oLi Nowlin-Sohl*
(admitted only in Washington)
Leslie Cooper*
Taylor Brown*
AMERICAN CIVIL LIBERTIES UNION FOUNDATION
125 Broad St.
New York, NY 10004
Tel: (212) 549-2584
lnowlin-sohl@aclu.org
lcooper@aclu.org
tbrown@aclu.org

Brad S. Karp*
Alexia D. Korberg*
Jackson Yates*
Dana L. Kennedy*
PAUL, WEISS, RIFKIND, WHARTON & GARRISON LLP
1285 Avenue of the Americas
New York, NY 10019
Tel: (212) 373-3000
bkarp@paulweiss.com
akorberg@paulweiss.com
jyates@paulweiss.com
dkennedy@paulweiss.com

Richard Eppink (ISB no. 7503)
Casey Parsons (ISB no. 11323)
David A. DeRoin (ISB no. 10404)
WREST COLLECTIVE
812 W. Franklin St.
Boise, ID 83702
Tel: (208) 742-6789
ritchie@wrest.coop
casey@wrest.coop
david@wrest.coop

*Admitted *pro hac vice*

Attorneys for Plaintiffs

Additional counsel for Plaintiffs identified on the following page

UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF IDAHO

PAM POE, by and through her parents and next friends, Penny and Peter Poe; **PENNY POE**; **PETER POE**; **JANE DOE**, by and through her parents and next friends, Joan and John Doe; **JOAN DOE**; **JOHN DOE**,

Plaintiffs,

v.

RAÚL LABRADOR, in his official capacity as Attorney General of the State of Idaho; **JAN M. BENNETTS**, in her official capacity as County Prosecuting Attorney for Ada, Idaho; and the **INDIVIDUAL MEMBERS OF THE IDAHO CODE COMMISSION**, in their official capacities,

Defendants.

Case No. 1:23-cv-00269-CWD

EXPERT REBUTTAL DECLARATION OF KARA CONNELLY, MD

Eric Alan Stone*
Ariella C. Barel*
Kyle Bersani*
GROOMBRIDGE, WU, BAUGHMAN AND STONE LLP
565 5th Avenue, Suite 2900
New York, NY 10017
Tel: (332) 269-0030
eric.stone@groombridgewu.com
ariella.barel@groombridgewu.com
kyle.bersani@groombridgewu.com

Jordan Orosz*
PAUL, WEISS, RIFKIND, WHARTON & GARRISON LLP
2001 K Street, NW
Washington, DC 20006-1047
Tel: (202) 223-7300
jorosz@paulweiss.com

Philip S. May*
GROOMBRIDGE, WU, BAUGHMAN AND STONE LLP
801 17th St. NW, Suite 1050
Washington, DC 20006
Tel: (202) 505-5830
philip.may@groombridgewu.com

Dina Flores-Brewer (ISB no. 6141)
ACLU OF IDAHO FOUNDATION
P.O. Box 1897
Boise, ID 83701
(208) 344-9750
dfloresbrewer@acluidaho.org

*Admitted *pro hac vice*

Attorneys for Plaintiffs

1. I am submitting this rebuttal declaration to respond to some of the assertions made by Defendants and their experts. While the Defendants' expert declarations are filled with many statements that I believe are not supported by evidence, I do not attempt to address all of them but rather focus on some of the issues that seem most pertinent.

DEFENDANTS AND THEIR EXPERTS' ASSERTIONS ABOUT RISKS OF GENDER-AFFIRMING MEDICAL CARE

Asserted risks of puberty blockers

2. Defendants' experts, *see*, *e.g*. Weiss ¶ 123. suggest that puberty blockers may negatively impact cognitive development. These medications have been used for decades for youth with central precocious puberty without any observed or measured negative impact on cognitive development. Wojniusz S et *al.* Cognitive, Emotional, and Psychosocial Functioning of Girls Treated with Pharmacological Puberty Blockage for Idiopathic Central Precocious Puberty. Front Psychol. 2016.

