#### IN THE UNITED STATES DISTRICT COURT FOR THE DISTRICT OF SOUTH CAROLINA Charleston Division

STERLING MISANIN, et al.,

Plaintiffs,

v.

ALAN WILSON, in his official capacity as Attorney General of South Carolina, et al.,

Defendants.

Case No.: 2:24-cv-04734-BHH

PLAINTIFFS' MOTION FOR A PRELIMINARY INJUNCTION

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Plaintiffs respectfully submit this motion for a preliminary injunction.<sup>1</sup>

#### PRELIMINARY STATEMENT

On April 29, 2024, the Fourth Circuit ruled that refusing state funding for gender-affirming medical care constitutes unlawful discrimination under the Equal Protection Clause, Section 1557 of the Affordable Care Act, and the Medicaid Act. *Kadel v. Folwell*, 100 F.4th 122 (4th Cir. 2024) (en banc). Less than a month later, South Carolina enacted a law that categorically denies medically necessary care for minors with gender dysphoria, excludes coverage for "gender transition procedures" under the Medicaid Act, and prohibits any state funding from being used "directly or indirectly" to provide "gender transition procedures." Because the law is facially discriminatory, flouts directly controlling precedent, and is already causing serious and irreparable harm, this Court should immediately grant a preliminary injunction enjoining enforcement of the law against Plaintiffs and members of the putative Classes, restoring the pre-enactment status quo.

House Bill 4624 ("H 4624"), codified in South Carolina Code Annotated §§ 44-42-310 *et seq.*, imposes significant barriers to healthcare for transgender people.<sup>2</sup> In particular, H 4624: (1) categorically prohibits medical professionals from providing necessary and potentially lifesaving care to adolescents under the age of 18 who have been diagnosed with gender dysphoria, even

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<sup>&</sup>lt;sup>1</sup> Plaintiffs do not submit an accompanying memorandum of law because a full explanation of the motion as set forth in Loc. Civ. R. 7.05 is contained within this motion. *See* Loc. Civ. R 7.04 (D.S.C.). Further, as of the filing of this motion, conferral with opposing counsel has not been possible under Loc. Civ. R. 7.02 because opposing counsel has not yet entered an appearance or otherwise identified themselves to Plaintiffs.

<sup>&</sup>lt;sup>2</sup> Transgender people are those whose gender identity is different from their sex assigned at birth. A transgender boy or man is someone who has a male gender identity but was designated female at birth. A transgender girl or woman has a female gender identity but was designated male at birth. A nonbinary person is someone whose gender identity does not clearly align with either male or female identity, and many nonbinary people identify themselves as transgender because their gender identity does not align with their sex assigned at birth. *See* Compl. ¶ 54.

though these treatments are available to non-transgender adolescents, S.C. Code Ann. § 44-42-320 (the "Healthcare Ban" or the "Ban"); (2) prohibits "public funds" from being used "directly or indirectly for gender transition procedures," regardless of age, S.C. Code Ann. § 44-42-340 (the "Public Funds Restriction"); and (3) excludes "gender transition procedures" from coverage under the South Carolina Medicaid Program, again regardless of age, S.C. Code Ann. § 44-42-350 (the "Medicaid Restriction" and, together with the Public Funds Restriction, the "Coverage Restrictions"). These provisions prevent transgender South Carolinians from receiving medically necessary care that remains available to non-transgender people.

Plaintiffs are adolescents and adults who have been diagnosed with gender dysphoria and who access medically necessary gender-affirming healthcare, as well as the parents of adolescent plaintiffs. Plaintiffs have either received denials of care or anticipate receiving such denials.

H 4624 took effect on May 21, 2024. Since then, some South Carolinians have already lost their care, while others face imminent loss of care or an inability to start care. Absent intervention by this Court, H 4624 will inflict irreparable harm on transgender adolescents and adults, as well as their families, who must suffer without essential healthcare or go to extreme lengths to secure it elsewhere for themselves or their loved ones.

All relevant considerations strongly weigh in favor of preliminary injunctive relief. The Fourth Circuit's recent ruling in *Kadel v. Folwell*, 100 F.4th 122 (4th Cir. 2024), which struck down virtually identical Coverage Restrictions, confirms that Plaintiffs' challenges to H 4624's Healthcare Ban and Coverage Restrictions under the Equal Protection Clause, the Due Process Clause, the Affordable Care Act and the Medicaid Act are likely to succeed. Because H 4624 is causing, and will continue to cause, immediate and irreparable harm to all Plaintiffs and the

corresponding Class members, and the balance of equities and the public interest both weigh heavily in favor of a preliminary injunction, this Court should grant Plaintiffs' requested relief.

#### **STATEMENT OF FACTS**

#### I. Guidelines for the Treatment of Gender Dysphoria

Gender identity is a person's "deeply felt, inherent sense of their gender." *Kadel*, 100 F.4th at 136; *see also* Karasic Decl. ¶ 31 (citing American Psychological Association, 2015, at 834). Gender identity does not always align with a person's sex assigned at birth, which is generally based on the appearance of a newborn's external genitalia. *See Kadel*, 100 F.4th at 137; Karasic Decl. ¶ 31; Olson-Kennedy Decl. ¶ 26. Gender identity, which has biological bases, is not a product of external influence and not subject to voluntary change. Karasic Decl. ¶ 31; Olson-Kennedy Decl. ¶ 27; *see Kadel v. N. Carolina State Health Plan for Tchrs. & State Emps.*, 12 F.4th 422, 427 (4th Cir. 2021).

The term "gender dysphoria" refers to "a condition characterized by clinically significant distress and anxiety resulting from the incongruence between an individual's gender identity and birth-assigned sex." *Kadel*, 100 F.4th at 137; *see also*, Karasic Decl. ¶ 32; Olson-Kennedy Decl. ¶ 29. For both adolescents and adults, the clinical diagnosis of gender dysphoria involves two major diagnostic criteria: (1) a marked incongruence between the gender experienced and expressed by an individual and the gender assigned to that individual, and (2) associated clinically significant distress or impairment in social, occupational, or other important areas of functioning. Karasic Decl. ¶¶ 34-35 (quoting *Diagnostic and Statistical Manual of Mental Disorders, Fifth Edition, Text Revision* ("DSM-5") (DSM-5 released in 2013)).

To reduce or eliminate this distress, treatment—referred to as gender-affirming medical care—seeks to align an individual's body and presentation with their gender identity. *See* Karasic

Decl. ¶ 52. The medical community recognizes gender-affirming medical care as well-established and evidence-based: it is neither experimental nor investigational. Antommaria Decl. ¶¶ 36, 71. The World Professional Association for Transgender Health ("WPATH") and the Endocrine Society have developed longstanding, continuously maintained, evidence-based guidelines for gender-affirming medical care (the "Guidelines"). \*\* \*\*Xadel\*\*, 100 F.4th at 137-38; Karasic Decl. ¶¶ 37-40. The Guidelines include WPATH's Standards of Care for the Health of Transgender and Gender Diverse People, Version 8 ("SOC 8"), and the Endocrine Society's standard of care for the provision of hormone therapy as treatment for gender dysphoria ("Endocrine Society Guideline").

The Guidelines recommend interventions that are individualized based on patient needs, and treatment may include puberty-delaying medications, hormone therapy, and surgeries. *Kadel*, 100 4th at 136–37; Karasic Decl. ¶ 41. Puberty-delaying medications are indicated primarily for adolescents to pause the development of secondary sex characteristics that are inconsistent with their gender identity (and avoid the accompanying distress) and to provide additional time for adolescents to explore their gender identity before making further decisions about puberty. Shumer Decl. ¶ 62, 67; *see also* SOC 8 at S60. Hormone therapy allows for physical development more closely aligning with a person's gender identity, helping alleviate gender dysphoria. Shumer Decl. ¶ 71; *see also* SOC 8 at S110. Both puberty-delaying medications and hormone

<sup>&</sup>lt;sup>3</sup> WPATH, an "interdisciplinary professional and educational organization devoted to transgender health," has issued published versions of standards of gender-affirming care since 1979 anchored in methodological and evidence-based medical science and based on a systemic review of all available scientific evidence and the clinical experience of many experts in the field. WPATH, *Mission and Vision*, www.wpath.org/about/mission-and-vision (last visited Aug. 28., 2024). The most recent version, published in 2022, is Standards of Care for the Health of Transgender and Gender Diverse People, Version 8 ("SOC 8"). The Endocrine Society, a professional society of endocrine scientists and clinicians, has promulgated a similar standard of care and a set of clinical practice guidelines for the provision of hormone therapy as a treatment for gender dysphoria in minors and adults ("Endocrine Society Guideline").

therapy (primarily testosterone and estrogen) are used in minors and adults to treat a variety of conditions other than gender dysphoria. Shumer Decl. ¶¶ 64, 68; Olson-Kennedy Decl. ¶¶ 39, 69-71; Antommaria Decl. ¶¶ 74-75. Gender-affirmation surgery (GAS) refers to a "constellation of procedures designed to align a person's body with their gender identity." SOC 8 at S128; *see also* Karasic Decl. ¶¶ 37-62. Many of these procedures are used to treat conditions other than gender dysphoria. *See, e.g.*, Antommaria Decl. ¶ 75.

The denial of medically indicated care to transgender people not only prolongs and intensifies their gender dysphoria, but also causes additional distress and poses other health risks, such as depression, posttraumatic stress disorder, and suicidality. Karasic Decl. ¶ 66. It is "undisputed that gender dysphoria is a serious diagnosis that, if left untreated, can lead to self-mutilation and suicide." *Kadel v. Folwell*, 620 F. Supp. 3d 339, 380 (M.D.N.C. 2022). Accordingly, major medical organizations, such as the American Medical Association, American Psychiatric Association, and American College of Obstetricians and Gynecologists, endorse the treatment guidelines contained in SOC 8 and the Endocrine Society Guideline, oppose the denial of this medically necessary care and support public and private health insurance coverage for treatment of gender dysphoria as recommended by the patient's physician. Karasic Decl. ¶ 59; Antommaria Decl. ¶ 34; Olson-Kennedy Decl. ¶ 32; Shumer Decl. ¶ 53.

#### II. Treatment of Adolescents with Gender Dysphoria

Recognizing the "unique aspects that distinguish adolescence from other developmental stages," SOC8 at S49, the Guidelines also provide specific evidence-based recommendations for

<sup>&</sup>lt;sup>4</sup> These aspects include identity exploration, caregiver/parent involvement, and the onset of puberty, all of which require a specialized regimen of treatment for gender dysphoria in adolescents. SOC8 at S49; Karasic Decl.¶¶ 43-47.

the treatment of adolescents with gender dysphoria. Karasic Decl. ¶¶ 37, 44; Shumer Decl. ¶ 36. Under the Guidelines, gender-affirming medical care is only provided when an adolescent patient has: (i) gender incongruence that is both marked and sustained over time; (ii) a diagnosis of gender dysphoria; (iii) sufficient emotional and cognitive maturity to understand the potential side effects and provide informed consent; (iv) actually provided informed consent; and (v) the absence or mitigation of any countervailing mental health concerns. Karasic Decl. ¶ 43; SOC 8 at S48. Parental consent is also required for adolescents to access medical care. Karasic Decl. ¶ 44; *see also* SOC 8 at S58; Antommaria Decl. ¶¶ 45, 47 ("The current treatment paradigm for treating gender dysphoria ... is consistent with general ethical principles instantiated in the practices of informed consent.").

Treatment for gender dysphoria depends on, among many other individualized factors, a patient's state of pubertal development. Under the Guidelines, no medical treatments are provided before the onset of puberty. Karasic Decl. ¶ 41; SOC 8 at S59. Adolescents diagnosed with gender dysphoria who have reached the stage of puberty wherein the physical effects of testosterone or estrogen production are first apparent on physical exam (referred to as "Tanner Stage 2") may begin medical treatment, usually starting with puberty-delaying medications, sometimes referred to as puberty-blockers. Shumer Decl. ¶ 62.

Puberty-delaying medications are a fully reversible treatment. Shumer Decl. ¶ 64; Olson-Kennedy Decl. ¶ 39. They work by pausing endogenous puberty at its present stage when the treatment begins, forestalling the influence of a person's endogenous hormones on their body. Shumer Decl. ¶ 63. For example, a transgender girl will pause progression of physical changes caused by testosterone, including facial and body hair, an Adam's apple, or masculinized facial

structures. *Id*. And, in a transgender boy, those medications pause progression of breast development, menstruation, and widening of the hips. *Id*.

For adolescents and adults, the Guidelines provide for medical interventions that are individualized based on patient needs and may include puberty-delaying medications, hormone therapy, or (rarely for adolescents) surgeries. *See* Karasic Decl. ¶¶ 47-49. As with all medical interventions, the ultimate course of treatment is individualized based on and responsive to the particular medical and mental health needs of each patient. *Id.* at ¶ 49.

In some cases, hormone therapy may be medically necessary. *Id.* at ¶ 46. For adolescents, gender-affirming hormone therapy in adolescence can minimize dysphoria later in life and may eliminate the need for surgery. *See id.* at ¶¶ 9-12. These hormone therapies are used to facilitate development of sex-specific physical changes congruent with one's gender identity. Shumer Decl. ¶ 71; Olson-Kennedy Decl. ¶ 51. For example, a transgender boy prescribed testosterone will develop a lower voice as well as facial and body hair, while a transgender girl prescribed estrogen will experience breast growth, female fat distribution, and softer skin. Shumer Decl. ¶ 71.

Regardless of the treatment plan prescribed, at every encounter with the care team, there is a re-evaluation of the patient's gender identity and their transition goals. Shumer Decl. ¶ 75. Should a patient desire to discontinue a medical intervention, the intervention is discontinued. *Id.* Studies in which participants have undergone comprehensive evaluation prior to gender-affirming medical care show low levels of regret. *Id.* at ¶ 75 (citing de Vries, et al., 2011; van der Loos, et al., 2022; Wiepjes, et al., 2018); Antommaria Decl. ¶ 60.

Without gender-affirming medical care, transgender adolescents may experience extreme distress as they go through puberty in accordance with the sex assigned to them at birth. Karasic Decl. ¶ 66; Olson-Kennedy Decl. ¶¶ 38-39. Provision of puberty blockers and gender-affirming

hormones for transgender youth decreases depression, anxiety, and suicidality. Shumer Decl. ¶ 34, 84, 87; Karasic Decl. ¶ 52. Denial of access to this care for transgender adolescents is thus opposed by mainstream organizations responsible for the care of youth, including the American Medical Association, American Psychiatric Association, the Endocrine Society, American College of Obstetricians and Gynecologists, American Academy of Family Physicians, and American Academy of Pediatrics. Karasic Decl. ¶ 6, 65 (citing American Medical Association, 2021; American Psychiatric Association, 2018; Endocrine Society, 2012, American Congress of Obstetricians and Gynecologists, 2021; American Academy of Family Physicians, 2020); Senate Comm. on Med. Affs – Senate Med. Affs. Subcomm on H 4624 (Feb. 14, 2024) (Testimony of Dr. Elizabeth Mack, President of the South Carolina Chapter of the American Academy of Pediatrics at 52:36-1:30:32) (citing the American Academy of Pediatrics' Guidelines opposing denial of gender-affirming care).

Furthermore, there is no evidence-based alternative to gender-affirming medical care for treating gender dysphoria in adolescents where such interventions are medically indicated. Karasic Decl. ¶ 67. While behavioral health interventions are an important component of treatment for many, the literature has established for decades that mental health interventions alone are insufficient to treat gender dysphoria. Karasic Decl. ¶ 68.

#### III. South Carolina Restricts Access to Gender-Affirming Care Through H 4624

H 4624, signed by Governor McMaster on May 21, 2024 and effective as of that date, prohibits healthcare professionals from "knowingly [providing] gender transition procedures to a person under eighteen years of age," § 44-42-320(A); categorically excludes the use of public funds "directly or indirectly" for *any* gender transition procedures, including procedures provided to adults, § 44-42-340; and prohibits Medicaid reimbursement from the South Carolina Medicaid

Program for "practices prohibited under the provision of this chapter," presumably referring to the provision of "gender transition procedures" to minors. § 44-42-350.<sup>5</sup>

The law defines "gender transition procedures" to include "puberty-blocking drugs," ("any drug to suppress or delay normal pubertal development in children"); "cross-sex hormones" ("testosterone, estrogen, or progesterone given to an individual in an amount greater than would normally be produced endogenously . . ."); and "gender reassignment surgery," including "any surgical service that seeks to surgically alter or remove healthy physical or anatomical characteristics . . . . typical for the individual's sex, in order to instill or create physiological . . . characteristics that resemble a sex different from the individual's sex." § 44-42-310.

The Healthcare Ban subjects healthcare professionals who provide minors with gender transition procedures to both professional discipline and criminal penalties. The provision of prohibited services is considered "unprofessional conduct . . . subject to discipline by the licensing entity with jurisdiction over the physician." § 44-42-360. Furthermore, "[a] physician who knowingly performs genital gender reassignment surgery in violation of [H 4624] is guilty of inflicting great bodily injury upon a child." § 44-42-320. (The crime of "great bodily injury upon a child" is a felony carrying a maximum penalty of twenty years imprisonment. S.C. Code Ann. § 16-3-95(A).) The healthcare professionals may also be sued by the Attorney General or private parties. § 44-42-365.

H 4624 is part of a wave of legislation in this state designed to isolate, stigmatize and discriminate against transgender people. During the most recent legislative session, the Senate introduced 12 bills targeting transgender people and the House introduced 17 such bills, in addition

<sup>&</sup>lt;sup>5</sup> Because the Public Funds Restriction, § 44-42-340, would necessarily include the Medicaid program, the prohibition on Medicaid reimbursement also extends to adult patients.

to H 4264.<sup>6</sup> In June, the General Assembly passed a state budget for Fiscal Year 2024-2025 that restricts transgender students' access to school restrooms and locker rooms. S.C. General Appropriations Bill H 5100, Part IB, Section 1, Proviso 1.120.

## IV. South Carolina's Ban on Gender-Affirming Care Inflicts Severe and Irreparable Harms

By cutting off access to treatment that transgender South Carolinians rely on for their health and well-being and limiting future access to treatment, H 4624 causes immediate, severe, and irreparable harm to all of the Plaintiffs and Classes. Minor Plaintiffs Grant Goe and Nina Noe are experiencing anxiety, distress, and potentially permanent physiological changes if they are denied the critical gender-affirming medical care they need for gender dysphoria. Adult Plaintiffs Sterling Misanin, Jane Doe, and Jill Ray are experiencing anxiety, distress, and potentially permanent physiological changes if they are cut off from the funding of their critical gender-affirming medical care, or from preferred providers of that care. Parent Plaintiffs Nancy Noe and Gary Goe have had their parental judgment and decision-making authority usurped by the government and will either have to disrupt their lives at great cost to seek care out of state or endure watching their children suffer without the medical treatment they need.

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<sup>&</sup>lt;sup>6</sup> SC H 4624; H 3197, H 3485, SB 1213, H 3304, H 3466, H 3728, H 3827, H 4663, H 4707, SB 0743, SB 234, SB 274, SB 424 (prohibiting mandatory gender or sexual diversity training in higher education and local education agencies, or limiting the discussion of transgender topics in education and schools, including use of "preferred" pronouns and/or forced outing of students); H 3551, H 4619, H 4624, SB 127, SB 243, SB 627 (alternate versions of gender-affirming care ban); H 3611, H 3801, SB 0975 (protecting the right to discriminate against transgender individuals on moral or religious grounds); H 3616, SB 585 (criminalizing drag shows in a manner that targets transgender performers); H 4535, H 4538, H 5407 (restricting transgender people's access to bathrooms); SB 623, SB 364 (restricting right of transgender individuals to obtain gender markers on identification documents).

#### LEGAL STANDARD

A preliminary injunction is warranted where a plaintiff (1) is "likely to succeed on the merits;" (2) is "likely to suffer irreparable harm in the absence of preliminary relief;" (3) can show "the balance of equities tips in [its] favor;" and (4) can show the injunction "is in the public interest." *Roe v. Dep't. of Def.*, 947 F.3d 207, 219 (4th Cir. 2020) (citation omitted) (citing *Winter v. Nat. Res. Def. Council, Inc.*, 555 U.S. 7, 20 (2008)). When a preliminary injunction is sought against the government, these last two factors merge. *Nken v. Holder*, 556 U.S. 418, 435, 129 S. Ct. 1749, 1762 (2009); *see also Guilford College v. McAleenan*, 389 F. Supp. 3d 377, 395 (M.D.N.C. 2019).

#### **ARGUMENT**

Plaintiffs here meet each of the requirements for a preliminary injunction.

First, as discussed further below, Plaintiffs are likely to succeed on each of their claims. The Fourth Circuit has already held that where, as here, a law or restriction bars transgender individuals from receiving categories of care available to others, that law or restriction violates the Equal Protection Clause. See Kadel v. Folwell, 100 F.4th at 141-157. Similarly, because H 4624 prevents Parent Plaintiffs from securing doctor-recommended care for their children, they are also likely to succeed on the merits of their substantive due process claim. See, e.g., Brandt v. Rutledge, 551 F. Supp. 3d 882, 892 (E.D. Ark. 2021) aff'd, 47 F.4th 661 (8th Cir. 2022). Finally, as with Plaintiffs' Equal Protection Claim, the Fourth Circuit has already confirmed in Kadel that similar restrictions on the provision of gender-affirming care violate both the ACA and the Medicaid Act. See Kadel, 100 F.4th at 161-64.

Second, by being denied access to necessary healthcare, and having their health insurance coverage cut off for this care, Plaintiffs and the members of the Classes they represent are likely

to—and have already suffered—irreparable harm due to H 4624. Although the State's violation of Plaintiffs' and the Classes' constitutional rights alone justifies an injunction, the harms in this case concern critical, and potentially lifesaving, medical care and go far beyond any legal formality.

Finally, given the significant harm suffered by Plaintiffs if South Carolina continues to block access to life-saving care, contrary to existing medical guidelines recognized as authoritative by all mainstream medical associations in the United States, and in the absence of any scientifically credible basis for denying that care or any articulated, permissible state interest, the balance of equities and public interest weighs in favor of a statewide injunction to prevent irreparable harm against Plaintiffs and the Classes.

#### I. Plaintiffs Are Likely to Succeed on Their Equal Protection Claim

H 4624 imposes the same categorical prohibitions on medical care for individuals diagnosed with gender dysphoria that the Fourth Circuit has already held impermissibly violates the Equal Protection Clause. In *Kadel*, the Fourth Circuit ruled that similar denials of gender-affirming medical care to people diagnosed with gender dysphoria through North Carolina and West Virginia's publicly-funded insurance plans violated those individuals' rights under the Equal Protection Clause. *See Kadel*, 100 F.4th at 141–157. As in *Kadel*, H 4624 classifies based on sex and transgender status, is not substantially related to a sufficiently important government interest and cannot survive the "exacting" test imposed by heightened equal protection scrutiny. *United States v. Virginia* ("*VMP*"), 518 U.S. 515, 555 (1996); *Grimm v. Gloucester Cnty. Sch. Bd.*, 972 F.3d 586, 608 (4th Cir. 2020).

# A. Heightened Scrutiny Applies Because H 4624 Classifies Based on Transgender Status and Sex

The Equal Protection Clause of the Fourteenth Amendment prohibits state action that "creates arbitrary or irrational distinctions between classes of people out of a bare ... desire to harm a

politically unpopular group." *Grimm*, 972 F.3d at 606–07. Different "level[s] of scrutiny" apply to state actions depending on the "basis of the distinction between the classes of persons." *Id.* at 607; *see also Morrison v. Garraghty*, 239 F.3d 648, 654 (4th Cir. 2001). Laws that employ "quasi-suspect" classifications are subject to heightened scrutiny, "meaning that they fail unless they are substantially related to sufficiently important governmental interests." *Grimm*, 972 F.3d at 608 (citation omitted).

Because H 4624 facially classifies based on transgender status and sex, it is subject to at least heightened scrutiny. *See Kadel*, 100 F.4th at 142–43 (applying heightened scrutiny to indistinguishable North Carolina and West Virginia healthcare bans); *Grimm*, 972 F.3d at 611–13.<sup>7</sup>

#### 1. H 4624 Classifies Based on Transgender Status

The plain text of H 4624 classifies based on transgender status. The title of the law itself—
"An Act to . . . Prohibit the Provision of Gender Transition Procedures to a Person Under Eighteen
Years of Age . . ."—uses "gender transition" as a proxy for transgender status to impose disparate
treatment. The Coverage Restrictions extend that classification to adults. The law expressly classifies patients—both adolescents and adults—for differential treatment based on transgender status. "[G]ender dysphoria is so intimately related to transgender status as to be virtually

<sup>&</sup>lt;sup>7</sup> Although this Court is bound by precedent to apply heightened scrutiny, H 4624 notably cannot withstand any level of scrutiny. There is no rational basis to conclude that allowing minors with gender dysphoria to receive gender-affirming medical care that they, their parents, and their doctors agree is medically necessary "would threaten legitimate interests of [South Carolina] in a way that" allowing that treatment for other purposes "would not." *City of Cleburne v. Cleburne Living Ctr.*, 473 U.S. 432, 448 (1985); *see also Eisenstadt v. Baird*, 405 U.S. 438, 452 (1972) (health risks of birth control pills not a rational basis for banning access for unmarried people while allowing access for married people). Nor is there any rational basis to conclude that funding gender-affirming medical care would threaten any legitimate interest of South Carolina. Even under rational basis review, the justifications for H 4624 "ma[k]e no sense in light of how the [statute] treat[s] other [procedures] similarly situated in relevant respects." *Bd. of Trs. of Univ. of Ala. v. Garrett*, 531 U.S. 356, 366 n.4 (2001).

indistinguishable from it." *Kadel*, 100 F.4th at 146; *see also id*. ("[I]ncongruity between sex assigned at birth and gender identity [is] the very heart of transgender status."); *Williams v. Kincaid*, 45 F.4th 759, 772 (4th Cir. 2022) (observing as a matter of constitutional avoidance that the Court has "little trouble concluding that a law excluding" gender dysphoria from protection "would discriminate against transgender people as a class").

As in *Kadel*, by prohibiting medical treatments based on whether they are "provided or performed for the purpose of assisting an individual with a physical gender transition"—"the process in which a person goes from identifying with and living as a gender that corresponds to his or her sex to identifying with and living as a gender different from his or her sex," § 44-42-310(5-6)—H 4624 expressly and exclusively targets transgender people. *See Kadel*, 100 F.4th at 143–49 (holding (1) treatments "in connection with sex changes" are "treatments for gender dysphoria," (2) "gender dysphoria, a diagnosis inextricable from transgender status, is a proxy for transgender identity," and (3) classifications that prevent treatment for gender dysphoria, "bar treatments on the basis of transgender identity by proxy"). Because non-transgender adolescents may continue receiving the very same puberty-delaying, hormonal, and, rarely, surgical treatments that H 4624 denies to transgender adolescents, § 44-42-310(6), 8 and because public funds may still be used to

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<sup>&</sup>lt;sup>8</sup> See Shumer Decl. ¶¶ 64, 68 ("As an experienced pediatric endocrinologist, I treat patients with these same medications for both precocious puberty and gender dysphoria and in both cases the side effects are comparable and easily managed."), 69 (Puberty delaying treatments are prescribed off-label for adolescents for conditions including for endometriosis and growth hormone deficiency.), 78, 80 (Puberty delaying treatments prescribed for adolescents for other conditions, including precocious puberty.), 85 (Hormone therapy is prescribed to adolescents to treat other conditions, including "delayed puberty, hypogonadism, Turner Syndrome, Klinefelter Syndrome, agonism, premature ovarian failure, and disorders of sex development."); Antommaria Decl. ¶¶ 38 (The level of evidence supporting prescription of GnRH to adolescents with gender dysphoria the same "as supports the use of GnRH analogs for the treatment of central precocious puberty which the Ban permits[.]"), 57 ("[T]he potential risks of gender affirming medical care are comparable

provide non-transgender adults with the same care that is no longer covered for those diagnosed with gender dysphoria, § 44-42-340, H 4624 "transparently discriminates against . . . transgender" people. *Kadel*, 620 F. Supp. 3d at 376; *see also*, *Kadel*, 100 F.4th at 152 (exclusions for treatment of gender dysphoria were "obviously discriminatory" against transgender people).

#### 2. H 4624 Facially Classifies Based on Sex

H 4624 is also subject to heightened scrutiny because, like the laws challenged in *Kadel*, the law on its face classifies based on sex and assigns disparate treatment based on that classification. *Kadel*, 100 F.4th at 153. As set forth above, H 4264's restrictions apply *if* the treatment in question is "provided or performed for the purpose of assisting an individual with a physical gender transition," defined as "the process in which a person goes from identifying with and living as a gender that corresponds to his or her sex to identifying with and living as a gender different from his or her <u>sex</u>." § 44-42-310(5-6), 44-42-320(A-B) (emphasis added). In other words, H 4624 is "textbook sex discrimination"; applying restrictions on care only when the purpose of that care is to "align a patient's gender presentation with a gender identity that does not match their sex assigned at birth." *Kadel*, 100 F.4th at 153. By prohibiting treatment if and only if one's gender presentation does not match their sex designated at birth, a person's sex necessarily determines their treatment under the law: it is a but-for cause of the disparate treatment. *Id.*; *see also id.* at 147 ("restriction on funding is impermissibly discriminatory when it "cannot be done ... without inquiring into a patient's sex assigned at birth and comparing it to their gender identity").

