

of the evidence-base supporting gender-affirming care is a gross mischaracterization

(Hruz Rep. ¶ 91). As a pediatric endocrinologist, when assessing any patient for any

condition, my job is to analyze all available information, determine an appropriate

diagnosis, and then discuss potential treatment options with patients and parents.

This is true regardless of whether I am seeing the patient for gender concerns, slow

growth, thyroid disease, or diabetes. Patients seen in gender clinic who do not have

gender dysphoria are not treated with hormonal interventions. Patients who feel that

their thyroid is "off" but have normal thyroid function, are not treated with thyroid

hormone. Patient "self-diagnosis" has not replaced competent assessment and

diagnosis in this field or any other. Rather, providers of gender-affirming care rely

upon the well-established and evidence-based standards of care for assessment,

diagnosis and management of gender dysphoria.

31. Dr. Laidlaw and Dr. Hruz suggest that because gender dysphoria is in

some ways different than other endocrine conditions that they are more comfortable

treating, it should not be treated with medication (Laidlaw Rep. ¶¶ 14-27; Hruz Rep.

¶¶ 34, 54). They argue that most endocrine disorders involve hormones made in

excess, hormone deficiencies, or structural abnormalities of endocrine glands.

Whether or not Dr. Laidlaw and Dr. Hruz would like to classify gender dysphoria as

an endocrine condition, several pertinent facts remain clear. First, there is ample

scientific evidence that gender identity has a strong biological foundation (Shumer

Rep. ¶¶ 29-33). Second, endocrinologists are uniquely suited to treat gender

dysphoria due to familiarity with prescribing and monitoring medications such as

GnRHa, testosterone, and estrogen. Third, countless medical conditions are

diagnosed with clinical observation and questioning rather than with a laboratory

test, an imaging test, or examination of cells under a microscope (e.g., migraines,

neuropathic pain, Alzheimer's disease, irritable bowel syndrome, fibromyalgia), but

are no less actual medical diagnoses which improve with medical interventions.

Fourth, the American Board of Internal Medicine requires knowledge of gender

dysphoria and its management in order to become certified as an Endocrinologist

(American Board of Internal Medicine, 2023). Ultimately, while I disagree with Dr.

Laidlaw's discomfort with classification of gender dysphoria as an endocrine

disorder, this debate is mere semantics and not pertinent to the appropriate

assessment and management of the condition.

32. Dr. Hruz states that the goal of endocrinology is to restore health (Hruz

Rep. ¶ 50). I would offer that this is a goal not only in endocrinology but all of

medicine. In my experience and in review of the literature, when I prescribe gender-

affirming care, consistent with the Endocrine Society's clinical practice guidelines

and WPATH SOC, I am helping to restore health to my patient.

33. Dr. Laidlaw correctly points out that the number of young people being

referred to the Gender Identity Development Service in the UK has increased

significantly over time (Laidlaw Rep. ¶ 29; see also Levine Rep. ¶ 94) but wrongly

attributes this increase to "social contagion" and "social media/internet use." I would

suggest an alternative explanation that is not only more likely, but also supported by

research. As transgender individuals face less cultural stigma than in previous generations, young people understand that they will be supported and valued by their family and community and are more likely to explore and discuss gender identity openly (Zhang, et al., 2020). Two unrelated examples may make this concept more understandable. First, it should come as no surprise that the rate of openly gay individuals is lower in countries that criminalize homosexuality. Would you suppose that it is more likely that citizens of country X, which criminalizes homosexuality, has very few openly gay citizens because there is naturally a very low rate of homosexuality in that country, or because gay citizens fear retribution for coming out as gay? Second, in many societies left-handed people have been historically encouraged as children to use their right hands for writing and other fine-motor skills. However, in the late 20th century, left-handedness became less stigmatized and the percentage of left-handed people rose from about 4 percent in 1920 to 12 percent in 1980, roughly the same percentage as today (McManus 2009).

34. Dr. Hruz, Dr. Levine, and Dr. Laidlaw also claim that the disproportionate increase in transmasculine adolescents means that gender identity is not biological, but social (Hruz Rep. ¶¶ 116-118; Laidlaw Rep. ¶ 88; Levine Rep. ¶ 95). While they point to research by Dr. Lisa Littman, that research has been heavily criticized, and her conclusions have been called into question (Restar, 2020).

What is more, their logic is flawed. There is no reason why we would necessarily expect the rates of transmasculine people and transfeminine people to be equal. And, it would make sense for those rates to change over time as cultural attitudes towards transmasculine people and transfeminine people change. So long as a cultural bias against transgender people remains, we might not know the true prevalence of transmasculine and transfeminine people. In addition, they ignore that adolescence is a common time for transmasculine people to present to care due to the onset of breast development and menstruation. Transfeminine patients present more commonly younger or older than the mid-adolescent phase which may be in part due to the extreme difficulty for transfeminine adolescents to be accepted and supported by peers (Urquhart, 2017). Furthermore, while they focus on transmasculine adolescents, they ignore that transgender girls and older transgender men are also coming out at higher rates than previously reported (James, 2016; Coleman, 2022).

III. Desistance

35. Dr. Laidlaw and Dr. Hruz assert that rates of "desistance" are very high and therefore treatments as outlined by current standards of care will cause serious and irreversible harm to children and adolescents (Laidlaw Rep. ¶¶ 32-35; Hruz Rep. ¶¶ 63-64). This fallacy, repeated by many opponents of gender-affirming care, misrepresents the data completely. As outlined in my report (Shumer Rep. ¶ 59), it

is true that the majority of prepubertal gender diverse children exploring their gender

do not develop gender dysphoria and are not expected to become transgender

adolescents or adults, but that is because they are not transgender in the first place.

First, as noted above, the studies included gay children and gender nonconforming

children who were never transgender. Second, while Dr. Laidlaw cites data from

studies of children across wide age groups, age 3-13 in one instance, he does not

attempt parse out important clinical information such as the age and pubertal stage

of so-called "desisters" in these studies. Lastly, because prepubertal children are not

treated with hormonal medications for gender dysphoria, studies that look at

prepubertal children, such as those Dr. Laidlaw has cited, have no relevance to the

question of how to treat adolescents. Dr. Laidlaw again ignores the fact that children

whose gender dysphoria persists into adolescence are highly likely to be transgender

(van der Loos, et al., 2022).

36. Dr. Laidlaw also wrongly suggests that the use of pubertal suppression

alters the natural course of "desistance," whereby patients prescribed pubertal

suppression are very likely to be prescribed gender-affirming hormones later in

adolescence (Laidlaw Rep. ¶¶ 111-112). Here Dr. Laidlaw is making a causal theory

error – making a claim of causation based on correlational evidence. Children with

persisting gender dysphoria into puberty (1) are very likely to have persisting gender

dysphoria into adulthood, and (2) are eligible for treatment with GnRHa. The use of

GnRHa is not actually influencing future gender identity. In other words, the fact

that patients prescribed pubertal suppression are very likely to later be prescribed

gender-affirming hormones simply indicates that clinicians are correctly identifying

patients who have gender dysphoria and benefit from medical intervention.

37. Dr. Hruz describes three "approaches" for treating children with gender

dysphoria: "reparative therapy," "watchful waiting," and "gender affirming" (Hruz

Rep. ¶¶ 60-87). As outlined in my report, gender exploration in childhood is

expected and healthy (Shumer Rep. ¶ 60). Of course, parents of a child exploring

their gender identity should not push the child to become transgender – this makes

no sense and would work just as poorly as parents pushing their children to identify

with their sex assigned at birth (referred to as reparative therapy by Dr. Hruz), which

is both ineffective and harmful (Shumer Rep. ¶ 28). Unlike the gender-affirming

approach, which is well supported by research and the experience of clinicians,

including my own, there is no evidence to support the "watchful waiting" approach

Dr. Hruz describes, which is not the same as the "watchful waiting" model adopted

by the Dutch.

38. Moreover, it is not clear how this approach is supposed to work as a

practical matter. When a child asks their parents to use a different name or pronouns,

the parent can either reject this request or accept this request, there is no "neutral"

response, as Dr. Hruz suggests. If honoring a child's chosen name and pronouns is

gender-affirming and rejecting the request is reparative therapy, what does the

watchful waiter do? If asked, I would suggest that parents allow their child to safely

explore gender identity, making it clear that whatever the future outcome, the child

will receive unconditional love, support, and respect. If using a different name or

pronoun would be helpful in the process of gender exploration, parents should

consider honoring that request.

39. Furthermore, at the start of puberty, a child with persistent and/or

intensifying gender dysphoria is much more likely to be transgender (van der Loos,

et al., 2022) and will begin to exhibit secondary sex characteristics. Watchful waiting

in this situation is no longer neutral. In these situations, it appears Dr. Hruz would

categorize the use of GnRHa as part of the "gender affirming" approach in his three-

approach schema, and no medical intervention as "watchful waiting." However, the

use of GnRHa in children exploring their gender identity was first described by

Delemarre-van de Waal and Cohen-Kettenis (2006) as a reversible intervention

allowing for delayed decision-making regarding hormone therapy, a strategy more

consistent with the "watchful waiting" concept.

40. I do not agree with Dr. Hruz that providers of gender-affirming care are

presuming that development of natural sex characteristics interfere with the

exploration of gender identity as an impetus to offer GnRHa (Hruz Rep. ¶ 71).

Rather, GnRHa can prevent intensification of dysphoria during puberty while

enhancing the future ability of the patient to present to the world in a gender

congruent manner.

41. I agree with Dr. Hruz that providers should use caution when

"interfering with the normal process of maturation" (Hruz Rep. ¶ 72). In my

experience, providers in this field are using caution when prescribing GnRHa and

gender-affirming hormones in adolescence, weighing potential benefits against

potential risks with each individual patient, in candid communication with parents,

and with the best intentions for the wellbeing of the adolescent in question.

IV. Side Effects of Puberty Suppression and Hormone Treatment

42. The report correctly defines a medical condition, hypogonadotropic

hypogonadism, as a condition in which the pituitary fails to send signals to the

gonads (Laidlaw Rep. ¶ 79). Dr. Laidlaw then describes gender affirmative therapy

(specifically, pubertal suppression) as deliberately causing the medical condition

hypogonadotropic hypogonadism and then, based on a limited review of some of the

plaintiffs' medical records, declares that the plaintiffs have developed

hypogonadotropic hypogonadism as a result of their medical care (Laidlaw Rep. ¶¶

87-91). In his report, Dr. Laidlaw described the use of GnRHa in treatment of

prostate cancer and precocious puberty. Interestingly, he did not frame GnRHa as

causing the medical condition hypogonadotropic hypogonadism in those patients but

described the use of GnRHa as effective treatment for these other conditions. He

ignores that GnRHa is also an effective treatment for gender dysphoria. Conflating

the goal of therapy (suppression of sex hormone production) with causing a medical

condition (hypogonadotropic hypogonadism) in one instance, but not others, is

inappropriate if not disingenuous.

43. Dr. Laidlaw repeats this same wordplay tactic in describing the

administration of testosterone as inducing hyperandrogenism in transgender men

(Laidlaw Rep. ¶¶ 124-148), and administration of estrogen as inducing

hyperestrogenism in transgender women (Laidlaw Rep. ¶¶ 150-159). He describes

the use of testosterone to treat gender dysphoria in transgender male plaintiffs as

inducing hyperandrogenism and speculates that one of the plaintiffs, a transgender

girl, is at risk for hyperestrogenemia if she requires estrogen treatment in the future

(Laidlaw Rep. ¶¶ 87-91).

44. In reality, when testosterone is prescribed for gender dysphoria as for

the transgender male plaintiffs, the goal is to achieve a normal male testosterone

level based on age, meaning a testosterone level that is consistent with the normal

testosterone levels for cisgender males of similar age; when estrogen is prescribed

for gender dysphoria as it is for transgender females, the goal is to achieve a normal

female estrogen level based on age, meaning an estrogen level that is consistent with

the normal estrogen levels for cisgender females of similar age. These goals mirror

what Dr. Laidlaw or any other endocrinologist would aim for when treating low

testosterone or ovarian failure (Laidlaw ¶¶ 115, 149).

45. Dr. Laidlaw frames evidence-based treatments for gender dysphoria as

causing medical conditions, rather than acknowledging the similarity in how these

medications are used in different contexts. The underlying premise of Dr. Laidlaw's

opinions seems to be that gender dysphoria is not a legitimate diagnosis worthy of

any medical treatment and that there should not be any transgender people.

46. Dr. Laidlaw also misconstrues the effect of GnRHa on fertility. As

outlined in my prior report, GnRHa treatments do not have long-term implications

on fertility (Shumer ¶ 79). Dr. Laidlaw correctly explains that giving GnRHa to a

four-year-old with precocious puberty will not impair fertility. Likewise, GnRHa

will also have no effect on fertility when used in older transgender adolescents.

47. It may seem that Dr. Laidlaw is claiming that GnRHa cause infertility,

but he is not; he is merely pointing out that progression through puberty – at some

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point – is needed for maturation of sperm and eggs. Dr. Laidlaw posits that gender-

affirming hormones could possibly damage immature gonads without providing

supportive data. So long as gonads remain in place, there remains fertility potential.

To be sure, this would require progression through the puberty associated with the

sex assigned at birth.

48. In the context of gender-affirming care, concerns about fertility are

discussed with adolescent patients and their families when receiving both GnRHa as

treatment and/or gender-affirming hormones. Indeed, SOC 8 recommends that

"health care professionals working with transgender and gender diverse adolescents

requesting gender-affirming medical or surgical treatments inform them, prior to

initiating treatment, of the reproductive effects including the potential loss of fertility

and available options to preserve fertility within the context of the youth's stage of

pubertal development." (Coleman, et al., 2022).

49. What is more, for transgender adolescents taking GnRHa and for whom

hormones appears to be indicated as treatment, it is fairly common for fertility

preservation to occur after a brief cessation of GnRHa treatment but before

hormones. For example, case reports, including one from Dr. Hruz's own

institution, illustrate the success of this approach in fertility preservation. (Martin, et

al., 2021; Rothenberg, et al., 2019).

- 50. Even if gender-affirming hormones were introduced following use of GnRHa, these hormones could be discontinued with a goal of progression through internal puberty and achieving fertility. Withdrawal of hormones in adulthood often is successful in achieving fertility when it is desired (Light, et al., 2014; Knudson, et al., 2017). Dr. Hruz is skeptical that a patient who received GnRHa followed by hormones would have any fertility potential (Hruz ¶ 86). While this would likely require discontinuation of all medication and progression through puberty, there has been a study aiming to investigate this question. Caanen et al demonstrated that transgender men have similar ovarian morphology to cisgender women, even when treated with GnRHa followed by testosterone. These treatments did not cause the ovarian changes which are seen in hyperandrogenic women with polycystic ovarian syndrome and infertility (Caanen, 2017). This lends credence to the expectation that the sequence of GnRHa to testosterone does not cause permanent infertility.
- 51. Dr. Laidlaw also raises concerns about future sexual function in patients prescribed GnRHa (Laidlaw ¶¶ 98-99). In my experience, it is essential to have open, age-appropriate discussions around sex and sexuality while respecting that all persons, including transgender people, are diverse in terms of sexual orientation and desires. Sexuality and sexual function should be considered and maximized as

transgender patients reach adulthood. However, it should not be underestimated how

a positive body image is also associated with better sexual function and satisfaction

(Nikkelen, 2018). Additionally, research clearly shows that persons with untreated

gender dysphoria may have significant challenges with sexuality and sexual function

(Holmberg, 2019).

52. Dr. Laidlaw's concerns about bone density in patients prescribed

GnRHa are likewise overblown, if not wholly unfounded (Laidlaw Rep. ¶¶ 100-109;

see also Hruz Rep. ¶ 87). It is accurate to state that pubertal hormones (either

testosterone or estrogen) contribute to bone density accrual. A person who never was

exposed to any sex hormones for their entire life would be at high risk of

osteoporosis. It is not surprising that the Carmichael study referenced (Laidlaw Rep.

