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UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF IDAHO
SOUTHERN DIVISION

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 DECLARATION OF KARA CONNELLY, MD

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Attorneys for Plaintiffs

I, Kara Connelly, MD, hereby declare and state as follows:

1. I am over 18 years of age and competent to testify.

2. I have been retained by counsel for Plaintiffs as an expert in connection with the above-captioned litigation.

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 opinions.

4. In preparing this declaration, I reviewed Idaho State Legislature House Bill 71 (hereinafter, "Ban"). My opinions contained in this declaration are based on my training as a pediatric endocrinologist; my clinical experience as a pediatric endocrinologist, including my experience treating youth and young adults with hormonal therapies for a variety of conditions, including gender dysphoria; my knowledge of peer-reviewed research relevant to the treatment of gender dysphoria and other medical conditions for which hormonal therapies are provided; and my knowledge of the clinical practice guidelines for the treatment of gender dysphoria set forth by professional organizations including the World Professional Association for Transgender Health ("WPATH") and the Endocrine Society, as well as clinical practice guidelines for the treatment of a wide range of conditions within the field of endocrinology.

5. I am being compensated at a rate of $350 per hour for the time I spend on this case. My compensation does not depend on the outcome of this litigation, the opinions I express, or the testimony I provide.

6. In the past four years, I have not given expert testimony at trial or deposition in any cases.

I. BACKGROUND AND QUALIFICATIONS

7. I received my medical doctor degree from the University of Texas Health Science Center at San Antonio in 2007. I completed my residency in pediatrics and fellowship in pediatric endocrinology at Oregon Health and Science University ("OHSU").

8. Since completing my fellowship in 2013, I have been a pediatric endocrinologist at OHSU, holding faculty appointments in the Division of Pediatric Endocrinology in the Department of Pediatrics (I am currently an Associate Professor of Pediatrics) and serving as an attending physician in Doernbecher Children's Hospital at OHSU. I am currently the medical director of the Doernbecher Gender Clinic and co-founder of the Doernbecher Sexual Development Program.

9. I have extensive experience treating a variety of endocrine conditions in children and adolescents and special expertise in treating youth with differences in sex differentiation as well as youth with gender dysphoria. I have attended specialized training sessions on these topics and routinely review the literature to remain knowledgeable of and familiar with all emerging research.

10. I have been providing medical care for youth with gender dysphoria since 2014. In 2015, I founded the Doernbecher Gender Clinic, which has grown over the years to an interdisciplinary team providing comprehensive medical and mental health care for youth with gender dysphoria and their families. In 2022, our team cared for 993 youth and their families. I have personally delivered care to over 700 patients with gender dysphoria.

11. I have been providing medical care for children and adolescents with intersex traits since 2010. In 2016, I co-founded the Doernbecher Sexual Development program. I have personally cared for nearly 100 intersex youth through this program.

12. I have published research on a variety of pediatric endocrine issues, including the treatment of gender dysphoria, in peer-reviewed scholarly journals. I also serve as a reviewer for scholarly journals in my field.

13. I am an active member of the Oregon Pediatric Society, American Academy of Pediatrics, Pediatric Endocrine Society, World Professional Association of Transgender Health (WPATH), and the United States Association of Transgender Health. I've also served as a faculty member for WPATH's General Education Initiative and have been an invited speaker on gender-affirming care for the Pediatric Endocrine Society. I have given numerous lectures on the treatment of gender dysphoria and other endocrine issues at meetings of medical professional associations.

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 declaration.

II. TREATMENT PROTOCOLS FOR GENDER DYSPHORIA

15. The Endocrine Society, in partnership with the Pediatric Endocrine Society, and WPATH have published clinical practice guidelines for the treatment of gender dysphoria that are based on systematic reviews of research and the expert opinions of clinicians in the field. The first version of the WPATH guidelines, known as the Standards of Care, was published in 1979, and the most recent version—version 8—was released in 2022.[1] The first clinical practice

[1] Coleman, E., et al. (2022). Standards of Care for Health of Transgender and Gender Diverse People, Version 8. *Int J Transgender Health*. 23:S1–S258. *Available at* https://doi.org/10.1080/26895269.2022.2100644 (hereinafter, "WPATH guideline").

guideline for the treatment of gender dysphoria issued by the Endocrine Society was published in 2009, and the most recent update was released in 2017.[2]

16. Like other clinical practice guidelines issued by the Endocrine Society and other professional medical organizations regarding the treatment of other medical conditions, the WPATH and Endocrine Society guidelines on the treatment of gender dysphoria provide recommendations to healthcare providers about how to approach treatment of a condition based on the best available evidence.