3. Defendants' experts' suggestion that the impact on cognitive development might be different with puberty blockers used for gender dysphoria compared to central precocious puberty is based on the mistaken assumption that youth treated with puberty blockers for gender dysphoria are left in a prolonged hypogonadal state. In practice, the timing of discontinuing pubertal suppression for patients who have been treated with puberty blockers for gender dysphoria is typically at ages when many of their peers are also starting puberty. Many youth begin puberty at age 13, 14 or even older. In the field of pediatric endocrinology there are no concerns about brain development in patients related to the age of pubertal onset. When delayed puberty is treated, the goals are to induce development of secondary sex characteristics or growth acceleration; concern about cognitive development is not a reason treatment is considered. Harrington H and Palmert MR. An Approach to the Patient With Delayed Puberty, *The Journal of Clinical Endocrinology & Metabolism*, Volume 107, Issue 6, June 2022, Pages 1739–1750. In my general endocrine clinic, many cisgender youth present after age 14, and not uncommonly at age 16 or 17, for evaluation of absent or delayed puberty. I have not had any concerns about cognition in these patients.

4. In addition, cognitive development during adolescence is a complex process relying on a number of different mechanisms, including the psychosocial environment. Chronic stress, particularly during adolescence, can impact cognitive development. Eiland L, Romeo RD. Stress and the developing adolescent brain. Neuroscience. 2013 Sep 26;249:162-71. Gender diverse youth who are denied the option of puberty blockers and thus are forced to undergo development of secondary sex characteristics can experience significant stress; the contribution of this to cognitive development cannot be ignored.

5. Defendants' experts also raise the risk of a negative impact on bone health with the use of puberty blockers. *See* Weiss ¶ 112. There is a risk of reduced bone density growth related to the use of puberty blockers, as I indicated in my opening declaration, whether used to treat gender dysphoria or central precocious puberty. This is something that is discussed with families prior to initiating treatment. Pubertal suppression can delay the peak accrual of bone mineralization that occurs during puberty. Research shows that bone mineral density increases when blockers are stopped and puberty resumes endogenously or with gender affirming hormone therapy. Schagen SEE, et *al*. Bone Development in Transgender Adolescents Treated With GnRH Analogues and Subsequent Gender-Affirming Hormones. J Clin Endocrinol Metab. 2020 Dec 1;105(12):e4252–63.; Vlot MC et *al*. Effect of pubertal suppression and cross-sex hormone therapy on bone turnover markers and bone mineral apparent density (BMAD) in transgender adolescents. Bone. 2017 Feb;95:11-19.

6. Defendants' expert Dr. Weiss points to a risk of idiopathic intracranial hypertension (IIH) for youth prescribed puberty blockers as a reason not to treat gender dysphoria with this medication. *See* Weiss ¶ 113. This is in relation to a warning issued by the Federal Drug Administration (FDA) in 2022 based on postmarketing surveillance data. This warning was based on 6 cases of IIH in youth treated with puberty blockers, 5 of whom were being treated for central precocious puberty and 1 treated for gender dysphoria. The nature of the postmarketing surveillance data collection did not allow for calculation of incidence. A recently published registry-based cohort study out of Sweden reported that of the 410 individuals with gender dysphoria treated with puberty blockers over the 10-year study period, no cases of IIH were identified. Karamanis G et *al.* Incidence of Idiopathic Intracranial Hypertension in Individuals With Gonadotropin-Releasing

Hormone Analogue Treatment for Gender Dysphoria in Sweden. JAMA Pediatr. 2023 Jul 1;177(7):726-727. I am not aware of any pediatric endocrinology practices that have ceased treatment with puberty blockers for central precocious puberty or any other condition based on this warning.

Asserted health risks of hormone therapy

7. The defendants' experts bring up concerns about health risks resulting from hormone therapy, such as heart disease, stroke, blood clots, and liver dysfunction. *See*, *e.g*. Weiss ¶¶ 133-149. However, these risks are the same when estrogen and testosterone are used to treat gender dysphoria as when they are used to treat delayed puberty or hypogonadism in cisgender adolescents. In other words, these risks for transgender girls receiving estrogen therapy are the same as these risks for cisgender girls receiving estrogen therapy, and these risks for transgender boys receiving testosterone therapy are the same as these risks for cisgender boys receiving testosterone therapy.[1] For cisgender or transgender youth receiving such treatments, it is important to monitor hormone levels to make sure they are in the appropriate range to avoid these adverse health consequences. These risks are well-managed (for cisgender and transgender patients) when care is provided and monitored by a physician. In my clinical experience with over 500 cisgender and gender diverse patients receiving hormone therapy, I have had no patients experience blood clots, heart disease, stroke or liver dysfunction. One patient taking testosterone developed higher red blood cell counts but these normalized with reduction in the testosterone dose.