H 4624 also discriminates on the basis of sex by punishing a person's failure to conform to sex stereotypes or expectations associated with a particular sex designated at birth. As *Grimm* 

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to the risks parents and adolescents are permitted to assume in numerous other treatment decisions, including decisions explicitly authorized by this legislation.")

recognized, "policies [that] punish transgender persons for gender non-conformity" constitute impermissible sex stereotyping. 972 F.3d at 608; see also Kadel, 100 F.4th at 154 ("[A] policy that conditions access to gender-affirming surgery on whether the surgery will better align the patient's gender presentation with their sex assigned at birth is a policy based on gender stereotypes."). H 4624 enforces such stereotypes. If an individual conforms with their sex assigned at birth, they can access care without restriction under H 4624. Shumer Decl. ¶¶ 64, 68, 69, 78, 80, 85; see also Antonmaria Decl. ¶¶ 38, 57. But if the care is for a gender transition—to live in accordance with a gender that diverges from sex assigned at birth—the law strictly prohibits any new course of care for that purpose and prohibits state funding to that end. Accordingly, H 4624 "tethers [people] to sex stereotypes which, as a matter of medical necessity, they seek to reject." Kadel, 446 F.Supp.3d at 14.9

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<sup>&</sup>lt;sup>9</sup> Although the Court need not reach this issue given that *Kadel*'s facial discrimination analysis controls, even if H 4624 did not explicitly classify based on transgender status and sex, it would still be subject to heightened scrutiny as a law passed in part "because of," not just "in spite of," its adverse effects on transgender individuals. Pers. Adm'r of Mass. v. Feeney, 442 U.S. 256, 279 (1979). In line with the title of the law that openly declares its aim to "Prohibit the Provision of Gender Transition Procedures," enforcing state-mandated gender conformity was not an incidental effect of the statute, but rather its purpose. This discriminatory intent is only understored by H 4624's legislative history. See Vill. of Arlington Heights v. Metro. Housing Dev. Corp., 429 U.S. 252, 266 (1977) (holding a clear pattern, unexplainable on grounds other than the protected characteristic, is determinative of discriminatory intent). The General Assembly passed H 4624 despite hearing from fifty-three South Carolinians, including parents of transgender children and their doctors, that the law would cause harm. Instead of heeding the warnings and lived experiences of their constituents, proponents of H 4624 within the General Assembly defended the bill based on general criticisms and stereotypes of transgender people. A sponsor of the bill described genderaffirming procedures as "heinous," and another house member identified gender dysphoria as the result of "peer pressure." House Med., Mil., Pub. and Mun. Affs. Comm. — 3-M Full Committee on H.4617 and H.4624 (Jan. 10, 2024) (Statement of Rep. Pace, Member, H. Comm. on Med., Mil. Pub. and Mun. Affs. at 32:18-21); Id. (Statement of Rep. Beach, Member, H. Comm. on Med., Mil. Pub. and Mun. Affs. at 37:10-15; 39:40-40:00). A third house member called transgender identity "a mental disorder." Id. (Statement of Rep. White, Member, H. Comm. on Med., Mil. Pub. and Mun. Affs. at (59:09-25). Members of the Senate Medical Affairs Committee compared

#### B. H 4624 Fails Heightened Equal Protection Scrutiny

To survive the heightened scrutiny required here, South Carolina must, at a minimum, provide an "exceedingly persuasive justification" for H 4624's classifications, *Kadel*, 100 F.4th at 156, which must be "substantially related to a sufficiently important governmental interest," *Grimm*, 972 F.3d at 607. H 4624 cannot survive this "exacting" test, which places a "demanding" burden of justification "entirely on the State." *VMI*, 518 U.S. at 533, 555.

South Carolina has not even attempted to meet its burden. H 4624 asserts no state interest and includes no legislative findings whatsoever. The State has thus provided no record to support any interest purportedly advanced by the law other than discriminatory animus toward transgender people.<sup>10</sup>

South Carolina has not presented, and cannot present, any evidence that would justify treating gender-affirming healthcare differently from all other healthcare posing similar risks and benefits or supported by comparable evidence of efficacy. As is now well recognized in this Circuit, 11 the gender-affirming medical treatments prohibited by H 4624 are safe, effective, and evidence-based. Karasic Decl. ¶ 25; Olson-Kennedy Decl. ¶¶ 50, 55-59; *see also* Antommaria Decl. ¶ 31 (explaining that gender-affirming medical care is neither harmful nor experimental.). Gender

students coming out to their teachers as transgender to students dressing up as animals. Senate Comm. on Med. Affs – Senate Med. Affs. Subcomm. on H 4624 (Feb. 21, 2024) (Statements of Sens. Garrett and Loftis, Members, S. Comm. on Med. Affs at 7:50-9:30).

<sup>&</sup>lt;sup>10</sup> In the absence of a factual record supporting a genuine contemporaneous interest, the State cannot retroactively construct a state interest in response to this action. *See Kadel*, 100 F.4th at 156 ("A law that discriminates against a quasi-suspect class 'must be genuine, not hypothesized or invented *post hoc* in response to litigation." (quoting *VMI*, 518 U.S. at 533)).

<sup>&</sup>lt;sup>11</sup> See, e.g., Kadel, 620 F. Supp. 3d 339, 380 (M.D.N.C. 2022) (Defendants West Virginia and North Carolina could not point to any evidence that WPATH standard treatments are ineffective in treating gender dysphoria).

dysphoria often intensifies if left untreated, leading to depression, anxiety, and suicidality. *See, id.* at ¶ 48; Karasic Decl. ¶ 67; Olson-Kennedy Decl. ¶ 78; Shumer Decl. ¶ 39.

Evidence supports the efficacy of these treatments for both adolescents and adults. The scientific literature supporting gender-affirming care for gender dysphoria includes cross-sectional and longitudinal studies, and extensive clinical experience. Karasic Decl. ¶ 50-59; Olson-Kennedy Decl. ¶¶ 40, 46, 53, 67; Shumer Decl. ¶ 40. This evidence base is comparable to the level of evidence supporting many other pediatric medical treatments. Antommaria Decl. ¶ 6; Karasic Decl. ¶ 38; Shumer Decl. ¶ 89-90. Again, this fact is well established both in the medical literature and by this Circuit's jurisprudence. See, e.g., Kadel, 620 F. Supp. 3d at 380 ("[Defendants] cover many [gender-affirming procedures] for other serious illnesses notwithstanding their risks and side effects."). All of the endocrine treatments—pubertal suppression, testosterone, estrogen and testosterone suppression—prohibited by H 4624 are used to treat other conditions in adolescents, including precocious puberty, and carry comparable risks and side effects regardless of the indication for which they are prescribed. Shumer Decl. ¶¶ 64, 68-69, 78,80, 85. Other medical treatments prohibited by H 4624, when prescribed to transgender adolescents, are used to treat other conditions in non-transgender adolescents and carry comparable risks and side effects regardless of the indication for which they are prescribed. See Antommaria Decl. ¶¶ 42, 54; see also Brandt v. Rutledge, 677 F. Supp. 3d 877, 902-04 (E.D. Ark. 2023). The treatments provided to adolescents with gender dysphoria do not affect an individual's future fertility any more than those who receive similar care for other indications. See Antommaria Decl. ¶¶ 49-52.

Ordinarily, "doctors and patients, when fully aware of the risks and elusive benefits of available treatments, should decide if medicine or surgery is necessary." *Kadel*, 620 F.Supp.3d at 380 (emphasis in original) (citing state expert's testimony). "This is Plaintiffs' request: that they

and their doctors, not their sex or transgender status, determine when their treatments are appropriate." *Id.* "There is nothing unique about the risks of gender-affirming medical care for adolescents that warrants taking this medical decision out of the hands of adolescent patients, their parents, and their doctors." *Brandt*, 677 F. Supp. 3d at 902–04.

Further, while all medical treatment comes with risk, decades of research and clinical experience show that any risks are greatly outweighed by the benefits of the care. Antommaria Decl. ¶ 56; Karasic Decl. ¶¶ 12, 38, 52-53; Olson-Kennedy Decl. ¶¶ 40-50, 53-63, 65-67, 76-77; Shumer Decl. ¶¶ 83-84. Indeed, the existing treatment protocols carefully address potential risks through a robust informed consent process that is tailored to the maturity of the adolescent and requires consent by the adolescent's parents or guardian. Antommaria Decl. ¶ 45; Karasic Decl. ¶¶ 45,53; Olson-Kennedy Decl. ¶ 68.

What is clear, however, is that transgender adolescents are severely and irreparably harmed when they are denied access to medically necessary gender-affirming care. Karasic Decl. ¶¶ 12, 67-69; Olson-Kennedy Decl. ¶ 78. The denial of gender-affirming medical care to transgender people when medically indicated "not only results in the prolonging of their gender dysphoria, but causes additional distress and poses other health risks, such as depression, posttraumatic stress disorder, and suicidality," as well as "directly contribut[ing] to poorer mental health outcomes." Karasic Decl. ¶ 67. Prohibiting this care would require transgender adolescents to undergo endogenous puberty, causing potentially severe or life-threatening distress, and in many cases irreversible changes to the body.

Simply put, gender-affirming medical care greatly improves the health and wellbeing of adolescent patients with gender dysphoria. It does not harm them. Rather, it allows them to thrive. "Without evidence that the treatments are ineffective to treat gender dysphoria, Defendants cannot

meet their burden to show that the risks substantially outweigh the benefits so as to justify their sex- and transgender-based policy." *Kadel*, 620 F.Supp.3d at 380. Because the State provides no credible justification explanation for why gender-affirming care should be treated differently from all other medical treatment, much less a "exceedingly persuasive" justification, H 4624 cannot survive heightened scrutiny review.

Even if the Healthcare Ban was intended to prevent some demonstrated medical harm to children, heightened scrutiny requires that the Ban be "substantially related to that end." Kadel, 100 F.4th at 156; see also, Sessions v. Morales-Santana, 582 U.S. 47, 68 (2017) ("[A] close meansend fit [is] required to survive heightened scrutiny."). Here, the treatments that are banned for transgender adolescents are not banned for other adolescents, thus the ends of protecting children from purported medical harm are not achieved by means of the Healthcare Ban. The statute expressly allows for similar procedures to be conducted in the cases of "precocious puberty, prostate cancer, breast cancer, endometriosis ... or a medically verifiable disorder of sexual development," § 44-42-310, and many of the banned treatments are routinely used to treat these and other conditions. Shumer Decl. ¶¶ 64, 68-69, 78, 80, 85; Antommaria Decl. ¶¶ 38, 49, 74. Furthermore, the complaints commonly leveled against these treatments—for, example, that they are based on "low" quality, observation evidence—can be leveled against other treatments not targeted by the Healthcare Ban, such as pediatric obesity and congenital adrenal hyperplasia. Antommaria Decl. ¶ 36. Therefore, the Ban is insufficiently tailored to the harm it purports to address. *Morales-San*tana. 582 U.S. at 49 (Statute did not pass heightened scrutiny because "the gender-based means scarcely serve the posited end.").

#### II. Parent Plaintiffs Are Likely to Succeed on the Merits of their Due Process Claim

The Healthcare Ban separately violates the Due Process Clause because it burdens parents' fundamental right "in the care, custody, and control of their children ... perhaps the oldest of the fundamental liberty interests recognized by [the Supreme Court]." *Troxel v. Granville*, 530 U.S. 57, 65 (2000).

The Healthcare Ban thus triggers strict scrutiny because it burdens the fundamental rights of parents to seek medical care that they and their medical providers have determined is appropriate for their minor children. As discussed above, H 4624 cannot survive any level of constitutional scrutiny, let alone the most stringent review required for intrusions into fundamental rights. Accordingly, the Parent Plaintiffs are likely to succeed on the merits of their substantive due process claim. *Brandt*, 551 F. Supp. 3d at 892 (holding that plaintiffs' parents were likely to succeed on similar claims because they "have a fundamental right to seek medical care for their children and, in conjunction with their adolescent child's consent and their doctor's recommendation, make a judgment that medical care is necessary"), *aff'd*, 47 F.4th 661 (8th Cir. 2022).

## A. The Ban Infringes Upon the Fundamental Rights of Parents to Direct the Medical Care of Their Minor Children

Parents have a fundamental right to direct their children's healthcare, *Brandt*, 551 F.Supp.3d at 892-93, a right anchored in the well-established liberty interest that parents hold in the "care, custody, and control of their children." *See Troxel*, 530 U.S. at 65 (tracing the long history of parents' due process rights to make decisions for their children); *see also*, *Parham v*. *J.R.*, 442 U.S. 584, 602 (1979) (parents have a right to "seek and follow medical advice" for their children). Where a medical treatment is recommended to a minor, parents are entrusted with the responsibility to weigh the risks and benefits of treatment—and in enacting the Healthcare Ban,

South Carolina strips parents of that role. *See, e.g., L. W. by & through Williams v. Skrmetti*, 83 F.4th 460, 507-09 (6th Cir.) (White, J., dissenting) (collecting cases).

Although "the State must play its part as parents patriae" in promoting the wellbeing of minors, *Schall v. Martin*, 467 U.S. 253, 265 (1984), no such interest is implicated here. When parents, their children, and their children's medical providers align on a particular course of care—care that has been recognized by every major medical association as safe, effective, and necessary—that decision should be protected against state interference. That is the context here: parents or legal guardians are the medical decision-makers, advised by healthcare providers and their adolescent child's informed assent. *See* Antommaria Decl. ¶ 45; Olson-Kennedy Decl. ¶ 64. H 4624 substitutes the judgment of the State for that of the parent. *See Brandt*, 551 F. Supp. 3d at 892 (finding that Arkansas' healthcare ban infringed "right to seek medical care for their children . . . in conjunction with their adolescent child's consent and their doctor's recommendation"); *cf. Santosky v. Kramer*, 455 U.S. 745, 760–61 (1982) (Heightened evidentiary standards are required where the "vital interest" of the parent and child in preserving their relationship "coincide.").

#### B. H 4624 Cannot Survive Strict Scrutiny

As discussed above, H 4624, which intrudes upon the fundamental rights bestowed on Parent Plaintiffs, cannot survive any level of review, let alone strict scrutiny. South Carolina's ban on gender-affirming care for minors is nowhere near the "least restrictive" means to address any purported interest. *See Bernal v. Fainter*, 467 U.S. 216, 219 (1984). In fact, the law is not narrowly tailored to *any* interest—compelling or not. Without any findings or justifications for legislation that impedes upon the fundamental right of parent to care for their child, "the State could not withstand either heightened scrutiny or rational basis review." *Brandt*, 551 F.Supp.3d at 893.

#### III. Plaintiffs Are Likely to Succeed on Their ACA Claim

"The Affordable Care Act's anti-discrimination mandate provides that, '[e]xcept as otherwise provided ... an individual shall not, on the grounds prohibited under Title VI of the Civil Rights Act ... [and] Title IX ... be excluded from participation in, be denied the benefits of, or be subjected to discrimination under, any health program or activity, any part of which is receiving Federal financial assistance." *Kadel*, 100 F.4th at 163-64 (quoting 42 U.S.C. § 18116(a)). The State cannot credibly dispute that South Carolina's public health insurance plans, including Medicaid and PEBA, receive financial assistance from the federal government. *See* Complaint (ECF 1) at ¶ 21, 24, 26, 29, 232-34, 261.

Because H 4624's Coverage Restrictions deny transgender individuals reliant on public insurance coverage, such as plaintiffs Jane Doe, Jill Ray, and Nina Noe, benefits on the basis of sex, the law thus violates Section 1557 of the ACA. Under the binding law of this Circuit, denial of benefits to a transgender person by a state Medicaid program qualifies as sex discrimination under Title IX, and thereby violates Section 1557 of the ACA, if the public insurance programs provide those same benefits to the state's non-transgender citizens. *Kadel*, 100 F.4th at 163-64. On the face of Section 340, transgender individuals insured by public health insurers will be denied coverage for procedures that are otherwise covered for other beneficiaries. *See* S.C. Code Ann. § 44-42-340. Further examination of South Carolina's public healthcare plans reveals many procedures which are available to the majority of those enrolled, but that are now unavailable to transgender individuals. *See, e.g.*, South Carolina Department of Health and Human Services, "Physicians Services Provider Manual," available at https://provider.scdhhs.gov/internet/pdf/manuals/Physicians/Manual.pdf. H 4624 is therefore facially discriminatory on the basis of sex and violates Section 1557 of the ACA.

#### IV. Plaintiffs Are Likely to Succeed on Their Medicaid Act Claim

The Coverage Restrictions violate the Medicaid Act's guarantees that programs receiving federal funding (1) not "arbitrarily deny or reduce the amount, duration, or scope of a required service . . . to an otherwise eligible beneficiary solely because of the diagnosis, type of illness, or condition," *Kadel*, 100 F.4th at 161 (quoting 42 C.F.R. § 440.230(c)), referred to as the "availability requirement," and (2) "ensure that services available to any categorically needy individual are equal in amount, duration, and scope for all beneficiaries within the group," known as the "comparability requirement," *id.* at 162 (quoting 42 C.F.R. § 440.240(b)(1)) (internal quotations omitted).

# A. H 4624's Categorical Prohibition on Gender-Affirming Medical Care Violates the Medicaid Act's Availability Requirement

The Coverage Restrictions violate the Medicaid Act's requirement that South Carolina cover both mandatory and optional services in sufficient "amount, duration, and scope to reasonably achieve its purpose." 42 C.F.R. § 440.230(b). While the State may place "appropriate limits on a service based on such criteria as medical necessity or utilization control procedures," 42 C.F.R. § 440.230(d), it must do so based on "reasonable standards" that are "consistent with the objectives" of the Medicaid Act, 42 U.S.C. § 1396(a)(17), and may not "arbitrarily deny ... a required service ... to an otherwise eligible beneficiary solely because of the diagnosis, type of illness, or condition." 42 C.F.R. § 440.230(c). Because gender-affirming medical treatments (1) fall within a category of mandatory or optional medical services that the State has elected to provide; and (2) are medically necessary, the Coverage Restrictions' blanket prohibition on such care for those diagnosed with gender dysphoria violates this requirement by denying medical care to those who cannot afford it themselves. *See Alvarez v. Betlach*, 572 F. App'x 519, 520–21 (9th Cir. 2014) (The Medicaid Act "prohibits states from denying coverage of 'medically necessary'

services that fall under a category covered in their Medicaid plans."); *Bontrager v. Indiana Fam.* & *Soc. Servs. Admin.*, 697 F.3d 604, 608 (7th Cir. 2012) (States are "required to provide Medicaid coverage for medically necessary treatments in those service areas that the State opts to provide such coverage[.]"); *Beal v. Doe*, 432 U.S. 438, 444 (1977).

There is no question that South Carolina is either required to or chooses to cover the procedures required by Plaintiffs—indeed, the Coverage Restrictions explicitly state that public funding will be denied for treatments only when those treatments are provided or performed as genderaffirming care. See S.C. Code Ann. §§ 44-42-310(5)-(6), -340, -350. These restrictions prevent those diagnosed with gender dysphoria from receiving medically necessary gender-affirming care. See Statement of Facts §III, supra. As recognized by the Fourth Circuit in Kadel, this categorical denial of coverage for "specific, medically necessary procedure[s]" required to address gender dysphoria "is not a reasonable standard consistent with the objectives of the Act." Kadel, F.4th at 162 (quoting Hern v. Beye, 57 F.3d 906, 911 (10th Cir. 1995)); see also Pinneke v. Preisser, 623 F.2d 546, 549 (8th Cir. 1980) (A policy establishing an "irrebuttable presumption that the procedure of sex reassignment surgery can never be medically necessary" violates Medicaid's availability requirement).

Further, by prohibiting coverage of various procedures only when they are "performed for the purposes of assisting an individual with a physical gender transition," § 44-42-310(6), the Coverage Restrictions facially bar coverage for medically necessary procedures "based on [a gender dysphoria] diagnosis alone," *cf. supra* Statement of Facts § IV, and thus violates the availability requirement. *Kadel*, 100 F.4th at 162.

# B. The Coverage Restrictions' Prohibition on Gender-Affirming Care Violates the Medicaid Act's Comparability Requirement

The Coverage Restrictions violate the comparability requirement by failing to ensure transgender individuals receive services "equal in amount, duration, and scope" with other Medicaid beneficiaries. *Kadel*, 100 F.4th at 162 (citing 42 C.F.R. § 440.240(b)(1)-(2)). As discussed in Section I.A, *supra*, these restrictions prohibit funding for care to transgender individuals that Medicaid would otherwise provide. Because South Carolina "cannot get around the comparability requirement by defining the relevant services as services aimed at treating only some medical conditions (i.e., non-gender dysphoria conditions) any more than it can get around the Equal Protection Clause by doing so," this restriction violates the Medicaid Act's comparability requirement. *Kadel*, 100 F.4th at 162–63; *see also White v. Beal*, 555 F.2d 1146, 1151 (3d Cir. 1977) ("[N]othing in the federal statute [] permits discrimination based upon etiology rather than need for the service.").

#### V. A Preliminary Injunction is Necessary

#### A. Plaintiffs Suffer Immediate and Irreparable Harm While H 4624 is in Effect

If permitted to remain in effect, H 4624 will continue to inflict severe and irreparable harm on Plaintiffs and members of the putative Plaintiff Classes for which no adequate remedy at law exists. As discussed above, the law violates the constitutional rights of transgender South Carolinians and their families, which is itself irreparable harm. "Because there is a likely constitutional violation, the irreparable harm factor is satisfied." *Leaders of a Beautiful Struggle v. Baltimore Police Dep't*, 2 F.4th 330, 346 (4th Cir. 2021).

But the harm of the statute goes much further. By enforcing H 4624, Defendants deprive patients of vitally important medical care by either preventing the initiation of treatment or cutting patients off from necessary treatment; force families to watch their children suffer or incur the significant expense of regular travel or relocation out-of-state to access care; and compel medical

providers to abandon their patients while also threatening their medical licenses. The irreversible harm to transgender adolescents who imminently may be forced to undergo endogenous puberty clearly outweighs any potential state interest in immediate enforcement of the Ban. The Coverage Restrictions similarly prevent adult South Carolinians that rely on public insurance for their healthcare coverage —and those receiving their care from public hospitals—from receiving medically necessary gender-affirming care.

Defendants' denial of this care not only results in the prolonging and intensification of gender dysphoria; the medical consensus is that it causes additional distress and poses other health risks, including depression, posttraumatic stress disorder, and suicidality. Karasic Decl. ¶¶ 65-66 (citing the recommendations of the American Medical Association, American Psychiatric Association, and American College of Obstetricians and Gynecologists). "[I]f left untreated," gender dysphoria diagnoses such as those received by Plaintiffs "can lead to self-mutilation and suicide." *Kadel*, 620 F. Supp. 3d at 380 (M.D.N.C. 2022).

Plaintiffs have suffered—and will continue to suffer—severe and irreparable harm as a result of H 4624, including the deprivation of medically necessary care, the denial of insurance coverage for necessary (and long scheduled) procedures, and the inability to access necessary care from the medical professionals who are best positioned to provide Plaintiffs with safe, effective care.

#### 1. Plaintiffs Cannot Access Medically Necessary Care

Plaintiff Nancy Noe and her 15-year-old daughter, Nina Noe live in South Carolina. Nancy Noe Decl. ¶ 2. Nina is transgender. Nancy Noe Decl. ¶ 5. Nina was assigned the male sex at birth, but she and her mother understood at a very young age that Nina was not a boy. Nancy Noe Decl. ¶ 5; Nina Noe Decl. ¶ 4. At age seven, Nina told her mother that she had a "girl brain and a

boy body." Nancy Noe Decl. ¶ 6; Nina Noe Decl. ¶ 5. Nina was later diagnosed with gender dysphoria. Nancy Noe Decl. ¶ 8. After consulting with physicians Nina and Nancy decided to start Nina on HRT as medically necessary treatment for her gender dysphoria. Nancy Noe Decl. ¶ 12. Nina has been on hormone treatment for several years now and is "elated" with the physical changes she has seen, which have helped relieve her gender dysphoria and brought her greater confidence. Nancy Noe Decl. ¶ 13; Nina Noe Decl. ¶ 13. Nina receives healthcare coverage through a Medicaid plan, and up until now Medicaid has covered her hormone therapy. Nancy Noe Decl. ¶ 14. Nina and Nancy are now deeply concerned that they will not be able to find care for Nina in South Carolina, and that they will not receive any coverage under Medicaid for treatment obtained elsewhere. Nancy Noe Decl. ¶ 16. Nina is deeply distressed over the prospect of losing access to gender-affirming care, and her mother is worried about her daughter's future and mental health. Nina Noe Decl. ¶ 14. Nancy is also worried about the financial future of her family should they be forced to pay for Nina's care out of pocket. Nancy Noe Decl. ¶ 16.

Plaintiff Gary Goe and his seventeen-year-old son Grant Goe live in Anderson County, South Carolina. Gary Goe Decl. ¶ 3; Grant Goe Decl. ¶ 3. Grant is transgender. Grant Goe Decl. ¶ 4. He has known since a very young age that his gender identity did not match his sex assigned at birth, and he has lived as the boy he is for nearly four years. Grant Goe Decl. ¶¶ 5, 7-8. After careful consideration by Gary, his wife, Grant, and Grant's medical team, Gary and his wife decided to start Grant on HRT as medically necessary treatment for his gender dysphoria. Gary Goe Decl. ¶¶ 10-17. Grant has been on HRT for the last four months and has experienced significant positive improvement, which his family has witnessed. Gary Goe Decl. ¶¶ 19, 22; Grant Goe Decl. ¶¶ 16-17. Grant is terrified at the possibility of not being able to access the care that has greatly improved his life because of the Healthcare Ban. Grant Goe Decl. ¶¶ 18-21. Gary and his

wife are so worried about the impact on Grant's health and life from stopping HRT that they have been forced to consider uprooting their family to go to a state that allows Grant to continue accessing this life-saving care. Gary Goe Decl. ¶ 27.

## 2. Plaintiffs Are Denied Insurance Coverage for Medically Necessary Care

*Plaintiff Jane Doe* is a transgender woman living in Charleston, South Carolina. Doe Decl. ¶ 3. She is scheduled for surgery on November 11, 2024 that will not go forward absent a preliminary injunction. Doe Decl. ¶ 10. She is a physician employed by the state of South Carolina and has been living in the state with her wife since 2020. Doe Decl. ¶ 4. Doe has experienced feelings of gender dysphoria from a young age, but did not feel that she had the space to come out as transgender. Doe Decl. ¶¶ 3, 6. Doe was able to safely live as herself in 2020, when she moved to South Carolina, and was formally diagnosed with gender dysphoria the next year. Doe Decl. ¶¶ 7, 8. After consulting with her physicians, Doe began hormone treatment. Doe Decl. ¶ 8. This treatment has dramatically relieved Doe's symptoms of dysphoria and her overall well-being. Doe Decl. ¶ 9. After further consultation with physicians, Doe had hoped to receive surgery this year as the next step in her treatment plan. Doe Decl. ¶ 4. Doe is insured through a state healthcare plan administered by PEBA. Doe Decl. ¶ 11. Doe had hoped to have her surgery completed before the end of the year so that she could be fully recovered before her wife gives birth in February of next year. Doe Decl. ¶ 10. However, she was informed in July of 2024 that PEBA is required to adhere to state law, thereby indicating to her that they would no longer cover her gender-affirming surgery. Doe Decl. ¶ 12. Doe and her family were devastated to receive this news, especially because she and her wife have already taken on a great financial burden to welcome a baby next year. Doe Decl. ¶ 14. Although she has scheduled her surgical procedure for November 11, 2024, she will not be able to access this care without insurance coverage due to the cost. Doe Decl. ¶ 10. Doe needs this medically necessary healthcare to be the best version of herself, for her family and for her patients at South Carolina hospitals. Doe Decl. ¶¶ 14, 16. She is disappointed that the state has interfered in a decision best left to patients and doctors, concerned about the financial effect it will have on her family, and terrified that she will not be able to access this care before the birth of her child. Doe Decl. ¶¶ 14, 16.

Plaintiff Jill Ray is a transgender woman living in South Carolina. Ray Decl. ¶¶ 3, 8. Ray has been receiving gender-affirming care for her gender dysphoria for almost four years. Ray Decl. ¶¶ 9-11. Before she began receiving gender-affirming care, Ray was so depressed and anxious she could not even leave her home. Ray Decl. ¶¶ 10. Gender-affirming care has given Ray her life back. It has brought her closer to her spouse and enabled her to build a loving and happy community. Ray Decl. ¶¶ 17, 18. Ray plans to undergo gender-affirming surgery, which her doctors have referred her for as medically necessary treatment for her gender dysphoria, to bring her body into alignment with who she is. Ray Decl. ¶¶ 19, 20. Without gender-affirming surgery, she will experience pain and harm because without it she cannot be her true self. Ray Decl. ¶¶ 20. Ray cannot pay the exorbitant cost of gender-affirming surgery out-of-pocket. Ray Decl. ¶¶ 14, 23. Without the PEBA coverage she receives through her spouse, Ray will not be able to get her medically necessary procedure. Ray Decl. ¶¶ 16, 22. Worrying about not being able to get the care she needs is stressful and debilitating for Ray, who is forced to contemplate feeling unsafe in her own body. Ray Decl. ¶25.

3. Plaintiffs Cannot Access Necessary Care from the Medical Professionals Well-Suited to Provide Them with Safe and Effective Care

**Plaintiff Sterling Misanin** is a transgender man living in Charleston, South Carolina. Misanin Decl. ¶ 3. Misanin has experienced feelings of gender dysphoria since he was a young child,

but first received a diagnosis of gender dysphoria in March of 2022. Misanin Decl. ¶¶ 6, 13. After consulting with physicians, Misanin began hormone therapy that year, and after further consultation, was able to undergo chest masculinization surgery. Misanin Decl. ¶ 13, 17. Misanin's gender affirming care has greatly improved his day-to-day life. Misanin Decl. ¶¶ 16-18, 28. After speaking with his primary care provider and other members of his care team at MUSC, Misanin determined that the next step in his treatment plan would be to receive a hysterectomy, and so Misanin scheduled a procedure with MUSC for June 28, 2024. Misanin Decl. ¶¶ 12, 19, 20. MUSC subsequently informed him, just a few days before surgery, that due to the passage of H 4624 they would no longer be able to provide gender affirming care. Misanin Decl. ¶ 23. The Public Funds Restriction not only has delayed his access to medically necessary care for months as he goes through the arduous process of finding another provider and receiving new preauthorization form his insurer, Misanin Decl. ¶ 25, 26, it continues to deprive him of the ability to access future care, including additional surgeries to alleviate his dysphoria, from his care team at MUSC. Misanin Decl. ¶¶ 12, 19, 23. Being turned away from MUSC has forced Misanin to seek care at clinics which are less able to protect his medical privacy. Misanin Decl. ¶ 19, 25.