¶ 104) found that there is a reduction in Z-scores in adolescents on GnRHa aged 12-

15 during the time of treatment when compared to age-matched controls. What is

misleading, however, is that these patients will be transitioned off GnRHa when a

decision is made regarding treatment with gender-affirming hormones or to resume

puberty consistent with their birth-assigned sex. After exposure to sex hormones,

bone density accrual will rise. In practice, risk of lower bone mineral density is

mitigated by screening for, and treating, vitamin D deficiency when present, and by

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limiting the number of years of treatment based on a patient's clinical course

(Rosenthal, 2014).

53. Dr. Scott and Dr. Laidlaw raise a hypothetical concern regarding brain

development, suggesting that somehow use of GnRHa has "unknown, but likely

negative consequences ... with respect to brain development" (Laidlaw Rep. ¶ 110;

see also Scott Rep. ¶ 15). I have heard this argument from opponents of GnRHa use

before but have difficulty understanding its basis. For example, when considering

children with naturally occurring delayed puberty, I find no published evidence of

negative consequences to brain development compared with children with normally

timed puberty. Likewise, Dr. Laidlaw can point to no published evidence in support

of this concern in transgender adolescents prescribed GnRHa.

54. As for Dr. Scott, she describes how the brain changes over time, but no

description about how pubertal hormones play a role in those changes. Her inclusion

of data reviewing GnRHa data in sheep and in girls with precocious puberty have

questionable applicability to gender care (Scott Rep. ¶ 15). The other article she cites

found, "GnRHa treated girls do not differ in their cognitive functioning ... from the

same age peers" (Wojniusz et al., 2016). The authors of this article came to this

conclusion because there was not a statistically significant difference in IQ, memory,

mental rotation, cognitive executive function, processing speed, attention or

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executive function in participants treated with GnRHa for precocious puberty. This

suggests that Dr. Scott's concerns about GnRHa and brain development are

unfounded.

55. Dr. Laidlaw also misrepresents the risks of using the hormone

testosterone to treat gender dysphoria (Laidlaw Rep. ¶¶ 114-122). He correctly

explains that when treating men with testosterone deficiency, the dose of

testosterone must be carefully considered and monitored to avoid excess levels

(Laidlaw Rep. ¶ 115). This is equally true when using testosterone for treatment of

gender dysphoria. He mentions that some individuals abuse testosterone by taking

more than prescribed, but it is unclear if he is implying that transgender men would

be more likely to do this than others, which I would not expect and find no data to

support. All of the adverse effects of excessive testosterone that Dr. Laidlaw avoids

by carefully monitoring his patients with low testosterone (e.g., increased libido,

headache, erythrocytosis) are similarly avoided by careful monitoring in transgender

men.

56. Dr. Laidlaw also appears to argue that transgender men can develop

erythrocytosis (elevation in the red blood cell measurement, hematocrit) while being

treated with testosterone (Laidlaw Rep. ¶ 148). Dr. Laidlaw is using the female

reference range for hematocrit to make this assertion, again considering these

patients as females with *hyperandrogenism* rather than transgender men receiving

evidence-based care for gender dysphoria. This is inappropriate; the male reference

range for hematocrit should be used for patients on testosterone treatment (Deutsch,

2016).

57. Similarly, Dr. Hruz suggests that testosterone administration to a

person assigned male at birth may have different effects than when given to a person

assigned female at birth since there are thousands of sex-differentially expressed

genes (Hruz Rep. ¶ 82). While this speculation could be potentially true, Dr. Hruz

does not provide a clinical example of how this could be of concern, and I am not

aware of any research confirming his suggestion.

58. Dr. Laidlaw makes parallel arguments regarding estrogen (Laidlaw

¶¶149-159) by pointing out the elevated estrogen can be associated with health

problems, while ignoring that the goal of treatment with estrogen in gender

dysphoria is maintenance of estrogen levels in the normal female range. Risk for the

health concerns he highlights are avoided by careful monitoring in transgender

women.

59. He states that the risk for breast cancer increases when a "male" is

treated with "high dose estrogen" (Laidlaw Rep. ¶ 157). This misunderstands the

risks. It is of course not surprising that transgender women with breasts are at higher

risk for breast cancer than men without breasts. What Dr. Laidlaw leaves out of his

discussion is the complete findings of the Christel article referenced. That article

found that despite an increased risk of breast cancer in transgender women compared

with cisgender men, there was a lower risk when comparted to cisgender women.

The article concluded that "breast cancer screening guidelines for cisgender people

are sufficient for transgender people using hormone treatment" (Christel, 2019).

60. Drs. Laidlaw and Hruz argue that risks of gender-affirming care

outweigh the benefits. They are incorrect; they have provided a grossly exaggerated

and erroneous description of risk while completely discounting the benefits of

treatment or the risks of withholding treatment.

V. Informed Consent

61. Dr. Laidlaw argues that it is not possible for parents to make a truly

informed consent decision regarding gender-affirming care, and suggests, without

reasoning or evidence, that this decision is somehow different than other complex

medical decisions that parents and guardians make regarding the health and wellness

of their children every day. In my experience as a pediatrician working with children

and families every day, Dr. Laidlaw is severely underestimating the capacity of

parents and guardians to understand and balance information pertaining to the health

of their children. He also ignores that WPATH SOC 8 clearly outlines criteria for

how providers obtain assent and consent for medical intervention (Coleman, et al.,

2022).

62. For his part, Dr. Hruz implies that providing care to transgender patients

using the standards of care violates principal tenants of medicine; he believes this

because he considers these treatments "experimental," and as a result, patients and

their parents cannot provide informed consent (Hruz Rep. ¶¶ 98, 105). However, as

detailed in my initial report and reiterated above, gender-affirming care is not

experimental – it is based on significant scientific research and clinical experience

and is supported by every major medical association in the country. As a provider of

gender-affirming care, it is my opinion that withholding gender-affirming care

would violate the basic tenants of medicine. Dr. Levine makes a similar point about

the Hippocratic Oath (Levine Rep. ¶ 87). Again, this oath has guided me and my

colleagues to provide gender-affirming care when appropriate, weighing the risk of

treatment against the harm of not treating.

63. Dr. Hruz further claims that parents cannot provide informed consent

because providers often threaten parents that "failure to allow a gender dysphoric

child to medically transition will result in suicide" (Hruz Rep. ¶ 106). Dr. Hruz

provides no support for this assertion, and I personally have never considered

making this kind of statement to patients or their families; this is not common

practice nor is it suggested in the SOC. In contrast, consistent with the SOC, I am

always clear with patients and parents that I consider every perspective in the room

valid, based on love, and rooted in the intention to make the best decision for the

health of the adolescent. Any complete assessment of an adolescent's gender identity

includes vital information from parents, who have much more knowledge of their

child than their health care providers could ever have. Most often, careful

exploration of the desires, fears, questions, and concerns of both patients and parents

leads to better understanding and improves collaboration and the ability to make

sound medical decisions together.

64. Raising similar concerns to Dr. Hruz, Dr. Scott believes that gender-

affirming care may be appropriate in children and adolescents but is concerned about

how to identify appropriate candidates for this care (Scott Rep. ¶ 7). Fortunately,

assessment by highly competent mental health professionals is a cornerstone of the

current standards of care in adolescent gender medicine and helps to identify

appropriate candidates for medical treatments.

65. That said, Dr. Hruz's assertion that rates of suicidal ideation and

attempt in transgender adolescents are similar to those found in adolescents without

gender identity is incorrect and wildly disconnected from the literature.

Unfortunately, the rates among transgender adolescents are significantly elevated (Reisner, et al., 2015).

66. Dr. Hruz then references Dr. Levine (another designated expert for the defendants) in stating that informed consent in this context fails with respect to discussion of the natural history of gender dysphoria in adolescents, the quality of evidence regarding gender-affirming care, and the handling of the question of suicidality (Hruz Rep. ¶108). In my own practice, consistent with the SOC, I am careful to review the evidence as outlined in my report with patients and families and reject the claim that the consent process is limited by "erroneous professional assumptions" or "poor quality of the initial evaluations".

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The following section of this rebuttal report (Section VI – Dr. Laidlaw's Opinions Regarding Plaintiffs) is designated as CONFIDENTIAL pursuant to the Protective Order in this matter (ECF No. 77).

VI. <u>Dr. Laidlaw's Opinions Regarding the Plaintiffs</u>

67. Dr. Laidlaw claims that plaintiffs K.F. (Laidlaw Rep. ¶¶ 230-250), Brit

Rothstein (Laidlaw Rep. ¶ 251-270), S.D. (Laidlaw Rep. ¶ 271-293), and August

Dekker (Laidlaw Rep. ¶¶294-305) should not be receiving gender-affirming care.

68. I have not spoken with the plaintiffs, the parents of the minor plaintiffs,

or their providers. However, as noted above, I have reviewed their medical records,

and based on that review, I disagree with Dr. Laidlaw's conclusions about the

plaintiffs' treatments. First, his opinions about the plaintiffs rest on his belief that

nobody should be prescribed GnRHa or hormones to treat gender dysphoria. Second,

his criticisms of the specific care the individual plaintiffs received are unfounded.

69. Based on the available medical records, I do not have any medical

concerns regarding the gender-affirming care received by K.F. In fact, I would posit

that K.F.'s mental health would deteriorate precipitously if he were unable to

continue to receive this care. In review of the clinical course of K.F., he appears to

have had clear and consistent male gender identity since at least the age of 6. The

decision to make a social transition appears to have been discussed by a mental

health professional as is recommended in the Endocrine Society Guidelines

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(Hembree, 2017). He happens to have been seen at Boston Children's Hospital in

September 2015, just after the completion of my training at this institution. All

patients seen at this clinic are assessed by a member of the mental health team. And,

regardless of how Dr. Laidlaw may personally feel about nurse practitioners

(Laidlaw Rep. ¶¶ 235-236), NPs – including Sara Pilcher, who I personally worked

alongside in Boston – are qualified to and provide excellent, thoughtful and

evidence-based care under supervision of physicians in pediatric endocrinology and

all other fields of medicine.

70. Dr. Laidlaw is looking for signed documentation of discussions

regarding risks and benefits of treatment, suggesting that if there is no signed

document these conversations must not have occurred. However, it is not my

practice, nor to my knowledge a common practice, to have parents sign documents

related to medical conversations that take place in gender clinics or other pediatric

endocrinology clinics for the treatment of gender dysphoria or other conditions. Dr.

Laidlaw attempts to conflate diagnoses of anxiety and ADHD as evidence of

deteriorating mental health as a result of gender-affirming therapy. Whether K.F. has

or does not have anxiety or ADHD has no bearing on whether the gender-affirming

care received is providing benefit for gender dysphoria, a separate medical problem.

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71. I disagree with Dr. Laidlaw's review of Brit Rothstein; I do not have

concerns about his care and would suggest Mr. Rothstein's mental health would

deteriorate if unable to receive gender-affirming care. Dr. Laidlaw's review of Brit

Rothstein is notably flawed in a few respects. Similar to his incredulity that nurse

practitioners can provide high quality evidence-based care, Dr. Laidlaw seems to

believe that the only mental health professionals able to competently work with

transgender adolescents are psychologists or psychiatrists (Laidlaw Rep. ¶¶ 254-

255). In fact, therapists and social workers not only are trained and licensed to do

this work, but in my experience are often more effective due to their ability to see

patients regularly and build understanding and rapport. At the Child and Adolescent

Gender Clinic at Michigan Medicine, where I serve as Clinical Director, our mental

health team consists of two social workers and a child and adolescent psychiatrist.

The social workers perform comprehensive biopsychosocial assessments for all new

patients, and the child and adolescent psychiatrist sees only a fraction of our patients

who have additional psychiatric needs.

72. Dr. Laidlaw points out that Mr. Rothstein is more medically complex

than other patients with gender dysphoria (Laidlaw Rep. ¶¶ 259-261). Certainly, a

careful review of a patient's medical history is important prior to starting gender-

affirming care. But none of Mr. Rothstein's co-occurring conditions contraindicate

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the gender-affirming care he has received. Indeed, medically complex patients do

present to gender clinics and may benefit from hormonal interventions; comorbid

medical problems should not and do not preclude gender-affirming treatment. My

review of Mr. Rothstein's records reveals that his providers have been carefully

considering his other medical problems and monitoring them in order to help him

transition safely.

73. Dr. Laidlaw opines that Mr. Rothstein has developed erythrocytosis

(elevation in the red blood cell measurement, hematocrit) while being treated with

testosterone (Laidlaw Rep. ¶ 148). But as noted above, Dr. Laidlaw is using the

female reference range for hematocrit to make this assertion, which is inappropriate,

because the male reference range for hematocrit should be used for patients on

testosterone treatment. Indeed, Mr. Rothstein's most recently documented

hematocrit was within the appropriate range for a male.

74. I also disagree with Dr. Laidlaw's review of S.D. who has received

appropriate care and would likely have deterioration in health if this care were

discontinued. In S.D.'s case Dr. Laidlaw again takes note of the fact that Dr. Linda

Ouellet and Rebecca Thipsingh are therapists - trained and licensed mental health

professionals. As I stated above, this is neither unusual nor inappropriate. He takes

particular umbrage with the parents' decision to help S.D. make a social transition,

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stating that this decision "had the iatrogenic effect of preventing the natural course

of desistance which would occur in the majority of children" (Laidlaw Rep. ¶ 276).

This is incorrect, wildly speculative, and unfounded. Social transition does not

significantly impact the natural course of a prepubertal child's gender identity. That

more children who make a social transition maintain a transgender identity into

adolescence can be clearly explained by the fact that children with stronger and more

intense identification are both: (1) more likely to make a social transition; and (2)

more likely to continue to identify this way as adolescents. Here, Dr. Laidlaw is

making the same causal theory error that he made previously when suggesting that

GnRHa actually influences future gender identity (see para 5, above).

75. Dr. Laidlaw says he is concerned that S.D. and her mother have

unrealistic expectations about gender-affirming care based on the statement that

"there is nothing worse in S.D.'s mind than male puberty" (Laidlaw Rep. ¶ 280). But

that statement makes complete sense given that S.D. identifies as a girl. What girl

wouldn't describe the prospect of going through male puberty as a nightmare? Dr.

Laidlaw suggest that "it is common for parents and children influenced by GAT

practitioners to believe that a child can go through puberty of the opposite sex.

However, they have been misinformed as this is not possible" (Laidlaw Rep. ¶ 280).

Dr. Laidlaw insults not only the competence of practitioners to provide complex

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information, but more glaringly the intelligence of patients and parents. Patients and

parents do not expect testicles to become ovaries. In S.D.'s case, if estrogen is

prescribed in the future, she would develop secondary sex characteristics consistent

with other girls. Whether or not Dr. Laidlaw refuses to call this "female puberty" is

of no practical consequence.

76. I also have no concerns about the care received by August Dekker,

disagree with Dr. Laidlaw's review of his care, and feel that he would be at high risk

for negative health outcomes if his care were discontinued. In discussing the case of

Mr. Dekker (Laidlaw Rep. ¶¶ 294-305), Dr. Laidlaw, an endocrinologist, describes

a sort of forensic investigation he performed related to August's mental health

professional. While I cannot comment on the status of Abbie Rolf's license, I can

state that (1) membership in WPATH is certainly not a reason to reject the

assessment of a mental health professional; (2) Dr. Laidlaw's re-assertion that only

psychiatrists and psychologists are capable of assessment of gender identity is

inappropriate and condescending to mental health professionals; and (3) there is no

reason that a mental health professional should require multiple visits with an adult

transgender man requiring chest surgery if it becomes clear that he meets criteria for

this surgery after a single visit. Dr. Laidlaw is also concerned as to whether Planned

Parenthood has an endocrinologist on staff. This is immaterial, as prescribing

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testosterone is not restricted to endocrinologists, and it is common and appropriate

for practitioners from various disciplines to provide hormone treatment. In my home

institution, adult transgender men receive their hormonal care from extremely well-

trained and competent providers in a variety of medical disciplines including

gynecology, family medicine, internal medicine, urology, and also endocrinology.