17. Under the WPATH and Endocrine Society guidelines, prior to onset of puberty, there are no medical interventions that are indicated or recommended for children with gender dysphoria.

18. For adolescents—youth who have started puberty—and adults, medical interventions may be appropriate to treat gender dysphoria depending on the patient's individual needs. These interventions may include medication to delay puberty, hormone therapy (e.g., testosterone for transgender boys and testosterone suppression and estrogen for transgender girls), and surgeries. These interventions are often collectively referred to as gender-affirming medical care.

19. The WPATH and Endocrine Society guidelines on the treatment of gender dysphoria are recognized as authoritative by the major medical and mental health professional organizations in the United States, including the American Academy of Pediatrics, the American Medical Association, the American Psychiatric Association, the American Psychological Association, the American Academy of Child & Adolescent Psychiatry, the American Academy

[2] Hembree, W.C., et al. (2017). Endocrine Treatment of Gender-Dysphoric/Gender-Incongruent Persons: An Endocrine Society Clinical Practice Guideline. *JCEM*. 102(11):3869–3903. *Available at* https://doi.org/10.1210/jc.2017-01658 (hereinafter, "Endocrine Society Guideline").

of Family Physicians, and the American College of Obstetricians and Gynecologists. These organizations all support the provision of gender-affirming medical care to adolescent patients with gender dysphoria when indicated.[3]

20. Gender-affirming medical care is provided to adolescents with gender dysphoria in many other countries. While some European national health authorities have issued guidelines recommending caution about providing such care, or providing that such care should occur in clinical research settings, care is provided when deemed appropriate for adolescents.

21. Gonadotropin releasing hormone agonists (GnRHa) can be used to suppress puberty and delay the development of secondary sex characteristics that are not in alignment with the individual's gender identity. These medications have been used successfully to delay pubertal changes in youth with central precocious puberty. If treatment is stopped, endogenous puberty resumes.

22. Under the Endocrine Society Guideline, adolescents with gender dysphoria may be eligible for pubertal suppression if they meet the following criteria:

1. A qualified mental health professional has confirmed that:
    a. the adolescent has demonstrated a long-standing pattern of gender nonconformity, gender incongruence or gender dysphoria (whether suppressed or expressed),
    b. gender dysphoria worsened with the onset of puberty,

[3] In contrast with the broad support of the medical community for gender-affirming medical care for adolescents with gender dysphoria, cosmetic genital surgeries on infants with intersex traits, which are permitted under the Ban, are highly controversial and many children's hospitals and major medical organizations such as the American Medical Academy have recommended that these surgeries be deferred until children are old enough to assent to these procedures. *See* Mulkey, N., Streed, C.G., & Chubak, B.M. (2021). A Call to Update Standard of Care for Children with Differences in Sex Development, AMA J Ethics. 23(7):E550–556.

c. any coexisting psychological, medical, or social problems that could interfere with treatment (e.g., that may compromise treatment adherence) have been addressed, such that the adolescent's situation and functioning are stable enough to start treatment,

d. the adolescent has sufficient emotional capacity and maturity to give informed consent to this (reversible) treatment,

2. And the adolescent:

a. has been informed of the effects and side effects of treatment (including potential loss of fertility if the individual subsequently continues with sex hormone treatment) and options to preserve fertility,

b. has given informed consent and (particularly when the adolescent has not reached the age of legal medical consent, depending on applicable legislation) the parents or other caretakers or guardians have consented to the treatment and are involved in supporting the adolescent throughout the treatment process,

3. And a pediatric endocrinologist or other clinician experienced in pubertal assessment:

a. agrees with the indication for GnRH agonist treatment,

b. has confirmed that puberty has started in the adolescent, and

c. has confirmed that there are no medical contraindications to GnRH agonist treatment.[4]

[4] Endocrine Society Guideline at 3878.

23. Hormone therapy—testosterone for transgender males and estrogen and anti-androgens (to suppress testosterone) for transgender females—can be used to initiate puberty consistent with a patient's gender identity.