## B. The Balance of Equities Favors Plaintiffs and a Preliminary Injunction is in the Public Interest

The balance of equities weighs heavily in favor of Plaintiffs. The harms inflicted by H 4624 far outweigh any potential harms that Defendants might face if preliminary injunctive relief is granted, as Defendants would only temporarily lose the ability to *disrupt* the *status quo*— a *status quo* grounded in years of established medical practice—with a new law that does not advance any legitimate state interest and is likely to be held unconstitutional. *See League of Women Voters of N.C. v. North Carolina*, 769 F.3d 224, 236 (4th Cir. 2014) ("[The Fourth Circuit has] defined the status quo for this purpose to be the last uncontested status between the parties which preceded the

controversy . . . [I]t is sometimes necessary to require a party who has recently disturbed the status quo to reverse its actions, but such an injunction restores, rather than disturbs, the status quo ante."). "[A] state is in no way harmed by issuance of a preliminary injunction which prevents the state from enforcing restrictions likely to be found unconstitutional. If anything, the system is improved by such an injunction." *Leaders of a Beautiful Struggle*, 2 F.4th at 346 (citations omitted).

Similarly, granting an injunction in this case will undoubtedly serve the public interest. As the Fourth Circuit has made clear, "it is well-established that the public interest favors protecting constitutional rights." *Id.*; *see also Centro Tepeyac v. Montgomery Cnty.*, 722 F.3d 184, 191 (4th Cir. 2013).

These harms—including the deprivation of medically necessary care, the denial of insurance coverage for necessary procedures, and the inability to access necessary care from the medical professionals who are well-suited to provide safe and effective care—are similarly being experienced by members of the proposed Plaintiff Classes all across the State of South Carolina.

#### VI. A Classwide Injunction Is Necessary to Protect the Classes

As discussed in Section V of the Complaint and in the Motion for Class Certification, the Class Representatives and the members of the Classes they represent have identical claims for injunctive relief, and the Class members have suffered the same injury as the Class Representatives. Courts have recognized that "the lack of formal class certification does not create an obstacle to classwide preliminary injunctive relief when activities of the defendant are directed generally against a class of persons." *Rodriguez v. Providence Comty. Corrs., Inc.*, 155 F. Supp. 3d 758, 767 (M.D. Tenn. 2015); *see also J.O.P. v. U.S. Dep't of Homeland Security*, 409 F. Supp. 3d 367, 376 (D. Md. 2019) ("[C]ourts may enter class-wide injunctive relief before certification of a class.");

Brandon v. Marshall, No. 2:24-CV-00265, 2024 WL 2834014 (S.D. W. Va. June 4, 2024) (granting a preliminary injunction to a putative, pre-certification class); Newberg on Class Actions § 4:30 (5th ed. 2013) ("[A] court may issue a preliminary injunction in class suits prior to a ruling on the merits."). Because the Healthcare Ban is directed against South Carolinian transgender minors and their parents and the Public Funds Restriction is directed against transgender South Carolinians who rely on state-funded health insurance and healthcare, the Court should grant a preliminary injunction enjoining enforcement of the harmful provisions of H 4624 against the respective putative Classes.

Plaintiffs' and the Classes' entitlement to classwide relief is especially strong in light of the prima facie case for class certification set forth in Plaintiffs' pending motion. Plaintiffs' sought-after relief—the enjoinment of the Healthcare Ban as to the members of the Minor Class and the Parent Class, Compl. at 60 (Request for Relief § B), and the enjoinment of the Public Funds Restriction as to the members of the Insurance Class and the MUSC Class, *id.*—is necessary to prevent irreparable harm against the members of each Class.

#### **CONCLUSION**

Plaintiffs respectfully request that the Court enjoin Defendants from enforcing H 4624 against the Plaintiffs and members of the putative Classes during the pendency of this litigation.

Date: August 30, 2024

Respectfully submitted,

#### /s/ Meredith McPhail

Allen Chaney (Fed. Id. No. 13181) Meredith McPhail (Fed. Id. No. 13500)

#### **ACLU OF SOUTH CAROLINA**

P.O. Box 1668 Columbia, SC 29202 T: 864-372-6881 achaney@aclusc.org mmcphail@aclusc.org

#### /s/ Sruti Swaminathan

Sruti Swaminathan\* Harper Seldin\*

## AMERICAN CIVIL LIBERTIES UNION FOUNDATION

125 Broad St., Fl 18 New York, NY 10004 T: 212-549-2500 hseldin@aclu.org sswaminathan@aclu.org

#### /s/ Julie Singer

David S. Flugman\* Corey Stoughton\* Julie Singer\*

#### **SELENDY GAY PLLC**

1290 Avenue of the Americas New York, NY 10104 T: 212-390-9000 dflugman@selendygay.com cstoughton@selendygay.com jsinger@selendygay.com

Attorneys for Plaintiffs

<sup>\*</sup> Application for Admission Pro Hac Vice Forthcoming

#### IN THE UNITED STATES DISTRICT COURT FOR THE DISTRICT OF SOUTH CAROLINA Charleston Division

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Plaintiffs,

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Case	NO.		

v.

ALAN WILSON, in his official capacity as the Attorney General of South Carolina, et al.,

Defendants.

#### EXPERT DECLARATION OF DAN H. KARASIC, M.D.

I, DAN H. KARASIC, 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.
- 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. In preparing this declaration, I reviewed South Carolina House Bill 4624 (hereafter, "the ban"). My opinions contained in this declaration are based on: my decades of clinical experience as a psychiatrist treating patients with gender dysphoria, including adolescents, and adults; my knowledge of the peer-reviewed research, regarding the treatment of gender dysphoria, which reflects advancements in the field of transgender health; my knowledge of the clinical practice guidelines for the treatment of gender dysphoria, including my work as a contributing author of the eighth edition of the World Professional Association for Transgender Health

("WPATH") Standards of Care for the Health of Transgender and Gender Diverse People (SOC 8); and my review of any of the materials cited herein.

5. The materials I have relied upon in preparing this declaration are the same types of materials that experts in my field of study regularly rely upon when forming opinions on the subject. I may wish to supplement these opinions or the bases for them as a result of new scientific research or publications or in response to statements and issues that may arise in my area of expertise.

#### **SUMMARY OF OPINIONS**

- 6. The ban prohibits medical treatments that are part of widely-accepted medical protocols for the treatment of adolescents with gender dysphoria. The following medical groups, among others, recognize that gender-affirming health care is safe and effective for adolescents: the American Academy of Child and Adolescent Psychiatry, the American Academy of Pediatrics, the American Psychological Association, the American Psychiatric Association, and the American Medical Association, among many other mainstream medical organizations.
- 7. The accepted protocols for the treatment of adolescents with gender dysphoria provide for careful mental health assessments, including of co-occurring conditions; stringent criteria for eligibility for each treatment; and a thorough informed consent process with the adolescent and their parents, before any medical interventions are initiated.
- 8. Decades of medical research and clinical experience have demonstrated that the banned medical treatments are safe, effective, and medically necessary to relieve gender dysphoria for many adolescents.
- 9. I have seen first-hand, countless times over decades of practice, the many benefits of this treatment. Denying gender-affirming medical care to adolescents for whom it is medically

indicated puts them at risk of significant harm to their health and well-being, including heightened risk of depression and suicidality.

- 10. For adolescents for whom gender-affirming medical care is indicated, no alternative treatments have been demonstrated to be effective.
- 11. When gender dysphoria persists until the beginning of puberty, it is rare for it to resolve on its own. The "watchful waiting" approach followed by some clinicians for prepubertal children does not apply to adolescents with gender dysphoria.
- 12. Gender affirming care for adults is efficacious and safe as treatment for gender dysphoria, with many decades of clinical experience and research demonstrating its benefits. The denial of medically indicated care to transgender people not only results in the prolonging of their gender dysphoria, but causes additional distress and poses other health risks, such as depression, posttraumatic stress disorder, and suicidality. For patients for whom genderaffirming medical care is indicated, no alternative treatments have been demonstrated to be effective.

#### I. BACKGROUND AND QUALIFICATIONS

- 13. I am a Professor Emeritus of Psychiatry at the University of California San Francisco ("UCSF") School of Medicine. I have been on faculty at the University of California San Francisco since 1991. I have also had a telepsychiatry private practice since 2020.
- 14. I received my Doctor of Medicine (M.D.) degree from the Yale Medical School in 1987. In 1991, I completed my residency in psychiatry at the University of California Los Angeles ("UCLA") Neuropsychiatric Institute, and from 1990 to 1991, I was a postdoctoral fellow at UCLA in a research training program in mental health services for persons living with AIDS.

- 15. For over thirty years, I have worked with patients with gender dysphoria. I am a Distinguished Life Fellow of the American Psychiatric Association and have been the chair of the American Psychiatric Association Workgroup on Gender Dysphoria, as well as the sole author of the chapter on transgender care in the American Psychiatric Press's Clinical Manual of Cultural Psychiatry, Second Edition.
- 16. Over the past 33 years, I have provided care for thousands of transgender patients. For 17 years, I was the psychiatrist for the Dimensions Clinic for transgender youth ages 12-25 years old in San Francisco, and also have provided care for many adolescents in my UCSF faculty practice and my current private practice.
- 17. I previously sat on the Board of Directors of the World Professional Association for Transgender Health (WPATH) and am a co-author of the WPATH Standards of Care for the Health of Transsexual, Transgender, and Gender Nonconforming People, Version 8, which are the internationally accepted guidelines designed to promote the health and welfare of transgender, transsexual, and gender variant persons. I was also a co-author of WPATH SOC 7.
- 18. As a member of the WPATH Global Education Initiative, I helped develop a specialty certification program in transgender health and helped train over 2,000 health providers. At UCSF, I developed protocols and outcome measures for the Transgender Surgery Program at the UCSF Medical Center. I also served on the Medical Advisory Board for the UCSF Center of Excellence for Transgender Care, and co-wrote the mental health section of the original *Guidelines for the Primary and Gender-Affirming Care of Transgender and Gender Nonbinary People* and the revision in 2016.
- 19. I have also worked with the San Francisco Department of Public Health, having developed and implemented programs for the care of transgender patients and for mental health

assessments for gender-affirming surgery. I served on the City and County of San Francisco Human Rights Commission's LGBT Advisory Committee, and I have been an expert consultant for California state agencies and on multiple occasions for the United Nations Development Programme on international issues in transgender care.

- 20. I have held numerous clinical positions concurrent to my clinical professorship at UCSF. Among these, I served as an attending psychiatrist for San Francisco General Hospital's consultation-liaison service for AIDS care, as an outpatient psychiatrist for HIV-AIDS patients at UCSF, as a psychiatrist for the Transgender Life Care Program and the Dimensions Clinic at Castro Mission Health Center, and the founder and co-lead of the UCSF Alliance Health Project's Transgender Team. In these clinical roles, I specialized in the evaluation and treatment of transgender, gender dysphoric, and HIV-positive patients. I also regularly provide consultation on challenging cases to psychologists and other psychotherapists working with transgender and gender dysphoric patients. I have been a consultant in transgender care to the California Department of State Hospitals and the California Department of Corrections and Rehabilitation on the care of incarcerated transgender people.
- 21. As part of my psychiatric practice treating individuals diagnosed with gender dysphoria and who receive medical and surgical treatment for that condition, as well as a co-author of the WPATH Standards of Care and UCSF's Guidelines for the Primary and Gender-Affirming Care of Transgender and Gender Nonbinary People, I am and must be familiar with additional aspects of medical care for the diagnosis of gender dysphoria, beyond mental health treatment, assessment, and diagnosis.

- 22. In addition to this work, I have done research on the treatment of depression. I have authored many articles and book chapters and edited the book *Sexual and Gender Diagnoses of the Diagnostic and Statistical Manual (DSM): A Reevaluation*.
- 23. Since 2018, I have performed over 130 independent medical reviews for the State of California to determine the medical necessity of transgender care in appeals of denial of insurance coverage.
- 24. In preparing this declaration, I have relied on my training and years of research and clinical experience, as set out in my curriculum vitae, and on the materials listed therein. A true and accurate copy of my curriculum vitae is attached hereto as **Exhibit A**. It documents my education, training, research, and years of experience in this field and includes a list of publications.
- 25. I have also reviewed the materials cited in the bibliography attached hereto as **Exhibit B**. These sources are authoritative, scientific peer-reviewed publications.
- 26. The materials I have relied upon in preparing this declaration are the same types of materials that experts in my field of study regularly rely upon when forming opinions on the subject. 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.

#### **Prior Testimony**

27. In the last four years, I have testified as an expert by deposition in *Kadel* v. *Folwell*, 19-cv-00272 (M.D.N.C.), *Fain v. Crouch*, 20-cv-00740 (S.D.W. Va.), *C.P. v. Blue Cross Blue Shield of Illinois*, No.20-cv-06145-RJB (W.D. Wash.), *K.C. et al. vs Individual Members of the* 

Indiana Licensing Board, et al, No. 23-2366, Boe v. Marshall, No. 2:22-cv-184-LCB (N.D. Ala. by deposition and trial in Dekker et al., v. Weida, et al., No. 4:22-cv-325 (N.D. Fla), Doe v. Ladapo, No. 4:23-cv-00114 (N.D. Fla.); and Dylan Brandt, et al., v. Leslie Rutledge, et al., No. 21-CV-450 (E.D. Ark.).

#### **Compensation**

28. I am being compensated for my work on this matter at a rate of \$400.00 per hour for preparation of declarations and expert reports. I will be compensated \$3,200.00 per day for any deposition testimony or trial testimony. My compensation does not depend on the outcome of this litigation, the opinions I express, or the testimony I may provide.

#### II. EXPERT OPINIONS

#### A. Gender Identity

- 29. At birth, infants are assigned a sex, either male or female, based on the appearance of their external genitalia.
- 30. The ban defines sex as "the biological state of being male or female, based on the individual's sex organs, chromosomes, and endogenous hormone profiles." But the reality is that sex is complicated and multifactorial. Aside from external genital characteristics, chromosomes, and endogenous hormones, other factors related to sex include gonads, gender identity, and variations in brain structure and function. Because these factors may not always be in perfect alignment as typically male or typically female, "the terms biological sex and biological male or female are imprecise and should be avoided." (Hembree, et al., 2017).
- 31. Gender identity is "a person's deep felt, inherent sense of being a girl, woman, or female; a man, or male; a blend of male or female; [or another] gender." (American Psychological

Association, 2015, p. 862). Everyone has a gender identity. Gender identity does not always align with a person's sex assigned at birth. Gender identity, which has biological bases, is not a product of external influence and not subject to voluntary change. As documented by multiple leading medical authorities, efforts to change a person's gender identity are ineffective, can cause harm, and are unethical. (American Psychological Association, 2021; Byne, et al., 2018; Coleman, et al., 2012, Coleman, et al., 2022).

32. For most people, their sex assigned at birth, or assigned sex, matches that person's gender identity. For transgender people, their assigned sex does not align with their gender identity.

#### B. Gender Dysphoria and Its Diagnostic Criteria

- 33. The term "gender dysphoria" is distress related to the incongruence between one's gender identity and attributes related to one's sex assigned at birth.
- 34. "Gender Dysphoria in Children" is a diagnosis applied only to pre-pubertal children in the Diagnostic and Statistical Manual Fifth Edition (DSM-5), released in 2013. The criteria are:
  - A. A marked incongruence between one's experienced/expressed gender and assigned gender, of at least 6 months duration, as manifested by at least six of the following (one of which must be Criterion A1):
    - 1. A strong desire to be of the other gender or insistence that one is the other gender (or some alternative gender different from one's assigned gender).
    - 2. In boys (assigned gender), a strong preference for cross-dressing or simulating female attire; or in girls (assigned gender), a strong preference for wearing only typical masculine clothing and a strong resistance to the wearing of typical feminine clothing.
    - 3. A strong preference for cross-gender roles in make-believe play or fantasy play.
    - 4. A strong preference for the toys, games, or activities stereotypically used or engaged in by the other gender.
    - 5. A strong preference for playmates of the other gender.
    - 6. In boys (assigned gender), a strong rejection of typically masculine toys, games, and activities and a strong avoidance of rough-and-tumble play; or in girls (assigned gender), a strong rejection of typically feminine toys, games, and activities.
    - 7. A strong dislike of one's sexual anatomy.

- 8. A strong desire for the primary and/or secondary sex characteristics that match one's experienced gender.
- B. The condition is associated with clinically significant distress or impairment in social circles, school, or other important areas of functioning.
- 35. The DSM-5 has a separate diagnosis of "Gender Dysphoria in Adolescents and Adults". The criteria are:
  - A. A marked incongruence between experienced/expressed gender and assigned gender, of at least 6 months' duration, as manifested by at least two of the following:
    - 1. A marked incongruence between one's experienced/expressed gender and primary or secondary sex characteristics (or in young adolescents, the anticipated secondary sex characteristics).
    - 2. A strong desire to be rid of one's primary and/or secondary sex characteristics because of a marked incongruence with one's experienced/expressed gender (or in young adolescents, a desire to prevent the development of the anticipated secondary sex characteristics).
    - 3. A strong desire for the primary and/or secondary sex characteristics of the other gender.
    - 4. A strong desire to be of the other gender (or some alternative gender different from one's assigned gender).
    - 5. A strong desire to be treated as the other gender (or some alternative gender different from one's assigned gender).
    - 6. A strong conviction that one has the typical feelings and reactions of the other gender (or some alternative gender different from one's assigned gender).
  - B. The condition is associated with clinically significant distress or impairment in social, occupational, or other important areas of functioning.
- 36. Simply being transgender or gender nonconforming is not a medical condition to be treated. As the DSM-5 recognizes, diagnosis and treatment are "focus[ed] on dysphoria as the clinical problem, not identity per se." (DSM-5, at 451). The DSM-5 unequivocally repudiated the outdated view that being transgender is a pathology by revising the diagnostic criteria (and

name) of gender dysphoria to recognize the clinical distress as the focus of the treatment, not the patient's transgender status.

#### C. Gender Dysphoria Treatment Protocols for Adolescents

- 37. The World Professional Association of Transgender Health (WPATH) has issued Standards of Care for the Health of Transsexual, Transgender, and Gender Nonconforming People ("WPATH SOC") since 1979. The current version, published in 2022, is WPATH SOC 8. The SOC 8 provides guidelines for multidisciplinary care of transgender individuals, including children and adolescents, and describes criteria for medical interventions to treat gender dysphoria, including hormone treatment and surgery when medically indicated.
- 38. The SOC 8 is based upon a rigorous and methodological evidence-based approach to outline treatment recommendations. These recommendations are evidence-based, informed by a systematic review of evidence and an assessment of the benefits and harms of alternative care options, as well as expert consensus. The process for development of SOC 8 incorporated recommendations on clinical practice guideline development from the National Academies of Medicine and The World Health Organization. Its recommendations were graded using a modified GRADE (Grading of Recommendations, Assessment, Development, and Evaluations) methodology considering the available evidence supporting interventions, risks and harms, and feasibility and acceptability.
- 39. The WPATH Standards of Care are widely accepted in the medical community and relied upon by clinicians treating patients with gender dysphoria.
- 40. A clinical practice guideline from the Endocrine Society (the Endocrine Society Guideline) provides similar protocols for the medically necessary treatment of gender dysphoria. (Hembree, et al, 2017).

- 41. In accordance with the WPATH SOC 8 and the Endocrine Society Guideline, medical interventions to treat gender dysphoria may include treatment with pubertal suppression, hormones, and surgery depending on the age and medical needs of each individual.
- 42. No medical or surgical treatment for gender dysphoria is provided to pre-pubertal children. For pre-pubertal children, interventions are directed at supporting the child with family, peers, and at school, as well as supportive individual psychotherapy for the child as needed.
- 43. Adolescents (which generally refers to minors after the onset of puberty) with gender dysphoria may be treated with medications to delay pubertal changes in the early stages of puberty if they are causing distress. Puberty blockers allow the adolescent time to better understand their gender identity, while delaying distress from the development of secondary sex characteristics such as breasts or facial hair.
- 44. Under the WPATH Standards of Care, puberty-delaying medication for transgender adolescents after the beginning of puberty and gender-affirming hormone therapy for older adolescents may be medically indicated if the following criteria are met: (a) Gender diversity/incongruence is marked and sustained over time; (b) Meets the diagnostic criteria of Gender Dysphoria; (c) Demonstrates the emotional and cognitive maturity required to provide informed consent/assent for the treatment; (d) Mental health concerns (if any) that may interfere with diagnostic clarity, capacity to consent, and gender-affirming medical treatments have been addressed; sufficiently so that gender-affirming medical treatment can be provided optimally; (e) Informed of the reproductive effects, including the potential loss of fertility and the available options to preserve fertility.

- 45. For minor patients, all treatment decisions are made in consultation with the patient and the patient's parents or guardian. Consent for medical intervention is provided by the parent in the case of any minor receiving treatment.
- 46. After ongoing work with mental health professionals and when the adolescent has lived in accordance with their gender identity for a significant period of time, they may start treatment with hormones (testosterone for transgender boys, estrogen and testosterone suppressants for transgender girls) if and when medically indicated.
- 47. Affirming care for transgender youth does not mean steering them in any particular direction, but rather supporting them through their period of exploration of gender expression and increasing self-awareness of their identity. (Coleman, et al., 2012, at 181; Ehrensaft, 2017).
- 48. The WPATH SOC 8 and the Endocrine Society Guideline further provide that before any medical or surgical interventions are provided to adolescents, a careful mental health assessment should be conducted to ascertain whether the diagnostic criteria for Gender Dysphoria in Adolescents and Adults are met, and the appropriateness of such care for the patient. The Endocrine Society Guideline states that only "[mental health professionals] who ha[ve] training/experience in child and adolescent gender development (as well as child and adolescent psychopathology) should make the diagnosis," which usually includes "a complete psychodiagnostic assessment." (Hembree, 2017). It further provides that because gender dysphoria "may be accompanied with psychological or psychiatric problems" it is necessary that clinicians involved in diagnosis and psychosocial assessment meet specific competency requirements and that they undertake or refer for appropriate psychological or psychiatric treatment. *Id.* And "in cases in which severe psychopathology" "interfere[s] with diagnostic work or make[s] satisfactory treatment unlikely, clinicians should assist the adolescent in managing these other issues." *Id.*

49. As with all medical care, the care provided to transgender young people with gender dysphoria is tailored to the unique needs of each patient based on their individual experiences, proximity to specialists, and general health, as well as the clinical experience of practitioners.

#### **D.** Evidence of Efficacy of Medical Treatments

- 50. There is substantial evidence that puberty blockers and hormone therapy are effective treatments for adolescents with gender dysphoria. This evidence includes scientific studies assessing mental health outcomes for adolescents who are treated with these interventions, and decades of clinical experience.
- 51. Medical treatment for gender dysphoria has been studied for over half a century, and there is substantial evidence that it improves quality of life and measures of mental health. (Cornell, "What We Know" review).
- 52. The studies on gender-affirming medical care for adolescents with gender dysphoria are consistent with decades of clinical experience of mental health providers across the U.S. and around the world. At professional conferences and other settings in which I interact with colleagues, clinicians report that gender-affirming medical care, for those for whom it is indicated, provides great clinical benefit. In my 30 years of clinical experience treating gender dysphoric patients, including 19 years working with adolescents, I have seen the benefits of gender affirming medical care on my patients' health and well-being. I have seen many patients show improvement in mental health, as well as in performance in school, in social functioning with peers, and in family relationships when they experience relief from gender dysphoria with gender-affirming medical care.
- 53. Claims that the risks outweigh the benefits of treatment are without foundation. The benefits of treatment, and risks of withholding care, for transgender youth with gender dysphoria

are clear, as described and referenced above. In addition, a treating doctor will not offer genderaffirming medical treatments unless they have concluded after weighing the risks and benefits of
care that treatment is appropriate. The risks and benefits of care are discussed with the minor's
parents, who must consent to treatment, and to the youth, who must assent. This process is no
different than the informed consent process for other treatments. However, for gender-affirming
medical care, there may be the additional safeguard of the assessment by a mental health
professional, who, in addition to diagnosing gender dysphoria, also reviews the risks and benefits
of treatment with the youth and parents.

- 54. Regret among those who are treated with gender-affirming medical care is rare. For example, in one study in the Netherlands, none of the youth who received puberty blockers, hormones, and surgery, and followed over an 8-year period expressed regret. (DeVries 2014.) Zucker et al. (2010), summarizing key studies on regret for adolescents referred for surgery when they reached the age of majority in the Netherlands, states, "there was virtually no evidence of regret, suggesting that the intervention was effective." This is consistent with my observations in decades of clinical practice. Cavve et al. (2024) examined the outcomes of 548 of the 552 youth referred to the pediatric gender clinic in Perth, Australia. This study is exceptional in medical literature generally for the extremely high share of former patients the researchers were able to reach. Of 196 youth who were started on puberty blockers or hormones, only 2 (1.0%) discontinued medical treatment because of reidentification with birth sex.
- 55. Regret rates for gender affirming surgery in adults are also very low. A pooled review across multiple studies of 7,928 patients receiving gender affirming surgery showed a regret rate of 1%. (Bustos, et al., 2021). Over 50 years of gender affirming surgery in Sweden, the regret rate, as measured by legal gender change reversal, was 2%. (Dhejne, et al 2014). A recent

study found very high satisfaction and very little regret among those receiving gender-affirming mastectomy at one U.S. center following a longitudinal period ranging from 2 to 30 years. (Bruce, et al 2023). Regret rates after gender-affirming surgeries are very low compared to other surgeries, (Thornton, et al 2024); for example, 47% of women expressed at least some regret after reconstructive breast surgery following mastectomy for breast cancer, (Sheehan et al 2008).

Many bills like the one passed in South Carolina claim that for most youth, gender 56. dysphoria will resolve on its own, making medical interventions unnecessary. These claims are inaccurate and are often in reference to a body of literature, sometimes referred to as "desistance" studies, that found that many pre-pubertal children diagnosed with Gender Identity Disorder in Children (a precursor diagnosis to Gender Dysphoria in Children in the DMS III-R and DSM-IV) identified with their sex assigned at birth at a later follow up. Reliance on this research is misplaced for two reasons. First, the diagnostic criteria for Gender Identity Disorder in Children were different from the diagnostic criteria for Gender Dysphoria in Children in meaningful ways that result in the desistance studies grossly overestimating the rate of desistance. Gender Identity Disorder in Children did not require identification with a gender other than the one assigned to the person at birth. A diagnosis could be made solely on the basis of gender atypical behavior, such as a boy who prefers playing with dolls and dress-up. This means that a child could be diagnosed with Gender Identity Disorder without ever having a transgender identity and, therefore, any study that selected subjects based on this diagnosis could include individuals who never had a gender identity that differed from the sex they were assigned at birth. This problem with the diagnosis was remedied with the DSM-V diagnosis of "Gender Dysphoria in Children," which requires a child to have "a strong desire to be of the other gender or an insistence that one is the other gender (or some alternative gender different from one's assigned gender)." Under this updated diagnosis,

a child could not be diagnosed based solely on gender atypical behavior without identifying as a different sex than the one assigned at birth. Because the desistance studies were all conducted prior to the DSM-V, a child did not need to have a transgender identity to be included in the study. Additionally, in some studies, the children did not even meet the looser criteria for Gender Identity Disorder, but were entered in the studies based on parents bringing the youth to the gender clinic. It is not surprising that many children in these studies did not identify as transgender at follow-up as these children were never transgender and never identified with a gender different from their assigned sex at birth.

- 57. Second, the desistance studies focused only on pre-pubertal children. Whatever conclusions can be drawn from them about the likelihood of persistence of gender dysphoria in pre-pubertal children, which again is uncertain given the diagnostic limitations identified above—data indicates that once youth reach the beginning of puberty and identify as transgender, desistance is rare. (DeVries, et al., 2011; Wiepjies, et al 2018, Brik, et al, 2020; Cavve, et al 2024). This data is consistent with clinical experience. In fact, the Amsterdam and Toronto gender centers that published the desistance data on pre-pubertal children referenced above provided medical interventions to youth whose gender dysphoria persisted into adolescence. (Zucker, et al 2010, DeVries, et al 2014). No medical treatments are used prior to adolescence, so the persistence and desistance rates of pre-pubertal children do not inform the decision whether or not to initiate gender affirming medical treatments in adolescents.
- 58. "Watchful waiting" is an approach that has been described with respect to the care of pre-pubertal children with gender dysphoria. This approach involves a stance that is neither affirming nor rejecting of a child's asserted gender, but generally does not support social transition in pre-pubertal children. "Watchful waiting" does not apply to adolescents or speak to the

appropriateness of medical interventions for adolescents with gender dysphoria. Indeed, the Dutch researchers who coined the term "watchful waiting" for pre-pubertal patients provided puberty blockers, then hormones, when medically indicated during adolescence and have published the successful use of this series of treatments. (Ehrensaft, 2017; DeVries, 2014).

59. Gender-affirming medical interventions in accordance with the WPATH SOC 8 and Endocrine Society Guideline are widely recognized in the medical community as safe, effective, and medically necessary for many adolescents with gender dysphoria. (*See* American Academy of Pediatrics, 2018; the American Medical Association, 2021; the Endocrine Society, 2020; the Pediatric Endocrine Society, 2021; the American Psychiatric Association, 2018; the American Psychological Association, 2021; the American Congress of Obstetricians and Gynecologists, 2021; the American Academy of Family Physicians, 2020; and WPATH,2022).