This marks the end of CONFIDENTIAL section of this rebuttal report.

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

Executed this 10th day of March 2023.

Daniel Shumer, M.D.

Exhibit C

Supplemental Bibliography

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

EXPERT REBUTTAL REPORT OF DR. DANIEL SHUMER, M.D.

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

AUGUST DEKKER, et al.,

Plaintiffs,

V.

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

JASON WEIDA, et al.,

Defendants.

EXPERT REBUTTAL REPORT OF ARON JANSSEN, M.D.

- I, Aron Janssen, M.D., hereby declare and state as follows:
- 1. I am over 18 years of age, of sound mind, and in all respects competent to testify.
- 2. I have been retained by counsel for Plaintiffs as an expert in connection with the above-captioned litigation. The opinions expressed herein are my own and do not express the views or opinions of my employer.
- 3. I have actual knowledge of the matters stated herein. If called to testify in this matter, I would testify truthfully and based on my expert opinion.

BACKGROUND AND QUALIFICATIONS

A. Qualifications

4. I am the Vice Chair of the Pritzker Department of Psychiatry and Behavioral Health at the Ann and Robert H. Lurie Children's Hospital of Chicago

("Children's Hospital"), where I also serve as Clinical Associate Professor of Child

and Adolescent Psychiatry. I maintain a clinical practice in Illinois where I treat

patients from Illinois and the surrounding states.

I received my medical degree from the University of Colorado School 5.

of Medicine and completed by residency in psychiatry and fellowship in child and

adolescent psychiatry at New York University Langone Medical Center.

6. In 2011, I founded the Gender and Sexuality Service at New York

University, for which I served as Clinical Director. I also previously served as Co-

Director of the New York University Pediatric Consultation Liaison Service for the

New York University Department of Child and Adolescent Psychiatry.

7. I am board certified in Child and Adolescent Psychiatry and Adult

Psychiatry.

8. I have been treating children and adolescents with gender dysphoria for

over 12 years. I have seen and treated over 500 children and adolescents with gender

dysphoria during my medical career. Currently, approximately 90 percent of the

patients in my clinical practice are transgender children and adolescents.

9. As part of my practice, I stay current on medical research and literature

relating to the care of transgender persons and patients with gender dysphoria. I am

an Associate Editor of the peer-reviewed publication Transgender Health and a

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reviewer for LGBT Health and Journal of the American Academy of Child and

Adolescent Psychiatry, both of which are peer-reviewed journals.

10. I am the author or co-author of 16 articles on care for transgender

patients and am the co-editor of Affirmative Mental Health Care for Transgender

and Gender Diverse Youth: A Clinical Casebook (Springer Publishing, 2018), which

is the first published clinical casebook on the mental health treatment for children

and adolescents with gender dysphoria. I have also authored or co-authored

numerous book chapters on treatment for transgender adults and youth.

11. I have been a member of the World Professional Association for

Transgender Health ("WPATH") since 2011. I was actively involved in the revision

of WPATH's Standards of Care for the Health of Transgender and Gender Diverse

People ("Standards of Care"), serving as a member of revision committees for both

the child and adult mental health chapters of version 8 of WPATH's Standards of

Care (SOC 8), published in 2022.

In addition to the above, I am involved in training other medical and 12.

mental health providers in the treatment of children and adolescents with gender

dysphoria. I have conducted trainings for over 1,000 medical and mental health

providers and have given dozens of public addresses, seminars, and lectures on the

treatment of gender dysphoria in children and adolescents.

13. I am also involved in a number of international, national, and regional committees that contribute to the scholarship and provision of care to transgender people. I am the Chair of the American Academy of Child and Adolescent Psychiatry's Sexual Orientation and Gender Identity Committee. I serve as a member of the Transgender Health Committee for the Association of Gay and Lesbian Psychiatrists. I was the Founder of the Gender Variant Youth and Family Network.

14. Further information about my professional background and experience is outlined in my curriculum vitae, a true and accurate copy of which is attached as **Exhibit A** to this report.

B. Prior Testimony

15. Within the last four years, I testified as an expert at trial or by deposition in: *B.P.J. v. W. Va. Bd. of Educ.*, Case No. 2:21-cv-00316 (S.D. W.Va.); and *L.E. v. Lee*, Case No. 3:21-CV-00835 (M.D. Tenn.).

C. Compensation

16.I am being compensated for my work on this matter at a rate of \$400 per hour for preparation of this report and for time spent preparing for and giving local deposition or trial testimony. In addition, I would be compensated \$2,500 per day for deposition or trial testimony requiring travel and \$300 per hour for time spent

travelling, plus reasonable expenses. My compensation does not depend on the outcome of this litigation, the opinions I express, or the testimony I may provide.

D. Bases for Opinions

Administrative Code 59G-1.050(7) (the "Challenged Exclusion"); the document titled "Florida Medicaid: Generally Accepted Professional Medical Standards Determination on the Treatment of Gender Dysphoria," published by the Florida Agency for Health Care Administration in June 2022, and its attachments; the expert reports of Drs. Armand Antommaria, Dan Karasic, Johanna Olson-Kennedy, Loren Schechter, Daniel Shumer, and Kellan Baker, submitted by plaintiffs; and the expert reports Drs. Michael Biggs, G. Kevin Donovan, Paul Hruz, Kristopher Kaliebe Michael Laidlaw, Patrick Lappert, Stephen Levine, Sophie Scott, and Joseph Zanga, submitted by defendants.

18. My opinions are based on: (1) my clinical experience as a psychiatrist treating patients with gender dysphoria, including transgender children, adolescents, and adults; (2) my knowledge of the peer-reviewed research, including my own, regarding the treatment of gender dysphoria, which reflects advancements in the field of transgender health; my knowledge of the clinical practice guidelines for the treatment of gender dysphoria, including my work as a contributing author of WPATH SOC 8; and (4) my review of any of the materials cited herein.

- 19. I have also reviewed the materials listed in the bibliography attached as **Exhibit B**. I may rely on those documents as additional support for my opinions.
- 20. In addition, I have relied on my years of research and clinical experience in child, adolescent, and adult psychiatry, as well as my professional knowledge, as set out in **Exhibit A** and the materials listed therein.
- 21. The materials I have relied upon in preparing this report are the same types of materials that experts in my field of study regularly rely upon when forming opinions on the subject. I may wish to supplement these opinions or the bases for them as a result of new scientific research or publications or in response to statements and issues that may arise in my area of expertise.
 - 22. I have not met or spoken with the Plaintiffs in this case.

SUMMARY OF OPINIONS

- 23. As with all of medicine, transgender medicine is a continuously evolving field. But this does not make medical treatment for gender dysphoria experimental or investigational. To the contrary, such treatment is well-established and large body of evidence (more so than exists for other non-experimental medical interventions) documents that safety and efficacy of these medical interventions.
- 24. Transgender people have always existed and the provision of medical care to address transgender people's gender incongruence/gender dysphoria goes back decades. In fact, the field of transgender medicine was built to increase

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oversight around patient care, and often requires consent processes that go above

and beyond what is expected for other medical decisions.

25. There is robust evidence demonstrating the value of social, medical and

surgical interventions for children, adolescents, and adults when in the context of an

appropriate psychosocial evaluation. And to be clear, no medical or surgical

interventions are recommended or provided to anyone until after the onset of

puberty, meaning such care is only available to adolescents and adults.

26. The Defendants and their designated experts spent much time arguing

about hypothetical concerns, for which there is no proof, and the limitations of

particular studies. But Defendants and their designated experts completely ignore

that the evidence-base for the safety and efficacy for gender-affirming care is not

based on any one particular study. Rather, as is the norm in all of science and

medicine, we look at the entire body of research surrounding gender-affirming care.

When one does so, the conclusion that gender-affirming medical care for the

treatment of gender dysphoria in transgender adolescents and adults is safe and

effective becomes inescapable. Decades on clinical experience further support this

conclusion.

Defendants and their designated experts further ignore the robust 27.

evidence for the potential harm faced by transgender individuals when barred access

to medically necessary gender-affirming care.

28. Defendants and their designated experts also ignore every transgender

adult was once a child. The Defendants' designated experts focus on children and

adolescents, but the Challenged Exclusion bans coverage for all care for an already

vulnerable population, including adults. None of them explain why this case is

experimental for transgender adults.

29. While there can be debate about the techniques and modalities of care

to support transgender youth, it is important to keep in mind that the opposite of

substandard care is excellent care, not no care. To be clear, however, gender-

affirming care is safe and effective, it is not substandard or experimental.

30. Understanding patients' experience of distress around gender is a vital

component of being an expert in this field. Without understanding the distress

transgender patients face – as well as the joy and resilience they experience when

they get the care they need – one is only spouting unmoored and unfounded opinions.

Medicine and science demand more than just personal opinions, it demands study

and experience in the field. For the most part, Defendants' designated experts lack

both.

EXPERT OPINIONS

A. Defendants' experts lack the experience and/or training to opine on the diagnosis, assessment, and treatment of gender dysphoria of transgender children and adolescents.

Dr. Levine

- 31. Because Dr. Levine does not appear to be board certified in child and adolescent psychiatry, he lacks the related experience and training in specific developmental considerations for children and adolescents that is critical for working with transgender youth and their families.
- 32. Moreover, Dr. Levine repeatedly acknowledges in his report that he has no firsthand knowledge of how gender-affirming mental health care is actually provided to children and adolescents. His descriptions are based on second-hand conversations and often sensationalized media reports. (*See*, *e.g.*, Levine Report, at ¶49 (offering opinions based on anecdotal reports from the internet)). He speaks in his report with authority on developmental and family factors that shape identity development in youth despite lacking the requisite training and experience and even ascribes reasons for why boys and girls may pursue social transition despite no clinical experience in the relevant population.

Dr. Kaliebe

33. Similarly, Dr. Kaliebe is not qualified to opine as an expert on the care of transgender children and adolescents. There is a difference between having an

interest in a topic and having expertise in a clinical or research domain. Dr. Kaliebe's report of the number of transgender patients he has seen is consistent with what many of our child psychiatry trainees are exposed to in their residency, and is not consistent with the volume of patients necessary to demonstrate expertise on the clinical nuance of the field. In addition to a lack of clinical expertise, Dr. Kaliebe's report calls into question his expertise in research methods or ethics. As an example, throughout his report Dr. Kaliebe makes claims about the quality of the evidence for gender affirming care while describing unscientific survey questions asked outside of the IRB process as having the same weight as data published in a peer-reviewed journal. Furthermore, nowhere in his CV does it describe a history of expertise in evolutionary biology or early human behavior, but this doesn't stop him from making unsubstantiated and uncited assertions about adaptive behaviors in "ancient evolutionary environments."

Defendants' other experts

34. Expertise in mental health care requires specialized training and ongoing work in the field with appropriate certification and licensure. To my knowledge, and based on a review of their respective CV's, Drs. Hruz, Laidlaw, Lappert, Biggs, Donovan, and Zanga have neither had the training nor the certification and licensure to weigh in as experts on the appropriateness of a mental health assessment or treatment plan. This lack of expertise, however, has not

stopped them from making broad generalizations about mental health care that bear little resemblance to the care as typically delivered. As such, their characterizations of the practice of mental health care should be seen as a lay opinion based on secondhand knowledge at best. Furthermore, expertise in the treatment of transgender individuals requires experience in the care of transgender individuals, a

B. Gender Identity

35. At birth, infants are assigned a sex, either male or female, based on the

appearance of their external genitalia. For most people, their sex assigned at birth,

or assigned sex, matches that person's gender identity. For transgender people, their

assigned sex does not align with their gender identity.

characteristic in short supply with the aforementioned experts.

36. Gender identity is a person's core sense of belonging to a particular

gender, such as male or female.

37. Gender identity is one of a person's multiple sex-related characteristics,

which also include, among others, internal reproductive organs, external genitalia,

chromosomes, hormones, and secondary sex characteristics.

38. In their reports, Defendants' designated experts state repeatedly that sex

is binary and conditions of sexual differentiation are not a "third sex." This simplistic

view, however, ignores that there is great variance among the multiple sex-related

characteristics that a person possesses, including gender identity, and that such

variance is a natural phenomenon with biological underpinnings. While conditions

of sexual differentiation (i.e., intersex conditions) are not a "third sex," they are

indicative of the natural variance regarding certain sex-related characteristics. These

are rare conditions with an estimated aggregate incidence of 0.1- 0.5% of live births

(Arboleda, et al., 2013). What is more, many people cannot make either eggs or

sperm, yet are recognized as female or male based on other sex-related

characteristics.

39. Every person has a gender identity and it is not a personal decision,

preference, or belief. A transgender boy cannot simply turn off his gender identity

like a switch, any more than a nontransgender boy or anyone else could.

40. Living in a manner consistent with one's gender identity is critical to

the health and wellbeing of any person, including transgender people.

41. The lack of evidence demonstrating that gender identity can be altered,

either for transgender or for nontransgender individuals, further underscores the

innate nature and immutability of gender identity. Past attempts to "cure"

transgender individuals by using talk therapy, and even aversive therapy, to change

their gender identity to match their birth-assigned sex were ineffective and caused

extreme psychological damage.

A recent study found that experiencing those conversion efforts was 42.

associated with greater odds of attempting suicide, especially for those had those

experiences in childhood (Turban, et al., 2020b). That conclusion is further supported by the extensive evidence that rejection of a young person's gender identity from family and peers are the strongest predictors for adverse mental health outcomes. Every leading medical and mental health organization has issued clear statements that those practices are discredited, harmful, and ineffective, including the American Medical Association (2022), the American Psychiatric Association (2018), the American Academy of Child & Adolescent Psychiatry (2018), the American Psychological Association (2021), and the American Academy of Pediatrics (Rafferty, et al., 2018), among others.

43. Dr. Levine notes in his report "it is widely agreed that the therapist should not directly challenge a claimed transgender identity in a child." (Levine Report, at ¶50). This characterization mischaracterizes gender affirming therapy and calls into question his understanding of conversion efforts in the context of prepubertal youth. Within the model of gender affirming care, challenging assumptions based on stereotypes of gender and encouraging a child to build nuance around identity is inherent to the process of care. However, what Dr. Levine seems to be arguing for is not to encourage a psychotherapeutic process that helps a child come to a clear and nuanced sense of self, whatever the gender identity may be, but instead recommending a psychotherapeutic intervention that privileges a non-transgender identity as inherently preferred. While Dr. Levine focuses much of his report on

children who desist during puberty, inherent in the literature on desistance includes

the substantial portion of prepubertal youth who persist in a transgender identity

through puberty and into adulthood. By foreclosing the possibility of a healthy

transgender identity and instead encouraging these transgender youth who will

persist into transgender adults to strive towards a cisgender outcome, as Defendants

and their experts argue, one is, by definition, practicing conversion therapy.

44. There is no one way by which people experience their gender identity

development from early questioning to consolidation and affirmation. Though it is

common for transgender youth to come out at puberty, for other transgender persons

this is not true, and it may take them longer to come to recognize and acknowledge

their gender identity. For the latter group, this is not due to some "late onset" of

dysphoric feelings or sudden understanding themselves as transgender, it is the result

of a long and difficult process toward accepting and understanding themselves in a

social context where being transgender is still a difficult reality due to external

stigma, fears of family and social rejection, and even internalized transphobia

(Pullen Sansfaçon, et al., 2020).