24. Under the Endocrine Society Guideline, adolescents may be eligible for gender-affirming hormone therapy if they meet the following criteria:

1. A qualified mental health professional has confirmed:
    a. the persistence of gender dysphoria,
    b. any coexisting psychological, medical, or social problems that could interfere with treatment (e.g., that may compromise treatment adherence) have been addressed, such that the adolescent's situation and functioning are stable enough to start sex hormone treatment,
    c. the adolescent has sufficient mental capacity to estimate the consequences of this (partly) irreversible treatment, weigh the benefits and risks, and give informed consent to this (partly) irreversible treatment,
2. And the adolescent:
    a. has been informed of the (irreversible) effects and side effects of treatment (including potential loss of fertility and options to preserve fertility),
    b. has given informed consent and (particularly when the adolescent has not reached the age of legal medical consent, depending on applicable legislation) the parents or other caretakers or guardians have consented to the treatment and are involved in supporting the adolescent throughout the treatment process,
3. And a pediatric endocrinologist or other clinician experienced in pubertal induction:

a. agrees with the indication for sex hormone treatment, and

b. has confirmed that there are no medical contraindications to sex hormone treatment.[5]

25. The WPATH standards of care have similar recommendations concerning eligibility of adolescents for pubertal suppression and gender-affirming hormone therapy.

26. Surgical care for gender dysphoria is rarely provided to youth under 18. If surgical services are offered, they are almost always gender-affirming chest surgeries for youth assigned female at birth—also known as gender-affirming mastectomy.[6] Under the Endocrine Society Guideline, genital surgery is not recommended to patients under age 18. The WPATH standards of care do not provide an age delineation for vaginoplasty, but strongly caution about the need to ensure that the patient has the maturity to make this decision.

27. Both the WPATH and Endocrine Society guidelines emphasize the importance of a comprehensive mental health evaluation prior to the initiation of gender-affirming medical care for adolescents. This evaluation should include an assessment of the youth's gender identity development; the presence of any co-occurring mental health conditions and whether symptoms may interfere with diagnosis or functioning to the extent that decision-making is compromised; and emotional maturity and decision-making capacity.

28. Gender-affirming medical interventions are not indicated for all individuals who present for care. Overall, about one-third of our patient population continues to see our team for support without accessing medical interventions.

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[5] *Id.*

[6] Surgery is not offered before an individual has reached their final adult height, and only after other attempts to relieve dysphoria are pursued.

29. The WPATH and Endocrine Society guidelines also highlight the importance of informing the patient and their parents of the potential risks and benefits of treatment, including the potential risk to fertility and options for fertility preservation, and obtaining informed consent from the parents or legal guardians. The WPATH guideline also recommends that doctors inform families of the limitations of the research and the possibility that some patients will come to experience their gender differently.

III. GENDER-AFFIRMING MEDICAL CARE FOR ADOLESCENTS IS EFFECTIVE

30. Gender-affirming medical care has been provided to adolescents for decades, and clinicians have seen the significant benefits of such treatment to patients.

31. In our clinic, when adolescents present for care, they often present with high degrees of anxiety, depression, and suicidal ideation. Most of our patients also come in experiencing challenges with social isolation, school attendance, and lack of desire to engage in relationships with family and peers. Most of these mental health and social challenges are linked to gender dysphoria and experiences of minority stress. While the social and political environment may continue to negatively impact a patient's mental health, we see dramatic improvements in our patients after they begin gender-affirming medical care. Depression, anxiety, self-harm, and suicidal ideation are significantly reduced, based on the screening tools, PHQ-9 and GAD-7, which patients complete at every visit. Patients routinely comment about finally feeling like themselves and being able to engage with the rest of their world. Parents regularly tell our clinical team that gender-affirming medical care has resulted in great improvement in their children's psychological well-being, school performance, and relationships. As treatment helps address their gender dysphoria, our patients feel motivated to apply for

college, join the military, and pursue employment and creative outlets. Many become leaders in their schools and communities.

32. Research conducted by investigators in the United States and around the world has evaluated a variety of mental health outcomes for minors with gender dysphoria who have been treated with puberty blockers, hormone therapy, or both, and their findings are consistent with what we experience in clinic—that treatment is associated with improvement in mental health.[7]

33. Research also demonstrates the negative impacts of not receiving treatment, or having to delay treatment into adulthood. For example, a study of 20,619 transgender adults found that access to pubertal suppression during adolescence resulted in lower odds of lifetime suicidal ideation (Turban 2020). Another survey of 11,914 transgender and nonbinary youth demonstrated that individuals who had access to gender-affirming hormones had lower odds of depression and suicidality (Green 2022).

