Exhibit HH

UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF MARYLAND

PFLAG, INC.; *et al.*, *Plaintiff*, v. DONALD J. TRUMP, in his official capacity as President of the United States; *et al.*, *Defendants*.	Civil Action No. 8:25-cv-00337-BAH

REPLY EXPERT DECLARATION OF DANIEL SHUMER, M.D.

I, Daniel Shumer, 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.

4. My background, qualifications, and the bases for my opinions are set forth my initial declaration.

5. I provide this reply expert declaration to respond to the amicus brief filed by the organization known as Do No Harm, Inc. ("DNH brief").

6. In preparing this reply expert declaration, I relied on my training and years of research and clinical experience, as set out in my curriculum vitae attached to my initial expert report as **Exhibit A**, and on the materials listed therein; the materials referenced in my initial declaration and listed in the bibliography attached thereto as **Exhibit B**; and the materials

referenced herein and listed in the supplemental bibliography attached hereto as **Exhibit C**. 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.

7. 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.

OPINIONS

8. Primum non nocere – *first, do no harm*. This phrase often is incorporated into the oath that medical students recite upon donning their white coats for the first time. I remember solemnly repeating the Hippocratic Oath at my white coat ceremony, pledging to keep patient welfare as the central focus of my career and practice. I take this oath extremely seriously. With humility, I understand that the medical advice I give, and the treatments I offer, have important implications on the health and wellbeing of my patients. It is within this context that I practice at the Child and Adolescent Gender Clinic at my institution.

9. It is not always straightforward to know how to apply the "do no harm" dictum, especially when there are multiple options for treatment, each having potential for benefit and risk (Shmerling, 2020).[1] It is then the role of the pediatrician to outline these possible treatment options with patients and families, explaining what is known and unknown, what are the potential risks, what are the desired benefits, what are the alternatives, and how the relevant body scientific literature helps to inform care decisions.

[1] RH Shmerling. *First, do no harm*. Harvard Health Blog (June 22, 2020), https://www.health.harvard.edu/blog/first-do-no-harm-201510138421.

10. The DNH brief refers to gender affirming care as a "medical scandal" which inflicts grave harms. Like Executive Order 14187, the DNH brief uses hyperbolic language such as "the child trans industry" and "biology-denying interventions" to disparage providers who are dedicated to the health and wellness of patients, while exposing DNH's own biases. The brief misrepresents the state of the evidence and draws inappropriate conclusions.

Quality of the Evidence

11. The DNH brief introduces the "pyramid of standards of evidence" to point out, correctly, that not all evidence is created equal. A case report on a topic doesn't carry as much weight as a large well-constructed clinical trial. Systematic reviews are important in that they review relevant studies related to a particular topic, based on the inclusion/exclusion criteria set forth in advance by the review's authors. What the brief gets wrong is how a body of evidence, including individual studies and systematic reviews, can and should be used to make medical decisions.

12. The Grading of Recommendations Assessment, Development, and Evaluation (GRADE) method for rating evidence is outlined by the DNH brief. The brief defines terms used by GRADE such as "High Quality Evidence" and "Very Low Quality Evidence." The Endocrine Society utilized the GRADE framework when publishing its Clinical Practice Guideline related to gender affirming care (Hembree, et al., 2017). According to GRADE, the Endocrine Society gender-care guidelines *did* in fact rely on low-quality and very-low-quality evidence in developing its recommendations. It must be understood that "low-quality" does not mean incorrect evidence or bad evidence. It does not mean that the studies relied upon were designed or carried out poorly. What it *does* mean is that there were no studies looking at gender-affirming medical interventions

that were considered of "high quality" *based on study design*, which usually means randomized controlled trials (RCTs).

13. While randomized control trials are an excellent study design in some contexts, for many complex medical problems RCTs are not feasible and/or are not ethical. If the only medicine practiced was that based on results of RCTs, the list of treatable medical conditions would be extremely short. Note that most of the Endocrine Society Clinical Practice Guidelines for conditions *other* than gender dysphoria *also* rely on "low" or "very-low-quality evidence," according to the GRADE framework.

14. For example, the Endocrine Society published a Clinical Practice Guideline (CPG) in 2017 titled *Pediatric Obesity – Assessment, Treatment, and Prevention: An Endocrine Society Clinical Practice Guideline* (Styne, et al., 2017). This guideline proposes 30 recommendations and uses the GRADE framework to grade these recommendations. Of the 30 recommendations in the pediatric obesity CPG, 25 are based on "low" or "very-low-quality evidence." For example, recommendations outlining when bariatric surgery should and should not be considered are based on "low-quality" or "very-low-quality" evidence based on the GRADE framework. This recommendation is not graded higher because there is no randomized control trial regarding bariatric surgery in youth, but there is nonetheless enough data through other methods of study to make these recommendations. This is the nature of complex medical problems. If a problem was simple enough to study with an RCT, it would not likely need a Clinical Practice Guideline to catalog and organize the literature and create best-practice recommendations for providers in the field.