8. One of the defendants' experts also makes the claim that testosterone therapy in birth-assigned females increases the risk of breast cancer; however, the references used, Weiss ¶ 139, are not represented accurately in the declaration. These studies report that

[1] Additionally, given that hormone prescribing protocols in published guidelines by the Endocrine Society simulate natural endogenous puberty, the health risk profile for transgender boys receiving testosterone therapy becomes more in line with that for cisgender boys who go through endogenous puberty, which means, for example, higher risks of heart attack than cisgender girls. Similarly, the health risk profile for transgender girls receiving estrogen therapy becomes more in line with that for cisgender girls who go through endogenous puberty, which means, for example, higher risks of breast cancer than cisgender boys.

transgender women treated with estrogen have a higher rate of breast cancer than cisgender men, but lower rate than cisgender women, and that transgender men treated with testosterone have a lower rate of breast cancer than cisgender women but a higher rate than cisgender men. Berliere M et *al*. Effects of Hormones on Breast Development and Breast Cancer Risk in Transgender Women. Cancers (Basel). 2022 Dec 30;15(1):245; Corso G et *al*. Risk and incidence of breast cancer in transgender individuals: a systematic review and meta-analysis. Eur J Cancer Prev. 2023 May 1;32(3):207-214. These findings are not surprising given that estrogen causes the development of breast tissue and cisgender men have very little breast tissue.

Asserted risks to fertility

9. Defendants' experts discuss the potential impact on fertility of gender-affirming medical care. While, as I discussed in my opening declaration, some treatments can impair fertility and this is thoroughly discussed with patients and their families, along with fertility preservation options, this outcome is not certain. There are many reports of transgender men who, after taking and stopping testosterone, are able to conceive children, with or without fertility treatment. Light AD et *al*. Transgender men who experienced pregnancy after female-to-male gender transitioning. Obstet Gynecol. 2014 Dec;124(6):1120-1127; Light AD et *al*. Family planning and contraception use in transgender men. Contraception. 2018 Oct;98(4):266-269; Stroumsa D et *al*. The Power and Limits of Classification - A 32-Year-Old Man with Abdominal Pain. N Engl J Med. 2019 May 16;380(20):1885-1888.[2] For this reason, in our informed consent process, we inform trans males that testosterone is not an effective contraception and they could become pregnant. Treatment can be tailored to minimize the risk to fertility where that is important to the family; for example, allowing some puberty to occur in transgender girls prior to starting puberty blockers so that they are able to preserve sperm, or temporarily stopping testosterone in transgender males to preserve eggs or try to get pregnant.

[2] Defendants suggest that the fact that I am not aware of any of my patients having conceived a child means they were unable to do so. Defs' brief. ¶ 20. My patients transition their care to adult medical providers by their early 20's, before they would be ready to start having families.

Asserted risk to sexual response

10. Dr. Cantor suggests that gender-affirming medical care will lead to "lifetime lack of orgasm and sexual function." *See* Cantor ¶ 208. In actuality, sexual satisfaction is impacted by a multitude of factors, including psychological well-being. Studies have shown that as psychological well-being improves steadily during gender affirming treatment, so does sexual satisfaction. Young transgender adults who started their gender affirming care during adolescence had more sexual activity and satisfaction compared with individuals not accessing gender affirming care until adulthood. Bungener SL et *al.* Sexual Experiences of Young Transgender Persons During and After Gender-Affirmative Treatment. Pediatrics. 2020 Dec;146(6):e20191411. One study of transgender women having undergone vaginoplasty after pubertal suppression in adolescence reported that most were able to achieve orgasm. Bouman MB et *al*. Patient-Reported Esthetic and Functional Outcomes of Primary Total Laparoscopic Intestinal Vaginoplasty in Transgender Women With Penoscrotal Hypoplasia. J Sex Med. 2016 Sep;13(9):1438-1444. Another study found no difference between transgender women who were treated with puberty blockers early in puberty versus late in puberty in their ability to orgasm after gender affirming genital surgery. van der Meulen I et *al.* The Effect of Puberty Suppression on Sexual Functioning in Transwomen after Gender Affirmative Surgery, *The Journal of Sexual Medicine*, Volume 20, Issue Supplement_4, July 2023.