[7] *See, e.g.*, de Vries, A.L., et al. (2011). Puberty Suppression in Adolescents With Gender Identity Disorder: A Prospective Follow-Up Study. *J Sex Med*. 8(8):2276–2283; de Vries, A.L., et al. (2014). Young Adult Psychological Outcome After Puberty Suppression and Gender Reassignment. *Pediatrics*. 134(4):696–704; Turban, J., et al. (2020). Pubertal Suppression for Transgender Youth and Risk of Suicidal Ideation. *Pediatrics*. 145(2):e20191725; van der Miesen, A.I., et al. Psychological Functioning in Transgender Adolescents Before and After Gender-Affirmative Care Compared with Cisgender General Population Peers. *J Adolesc Health*. 66(6):699–704; Achille, C., et al. (2020). Longitudinal Impact of Gender-Affirming Endocrine Intervention on the Mental Health and Well-Being of Transgender Youths: Preliminary Results. *Int J Pediatr Endocrinol*. 2020:8; Chen, D., et al. (2023). Psychosocial Functioning in Transgender Youth after 2 Years of Hormones. *New England J Med*. 388:240–250; Allen, L.R., et al. (2019). Well-Being and Suicidality Among Transgender Youth After Gender-Affirming Hormones. *Clin Pract Ped Psychol*. 7(3):302–311; de Lara, D.L., et al. (2020). Psychosocial Assessment in Transgender Adolescents. *Anales de Pediatría (Eng Ed)*. 93(1):41–48; Green, A.E., et al. (2022). Association of gender-affirming hormone therapy with depression, thoughts of suicide, and attempted suicide among transgender and nonbinary youth. *J Adol Health*. 70(4):643–649.

34. Research also shows the benefit of access to care during adolescence as opposed to waiting until adulthood. A study of 27,715 transgender and nonbinary adults revealed lower lifetime odds of suicidality for those who were able to access gender-affirming care during adolescence compared to those who could not access care until adulthood.[8]

35. The findings of the research on adolescents who receive gender-affirming hormone therapy are consistent with findings of the body of research on treatment of adults. Numerous studies have found that hormone therapy is effective at alleviating gender dysphoria and improving mental health in adults.[9]

IV. GENDER-AFFIRMING MEDICAL CARE FOR ADOLESCENTS IS SAFE

36. Pubertal suppression with GnRHa medications, hormone therapy, and mastectomy are treatments that have been used for many years for a range of conditions in adolescents.

37. GnRHa medications have been used for 40 years to treat central precocious puberty (CPP), a condition that causes early pubertal development in children. The medications pause pubertal development until the child reaches the typical age for puberty, at which point the medication is stopped, endogenous hormone production resumes, and typical secondary sex characteristics develop. GnRHa medications are also used to treat endometriosis, uterine

[8] Turban, J.L., et al. (2022). Access to gender-affirming hormones during adolescence and mental health outcomes among transgender adults. *PLoS ONE* 17(1):e0261039.

[9] *See, e.g.*, van Leerdam, T.R., Zajac, J.D., & Cheung, A.S. (2023). The Effect of Gender-Affirming Hormones on Gender Dysphoria, Quality of Life, and Psychological Functioning in Transgender Individuals: A Systematic Review, *Transgender Health*. 8(1); Colizzi, M., Costa, R., & Todarello., O. (2014). Transsexual patients' psychiatric comorbidity and positive effect of cross-sex hormonal treatment on mental health: results from a longitudinal study. *Psychoneuroendocrinology*. 39:65–73.

leiomyoma, ovarian cancer, fertility preservation in women with cancer, premenstrual syndrome, and as an adjunct to growth hormone therapy in youth with idiopathic short stature.

38. Some adolescents have medical conditions (i.e., ovarian failure, Turner syndrome, hypogonadotropic hypogonadism, Klinefelter syndrome, or constitutional delay of puberty) which require the use of sex steroid hormone therapy. Cisgender girls also utilize estrogen-containing medications to manage menstrual cycles and prevent pregnancy.