15. Specific to the study of the management of gender dysphoria, RCTs measuring the most meaningful outcome – long-term quality of life – are not feasible and not ethical. Because

the goal of the provision of gender-affirming medical care in adolescents is long term reduction in gender dysphoria and improvement in quality of life and well-being, in order to conduct a meaningful RCT, patients would have to be randomized to treatment versus no treatment, and quality of life would have to be measured many years later in adulthood. 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. In addition, due to the current evidence supporting gender-affirming care, it would be unethical to propose a study randomly assigning patients to a placebo group (Ashley, et al., 2023). And patients/families desiring treatment with GnRHa or hormones 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 changes in symptoms over the course of treatment (de Vries, et al., 2014), or cross-sectional studies comparing treated and untreated persons (Turban, et al., 2022).

16. In my initial declaration I introduced the RAND review (Dopp, et al., 2024) which gives critical context to the concerns raised by the DNH brief, and which the DNH brief does not discuss. The RAND review states: "The available research evidence – although limited – can inform recommendations on interventions for gender dysphoria and related health problems in TGE youth…" The review continues, "challenges with certainty of evidence are not unique to interventions for gender dysphoria and related health problems in TGE youth; many fields of study encounter such challenges when using research evidence to inform standards of care. In fact, systemic reviews of the application of GRADE (Fleming et al., 2016; Howick et al., 2020) have found that 22-24 percent of evidence summaries for the primary study outcome were rated as very low certainty, and 81 percent of reviews included no outcomes with evidence that was high

certainty…Yet such guidelines have been developed and are used to inform widely applicable population health assessments … Absence of high-certainty evidence on effectiveness is not equivalent to evidence that effects are absent."

17. Setting aside for a moment the quality of evidence supporting the safety and efficacy of gender-affirming medical care, let's consider the evidence supporting the alternative. The DNH brief does not provide data supporting an alternative. This is because there is not high-quality, low-quality, or any type of evidence at all demonstrating the safety and efficacy of not treating gender dysphoria where such medical care is clinically indicated. The RAND review articulates this clearly: "evidence-based policymaking decisions about banning or restricting gender dysphoria interventions for TGE youth ought to consider the certainty of whether the policy is preventing harm that exceeds the potential harm of withholding clinical standards of care (Barbee, Deal, and Gonzales, 2022). In this review, the intervention for which harms were most clearly documented was GIECE [gender identity and expression change efforts, i.e. conversion therapy], an alternative to the standards of care."

Risks and Benefits

18. In Section III of the DNH brief, its authors contend that describing how medications like hormones and puberty blockers work in treating other conditions is meaningless when outlining safety. That is false. To be clear, these medications – testosterone, estrogen, and GnRH agonists – do in fact have the same mechanism of action when used to treat disorders of puberty as they do to treat gender dysphoria. There are certainly different considerations that are discussed in the informed consent process depending on the clinical scenario. But it is not appropriate to imply that all knowledge of the risks and benefits of these medications for treatment of other conditions is meaningless or meritless when it comes to treating gender dysphoria. The brief

attempts to insert its own value system when comparing risk-benefit considerations for gender-affirming medical care alongside those of whether to use fluoride toothpaste or use an experimental drug to treat cancer. The brief quotes me when I suggest that I wouldn't provide treatments if I had little confidence that they would achieve benefit, which of course is true. In each patient encounter I am working with a patient and their family to weight the evidence and the individualized risks and benefits of treatment against the evidence, risks and benefits of alternatives. This is as true when I see a patient in the Child and Adolescent Gender Clinic, as when I see a patient in the Type 1 Diabetes Clinic.

19. Both Executive Order 14187 and the DNH brief insinuate that infertility is an inevitable outcome for patients who receive gender affirming medical care. That is not true. The DNH brief cannot claim that puberty blockers cause infertility; it can only correctly point out that progression through puberty – at some point – is needed for maturation of sperm and eggs. So long as gonads remain in place, there remains fertility potential. To be sure, this would require some progression through the puberty associated with the sex assigned at birth.

20. In the context of gender affirming medical care, concerns about fertility are discussed with adolescent patients and their families when receiving both puberty blockers 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).

21. Egg retrieval and cryopreservation can be offered after a brief cessation of GnRHa treatment but before testosterone (Martin, et al., 2021) and has also been successful during GnRHa

treatment (Rothenberg, et al., 2019).

22. Even if gender-affirming hormones were introduced following use of GnRHa, these hormones could be discontinued with a goal of progression through endogenous puberty and achieving fertility. The DNH brief is clearly skeptical that a patient who received puberty blockers followed by hormones would have fertility. While fertility potential would likely require discontinuation of gender affirming hormone therapy and progression through endogenous 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 same kinds of 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 puberty blockers to testosterone does not necessarily cause permanent infertility.