45. Dr. Levine, Dr. Kaliebe, and Defendants' other designated experts

devote a great deal of space to discussing a theory that an increasing number of

people who are assigned female at birth are suddenly identifying as males in mid-to-

late adolescence as a result of peer pressure and social contagion. (See, e.g., Levine

Report, at ¶¶ 38, 96; Kaliebe Report, at ¶¶30-31, 40-43; Laidlaw Report, at ¶29; Hruz Report, at ¶¶ 117, 131). The theory that some adolescents experience "rapid-onset gender dysphoria" as a result of social influences is based almost exclusively on one highly controversial study (Littman, 2018). Although purporting to provide a basis for Dr. Levine's speculations, the study was based on an anonymous survey, allegedly of parents, about the etiology of their child's gender dysphoria. Participants were recruited from websites promoting this social contagion theory, and the children were not surveyed or assessed by a clinician. Those serious methodological flaws render the study meaningless. The only conclusion that can be drawn from that study is that a self-selected sample of anonymous people recruited through websites that predisposed participants to believe transgender identity can be influenced by social factors do, in fact, believe those social factors influence children to identify as transgender.¹

46. Dr. Kaliebe seems to argue that the fact that transgender adolescents find other transgender adolescents online is proof of a "social contagion." He cites to no scientific study to support this speculation, other than Littman study discussed above. But Dr. Kaliebe ignores that online spaces often provide a safe place for transgender youth to come out and be themselves, allowing them to explore their

¹ Aside from these serious methodological flaws, Littman's hypothesis of "rapid onset gender dysphoria" focuses specifically on gender dysphoria in boys who are transgender and were assigned a female sex at birth.

identity. This is no different from a host of other affinity-type groupings one can find on social media. Just like many other minoritized youth, adolescents often search out groups that share core characteristics. Dr. Kaliebe's assertion that social media is a leading cause of the increased prevalence of transgender identifying youth is not demonstrated in the extant literature, and it is also beside the point. Part of an assessment of gender dysphoria includes an inquiry into the social context of the patient – this includes online spaces and potential positive and negative reinforcing factors, including social group status online. This also includes assessing for the concerns Dr. Kaliebe describes that assigned females at birth often face at puberty.

47. Notwithstanding the above, Dr. Kaliebe goes on to assert that "psychiatrists believe social media has significantly contributed to the rise in gender dysphoria." In support thereof, Dr. Kaliebe references conversations as his evidence and further asserts that "most child psychiatrists admit to me they will not speak publicly on this subject due to how sensitive the topic is." But such anecdotal evidence is not the type of evidence one would look to in answering scientific question nor whether a particular form of care is experimental or investigative. (Kaliebe Report, at ¶41). Dr. Kaliebe then cites not one but two unscientific polls of attendees to a particular session at a conference as support for the bold assertion that such data "confirm[] that the vast majority of a group of child and adolescent psychiatrists acknowledge social contagion is a major contributor to the rise in

gender dysphoria." But this is not how scientific study is conducted in medicine.

There is no plausible basis for Dr. Kaliebe to extrapolate the poll results of an

unscientific survey of attendees to a panel as proof that a "majority of a group of

child and adolescent psychiatrists acknowledge social contagion is a major

contributor to the rise in gender dysphoria." To the contrary, what Dr. Kaliebe is

doing can hardly be considered science and illustrates how D. Kaliebe does not

understand what selection bias is nor what a study is.

C. Gender Dysphoria and Its Diagnostic Criteria

48. The term "gender dysphoria" is the distress related to the incongruence

between one's gender identity and one's sex assigned at birth.

49. Gender dysphoria is the clinical diagnosis for the significant distress

that results from the incongruity between one's gender identity and sex assigned at

birth. It is a serious medical condition, and it is codified in the American Psychiatric

Association's in the Diagnostic and Statistical Manual of Mental Disorders, Fifth

Edition, Text Revision (DSM-5-TR) (DSM-5 released in 2013 and DSM-5-TR

released in 2022).

50. The DSM-5 defines gender dysphoria as a: "marked difference between

the individual's expressed/experienced gender and the gender others would assign

him or her, and it must continue for at least six months. In children, the desire to be

of the other gender must be present and verbalized. This condition causes clinically

significant distress or impairment in social, occupational, or other important areas of

functioning."

51. The DSM-5 also states that: "gender dysphoria is manifested in a

variety of ways, including strong desires to be treated as the other gender or to be

rid of one's sex characteristics, or a strong conviction that one has feelings and

reactions typical of the other gender."

52. "Gender Dysphoria in Children" is a diagnosis applied only to pre-

pubertal children in the DSM-5. The DSM-5 has a separate diagnosis of "Gender

Dysphoria in Adolescents and Adults." The diagnostic criteria for these diagnoses

are distinct. Understanding that children have less capacity to articulate abstract

concepts about the sense of self as well as a reflection of what can be a lack of

specificity of gender nonconforming behaviors in childhood, there are more nuanced

criteria to make the diagnosis for children. Furthermore, prepubertal youth are not

eligible for medical or surgical intervention while the diagnosis of gender dysphoria

in adolescents/adults is required for medical and/or surgical treatments,

53. Simply being transgender or gender diverse is not a medical condition

or pathology to be treated. As the DSM-5 recognizes, diagnosis and treatment are

"focus[ed] on dysphoria as the clinical problem, not identity per se." (DSM-5, at

451). The DSM-5 unequivocally repudiated the outdated view that being

transgender is a pathology by revising the diagnostic criteria (and name) of gender

dysphoria to recognize the clinical distress as the focus of the treatment, not the

patient's transgender status.

54. When untreated, gender dysphoria can cause significant distress

including increased risk of depression, anxiety, and suicidality. This is noted both in

adolescents and adults. However, these risks decline when transgender individuals

are supported and live according to their gender identity. Not only is this

documented in scientific literature and published data, but I witness this each time I

see my patients being supported by their community, family, school, and medical

providers.

D. The Guidelines for the Treatment of Gender Dysphoria Are Evidence-

Based.

55. The World Professional Association of Transgender Health (WPATH)

has issued Standards of Care for the Health of Transgender and Gender Diverse

People ("WPATH Standards of Care") since 1979. The current version is SOC 8,

published in 2022. The WPATH Standards of Care provide guidelines for

multidisciplinary care of transgender individuals, including children and

adolescents, and describes criteria for medical interventions to treat gender

dysphoria, including hormone treatment and surgery when medically indicated, for

adolescents and adults.

56. The SOC 8 is based upon a rigorous and methodological evidence-

based approach. (Coleman, et al., 2022). Its recommendations are evidence-based,

informed by a systematic review of evidence and an assessment of the benefits and

harms of alternative care options, as well as expert consensus via a Delphi procedure.

The process for development of SOC 8 incorporated recommendations on clinical

practice guideline development from the National Academies of Medicine and The

World Health Organization. Its recommendations were graded using a modified

GRADE methodology (Guyatt, et al., 2011), considering the available evidence

supporting interventions, risks and harms, and feasibility and acceptability.

57. A clinical practice guideline from the Endocrine Society (the Endocrine

Society Guidelines) provides similar protocols for the medically necessary treatment

of gender dysphoria. (Hembree, et al., 2017).

58. Each of these guidelines are evidence-based and supported by scientific

research and literature, as well as extensive clinical experience.

59. Each of these guidelines also provides distinct guidance for age-

appropriate care for children, adolescents, and adults with gender dysphoria. And

none of these guidelines recommend medical treatment for prepubertal children,

meaning no medical treatment is recommended until after the onset of puberty.

60. The protocols and policies set forth by the WPATH Standards of Care

and the Endocrine Society Guidelines are endorsed and cited as authoritative by the

major professional medical and mental health associations in the United States,

including the American Medical Association, the American Academy of Pediatrics,

the American Psychiatric Association, the American Psychological Association, the

American College of Obstetrics and Gynecology, the American College of

Physicians, and the World Medical Association, among others.

E. Assessment and Treatment of Gender Dysphoria in Children

61. Defendants' experts spend substantial portions of their expert reports to

criticizing gender-affirming care for prepubertal transgender children. For example,

according to Dr. Levine, studies have indicated that gender dysphoria in prepubertal

gender diverse children may desist by the time the children reach puberty, and thus

medical professionals should adopt a "watchful waiting" approach and avoid

affirming a prepubertal child's gender identity.

62. However, with regards to prepubertal gender diverse children, the

Standards of Care state that prepubertal gender diverse children "are not eligible to

access medical intervention," and therefore focuses on developmentally appropriate

psychosocial practices. However, this case concerns coverage of medical treatment,

namely, puberty delaying medications, hormones, and surgery, and none of those

treatments are recommended for transgender youth until after the onset of puberty

(i.e., until adolescence), and even then it is only a subset of those, when it is

medically necessary, age appropriate, and the legal caregivers consent.

63. As such, many of Dr. Levine's and Defendants' other designated

experts' litany of criticisms is largely irrelevant to the population of people affected

by the Challenged Exclusion. For example, a significant number of Dr. Levine's

and Defendants' other designated experts' arguments relate to prepubertal children

who "desist" from expressing a transgender identity once they reach puberty. While

the statements being made about this population are erroneous, they are also largely

irrelevant.

64. That said, to avoid any confusion, I address some of Dr. Levine's and

Defendants' other designated experts' arguments pertaining to transgender youth

prepubertal here.

65. As with all health care, treatment of prepubertal gender diverse children

is individualized based on the needs of the child and the family and other

psychosocial considerations and is decided upon only after a discussion of possible

benefits and risks (Hidalgo, et al., 2013). As part of those discussions, the child and

their family are advised that prepubertal gender diverse children do not always go

on to identify as transgender when they reach adolescence, and that children are

encouraged to continue developing an understanding of their gender identity without

expectation of a specific outcome even after social transition takes place (American

Psychological Association, 2015; Edwards-Leeper and Spack, 2012).

The term "gender diverse" includes transgender children as well as 66.

children who will ultimately not identify as transgender later in life (Coleman, et al.,

2022).

67. Dr. Levine and Defendants' other designated experts present a

caricatured description of prevailing standards of care that reflects a profound

misunderstanding of the subject with respect to prepubertal gender diverse children.

Mental health providers cannot change a prepubertal child's gender identity or

prevent them from being transgender, just as mental health providers cannot change

a cisgender child's gender identity. Furthermore, it is far from the standard of care

for clinicians to blindly support a child's potential social transition without careful

assessment and a thorough discussion of the risks, benefits and alternatives of this

intervention.

Prepubertal children who "desist" are children with nonconforming 68.

gender expression who realize with the onset of puberty that their gender identity is

consistent with their sex assigned at birth. Their understanding of their gender

identity changes with the onset of puberty, but their gender identity does not. We

cannot definitively determine which prepubertal children will go on to identify as

transgender when they reach adolescence, but we know that children with gender

dysphoria who persist into puberty are more likely to have expressed a consistent,

persistent, and insistent understanding of their gender identity from a young age

(Steensma, et al., 2013).

69. The focus of gender-affirming care and SOC 8 is thus in supporting

the overall health and wellbeing of the child. In this manner, the primary goal of

gender-affirming care is to help a child understand their own gender identity and

build resilience and mental wellness in a child and family, without privileging any

one outcome over another.

70. Important considerations in deciding whether social transition is in a

child's best interest include: whether there is a consistent, stable articulation of a

gender different from the child's sex assigned at birth, which should be distinguished

from merely dressing or acting in a gender non-conforming manner; whether the

child is expressing a strong desire or need to transition; the degree of distress the

child is experiencing as a result of the gender dysphoria; and whether the child will

be emotionally and physically safe during and following transition (Coleman, et al.,

2022; American Psychological Association, 2015).

71. A treatment plan is informed by a psychosocial assessment, which may

vary greatly depending on the patient's presentation and the complexity of the issues

the patient is navigating. Further, in conducting that assessment, the mental health

provider is drawing from their professional training and experience in working with

transgender young people, exercising professional judgment, and tailoring the

assessment to each individual patient.

72. There is also no requirement that prepubertal children who socially

transition receive mental health therapy. Many prepubertal children who express a

gender identity different from their sex assigned at birth do not experience any co-

occurring conditions or other psychological distress requiring treatment (Coleman,

et al., 2022; de Vries, et al., 2011a). Mental health therapy may be useful for some

prepubertal children but is not necessary or appropriate for everyone. Forcing

children to undergo therapy when it is not medically indicated is both harmful and

unethical.

73. What makes gender-affirming care "gender affirming" is that it does

not presume that being transgender is incompatible with a young person's short- and

long-term health and wellbeing. It is also important to note that clinicians utilizing

gender affirming care do not assume that all children asserting a gender identity

incongruent with their sex assigned at birth are inherently transgender. A clinician

doing a careful assessment and recommending a child not socially transition or an

adolescent not pursue medical care is fully aligned with this treatment paradigm.

74. Dr. Levine and Defendants' additional designated experts seem to think

social transition is a single decision that irrevocably alters a child's trajectory over

time. This belief belies their lack of clinical experience in working with gender

diverse pre-pubertal youth. Clinically, social transition is often a series of steps taken

gradually with feedback from the child, the family, and the clinician elicited over

time. It is false that allowing prepubertal transgender children to socially transition

puts these children on a path to becoming transgender adolescents and adults.

Rather, the evidence shows that the same prepubertal children who are likely to have

a stable transgender identity into adolescence are the children who are most likely to articulate a strong and consistent need to socially transition (Steensma, et al., 2013). For example, a recent study found that a group of transgender children who transitioned before puberty and a group of transgender children who waited to transition until after puberty both showed the same intensity of cross-gender

identification. In other words, socially transitioning before puberty did not increase

children's cross-gender identification, and deferring transition did not decrease

cross-gender identification (Rae, et al., 2019).

75. Intense cross-gender identification and a strong, persistent desire to transition is simply an indicator that a child is more likely to be transgender and not

merely gender nonconforming.

F. Assessment and Treatment of Gender Dysphoria in Adolescents

76. WPATH SOC 8 recommends that health care professionals working

with transgender and nonbinary adolescents be licensed, hold a postgraduate degree

in relevant clinical field, have received training and developed expertise in working

with children and adolescents, and have received training and developed expertise

in gender identity and diversity in youth and in the ability of youth to assent/consent

to care (Coleman, et al., 2022).

77. The Standards of Care also recommend a "comprehensive

biopsychosocial assessment" for adolescents "prior to any medically necessary

medical or surgical intervention" for gender dysphoria. The assessment should

include gender identity development, social development and support, diagnostic

assessment of co-occurring mental health or developmental concerns, and capacity

for decision-making (Coleman, et al., 2022). So do the Endocrine Society Guidelines

(Hembree, et al., 2017).

78. Defendants' experts point to the rates of co-occurring psychiatric

diagnoses among youth presenting with gender identity concerns. But not only are

some of these co-occurring diagnoses, like anxiety and depression, often associated

with dysphoria, but because youth experiencing gender identity concerns present for

care before mental health providers more often, it is easier to diagnose other co-

occurring diagnoses that would otherwise often go undiagnosed. In any event, it is

precisely because of these co-occurring mental health diagnoses that specialized

training is required to do a comprehensive biopsychosocial assessment that takes

into account the possibility of diagnoses that may lead a child to experience

confusion around gender identity that is inconsistent with a diagnosis of gender

dysphoria. However, once properly assessed and the other conditions are properly

managed, the presence of these diagnoses is not a contraindication to provide

medical care to adolescents with gender dysphoria.

79. For transgender adolescents, the onset of puberty is often a painful

and sometimes traumatic experience that brings increased dysphoria and the

potential development of a host of comorbidities including depression, anxiety,

substance abuse, self-harming behaviors, social isolation, high-risk sexual

behaviors, and increased suicidality. It is notable that Dr. Levine acknowledges that

many transgender adults have derived significant benefit from gender affirming

medical and surgical care but fails to recognize that all transgender adults were once

adolescents and that much of the stigma faced by transgender adults that he

recognizes as a source of distress and dysfunction would be avoided had they had

access to this care during adolescence.

80. Some transgender people who do not come forward until adolescence

may have experienced symptoms of gender dysphoria for long periods of time but

have been uncomfortable disclosing those feelings to parents. Other transgender

people do not experience distress until they experience the physical changes

accompanying puberty. In either case, gender-affirming care requires a

comprehensive assessment and evidence of persistent, sustained gender dysphoria

before medical treatment is recommended.