#### C. Treatment Protocols for Adults with Gender Dysphoria

60. If an adult patient is assessed to have a medical need for hormone therapy, genderaffirming hormone therapy involves administering steroids of the experienced sex (i.e., their
gender identity), such as testosterone in transgender male individuals and estrogen in transgender
female individuals. The purpose of this treatment is to attain the appropriate masculinization or
feminization of the transgender person to achieve a gender phenotype that matches as closely as
possible to their gender identity. For adults, this treatment allows patients to live more comfortably
in their identified gender, with relief from gender dysphoria. Gender-affirming hormone therapy
is a partially reversible treatment in that some of the effects produced by the hormones are
reversible (e.g., changes in body fat composition, decrease in facial and body hair) while others
are irreversible (e.g., deepening of the voice, decreased testicular mass).

- 61. Some transgender adults need surgical interventions to help bring their phenotype into alignment with their gender. Surgical interventions may include, inter alia, vaginoplasty and orchiectomy for transgender female individuals, and chest reconstruction and hysterectomy for transgender male individuals.
- 62. Regret rates for gender-affirming surgery in adults are also very low. A pooled review across multiple studies of 7,928 patients receiving gender-affirming surgery showed a regret rate of 1%. (Bustos, et al., 2021). Over 50 years of gender-affirming surgery in Sweden, the regret rate, as measured by legal gender change reversal, was 2%. (Dhejne, et al., 2014). A recent study found very high satisfaction and very little regret among those receiving gender-affirming mastectomy at one U.S. center following a longitudinal period ranging from 2 to 30 years. (Bruce, et al 2023). Regret rates after gender-affirming surgeries are very low compared to other surgeries, (Thornton, et al 2024); for example, 47% of women expressed at least some regret after reconstructive breast surgery following mastectomy for breast cancer. (Sheehan, et al., 2008).
- 63. In the past 10 years, there has been a reversal in longstanding coverage policies that had excluded reimbursement of gender-affirming care for transgender people. There are many more clinics providing care to transgender youth and adults in academic medical centers than a decade ago, because funding is now available. This change is allowing clinical researchers to expand the body of research in the United States, as well as increasing access to care.
- 64. The cost of providing coverage for gender-affirming care is also generally very low. To begin, transgender people constitute a small percentage of the overall population, approximately 0.5%. (Crissman, et. al., 2017). Furthermore, the fraction of the population receiving clinical care for Gender Dysphoria is much smaller, well under one in a thousand patients (Zhang, et al., 2020). As a result, one study estimated an average cost of \$0.016 cents per member

per month to provide gender-affirming care. (Padula, et al., 2016). A study by Herman (2013) similarly found low costs to providing health coverage for gender-affirming care. Additionally, when a form of treatment is covered for cisgender people under an insurance plan, it is generally not disproportionately costly to cover the same treatment for transgender people simply because it is provided to treat gender dysphoria.

- Association, the American Psychiatric Association, the Endocrine Society, the American College of Obstetricians and Gynecologists, and the American Academy of Family Physicians oppose the denial of this medically necessary care and support public and private health insurance coverage for treatment of gender dysphoria as recommended by the patient's physician. (American Medical Association, 2021; American Psychiatric Association, 2018; Endocrine Society, 2012; American College of Obstetricians and Gynecologists, 2021; American Academy of Family Physicians, 2020).
- 66. For all the reasons above, I am aware of no basis in medicine or science for categorical exclusion of coverage for gender-affirming care.

#### D. Harms of Denying Gender-Affirming Care

67. The overarching goal of treatment is to eliminate the distress of gender dysphoria by helping align an individual patient's body and presentation with their gender identity. The denial of medically indicated care to patients with gender dysphoria not only results in the prolonging of their dysphoria, but also causes additional distress and poses other health risks, such as depression, posttraumatic stress disorder, and suicidality. In other words, lack of access to gender-affirming care directly contributes to poorer mental health outcomes for transgender people. (Owen-Smith, et al., 2018).

- 68. For patients for whom gender-affirming medical care is indicated, no alternative treatments have been demonstrated to be effective. To the extent one proposed alternative is psychotherapeutic treatment to encourage identification with a person's assigned sex at birth, the American Psychological Association has stated that such efforts provide no benefit and instead do harm. (APA 2021). Or if an alternative approach is to treat the worsening dysphoria only with therapy, that has not shown to be effective in any research.
- 69. I have had patients over the years who were unable to access gender-affirming care when it was clinically indicated, including in the years before this care was more widely available, as well as minors who could not access care due to lack of parental consent. In many of these patients, delayed or denied care resulted in increased depression, anxiety, suicidal ideation and self-harm, increased substance use, and a deterioration in school performance. For patients with severe distress due to sex characteristics, psychotherapeutic approaches did not alleviate this distress absent medical intervention. Some of my patients had years of intensive mental health interventions, including long-term psychotherapy, without relief of gender dysphoria until receiving medical intervention.
- Association, the American Psychiatric Association, the Endocrine Society, the American College of Obstetricians and Gynecologists, and the American Academy of Family Physicians oppose the denial of this medically necessary care for transgender individuals and support public and private health insurance coverage for treatment of gender dysphoria as recommended by the patient's physician. (American Medical Association, 2021; American Psychiatric Association, 2018; Endocrine Society, 2012, American Congress of Obstetricians and Gynecologists, 2021; American Academy of Family Physicians, 2020). Denial of this appropriate care for transgender adolescents

is also opposed by medical professional organizations responsible for the care of youth, including the American Academy of Pediatrics, the Academy of Child and Adolescent Psychiatry, and the Pediatric Endocrine Society. (American Academy of Pediatrics, 2018; American Academy of Child and Adolescent Psychiatry, 2019; The Pediatric Endocrine Society, 2021).

#### **CONCLUSION**

71. The ban prohibits widely-accepted, evidence-based medical treatments for gender dysphoria in adolescents. Decades of medical research and clinical experience demonstrate that these medical treatments are safe, effective, and medically necessary to relieve gender dysphoria for many adolescents. The ban prohibits the only treatments demonstrated to be effective for adolescents with gender dysphoria for whom gender-affirming medical care is indicated. The ban also severely limits access to care for transgender adults in South Carolina by restricting the use of public funds for the study and provision gender affirming care. Consistent with my first-hand clinical experience over decades of practice, denying gender-affirming medical care to transgender people for whom it is medically indicated puts them at risk of significant harm to their health and well-being.

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

Executed on: <u>8/21/24</u>.

Dan H. Karasic, M.D.

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# **EXHIBIT A**

## University of California, San Francisco CURRICULUM VITAE

Name: Dan H. Karasic, MD

**Position:** Professor Emeritus

Psychiatry

School of Medicine

Voice: 415-935-1511 Fax: 888-232-9336

EDII	$C \Lambda T$	ION
<b>EDU</b>	CAI	

1978 - 1982	Occidental College, Los Angeles	A.B.; Summa Cum Laude	Biology
1982 - 1987	Yale University School of Medicine	M.D.	Medicine
1987 - 1988	University of California, Los Angeles	Intern	Medicine, Psychiatry, and Neurology
1988 - 1991	University of California, Los Angeles; Neuropsychiatric Institute	Resident	Psychiatry
1990 - 1991	University of California, Los Angeles; Department of Sociology	Postdoctoral Fellow	Research Training Program in Mental Health Services for Persons with AIDS

#### LICENSES, CERTIFICATION

1990	Medical Licensure, California, License Number G65105
1990	Drug Enforcement Administration Registration Number BK1765354
1993	American Board of Psychiatry and Neurology, Board Certified in Psychiatry

#### PRINCIPAL POSITIONS HELD

1991 - 1993	University of California, San Francisco	Health Sciences Psychiatry
		Clincial Instructor
1993 - 1999	University of California, San Francisco	Health Sciences Psychiatry
		Assistant Clinical Professor

1999 - 2005	University of California, San Francisco	Health Sciences Associate Clinica Professor	•
2005 - 2020	University of California, San Francisco	Health Sciences Professor	Psychiatry Clinical
2020-present	University of California, San Francisco	Professor Emerit	us of Psychiatry
OTHER POSIT	TIONS HELD CONCURRENTLY		
1980 - 1980 A	ssociated Western Universities / U.S.  Department of Energy	Honors UCI Undergraduate Research Fellow	LA Medicine
	niversity of California, Los Angeles; Sumn American Heart Association, California Affiliate	ner Student UCl Research Fellow	LA
1986 - 1987	Yale University School of Medicine; American Heart Association, Connecticut Affiliate	Medical Student Research Fellow	Psychiatry
1990 - 1991 U	niversity of California, Los Angeles Postdo	octoral Sociology Fe	ellow
1991 - 2001 S	FGH Consultation-Liaison Service; Attend AIDS Care	ing Psychiatry Psychiatrist	
1991 - 2001	AIDS Consultation-Liaison Medical Student Elective	Course Director	Psychiatry
1991 - present	UCSF Positive Health Program at San General Hospital (Ward 86) Outpa	•	chiatry Francisco
1991 - present	UCSF AHP (AIDS Health Project/Alliance Health Project)	HIV/AIDS Outpatient Psychiatrist	Psychiatry
1994 - 2002	St. Mary's Medical Center CARE Unit. The CARE Unit specializes in the care of AIDS dementia.	Consultant patients with	Psychiatry
2001 - 2010	Depression and Antiretroviral Adherence Study (The H.O.M.E. study: Health Outcomes of Mood Enhancement)	e Clinical Director	Psychiatry and Medicine
2003 - 2020 Tr	ansgender Life Care Program and Psychia Clinic, Castro Mission Health Clinic	atrist Dimensions Center	s Dimensions
2013 - 2020 UC	CSF Alliance Health Project, Co-lead, Transgender Team	Co-Lead and Psychiatrist	Psychiatry

#### **HONORS AND AWARDS**

1981	Phi Beta Kappa Honor	r Society	Phi Beta Kappa
1990	NIMH Postdoctoral Fe Health Services for Pe	I	onal Institute of Mental Health Mental
	AIDS (1990-1991)		
2001	Lesbian Gay Bisexual Leadership Award, LG of the Cultural Compe Diversity Program	BT Task Force	SFGH Department of Psychiatry
2006	Distinguished Fellow		American Psychiatric Association
2012	Chancellor's Award fo LGBT Health	r Leadership in	UCSF
2023 Alumni Se	eal Award for Achievement	Occidental Colle	ge Professional

#### **MEMBERSHIPS**

- 1992 present Northern California Psychiatric Society
- 1992 present American Psychiatric Association
- 2000 2019 Bay Area Gender Associates (an organization of psychotherapists working with transgendered clients)
- 2001 present World Professional Association for Transgender Health

#### **SERVICE TO PROFESSIONAL ORGANIZATIONS**

1981 - 1982	The Occidental	News Editor
1984 - 1985	Yale University School of Medicine	Class President
1989 - 1991	Kaposi's Sarcoma Group, AIDS Project Los Angeles	Volunteer Facilitator
1992 - 1996	Early Career Psychiatrist Committee, Association of Gay Lesbian Psychiatrists	Chair and
1992 - 1996 Bo	oard of Directors, Association of Gay and Lesbian Membe	er Psychiatrists
1993 - 1993 Lo Psychiatri	ocal Arrangements Committee, Association of Gay and Chasts	nair Lesbian
	ducational Program, Association of Gay and Lesbian ual Meeting	Director Psychiatrists,
1994 - 1998	Board of Directors, BAY Positives	Member
1994 - 2020 Co	mmittee on Lesbian, Gay, Bisexual and Transgender Me	mber

#### Issues, Northern California Psychiatric Society

1005 1007	Board of Directors.	Ray Area Vounc	Docitivos RAV	Drocidont
1000 - 1001	DUMIN DI DII GUUIS.	. Day Alba Luuli	1 E OSIHVES, DA I	LICONGIL

Positives is the nation's first community-based organization providing psychosocial and recreational services to HIV-positive youth

- 1995 1997 Executive Committee, Bay Area Young Positives. Chair
- 1996 2004 Committee on Lesbian, Gay, Bisexual and Transgender Chair Issues, Northern California Psychiatric Society
- 1998 2002 City of San Francisco Human Rights Commission, Member Lesbian, Gay Bisexual Transgender Advisory Committee
- 2000 2004 Association of Gay and Lesbian Psychiatrists. Vice President Responsible for the organization's educational programs
- 2004 2005 Association of Gay and Lesbian Psychiatrists President-elect
- 2005 2007 Caucus of Lesbian, Gay, and Bisexual Psychiatrists of the Chair American Psychiatric Association
- 2005 2007 Association of Gay and Lesbian Psychiatrists President

  2007 2009 Association of Gay and Lesbian Psychiatrists Immediate Past
  President
- 2009 2010 Consensus Committee for Revision of the Sexual and Member Gender Identity Disorders for DSM-V, GID of Adults subcommittee. (Wrote WPATH recommendations as advisory body to the APA DSM V Committee for the Sexual and Gender Identity Disorders chapter revision.)
- 2010 2011 Scientific Committee, 2011 WPATH Biennial Symposium, Member Atlanta
- 2010 -2022 World Professional Association for Transgender Care Member Standards of Care Workgroup and Committee (writing seventh and eighth revisions of the WPATH Standards of Care, which is used internationally for transgender care.)
- 2010 2018 ICD 11 Advisory Committee, World Professional Member Association for Transgender Health
- 2012 2014 Psychiatry and Diagnosis Track Co-chair, Scientific Member Committee, 2014 WPATH Biennial Symposium, Bangkok
- 2014 2016 Scientific Committee, 2016 WPATH Biennial Symposium, Member Amsterdam
- 2014 2018 Board of Directors (elected to 4 year term), World Member Professional Association for Transgender Health
- 2014 2018 Public Policy Committee, World Professional Association Chair for Transgender Health
- 2014 2018 WPATH Global Education Initiative: Training providers Trainer and and specialty certification in transgender health Steering

Committee Member

2014 - 2016 American Psychiatric Association Workgroup on Gender Member Dysphoria 2016 - present American Psychiatric Association Workgroup on Gender Chair Dysphoria

2016 USPATH: Inaugural WPATH U.S. Conference, Los Conference Chair Angeles, 2017

#### SERVICE TO PROFESSIONAL PUBLICATIONS

- 2011 present Journal of Sexual Medicine, reviewer
- 2014 present International Journal of Transgenderism, reviewer
- 2016 present LGBT Health, reviewer

#### **INVITED PRESENTATIONS - INTERNATIONAL**

2009	World Professional Association for Transgender Health, Oslo, Norway	Plenary Session Speaker
2009	World Professional Association for Transgender Health, Oslo, Norway	Symposium Speaker
2009	Karolinska Institutet, Stockholm Sweden	Invited Lecturer
2012	Cuban National Center for Sex Education (CENESEX), Cuba	Invited Speaker Havana,
2013	Swedish Gender Clinics Annual Meeting, Stockholm, Sweden	Keynote Speaker
2013	Conference on International Issues in Transgender care, United Nations Development Programme - The Lancet, E	•
2014	World Professional Association for Transgender Health, Thailand	Track Chair Bangkok,
2014	World Professional Association for Transgender Health, Bangkok, Thailand	Invited Speaker
2014	World Professional Association for Transgender Health, Bangkok, Thailand	Invited Speaker
2015	European Professional Association for Transgender Ghent, Belgium	Invited Speaker Health,
2015	European Professional Association for Transgender Health, Ghent, Belgium	Symposium Chair
2015	Israeli Center for Human Sexuality and Gender Identity,	Invited Speaker Tel Aviv
2016	World Professional Association for Transgender Health, Amsterdam	Symposium Chair
2016	World Professional Association for Transgender Health, Amsterdam	Invited Speaker

2016	World Professional Association for Transgender Health, Invited Speaker
Amster	dam 2017
Brazil F	Professional
Association for	· · · · · · · · · · · · · · · · · · ·
Health, Sao	Paulo
2017	Vietnam- United Nations Development Programme Asia Transgender Health Conference, Hanoi
2018	United Nations Development Programme Asia Conference on Transgender Health and Human Rights, Bangkok
2018	World Professional Association for Transgender Health, Invited Speaker Buenos Aires
2021	Manitoba Psychiatric Association, Keynote Speaker
2022	World Professional Association for Public Health, invited speaker, Montreal

#### **INVITED PRESENTATIONS - NATIONAL**

1990	Being Alive Medical Update, Century Cable Television Televised Lecturer			
1992 Institute on Hospital and Community Psychiatry, Toronto Symposium Speaker				
1992	Academy of Psychosomatic Medicine Annual Meeting, Symposium San Diego Speaker			
1994	American Psychiatric Association 150th Annual Meeting, Workshop Chair Philadelphia			
1994	American Psychiatric Association 150th Annual Meeting, Workshop Speaker Philadelphia			
1994	American Psychiatric Association 150th Annual Meeting, Paper Session Co- Philadelphia chair			
1995	Spring Meeting of the Association of Gay and Lesbian Symposium Chair Psychiatrists, Miami Beach			
1996	American Psychiatric Association 152nd Annual Meeting, Workshop Speaker New York			
1997	American Psychiatric Association Annual Meeting, San Workshop Speaker Diego			
1997	Gay and Lesbian Medical Association Annual Invited Speaker Symposium	1		
1998	American Psychiatric Association Annual Meeting, Workshop Chair Toronto			
1998	American Psychiatric Association Annual Meeting, Workshop Chair Toronto			

1998	American Psychiatric Association Annual Meeting, Toronto	Media Session Chair	
1998	American Psychiatric Association Annual Meeting, Toronto	Media Session Chair	
1999	American Psychiatric Association Annual Meeting, Washington, D.C.	Symposium Chair	
1999	American Psychiatric Association Annual Meeting, Washington, D.C.	Symposium Presenter	
1999	American Psychiatric Association Annual Meeting, Washington, D.C.	Workshop Chair	
2000	American Psychiatric Association Annual Meeting, Chicago	Workshop Chair	
2000	National Youth Leadership Forum On Medicine, Invited Speaker University of California, Berkeley		
2001	American Psychiatric Association Annual Meeting, New Workshop Chair Orleans		
2001	American Psychiatric Association Annual Meeting, New Orleans	Media Program Chair	
2001	Association of Gay and Lesbian Psychiatrists Chair Orleans	Symposium, New	
2001	Harry Benjamin International Gender Dysphoria Invited Speaker Association Biennial Meeting, Galveston, Texas		
2002	American Psychiatric Association Annual Meeting, Philadelphia	Media Program Chair	
2002	American Psychiatric Association Annual Meeting, Philadelphia	Workshop Chair	
2002	American Psychiatric Association Annual Meeting, Philadelphia	Workshop Chair	
2003	Association of Gay and Lesbian Psychiatrists CME	Chair Conference	
2003	American Psychiatric Association Annual Meeting, San Francisco	Symposium Chair	
2003	American Psychiatric Association Annual Meeting, San Francisco	Symposium Co- Chair	
2003	American Psychiatric Association Annual Meeting, San Workshop Chair Francisco		
2003	American Public Health Association Annual Meeting, San Invited Speaker Francisco		
2004	Mission Mental Health Clinic Clinical Conference Invited	l Speaker	

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2004	Association of Gay and Lesbian Psychiatrists Conference, New York	Co-Chair
2004	Mental Health Care Provider Education Program: Los Angeles. Sponsored by the American Psychiatric Association Office of HIV Psychiatry	Invited Speaker
2005	American Psychiatric Association Annual Meeting, Atlanta	Workshop Speaker
2005	Association of Gay and Lesbian Psychiatrists Saturday Symposium	Invited Speaker
2008	Society for the Study of Psychiatry and Culture, San Francisco	Invited Speaker
2009	American Psychiatric Association Annual Meeting, San Francisco	Symposium Speaker
2011	National Transgender Health Summit, San Francisco	Invited Speaker
2011	National Transgender Health Summit, San Francisco	Invited Speaker
2011	American Psychiatric Association Annual Meeting, Honolulu, HI	Symposium Chair
2011	American Psychiatric Association Annual Meeting, Honolulu, HI	Symposium Speaker
2011	World Professional Association for Transgender Health Conference, Atlanta, GA	Invited Speaker Biennial
2011	World Professional Association for Transgender Health Conference, Atlanta, GA	Invited Speaker Biennial

# Invited Speaker

2011	World Professional Association for Transgender Health Biennial Conference, Atlanta, GA	
2011	Institute on Psychiatric Services, San Francisco Invited	Speaker
2012	Gay and Lesbian Medical Association Annual Meeting	Invited Speaker
2013	National Transgender Health Summit, Oakland, CA	Invited Speaker
2013	National Transgender Health Summit, Oakland, CA	Invited Speaker
2013	National Transgender Health Summit, Oakland, CA	Invited Speaker
2013	American Psychiatric Association Annual Meeting, San Francisco	Invited Speaker
2013	Gay and Lesbian Medical Association, Denver, CO	Invited Speaker
2014	American Psychiatric Association Annual Meeting, New	Invited Speaker York
2014	Institute on Psychiatric Services, San Francisco	Moderator
2014	Institute on Psychiatric Services, San Francisco	Invited Speaker
2014	Institute on Psychiatric Services, San Francisco Invited	Speaker
2015	National Transgender Health Summit, Oakland, CA	Invited Speaker
2015	National Transgender Health Summit, Oakland, CA	Invited Speaker
2015	American Psychiatric Association Annual Meeting, Toronto	Workshop Speaker
2015	American Psychiatric Association Annual Meeting, Toronto	Course Faculty
2016	American Psychiatric Association Annual Meeting	Course Faculty
2016	World Professional Association for Transgender Health Global Education Initiative, Atlanta	Course Faculty
2016	World Professional Association for Transgender Health Global Education Initiative, Springfield, MO	Course Faculty
2016	World Professional Association for Transgender Health Global Education Initiative, Fort Lauderdale, FL	Course Faculty
2017	World Professional Association for Transgender Health, GEI, Los Angeles Course Faculty	
	World Professional Association for Transgender Health	

# Surgeon's Training, Irvine, CA Course Faculty

2017	American Urological Association Annual Meeting, San Francisco CA Invited Speaker
2018	World Professional Association for Transgender Health GEI, Portland OR, Course Faculty
2018	World Professional Association for Transgender Health GEI, Palm Springs, Course Faculty
2019	American Society for Adolescent Psychiatry Annual Meeting, San Francisco, Speaker
2019	American Psychiatric Association Annual Meeting, San Francisco, Session Chair
2020	Psychiatric Congress, Invited Speaker
2022	World Professional Association for Transgender Health, Montreal, invited speaker
2023	National Transgender Health Summit, San Francisco, invited speaker
2023	American Psychiatric Association Annual Meeting, San Francisco, invited speaker
2023`	US Professional Association for Transgender Health, speaker

# **INVITED PRESENTATIONS - REGIONAL AND OTHER INVITED PRESENTATIONS**

1990	Advanced Group Therapy Seminar, UCLA Invited Lecturer Neuropsychiatric Institute
1991	Joint Project of the Southern California AIDS Interfaith Symposium Council and UCLA School of Medicine Speaker
1991	Joint Project of the Southern California AIDS Interfaith Workshop Panelist Council and UCLA School of Medicine
1992	Advanced Group Therapy Seminar, UCLA Invited Lecturer Neuropsychiatric Institute
1993	UCSF School of Nursing Invited Lecturer
1995	UCSF/SFGH Department of Medicine Clinical Care Invited Speaker Conference
1996	UCSF School of Nursing Invited Speaker

	Invited Speaker
1996	Psychopharmacology for the Primary Care AIDS/Clinician, Invited Lecturer series of four lectures, UCSF Department of Medicine
1996	UCSF AIDS Health Project Psychotherapy Internship Training Program
1996	UCSF/SFGH Department of Medicine AIDS Quarterly Invited Speaker Update
1996	San Francisco General Hospital, Division of Addiction Invited Speaker Medicine
1996	UCSF Langley Porter Psychiatric Hospital and Clinics Invited Speaker Grand Rounds
1997	UCSF School of Nursing Invited Speaker
1997	UCSF Department of Medicine AIDS Program Invited Speaker
1997	Northern California Psychiatric Society Annual Meeting, Workshop Speaker Monterey
1997	San Francisco General Hospital Department of Psychiatry Invited Speaker Grand Rounds
1997	San Francisco General Hospital Department of Psychiatry Invited Speaker Grand Rounds
1997	Northern California Psychiatric Society LGBT Committee Chair Fall Symposium
1997	Progress Foundation, San Francisco Invited Speaker
1998	San Francisco General Hospital Department of Psychiatry Invited Speaker Grand Rounds
1999	Northern California Psychiatric Society Annual Meeting, Invited Speaker Santa Rosa
1999	Northern California Psychiatric Society Annual Meeting, Invited Speaker Santa Rosa
1999	University of California, Davis, Department of Psychiatry Invited Speaker Grand Rounds
1999	California Pacific Medical Center Department of Invited Speaker Psychiatry Grand Rounds
1999	San Francisco General Hospital Department of Psychiatry Discussant Departmental Case Conference
2000	Langley Porter Psychiatric Hospital and Clinics Invited Speaker Consultation Liaison Seminar
2000	San Francisco General Hospital, Psychopharmacology Invited Speaker Seminar

2000	UCSF Transgender Health Conference, Laurel Heights Invited Speaker Conference Center
2000	Psychiatry Course for UCSF Second Year Medical Invited Lecturer Students
2000	Community Consortium Treatment Update Symposium, Invited Speaker California Pacific Medical Center, Davies Campus
2000	San Francisco General Hospital Department of Psychiatry Invited Speaker Grand Rounds
2001	Psychiatry Course for UCSF Second Year Medical Invited Lecturer Students
2003	Tom Waddell Health Center Inservice Invited Speaker
2003	San Francisco Veterans Affairs Outpatient Clinic Invited Speaker
2004	San Francisco General Hospital Psychiatric Emergency Invited Speaker Service Clinical Conference
2004	South of Market Mental Health Clinic, San Francisco Invited Speaker
2005	Northern Psychiatric Psychiatric Society Annual Meeting Invited Speaker
2005	Equality and Parity: A Statewide Action for Transgender Invited Speaker HIV Prevention and Care, San Francisco
2005	San Francisco General Hospital Department of Psychiatry Invited Speaker Grand Rounds.
2006	SFGH/UCSF Department of Psychiatry Grand Rounds Invited Speaker
2007	UCSF Department of Medicine, HIV/AIDS Grand Rounds, Invited Speaker Positive Health Program
2007	California Pacific Medical Center LGBT Health Invited Speaker Symposium, San Francisco LGBT Community Center
2007	UCSF CME Conference, Medical Management of Invited Speaker HIV/AIDS, Fairmont Hotel, San Francisco
2008	UCSF Department of Medicine, Positive Health Program, Invited Speaker HIV/AIDS Grand Rounds
2008	San Francisco General Hospital Psychiatry Grand Rounds Invited Speaker
2008	UCSF CME Conference, Medical Management of Invited Speaker HIV/AIDS, Fairmont Hotel, San Francisco
2010	Northern California Psychiatric Society Annual Meeting, Invited Speaker Monterey, CA
2011	Transgender Mental Health Care Across the Life Span, Invited Speaker Stanford University
2011	San Francisco General Hospital Department of Psychiatry Invited Speaker Grand Rounds

2012	Invited Speaker UCSF AIDS Health Project Invited Speaker 2012 San Francisco
	Veterans Affairs Medical Center.
2013	Association of Family and Conciliation Courts Conference, Invited Speaker Los Angeles, CA
2014	UCSF Transgender Health elective Invited Speaker
2014	UCSF Department of Psychiatry Grand Rounds Invited Speaker
2014	California Pacific Medical Center Department of Invited Speaker Psychaitry Grand Rounds
2014	UCLA Semel Institute Department of Psychiatry Grand Invited Speaker Rounds
2015	UCSF Transgender Health elective Invited Speaker
2015	Fenway Health Center Boston, MA (webinar) Invited Speaker
2015	Transgender Health Symposium, Palm Springs Invited Speaker
2015	Transgender Health Symposium, Palm Springs Co-Chair
2015	Santa Clara Valley Medical Center Grand Rounds Invited Speaker
2016	UCSF School of Medicine Transgender Health elective Invited Speaker
2016 Langley	Porter Psychiatric Institute APC Case Conference Invited Speaker (2 session series)
2016	Zuckerberg San Francisco General Department of Invited Speaker Psychiatry Grand Rounds
2016	UCSF Mini-Medical School Lectures to the Public Invited Speaker
2021	Los Angeles County Department of Mental Health, Invited Speaker
2023	Alameda County Department of Behavioral Health, Invited Speaker

## CONTINUING EDUCATION AND PROFESSIONAL DEVELOPMENT ACTIVITIES

2005	Northern California Psychiatric Society
2005	Northern California Psychiatric Society Annual Meeting, Napa
2005	Association of Gay and Lesbian Psychiatrist Annual Conference
2006	Annual Meeting, American Psychiatric Association, Atlanta
2006	Annual Meeting, American Psychiatric Association, Toronto
2006	Institute on Psychiatric Services, New York
2007	Association of Gay and Lesbian Psychiatrists Annual Conference

2007	American Psychiatric Association Annual Meeting, San Diego
2007	The Medical Management of HIV/AIDS, a UCSF CME Conference
2008	Society for the Study of Psychiatry and Culture, San Francisco
2009	American Psychiatric Association, San Francisco
2009	World Professional Association for Transgender Health, Oslo, Norway
2010	Annual Meeting of the Northern California Psychiatric Society, Monterey, CA
2011	Transgender Mental Health Care Across the Life Span, Stanford University
2011	National Transgender Health Summit, San Francisco
2011	American Psychiatric Association Annual Meeting, Honolulu, HI
2011	World Professional Association for Transgender Health Biennial Conference, Atlanta, GA
2011	Institute on Psychiatric Services, San Francisco
2012	Gay and Lesbian Medical Association Annual Meeting, San Francisco
2013	National Transgender Health Summit, Oakland, CA
2013	American Psychiatric Association Annual Meeting, San Francisco
2013	Gay and Lesbian Medical Association, Denver, CO
2014	American Psychiatric Association Annual Meeting, New York
2014	Institute on Psychiatric Services, San Francisco
2015	European Professional Association for Transgender Health, Ghent, Belgium
2015	National Transgender Health Summit, Oakland
2015	American Psychiatric Association Annual Meeting, Toronto
2016	American Psychiatric Association Annual Meeting, Atlanta
2016	World Professional Association for Transgender Health, Amsterdam

## **GOVERNMENT AND OTHER PROFESSIONAL SERVICE**

1998 - 2002 City and County of San Francisco Human Rights Member Commission LGBT Advisory Committee

I am the chair of the American Psychiatric Association Workgroup on Gender Dysphoria, which developed a CME course fort the 2015 and 2016 APA Annual Meetings, and has an larger educational mission to train American psychiatrists to better care for transgender patients. I have been leading education efforts in transgender health at APA meetings since 1998. On the APA Workgroup on Gender Dysphoria, I am a co-author of a paper of transgender issues that has been approved by the American Psychiatric Association as a resource document and is in press for the American Journal of Psychiatry. I am also the sole author of the chapter on transgender care in the American Psychiatric Press's Clinical Manual of Cultural Psychiatry, Second Edition.