39. Cisgender girls with polycystic ovarian syndrome ("PCOS") utilize spironolactone—an anti-androgen medication—to manage the increased facial and body hair that is often associated with that condition.

40. Mastectomy is a commonly performed and widely accepted surgical procedure to treat gynecomastia in adolescent cisgender boys. Gynecomastia is enlargement of the breast tissue in cisgender boys or men.

41. In some cases, these medications or surgical treatments are aimed at bringing cisgender adolescent patients' bodies into alignment with their gender. For example, mastectomy is often provided to cisgender boys with gynecomastia to address the distress related to being a boy with breasts. And for some cisgender girls with PCOS, treatment with spironolactone addresses distress related to being a girl with facial hair.

42. Children and adolescents of all gender identities often need the assistance of medicine when their bodies start puberty too early, they are delayed in starting puberty or not able to start puberty at all, they experience the development of secondary sex characteristics that do not accord with their cisgender identity, or they start a puberty that causes secondary sex characteristics causing or exacerbating gender dysphoria.

43. GnRHa medications for pubertal suppression, testosterone, estrogen, and anti-androgens have all been demonstrated to be safe in clinical experience and research studies. The same is true of mastectomies.

44. There are risks and benefits to any medical treatment; gender-affirming medical treatments are not an exception.

45. The risks of puberty blockers are decreased bone density with prolonged use, sterile abscess at an injection site, and, very rarely, prolonged cardiac QT and increased intercranial hypertension. These risks are the same for youth receiving treatment for gender dysphoria as those being treated for central precocious puberty and other conditions.

46. Pubertal suppression does not result in any permanent changes to the body and has no permanent impact on fertility as a stand-alone medication.

47. Risks of estrogen therapy include blood clots, elevated blood pressure, diabetes, and migraine headaches. These risks are not higher than for the general population in the absence of individual or family history, or the use of nicotine. These risks exist whether the treatment is for transgender girls with gender dysphoria or for cisgender girls with ovarian failure, or any other hypogonadal condition.

48. Risks of testosterone therapy include increased red blood cells, liver inflammation (research studies show that risk of liver inflammation is very low), high cholesterol, high blood pressure, and heart disease, especially with a positive family history. These same risks exist whether the treatment is for transgender boys with gender dysphoria or for cisgender boys with testicular failure or any other hypogonadal condition.

49. For all of these medications, the risks are well-managed when care is provided and monitored by a healthcare provider. The risks become more significant when patients resort

to self-treatment. There are well-documented stories, including those we have witnessed in our own clinic, where adolescents were unable to access this care through a doctor and instead turned to black markets or took medications from friends/family to self-treat. Self-treatment can result in non-therapeutic hormone levels, which can negatively impact mood and increase several health risks, such as blood clots, cardiovascular problems, and liver and kidney dysfunction.

50. Gender-affirming hormone therapy may have an impact on future fertility potential,[10] although treatment can be tailored to minimize that risk if maintaining fertility is important to the family and there are options for fertility preservation. Impairment of fertility is not unique to gender-affirming hormone therapy. For example, treatments for some pediatric cancers cause likely loss of fertility. Some youth with intersex traits have their gonads surgically removed if they are at high risk of developing gonadal cancer.

51. As with all medical treatments, doctors are expected to fully inform patients and their parents, based on the available evidence, of the potential risks, benefits, and alternatives to treatment so that the families can weigh them and make an informed decision about whether to pursue treatment. The informed consent process is the hallmark of medical decision-making. Patients—and if minors, their parents—make the decision after being provided the information necessary to make an informed decision. The informed consent process for gender-affirming

[10] Many individuals assigned female at birth who take testosterone are able to achieve pregnancy or use assisted reproductive technology to conceive after discontinuing testosterone. *See, e.g.*, Light, A.D., et al. (2014). Transgender Men Who Experienced Pregnancy after Female to Male Gender Transitioning, *Obstetrics & Gynecology*, 124(6):1120–1127. In addition, testosterone is not an effective form of contraception and some transgender men have conceived while taking testosterone. *See, e.g.*, Thornton, K.G. & Mattatall, F. (2021). Pregnancy in transgender men. *CMAJ*. 193(33):E1303. Some transgender women may elect to use only anti-androgen medications without estrogen to preserve sperm production and fertility potential. Sperm production may resume in some transgender women. *See, e.g.*, Jiang, D.D., et al. (2019). Effects of Estrogen on Spermatogenesis in Transgender Women. *Urology*. 132:117–122.

medical care for minors is no different than how medical decision-making for minors occurs in other areas of medicine.