23. Moreover, the above concern applies solely to patients who start treatment with GnRHa at the start of puberty and then go on to receiving gender-affirming hormones. While this is the course of treatment for some adolescent patients, it is by no means the majority of them. As with all medical care, medical treatment for gender dysphoria depends on the individualized needs and circumstances of each patient. And many, if not most, adolescent patients present for care *after* they have already begun pubertal changes, not before. For example, in my clinical experience, about two-thirds of patients are presenting to care after puberty has already occurred.

24. For the patients who receive gender-affirming hormone therapy after undergoing endogenous puberty, fertility potential can be achieved by pausing hormone therapy. Withdrawal of hormones in adulthood often is successful in achieving fertility when it is desired (Light, et al., 2014; Knudson, et al., 2017).

25. That said, the topic of fertility is critically important to discuss with patients and families considering any gender-affirming medical intervention. It should be made clear that endogenous puberty is necessary for fertility potential. It is also critical to understand that the value placed on fertility and the subsequent weight given to the risk for infertility may not be the same for all persons. While fertility may be a very important consideration for some transgender youth and their parents, the same may not be true for others. Persky, et al. 2020 explored these topics with youth and parents, finding that few youth (20%) and parents (13%) found it important to have biological children or grandchildren, and 3% of youth and 33% of parents would be willing to delay gender-affirming medical treatments for fertility preservation. Clearly a person's individual attitudes on fertility can and do change. That said, individual values and priorities affect the weight given to potential risks and benefits in all areas of medicine, including gender-affirming medical care. In my practice, our multidisciplinary team works with every patient and family to identify their values and priorities and how these priorities affect the weight given to potential risks and benefits of medical intervention in the context of the patient's gender dysphoria.

Additional Responses

26. The DNH brief presents snippets of my prior testimony out of context and displays them as bullet points, ignoring the full context of my expert opinion on these topics. It points out that I stated, "We do not know what causes gender dysphoria," in a deposition in the *Misanin v. Wilson* case (Tr. 33:18-21). However, in paragraphs 32-27 of my Expert Declaration, I provide a review of what is known about the biology of gender identity, and while do not know the specific etiology of gender dysphoria, we do know that it has a biological basis.

27. The DNH brief similarly cites to prior deposition testimony for the proposition that we cannot determine whether any particular individual with gender dysphoria will continue to be

transgender in the future (citing *Misanin* Tr. 33:22-25). This statement is presented in a way to imply that there is nothing to guide clinicians in providing anticipatory guidance to patients and families. In fact, after careful evaluation and assessment, providers can indeed provide guidance to patients and families on the likelihood of persistence. *See* Shumer Declaration, ¶¶61-63. As I stated in my initial declaration, "Persistence or intensification of gender dysphoria as puberty begins is used as a helpful diagnostic tool as it becomes more predictive of gender identity persistence into adolescence and adulthood." *Id.*, ¶63.

28. Snippets of Dr. Antommaria's prior testimony are presented in a similar fashion to imply that risks of gender affirming interventions are unknown and unknowable. This is untrue, as discussed in detail in Section E of my initial Expert Declaration. Indeed, van der Loos et al. (2023) does present data from 1,766 patients treated with this sequence of therapies seen between 1997 and 2018 to demonstrate very low rates of detransition.

29. The DNH brief also alludes to purported unknown long-term effect of pubertal suppression on neurodevelopment. There is no evidence for this concern. Indeed, I 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. DNH can point to no published evidence in support of this concern in transgender adolescents prescribed GnRHa.

30. Finally, the DNH brief concludes by pointing out correctly that all three Plaintiffs' experts agree that there is no study specifically demonstrating that gender affirming care directly reduces the rate of completed suicide. Completed suicide is a terrible, and fortunately very rare event. In order to study how a particular intervention affects the incidence of a very rare event, it would require an extremely large study. Studies outlining efficacy of gender affirming medical

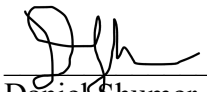
care rely on more frequent and readily measurable events such as reduction in gender dysphoria, as well as reductions in suicidality, depression, or anxiety, or improvements in quality of life. I agree that using suicidality as a proxy for completed suicide is inappropriate. However, as a clinician, if my patient has a reduction in suicidality, I consider that to be a very positive outcome and can celebrate that outcome with the patient as we work together to continue to treat their gender dysphoria.

Conclusion

31. The DNH brief presents inaccurate, incomplete, and inappropriate conclusions and should not be used as justification to deny patients access to essential medical care.

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

Executed this 26th day of February 2025.



Daniel Shumer, M.D.

Exhibit C

Exhibit C

Supplemental Bibliography

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