I have been active internationally in transgender health through my work as a member of the Board of Directors of the World Professional Association for Transgender Health. I am an author of the WPATH Standards of Care, Version 7, and am Chapter Lead for the Mental Health Chapter of SOC 8.

I chaired of the WPATH Public Policy Committee and was a member of the Global Education Initiative, which developed a specialty certification program in transgender health. I helped plan the 2016 WPATH Amsterdam conference, and was on the scientific committee for the last four biennial international conferences. I was on the founding committee of USPATH, the national affiliate of WPATH, and I chaired the inaugural USPATH conference, in Los Angeles in 2017. As a member of the steering committee of the WPATH Global Educational Initiative, I helped train over 2000 health providers in transgender health, and helped develop a board certification program and examination in transgender health.

### UNIVERSITY SERVICE UC SYSTEM AND MULTI-CAMPUS SERVICE

	UNIVERSITY SERVICE OC SYSTEM AND MOLTI-CAMPOS SERVICE		
	1991 – 2003 HIV/AIDS Task Force Member		
1992 - 1993 HIV Research Group Member			
	1992 - 1997	Space Committee	Member
	1992 - 2003 Ga	y, Lesbian and Bisexual Issues Task Force	Member
	1994 - 1997	SFGH Residency Training Committee	Member
	1996 - 1997	Domestic Partners Benefits Subcommittee.	Chair
	1996 - 2000	Chancellor's Advisory Committee on Gay, Lesbian, and Transgender Issues.	Member Bisexual
	1996 - 2003	HIV/AIDS Task Force	Co-Chair
	1996 - 2003	Cultural Competence and Diversity Program	Member
2009 - present Medical Advisory Board, UCSF Center of Excellence for Member Transgender Health			
	2010 - 2013 Steering Committee, Child Adolescent Gender Center Member		
	2011 – 2017 Mental Health Track, National Transgender Health Summit Chair		

### **DEPARTMENTAL SERVICE**

- 1991 2003 San Francisco General Hospital, Department of Psychiatry, Member HIV/AIDS Task Force
- 1992 1993 San Francisco General Hospital, Department of Psychiatry, Member HIV Research Group
- 1992 1997 San Francisco General Hospital, Department of Psychiatry, Member Space Committee
   1992 2003 San Francisco General Hospital, Department of Psychiatry, Member GLBT Issues Task Force
   1994 1997 San Francisco General Hospital, Department of Psychiatry, Member Residency Training Committee
- 1996 2003 San Francisco General Hospital, Department of Psychiatry, Member Cultural Competence and Diversity Program
- 1996 2003 San Francisco General Hospital, Department of Psychiatry, Co-Chair HIV/AIDS Task Force
- 2012 2020 San Francisco Department of Public Health Gender Member Competence Trainings Committee
- 2013 2020 San Francisco Department of Public Health Transgender Member Health Implementation Task Force
- 2014 2020San Francisco General Hospital, Department of Psychiatry, Member Transgender Surgery Planning Workgroup

#### PEER REVIEWED PUBLICATIONS

- 1. Berliner JA, Frank HJL, **Karasic D**, Capdeville M. Lipoprotein-induced insulin resistance in aortic endothelium. Diabetes. 1984; 33:1039-44.
- 2. Bradberry CW, **Karasic DH**, Deutch AY, Roth RH. Regionally-specific alterations in mesotelencephalic dopamine synthesis in diabetic rats: association with precursor tyrosine. Journal of Neural Transmission. General Section, 1989; 78:221-9.
- 3. Targ EF, **Karasic DH**, Bystritsky A, Diefenbach PN, Anderson DA, Fawzy FI. Structured group therapy and fluoxetine to treat depression in HIV-positive persons. Psychosomatics. 1994; 35:132-7.
- 4. Karasic DH. Homophobia and self-destructive behaviors. The Northern California Psychiatric Physician. 1996; 37 Nov.-Dec. Reprinted by the Washington State Psychiatric Society and the Southern California Psychiatric Society newsletters.
- 5. Karasic D. Anxiety and anxiety disorders. Focus. 1996 Nov; 11(12):5-6. PMID: 12206111
- 6. Polansky JS, **Karasic DH**, Speier PL, Hastik KL, Haller E. Homophobia: Therapeutic and training considerations for psychiatry. Journal of the Gay and Lesbian Medical Association. 1997 1(1) 41-47.

- 7. Karasic DH. Progress in health care for transgendered people. Editorial. Journal of the Gay and Lesbian Medical Association, 4(4) 2000 157-8.
- 8. Perry S, **Karasic D**. Depression, adherence to HAART, and survival. Focus: A Guide to AIDS Research and Counseling. 2002 17(9) 5-6.
- 9. Fraser L, **Karasic DH**, Meyer WJ, Wylie, K. Recommendations for Revision of the DSM Diagnosis of Gender Identity Disorder in Adults. International Journal of Transgenderism. Volume 12, Issue 2. 2010, Pages 80-85.
- Coleman, E., Bockting, W., Botzer, M., Cohen-Kettenis, P., DeCuypere, G., Feldman, J., Fraser, L., Green, J., Knudson, G., Meyer, W., Monstrey, S., Karasic D and 22 others. (2011). Standards of Care for the Health of Transsexual, Transgender, and Gender Nonconforming People, 7th Version. International Journal of Transgenderism, 13:165-232, 2011
- 11. Tsai AC, **Karasic DH**, et al. Directly Observed Antidepressant Medication Treatment and HIV Outcomes Among Homeless and Marginally Housed HIV-Positive Adults: A Randomized Controlled Trial. American Journal of Public Health. February 2013, Vol. 103, No. 2, pp. 308-315.
- 12. Tsai AC, Mimmiaga MJ, Dilley JW, Hammer GP, Karasic DH, Charlebois ED, Sorenson JL, Safren SA, Bangsberg DR. Does Effective Depression Treatment Alone Reduce Secondary HIV Transmission Risk? Equivocal Findings from a Randomized Controlled Trial. AIDS and Behavior, October 2013, Volume 17, Issue 8, pp 2765-2772.
- 13. **Karasic DH**. Protecting Transgender Rights Promotes Transgender Health. LGBT Health. 2016 Aug; 3(4):245-7. PMID: 27458863
- 14. Winter S, Diamond M, Green J, **Karasic D**, Reed T, Whittle S, Wylie K. Transgender people: health at the margins of society. Lancet. 2016 Jul 23;388(10042):390-400. doi: 10.1016/S0140-6736(16)00683-8. Review./> PMID: 27323925
- 15. Grelotti DJ, Hammer GP, Dilley JW, Karasic DH, Sorensen JL, Bangsberg DR, Tsai AC. Does substance use compromise depression treatment in persons with HIV? Findings from a randomized controlled trial. AIDS Care. 2016 Sep 2:1-7. [Epub ahead of print]/> PMID: 27590273
- 16. Strang JF, Meagher H, Kenworthy L, de Vries AL, Menvielle E, Leibowitz S, Janssen A, Cohen-Kettenis P, Shumer DE, Edwards-Leeper L, Pleak RR, Spack N, Karasic DH, Schreier H, Balleur A, Tishelman A, Ehrensaft D, Rodnan L, Kuschner ES, Mandel F, Caretto A, Lewis HC, Anthony LG. Initial Clinical Guidelines for Co-Occurring Autism Spectrum Disorder and Gender Dysphoria or Incongruence in Adolescents. J Clin Child Adolesc Psychol. 2016 Oct 24:1-11. [Epub ahead of print]/> PMID: 27775428
- 17. Milrod C, **Karasic DH**. Age Is Just a Number: WPATH-Affiliated Surgeons' Experiences and Attitudes Toward Vaginoplasty in Transgender Females Under 18 Years of Age in the United States. J Sex Med 2017;14:624–634.
- 18. William Byne, Dan H. Karasic, Eli Coleman, A. Evan Eyler, Jeremy D. Kidd, Heino F.L. Meyer-Bahlburg, Richard R. Pleak, and Jack Pula.Gender Dysphoria in Adults:

- An Overview and Primer for Psychiatrists. Transgender Health. Dec 2018.57-A3. http://doi.org/10.1089/trgh.2017.0053
- 19. Identity recognition statement of the world professional association for transgender health (WPATH). International Journal of Transgenderism. 2018 Jul 3; 19(3):1-2. Knudson KG, Green GJ, Tangpricha TV, Ettner ER, Bouman BW, Adrian AT, Allen AL, De Cuypere DG, Fraser FL, Hansen HT, Karasic KD, Kreukels KB, Rachlin RK, Schechter SL, Winter WS, Committee and Board of Direct
- Karasic, DH & Fraser, L Multidisciplinary Care and the Standards of Care for Transgender and Gender Non-conforming Individuals. Schechter, L & Safa, B. (Eds.) Gender Confirmation Surgery, Clinics in Plastic Surgery Special Issue, Vol 45, Issue 3, pp 295-299. 2018 Elsevier, Philadelphia. <a href="https://doi.org/10.1016/j.cps.2018.03.016">https://doi.org/10.1016/j.cps.2018.03.016</a>
- 21. Milrod C, Monto M, Karasic DH. Recommending or Rejecting "the Dimple": WPATHAffiliated Medical Professionals' Experiences and Attitudes Toward GenderConfirming Vulvoplasty in Transgender Women. <u>J Sex Med.</u> 2019 Apr;16(4):586-595. doi: 10.1016/j.jsxm.2019.01.316. Epub 2019 Mar 2.
- 22. ICD-11 and gender incongruence of childhood: a rethink is needed. Lancet Child Adolesc Health. 2019 10; 3(10):671-673. Winter S, <u>Ehrensaft D</u>, Telfer M, T'Sjoen G, Koh J, Pickstone-Taylor S, Kruger A, Griffin L, Foigel M, De Cuypere G, **Karasic D**. PMID: 31439494.
- 23. Gender Dysphoria in Adults: An Overview and Primer for Psychiatrists. Focus (Am Psychiatr Publ). 2020 Jul; 18(3):336-350. Byne W, **Karasic DH**, Coleman E, Eyler AE, Kidd JD, Meyer-Bahlburg HFL, Pleak RR, Pula J. PMID: 33343244; PMCID: PMC7587914.
  - 24. WPATH Standards of Care for the Health of Transgender and Gender Diverse People, Version 8. E. Coleman, A. E. Radix, W. P. Bouman, G. R. Brown, A. L. C. de Vries, M. B. Deutsch, R. Ettner, L. Fraser, M. Goodman, J. Green, A. B. Hancock, T. W. Johnson, **D. H. Karasic...** J. Arcelus (2022) Standards of Care for the Health of Transgender and Gender Diverse People, Version 8, International Journal of Transgender Health, 23:sup1, S1-S259, DOI: 10.1080/26895269.2022.2100644

### **BOOKS AND CHAPTERS**

- Karasic DH, Dilley JW. Anxiety and depression: Mood and HIV disease. In: The UCSF AIDS Health Project Guide to Counseling: Perspectives on Psychotherapy, Prevention, and Therapeutic Practice. Dilley JW and Marks R, eds. Jossey-Bass. San Francisco, 1998, pp.227-248.
- 2. **Karasic DH**, Dilley JW. Human immunodeficiency-associated psychiatric disorders. In: The AIDS Knowledge Base, Third Edition. Cohen PT, Sande MA, Volberding PA, eds. Lippincott-Williams &Wilkens, Philadelphia, 1999, pp. 577-584.

- Karasic DH and Drescher J. eds. Sexual and Gender Diagnoses of the Diagnostic and Statistical Manual (DSM): A Reevaluation. 2005. Haworth Press, Binghamton, NY. (Book Co-Editor)
- Karasic DH. Transgender and Gender Nonconforming Patients. In: Clinical Manual of Cultural Psychiatry, Second Edition. Lim RF ed. pp 397-410. American Psychiatric Publishing, Arlington VA. 2015.
- 5. **Karasic DH**. Mental Health Care of the Transgender Patient. In: Comprehensive Care of the Transgender Patient, Ferrando CA ed. pp. 8-11. Elsevier, 2019.
- Karasic DH. The Mental Health Assessment for Surgery. In: Gender Confirmation Surgery – Principles and Techniques for an Emerging Field. Schechter L ed. Springer Nature, in press 2019.

### OTHER PUBLICATIONS

- Karasic DH, Dilley JW. HIV-associated psychiatric disorders: Treatment issues. In: Cohen P, Sande MA, Volberding P, eds., The AIDS Knowledge Base. Waltham, MA: The Medical Publishing Group/ Massachusetts Medical Society. 1994. pp. 5.31-1-5.
- 2. **Karasic DH**, Dilley JW. HIV-associated psychiatric disorders: Clinical syndromes and diagnosis. In: Cohen P, Sande MA, Volberding P, eds., The AIDS Knowledge Base, Second Edition. Waltham, MA: The Medical Publishing Group/Massachusetts Medical Society. 1994 pp. 5.30-1-5.
- 3. **Karasic DH**. A primer on transgender care. In: Gender and sexuality. The Carlat Report Psychiatry. April 2012. Vol 10, Issue 4.
- 4. **Karasic D and Ehrensaft D.** We must put an end to gender conversion therapy for kids. Wired. 7/6/15.

### **EXPERT WITNESS AND CONSULTATION ON TRANSGENDER CARE AND RIGHTS**

2008 Consultant, California Department of State Hospitals

2012 Dugan v. Lake, Logan UT

2012 XY v. Ontario http://www.canlii.org/en/on/onhrt/doc/2012/2012hrto726/2012hrto726.html

2014 Cabading v California Baptist University

2014 CF v. Alberta

http://www.canlii.org/en/ab/abgb/doc/2014/2014abgb237/2014abgb237.html

2017 United Nations Development Programme consultant, transgender health care and legal rights in the Republic of Vietnam; Hanoi.

- 2017- 2018 Forsberg v Saskatchewan; Saskatchewan Human Rights v Saskatchewan <a href="https://canliiconnects.org/en/summaries/54130">https://canliiconnects.org/en/summaries/54130</a> <a href="https://canliiconnects.org/en/cases/2018skgb159">https://canliiconnects.org/en/cases/2018skgb159</a>
- 2018 United Nations Development Programme consultant, transgender legal rights in Southeast Asia; Bangkok.
- 2018 Consultant, California Department of State Hospitals
- 2019, 2021 Consultant/Expert, Disability Rights Washington
- 2019, 2021 Consultant/Expert, ACLU Washington
- 2021 Consultant, California Department of Corrections and Rehabilitation
- 2021 Expert, Kadel v. Folwell, 1:19-cv-00272 (M.D.N.C.).
- 2021 Expert, Drew Glass v. City of Forest Park Case No. 1:20-cv-914 (Southern District Ohio)
- 2021-2022 Expert, Brandt et al v. Rutledge et al. 4:21-cv-00450 (E.D. Ark.)
- 2021-2022 Expert, Fain v. Crouch, 3:20-cv-00740 (S.D.W. Va.)
- 2022 Expert, C.P. v. Blue Cross Blue Shield of Illinois, No. 3:20-cv-06145-RJB (W.D. Wash.)
- 2022-3 Expert, Dekker, et al. v. Weida, et al., No. 4:22-cv-00325-RH-MAF
- 2019-2023 Expert, Disability Rights Washington v Washington State Department of Corrections
- 2023 Expert, K.C. et al. v Individual Members of the Indiana Licensing Board, et al. No. 1:23-CV-595
- 2023 Expert, Doe, et al v Ladapo -No. 4:23-cv-00114-RH-MAF
- 2023 Expert, Doe et al v Thornbury -No. 3:23-cv-00230-DJH
- 2023 Expert Voe v Mansfield

### EXHIBIT B – DAN KARASIC BIBLIOGRAPHY

Allen, L. R., Watson, L. B., Egan, A. M., & Moser, C. N. (2019). Well-being and suicidality among transgender youth after gender-affirming hormones. *Clinical Practice in Pediatric Psychology*, 7(3), 302–311. https://doi.org/10.1037/cpp0000288.

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American Academy of Pediatrics (2018). Policy Statement: Ensuring Comprehensive Care and Support for Transgender and Gender Diverse Children and Adolescents, *available at* https://pediatrics.aappublications.org/content/142/4/e20182162.

American College of Obstetricians and Gynecologists (2021). Committee Opinion No. 823: Health Care for Transgender and Gender Diverse Individuals, *available at* https://www.acog.org/clinical/clinical-guidance/committee-opinion/articles/2021/03/health-care-for-transgender-and-gender-diverse-individuals.

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- Brik, T., Vrouenraets, L.J.J.J., de Vries, M.C. et al. (2020). Trajectories of Adolescents Treated with Gonadotropin-Releasing Hormone Analogues for Gender Dysphoria. Arch Sex Behav 49, 2611–2618, *available at* https://doi.org/10.1007/s10508-020-01660.
- Bustos, V. P., Bustos, S. S., Mascaro, A., Del Corral, G., Forte, A. J., Ciudad, P., Kim, E. A., Langstein, H. N., & Manrique, O. J. (2021). Regret after Gender-affirmation Surgery: A Systematic Review and Meta-analysis of Prevalence. Plastic and reconstructive surgery. Global open, 9(3), e3477, available at https://doi.org/10.1097/GOX.0000000000003477.
- Byne, W., Karasic, D. H., Coleman, E., Eyler, A. E., Kidd, J. D., Meyer-Bahlburg, H. F. L., ... Pula, J. (2018). Gender dysphoria in adults: An overview and primer for psychiatrists. *Transgender Health*, 3(1), 57-70, *available at* https://doi.org/10.1089/trgh.2017.0053.
- Coleman, E., Radix, A. E., Bouman, W. P., Brown, G. R., de Vries, A. L. C., Deutsch, M. B., Ettner, R., Fraser, L., Goodman, M., Green, J., Hancock, A. B., Johnson, T. W., Karasic, D. H., Knudson, G. A., Leibowitz, S. F., Meyer-Bahlburg, H. F. L., Monstrey, S. J., Motmans, J., Nahata, L., Nieder, T. O., ... Arcelus, J. (2022). Standards of Care for the Health of Transgender and Gender Diverse People, Version 8. *International Journal of Transgender Health*, 23(Suppl 1), S1–S259.
- Coleman, E., Bockting, W., Botzer, M., Cohen-Kettenis, P., DeCuypere, G., Feldman, J., ... & Zucker, K. (2012). Standards of care for the health of transsexual, transgender, and gender nonconforming people, version 7. *International Journal of Transgenderism*, 13(4), 165-232.
- Colton-Meier, S. L., Fitzgerald, K. M., Pardo, S. T., & Babcock, J. (2011). The effects of hormonal gender affirmation treatment on mental health in female-to-male transsexuals. *Journal of Gay & Lesbian Mental Health*, 15(3), 281-299.
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Herman, J., et al. (2022). How Many Adults and Youth Identify as Transgender in the United States? *The Williams Institute, available at* <a href="https://williamsinstitute.law.ucla.edu/wp-content/uploads/Trans-Pop-Update-Jun-2022.pdf">https://williamsinstitute.law.ucla.edu/wp-content/uploads/Trans-Pop-Update-Jun-2022.pdf</a>.

Howick, J., Koletsi, D., Pandis, N., et al. (2020). The quality of evidence for medical interventions does not improve or worsen: a metaepidemiological study of Cochrane reviews. *The Journal of Clinical Epidemiology*. Vol. 126, 154-159, *available at* <a href="https://doi.org/10.1016/j.jclinepi.2020.08.005">https://doi.org/10.1016/j.jclinepi.2020.08.005</a>.

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## UNITED STATES DISTRICT COURT FOR THE DISTRICT OF SOUTH CAROLINA

STERLING MISANIN, et al.,	
Plaintiffs,	
v.  ALAN WILSON, in his official capacity as the Attorney General of South Carolina, et al.,	Case No.:
Defendants.	

# EXPERT DECLARATION OF JOHANNA OLSON-KENNEDY, M.D., M.S.

- I, Johanna Olson-Kennedy, M.D., M.S., hereby declare and state as follows:
- 1. I have been retained by counsel for Plaintiffs as an expert in connection with the above-captioned litigation.
- 2. I am over the age of 18. I have actual knowledge of the matters stated herein. If called to testify in this matter, I would testify truthfully and based on my expert opinion.

### **BACKGROUND AND QUALIFICATIONS**

3. I have been retained by counsel for Plaintiffs in the above-captioned lawsuit to provide expert opinions on gender identity; the diagnosis and treatment of gender dysphoria; and the impact on adolescents with gender dysphoria of South Carolina H 4624 ("H 4624"), which prohibits gender-affirming medical care for transgender patients under the age of 18.

### A. Qualifications and Experience

- 4. I am a double board-certified physician in Pediatrics and Adolescent Medicine. I specialize in the care of transgender youth and gender diverse children. I am a recognized expert in this field.
- 5. I received my Doctor of Medicine (M.D.) degree from the Chicago Medical School in 1997. In 2000, I completed my residency in pediatrics at the Children's Hospital of Orange County, California. In 2003, I completed a three-year fellowship in adolescent medicine at Children's Hospital Los Angeles.
  - 6. I have been a licensed physician in California since 2000.
- 7. I am currently the Medical Director of the Center for Transyouth Health and Development, in the Division of Adolescent Medicine at Children's Hospital Los Angeles in California. The Center is the largest clinic in the United States for transgender and gender diverse youth and provides over 2500 individuals with both medical and mental health services. Services at the Center include consultation and support for families with transgender and gender diverse children; gender-affirming medical treatments, when indicated, including medications to suppress puberty in peri-pubertal youth (i.e., youth at the onset of puberty), gender-affirming hormones used for masculinization or feminization; and surgical referrals when indicated. Under my direction, the Center conducts rigorous research aimed at understanding the experience of gender diversity and gender dysphoria from childhood through early adulthood.

- 8. Over the course of my work with this population during the past 18 years, I have provided services for approximately 1,200 young people and their families, and currently have an active panel of around 650 patients of varying ages, up to 25 years old.
- 9. I have been awarded research grants to examine the impact of early interventions including puberty-delaying medication (commonly known as puberty blockers) and gender-affirming hormones on the physiological and psychosocial development of gender diverse and transgender youth.
- 10. I have lectured extensively across the United States and internationally on the treatment and care of gender diverse children and transgender adolescents, the subjects including pubertal suppression, gender-affirming hormone therapy, transitioning teens and the adolescent experience, age considerations in administering hormones, and the need for, risks, and outcomes of hormonal treatments.
- 11. I have published 30 peer-reviewed journal articles on transgender health-related issues, as well as over two dozen additional publications, such as articles, chapters, and editorials, both peer-reviewed and non-peer-reviewed.
- 12. I am the principal investigator on a multisite National Institutes of Health grant (currently in its 8<sup>th</sup> year), an ongoing study examining the impact of gender-affirming medical care for transgender youth on physiologic and psychological health and well-being. The first eight years have already been completed. This was the first study of its kind in the U.S. to determine longitudinal outcomes among this population of vulnerable youth. The study to date has yielded approximately 28 manuscripts.

- 13. I am a Professor at the Keck School of Medicine at the University of Southern California and an attending physician at Children's Hospital Los Angeles.
- 14. I have been a member of the World Professional Association for Transgender Health ("WPATH") since 2010, and a Board Member of the U.S. Professional Association for Transgender Health ("USPATH") since 2017. In 2022, I was appointed to the Executive Board of the USPATH. In 2023 I was nominated as the president elect for USPATH and will assume the presidency in 2025. I am also a member of the Society for Adolescent Health and Medicine and the American Academy of Pediatrics. In addition, I am a member of the LGBT Special Interest Group of the Society for Adolescent Health and Development.
- 15. I am the 2014 Recognition Awardee for the Southern California Regional Chapter of the Society for Adolescent Health and Medicine.
- 16. In 2019, I was invited by the University of Bristol as a Benjamin Meaker visiting professor, the purpose of which is to bring distinguished researchers from overseas to Bristol in order to enhance the research activity of the university.
- 17. My professional background, experience, publications, and presentations are further detailed in my curriculum vitae ("CV"). A true and correct copy of my most up-to-date CV is attached as **Exhibit A**.

### **Previous Testimony**

18. In the last four years, I have testified as an expert at trial or by deposition in the following cases: *Noe v. Parson*, No. 23AC-CC04530 (Cole Cnty. Cir. Ct., Mo.); *Loe v. Texas*, No. GN-23-003616 (Travis Cnty. Dist. Ct., Tex.); *Dekker v Weida*, Case No. 4:22-cv-00325-RH-MAF (N.D. Fla.); *Fain v. Crouch*, No. 3:20-cv-00740 (S.D. W.Va.); *Kadel v.* 

Folwell, Case No. 1:19-cv-00272-LCB-LPA (M.D.N.C.); Miller v. Purdue (Colorado); and In the interest of JA.D.Y. and JU.D.Y., Children, Case No. DF-15-09887 (255th Jud. District Ct., Dallas Cty., Tex.).

### **Compensation**

19. I am being compensated for my work on this matter at a rate of \$400.00 per hour for preparation of declarations and expert reports, as well as any pre-deposition and/or pre-trial preparation, and a flat fee of \$3,200 per day for any deposition or trial testimony. My compensation does not depend on the outcome of this litigation, the opinions I express, or the testimony I may provide.

### **Bases for Opinions**

- 20. In preparing this report, I have relied on my training and years of research and clinical experience, as set out in my CV, and the materials listed in the CV. *See* Exhibit A.
- 21. I have also relied on the published research relating to gender dysphoria and its treatments, including the materials listed in the attached bibliography. *See* Exhibit B. The sources cited therein are authoritative, scientific peer-reviewed publications. Some of these publications are specifically cited as supportive examples in particular sections of this declaration.
- 22. The materials I have relied upon in preparing this report are the same types of materials that experts in my field of study regularly rely upon when forming opinions on the subject. I 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.

23. In addition, I have reviewed South Carolina H 4624.

### **EXPERT OPINIONS**

## A. Gender Identity

- 24. The term gender identity was originally coined in 1964 by American psychiatrist Robert J. Stoller, a noted psychoanalyst who studied sexual orientation, gender identity, and differences in sexual development. Gender identity is a distinct characteristic and is defined as one's internal sense of being male or female (or rarely, both or neither). It has a strong biological basis. Every person has a gender identity.
- 25. The concept of gender identity is contemporaneously understood both colloquially and within the domain of science and medicine to denote someone's gender. It is a concept well-understood and accepted in medicine and science. Indeed, gender identity information is commonly collected and reported on within the context of scientific research.<sup>2</sup>
- 26. Generally, a person is assigned a sex, either male or female, when they are born, often based solely on observation of their external genitalia. However, the more contemporary understanding of sex shows that it is actually determined by multiple characteristics, such as genitalia, chromosomal makeup, hormones, variations in brain structure and function, and gender identity. For some of these characteristics there is significant variance as reflected by

<sup>1</sup> Stoller, R.J. (1964). A Contribution to the Study of Gender Identity, *The International journal of psycho-analysis*, 45, 220–226.

<sup>2</sup> Clayton JA, Tannenbaum C. (2016). Reporting Sex, Gender, or Both in Clinical Research? *JAMA*. 316(18): 1863–1864.

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the dozens of intersex mechanisms and varying gender identities. Additionally, not all sex characteristics, including gender identity, are always in alignment. Accordingly, the Endocrine Society Guidelines state that, "As these may not be in line with each other (e.g., a person with XY chromosomes may have female-appearing genitalia), the terms biological sex and biological male or female are imprecise and should be avoided."<sup>3</sup>

- 27. For decades, it has been understood that gender identity cannot be changed.

  Efforts to do so have been shown to be unsuccessful and harmful.<sup>4</sup>
- 28. The term cisgender refers to a person whose gender identity matches their sex assigned at birth. The term transgender refers to a person whose gender does not match their sex assigned at birth.

## B. Gender Dysphoria and its Treatment

29. Gender Dysphoria (GD) is a serious medical condition characterized by distress due to a mismatch between assigned birth sex and a person's internal sense of their gender. GD was formerly categorized as Gender Identity Disorder (GID) but the condition was renamed in May 2013, with the release of the American Psychiatric Association (APA)'s fifth edition of the Diagnostic and Statistical Manual of Mental Disorders (DSM-5). In announcing this change, the APA explained that in addition to the name change, the criteria for the diagnosis were revised "to better characterize the experiences of affected children, adolescents,

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<sup>&</sup>lt;sup>3</sup> Hembree, W.C., Cohen-Kettenis, P.T., Gooren, L., et al. (2017). Endocrine Treatment of Gender-Dysphoric/Gender-Incongruent Persons: An Endocrine Society Clinical Practice Guideline, *The Journal of Clinical Endocrinology & Metabolism*, 102(11): 3869–3903.

<sup>&</sup>lt;sup>4</sup> Benjamin, H. (1966). The Transsexual Phenomenon. New York: The Julian Press, Inc. Publishers.