11. In my clinical experience with patients, gender affirming medical care improves sexual function and experiences due to the positive effect of physical effects on alignment with gender identity. Transgender men treated with testosterone do not experience any negative effects on sexual function, aside from possible vaginal dryness. Transgender women treated with estrogen can have diminished ability to achieve and sustain erections (which may be a desired effect), but treatment can be tailored to avoid that if desired.

Assertions regarding regret and detransition

12. Defendants and their experts devote significant time to suggesting that it is common for patients treated with gender-affirming medical care to detransition and regret treatment. There is no evidence to support this. One study of a large sample demonstrated that less

than 2% of people who transition ever detransition due to a shift in gender identity. Turban JL et *al*. Factors Leading to "Detransition" Among Transgender and Gender Diverse People in the United States: A Mixed-Methods Analysis. LGBT Health. 2021 May-Jun;8(4):273-280. Regret related to gender-affirming hormone use is rare. Wiepjes CM et *al*. The Amsterdam Cohort of Gender Dysphoria Study (1972-2015): Trends in Prevalence, Treatment, and Regrets. J Sex Med. 2018 Apr;15(4):582-590. In my experience with hundreds of patients with gender dysphoria who have received puberty blockers and/or gender-affirming hormones, a number of patients have discontinued hormones because they were satisfied and happy with the physical changes they had experienced and did not feel the need to continue treatment. These patients did not come to identify with their sex assigned at birth or regret treatment. I am aware of just two patients who, after undergoing gender affirming medical care, have said they had a shift in their gender identity to their birth-assigned sex and neither have any regrets about their treatment.

13. Defendants' assertion, Defs' brief, ¶ 30, that I view detransitioners as "an inconvenient fact to be minimized" cannot be further from the truth. Defendants are aware of (and presented to me at my deposition) a paper I co-authored that details a multidisciplinary approach to adult patients who expressed desire to reverse their gender affirming surgery (0.3% in our institution). The study aimed to better understand factors impacting patient's experiences to aid in the development of protocols to support them. Patients in my clinic are all counseled about the possibility that their experience regarding their gender may shift and change and we encourage them to come to us for support if that occurs.

14. The possibility of regretting medical decisions is part of medicine. A review of the body of research on this topic found that the mean rate of medical decision regret across studies was 16.5%. Perez, MMB, *et al*. Extent and Predictors of Decision Regret About Health Care Decisions: A Systematic Review. Medical Decision Making. Aug. 2016:777. A review of the research on regret in the context of surgeries found that across studies the average rate of regret was 14.4%. Wilson, A, *et al*. Regret in Surgical Decision Making: A Systematic Review of Patient and Physician Perspectives. World J. Surgery (2017) 41L1454-1465.

DEFENDANTS AND THEIR EXPERTS' ASSERTIONS REGARDING THE EFFICACY OF GENDER-AFFIRMING MEDICAL CARE FOR ADOLESCENTS

15. Defendants and their experts assert that there is a lack of evidence of efficacy of gender-affirming medical care. First, they suggest that the research evidence we have demonstrating efficacy is not valuable because it is "low quality". The defendants are referring to the Grading of Recommendations Assessment, Development and Evaluation (GRADE) approach to rating quality of evidence. This approach includes four levels of evidence quality, and is largely dependent on the type and methods of investigation. As such, observational studies including cross-sectional studies with comparison groups and longitudinal cohort studies—the types of studies done on gender-affirming medical care— are generally rated lower quality than randomized controlled clinical trials. Observational studies are critical to medical research and informing the practice of medicine, and the label of "low quality" under GRADE does not mean that the evidence is unreliable or of poor quality. Indeed, one recent study found that only 12% of health care interventions are supported by "high quality" evidence as defined by the GRADE standard, and more than half are supported by "low quality" or "very low quality" evidence. Howick J et *al*. Most healthcare interventions tested in Cochrane Reviews are not effective according to high quality evidence: a systematic review and meta-analysis. J Clin Epidemiol. 2022 Aug;148:160-169.

16. As I discussed in my opening declaration, Connelly ¶ 56, randomized controlled trials are not always feasible due to ethical concerns and methodological limitations. Ashley F et *al,* Randomized-controlled trials are methodologically inappropriate in adolescent transgender healthcare, Int J Trans Health. Well-designed observational studies are necessary and valuable, and can provide reliable evidence, sometimes more reliable than randomized controlled trials. This is not limited to research pertaining to gender affirming medical care.