52. As discussed above, the WPATH and Endocrine Society guidelines offer recommendations about information that should be provided to families regarding gender-affirming medical care, including information about limitations in research—what is known and unknown; the potential impacts of some gender-affirming medical interventions on fertility; and the rare but potential possibility of returning to living consistently with their birth-assigned gender.[11]

53. Informed consent is a dynamic process; frequent assessment of the benefits of medications, and whether they continue to align with the individual's goals and outweigh risks, occurs in both medical and behavioral health follow-up visits.

54. There is nothing unique about gender-affirming medical care that warrants departing from the normal principles of medical decision-making for youth that parents make the decision after being informed of the risks, benefits, and alternatives by physicians.

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[11] Both clinical experience and research show that adolescents and adults who have received gender-affirming medical care rarely later come to identify with their sex assigned at birth and/or regret the care. For example, a prospective longitudinal study by de Vries, et al. found that none of the 55 adults who had initiated puberty blockers and hormones in adolescence reported regret with any of their treatment (de Vries 2014). Wiepjes, et al. (2018) found that 0.6% of transgender women and 0.3% of transgender men experienced regret (n=6793) related to gender-affirming medical interventions. Their study also noted that in many of those cases, the regret was "social regret"—regret related to rejection, loss of community, or threats of violence. *See* Wiepjes, C.M., et al. (2018). The Amsterdam Cohort of Gender Dysphoria Study (1972–2015): Trends in Prevalence, Treatment, and Regrets. *J Sexual Med*. 15(4):582–590. *See also* Brik, T., et al. (2020). Trajectories of adolescents treated with gonadotropin-releasing hormone analogues for gender dysphoria. *Archives of Sexual Behavior*. 49(7):2611–2618 (finding that 3.5% of study cohort discontinued GnRHa and did not go on to hormone therapy because they no longer wished gender-affirming treatment); Wiepjes, et al. (2018) (finding 1.9% of cohort discontinued GnRHa but reasons not provided); Olson, K.R., et al. (2022). Gender Identity 5 Years After Social Transition. *Pediatrics*. 150(2) (2.5% of study cohort returned to cisgender identity by five years after their initial social transition).

V. THE EVIDENCE SUPPORTING GENDER-AFFIRMING CARE IS COMPARABLE TO EVIDENCE SUPPORTING MANY OTHER MEDICAL TREATMENTS

55. The studies on gender-affirming medical care for adolescents (and adults) use a variety of commonly used research methods including prospective observational and retrospective cross-sectional studies comparing individuals who receive treatment to those who do not, and longitudinal studies that follow individuals over a period of time. These research methods are widely used in the field of medicine to evaluate the efficacy of treatment.

56. While randomized controlled clinical trials ("RCTs") can provide especially strong evidence in medical research by limiting confounding variables, given that such studies require that outcomes of a particular treatment are compared to outcomes of patients not receiving the treatment, it is frequently not feasible or ethical to rely on RCTs. Thus, many medications used to treat medical conditions in both pediatrics and adults are used based only on observational and retrospective research studies—or clinical experience alone—without randomized controlled clinical trials. For example, insulin, the hormone discovered in the 1920s as a treatment for type 1 diabetes mellitus, was used successfully to prevent death in several patients with diabetic ketoacidosis. Based on the outcomes of these clinical experiences, insulin became widely accepted as the standard treatment for type 1 diabetes mellitus; a randomized controlled trial would have been unethical given the high rate of death associated with other earlier attempted treatments.[12] Because pubertal suppression and gender-affirming hormones to treat gender dysphoria are now widely accepted in the medical field based on decades of clinical experience and research studies demonstrating efficacy, denying this care for a population of youth to serve as the "control," or comparison, group for an RCT would be unethical.

[12] Rosenfeld, L. (2002). Insulin: discovery and controversy. *Clin Chem.* 48:2270–2288.

57. While the body of research on gender-affirming medical care for adolescents continues to grow, we presently have sufficient clinical and research evidence in both youth and adult populations that shows the risks and benefits of providing this care, in addition to the risks of not providing care. The evidence is comparable in quantity and quality to evidence we have in support of many other medical interventions.