<sup>&</sup>lt;sup>5</sup> A text revision to the Diagnostic and Statistical Manual of Mental Disorders, Fifth Edition was published in 2022 ("DSM-5-TR").

and adults."<sup>6</sup> The APA further stressed that "gender nonconformity is not in itself a mental disorder. The critical element of gender dysphoria is the presence of clinically significant distress associated with the condition."<sup>7</sup>

- 30. For a person to be diagnosed with GD, there must be a marked difference between the individual's expressed/experienced gender and the gender others would assign to the individual, present for at least six months. In children, the desire to be of the other gender must be present and verbalized.<sup>8</sup> The condition must cause clinically significant distress or impairment in social, occupational, or other important areas of functioning.
- 31. The World Professional Association of Transgender Health (WPATH) has clear recommendations for the health of transgender and gender non-conforming people in what is now the Standards of Care version 8 (SOC 8). The SOC are based on the best available science and expert professional consensus in transgender health; its recommendation statements were developed based on data derived from independent systematic literature reviews, background reviews, and expert opinions; and its grading of recommendations was based on the available evidence supporting interventions, a discussion of risks and harms, as well as the feasibility and acceptability of these. SOC 8 continues to recommend the provision of medical interventions for adolescents and adults (but not for prepubertal children) based on an individual patient's needs. These medical interventions include puberty blockers, hormone

<sup>&</sup>lt;sup>6</sup> DSM-5.

<sup>&</sup>lt;sup>7</sup> *Id*.

<sup>&</sup>lt;sup>8</sup> Notably, the DSM-IV included a separate diagnosis for GID in children, which required the child to display a number of behaviors stereotypical of the non-natal gender. That diagnosis, and its list of behavioral requirements, have been deleted from the DSM-5 and replaced by updated and more precise diagnostic criteria.

<sup>&</sup>lt;sup>9</sup> Coleman, et al. (2022) (SOC 8).

therapy, and surgery. These medical interventions are intended to alleviate the patient's gender dysphoria by bringing their body into closer alignment with their gender identity and minimizing or eliminating the physical characteristics generally associated with their sex assigned at birth.

- 32. The WPATH SOC have been cited as authoritative by the major medical associations in the United States, including the American Academy of Pediatrics, the American Medical Association, the American Psychiatric Association, the American Psychological Association, the Endocrine Society, the Pediatric Endocrine Society, the American College of Physicians, and the American Academy of Family Physicians.
- 33. The UCSF Center for Excellence in Transgender Care as well as the Endocrine Society have both published comprehensive guidelines for the care of transgender and non-binary individuals that are largely consistent with the WPATH SOC.<sup>10</sup>
- 34. Under the WPATH SOC and other well-accepted clinical practice guidelines for the treatment of gender dysphoria, care should be provided using an individualized approach.
- 35. For children who have not yet reached puberty, medical intervention other than mental health support is unnecessary and unwarranted. After the onset of puberty, medical interventions such as puberty blockers, and later hormones and surgery, may be appropriate.

<sup>10</sup> Deutsch, M.B. (ed.). (2016). Guidelines for the Primary and Gender-Affirming Care of Transgender and Gender Nonbinary People (2d ed.). San Francisco, CA: UCSF Center of Excellence for Transgender Health, <a href="https://transcare.ucsf.edu/guidelines">https://transcare.ucsf.edu/guidelines</a> (UCSF Guidelines);

Hembree, et al. (2017) (Endocrine Society Guidelines).

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36. Under the current widely accepted clinical practice guidelines, medical and surgical interventions for adolescents with gender dysphoria are determined by the care team (usually a medical and mental health professional) in collaboration with the patient, and the patient's family, and after an assessment of the patient's social situation, level of gender dysphoria, developmental stage, existing health status, and other relevant factors. Sometimes treatment begins with puberty delaying medications (also referred to as puberty blockers), later followed by gender-affirming hormones. The majority of youth, and certainly all adults accessing treatment are already well into or have completed puberty.

### **Puberty Blockers**

- 37. The beginning signs of puberty in transgender youth (the development of breast buds in assigned birth females and increased testicular volume in assigned birth males) is often a painful and sometimes traumatic experience that brings increased gender dysphoria and the potential development of a host of comorbidities including depression, anxiety, substance abuse, self-harming behaviors, social isolation, high-risk sexual behaviors, and increased suicidality. The development of secondary sex characteristics is a permanent change in an individual's phenotype and may not be reversible even with subsequent hormone therapy and surgery in adulthood, thus exacerbating lifelong gender dysphoria in patients who are denied access to this essential treatment. Secondary sex characteristics such as stature, genital growth, deepening of the voice, and breast development are some of the changes that are difficult, if not impossible to counteract.
- 38. Puberty suppression, which involves the administration of gonadotrophinreleasing hormone analogues (GnRHa), essentially pauses puberty by temporarily

interrupting the sequence of hormonal signals from the brain that control puberty. This allows the young person the opportunity to explore gender without having to experience the anxiety and distress associated with developing undesired secondary sexual characteristics. In addition, for parents/guardians who have not had an opportunity to learn about gender diversity and/or who have only recently become aware of their child's transgender identity, puberty blockers provide additional time and opportunity to integrate this new information into their own experience and to develop skills to support their child. Puberty suppression also has the benefit of potentially rendering obsolete some gender-affirming surgeries down the line, such as male chest reconstruction, tracheal shave, facial feminization, and vocal cord alteration, which otherwise would be required to correct the initial misaligned puberty.

- decades in children with other medical conditions, including precocious puberty, and is a reversible intervention. <sup>11</sup> Both the Endocrine Society and the WPATH's SOC, recommend initiation of puberty suppression for youth with gender dysphoria at the earliest stages of puberty (usually, Tanner 2) (assuming someone has engaged in services before or around this time), regardless of chronological age, in order to avoid the stress and trauma associated with developing secondary sex characteristics of the natal sex. If the medication is discontinued, the young person continues their endogenous puberty.
- 40. A growing body of evidence, including peer-reviewed cross-sectional and longitudinal studies, demonstrates the positive impact of pubertal suppression in youth with

<sup>11</sup> Mul, D. & Hughes, I. (2008). The use of GnRH agonists in precocious puberty. *European journal of endocrinology / European Federation of Endocrine Societies*. 159 Suppl 1. S3-8.

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GD on psychological functioning, including a decrease in behavioral and emotional problems, a decrease in depressive symptoms, and improvement in general functioning.<sup>12</sup>

- 41. The initial follow-up studies evaluating the use of puberty suppression in relation to psychological well-being in adolescents with GD came from the Netherlands and demonstrated that behavioral and emotional problems and depressive symptoms decreased and general functioning significantly improved during treatment.<sup>13</sup>
- 42. A study from the United Kingdom demonstrated that a combination of psychological support and puberty suppression were associated with improved psychosocial functioning in adolescents with gender dysphoria than psychological support only.<sup>14</sup>
- 43. A more recent cross-sectional study from the Dutch team demonstrated that transgender youth undergoing pubertal suppression had better psychological functioning than those youth who had not yet begun puberty blockade.<sup>15</sup>

<sup>&</sup>lt;sup>12</sup> See for example: de Vries, A.L., Steensma, T.D., Doreleijers, T.A., & Cohen-Kettenis, P.T. (2011). Puberty Suppression in Adolescents with Gender Identity Disorder: A Prospective Follow-Up Study. *The Journal of Sexual Medicine*, 8(8), 2276-2283; Turban, J.L., King, D., Carswell, J.M., & Keuroghlian, A.S. (2020). Pubertal Suppression for Transgender Youth and Risk of Suicidal Ideation. *Pediatrics*, 145(2):e20191725; van der Miesen, A.I., Steensma, T.D., de Vries, A.L., *et al.* (2020). Psychological Functioning in Transgender Adolescents Before and After Gender-Affirmative Care Compared with Cisgender General Population Peers. *Journal of Adolescent Health*, 66(6), 699-704; Achille, C., Taggart, T., Eaton, N.R., *et al.* (2020). Longitudinal Impact of Gender-Affirming Endocrine Intervention on the Mental Health and Well-Being of Transgender Youths: Preliminary Results. *International Journal of Pediatric Endocrinology*, 2020(8), 1-5; and Costa, R., Dunsford, M., Skagerberg, E., Holt, V., Carmichael, P., & Colizzi, M. (2015). Psychological Support, Puberty Suppression, and Psychosocial Functioning in Adolescents with Gender Dysphoria. *The journal of sexual medicine*, *12*(11), 2206–2214.

<sup>&</sup>lt;sup>13</sup> de Vries, et al. (2011); de Vries, et al. (2014).

<sup>&</sup>lt;sup>14</sup> Costa, et al. (2015).

<sup>&</sup>lt;sup>15</sup> Van der Miesen, et al. (2020).

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- 45. Achille et al. demonstrated a positive effect of puberty blockade on mental health in a small, prospective investigation. The study characterized a treatment cohort over progressive interventions moving from puberty blockade to GAH treatment. 17
- 46. Overall, this growing body of evidence is consistent with clinical experience demonstrating significant positive effects of puberty blockade in youth with gender dysphoria.
- 47. Over the course of my work in the past eighteen years with gender diverse and transgender youth, I have prescribed hormone suppression for over 350 patients. All of those patients have benefitted from putting their endogenous puberty process on pause, even the small handful who discontinued GnRH analogues and went through their endogenous puberty. Many of these young people were able to matriculate back into school

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<sup>&</sup>lt;sup>16</sup> McGregor K, McKenna JL, Williams CR, Barrera EP, Boskey ER. Association of Pubertal Blockade at Tanner 2/3 With Psychosocial Benefits in Transgender and Gender Diverse Youth at Hormone Readiness Assessment. Journal of adolescent health. 2024;74(4):801-807. doi:10.1016/j.jadohealth.2023.10.028.

<sup>&</sup>lt;sup>17</sup> Achille, et al. (2020).

environments, begin appropriate peer relationships, and participate meaningfully in therapy and family functions. Children who had contemplated or attempted suicide or self-harm (including cutting and burning) associated with monthly menstruation or the anxiety about their voice dropping were offered respite from those dark places of despair. GnRH analogues for puberty suppression are, in my opinion, a sentinel event in the history of transgender medicine, and have changed the landscape almost as much as the development of synthetic hormones.

- 48. In my professional interactions with other doctors who provide pubertal suppression to patients with gender dysphoria—through attending conferences and other professional meetings—the same positive outcomes are reported.
- 49. Puberty blockers, thus, can significantly alleviate and prevent worsening distress of gender dysphoria that frequently comes with puberty.
- 50. Puberty blockers also afford youth the opportunity to undergo a single, congruent pubertal process and avoid many of the surgical interventions previously necessary to physically align with their gender, and other physical changes that cannot be addressed later by surgery. It is a simple reversible intervention that has the capacity to improve health outcomes and, for some patients, save lives.

### Gender-Affirming Hormones

51. Gender-affirming hormone therapy involves administering steroids of the experienced sex (i.e., their gender identity) (estrogen for transferminine individuals and testosterone for transmasculine individuals). The purpose of this treatment is to attain the appropriate masculinization or feminization of the transgender person to achieve a gender

phenotype that matches as closely as possible to their gender identity. Gender-affirming hormone therapy is a partially reversible treatment in that some of the effects produced by the hormones are reversible (e.g., changes in body fat composition, decrease in facial and body hair) while others are irreversible (e.g., deepening of the voice, breast tissue development).

- 52. Under the WPATH and other well-accepted clinical guidelines, eligibility and medical necessity should be determined case-by-case, based on an assessment of the youth's unique circumstances and needs and their cognitive and emotional maturation and ability to provide a knowing and informed consent. As explained further below, the decision should be made only after a careful review with the youth and parents/guardians of the potential risks and benefits of hormone therapy. The youth's primary care provider, therapist, or another experienced professional with training or experience in mental health or adolescent development can help document and confirm the patient's history of GD, the medical necessity of the intervention, and the youth's readiness to transition medically.
- 53. As with the use of puberty blockers, the data demonstrating the positive effects of gender affirming hormones (GAH), including in adolescents, is well established and growing.
- 54. The Dutch team at The Center of Expertise on Gender Dysphoria at the VU University Medical Center Amsterdam continued to report the improvement within their cohort of youth with gender dysphoria after GAH. De Vries et al reported in 2014 that their cohort of young adults who began care in adolescence had steadily improving mental health

(including depression, anxiety, anger, internalizing and externalizing psychopathologic symptoms) following puberty blockade, GAH and gender affirming surgery. <sup>18</sup>

- 55. A German observational study reported that among the participants at followup, adolescents in the gender-affirming hormone (GAH) and surgery (GAS) group reported emotional and behavioral problems and physical quality of life scores similar to the German norm mean. 19
- 56. Also from Germany, Neider et al. reported that among a group of 75 adolescents with gender dysphoria satisfaction improved the further along the treatment course had progressed.<sup>20</sup>
- 57. From the United States, Kuper et al. carried out a prospective study and reported their cohort of transgender and non-binary youth starting either pubertal blockade or GAH demonstrated improvement at follow up (around a year) in depression, anxiety and body esteem.<sup>21</sup>

<sup>&</sup>lt;sup>18</sup> de Vries, et al. (2014).

<sup>&</sup>lt;sup>19</sup> Becker-Hebly, I., Fahrenkrug, S., Campion, F., Richter-Appelt, H., Schulte-Markwort, M., & Barkmann, C. (2021). Psychosocial health in adolescents and young adults with gender dysphoria before and after gender-affirming medical interventions: A descriptive study from the Hamburg Gender Identity Service. European Child & Adolescent Psychiatry, 30(11), 1755–1767.

<sup>&</sup>lt;sup>20</sup> Nieder, T. O., Mayer, T. K., Hinz, S., Fahrenkrug, S., Herrmann, L., & Becker-Hebly, I. (2021). Individual treatment progress predicts satisfaction with transition-related care for youth with gender dysphoria: A prospective clinical cohort study. The Journal of Sexual *Medicine*, 18(3), 632–645.

<sup>&</sup>lt;sup>21</sup> Kuper, L. E., Stewart, S., Preston, S., Lau, M., & Lopez, X. (2020). Body dissatisfaction and mental health outcomes of youth on gender-affirming hormone therapy. *Pediatrics*, 145(4).

- 58. While small, Grannis et al. demonstrated decreased depression and anxiety in a group of transmasculine youth taking testosterone versus an untreated control group.<sup>22</sup>
- 59. In 2023 our team at the Trans Youth Care United States (TYC-US) reported in the New England Journal of Medicine an improvement among 315 youth in positive affect and life satisfaction as well as a decrease in depressive and anxiety symptoms after two years of GAH among transmasculine youth.<sup>23</sup>
- 60. The data documenting the efficacy of hormone treatment in transgender adults is robust and goes back even further. Numerous longitudinal studies document improvement in various mental health parameters including depression, anxiety, self-confidence, body image and self-image, general psychological functioning.<sup>24</sup>

<sup>22</sup> Grannis, C., Leibowitz, S. F., Gahn, S., Nahata, L., Morningstar, M., Mattson, W. I., Chen, D., Strang, J. F., & Nelson, E. E. (2021). Testosterone treatment, internalizing symptoms, and body image dissatisfaction in transgender boys. *Psychoneuroendocrinology*, 132, 105358, 1-8

<sup>&</sup>lt;sup>23</sup> Chen D, Berona J, Chan YM, Ehrensaft D, Garofalo R, Hidalgo MA, Rosenthal SM, Tishelman AC, Olson-Kennedy J. (2023). Psychosocial Functioning in Transgender Youth after 2 Years of Hormones. *New England Journal of Med.* 2023 Jan 19;388(3):240-250.

<sup>&</sup>lt;sup>24</sup> See for example: Colizzi, M., et al. (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; Colizzi, M., et al. (2013). Hormonal treatment reduces psychobiological distress in gender identity disorder, independently of the attachment style. *The journal of sexual medicine*, *10*(12), 3049–3058; Corda, E., et al. (2016). Body image and gender role perceived in gender dysphoria: Cross-sex hormone therapy effects. *European Psychiatry*, 33(S1), S589-S589; Fisher, A. D., et al. (2016). Cross-Sex Hormone Treatment and Psychobiological Changes in Transsexual Persons: Two-Year Follow-Up Data. *The Journal of clinical endocrinology and metabolism*, *101*(11), 4260–4269; Heylens, G., et al. (2014). Effects of different steps in gender reassignment therapy on psychopathology: a prospective study of persons with a gender identity disorder. *The journal of sexual medicine*, *11*(1), 119–126; Keo-Meier, C. L., et al. (2015). Testosterone treatment and MMPI-2 improvement in transgender men: a prospective controlled study. *Journal of consulting and clinical psychology*, *83*(1), 143–156; Manieri, C., et al. (2014) Medical Treatment of Subjects with Gender Identity Disorder: The Experience in an Italian Public

- decades, this field of medicine has grown and become more sophisticated: research has continued to occur in the United States and internationally. WPATH (formerly the Henry Benjamin International Gender Dysphoria Association) published the first iteration of the Standards of Care in 1979, which is now in its 8th version; the DSM stopped classifying transgender identification as a mental disorder; the American Psychological Association and Endocrine Society, as well as other medical organizations, adopted clinical guidelines consistent with the WPATH Standards of Care; and dozens of interdisciplinary gender clinics associated with research institutions and teaching hospitals have been providing gender affirming care for transgender youth and adults with gender dysphoria across the United States.
- 62. The established and growing body of evidence indicating the efficacy of GAH is consistent with decades of clinical experience demonstrating the positive effect of gender affirming hormones in adolescents and adults with gender dysphoria.
- 63. Over the past 18 years, I have prescribed gender-affirming hormones for over 1,200 adolescents and young adults. Many of my patients have described the opportunity to align their physical body with their gender as life-saving. Being afforded the opportunity to

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Health Center, *International Journal of Transgenderism*, 15:2, 53-65; Motta, G., et al. (2018). Does Testosterone Treatment Increase Anger Expression in a Population of Transgender Men?. *The journal of sexual medicine*, *15*(1), 94–101; Oda, H., & Kinoshita, T. (2017). Efficacy of hormonal and mental treatments with MMPI in FtM individuals: cross-sectional and longitudinal studies. *BMC psychiatry*, *17*(1), 256; and Turan, Ş., et al. (2018). Alterations in Body Uneasiness, Eating Attitudes, and Psychopathology Before and After Cross-Sex Hormonal Treatment in Patients with Female-to-Male Gender Dysphoria. *Archives of sexual behavior*, *47*(8), 2349–2361.

be perceived accurately in regards to gender changes the life trajectory of adolescents and young adults. When I began doing this work in 2006, I considered it a victory for transgender adolescents to finish high school. Currently I witness my patients being able to go to college, graduate school, learn trades, become doctors, lawyers, filmmakers, artists, get married, raise families and many other things. This shift directly correlates with access to early gender affirming care, as gender dysphoria takes up an enormous amount of energy that prevents adolescents from performing the tasks required of all adolescents. If gender dysphoria gets addressed early, adolescents and young adults can carry on with the tasks of school, family, relationships, friendships and others. Prior to accessing gender affirming care, many young people with gender dysphoria can't imagine their futures, and many consider and sometimes actively try to end their own lives.

64. As is the case for all medical interventions for minors, the initiation of puberty blockers and GAH commences following the process of informed consent, as explained further below. Youth and their parent(s) or legal guardian are given information about the permanent changes as well as those that require ongoing use of hormones, potential side effects and what is known and unknown about each medication. Youth and family members have the opportunity to ask and get answers to questions. Parents must consent before treatment is provided.

#### Gender-Affirming Surgeries

65. Some transgender individuals need surgical interventions to help bring their phenotype into alignment with their gender. For youth with gender dysphoria under the age of 18, surgery is rare. Among those under 18, the most common gender-affirming surgery by far

is masculinizing chest surgery, and even in these cases it rarely occurs under the age of 16 years. For youth younger than 18 years any other type of gender-affirming surgical care is extraordinarily rare. As with puberty blockers and gender affirming hormones, surgery performed on minors requires informed consent from the parent(s) or legal guardian of the youth, as well as assent from the youth.

- 66. A recent systematic review that included data from 1,052 transmasculine patients who obtained chest surgery found that pooled overall postoperative satisfaction was 92%,<sup>25</sup> while another recent study that examined 209 adolescents who had undergone genderaffirming chest surgery between 2013 and 2020 found an extremely low rate of post-operative regret (0.95%).<sup>26</sup>
- 67. With regards to transgender adolescents, peer-reviewed research has also shown improvements in mental health following gender-affirming chest surgery for transgender males with gender dysphoria where medically indicated.<sup>27</sup>

#### **Informed Consent**

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<sup>&</sup>lt;sup>25</sup> Bustos, V. P., Bustos, S. S., Mascaro, A., Del Corral, G., Forte, A. J., Ciudad, P., Kim, E. A., Langstein, H. N., & Manrique, O. J. (2021). Regret after Gender-affirmation Surgery: A Systematic Review and Meta-analysis of Prevalence. *Plastic and reconstructive surgery*. *Global open*, *9*(3), e3477.

<sup>&</sup>lt;sup>26</sup> Tang, A., Hojilla, J. C., Jackson, J. E., Rothenberg, K. A., Gologorsky, R. C., Stram, D. A., ... & Yokoo, K. M. (2022). Gender-affirming mastectomy trends and surgical outcomes in adolescents. *Annals of Plastic Surgery*, 88(4), S325-S331.

<sup>&</sup>lt;sup>27</sup> Mehringer, J. E., et al. (2021). Experience of Chest Dysphoria and Masculinizing Chest Surgery in Transmasculine Youth. *Pediatrics*, *147*(3), e2020013300; Olson-Kennedy, J., et al. (2018). Chest Reconstruction and Chest Dysphoria in Transmasculine Minors and Young Adults: Comparisons of Nonsurgical and Postsurgical Cohorts. *JAMA pediatrics*, *172*(5), 431–436.

- 68. WPATH and other well-accepted medical guidelines provide that, as with all medical treatments, the decision to initiate a particular medical intervention should be made after a careful discussion with the youth and their parent or guardian of the benefits and risks of the medical intervention. Patients and their parents make an informed decision together after receiving the necessary information.
- 69. The same medications that are prescribed to treat gender dysphoria, whether in the form of puberty blockers or gender-affirming hormones, are commonly used to treat other conditions among cisgender (meaning non-transgender) youth, and the same risks exist in either group. In either context, the families of both transgender and cisgender youth commonly make the decision to initiate treatment after being informed of the risks.
- 70. GnRHa medications to suppress puberty have been prescribed to cisgender children to treat central precocious puberty, a condition that causes early sexual development, for decades. Among adolescents GnRH analogs are utilized for endometriosis and for induction of amenorrhea in youth undergoing cancer care and/or those who have low platelets and a proclivity for excess bleeding.<sup>28</sup> Research has demonstrated these medications to be safe, and the risks, including any potential implications for bone density, are present whether used to treat gender dysphoria or central precocious puberty.<sup>29</sup>
- 71. Estrogen and testosterone therapy have been prescribed to cisgender children to treat a range of conditions, including Turner syndrome and hypogonadism, for many years.

<sup>28</sup> Martin-Johnston MK, Okoji OY, Armstrong A. Therapeutic amenorrhea in patients at risk for thrombocytopenia. Obstet Gynecol Surv. 2008 Jun;63(6):395-402; quiz 405. doi: 10.1097/OGX.0b013e3181706620. PMID: 18492296; PMCID: PMC4790444.

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<sup>&</sup>lt;sup>29</sup> Mul, D. & Hughes, I. (2008). The use of GnRH agonists in precocious puberty. *European journal of endocrinology / European Federation of Endocrine Societies*. 159 Suppl 1. S3-8.

These medications have been proven to be safe, and the risks, including elevated blood pressure or increased red blood cells, are present whether used to treat gender dysphoria or to treat other conditions among cisgender youth. Similarly, cisgender girls with polycystic ovarian syndrome can use the testosterone blocker spironolactone to manage the increased facial and body hair that is often associated with that condition. Estrogen and progesterone have been used extensively for contraception since 1960.

- 72. In either context, the families of both transgender and cisgender youth commonly make the decision to initiate treatment after being informed of the risks, which are well-managed under appropriate care. 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 of adolescents who were unable to access this care through a medical provider and instead turned to black markets or took medications from friends/family to self-treat. Self-treatment can result in unsafe hormone levels, which can negatively impact mood and increase several health risks, such as blood clots, cardiovascular problems, and liver and kidney dysfunction.
- 73. "From the FDA perspective, 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." Indeed, for over 40 years, the FDA has informed the medical community that "once a [drug] product has been approved …, a physician may prescribe it for uses or in treatment regimens of patient populations that are not included in

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<sup>&</sup>lt;sup>30</sup> U.S. Food and Drug Admin. Understanding Unapproved Use of Approved Drugs "Off Label" (Feb. 5, 2018), https://www.fda.gov/patients/learn-about-expanded-access-and-other-treatmentoptions/understanding-unapproved-use-approved-drugs-label.

approved labeling."<sup>31</sup> Accordingly, the American Academy of Pediatrics has stated that "off-label use of medications is neither experimentation nor research."<sup>32</sup> Thus, "[t]he administration of an approved drug for a use that is not approved by the FDA is not considered research and does not warrant special consent or review if it is deemed to be in the individual patient's best interests

74. The use of "off-label" medications is extremely common across all fields in medicine and there are many medications that are used "off-label" in the pediatric population. Most of the therapies prescribed to children are on an off-label or unlicensed basis.<sup>33</sup> Common medications that are used "off-label" in pediatrics include antibiotics, antihistamines, antidepressants and not rarely chemotherapeutic medications.<sup>34</sup> That is because the majority of drugs prescribed have not been tested in children and safety and efficacy of children's medicines are frequently supported by low quality evidence. This is explained by the lack of clinical research in this population, caused by ethical, scientific, and technical issues, as well as commercial priorities.

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<sup>&</sup>lt;sup>31</sup> U.S. Food and Drug Admin, "Citizen Petition Regarding the Food and Drug Administration's Policy on Promotion of Unapproved Uses of Approved Drugs and Devices; Request for Comments," 59 Fed. Reg. 59,820 (Nov. 18, 1994).

<sup>&</sup>lt;sup>32</sup> Frattarelli, D. A., Galinkin, J. L., Green, T. P., Johnson, T. D., Neville, K. A., Paul, I. M., Van Den Anker, J. N., & American Academy of Pediatrics Committee

<sup>&</sup>lt;sup>33</sup> Allen, H.C., Garbe, M.C., Lees, J., Aziz, N., Chaaban, H., Miller, J.L., Johnson, P., & DeLeon, S. (2018). Off-Label Medication use in Children, More Common than We Think: A Systematic Review of the Literature. The Journal of the Oklahoma State Medical Association, 111(8), 776–783.

<sup>&</sup>lt;sup>34</sup> Lim M, Shulman DS, Roberts H, Li A, Clymer J, Bona K, Al-Sayegh H, Ma C, DuBois SG. Off-label prescribing of targeted anticancer therapy at a large pediatric cancer center. Cancer Med. 2020 Sep;9(18):6658-6666. doi: 10.1002/cam4.3349. Epub 2020 Aug 4. PMID: 32750219; PMCID: PMC7520353.

75. 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 doctors.

#### **CONCLUSION**

- 76. Gender-affirming medical and surgical care is effective, beneficial, and necessary for transgender people suffering with gender dysphoria, including transgender youth after the onset of puberty. It is well documented and studied, through years of clinical experience, observational scientific studies, and even some longitudinal studies. It is also the accepted standard of care by all major medical organizations in the United States.
- 77. The denial of gender-affirming care, on the other hand, is harmful to transgender people. It exacerbates their dysphoria and may cause anxiety, depression, and suicidality, among other harms.
  - 78. The denial of much needed care only serves to harm transgender people.