81. Gender-affirming treatment also requires a careful and thorough

assessment of a patient's mental health, including co-occurring conditions, history

of trauma, and substance use, among many other factors (Olson-Kennedy, et al.,

2019; Edwards-Leeper and Spack, 2012). As a result, I have had patients who

presented with some symptoms of gender dysphoria, but who ultimately did not meet

the diagnostic criteria for a variety of reasons, and therefore I recommended

treatments other than transition to alleviate their psychological distress. I have also

seen patients that did meet the diagnostic criteria for gender dysphoria but had

mental health impairments that precluded proceeding with gender affirming

hormonal and surgical care.

82. Studies on transgender young people have long reported data on co-

occurring conditions, including some of my own (e.g., Janssen, et al., 2019; Olson,

et al., 2015; Reisner, et al., 2015; Spack, et al., 2012; Mustanski, et al., 2010).

83. The existence—and prevalence—of co-occurring conditions among

transgender young people is unsurprising. Transgender young people must cope

with many stressors, from the fear of rejection by family and peers to pervasive

societal discrimination. Not to mention, their underlying gender dysphoria can cause

significant psychological distress which, if left untreated, can result in or exacerbate

the co-occurring conditions identified in studies on transgender young people (van

der Miesen, et al., 2020; Turban, et al., 2021). And, given that transgender young

people typically delay disclosing their transgender status or initially experience

family rejection following disclosure, it is not uncommon for transgender young

people to engage with psychological or psychiatric care for other reasons prior to

being diagnosed with gender dysphoria.

84. Transgender young people, however, are not outliers in this regard.

Research and clinical experience show that most psychiatric conditions are highly

correlated with other co-occurring psychiatric conditions. For example, young

people with depression are very likely to have at least one other diagnosable

condition, most often anxiety (Costello, et al., 2003). Likewise, a study on children

diagnosed with Attention-Deficit/Hyperactivity Disorder found between 74-79%

participants had additional co-occurring psychiatric conditions (Wilens, et al., 2002).

85. Requiring that a transgender patient resolve all co-occurring conditions,

many of which are chronic with no reasonable expectation that they be "resolved,"

prior to receiving gender-affirming care is not possible, nor is it ethical. No relevant

organizations cite the need for co-occurring mental health conditions to be resolved

before a patient may receive gender-affirming care. Rather, such conditions should

be reasonably well-controlled and not impair the ability of the patient to make an

informed decision or interfere with the accuracy of the diagnosis of gender

dysphoria. Indeed, some co-occurring conditions (for example, Attention Deficit

Hyperactivity Disorder and Autism Spectrum Disorder, to name a few) could be

chronic disorders where complete resolution is impossible and the goal of treatment

is mitigating harm and improving functioning.

86. WPATH SOC 8 recommends that "mental health professionals address

mental health symptoms that interfere with a person's capacity to consent to gender-

affirming treatment before gender-affirming treatment is initiated," but note that

"mental health symptoms such as anxiety or depressive symptoms that do not affect

the capacity to give consent should not be a barrier for gender-affirming medical

treatment, particularly as this treatment has been found to reduce mental health

symptomatology" (Coleman, et al., 2022). Indeed, SOC 8's chapter on adolescents

specifically notes that "while addressing mental health concerns is important during

the course of treatment, it does not mean all mental health challenges can or should

be resolved completely" (Coleman, et al., 2022).

87. The Endocrine Society Guidelines similarly provide that because

gender dysphoria "may be accompanied with psychological or psychiatric

problems," "in cases in which severe psychopathology" "interfere[s] with diagnostic

work or make[s] satisfactory treatment unlikely, clinicians should assist the

adolescent in managing these other issues" (Hembree, et al., 2017). The Guidelines

thus require that these issues be managed, not resolved.

88. Gender dysphoria, by definition, is accompanied by clinically

significant psychological distress. That distress can take on many different forms

(e.g., anxiety, mood disorders, and depression) and vary greatly in severity, resulting

in co-occurring conditions. Because psychological distress is not easily

compartmentalized, the distress associated with gender dysphoria can also amplify

co-occurring conditions that developed independently of the gender dysphoria. In

either situation, gender dysphoria limits the effectiveness of treatment of any co-

occurring mental health conditions. Thus, treating the underlying gender dysphoria

is essential to alleviating the psychological distress associated with co-occurring

conditions.

G. Efficacy of Gender-Affirming Treatment for Gender Dysphoria in

Adolescents

89. "For some youth, obtaining gender-affirming medical care is

important while for others these steps might not be necessary." (Coleman, et al.,

2022). In my clinical experience, some adolescent patients have a critical need for

medical interventions at or at some point after the onset of puberty and others do not.

As with all medical interventions, it is highly individualized and responsive to the

particular medical and mental health needs of each patient as well as the

understanding and preferences of the legal guardians who ultimately make these

healthcare decisions.

90. The criticisms of gender-affirming care for adolescents by Dr. Levine

and Defendants' other designated experts reflect a distorted interpretation of the

relevant scientific literature and what gender-affirming care is. Despite Dr. Levine's

and Defendants' other designated experts' suggestion to the contrary, there is no

"watchful waiting" approach for transgender adolescents. Even practitioners who

oppose social transition in childhood provide gender-affirming care for transgender

adolescents, including puberty-delaying medication and gender-affirming hormone

treatments for gender dysphoria (Turban, et al., 2018; Ehrensaft, 2017).

91. Dr. Levine and Defendants' other designated experts criticize the

methodology of studies supporting gender-affirming care while proposing a

"therapy only" treatment without any empirical or scientific support whatsoever.

They also fail to understand that not all patients in a gender-affirming model of care

will initiate medical or surgical care. The difference is that in the affirming care

model, those decisions are made in concert with the young person and their family.

92. Adolescents with gender dysphoria who have entered puberty may be

prescribed puberty-delaying medications (GnRHa) to prevent the distress of

developing permanent, unwanted physical characteristics that do not align with the

adolescent's gender identity. Puberty-delaying medications allow the adolescent

time to better understand their gender identity, while delaying distress from the

progression of the development of secondary sex characteristics such as breasts or

facial hair.

93. Prior to initiation of puberty-delaying medications, providers counsel

patients and their families extensively on potential benefits and risks. The intended

benefit of treatment is to reduce the risk of worsening gender dysphoria and mental

health deterioration. More specifically, use of puberty-delaying medications in

transmasculine adolescents allows for decreased chest development, reducing the

need for breast binding and surgical intervention in adulthood. For transfeminine adolescents, puberty-delaying medications limit facial and body hair growth, voice deepening, and masculine bone structure development, which greatly reduce distress both at the time of treatment and later in life and reduce the need for later interventions such as voice therapy, hair removal, and facial feminization surgery. The goal in using puberty-delaying medications is to minimize the patient's dysphoria related to progression of puberty and allow for later initiation of puberty consistent with gender identity. The pubertal stage and individual needs of the patient direct conversations regarding care options.

94. A growing body of evidence, including peer-reviewed cross-sectional and longitudinal studies, demonstrates the positive impact of pubertal suppression in adolescents with gender dysphoria on psychological functioning and quality of life, including a decrease in behavioral and emotional problems, a decrease in depressive symptoms, and improvement in general functioning (e.g., Achille, et al., 2020; Turban, et al., 2020a; van der Miesen, et al., 2020; Costa, et al., 2015; de Vries, et al., 2011b). Furthermore, studies show improvements in body satisfaction with gender-affirming treatment, and the extant literature recognizes that the body satisfaction is a mediator for improved quality of life and mental health outcomes. (Chen, et al., 2023).

95. In my own practice, I have had patients describe pubertal suppression

as life saving and a vast majority have experienced a great deal of relief when the

treatment is initiated. In contrast to Dr. Levine's assertion that starting pubertal

suppression is a one-way road to hormones, I have also had patients who, through

gender affirming psychotherapy, came to understand their gender identity to be

congruent with their sex assigned at birth and discontinued this treatment with a

resumption of puberty. While each patient and each family is unique, a thorough

assessment and a clear discussion of the risks, benefits and alternatives of this

interventions is consistent among all of my patients.

After ongoing work with mental health professionals and when the 96.

adolescent has lived in accordance with their gender identity for a significant period

of time, they may start treatment with hormones (testosterone for transgender boys,

estrogen and testosterone suppressants for transgender girls), if and when medically

indicated.

97. There is no credible basis for Dr. Levine's assertion that an adolescent's

decision to begin puberty-blocking medication "act[s] as a psychosocial 'switch,'

decisively shifting many children to a persistent transgender identity." (Levine

Report, ¶133). Studies showing that a high percentage of transgender adolescents

who receive puberty blockers ultimately decide to move forward with gender-

affirming hormone therapy more likely reflect the fact that participants were

rigorously screened and had demonstrated sustained, persistent gender dysphoria

before receiving medical treatment.

Eligibility and medical necessity are determined case-by-case, based on 98.

an assessment of the adolescent's unique cognitive and emotional maturation and

ability to provide a knowing and informed assent in addition to the informed consent

of the legal medical decision maker, most often the parent or guardian. The decision

would be made only after a careful review with the youth and parents/guardians of

the potential risks and benefits of hormone therapy.

99. Under SOC 8 and the Endocrine Society Clinical Guidelines, hormone

therapy is an appropriate treatment for transgender adolescents with gender

dysphoria when the experience of dysphoria is marked and sustained over time, the

adolescent demonstrates emotional and cognitive maturity required to provide and

informed consent/assent for treatment, other mental health concerns (if any) that may

interfere with diagnostic clarity and capacity to consent have been addressed, and

the adolescent has discussed reproductive options with their provider. SOC 8 also

highlights the importance of involving parent(s)/guardian(s) in the assessment and

treatment process for minors (Coleman, et al., 2022; Hembree, et al., 2017).

100. As with puberty-delaying medications, the risks and benefits of

hormone treatment are discussed with the patient and their families, prior to

initiation of gender affirming hormone therapy.

101. And, as with the use of puberty-delaying medications, treatment of

gender dysphoria with testosterone or estrogen is highly beneficial for both short-

term and long-term psychological functioning of adolescents with gender dysphoria

and withholding treatment from those who need it is harmful (e.g., Achille, et al.,

2020; Allen, et al., 2019; Chen, et al., 2023; de Lara, et al., 2020; de Vries, et al.,

2014; Grannis, et al., 2021; Green, et al., 2022; Kaltiala, et al., 2020; Kuper, et al.,

2020).

102. In my own practice, I have seen youth with severe gender dysphoria

who avoided all social contacts who were able to thrive with the initiation of gender

affirming hormones and feel confident with the changes seen as they developed

secondary sex characteristics aligned with their gender identity. I have seen my

patients start hormones and find themselves more able to build social and romantic

relationships, and begin to address underlying co-occurring psychiatric disorders.

103. For some older transgender adolescents, surgery may be provided prior

to age 18 if medically indicated (typically, chest surgery for transgender male

adolescents). Peer-reviewed research has also shown improvements in mental health

following gender-affirming chest surgery for transgender males with gender

dysphoria where medically indicated (Mehringer, et al., 2021; Olson-Kennedy, et

al., 2018).

104. As part of the treatment process for gender dysphoria, adolescent

patients provide assent to their care, while their parents or guardians provide

informed consent. In addition, a treating doctor will not offer gender-affirming

medical treatments unless they have concluded after weighing the risks and benefits

of care for the specific patient that treatment is appropriate. The risks and benefits

of care are discussed with the adolescent patient and their family. This process is no

different than the informed consent process for other medical treatments. However,

for gender-affirming medical care, there is the additional safeguard of the

recommended assessments by a mental health care professional, who must not only

be experienced in the assessment of gender dysphoria, but also in the assessment of

a patient's capacity to consent/assent to treatment and ability to understand the risks

and benefits of treatment. Indeed, SOC 8 notes that mental health professionals are

the best positioned practitioners to conduct these assessments for adolescents and

also recommends that a mental health professional address any mental health issues

that may interfere with a patient's ability to consent prior to the initiation of gender-

affirming care.

105. Dr. Levine and Dr Kaliebe fail to discuss many of the studies

documenting the benefits of puberty-delaying medication and gender-affirming

hormone therapy (Chen, et al., 2023; de Vries, 2023). When viewed as a

comprehensive body of research, the weight of the evidence and the experience of

clinicians as well as from the experience of patients has demonstrated that puberty-

delaying medication and hormones have been associated with a variety of mental

health benefits across different contexts (Chen, et al., 2023).

106. Dr. Levine and Dr. Kaliebe also criticize the quality of evidence

supporting treatment of gender dysphoria. (See, e.g., Levine Report, at ¶¶136-141;

Kaliebe Report, at 45-70). But treatments for gender dysphoria have the same or

similar level of evidentiary support as many other well-established treatment

protocols in psychiatry—and other disciplines of medicine. The evidentiary basis for

those treatment protocols is developed, and regularly updated, using a combination

of peer-reviewed research and the extensive clinical experience of providers who

regularly treat patients with that condition. Those treatment protocols are considered

the standard of care and are safe and effective for the conditions they are intended

to treat.

107. Dr. Levine also suggests that the lack of FDA approval of gender-

affirming medical treatments for these specific uses indicates that the treatments are

not supported by evidence of safety. (See, e.g., Levine Repport, ¶179). But off-label

use of medication is common in medicine, especially treatments for children and

adolescents. For example, in children, Zoloft is FDA approved to treat Obsessive-

Compulsive Disorder, but is also regularly used to treat depression and anxiety, such

that the use of Zoloft is considered the standard of care for children who require

medication to treat those conditions despite the lack of FDA approval for those

indications.

108. In their reports, Dr. Levine and Dr. Kaliebe present a distorted picture

of the gender affirming model of care where they imply that gender-affirming care

requires the unquestioned and automatic affirmation of an adolescent's desires. But

gender-affirming medical care such as GAH is only provided to an adolescent after

working with the adolescent and their parents/guardians, who are the ones who

provide the informed consent. Indeed, in my practice, I have had patients with

unrealistic expectations of the impact of testosterone or estrogen including on a

belief that initiation of gender affirming medical care would eradicate any co-

occurring psychiatric disorders despite many of these being chronic and predating

any symptoms of gender dysphoria. But in accordance with SOC 8 and Endocrine

Society Guidelines, the gender-affirming model of care requires that these patients

be provided with additional psychotherapy and psychoeducation to determine the

appropriateness of moving forward, and for some of these youth a delay in initiation

of hormones, or even potentially a recommendation to not pursue hormones, is

aligned with the gender affirming model of care.

40

EXPERT REBUTTAL REPORT OF DR. ARON C. JANSSEN *Dekker v. Weida*, No. 4:22-cv-00325-RH-MAF (N.D. Fla.)

H. Assessment and Treatment of Gender Dysphoria in Adults

109. In the DSM-5, the diagnostic criteria for Gender Dysphoria are shared

by adolescents and adults. The assessment and treatment of a gender dysphoric

adolescent is very similar to the assessment of the gender dysphoric adult.

110. As with any condition that typically presents with symptoms in

childhood or adolescence, collateral information from caregivers, partners,

employers, etc. is often useful in informing the initial diagnostic assessment. For

children and adolescents, the legal structures of consent and assent as well as best

practice and ethics of care require parental involvement in ongoing mental health

care, and standard practice is to gather history of the child from the parent and

guardian. For adults, the individual patient can make decisions about whom they

want involved in their care. That said, the assessment process of gathering a detailed

history and developing a biopsychosocial assessment takes the same factors into

account as one does with adolescents. And similar to adolescents, the risks, benefits

and alternatives to social transition, hormonal care and surgical options are weighed

in collaboration with the patient prior to making any recommendations. The

evidence supporting this process of assessment and care is documented in the

plaintiffs' experts' reports.

111. Despite that the Challenged Exclusion impacts the ability of both

adolescent and adult Medicaid beneficiaries to get coverage, and therefore get

access, to medical treatment for gender dysphoria, neither Drs. Levine nor Kaliebe address the impact of losing access to medical care for transgender adults in the state

of Florida. This same flaw characterizes all of the defendants' designated experts'

reports, as well as the GAPMS Memo itself.

