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

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

- 1. I have been retained by counsel for the Defendants as an expert witness in the above captioned litigation. On February 15, 2023, I submitted an expert report detailing my serious concerns about the safety, efficacy, and scientific validity of the controversial, unproven, and experimental treatment paradigm for the medical management of sex-gender identity discordance. My qualifications, publications, prior expert testimony, and compensation are discussed in that prior report.
- 2. I have read the declarations of Dr. Antommaria and Dr. Shumer, who are serving as witnesses for Plaintiffs. In these reports, Drs. Antommaria and Shumer make several assertions that are erroneous or highly misleading. This includes inaccurate or incomplete discussion of cited references, omission of key data, and demonstration of bias in the interpretation of published scientific literature in this controversial field of medicine. For several of the references cited in their reports, a summary of major study limitations and weaknesses was contained in my previously filed expert report. I provide here additional scientific evidence and discussion of key assertions made by the Plaintiffs' witnesses. This response is not exhaustive of all of my opinions. I reserve the right to supplement or amend this report based on any new future information that is provided to me.
- 3. The bases for my opinions expressed in this report are my review of the Antommaria and Shumer reports, my professional experience as a psychiatrist, and

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

Declaration of Dr. Shumer

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

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

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

- 5. Dr. Shumer's attempt to establish a biological basis for sex-discordant gender identity by citing literature on brain anatomy, exposure to sex hormones during development, and twin studies fails to acknowledge the limitations of this type of evidence. Each of the studies he cites to support his opinion are insufficient to establish his conclusions, and many lead to questions about alternate hypotheses. In considering this evidence, as with all of the published data in this field, it is essential to distinguish between influencing factors and determining factors. Indeed, the very argument that gender identity can be fluid points strongly against a conclusion of biological determinism.
- 6. There have been a number of published reports examining brain anatomy and function that have attempted to demonstrate the "born in the wrong body" hypothesis for sex-discordant identity. In my first declaration, I discussed in general the limitations of small sample sizes, wide overlap in measured parameters, and the known phenomenon of neuronal plasticity in objectively assessing these data. Given Dr. Shumer's assertions, it is necessary to consider in greater depth the studies he cites to support his conclusions.

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

- 7. The 2009 study by Luders³ compares brain MRI findings among 24 males who identify as women compared to 30 males who identify as men and 30 females who identity as women. The authors' main study result is an observation of "a significantly larger volume of regional gray matter in the right putamen [in males who identify as women] compared to men." Importantly, the authors themselves acknowledge that these data merely show an association, not a causal relationship between this finding and gender identity. They also acknowledge that there are multiple factors including psychosocial and environmental influences that could account for the differences observed.
- 8. The 2011 study by Rametti et al.⁴ similarly compared structural brain differences in 18 females who identified as men compared to 24 males who identified as men and 19 females who identified as women. In general, control males had higher connectivity in specific brain regions than control females. Their primary study finding was that white matter brain connectivity in several of the measured brain regions of female transgender subjects was higher than control females (i.e. closer to the values seen in males). A strength of this study is that it investigated

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

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

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

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

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

- The 2011 study by Savic et al.⁶ used magnetic resonance imaging 10. (MRI) to compare the brain structures of 24 males identifying as female to 48 "heterosexual males and females". The investigators confirmed previously reported structural differences in the brains of males versus females. Yet they observed that the structures of the transgender subjects aligned with sex not gender identity. While this study is also limited by its small sample size similar to other brain studies, the observed results contradict the hypothesis of Dr. Shumer regarding an established biological basis for sex-discordant gender identity. The authors specifically state that "contrary to the primary hypothesis, no sex-atypical features with signs of 'feminization' were detected in the transsexual group." They conclude: "The present study does not support the dogma that MtF-TR [male to female transsexuals] have atypical sex dimorphism in the brain but confirms the previously reported sex differences in structural volumes, gray, and WM [white matter] fractions."
- 11. The 2002 study by Chung et al.⁷ compares the size differences in an area of the brain previously shown to differ between males and females. Prior reports had shown that the size of this BST (bed nucleus of the stria terminalis) region in autopsy specimens from transgender subjects correlated with the lived

⁶ Savic I, Arver S. Sex dimorphism of the brain in male-to-female transsexuals. Cereb Cortex. 2011 Nov;21(11):2525-33. doi: 10.1093/cercor/bhr032.

⁷ Chung WC, De Vries GJ, Swaab DF. Sexual differentiation of the bed nucleus of the stria terminalis in humans may extend into adulthood. J Neurosci. 2002 Feb 1;22(3):1027-33. doi: 10.1523/JNEUROSCI.22-03-01027.2002.