17. Also as discussed in my opening declaration, in my clinical experience, I've seen the profoundly beneficial impact of gender affirming medical care on my patients. Defendants assert, Defs' brief, at 26-27, that my statement that gender affirming medical care improves depression and anxiety in patients is contradicted by a study published by my clinical team. Cantu AL et *al*. Changes in Anxiety and Depression from Intake to

First Follow-Up Among Transgender Youth in a Pediatric Endocrinology Clinic. Transgend Health. 2020 Sep 2;5(3):196-200. This study looked at depression and anxiety screener data at the first follow up visit, which was typically just a few months after initiating hormone therapy (follow-up visits are recommended at 3-4 months after initial visit.[3] We know from patients that physical changes occur very slowly, and often, patients do not notice physical differences until 3 to 6 months after initiating treatment; thus, we were not surprised that the improvements in depression and anxiety were not detected at the three month point. Over time, as patients see their bodies begin to match their gender, we consistently see significant improvement in patient mental health. In addition to seeing improvement in GAD-7 and PHQ-9 scores measuring anxiety and depression, we see reduction or elimination in suicidal ideation, improved family functioning and social relationships, and improved school engagement and performance. We get this information from the patients as well as their parents, who are often surprised to see such dramatic changes in their children's lives and well-being.

18. Defendants and their experts assert that clinical experience is not reliable evidence and appear to suggest that it should be disregarded. *See* Cantor ¶¶ 284 et seq. Yet Dr. Cantor seems to acknowledge that such evidence may be useful, as it "might be the only option available" if there aren't systematic cohort studies available. While we would ideally always have more and stronger research to support all medical practices, as clinicians we must rely on the best evidence available to guide clinical care. Clinical practice guidelines like those of the Endocrine Society and the WPATH Standards of Care make recommendations based on the best evidence that exists. In all areas of medicine, sometimes treatment recommendations are made based on expert opinion from clinical experience. Gender affirming medical care for adolescents is supported by multiple cohort and retrospective studies; however, the experience of clinicians is also valuable.

19. Defendants and their experts suggest that lack of FDA approval of puberty blockers, testosterone, and estradiol for the treatment of gender dysphoria supports their position that these treatments are not effective. My opening declaration discusses the wide-spread

[3] Our study was intended to continue to follow-up at additional time points, however our clinical operations shifted dramatically after this paper's publication due to the COVID-19 pandemic. We plan to collect more long-term data on the patients included in that study.

use of medications off-label (without FDA approval for a particular indication). The defendants' suggestion that lack of FDA approval for an indication means the FDA does not support that use[4] is erroneous. The lack of FDA approval does not mean disapproval of these medications for this indication; it says nothing at all about the FDA's views of the treatment. That is because the FDA does not opine on the safety or efficacy of a treatment for a particular indication unless a pharmaceutical company applies for approval for that indication. Making an application may not be financially reasonable or feasible if the treatment has already been approved for other conditions because, as the FDA states, "once the FDA approves a drug, healthcare providers generally may prescribe the drug for an unapproved use when they judge that it is medically appropriate for their patient." (https://www.fda.gov/patients/learn-about-expanded-access-and-other-treatment-options/understanding-unapproved-use-approved-drugs-label).

DEFENDANTS AND THEIR EXPERTS' ASSERTIONS REGARDING WPATH'S GUIDELINES REGARDING GENDER-AFFIRMING SURGERIES

20. Defendants' experts suggest that the fact that the WPATH Standards of Care 8 does not include a minimum age for genital surgery is equivalent to WPATH endorsing such surgeries at any age. *See* Cantor ¶ 249. This claim disregards the strong cautionary language included in the WPATH SOC 8 about assessing the patient's emotional and cognitive maturity to make each treatment decision and guidance about how to make that assessment. *See* WPATH SOC 8at S61-62. The age at which an individual has the maturity and cognitive ability to develop realistic expectations for surgical outcomes and understand long-term consequences varies greatly from person to person, and is elucidated in the comprehensive mental health evaluation that is required prior to consideration of any surgical interventions.

[4] See Defs' brief,at 9 (stating that "the FDA is not prepared to put its credibility and careful testing protocols behind the use" of puberty blockers, estrogen and testosterone to treat gender dysphoria).

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

Executed on October 13, 2023.

Kara Connelly MD

Kara Connelly, MD