112. Their reports focus primarily on pre-pubertal youth, which are not

subject to this ban, and seek to call into question practices in assessing and treating

transgender adolescents. This report seeks to rebut their mischaracterization of the

current standard of care for transgender adolescents as well as the

mischaracterization of the current standard of care for transgender adults. However,

neither expert in their report sought to undermine the evidence base for the treatment

of transgender adults and Dr. Levine even acknowledges the benefit of hormonal

and surgical care for some adults.

I. Additional Responses to Defendants' Designated Experts

113. In his report, Dr. Kaliebe states that the Chen et al. study did not address

the suicides in the study population and that "the most research shows a much higher

than expected rate of suicide in the condition of affirmative hormone treatment."

(Kaliebe Repport, at ¶70). This is not true. For one, the Chen et al. study looked at

the study population at baseline (pre-intervention), which shows that 66% endorsed

lifetime suicidal ideation; 29% endorsed lifetime suicidal ideation with a plan, and

a full 25% had reported having already had at least one suicide attempt prior to

engaging in care. This is not much different from the suicide completion rate in the Ghent clinic (5/235) compared to the NIH 4 site (2/315). For another, Dr. Kaliebe compares the study population in Chen et al. to apparent suicides of transgender youth purportedly associated with the Gender Identity Development Service (GIDS) in the United Kingdom. For these numbers, Dr. Kaliebe cites to a letter to the editor from a sociologist, not a peer-reviewed study or a letter from someone experienced in this care. But two of the GIDS youth never saw a doctor for gender-affirming care, and there is no evidence the two others were receiving care. What is more, even the letter to the editor Dr. Kaliebe cites states: "One final caveat is that these data shed no light on the question of whether counseling or endocrinological interventions—gonadotropin-releasing hormone agonist or cross-sex hormones—affect the risk of suicide." (Biggs, 2022).

114. Defendants' designated experts, including several who are not mental health professionals, continue to misconstrue the practice of psychiatry and misunderstand what occurs in a mental health assessment. They indicate that mental health clinicians believe without scrutiny what a patient is telling them on face value. In fact, mental health professionals are trained to assess not just the words being said, but also to recognize behaviors, gather collateral data from other informants, and assess the meaning of the inherent disparities between these various data points to help understand the patient's experience. These assessments require training and

skill which the non-mental health providers lack. As an example, it is not uncommon for a patient to deny suicidal intent despite having clear risk factors – this denial occurs even after some have been discovered post-suicide attempt. To argue that highly trained clinicians simply believe everything a patient says is a farce. Furthermore, many of the defendants' experts attempt to invalidate Gender Dysphoria, as well as nearly all psychiatric diagnoses because these diagnoses rely on a patient's description of their symptoms to make the diagnosis. Every mental condition, and many physical conditions, rely on the patient's self-expressed disclosure of phenomenology. Do migraines not exist because they require patient self-report? Is depression not a cause of disability unless there is a blood test to diagnose it? Did auto-immune encephalitis not exist as a phenomenon until the antibody test was developed? Mental health providers, as well as all physicians rely on patient reports of symptoms and an exercise of independent judgment based on training and experience to make a diagnosis.

115. Dr. Kaliebe criticizes AACAP for purportedly being inconsistent about the capacity of minors, suggesting there is a discrepancy between their arguments protecting adjudicated youth vis-à-vis the ability of transgender youth to obtain care. But this criticism has no basis and is more indicative of Dr. Kaliebe's lack of experience and familiarity with this field. In its amicus brief, AACAP argued the U.S. Supreme Court should have taken adolescents' mental capacity into account

when evaluating the question of whether adjudicated youth should be sentenced to

life without the possibility of parole. Not only is the context of gender-affirming

medical care entirely inapposite, but in such context, adolescents do not make

decisions on their own. In order to access gender-affirming medical care, the

adolescents work in conjunction with their parents/legal guardians and their doctors.

And while adolescents provide assent to care, it is their parents/legal guardians who

provide consent.

116. There appears to be a consistent lack of understanding of the consent

process for pediatric medical care among the defendants' designated experts. This is

most starkly demonstrated in Dr. Hruz's report. In his report, he highlights many

potential reasons why adolescents may be unable to provide consent to gender

affirming care. However, he neglects to understand that minors do not consent to

gender affirming care. Parents/legal caregivers and at time the state maintain the

capacity to consent on behalf of the adolescent, who depending on their age may

provide assent. While his arguments are spurious, they are also irrelevant to the

matter at hand.

117. Furthermore, there are also misstatements about the impact of

psychiatric diagnoses on the capacity to consent. In Dr. Hruz's report, he notes

"individuals with transgender identity who also have clinical depression or other

serious psychiatric comorbidity may have limited capacity to objectively weigh

proposed clinical interventions with potentially irreversible consequences and would

therefore fail to meet psychological abilities criteria." (Hruz Report, at ¶ 103). His

reference justifying this sentence is an ethics analysis of participation in clinical

research not in clinical care, and makes no reference to "psychological abilities

criteria," which may sound official but has no bearing on evidence-based

assessments of capacity to consent. Dr. Hruz further mischaracterizes Helmchen's

paper which speaks specifically about excluding patients with "suicidal intentions"

which is a separate phenomenology than clinical depression.

118. Similarly, Dr. Lappert reports "as is known by all surgeons, it is

considered imprudent to obtain informed consent from patients suffering from

psychological conditions that provoke the patient to acts of self-harm, or to suicidal

ideation." (Lappert Report, at ¶69). This uncited assertion is drawn from ignorance

about the capacity to consent to care for psychiatric patients. First, capacity to

consent is specific to the intervention at hand. While a patient with suicidal ideation

may lack capacity to end life-saving medical care, they may still retain capacity to

consent to an appendectomy. To assume that all patients with psychiatric illness lack

capacity to consent across all contexts is both unfounded and unethical.

119. Even in the context of clinical research, when the question of retention

of capacity is actually studied as opposed to assumed it is of concern, individuals

with both severe depression and schizophrenia demonstrate relatively high-decision

making capacity as measured by the MacArthur Competence Assessment Tool-

Clinical Research (Cohen, et al., 2004).

120. Dr. Kaliebe makes an assertion that medical academies are

delegitimizing and politicizing care by convening expert committees to advise the

organization on a topic. But this is well within the norms of academic medicine and

speaks to a wish to be informed by experts in the field; it is not evidence of

malfeasance. Speaking from personal experience as a member of several committees

on transgender health, professional disagreements and debates about approaches,

practices and priorities for care and research are commonplace, and dissenting

opinions are welcomed, particularly when informed by their own expertise and a fair

review of the literature.

121. Dr. Laidlaw makes many of the same mistakes about consent as the

other experts, namely mistaking that children consent to gender affirming medical

and surgical care. But he goes further and notes that in his opinion, even parents are

unable to provide consent because the full accounting of the potential risks is,

according to him, unknown. If Dr. Laidlaw's rubric were to be applied to the rest of

medicine, medicine would never evolve. There are inherent unknown risks to every

intervention, and it is the role of the provider to incorporate what is known and what

is not known about these risks into a discussion about informed assent and informed

consent. Moreover, the fact that we do not know everything about an intervention

does not make that intervention experimental. In medicine and in science, every day

we discover something and with the advent of new techniques or investigative tools

we are able to learn new information about the effects of well-established and

longstanding medical interventions. None of this renders a medical intervention to

be experimental.

122. Additionally, Dr. Laidlaw spends much of his report opining on the

appropriateness of the psychiatric care of the patients involved in this case. However,

Dr. Laidlaw is not a psychiatrist and has no authority to comment on the psychiatric

care of either patient. It is unethical for him to do so.

J. Prohibiting Access to Gender-Affirming Care Harms Transgender

People

123. Defendants' experts completely ignore the harms associated with

prohibiting access to gender-affirming care to adolescents and adults with gender

dysphoria for whom it is necessary and appropriate. They also ignore the harmful

effects of governmental like the Challenged Exclusion adopted by Defendants.

124. The overarching goal of treatment for gender dysphoria is to eliminate

clinically significant distress. For some, this is achieved by aligning an individual

patient's body and presentation with their internal sense of self. The denial of

medically indicated care to transgender adolescents and adults not only frustrates

this goal and results in the prolonging of their gender dysphoria, but also causes

additional distress and poses other health risks, such as depression, trauma, self-

harm, and suicidality.

125. Defendants and their designated experts not only ignore the volumes of

data showing the efficacy of gender-affirming medical care, but they also cannot

deny that there are transgender adolescents that persist into transgender adults and

who benefit from this care. But notwithstanding this latter undeniable fact neither

Defendants nor their designated experts are interested in a nuanced discussion about

prevalence, process, or technique, instead they advocate for a complete bar to the

coverage of this safe, efficacious, and medically necessary care for all transgender

adolescents and adults.

126. Lack of access to gender-affirming care therefore directly contributes

to poorer mental health outcomes for transgender people (Owen-Smith, et al., 2018).

127. It is also well documented that experiencing discrimination has

negative impacts on people's mental health and wellbeing. For example, a 2019

study found that experiencing discrimination in health care settings posed a unique

risk factor for heightened suicidality among transgender individuals, a population

already at heightened risk compared with the general population (Herman, et al.,

2019). And of note, the 2022 National Survey on LGBTQ Youth Mental Health

found that LGBTQ youth who had experienced discrimination based on sexual

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orientation or gender identity had attempted suicide in the past year at nearly three

times the rate as those who had not (19% vs. 7%) (The Trevor Project, 2022).

128. In addition, the 2022 National Survey on LGBTQ Youth Mental Health

found that 93% of transgender and nonbinary youth said that they have worried about

transgender people being denied access to gender-affirming medical care due to state

or local laws (The Trevor Project, 2022).

129. Research has shown that the mere introduction, debate, and adoption of

discriminatory laws and policies like the Challenged Exclusion negatively affects

the mental health of transgender youth. A prospective study with sexual minority

populations found that living in states with discriminatory policies was associated

with a statistically significant increase in the number of psychiatric disorder

diagnoses (Hatzenbuehler, et al., 2010). Other studies "shown that restrictive laws

and policies are related to destructive health behaviors on the part of transgender

individuals" (Cunningham, et al., 2022; Du Bois, et al., 2018).

130. Recent studies show the negative toll that anti-LGBTQ measures, like

the Challenged Exclusion, and debates surrounding them have had on the mental

health of transgender youth. For example, in a survey of youth in November 2022,

86% of transgender and nonbinary youth said that the debates about anti-transgender

bills had negatively impacted their mental health (Movement Advancement Project,

2023; The Trevor Project and Morning Consult, 2023). And a study from 2022,

though with limitations, showed that the passage of anti-transgender bills is linked

with Internet searches related to depression and suicide (Cunningham, et al., 2022).

131. Perhaps, more poignantly, those of us with clinical experience hear

from our patients about how it feels to be targeted with this kind of legislation. As

two of my transgender patients expressed to me within the past few weeks, "why

does everyone hate me just for existing?" and "it's a hard time to be transgender

right now."

CONCLUSION

132. By denying coverage and therefore access to necessary, safe, and

effective medical care as treatment for gender dysphoria, the Challenged Exclusion

endangers the mental health and well-being of transgender Medicaid beneficiaries

in Florida.

133. Defendants and their designated experts, who for the most part have no

experience in transgender health, not only ignore the robust evidence for the

potential harm faced by transgender individuals when barred access to medically

necessary gender-affirming care, but they also mischaracterize, misapprehend, and

even ignore the robust body of evidence showing that gender-affirming medical care

is safe, effective, and not experimental or investigational.

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

Executed this 9th day of March 2023.

Aron Janssen, M.D.

Exhibit A Curriculum Vitae

Curriculum Vitae

Aron Janssen, M.D. 312-227-7783 aronjans@gmail.com

Personal Data

Citizenship **USA**

Academic Appointments

2011-2017	Clinical Assistant Professor of Child and Adolescent Psychiatry
2011-2019	Founder & Clinical Director, NYU Gender and Sexuality Service
	Director, LGBT Mental Health Elective, NYULMC
2015-2019	Co-Director, NYU Pediatric Consultation Liaison Service
	New York University Department of Child and Adolescent Psychiatry
2017-present	Clinical Associate Professor of Child and Adolescent Psychiatry
2019-present	Vice Chair, Pritzker Department of Psychiatry and Behavioral Health
	Ann and Robert H. Lurie Children's Hospital of Chicago
2020-present	Medical Director, Outpatient Psychiatric Services
-	Ann and Robert H. Lurie Children's Hospital of Chicago

Education

Year	Degree	Field	Institution
6/97	Diploma		Liberty High School
5/01	B.A.	Biochemistry	University of Colorado
5/06	M.D.	Medicine	University of Colorado

Postdoctoral Training

2006-2009	Psychiatry Residency	Ze'ev Levin, M.D.	NYU Department of Psychiatry
2009-2011	Child and Adolescent Ps	sychiatry Fellowship –	Fellow and Clinical Instructor

Jess Shatkin, M.D. NYU Dept of Child/Adolescent Psychiatry

Licensure and Certification

2007-2018	New York State Medical License
2017-present	Illinois Medical License
2011-present	Certification in Adult Psychiatry, American Board of Psychiatry and Neurology
2013-present	Certification in Child and Adolescent Psychiatry, ABPN

Academic Appointments

2009-2011	Clinical Instructor, NYU Department of Child and Adolescent Psychiatry
2011-2017	Clinical Asst Professor, NYU Dept of Child and Adolescent Psychiatry
2017-2019	Clinical Assoc Professor, NYU Dept of Child and Adolescent Psychiatry
2011-2019	Clinical Director, NYU Gender and Sexuality Service
2015-2019	Co-Director, NYU Pediatric Consultation-Liaison Service
2019-present	Associate Professor of Child and Adolescent Psychiatry, Northwestern University
2019-present	Vice Chair of Clinical Affairs, Pritzker Department of Psychiatry and Behavioral
•	Health Lurie Children's Hospital of Chicago

Health, Lurie Children's Hospital of Chicago

Major Committee Assignments

International, National and	Regional
2021-present	Sexual Orientation and Gender Identity Committee, Chair, AACAP
2019-present	WPATH Standards of Care Revision Committee, Children
2019-present	WPATH Standards of Care Revision Committee, Adult Mental Health
2015-2019	Department of Child Psychiatry Diversity Ambassador
2013-2017	Sexual Orientation and Gender Identity Committee Member, AACAP
2013-2021	Founder and Director, Gender Variant Youth and Family Network
2012-2019 2012-present	Association of Gay and Lesbian Psychiatrists, Transgender Health
2012-present	Committee
2012-2019	NYULMC, Chair LGBTQ Advisory Council
2012-2019	NYULMC, Child Abuse and Protection Committee
2013-2015	NYULMC, Pediatric Palliative Care Team
2003-2004	American Association of Medical Colleges (AAMC), Medical Education
	Delegate
2004-2006	AAMC, Western Regional Chair
Psychiatry Residency	
2006-2009	Resident Member, Education Committee
2007-2008	Resident Member, Veterans Affairs (VA) Committee
Medical School	
2002-2006	Chair, Diversity Curriculum Development Committee
2002-2006	AAMC, Student Representative
2003-2004	American Medical Student Assoc. (AMSA) World AIDS Day Coordinator
2003-2004	AMSA, Primary Care Week Coordinator
2004-2006	Chair, Humanism in Medicine Committee
Memberships Offices and	l Committee Assignments in Professional Societies
2006-present	American Psychiatric Association (APA)
2009-present	American Academy of Child and Adolescent Psychiatry (AACAP)
2011-present	World Professional Association for Transgender Health (WPATH)
2011-2019	Director, Gender Variant Youth and Family Network, NYC
2013-2019	Chair, NYU Langone Medical Center LGBTQ Council
Editorial Positions	
2016-2018	Clinical Assistant Editor, Transgender Health
2014-present	Ad Hoc Reviewer, LGBT Health.