58. Some who oppose gender-affirming medical care have asserted that this care is "experimental," suggesting this is an area of medicine where there is no clear understanding of the impact of an intervention. Here, we have decades of experience providing care and a growing body of research also supporting the efficacy and safety of this care, in addition to substantial evidence about the use of these medications in other areas of medicine.

59. Once the Food and Drug Administration ("FDA") has approved a medication as safe and effective for an indication, prescribers are generally free to prescribe it for other indications. The fact that the FDA has not approved puberty blockers, testosterone, or estrogen specifically for the treatment of gender dysphoria does not mean that the treatment is experimental or unproven. The use of medication for indications that have not received FDA approval—often called "off-label use"—is a widely accepted practice in medicine. This practice is legal, ethical, and common. The Agency for Healthcare Research and Quality estimates that one in five medications prescribed is prescribed off-label. Off-label use is even more common in pediatrics: 45% of pediatric outpatient prescriptions are off-label, and nearly 80% of hospitalized children receive at least one drug off-label.[13] Off-label use is so common because it is often not worth the cost to pharmaceutical companies to pursue approval for additional indications once a

[13] Antoon, J.W., et al. (2023). . Advancing pediatric medication safety using real-world data: Current problems and potential solutions. *J Hosp Med*. doi:10.1002/jhm.13068. Epub ahead of print. PMID: 36855275.

medication has been approved by the FDA. For example, Gabapentin has an FDA indication for treating seizures and fibromyalgia, but is often (more than 80% of the time) used off-label to treat bipolar disorder, subacute low back pain, neuropathy, as migraine prophylaxis, and for additional indications.[14] Some of the same medications used off-label in gender-affirming medical care are also widely used off-label for other purposes. Spironolactone, which was approved by the FDA for controlling blood pressure, is used in cisgender women and girls off-label to control side effects of PCOS. And GnRHa medications have been approved for the treatment of precocious puberty but not for many other indications for which they are commonly used, including ovarian cancer, premenstrual syndrome, fertility preservation in women and adolescent girls with cancer, and as an adjunct to growth hormone therapy in youth with idiopathic short stature.

VI. HARM TO ADOLESCENTS WITH GENDER DYSPHORIA AND THEIR FAMILIES IF THE BAN TAKES EFFECT

60. We know from clinical experience and research that delaying or denying patients gender-affirming medical care when needed comes with an increase in emotional harm. Social transition can offer many benefits, but social transition alone does not prevent an adolescent from experiencing the trauma of seeing their body change in ways that do not align with their gender identity. Additionally, many of these body changes would require major surgical interventions in the future to address, and some are not fully treatable by future medical intervention. For example, once vocal cords are exposed to testosterone, only vocal training can potentially shift the deepening of the voice, but this treatment has mixed success. Pubertal

[14] *See* Fukada C., et al. (2012). Prescribing gabapentin off label: perspectives from psychiatry, pain and neurology specialists. *Can Pharm J (Ott)*. 145:280–284.e1.

suppression prevents this psychological trauma and the need for more invasive medical interventions in the future.

61. As previously discussed, clinical experience and research have shown that gender-affirming medical care improves mental health outcomes; the converse is also true—that being unable to access care increases mental health distress. We see a marked difference in the social functioning, emotional wellness, and psychological stability of our patients after they are able to access pubertal suppression and hormone therapy when indicated.

62. Additionally, our older adolescent patients who have experienced at least some secondary sex characteristics not aligned with their identity report higher levels of depression and anxiety, lower participation in school, and less ability to engage in social relationships.

63. Adolescents in Idaho who are already receiving gender-affirming medical care will be forced to medically detransition by the Ban. Abruptly discontinuing hormone therapy can result in emotional instability and dysregulation as well as adverse medical outcomes such as profound fatigue, hot flashes, and difficulty concentrating.

64. If this Ban takes effect, patients who have had the benefit of pubertal suppression and/or hormone therapy will see their bodies change in ways that will cause profound distress. And for some, discontinuing care will not return their body to match their assigned sex but will leave them with a mix of typically male and female phenotype. Adolescents assigned male at birth who have been treated with pubertal suppression and estrogen will have had permanent breast development from the estrogen and suppression of testosterone. Once these medications are stopped, endogenous testosterone becomes the dominant hormone, leading to masculinizing physical changes. Patients assigned female at birth who have taken testosterone may have experienced permanent voice deepening, masculinized facial structure, and facial and body hair

growth. Discontinuing care would be followed by breast development and resumption of menses, which often cause significant distress.