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

Executed this 27thday of August

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

# **EXHIBIT A**

# CURRICULUM VITAE JOHANNA OLSON-KENNEDY MS, MD AUGUST 11, 2024

#### **PERSONAL INFORMATION:**

Work	Home
4650 Sunset Blvd. MS 2	1621 Fair Oaks Ave
Los Angeles, CA 90027	South Pasadena, CA 91030
Phone: 323-361-3128	Citizenship: USA
Fax: 323-953-8116	Phone (323) 399-1087
Work Email: jolson@chla.usc.edu	

#### **EDUCATION AND PROFESSIONAL APPOINTMENTS**

#### **EDUCATION:**

Year	Degree, Field, Institution, City
1992	BA, Mammalian Physiology, UC San Diego, San Diego
1993	MS, Animal Physiology, The Chicago Medical School, Chicago
1997	MD, Medical Doctor, The Chicago Medical Shool, Chicago
2015	MS, Clinical and Biomedical Investigations in Translational Science, USC, Los Angeles

#### **POST-GRADUATE TRAINING:**

Year-Year	Training Type, Field, Mentor, Department, Institution, City
1997 - 1998	Internship, Pediatrics, Children's Hospital Orange County, Orange
1998 - 2000	Residency, Pediatrics, Antonio Arrieta, Children's Hosptial Orange County, Orange
2000 - 2003	Fellowship, Adolescent Medicine, Children's Hospital Los Angeles, Los Angeles
2012 - 2015	Master's Degree, Clinical and Biomedical Investigations in Translational Science,
	USC

#### **ACADEMIC APPOINTMENTS:**

Year-Year	Appointment Department, Institution, City, Country		
2006 - 2016 Assistant Professor of Clinical Pediatrics		Division of Adolescent Medicine, Children's Hospital Los Angeles/USC Keck School of Medicine, Los Angeles, USA	
1 /1116 /11/4 1		Division of Adolescent Medicine, Children's Hospital Los Angeles/USC Keck School of Medicine, Los Angeles, USA	
/II/4 Precent		Division of Adolescent Medicine, Children's Hospital Los Angeles/USC Keck School of Medicine, Los Angeles, USA	

#### CLINICAL/ADMINISTRATIVE APPOINTMENTS:

2008 - 2012	Fellowship Director	Division of Adolescent Medicine, Children's Hospital Los Angeles, Los Angeles, USA
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2012 - present	Medical Director	The Center for Transyouth Health and Development, Division of Adolescent Medicine, Children's Hospital Los Angeles, Los Angeles, USA	
2021 - 2023	Clinical consultant	Santa Barbara Neighborhood Clinics	

#### LICENSURE, CERTIFICATIONS

#### LICENSURE:

Year	License number, State, Status
2000	A-67352, California, Active

#### **BOARD CERTIFICATION OR ELIGIBILITY:**

Year	Board, State, Status
2001, 2009, 2015	Pediatrics, California, active

#### **SPECIALTY CERTIFICATION:**

Year	Specialty Certification, Status
2003, 2013	Adolescent Medicine, California, active

#### **HONORS, AWARDS:**

Year	Description	Awarding agency, address, city	
2009	Health Care Advocacy Champion	Democratic Advocates for Disability Issues, Los Angeles	
2010	Clinical Research Academic Career Development Award	Saban Research Center TSRI Program: Community Health Outcomes and Intervention, Los Angeles	
2012	Extraordinary Service Award	Equality California, 202 W 1st St., Suite 3-0130, Los Angeles	
2013	Top Doctor	Castle Connolly	
2014	Anne Marie Staas Ally Award	Stonewall Democratic Club; 1049 Havenhurst Drive #325, West Hollywood	
2014	Top Doctor	Castle Connolly	
2014	Recognition Award for Outstanding, Compassionate and Innovative Service	SoCal Society for Adolescent Health and Medicine Regional Chapter, Los Angeles	
2015	The Champion Award	The Division of Adolescent Medicine; CHAMPION FUND 5000 Sunset Blvd. Los Angeles	
2016	America's Most Honored Professional's – Top 10%	America's Most Honored Professional's	
2016	Regional Top Doctor	Castle Connolly	
2017	Exceptional Women in Medicine	Castle Connolly	
2017	Regional Top Doctor	Castle Connolly	
2017	America's Most Honored Professional's – Top 5%	America's Most Honored Professional's	
2018	Regional Top Doctor	Castle Connolly	
2019	Benjamin Meaker Visiting Professorship	University of Bristol, Bristol UK	
2019	Regional Top Doctor	Castle Connolly	
2019	L.A's Top Docs	Los Angeles Magazine	
2019	Top Docs	Pasadena Health	

2019	America's Most Honored Professional's – Top 1%	America's Most Honored Professional's
2020	Regional Top Doctor	Castle Connolly
2020	Southern California Top Doc	Castle Connolly
2020	Southern California Top Doctors	
2020	L.A's Top Docs	Los Angeles Magazine
2020	America's Most Honored Professional's – Top 1%	America's Most Honored
2021	Southern California Top Doc	Castle Connolly
2021	America's Most Honored Doctors – Top 1%	America's Most Honored
2021	Top Doctors	Castle Connolly
2022	America's Most Honored Doctors – Top 1%	America's Most Honored
2022	Top Doctors	Castle Connolly

#### **TEACHING**

#### **DIDACTIC TEACHING:**

Keck School of Medicine at USC

Keck School of Med	icine di OSC		
Year-Year	Course Name	Units/Hrs	Role
2019	Puberty Suppression and Hormones;	One hour	Curriculum development and
	Medical Interventions for Transgender		delivery
	Youth		
2020, 2021, 2022	Approach to the Care of Gender Non-	One hour	Curriculum development and
	conforming Children and Transgender		delivery
	Youth		
2023	Transgender and Non-binary Youth and	One hour	Curriculum development and
	Young Adults 101		delivery

#### CalState Fullerton

Year-Year	Course Name	Units/Hrs	Role
2017	Gender Nonconforming and	One hour	Curriculum development and
	Transgender Youth		delivery

UNDERADUATE, GRADUATE AND MEDICAL STUDENT (OR OTHER) MENTORSHIP:

Year-Year	Trainee Name	Trainee Type	Dissertation/Thesis/Project Title
2015 - 2016	David Lyons	MD	Transgender Youth Clinical Clerkship
2016 - 2019	Jonathan Warus	MD	Chest Reconstruction and Chest Dysphoria in Transmasculine Minors and Young Adults: Comparisons of Nonsurgical and Postsurgical Cohorts
2019 - 2021	Laer Streeter	MD	Comparison of Histrelin Implants
2020 - Present	Richard Mateo Mora	MD	Fertility Preservation Among Transgender Women
2022	Avery Everhart	PhD	Incomplete Data & Insufficient Methods: Transgender Population Health Research in the US
2023-present	Kenedy Ramos	PsyD	Transyouth Sexual Functioning and Development

#### GRADUATE STUDENT THESIS, EXAM AND DISSERTATION COMMITTEES:

Year-Year	Trainee Name	Committee Type	Student Department
2022	Avery Everhart	Dissertation	Social Work

#### POSTGRADUATE MENTORSHIP:

Year-Year	Trainee Name	If past trainee, current position and location
2012-2013	Lisa Simons, MD	Clinical Instructor – Lurie Children's Hospital
2013	Shelley Aggarwal, MD	Clinical Instructor – Stanford University School of Medicine
2014	Julie Spencer, MD	Adolescent Medicine Provider Kaiser Hospital
2014-2015	Michael Haymer, MD	Program Director, Psychiatry Department UCLA
2015-2017	Patrick Shepherd, MD	CHLA Endocrinology Fellow
2015-2018	Jonathan Warus, MD	Faculty, CHLA/USC Keck School of Medicine
2015-2020	Shannon Dunlap, PhD	Postdoctoral Scholar - Research Associate, University of Southern California, Suzanne Dworak-Peck School of Social Work
2020-Present	Marianela Gomez-Rincon, MD	Adolescent Medicine Fellow
2020-Present	Jonathan Warus, MD	CHLA, Assistant Professor of Clinical Pediatrics
2022	Emmett Henderson, PhD, MS	USC Suzanne Dworak-Peck School of Social Work Senior mentor K99; USC

#### MENTORSHIP OF FACULTY:

Year-Year	Mentee Name	Mentee Department
2021 - present	Jonathan Warus, MD	Division of Adolescent Medicine, CHLA
2022 - present	Brigid Conn, PhD	Clinical Psychologist, CHLA
2023 - present	Marianella Gomez, MD	Division of Adolescent Medicine, CHLA

#### **SERVICE**

#### **DEPARTMENT SERVICE:**

Year-Year	Position, Committee	Organization/Institution
2010-2015	Secretary, The CHAMPION	The Division of Adolescent Medicine, Children's
	Fund Executive Board	Hospital Los Angeles

#### HOSPITAL OR MEDICAL GROUP SERVICE:

Year-Year	Position, Committee	Organization/Institution	
2021 - present	Committee Member	SOGI work group, CHLA	

#### **PROFESSIONAL SERVICE:**

Year-Year	Position, Committee	Organization/Institution
2012-present Member, LGBT Special Interest		Society for Adolescent Health and Medicine
	Group	
2016-present	Board Member	US Professional Association of Transgender Health
2022	Secretary, Executive Board of	US Professional Association of Transgender Health
	Directors	
2023	President Elect	US Professional Association of Transgender Health

#### CONSULTANTSHIPS AND ADVISORY BOARDS:

Year	Position, Board	Organization/Hospital/School, Institution
2010-2017	Member, Advisory Board	Transyouth Family Allies
2017-present	Member, National Medical Committee	Planned Parenthood
2017 - Present	Board Member	US Professional Association of Transgender Health
2021	Expert Panelist	Robert Wood Johnson Foundation - National
2021	Member, Advisory Board	Commission on Data Transformation for Health Equity The National LGBTQIA+ Health Education Center
2023	Working Group Member; Expanding the Evidence Base in Gender- Affirming Care for Transgender and Gender Diverse Populations	NIH, Sexual & Gender Minority Research Office
2023	Consultant	Behavioral Health Excellence-Technical Assistance Center funded by the Health Resources and Services Administration (HRSA) to provide technical assistance, training, resources, tools, and consultation to their BHWET (Behavioral Health Workforce Education and Training), OWEP (Opioid Workforce Expansion Program) and GPE (Graduate Psychology Education) grantees.

#### **PROFESSIONAL SOCIETY MEMBERSHIPS:**

Year- Year	Society	
2003 - present Society for Adolescent Health and Medicine		
2005 - present American Academy of Pediatrics		
2006 - 2011 Los Angeles Pediatric Society (Past president 2010)		
2010 - present Professional Association for Transgender Health		
2014 - present Society for Pediatric Research		
2017 - present US Professional Association for Transgender Health		

# MAJOR LEADERSHIP POSITIONS: (E.G., DEAN, CHAIR, INSTITUTE DIRECTOR, HOSPITAL ADMINISTRATION, ETC.)

#### RESEARCH AND SCHOLARSHIP

#### **EDITORSHIPS AND EDITORIAL BOARDS:**

Year-Year	Position	Journal/Board Name
2015 - present	Associate Editor	Journal of Transgender Health

#### MANUSCRIPT REVIEW:

Year-Year	Journal	
2014 - present Pediatrics		
2014 - present	Journal of Adolescent Health	
2014 - present	LGBT Health	
2014 - present International Journal of Transgenderi Health		
2015 - present Journal of Transgender Health		
2018 - present	2018 - present Clinical Child Psychology and Psychiatry	
2018 - present Journal of Sexual Medicine		
2021 - present JAMA Peds		

#### **GRANT REVIEWS:**

Year	Description	Awarding agency, City, State, Country
2017	Cognition and Perception Study Section	National Institutes of Health, Bethesda, Maryland, USA
2017	Neurological, Aging and Musculoskeletal Epidemiology Study Section	National Institutes of Health, Bethesda, Maryland, USA
2018	Social Psychology, Personality and Interpersonal Processes Study Section	National Institutes of Health, Bethesda, Maryland, USA
2018	Neurological, Aging and Musculoskeletal Epidemiology Study Section	National Institutes of Health, Bethesda, Maryland, USA
2019	Special Emphasis Panel Review of Research Conference (R13) Grants	National Institutes of Health, Bethesda, Maryland, USA
2019	The Einstein Foundation Award for Promoting Quality in Research	Einstein Foundation, Berlin
2020	Biobehavioral and Behavioral Sciences Study Section	National Institutes of Health, Bethesda, Maryland, USA
2021	Social Psychology, Personality and Interpersonal Processes Study Section	National Institutes of Health, Bethesda, Maryland, USA

#### MAJOR AREAS OF RESEARCH INTEREST

Research Areas	
1. Transgender and non-binary children, adolescents and young adults	
2. HIV medication adherence	

#### **GRANT SUPPORT - CURRENT:**

Grant No. (PI)2R01HD082554-06A1 (Olson-Kennedy)	Dates of Award: 2021-2026	
Agency: NICHD Percent Effort 25%		
Title: The Impact of Early Medical Treatment in Transgender Youth		
Description: This is the continuations of a multicenter study, the first of its kind in the U.S. to evaluate the long-term outcomes of medical treatment for transgender youth. This study will provide essential, evidence-based information on the physiological and psychosocial impact, as well as safety, of hormone blockers and cross-sex hormones use in this population.		
Role: Principle Investigator		
Total Direct Costs: \$4,918,586		

Grant No. 1R01HD097122-01 (Hidalgo)	Dates of Award: 2019-2024
Agency: NICHD	Percent Effort 2.5%

Title: A Longitudinal Study of Gender Nonconformity in Prepubescent Children

*Description:* The purpose of this study is to establish a national cohort of prepubertal transgender/gender nonconforming (TGNC) children (and their parents), and longitudinally observe this cohort to expand the body of empirical knowledge pertaining to gender development and cognition in TGNC children, their mental health symptomology and functioning over time, and how family-initiated social gender transition may predict or alleviate mental health symptoms and/or diagnoses.

Role: Site PI	
Total Direct Costs: \$2,884,950	

Grant No. LGBT Health Equity Dates of Award: 2023-2025		
Agency: California Department of Public Health Percent Effort 10%		
Title: Beliefs, Knowledge, and Attitudes of Pediatric Primary Care Providers Serving		
Latine Communities Regarding Gender-Affirming Care for Minors		
Description: This study aims to better understand the current barriers facing Latine pubertal TGNB		

Description: This study aims to better understand the current barriers facing Latine pubertal TGNB youth and their parents/caretakers in accessing gender affirming care, assess the attitudes, beliefs, knowledge, perspectives, and comfort level of pediatric primary care providers serving people in predominately Latine communities regarding TGNB youth.

Role: Principle Investigator
Total Direct Costs: \$237,857

#### **GRANT SUPPORT - PAST:**

GRANT SULLORI - LASI.	
Grant No. (PI) 1RO1HD082554-01A1	Dates of Award: 2015-2020
Agency: NICHD	Percent Effort 45%
Title: The Impact of Early Medical Treatment in Transgender Yo	outh
Description: This is a multicenter study, the first of its kind in the	he U.S. to evaluate the long-term
outcomes of medical treatment for transgender youth. This study	will provide essential evidence-based

information on the physiological and psychosocial impact, as well as safety cross-sex hormones use in this population.	y, of hormone blockers and
Role: Principle Investigator	
Total Direct Costs: \$4,631,970	
Grant No. (COI) R01AI128796-01	Dates of Award: 2/24/17-1/31/18
Agency: NIAID	Percent Effort: 5%
Title: Maturation, Infectibility and Trauma Contributes to HIV Susceptibil	ity in Adolescents
Description: This proposal explores the overarching hypothesis that fluctuations in sex steroid levels and mucosal trauma (sexual activity) are key determinants of mucosal immune activation and epithelial integrity, and that microbial communities are central to these processes. We will pursue this hypothesis by examining longitudinal changes in the anogenital microbiome as well as protein expression at these mucosal sites during sexual maturation (cisgender youth) and in hormonally-controlled sexual maturation (transgender youth). Associations between sex steroid levels, microbial community composition, mucosal	

Role: Co-Investigator	
Total Direct Costs: \$44,816	_

trauma, and vaginal proteins will be determined and modeled.

Grant No. (PI) U01HD040463	Dates of Award 2006 – 2016	
Agency: NIH/NICHD Percent Effort: 10%		
Title: Adolescent Medicine Trials Network for HIV/AIDS		
Description: Adolescent Medicine Trials Network for HIV/AIDS		
Role: Co-Investigator		
Total Direct Costs: 2,225,674		

Grant No. (PI) SC CTSI	Dates of Award: 2012-2014	
8KL2TR000131	·	
Agency: KL2 Mentored Career Research Development	Percent Effort: 37.5%	
Program of the Center for Education, Training and Career		
Development		
Title: The Impact of Hormone Blockers on the Physiologic and Psychosocial Development of Gender		
Non-Conforming Peri-Pubertal Youth		
Description: This study aimed to understand the impact of puberty blocking medications on mental health		
and physiolgic parameters in peri-pubertal transgender youth.		
Role: Principal Investigator		
Total Direct Costs: 191,525		

#### Invited Lectures, Symposia, keynote addresses

Date	Type	Title, Location
2014	Invited Lecture	Transgender Youth; Needs, Risks, Outcomes and the Role of the System, Including Permanency and Inclusion for Our Youth, Administrative Office of the Courts, Center for Families and Children, San Diego, California

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2015	Invited Lecture	Caring for Gender Non-Conforming and Transgender Youth, Lopez Family Foundation Special Lecture for Puerto Rico and Panama, Lopez Family Foundation, Children's Hospital Los Angeles, Los Angeles, California
2015	Symposium	Transgender Youth – An Overview of Medical and Mental Health Needs of Gender Non-Conforming Children and Transgender Adolescents, Public Child Welfare Training Academy, Academy for Professional Excellence at San Diego State University School of Social Work, San Diego, California
2015	Invited Lecture	Meeting the Needs of Transgender Adolescents; 1 <sup>st</sup> Annual Southern California LGBT Health Symposium; USC/UCLA, Los Angeles, California
2015	Symposium	Transgender Youth; An Overview of Medical and Mental Health Needs of Gender Non-conforming Children and Transgender Adolescents; GetReal California's Initiative; "Integrating Sexual Orientation, Gender Identity, and Expression (SOGIE) into California's Child Welfare System," Oakland, California
2016	Invited Symposium	Caring for Gender Nonconforming and Transgender Youth; Idyllwild, California
2016	Educational symposium	Gender 101: A Primer; Vista Mar, California
2016	Invited Lecture	Caring for Gender Non-conforming Children and Teens in the New Millennium - A Multidisciplinary Team Approach, California Association of Marriage and Family Therapists, Los Angeles, California
2016	Invited Lecture	Caring for Gender Nonconforming Children and Transgender Youth, California Psychological Association, Continuing Education Institute, Irvine, California
2016	Invited Lecture	Health Issues Related to Transgender Youth; LA City Health Commission, Los Angeles, California
2016	Invited Lecture	Caring for Gender Nonconforming and Transgender Youth, Medical Directors 12th Annual Update on Reproductive Health and Medical Leadership, Planned Parenthood, Steamboat Springs, Colorado
2016	Invited Lecture	Caring For Transgender Teens, UCLA Meet the Professor, Los Angeles, CA
2017	Symposium	Caring for Gender Non-Conforming and Transgender Youth, TransYouth Care, Santa Barbara, CA
2017	Invited Lecture	Healthcare for TGNC Youth, Expanding Competency for LGBT Youth in the System Conference, Center for Juvenile Justice Reform, Washington DC
2017	Invited Lecture	Gender Non-conforming and Transgender Children and Youth; Center for Early Education, West Hollywood, CA
2017	Invited Lecture	Gender Non-Conforming Children and Transgender Youth, Board of Behavioral Sciences, Orange, CA
2017	Invited Lecture	Puberty Suppression and Hormones; Medical Interventions for Transgender Youth, Santa Monica Rape Treatment Center, Santa Monica, CA
2017	Invited Lecture	Transgender Youth Care in the New Millennium, USC Law and Global Health Initiative, Los Angeles, CA
2018	Invited Lecture	Supporting Gender Diverse and Transgender Youth: A Deeper Look at Gender Dysphoria, Invited lecture, Oakwood School, Studio City, California, 2018
2018	Invited Lecture	Working with Trans and Gender Non-Conforming Youth, Children's Hospital Orange County, CA
2018	Invited Lecture	Caring for gender Non-conforming and Transgender Youth and Young Adults, Ascend Residential, Encino CA

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2018	Invited Lecture	Caring for gender Non-conforming and Transgender Youth and Young Adults, California State University Northridge, Northridge, CA
2018	Invited Lecture	Gender Dysphoria; School Nurse Association of Idaho Annual Conference, School Nurse Association of Idaho Association, Boise Idaho
2018	Invited Lecture	Gender and What You Should Know, Archer School for Girls, Brentwood, CA
2018	Symposium	Caring for Gender Non-Conforming and Transgender Youth, TransYouth Care, Oceanside, CA
2018	Invited Lecture	Gender Dysphoria: Beyond the Diagnosis, Advance LA Thriving Through Transitions Conference, The Help Group, Los Angeles, California
2018	Invited Lecture	Caring for Gender Non-Conforming and Transgender Youth, Andrology Society of America Clinical Symposium, Andrology Society of America, Portland, Oregon
2018	Symposium	Caring for Gender Non-Conforming and Transgender Youth, TransYouth Care, Los Angeles, CA
2018	Invited Lecture	Caring for Gender Non-Conforming and Transgender Youth, Center for Early Education, Los Angeles, CA
2019	Symposium	The Care of Trans and Gender Non-Conforming Youth and Young Adults, Cal State Los Angeles, California
2019	Symposium	The Care of Trans and Gender Non-Conforming Youth and Young Adults, Claremont Colleges, California
2019	Symposium	TransYouth Care; Flagstaff, AZ
2019	Invited Lecture	Transgender and Gender Non-conforming Youth, Invited lecture, Elevations Residential Treatment, Salt Lake City, Utah
2019	Invited Lecture	Gender Diverse and Transgender Youth; What Pediatricians Should Know, Common Problems in Pediatrics Conference, Utah AAP, Utah
2019	Invited Lecture	Caring for Gender Diverse and Transgender Youth, Grand Rounds, UCLA Olive View, CA
2019	Invited Lecture	Caring for Gender Diverse and Transgender Youth, Grand Rounds, Good Samaritan, Los Angeles, California
2019	Invited Lecture	Puberty Suppression in Youth with Gender Dysphoria, Fenway Trans Health Program, Boston
2019	Invited Lecture	Recognizing the Needs of Transgender Youth, California Department of Corrections and Rehabilitation, Ventura, CA
2019	Invited Lecture	Gender Dysphoria; Beyond the Diagnosis, Gender Education Demystification Symposium, Gender Education and Demystification, Atlanta, Georgia
2019	Invited Lecture	Caring for Gender Nonconforming and Transgender Youth, Los Angeles Superior Court/Los Angeles Bar Association Training, CA
2019	Invited Lecture	Supporting Gender Diverse and Transgender Youth; A Deeper Look at Gender Dysphoria, Oakwood School, CA
2020	Symposium	Trans Youth Care, Chico Transgender Week, Virtual Presentation
2020	Invited Lecture	Gender Nonconforming and Transgender Youth, Novartis, Virtual Presentation
2020	Invited Lecture	Advanced Hormones; More than Just T and E, CHLA, Virtual Presentation
2020	Invited Lecture	Video Telehealth and Transgender Youth, Telehealth Best Practices for the Trans Community, The Central Texas Transgender Health Coalition, Virtual Presentation

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2020	Invited Lecture	Gear Talk, Transforming Families, Virtual Lecture
2020	Invited Lecture	Tips for Parenting a Trans or Gender Diverse Youth, Models of Pride, Virtual Presentation
2020	Invited Lecture	Caring for Gender Diverse and Transgender Youth, LGBTQ+ Clinical Academy, Palo Alto University, Virtual presentation
2020	Invited Lecture	Medical Interventions for transgender youth, Cal State Los Angeles, Los Angeles
2020	Plenary Session	Understanding Issues Involving Gender Non-Conforming and Transgender Individuals Coming to a Courtroom Near You, Mid-Winter Workshop for Judges of the Ninth Circuit, Palm Springs, CA
2021	Invited Lecture	Gender Affirmation through a Social Justice Lens; Center for Gender Equity in Medicine and Science (GEMS) at Keck School of Medicine, Los Angeles
2021	Invited Lecture	Introduction to the Care of Gender Diverse and Transgender Youth, Providence Medical Group – South Bay Pediatrics (Torrance, San Pedro, Redondo Beach), virtual lecture
2021	Invited Lecture	Caring for Gender Diverse and Transgender Youth. San Luis Obispo Acceptance, Cal Poly, Virtual Presentation
2022	Invited Lecture	Transgender and Non-binary children and youth, Board of Behavioral Sciences
2022	Invited Lecture	Gender Affirmation through a Social Justice Lens; University of Arizona Health Sciences LGBTQ+ Symposium & Health Fair
2022	Invited Lecture	Gender Dysphoria in Children, Adolescents and Young Adults, MedLambda and Psych SIG Keck USC School of Medicine, Virtual Lecture
2022	Invited Lecture	Caring for Transgender and Gender Nonconforming Youth, Presbyterian Healthcare Services, New Mexico, Virtual lecture
2022	Invited Lecture	Transgender and Non-Binary Youth, Rogers Behavioral Health, Virtual Lecture
2023	Invited Lecture	Transgender and Non-binary Youth and Young Adults 101, When Healthcare Gets Political; Health Justice and Systems of Care course, Keck USC School of Medicine, Los Angeles
2023	Invited Lecture	Transgender and Non-Binary Youth; Navigating Gender Care in 2023, Improving Outcomes Conference, UC Davis, Sacramento, CA
2023	Invited Lecture	Gender Affirming Medical and Mental Health Care for Transgender Adolescents, California Association of Marriage and Family Therapists Annual Conference, Santa Clara, CA
2023	Invited Lecture	Trans Youth Care in 2023; What's New, What's Not, Behavioral Health Excellence-Technical Assistance Center
2023	Invited Lecture	Pharmacology for Transgender Children and Adolescents, NICHD Pediatric Clinical Pharmacological Lecture Series, May 2023
2023	Invited Lecture	The Transyouth Center for Health and Development at CHLA, USC Ellison Institution, Pride Week, June 2023
2023	Invited Lecture	Transgender Youth Care, Congressional Research Service, Washington DC
2023	Invited Lecture	Caring for Gender Diverse and Transgender Youth, LGBTQ+ Clinical Academy, Palo Alto University, Virtual presentation
2024	Symposium	Comprehensive Approach to the Care of Gender Non-conforming and Transgender Youth, Trusted Provided Network, virtual training

### **Invited Grand Rounds, CME Lectures**

Date	Туре	Title, Location
2014	Grand Rounds	Caring for Gender Non-conforming Children and Teens in the New Millennium - A Multidisciplinary Team Approach; Seattle Children's Hospital, Seattle, Washington
2014	CME lecture	Transgender Youth; An Overview of Medical and Mental Health Needs of Gender Non-conforming Children and Transgender Adolescents; Eisenhower Medical Center Transgender Health Symposium, Palm Springs, California
2014	Grand Rounds	Toddlers to Teens: Comprehensive Health Care for the Transgender Child, Cultural Psychiatry Lecture Series, University of Iowa Carver College of Medicine, Iowa City, Iowa
2014	Grand Rounds	Caring for Gender Non-conforming Children and Teens in the New Millennium; A Multidisciplinary Team Approach, Children's Hospital Los Angeles, Los Angeles, California
2014	CME lecture	Difficult Cases, Gender Spectrum Family Conference, Gender Spectrum, Moraga, California
2014	CME lecture	Cross-sex Hormones for Teenagers, How Young is Too Young? Philadelphia Trans Health Conference, Philadelphia, Pennsylvania
2014	CME lecture	Pediatric Update, Philadelphia Trans Health Conference, Philadelphia, Pennsylvania
2015	Grand Rounds	Caring for Gender Nonconforming and Transgender Youth, Stanford Division of Adolescent Medicine, Palo Alto, CA
2015	CME Educational Lecture	Update on the Transgender Patient for the PCP, St. Joseph's Providence, Burbank, CA
2015	CME Educational Lecture	Caring for Gender Non-Conforming Children and Transgender Teens, Providence Tarzana, CA
2015	Grand Rounds	Caring for Gender Nonconforming and Transgender Youth, University of Southern California, Los Angeles, California
2015	Grand Rounds	Puberty Blockers and Cross Sex Hormones, Pediatric Endocrinology, Children's Hospital Los Angeles, Los Angeles, California
2015	CME lecture	Youth and Hormones, 2015 Gender Expansion Conference, University of Montana, Missoula Montana
2015	CME lecture	Transyouth Healthcare, 2015 Gender Expansion Conference, University of Montana, Missoula Montana
2015	CME lecture	Supporting Transgender Youth, Southern Oregon University Student Health and Wellness Center Workshop, Southern Oregon University, Ashland, Oregon
2015	PCS Grand Rounds	Caring for Gender Nonconforming Children and Transgender Youth, Children's Hospital Los Angeles, Los Angeles, California
2015	CME lecture	Medical Care for Gender Non-Conforming Children, Transgender Adolescents and Young Adults in the New Millennium, Continuing Medical Education of Southern Oregon, Medford, Oregon
2015	Grand Rounds	Medical Care for Gender Non-Conforming Children and Transgender Youth, Olive View Medical Center-UCLA, Sylmar, California
2015	Grand Rounds	Caring for Gender Non-conforming Children and Transgender Teens, Harbor-UCLA Department of Pediatrics, Torrance, California

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2015	CME lecture	Caring for Gender Non-conforming Children and Teens in the New Millennium, Healthcare Partners Pediatric Town Hall Meeting, Healthcare Partners CME, Glendale, California
2016	Pediatric Grand Rounds	Puberty Suppression and Hormones; Medical Interventions for Transgender Youth; Children's Hospital Los Angeles, Los Angeles, California
2016	Endocrine Grand Rounds	Approach to Care of Gender Non-Conforming Children and Transgender Adolescents; Cedars Sinai Hospital, Los Angeles, California
2016	Pediatric Grand Rounds	Care of Gender Non-Conforming Children and Transgender Adolescents in the New Millennium, Stanford Lucille Packard Children's Hospital, Palo Alto, California
2016	Pediatric Update	Caring for Gender Variant Children and Adolescents, Pediatric Update for the Primary Provider, Children's Hospital St. Louis, St. Louis, Missouri
2016	Grand Rounds	Care of Gender Non-Conforming Children and Transgender Adolescents in the New Millennium, St. Jude's Grand Rounds, Memphis, Tennessee
2016	CME Educational Lecture	Transgender and Gender Non-Conforming Youth: Innovative Approaches to Care in 2016; Integrating Substance Use, Mental Health, and Primary Care Services: Courageous and Compassionate Care, Los Angeles, California
2016	CME; professional conference	Caring for Gender Non-conforming Children and Teens in the New Millennium - A Multidisciplinary Team Approach, Arizona Psychiatric Society, Tempe, Arizona
2016	CME/Educati onal Symposium	Caring for Gender Nonconforming and Transgender Youth, San Diego, California
2016	CME/CEU Educational Training	Medical Interventions for Transgender Youth and Young Adults, San Diego State University, San Diego, California
2016	Grand Rounds	Caring for Gender Nonconforming Children and Transgender Youth, Mt. Sinai Hospital, Pediatric Grand Rounds George J. Ginandes Lecture, New York, New York
2016	CME Educational Lecture	The Transgender Experience, Providence Tarzana, CA
2017	CME Educational Seminar	Caring for Gender Non-Conforming and Transgender Youth, TransYouth Care, San Diego, CA
2017	CME Educational Seminar	The Care of Gender Non-Conforming children and Transgender Youth; Orange County Health Care Agency, Orange County, CA
2017	CME Educational Lecture	Rethinking Gender, Adolescent Grand Rounds, Children's Hospital Los Angeles, Los Angeles, CA
2017	CME Educational Lecture	Gender Non-Conforming Children and Transgender Youth, CME lecture for OB/Gyn, Omnia-Prova Education Collaborative, inc. Pasadena, California
2017	CME Educational Lecture	Gender Non-Conforming and Transgender Children and Adolescents, Developmental Pediatrics continuing education lecture, Children's Hospital Los Angeles, CA