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

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

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

- or discordance of gender identity disorder among 29 identical (monozygotic) and non-identical (dizygotic) twin pairs. The concordance rate among identical twins was 39%. This means this trait was discordant in nearly two-thirds (61%) of monozygotic twin pairs. While this supports a potential genetic *influence* of gender dysphoria, it clearly demonstrates that this condition is **not** genetically *determined*. If it were, one would have seen 100% concordance among identical twins. The authors of this study acknowledge that the "etiology of GID is a complex process of biopsychosocial components with unexplained interaction." To put this data in proper perspective, there is a 50% concordance of alcoholism among identical twins.
- 14. The 2005 study by Henningsson et al.¹⁰ reports on DNA sequence variations in sex-steroid related genes among 29 males who identify as women and 29 males who identify as men. The main study conclusion was that differences (polymorphisms) could be found at a higher rate in one of the estrogen receptor genes between the two groups. Setting aside major concerns related to the rigor of

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

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

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

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

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

- 16. Taken together, the evidence that Dr. Shumer provides in an attempt to support his assertion for a biological basis for sex-discordant gender identity reinforces the concerns that I raised in my declaration. Specifically, research in this area remains inconclusive with serious methodological limitations. Many alternative hypotheses for the development of this condition remain untested and are not even considered by Dr. Shumer in his declaration. Most glaring is the failure to address prior physical or psychological abuse, autism, and effect of social networking. At best, the existing data suggest that gender dysphoria is contributed to by several different influences that differ in both type and degree among affected Contributing factors for the current wave of adolescent females individuals. presenting with male gender identification without any antecedent gender dysphoria during childhood likely differ substantially from prior cohorts of predominately males presenting with sex-discordant gender identity prior to the onset of puberty.
- 17. To support Dr. Shumer's assertion that untreated gender dysphoria "can <u>result</u> in severe anxiety and depression, eating disorders, substance abuse, self-harm, and suicidality," he cites a 2015 study by Reisner et al. 12 In doing so, he further perpetuates the error of incorrectly making a causal conclusion where only

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

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

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

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¹³ Light AD, Obedin-Maliver J, Sevelius JM, Kerns JL. Transgender men who experienced pregnancy after female-to-male gender transitioning. Obstet Gynecol. 2014 Dec;124(6):1120-1127. doi: 10.1097/AOG.00000000000000040.

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

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

Declaration by Dr. Antommaria

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

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

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

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

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

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

- 23. In paragraphs 32 and 33 of his declaration, Dr. Antommaria asserts that the affirmative model for treating gender dysphoria is not experimental in nature. This claim is at odds with the official statement of the National Board of Health and Welfare in Sweden. In their "Updated recommendations for hormone therapy for gender dysphoria in young people" published on 02-22-2022, ¹⁵ the board concluded that "the risks of anti-pubertal and sex reassuring hormone therapy for those under 18 years of age currently outweigh the potential benefits for the group as a whole," and that hormone treatment should continue only *in the context of research*. Board spokesman Thomas Lindén stated "more knowledge is needed about the impact of treatments on gender dysphoria and the mental health and quality of life of minors, both in the short and long term."
- 24. Contrary to the apparent claim of Dr. Antommaria in paragraph 30 of his declaration that there is professional consensus on the best approach to managing gender dysphoria, growing concerns about the medical affirmation model for treating gender dysphoria have arisen among several international organizations and

¹⁴ Chen D, Berona J, Chan YM, Ehrensaft D, Garofalo R, Hidalgo MA, Rosenthal SM, Tishelman AC, Olson-Kennedy J. Psychosocial Functioning in Transgender Youth after 2 Years of Hormones. N Engl J Med. 2023 Jan 19;388(3):240-250. doi: 10.1056/NEJMoa2206297.

¹⁵ https://www.socialstyrelsen.se/om-socialstyrelsen/pressrum/press/uppdaterade-rekommendationer-for-hormonbehandling-vid-konsdysfori-hos-unga/.

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

- 25. Dr. Antommaria's discussion of the ability of adolescents to provide informed consent fails to acknowledge the complexity of developmental processes that significantly impact decision making ability in gender dysphoric youth. 17 Contrary to his portrayal, there remains a lack of consensus among healthcare professionals as to whether and to what degree adolescents are capable of providing informed consent. Concerns are magnified by the co-occurrence of psychological distress, peer influences, and motivations of the affected adolescent.
- 26. In summary, contrary to the biased and inaccurate conclusions of Drs. Shumer and Antommaria as conveyed in their reports, serious questions

¹⁶ Block J. Gender dysphoria in young people is rising-and so is professional disagreement. BMJ. 2023 Feb 23;380:p382. doi: 10.1136/bmj.p382.

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

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

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

Executed on March 10, 2023.

/s/ Paul W. Hruz

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

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