65. Psychologically, adolescents who have been receiving care for years and have to discontinue treatment will see a return of, or dramatic increase in, distress related to gender dysphoria. Based on what we know about patients' experiences prior to receiving care, if care is cut off or denied, we will see increased rates of depression, anxiety, suicidal ideation, and hospitalizations for suicide attempts. We also will likely see the tragedy of lives ended by suicide.

66. Patients may be the most directly and seriously harmed by these care bans, but their families are also suffering. At our clinic in Oregon, we are already seeing the impact on families who have already or are planning to leave their states because of healthcare bans; there are also families deciding to attempt to seek care in states where the care is available. Our clinic has already received inquiries from Idaho families wanting to travel for care. We do not yet have a clear answer of whether or how we will have the capacity to be able to meet the care needs of these patients. Idaho parents and providers are calling in states of desperation and hopelessness, unable to confirm that they will have access to care in Oregon.

67. Parents are having to make the difficult decision to relocate the family so that their children can continue to access care. In some cases, it is more financially viable to relocate, rather than to regularly travel. In others, the families are afraid that traveling for care and bringing medications back to a state with a ban may put their providers or their family at risk. The need to relocate removes patients and families from their support systems at a time when direct emotional and material support is most needed. Financial resources are drained and family units are split up. For example, in one family from another state that we see in the clinic, one

parent was able to secure a job in Oregon, but the other parent has not yet and has stayed behind with the cisgender sibling. The family is paying for a mortgage, plus the cost of relocation and temporary housing. Another clinic family that came to Oregon from a state with a ban does not have the means to afford housing and is living in a camper van in a city where they are at risk of being ticketed and towed.

68. Parents of families from out of state are often in a state of grief, unable to believe that the state that they've called home, many for generations, is harming their children. The emotional and logistical burden for parents is high, and the areas that they are moving to do not have the infrastructure or resources to absorb the increasing demand and severity of mental health issues. Many existing clinics are challenged in getting patients in on a timeline that will not result in a gap in treatment. As parental stress increases, we've seen parental mental health declines and the overall health of the family system decrease.

69. Adolescents are painfully aware of the sacrifices their families are making to get them care and many see this as evidence that they are a burden; belief of the adolescent that they are a burden is an intrusive thought that drives suicidal ideation and attempts.[15]

70. We are seeing these scenarios unfold as families move to Oregon from Texas, Tennessee, Arkansas, Iowa, Florida, Alabama, and Idaho. Others are exploring traveling to Oregon for care. Our clinic wait-times continue to increase, which increases patient distress (for both existing Oregonians and those relocating to Oregon) and risk for psychological harm.

71. Idaho families that have reached out to our clinic are already suffering and feeling the impact of this Ban, even before it goes into effect. We are receiving an increasing number of

[15] *See, e.g.*, Chu, C., et al. (2017). The interpersonal theory of suicide: A systematic review and meta-analysis of a decade of cross-national research, *Psychol Bull*. 143(12):1313–1345.

calls and emails requesting care from families and providers in Idaho and other states who are desperate to continue the care their adolescents need. Providers are distraught because they will be forced to abandon their patients and/or force them to medically detransition, which directly violates their code of medical ethics—to do no harm.

72. It is often the most well-connected and resourced families that are able to relocate. If the Ban goes into effect, Idaho families will feel the pain more deeply and Idaho will continue to lose medical providers and other front-line healthcare staff, business owners, teachers, first responders, and individuals in the hospitality industry, to name a few of the occupations held by parents who are seeking to relocate.

73. For those families that are less resourced and unable to move or travel out of state for care, they will have to watch as their children are withdrawn from treatment that has enabled them to flourish and see them return to the suffering that brought them to care. We know that gender diverse people from communities of color and families living in poverty have significantly worse mental health outcomes than their white and financially resourced peers.[16]

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

Executed on: _7/14/2023_

Kara Connelly MD

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[16] James, S.E., et al. (2016). The Report of the 2015 U.S. Transgender Survey. Washington, DC: National Center for Transgender Equality.