2016-2018	Clinical Assistant Editor, Transgender Health
2014-present	Ad Hoc Reviewer, LGBT Health.
2016-present	Ad Hoc Reviewer, JAACAP
2018-present	Associate Editor, Transgender Health
2020-present	Ad Hoc Reviewer, <i>Pediatrics</i>

Principal Clinical and Hospital Service Responsibilities

1	
2011-2019	Staff Psychiatrist, Pediatric Consultation Liaison Service
2011-2019	Faculty Physician, NYU Child Study Center
2011-2019	Founder and Clinical Director, NYU Gender & Sexuality Service
2015-2019	Co-Director, Pediatric Consultation Liaison Service
2019-present	Vice Chair, Pritzker Dept of Psychiatry and Behavioral Health
2019-present	Chief Psychiatrist, Gender Development Program

2020-present Medical Director, Outpatient Psychiatry Services

Relevant Program Development

Gender and Sexuality Service

- -founded by Aron Janssen in 2011, who continues to direct the service
- -first mental health service dedicated to transgender youth in NYC
- -served over 200 families in consultation, with 2-3 referrals to the gender clinic per week
- -trained over 500 mental health practitioners in transgender mental health 1 or 2 full day trainings in partnership with the Ackerman Institute's Gender and Family Project (GFP) and with WPATH Global Educational Initiative (GEI)
- -New hires in Adolescent Medicine, Psychology, Plastic Surgery, Urology, Gynecology, Endocrinology, Social Work, Department of Population Health with focus on transgender care has led to expansion of available services for transgender youth at NYULMC in partnership with the Gender and Sexuality Service
- -development of partnerships with Ackerman Institute, Callen-Lorde Health Center both institutions have been granted access to our IRB and have agreed to develop shared research and clinical priorities with the Gender and Sexuality Service.
- -multiple IRB research projects underway, including in partnership with national and international clinics
- -model has been internationally recognized

Clinical Specialties/Interests

Gender and Sexual Identity Development

Co-Occurring Mental Health Disorders in Transgender children, adolescents and adults Pediatric Consultation/Liaison Psychiatry

Psychotherapy

-Gender Affirmative Therapy, Supportive Psychotherapy, CBT, MI

Teaching Experience

- 2002-2006 Course Developer and Instructor, LGBT Health (University of Colorado School of Medicine
- 2011-2019 Instructor, Cultural Competency in Child Psychiatry (NYU Department of Child and Adolescent Psychiatry) 4 hours per year
- 2011-2019 Course Director, Instructor "Sex Matters: Identity, Behavior and Development" 100 hours per year
- 2011-2019 Course Director, LGBT Mental Health Elective (NYU Department of Psychiatry) 50 hours of direct supervision/instruction per year
- 2011-2019 Course Director, Transgender Mental Health (NYU Department of Child and Adolescent Psychiatry course to begin in Spring 2018.
- 2015-2019 Instructor, Gender & Health Selective (NYU School of Medicine) 4 hours per year.

Academic Assignments/Course Development

New York University Department of Child and Adolescent Mental Health Studies

-Teacher and Course Director: "Sex Matters: Identity, Behavior and Development."

A full semester 4 credit course, taught to approximately 50 student per year since 2011, with several students now in graduate school studying sexual and gender

identity development as a result of my mentorship.

NYU Department of Child and Adolescent Psychiatry

-Instructor: Cultural Competency in Child and Adolescent Psychiatry

-Director: LGBTQ Mental Health Elective

World Professional Association of Transgender Health

-Official Trainer: Global Education Initiative – one of two child psychiatrists charged with training providers in care of transgender youth and adults.

Peer Reviewed Publications

- 1. Janssen, A., Erickson-Schroth, L., "A New Generation of Gender: Learning Patience from our Gender Non-Conforming Patients," Journal of the American Academy of Child and Adolescent Psychiatry, Volume 52, Issue 10, pp. 995-997, October, 2013.
- 2. Janssen, A., et. al. "Theory of Mind and the Intolerance of Ambiguity: Two Case Studies of Transgender Individuals with High-Functioning Autism Spectrum
- 3. Janssen A, Huang H, and Duncan C., Transgender Health. February 2016, "Gender Variance Among Youth with Autism: A Retrospective Chart Review." 1(1): 63-68. doi:10.1089/trgh.2015.0007.
- Goedel WC, Reisner SL, Janssen AC, Poteat TC, Regan SD, Kreski NT, Confident G, Duncan DT. (2017). Acceptability and Feasibility of Using a Novel Geospatial Method to Measure Neighborhood Contexts and Mobility Among Transgender Women in New York City. Transgender Health. July 2017, 2(1): 96-106.
- 5. Janssen A., et. al., "Gender Variance Among Youth with ADHD: A Retrospective Chart Review," in review
- 6. Janssen A., et. al., "Initial Clinical Guidelines for Co-Occurring Autism Spectrum Disorder and Gender Dysphoria or Incongruence in Adolescents," Journal of Child & Adolescent Psychology, 105-115, January 2018.
- 7. Janssen A., et. al., "A Review of Evidence Based Treatments for Transgender Youth Diagnosed with Social Anxiety Disorder," Transgender Health, 3:1, 27–33, DOI: 10.1089/trgh.2017.0037.
- 8. Janssen A., et. al., "The Complexities of Treatment Planning for Transgender Youth with Co-Occurring Severe Mental Illness: A Literature Review and Case Study," Archives of Sexual Behavior, 2019. # 3563492
- 9. Kimberly LL, Folkers KM, Friesen P, Sultan D, Quinn GP, Bateman-House A, Parent B, Konnoth C, Janssen A, Shah LD, Bluebond-Langner R, Salas-Humara C., "Ethical Issues in Gender-Affirming Care for Youth," Pediatrics, 2018 Dec;142(6).
- 10. Strang JF, Janssen A, Tishelman A, Leibowitz SF, Kenworthy L, McGuire JK, Edwards-Leeper L, Mazefsky CA, Rofey D, Bascom J, Caplan R, Gomez-Lobo V, Berg D, Zaks Z, Wallace GL, Wimms H, Pine-Twaddell E, Shumer D, Register-Brown K, Sadikova E, Anthony LG., "Revisiting the Link: Evidence of the Rates of Autism in Studies of Gender Diverse Individuals," Journal of the American Academy of Child and Adolescent Psychiatry, 2018 Nov;57(11):885-887.
- 11. Goedel William C, Regan Seann D, Chaix Basile, Radix Asa, Reisner Sari L, Janssen Aron C, Duncan Dustin T, "Using global positioning system methods to explore mobility patterns and exposure to high HIV prevalence neighbourhoods among transgender women in New York City," Geospatial Health, 2019 Jan; 14(2): 351-356.
- 12. Madora, M., Janssen, A., Junewicz, A., "Seizure-like episodes, but is it really epilepsy?" Current Psychiatry. 2019 Aug; 18(8): 42-47.

- 13. Janssen, A., Busa, S., Wernick, J., "The Complexities of Treatment Planning for Transgender Youth with Co-Occurring Severe Mental Illness: A Literature Review and Case Study," Archives of Sexual Behavior. 2019 Oct; 48(7): 2003-2009.
- 14. Wernick Jeremy A, Busa Samantha, Matouk Kareen, Nicholson Joey, Janssen Aron, "A Systematic Review of the Psychological Benefits of Gender-Affirming Surgery," Urol Clin North Am. 2019 Nov; 46(4): 475-486.
- 15. Strang, J.F., Knauss, M., van der Miesen, A.I.R., McGuire, J., Kenworthy, L., Caplan, R., Freeman, A.J., Sadikova, E., Zacks, Z., Pervez, N., Balleur, A., Rowlands, D.W., Sibarium, E., McCool, M.A., Ehrbar, R.D., Wyss, S.E., Wimms, H., Tobing, J., Thomas, J., Austen, J., Pine, E., Willing, L., Griffin, A.D., Janssen, A., Gomez-Lobo, A., Brandt, A., Morgan, C., Meagher, H., Gohari, D., Kirby, L., Russell, L., Powers, M., & Anthony, L.G., (in press 2020). A clinical program for transgender and gender-diverse autistic/neurodiverse adolescents developed through community-based participatory design. *Journal of Clinical Child and Adolescent Psychology*. DOI 10.1080/15374416.2020.1731817
- 16. Coyne, C. A., Poquiz, J. L., Janssen, A., & Chen, D. Evidence-based psychological practice for transgender and non-binary youth: Defining the need, framework for treatment adaptation, and future directions. Evidence-based Practice in Child and Adolescent Mental Health.
- 17. Janssen, A., Voss, R.. Policies sanctioning discrimination against transgender patients flout scientific evidence and threaten health and safety. Transgender Health.
- 18. Dubin, S., Cook, T., Liss, A., Doty, G., Moore, K., Janssen, A. (In press 2020). Comparing Electronic Health Records Domains' Utility to Identify Transgender Patients. Transgender Health, DOI 10.1089/trgh.2020.0069
- 19. Busa, S., Wernick, J.,...Janssen, A. A Descriptive Case Study of a Cognitive Behavioral Therapy Group Intervention Adaptation for Transgender Youth With Social Anxiety Disorder, Behavioral Therapy, April, 2022
- 20. Ramsden SC, Pergjika A, Janssen AC, Mudahar S, Fawcett A, Walkup JT, Hoffmann JA. A Systematic Review of the Effectiveness and Safety of Droperidol for Pediatric Agitation in Acute Care Settings. Acad Emerg Med. May, 2022.
- 21. Janssen, A., Walkup, J., More is Not Always Better, When Different is Required, J Am Acad Child Adolesc Psychiatry. June, 2022 doi: 10.1016/j.jaac.2022.05.006.
- 22. Wanta, J., Gianakakos, G., Belfort, A., Janssen, A., Considering "Spheres of Influence" in the Care of LGBTQ Youth, CAP Clinics of North America. Volume 31, Issue 4, p649-664, October 2022 doi: 10.1016/j.chc.2022.05.008
- 23. Coleman, E., Radix, A.... Janssen, A., et. al., Standards of Care for the Health of Transgender and Gender Diverse People, Version 8. International Journal of Transgender Health, 23:sup1, S1-2259, September 2022. doiL 10.1080/26895269.2022.2100644
- 24. Westley, L., Richey, K.,.. Janssen, A., Using Hospital Incident Command Systems to Respond to the Pediatric Mental and Behavioral Health Crisis of the COVID-19 Pandemic, Journal of Nursing Administration, Feb 2023.

Published Abstracts

1. Thrun, M., Janssen A., et. al. "Frequency of Patronage and Choice of Sexual Partners may Impact Likelihood of HIV Transmission in Bathhouses," original research poster

- presented at the 2007 Conference on Retroviruses and Opportunistic Infections, February, 2007.
- 2. Janssen, A., "Advocating for the mental health of Lesbian, Gay, Bisexual and Transgender (LGBT) population: The Role of Psychiatric Organizations." Workshop for the American Psychiatric Association Institute of Psychiatric Services Annual Meeting, October 2012.
- 3. Janssen, A., "Gender Variance in Childhood and Adolescents: Training the Next Generation of Psychiatrists," 23rd Symposium of the World Professional Association for Transgender Health, Amsterdam, The Netherlands, February 2014.
- 4. Janssen, A., "When Gender and Psychiatric Acuity/Comorbidities Overlap: Addressing Complex Issues for Gender Dysphoric and Non-Conforming Youth," AACAP Annual Meeting, October 2014.
- 5. Janssen, A., "Patient Experiences as Drivers of Change: A unique model for reducing transgender health disparities as an academic medical center," Philadelphia Transgender Health Conference, June 2016.
- 6. Janssen, A., "How much is too much? Assessments & the Affirmative Approach to TGNC Youth," 24th Symposium of the World Professional Association for Transgender Health, Amsterdam, The Netherlands, June 2016.
- 7. Janssen, A., "Trauma, Complex Cases and the Role of Psychotherapy," 24th Symposium of the World Professional Association for Transgender Health, Amsterdam, The Netherlands, June 2016.
- 8. Janssen, A., "Gender Variance Among Youth with Autism: A Retrospective Chart Review," Research Poster, 24th Symposium of the World Professional Association for Transgender Health, Amsterdam, The Netherlands, June 2016.
- 9. Janssen, A., "Gender Fluidity and Gender Identity Development," Center for Disease Control STD Prevention Conference, September 2016.
- 10. Janssen, A., "Transgender Identities Emerging During Adolescents' Struggles With Mental Health Problems," AACAP Annual Conference, October 2016.
- 11. Janssen, A., "How Much is Too Much? Assessments and the Affirmative Approach to Transgender and Gender Diverse Youth," US Professional Association for Transgender Health Inaugural Conference, Los Angeles, February 2017.
- 12. Janssen, A., "Trauma, Complex Cases and the Role of Psychotherapy," US Professional Association for Transgender Health Inaugural Conference, Los Angeles, February 2017.
- 13. Sutter ME, Bowman-Curci M, Nahata L, Tishelman AC, Janssen AC, Salas-Humara C, Quinn GP. Sexual and reproductive health among transgender and gender-expansive AYA: Implications for quality of life and cancer prevention. Oral presentation at the Oncofertility Consortium Conference, Chicago, IL. November 14, 2017.
- 14. Janssen, A., Sidhu, S., Gwynette, M., Turban, J., Myint, M., Petersen, D., "It's Complicated: Tackling Gender Dysphoria in Youth with Autism Spectrum Disorders from the Bible Belt to New York City," AACAP Annual Conference, October 2017.
- 15. May 2018: "A Primer in Working with Parents of Transgender Youth," APA Annual Meeting.
- 16. October 2018: "Gender Dysphoria Across Development" Institute for AACAP Annual Conference.

- 17. November 2018: "Gender Variance Among Youth with Autism," World Professional Association for Transgender Health Biannual Conference.
- 18. March 2019: "Gender Trajectories in Child and Adolescent Development and Identity," Austin Riggs Grand Rounds.
- 19. Janssen, A., et. al., "Ethical Principles in Gender Affirming Care," AACAP Annual Conference, October 2019.
- 20. Janssen, A., "Gender Diversity and Gender Dysphoria in Youth," EPATH Conference, April 2019
- 21. Englander, E., Janssen A., et. al., "The Good, The Bad, and The Risky: Sexual Behaviors Online," AACAP Annual Conference, October 2020
- 22. Englander, E., Janssen, A., et. al., "Love in Quarantine," AACAP Annual Conference, October 2021
- 23. Janssen, A., Leibowitz, S., et. al., "The Evidence and Ethics for Transgender Youth Care: Updates on the International Standards of Care, 8th Edition," AACAP Annual Conference, October 2021
- 24. Turban, J., Janssen, A., et. al., "Transgender Youth: Understanding "Detransition," Nonlinear Gender Trajectories, and Dynamic Gender Identities," AACAP Annual Conference, October 2021
- 25. Hoffmann JA, Pergjika, A, Liu X, Janssen AC, Walkup JT, Alpern ER, Johnson EJ, Corboy JB. Standardizing and Optimizing Care for Pediatric Acute Agitation Management in the Emergency Department. Oral Abstract Presentation. Academic Pediatric Association Annual Conference on Advancing Quality Improvement Science for Children's Healthcare. New Orleans. Accepted for presentation on April 22, 2022.
- 26. Janssen, A., Malpas, J., Glaeser, E., "Family-Based Interventions with Transgender and Gender Nonbinary Youth," World Professional Association of Transgender Health 27th Scientific Symposium, September 2022.
- 27. Tishelman, A., Janssen A., et. al., WPATH Standards of Care "Child Chapter," World Professional Association of Transgender Health 27th Scientific Symposium, September 2022
- 28. Janssen, A., Leibowitz, S., et al, "The Evidence and Ethics for Transgender Youth Care: Updates on the New International Standards of Care, Eighth Edition. AACAP Annual Conference, October 2022.
- 29. Turban, J., Janssen, A., et al, "Transgender Youth: Evolving Gender Identities and "Detransition," AACAP Annual Conference, October 2022.

Books

1. Janssen, A., Leibowitz, S (editors), Affirmative Mental Health Care for Transgender and Gender Diverse Youth: A Clinical Casebook, Springer Publishing, 2018.

Book Chapters

- 1. Janssen, A., Shatkin, J., "Atypical and Adjunctive Agents," Pharmacotherapy for Child and Adolescent Psychiatric Disorders, 3rd Edition, Marcel Dekker, Inc, New York, 2012.
- 2. Janssen, A; Liaw, K: "Not by Convention: Working with People on the Sexual & Gender Continuum," book chapter in The Massachusetts General Hospital Textbook on Cultural Sensitivity and Diversity in Mental Health. Humana Press, New York, Editor R. Parekh, January 2014.

- 3. Janssen, A; Glaeser, E., Liaw, K: "Paving their own paths: What kids & teens can teach us about sexual and gender identity," book chapter in Cultural Sensitivity in Child and Adolescent Mental Health, MGH Psychiatry Academy Press, Editor R. Parekh, 2016
- 4. Janssen A., "Gender Identity," Textbook of Mental and Behavioral Disorders in Adolescence, February 2018.
- 5. Busa S., Wernick, J., & Janssen, A. (In Review) Gender Dysphoria in Childhood. Encyclopedia of Child and Adolescent Development. Wiley, 2018.
- 6. Janssen A., Busa S., "Gender Dysphoria in Childhood and Adolescence," Complex Disorders in Pediatric Psychiatry: A Clinician's Guide, Elsevier, Editors Driver D., Thomas, S., 2018.
- 7. Wernick J.A., Busa S.M., Janssen A., Liaw K.RL. "Not by Convention: Working with People on the Sexual and Gender Continuum." Book chapter in The Massachusetts General Hospital Textbook on Diversity and Cultural Sensitivity in Mental Health, editors Parekh R., Trinh NH. August, 2019.
- 8. Weis, R., Janssen, A., & Wernick, J. The implications of trauma for sexual and reproductive health in adolescence. In *Not Just a nightmare: Thinking beyond PTSD to help teens exposed to trauma.* 2019
- 9. Connors J., Irastorza, I., Janssen A., Kelly, B., "Child and Adolescent Medicine," The Equal Curriculum: The Student and Educator Guide to LGBTQ Health, editors Lehman J., et al. November 2019.
- 10. Janssen, A., et. al., "Gender and Sexual Diversity in Childhood and Adolescence," Dulcan's Textbook of Child and Adolescent Psychiatry, 3rd edition, editor Dulcan, M., (in press)
- 11. Busa S., Wernick J, Janssen, A., "Gender Dysphoria," The Encyclopedia of Child and Adolescent Development, DOI: 10.1002/9781119171492. Wiley, December 2020.

Invited Academic Seminars/Lectures

- 1. April 2006: "How to Talk to a Gay Medical Student" presented at the National AAMC Meeting.
- 2. March 2011: "Kindling Inspiration: Two Model Curricula for Expanding the Role of Residents as Educators" workshop presented at National AADPRT Meeting.
- 3. May 2011: Janssen, A., Shuster, A., "Sex Matters: Identity, Behavior and Development," Grand Rounds Presentation, NYU Department of Child and Adolescent Psychiatry.
- 4. March 2012: Janssen, A., Lothringer, L., "Gender Variance in Children and Adolescents," Grand Rounds Presentation, NYU Department of Child and Adolescent Psychiatry.
- 5. June 2012: Janssen, A., "Gender Variance in Childhood and Adolescence," Grand Rounds Presentation, Woodhull Department of Psychiatry
- 6. October 2012: "Advocating for the mental health of Lesbian, Gay, Bisexual and Transgender (LGBT) population: The Role of Psychiatric Organizations." Workshop for the American Psychiatric Association Institute of Psychiatric Services Annual Meeting.
- 7. March 2013: "Gender Variance in Childhood and Adolescence," Sexual Health Across the Lifespan: Practical Applications, Denver, CO.
- 8. October 18th, 2013: "Gender Variance in Childhood and Adolescence," Grand Rounds Presentation, NYU Department of Endocrinology.

- 9. October, 2014: GLMA Annual Conference: "Theory of Mind and Intolerance of Ambiguity: Two Case Studies of Transgender Individuals with High-Functioning ASD," Invited Presentation
- 10. October 2014: New York Transgender Health Conference: "Mental Health Assessment in Gender Variant Children," Invited Presentation.
- 11. November, 2014: Gender Spectrum East: "Affirmative Clinical Work with Gender-Expansive Children and Youth: Complex Situations."
- 12. October 2015: "Gender Dysphoria and Complex Psychiatric Co-Morbidity," LGBT Health Conference, Invited Speaker
- 13. October 2015: "Transgender Health Disparities: Challenges and Opportunities," Grand Rounds, Illinois Masonic Department of Medicine
- 14. November 2015: "Autism and Gender Variance," Gender Conference East, Invited Speaker
- 15. February 2016: "Working with Gender Variant Youth," New York State Office of Mental Health State Wide Grand Rounds, Invited Speaker
- 16. March, 2016: "Working with Gender Variant Youth," National Council for Behavioral Health Annual Meeting, Invited Speaker
- 17. March 2016: "Gender Variance Among Youth with Autism: A Retrospective Chart Review and Case Presentation," Working Group on Gender, Columbia University, Invited Speaker.
- 18. September, 2016: "Best Practices in Transgender Mental Health: Addressing Complex Issues for Gender Dysphoric and Non-Conforming Youth," DeWitt Wallace Institute for the History of Psychiatry, Weill Cornell.
- 19. October, 2016: "LGBTQ Youth Psychiatric Care," Midwest LGBTQ Health Symposim
- 20. October, 2016: "Gender Fluidity and Gender Identity Development," NYU Health Disparities Conference.
- 21. February, 2017: "Best Practices in Transgender Mental Health," Maimonides Grand Rounds
- 22. March, 2017: "Transgender Health: Challenges and Opportunities," Invited speaker, Center for Disease Control STD Prevention Science Series.
- 23. September 2017: "Autism and Gender Dysphoria," Grand Rounds, NYU Department of Neurology.
- 24. November 2017: "Consent and Assent in Transgender Adolescents," Gender Conference East.
- 25. November 2017: "Transgender Mental Health: Challenges and Opportunities," Grand Rounds, Lenox Hill Hospital.
- 26. April 2018: "Gender Trajectories in Childhood and Adolescent Development and Identity," Sex, Sexuality and Gender Conference, Harvard Medical School.
- 27. September 2019: "Social and Psychological Challenges of Gender Diverse Youth," Affirmative Mental Health Care for Gender Diverse Youth, University of Haifa.
- 28. October 2019: "Best Practices in Transgender Mental Health," Grand Rounds, Rush Department of Psychiatry.
- 29. February 2020: "The Overlap of Autism and Gender Dysphoria," Grand Rounds, Northwestern University Feinberg School of Medicine Department of Psychiatry
- 30. February 2020: "Gender Dysphoria and Autism," Grand Rounds, University of Illinois at Chicago Department of Psychiatry
- 31. September 2021: "Gender Diversity and Autism," Grand Rounds, Kaiser Permanente Department of Pediatrics

32. October 2021: Gender Dysphoria and Autism," Grand Rounds, Case Western Reserve University Department of Psychiatry.

Selected Invited Community Seminars/Lectures

- 1. April 2012: "Gender and Sexuality in Childhood and Adolescence," Commission on Race, Gender and Ethnicity, NYU Steinhardt Speakers Series.
- 2. February 2013: "Supporting Transgender Students in School," NYC Independent School LGBT Educators Panel, New York, NY.
- 3. June 2013: "LGBT Health," Presentation for Neuropsychology Department
- 4. August 2013: "Chronic Fatigue Syndrome: Etiology, Diagnosis and Management," invited presentation.
- 5. September 2013: Panelist, "LGBTQ Inclusive Sex Education."
- 6. April 2015: Transgender Children, BBC News, BBCTwo, invited expert
- 7. January 2016: Gender Dysphoria and Autism Ackerman Podcast http://ackerman.podbean.com/e/the-ackerman-podcast-22-gender-dysphoria-autism-with-aron-janssen-md/
- 8. February 2016: "Best Practices in Transgender Mental Health," APA District Branch Meeting, Invited Speaker.
- 9. May 2016: "Best Practices in Transgender Mental Health," Washington D.C., District Branch, APA, Invited Speaker
- 10. July 2016: "Transgender Youth," Union Square West
- 11. November 2017: "Understanding Gender: Raising Open, Accepting and Diverse Children," Heard in Rye, Conversations in Parenting.
- 12. January 2018: "The Emotional Life of Boys," Saint David's School Panel, Invited Speaker
- 13. June 2018: "Supporting Youth Engaged in Gender Affirming Care," NYU Child Study Center Workshop.
- 14. October 2018: "Medicine in Transition: Advances in Transgender Mental Health," NYCPS HIV Psychiatry and LGBT Committee Meeting.
- 15. October 2018: "Understanding Gender Fluidity in Kids," NYU Slope Pediatrics.
- 16. October, 2021: Issues of Ethical Importance: Health Care for Pediatric LGBTQ+ Patients, American Medical Association, Invited Talk

Major Research Interests

Gender and Sexual Identity Development Member, Research Consortium for Gender Identity Development Delirium: Assessment, Treatment and Management Suicide Prevention

Research Studies

Study Title Suicide Attempts Identified in a Children's Hospital Before and During COVID-19	IRB Study# 2021-4428	<u>Dates</u> 2/26/21-present
Lurie Children's Sex & Gender Development Program Clinical Measure Collection	2019-2898	2019-present

Adolescent Gender Identity Research Study (principal investigator) - unfunded	s15-00431	4/15-5/19
Co-Occurrence of Autism Spectrum Disorders and Gender Variance: Retrospective Chart Review (principal investigator) - unfunded	s14-01930	10/14-5/19
Expert Consensus on Social Transitioning Among Prepubertal Children Presenting with Transgender Identity and/or Gender Variance: A Delphi Procedure Study (principal investigator) - unfunded	s13-00576	3/16-5/19
Co-Occurrence of ADHD/Gender Dysphoria (principal investigator) - unfunded	s16-00001	1/16-5/19
PICU Early Mobility- unfunded	s16-02261	12/16-5/19
Metformin for Overweight and Obese Children and Adolescents with Bipolar Spectrum Disorders Treated with Second-Generation Antipsychotics – Funded by PCORI	s16-01571	8/16-5/19

Other

Grant Funding:

Zero Suicide Initiative, PI Aron Janssen, M.D. Awarded by Cardinal Health Foundation, 9/2020

Total amount: \$100,000

Catalyst Fund, PI Aron Janssen, M.D. Suicide Prevention in Pediatric Primary Care

Total amount: \$750,000

Selected Media Appearances:

Guest Expert on Gender Identity on Anderson, "When Your Husband Becomes Your Wife," Air Date February 8th, 2012

Guest Host, NYU About Our Kids on Sirius XM, 2011

NYU Doctor Radio: LGBT Health, September 2013

NYU Doctor Radio: LGBT Kids, November 2013

NYU Doctor Radio: LGBT Health, July 2014

NYU Doctor Radio: Gender Variance in Childhood, December 2014

BBC Two: Transgender Youth, April 2015

NYU Doctor Radio: Transgender Youth, June 2015

Fox-5 News: Trump's proposed military ban and Transgender Youth, July, 2017

Healthline.com: Mental Health Experts Call President's Tweets 'Devastating' for Trans Teens, July, 2017

Huffington Post: What the Military Ban Says to Our Transgender Youth: August, 2017

Metro: How to talk to your transgender kid about Trump, August 2017

NYU Doctor Radio: Transgender Youth, August 2017

Exhibit B Bibliography

BIBLIOGRAPHY

Achille, C., Taggart, T., Eaton, N. R., Osipoff, J., Tafuri, K., Lane, A., & Wilson, T. A. (2020). Longitudinal impact of gender-affirming endocrine intervention on the mental health and well-being of transgender youths: preliminary results. *International journal of pediatric endocrinology*, 2020, 8.

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.

American Academy of Child and Adolescent Psychiatry. (2018). Policy Statement: Conversion Therapy. Available at:

https://www.aacap.org/AACAP/Policy Statements/2018/Conversion Therapy.asp x.

American Medical Association and GLMA. (2022). Issue Brief: Sexual orientation and gender identity change efforts (so-called "conversion therapy"). Available at: https://www.ama-assn.org/system/files/conversion-therapy-issue-brief.pdf.

American Medical Association and GLMA. (2019). Issue Brief: Health insurance coverage for gender- affirming care of transgender patients. Available at: https://www.ama-assn.org/system/files/2019-03/transgender-coverage-issue-brief.pdf.

American Psychiatric Association. (2022). Diagnostic and statistical manual of mental disorders (5th ed., text rev.). Arlington, VA: American Psychiatric Publishing.

American Psychiatric Association. (2018). Position Statement on Conversion Therapy and LGBTQ Patients. Available at: https://www.psychiatry.org/getattachment/3d23f2f4-1497-4537-b4de-

fe32fe8761bf/Position-Conversion-Therapy.pdf.

American Psychiatric Association. (2013). Diagnostic and Statistical Manual of Mental Disorders (5th ed.). Arlington, VA: American Psychiatric Publishing.

American Psychological Association (2021). APA Resolution on Gender Identity Change Efforts. Available at: https://www.apa.org/about/policy/resolution-gender-identity-change-efforts.pdf.

American Psychological Association (2015). Guidelines for psychological practice with transgender and gender nonconforming people. *American Psychologist*, 70, 832-864.

Arboleda, V. A., Lee, H., Sánchez, F. J., Délot, E. C., Sandberg, D. E., Grody, W. W., Nelson, S. F., & Vilain, E. (2013). Targeted massively parallel sequencing provides comprehensive genetic diagnosis for patients with disorders of sex development. *Clinical genetics*, 83(1), 35–43.

Biggs M. (2022). Suicide by Clinic-Referred Transgender Adolescents in the United Kingdom. *Archives of sexual behavior*, 51(2), 685–690.

Chen D, Berona J, Chan YM, Ehrensaft D, Garofalo R, Hidalgo MA, Rosenthal SM, Tishelman AC, Olson-Kennedy J. (2023). Psychosocial Functioning in Transgender Youth after 2 Years of Hormones. *New England Journal of Medicine*, 2023 Jan 19;388(3):240-250.

Cohen, B. J., McGarvey, E. L., Pinkerton, R. C., & Kryzhanivska, L. (2004). Willingness and competence of depressed and schizophrenic inpatients to consent to research. *The journal of the American Academy of Psychiatry and the Law*, 32(2), 134–143.

Coleman, E., Radix, A. E., Bouman, W. P., Brown, G. R., de Vries, A. L. C., Deutsch, M. B., Ettner, R., Fraser, L., Goodman, M., Green, J., Hancock, A. B., Johnson, T. W., Karasic, D. H., Knudson, G. A., Leibowitz, S. F., Meyer-Bahlburg, H. F. L., Monstrey, S. J., Motmans, J., Nahata, L., Nieder, T. O., ... Arcelus, J. (2022). Standards of Care for the Health of Transgender and Gender Diverse People, Version 8. *International journal of transgender health*, *23*(Suppl 1), S1–S259.

Costa, R., Dunsford, M., Skagerberg, E., Holt, V., Carmichael, P., & Colizzi, M. (2015). Psychological Support, Puberty Suppression, and Psychosocial Functioning in Adolescents with Gender Dysphoria. *The journal of sexual medicine*, *12*(11), 2206–2214.

Costello, E. J., Mustillo, S., Erkanli, A., Keeler, G., & Angold, A. (2003). Prevalence and development of psychiatric disorders in childhood and adolescence. *Archives of general psychiatry*, 60(8), 837–844.

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