2017	CME Educational Lecture	Care of Gender Non-Conforming Children and Transgender Adolescents, Lopez Family Foundation Educational Lecture, Los Angeles, CA
2017	CME Educational Lecture	Puberty Suppression and Hormones; Medical Interventions for Transgender Youth, USC Keck School of Medicine Reproductive Health, Los Angeles, CA
2017	CME Educational Seminar	Caring for Gender Non-Conforming and Transgender Youth, TransYouth Care, San Diego, CA
2018	CME Symposium	Caring for Gender Nonconforming and Transgender Youth, Glendale Unified School District, CA
2018	CME Educational Lecture	Caring for Gender Non-Conforming Children and Transgender Youth, CME by the Sea, CA
2018	CME Symposium	Caring for Gender Non-Conforming and Transgender Youth, TransYouth Care, Austin, TX
2018	CME Educational Lecture	Approach to the Care of Gender Non-Conforming Children and Transgender Youth, Desert Oasis Healthcare, Palm Desert, CA
2018	CME Workshop	Mental and Medical Healthcare for Transgender Adolescents, California Association of Marriage and Family Therapists, Garden Grove, CA
2018	CME Educational Lecture	Approach to the Care of Gender Non-Conforming Children and Transgender Youth, Keck School of Medicine, Los Angeles, CA
2018	Grand Rounds	Caring for Gender Non-Conforming Children and Transgender Adolescents, Primary Children's Hospital, Salt Lake City, UT
2018	CME Educational Lecture	Caring for Transgender Youth, Chico Trans Week, Chico, CA
2018	CME Educational Lecture	Rethinking Gender, UCSD Medical School, San Diego, CA
2018	CME Educational Lecture	Rethinking Gender, UCLA Medical School, Los Angeles, CA
2019	Symposium	Recognizing the Needs of Transgender Youth, California Department of Corrections and Rehabilitation, Stockton, CA
2019	Symposium	The Care of Trans and Gender Non-Conforming Youth and Young Adults, Cal State Los Angeles, California
2019	Symposium	The Care of Trans and Gender Non-Conforming Youth and Young Adults, Claremont Colleges, California
2019	CME Lecture	Gender Diverse and Transgender Youth, Harbor UCLA Medical Center Grand Rounds, Torrance, CA
2019	CME Lecture	Gender Dysphoria – Beyond the Diagnosis, Gender Odyssey San Diego, San Diego, CA
2019	Grand Rounds	Transgender Youth; What's New in 2019?, Children's Hospital Los Angeles, CA

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2019	CME Symposium	Caring for Gender Nonconforming and Transgender Youth, Children's Hospital Orange County, CA	
2019	CME Symposium	Caring for Gender Nonconforming and Transgender Youth, Stanislaus County Behavioral Health and Recovery Services, CA	
2019	CME Eduational Lecture	Rethinking Gender, Olive View Medical Center Grand Rounds, CA	
2020	CME Lecture	Gender Affirmation Through a Social Justice Lens, SAHM Conference, Virtual Presentation	
2020	CME Lecture	Introduction to the Care of Gender Diverse and Transgender Youth, AAP Conference, Virtual Lecture	
2020	CME Lecture	Conversations with LGBTQ youth; the role of the pediatrician, AAP Conference, Virtual Lecture	
2020	Grand Rounds	Creating Affirming Environments for Trans and Gender Diverse Patients, USC OB/Gyn Grand Rounds, Virtual Presentation	
2020	CME Lecture	Introduction to the Care of Gender Diverse and Transgender Youth, Resident Lecture, CHLA	
2020	CME Lecture	Introduction to the Care of Gender Diverse and Transgender Youth, Facey Medical Group, Los Angeles, CA	
2020	Plenary Lecture	Reframing Gender Dysphoria, LEAH Conference, Los Angeles, CA	
2020	CME Lecture	Gender Affirming Care for Pre and Peri-pubertal Trans and Gender Diverse Youth, LEAH Conference, Los Angeles, CA	
2020	CME Lecture	Introduction to the Care of Gender Diverse and Transgender Youth, Division of Endocrinology, USC, Los Angeles, CA	
2021	CME Lecture	Transitioning from Invalidation and Trauma to Gender Affirming Care; ACCM Grand Rounds, Children's Hospital Los Angeles, Virtual presentation	
2021	CME Symposium	TransYouth Care; Transfamily Support San Diego, Virtual Symposium	
2021	Symposium	TransYouth Care for Parents; Santa Clara, CA	
2022	CME Lecture	Gender affirming medical interventions; An Evolving landscape, Critical Issues in Child and Adolescent Mental Health Conference, San Diego, California	
2022	CME Symposium	TransYouth Care for Mental Health Providers; Santa Clara, CA	
2022	CME Symposium	TransYouth Care; Transfamily Support San Diego, Virtual Symposium	
2023	CME Lecture	Transgender Patients, Unique Considerations, Scripps Mercy Hospital, Virtual Symposium, Aug 2023	
2023	Mini- symposium	Developmental Trajectories and Medical Decisions; Transitions in Childhood and Adolescents and Young Adults, USPATH Conference, Weminister CO	
2024	Workshop	Developmental Trajectories and Medical Decisions; Transitions in Childhood and Adolescents and Young Adults, Society for Adolescent Health and Medicine Conference, San Diego, CA	
2024	Symposium	TransYouth Care; Transfamily Support San Diego, Virtual Symposium	

#### **International Lectures**

Date	Type	Title, Location
2013	Keynote	Caring for Gender Non-conforming Children and Adolescents in the New Millennium, Vancouver, Canada
2016	CME; professional conference	Social Transitions in Pre-pubertal Children; What do we know? World Professional Association of Transgender Health, Amsterdam, The Netherlands
2016	CME; professional conference	Beyond Male and Female; Approach to Youth with Non-Binary Gender Identities, World Professional Association of Transgender Health, Amsterdam, The Netherlands
2016	CME; professional conference	Workgroup on Gender Nonconforming/Transgender Youth: Biopsychosocial Outcomes and Development of Gender Identity, World Professional Association of Transgedner Health, Amsterdam, The Netherlands
2017	Invited Lecture	Gender Dysphoria, Beyond the Diagnosis, Pink Competency, Oslo Norway
2017	Invited Lecture	Caring for Gender Non-Conforming Children and Transgender Adolescents: A United States Perspective, Pink Competency, Oslo Norway
2017	Invited Lecture	Caring for Gender Non-conforming and Transgender youth and Young Adults, Diverse Families Forum: The Importance of Family Support in The Trans And LGBT Children, Organized by COPRED and The International Association Of Families For Diversity (FDS), Mexico City, Mexico
2018	Invited Lecture	Chest Reconstruction and Chest Dysphoria in Transmasculine Adolescents and Young Adults: Comparison of Nonsurgical and Postsurgical Cohorts, Buenos Aires, Argentina
2018	Invited Lecture	Transgender Youth and Gender Affirming Hormones; A 6-8 year follow- up, Buenos Aires, Argentina
2018	Invited Lecture	Transyouth Care – An NIH Multisite Study About the Impact of Early Medical Treatment in Transgender Youth in the US, Buenos Aires, Argentina
2018	Invited Lecture	Uso de Hormonas Reaffirmantes de Genero en Adolescentes Transgenero, Trans Amor Congreso Nacional de Transexualidad Juvenil y Infantos, Monterey, Mexico
2018	Invited Lecture	Bloquedores de la Pubertad, Trans Amor Congreso Nacional de Transexualidad Juvenil y Infantos, Monterey, Mexico
2018	CME Educational Lecture	Puberty Blockers and Gender Affirming Hormones for Transgender Youth: What Do We Know, and What Have We Learned, Pediatric Academic Societies, Toronto, Canada
2019	Grand Rounds	Rethinking Gender, Grand Rounds, The Hospital for Sick Children, Toronto, Canada
2019	Keynote	Gender Dysphoria; Beyond the Diagnosis, Promoting Innovation and Collaboration to Support Gender Diverse Youth Conference, The Hospital for Sick Children, Toronto, Canada, December 2019

2019	Invited Lecture	Hormonas que Affirman el Genero pasa Juventud y Adultos Menores Trans, Transformando Desde el Amor y Las Familias, Colombia
2019	Invited Lecture	Infancia Trans y da Genero Diverso, Transformando Desde el Amor y Las Familias, Colombia
2019	Invited Lecture	Transgender Youth: Medical and Mental Health Needs, Bristol, United Kingdom
2019	Invited Lecture	Rethinking Gender, University of Bristol, United Kingdom
2019	CME; professional conference	Male Chest Reconstruction and Chest Dysphoria in Transmasculine Adolescents and Young Adults, European Professional Association of Transgender Health, Rome Italy
2019	CME; professional conference	Transgender Youth and Gender Affirming Hormones; 5-7 Year Follow Up, European Professional Association of Transgender Health, Rome Italy
2019	CME Educational Lecture	Gender Dysphoria; Beyond the Diagnosis, European Professional Association of Transgender Health, Rome Italy
2022	Plenary Session	The Landscape of Gender Affirming Care for Youth in the US, AusPATH, Virtual
2022	CME; professional conference	Emotional Functioning of Adolescents with Gender Dysphoria After Two Years of Treatment; WPATH Conference, Montreal, Canada
2022	CME; Professional Conference	Creating Enduring Materials; WPATH Conference, Montreal, Canada

## **Keynote/Plenary Presentations**

Date	Type	Title, Location
2015	Varmata	The Future of Trans Care in the New Millennium, Gender Infinity
2013	Keynote	Conference, Houston, Texas
2016	Dlanamy Sassian	Caring for Trans Youth and Gender Non-Conforming Children,
2010	Plenary Session	Transgender Spectrum Conference, St. Louis, Missouri
		Rethinking Gender, Keynote, Annual Convocation Welcome Luncheon
2017	Invited Lecture	for the LGBTA Community, University of Massachusetts, Worcester,
		Massachusetts, 2017
2018	Keynote	Future Directions, USPATH, Washington DC
2019	Varmata	Gender Dysphoria; A Deeper Dive Beyond the Diagnosis, Inaugural
2019	Keynote	LGBTQ summit, Santa Clara CA
	CME;	Advances and Challenges in the Care of Transgender/Gender Diverse
2021	professional	Youth; USPATH Conference, Virtual presentation
	conference	· · · · · · · · · · · · · · · · · · ·
2022	Keynote	Gender Affirmation Through a Social Justice Lens, Indiana University
2022	Reynote	School of Medicine
		Transgender and Non-Binary Youth, Supporting the Well-Being of
2022	Invited Lecture	LGBTQ Youth Certificate Program Center for Juvenile Justice Reform
		Georgetown University, virtual training

2022	Invited Lecture	Transgender and Non-Binary Youth, Young Women's Career Conference (YWCC) for the Girls Academic Leadership Academy; virtual lecture
2023	Plenary	TransYouth Care Network; An Update on the Research, USPATH Conference, Westminister, CO

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<sup>\*</sup> INDICATES TRAINEES

<sup>\*\*</sup> INDICATE YOURSELF AS CO-FIRST OR CO-CORRESPONDING OR SENIOR AUTHORS

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- 14. **Olson J**, Puberty Suppression in Gender Non-conforming Children, Gender Odyssey Conference, Gender Odyssey, Seattle, WA, 2014
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- 16. **Olson J**, Just a Boy, Just a Girl, Gender Spectrum, Gender Spectrum Professional Conference, Moraga, California, 2015
- 17. **Olson J**, Transition for Teens and Young Adults, Gender Infinity Provider and Advocacy Day, Gender Infinity Conference, Houston, TX, 2015
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2011, Transgender Youth, Rosie O'Donnell's The DOC Club

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# IN THE UNITED STATES DISTRICT COURT FOR THE DISTRICT OF SOUTH CAROLINA

STERLING MISANIN, et al.,	
Plaintiffs,	
v.	Case No.:
ALAN WILSON, in his official capacity as the Attorney General of South Carolina, et al.,	
Defendants.	

I

# EXPERT DECLARATION OF ARMAND H. MATHENY ANTOMMARIA, MD, PhD, FAAP, HEC-C

#### INTRODUCTION

- I, Armand H. Matheny Antommaria, hereby state as follows:
- 1. I have been retained by counsel for Plaintiffs as an expert in connection with the above-captioned litigation. I am over 18 years old, of sound mind, and in all respects competent to testify.
  - 2. I have actual knowledge of the matters stated herein.
- 3. In preparing this declaration, I reviewed South Carolina House Bill 4624 ("H 2624"). In addition to this legislation and the materials cited herein, I have also relied on my years of research and other experience, as set out in my curriculum vitae (CV) (Exhibit A), in forming my opinions. The materials I have relied upon in preparing this declaration are the same types of materials that experts in my fields of study regularly rely upon when forming opinions on subjects. I may wish to supplement these opinions or the bases for them as a result of new scientific research or publications or in response to statements and issues that may arise in my areas of expertise.

#### **OVERVIEW**

- 4. I am a pediatrician and bioethicist with extensive clinical and research experience. I am the author of 43 peer-reviewed articles, which have been published in high-impact journals including the *Journal of the American Medical Association* and *Annals of Internal Medicine*, and I direct the Ethics Center at Cincinnati Children's Hospital Medical Center. I have reviewed H 4624 and submit this declaration to explain my disagreement with and concerns about its conclusions.
- 5. H 4624, among other restrictions, prohibits physicians from "knowingly provid[ing] gender transition procedures to a person under eighteen years of age," S.C. Code § 44-42-320(A) with a provision requiring ongoing treatment with puberty-blocking drugs or cross-sex hormones be discontinued prior to January 1, 2026. "Gender transition procedures" are defined as "puberty-blocking drugs, cross-sex hormones, or genital or nongenital gender reassignment surgery, provided or performed for the purpose of assisting an individual with a physical gender transition." S.C. Code § 44-42-310. I will refer to puberty-blocking drugs as gonadotropin releasing hormone (GnRH) analogs, cross-sex hormones as sex hormones or as gender-affirming hormones, these treatments collectively as gender-affirming medical care, and the individuals to whom they are prescribed as minors or adolescents. H 4624 prohibits physicians from providing this care under the threat of professional administrative and civil penalties, and enforcement by the Attorney General. I will refer to these provisions of H 4624 as "the Healthcare Ban" or simply "the Ban."
- 6. There is no sound medical or ethical basis for the Ban. Gender-affirming medical care is evidence-based and the evidence for it is comparable to the evidence for many other treatments in pediatrics. The potential benefits and risks of gender-affirming medical care are comparable to those of other forms of medical treatment—treatment for which parents or legal

guardians are capable of providing informed consent and minor adolescents are capable of providing assent. Recent decisions in several Northern European countries do not support the Ban.

- 7. As a result, the Ban puts clinicians in the untenable position of either following state law and violating their ethical duties to promote their patients' well-being and protect them from harm or facing professional administrative and civil penalties. Either outcome results in harm to patients.
- 8. H 4624 also provides that "Public funds may not be used directly or indirectly for gender transition procedures." S.C. Code § 44-42-340. This provision applies to gender transition procedures for all individuals, regardless of age. I will refer to this portion of H 4624 as "the Funding Restriction."
- 9. Finally, H 4624 further provides that "The South Carolina Medicaid Program shall not reimburse or provide coverage for practices prohibited under the provisions of this chapter." S.C. § 44-42-350. This provision applies to gender transition procedures for all individuals, regardless of age. I will refer to this portion of H 4624 as "the Medicaid Restriction."
- 10. There is no sound medical or ethical basis for singling out gender-affirming medical care for exclusion via the Funding Restriction or the Medicaid Restriction. Treatment of gender dysphoria is not experimental, is supported by evidence of safety and efficacy, and is consistent with generally accepted professional medical standards. As a result, the Funding Restriction and Medicaid Restriction exclude such care from coverage in a manner inconsistent with other medical coverage decisions.

#### **BACKGROUND AND QUALIFICATIONS**

11. I am the Director of the Ethics Center, the Lee Ault Carter Chair of Pediatric Ethics, and an Attending Physician in the Division of Hospital Medicine at Cincinnati Children's Hospital

Medical Center ("Cincinnati Children's"). I am also a Professor in the Departments of Pediatrics and Surgery at the University of Cincinnati College of Medicine.

- 12. I received my medical degree from Washington University School of Medicine in St. Louis, Missouri in 2000. I received my PhD in Religious Ethics from The University of Chicago Divinity School in 2000. I completed my pediatrics residency at the University of Utah in 2003.
- 13. I have been licensed to practice medicine since 2001 and am currently licensed to practice medicine in Ohio. I have been Board Certified in General Pediatrics since 2004 and in Pediatric Hospital Medicine since the inception of this certification in 2019. I have been certified as a Healthcare Ethics Consultant since the inception of this certification in 2019.
- 14. I have extensive experience as a pediatrician and as a bioethicist. I have been in clinical practice since 2003 and 30% of my current effort is dedicated to caring for hospitalized patients. I was Chair of the Ethics Committee at Primary Children's Medical Center in Salt Lake City, Utah from 2005 to 2012 and have been Director of the Ethics Center at Cincinnati Children's since 2012. I regularly consult on the care of patients in the Transgender Health Clinic at Cincinnati Children's and participate in the Clinic's monthly multidisciplinary team meetings. I remain current with the medical and bioethics literature regarding the treatment of individuals with gender dysphoria, particularly minors. I am also part of Cincinnati Children's team that cares for patients born with differences or disorders of sex development (DSD), also known as intersex traits. I chair Cincinnati Children's Fetal Care Center's Oversight Committee, which provides the Center recommendations on the use of innovative treatments and experimental interventions.
- 15. As an academic pediatric hospitalist, I practice and teach evidence-based medicine, including the development and use of clinical practice guidelines. As a bioethicist, I help patients, parents, and healthcare providers address ethical dilemmas and resolve ethical conflicts. This

involves analyzing the evidence and reasons supporting different treatment options. I also assist my institution to develop ethically sound policies and procedures.

- 16. I am a member of the American Academy of Pediatrics (AAP), the American Society for Bioethics and Humanities (ASBH), the Association of Bioethics Program Directors, and the Society for Pediatric Research. I was a member of the AAP Committee on Bioethics from 2005 to 2011. I have also served as a member of ASBH's Clinical Ethics Consultation Affairs Committee from 2009 to 2014 and recently completed my service on its Healthcare Ethics Consultant Certification Commission.
- 17. I am the author of 43 peer-reviewed journal articles, 11 non-peer-reviewed journal articles, 6 book chapters, and 28 commentaries. My peer-reviewed journal articles have been published in high-impact journals, including the *Journal of the American Medical Association* and *Annals of Internal Medicine*. I am also an author of 17 policy statements and technical reports, including 4 as lead author, by the AAP.
- 18. I am a member of *Pediatrics*' Executive Editorial Board and its Associate Editor for Ethics Rounds. I am an active peer reviewer for many medical journals, including the *American Journal of Bioethics* and the *Journal of Pediatrics*. I am chair of the National Library of Medicine's Literature Selection Technical Review Committee. I also review abstracts for meetings of professional organizations, including the Pediatric Academic Societies and ASBH. I was previously a member of the editorial boards of the *Journal of Clinical Ethics* and the *Journal of Medical Humanities*.
- 19. I have previously testified at deposition and/or in court in *Boe et al. v. Marshall et al.*, United States District Court, Middle District of Alabama, Case No. 22-cv-00184; *Brandt et al. v. Griffin et al.*, United States District Court, Eastern District of Arkansas, Case No. 4:21-CV-

00450; Dekker et al. v. Weida et al., United States District Court, Northern District of Florida, Case No. 4:22-cv-00325; Doe et al. v. Abbott et al., District Court of Travis County, Texas, Case No. D-1-GN-22-000977; Moe v. Yost, Franklin County Court of Common Pleas, Ohio, Case No. 24CVH03-2481; Noe et al. v. Parson et al., Circuit Court of Cole County, Missouri, Case No. 23AC-CC04530; and Zayre-Brown v. North Carolina Department of Public Safety et al., United States District Court, Western District of North Carolina, Case No. 3:22-CV-01910. The cases in which I have authored reports but have not testified are listed in my CV (Exhibit A). I am being compensated at a rate of \$400 per hour for preparation of expert declarations and reports, and a flat fee of \$3,200 per day for deposition or trial testimony. My compensation does not depend on the outcome of this litigation, the opinions I express, or the testimony I provide.

### THE TREATMENT OF GENDER DYSPHORIA IS SUPPORTED BY EVIDENCE COMPARABLE TO THE EVIDENCE FOR MANY OTHER MEDICAL TREATMENTS

#### **Clinical Practice Guidelines**

20. Medical professional organizations develop clinical practice guidelines to provide clinicians with helpful, evidence-based recommendations and improve patient care and outcomes. Clinical practice guidelines are developed using systematic processes to select and review scientific evidence. Guidelines typically rate the quality of the evidence and grade the strength of recommendations. 1 One widely used method of grading the quality of the evidence and the

2004;114(3):874-877.

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<sup>&</sup>lt;sup>1</sup> American Academy of Pediatrics Steering Committee on Quality Improvement and Management. Classifying recommendations for clinical practice guidelines. *Pediatrics*.

strength of recommendations is the Grading of Recommendations Assessment, Development, and Evaluation (GRADE) system.<sup>2</sup>

- 21. GRADE states, "In the context of making recommendations, the quality ratings reflect the extent of our confidence that the estimates of an effect are adequate to support a particular decision or recommendation." The GRADE system is more nuanced than the Levels of Evidence Pyramid. In addition to study design, GRADE characterizes the quality of evidence based on risk of bias, consistency, and directness. GRADE distinguishes four levels of evidence: "high," "moderate," "low," and "very-low." These levels are relative to one another and "low" does not necessarily mean poor or inadequate. As discussed below, a recommendation in a clinical practice guideline may be based on "low" or "very low" quality evidence, not just "high" or "moderate" quality evidence.<sup>4</sup>
- 22. With respect to study design, randomized controlled trials generally provide "high" quality evidence. <sup>5</sup> In a randomized controlled trial, participants are randomly assigned to a treatment or a comparison group. The major benefit of a randomized trial is that it decreases the

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<sup>&</sup>lt;sup>2</sup> Atkins D, Best D, Briss PA, et al. Grading quality of evidence and strength of recommendations. *BMJ*. 2004;328(7454):1490.

<sup>&</sup>lt;sup>3</sup> Balshem H, Helfand M, Schünemann HJ, et al. GRADE guidelines: 3. Rating the quality of evidence. *J Clin Epidemiol*. 2011;64(4):403.

<sup>&</sup>lt;sup>4</sup> Balshem H, Helfand M, Schünemann HJ, et al. GRADE guidelines: 3. Rating the quality of evidence. *J Clin Epidemiol*. 2011;64(4):401-406.

<sup>&</sup>lt;sup>5</sup> Balshem H, Helfand M, Schünemann HJ, et al. GRADE guidelines: 3. Rating the quality of evidence. *J Clin Epidemiol*. 2011;64(4):401-406.

likelihood that any differences in the outcomes between the groups is the result of baseline differences between the groups rather than the result of the intervention.<sup>6</sup>

Observational studies include cross-sectional and longitudinal studies. In cross-sectional studies, investigators collect data at a single point in time. A cross-sectional design permits investigators to examine potential associations between factors, but it cannot prove one factor caused the other. An example of a cross-sectional study related to gender-affirming medical care is Jack L. Turban and colleagues' analysis of data from the 2015 United States (US) Transgender Survey. The survey asked transgender adults, who were recruited through community outreach, about their demographics, past gender-affirming medical care, family support, and mental health outcomes. The investigators found that those who received pubertal suppression had lower odds of lifetime suicidal ideation compared to those who wanted treatment with pubertal suppression but did not receive it.<sup>8</sup> In longitudinal studies, researchers follow individuals over time, making continuous or

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<sup>&</sup>lt;sup>6</sup> Browner WS, Newman TB, Cummings SR, et al. *Designing Clinical Research*. 5th ed. Wolters Kluwer; 2022.

<sup>&</sup>lt;sup>7</sup> Balshem H, Helfand M, Schünemann HJ, et al. GRADE guidelines: 3. Rating the quality of evidence. *J Clin Epidemiol*. 2011;64(4):401-406.

<sup>&</sup>lt;sup>8</sup> Turban JL, King D, Carswell JM, Keuroghlian AS. Pubertal suppression for transgender youth and risk of suicidal ideation. *Pediatrics*. 2020;145(2):e20191725.

repeated measures. <sup>9</sup> Examples of longitudinal studies include the studies of the associations between gender-affirming medical care and psychological outcomes discussed below. <sup>10</sup>

- 24. While randomized trials generally provide "high" quality evidence and observational studies "low," the quality of a study or group of studies may be moved up or down based on other considerations such as the risk of bias.<sup>11</sup>
- 25. The labels "high" and "low" quality evidence can be misleading if the latter is used in the colloquial sense of poor or inadequate. While randomized controlled trials are described in the medical literature as "high" quality evidence and observational studies as "low" quality evidence, randomized controlled trials may not be feasible or ethical, may have intrinsic methodological limitations, or may be unavailable in some contexts. "High" quality evidence is not required for a treatment to no longer be considered experimental. A particular quality of evidence as specified by the GRADE system does not necessarily entail a particular strength of recommendation; as described below, "low" quality evidence can be sufficient to justify "strong" recommendations. <sup>12</sup>
- 26. At times, it may be unethical to conduct randomized trials. For randomized trials to be ethical, clinical equipoise must exist; there must be uncertainty about whether the efficacy of

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<sup>&</sup>lt;sup>9</sup> Browner WS, Newman TB, Cummings SR, et al. *Designing Clinical Research*. 5th ed. Wolters Kluwer; 2022.

<sup>&</sup>lt;sup>10</sup> See, for example, de Vries AL, Steensma TD, Doreleijers TA, Cohen-Kettenis PT. Puberty suppression in adolescents with gender identity disorder: A prospective follow-up study. *J Sex Med.* 2011;8(8):2276-2283.

<sup>&</sup>lt;sup>11</sup> Balshem H, Helfand M, Schünemann HJ, et al. GRADE guidelines: 3. Rating the quality of evidence. *J Clin Epidemiol*. 2011;64(4):401-406.

<sup>&</sup>lt;sup>12</sup> Balshem H, Helfand M, Schünemann HJ, et al. GRADE guidelines: 3. Rating the quality of evidence. *J Clin Epidemiol*. 2011;64(4):401-406; Swiglo BA, Murad MH, Schünemann HJ, et al. A case for clarity, consistency, and helpfulness: State-of-the-art clinical practice guidelines in endocrinology using the Grading of Recommendations Assessment, Development, and Evaluation system. *J Clin Endocrinol Metab*. 2008;93(3):666-673.

the intervention or the control is greater. Otherwise, it would be unethical to knowingly expose trial participants to an inferior intervention or control. Trials must also be feasible; it would also be unethical to expose individuals to the risks of trial participation without the benefit of the trial generating generalizable knowledge. A randomized trial that is unlikely to find enough people to participate because they believe they might be randomized to an inferior intervention would be unethical because it could not produce generalizable knowledge due to an inadequate sample size. <sup>13</sup>

- 27. Clinical research focusing on children is less likely to use randomized trials than is clinical research for adults. Potential reasons for this disparity include the low prevalence of childhood disease, small market share for therapeutic agents in children, low level of National Institutes of Health funding, and difficulty enrolling children in research.<sup>14</sup>
- 28. The process for assessing the quality of the evidence is separate and distinct from the process for grading the strength of recommendations based on this evidence. When making recommendations, the authors of guidelines consider a variety of factors; the quality of the evidence is only one factor considered in making recommendations. Other considerations include the balance between desirable and undesirable outcomes, confidence and variability in patients' values and preferences, and resource use. The GRADE system distinguishes "strong" and

<sup>&</sup>lt;sup>13</sup> Emanuel EJ, Wendler D, Grady C. What makes clinical research ethical? *JAMA*. 2000;283(20):2701-2711.

<sup>&</sup>lt;sup>14</sup> Martinez-Castaldi C, Silverstein M, Baucher H. Child versus adult research: The gap in high quality study design. *Pediatrics*. 2008;122(1):52-57.

<sup>&</sup>lt;sup>15</sup> Balshem H, Helfand M, Schünemann HJ, et al. GRADE guidelines: 3. Rating the quality of evidence. *J Clin Epidemiol*. 2011;64(4):401-406.

<sup>&</sup>lt;sup>16</sup> Andrews JC, Schünemann HJ, Oxman AD, et al. GRADE guidelines: 15. Going from evidence to recommendation-determinants of a recommendation's direction and strength. *J Clin Epidemiol*. 2013;66(7):726-735.

"weak" recommendations; if the authors are highly confident in the balance between desirable and undesirable consequences, they make a "strong" recommendation and, if they are less confident, a "weak" recommendation. The larger the differences between the desirable and undesirable consequences and the smaller the variability in patient values and preferences, the more likely a "strong" recommendation is warranted. "Low" quality evidence may be sufficient to make a "strong" recommendation. The larger the differences between the desirable and undesirable consequences and the smaller the variability in patient values and preferences, the more likely a "strong" recommendation is warranted. "Low" quality evidence may be sufficient to make a "strong" recommendation.

- 29. Recommendations for pediatric care made by professional associations in clinical practice guidelines are seldom based on well-designed and conducted randomized controlled trials due to their rarity. Instead, recommendations are frequently based on observational studies or, if such studies are unavailable, expert opinion. The medical use of the term "expert opinion" in this context refers to the consensus of experts when studies are not available.
- 30. For example, of the 130 recommendations in the American Heart Association's (AHA's) guideline for Pediatric Basic and Advanced Life Support, only 1 (0.8%) is based on "high-quality evidence from more than 1 [randomized clinical trial]" and 3 (2.3%) on "moderate-quality evidence from 1 or more [randomized clinical trials]." The remainder of the recommendations were based on lower quality evidence. Among its 57 "strong" recommendations

<sup>&</sup>lt;sup>17</sup> Andrews J, Guyatt G, Oxman AD, et al. GRADE guidelines: 14. Going from evidence to recommendations: The significance and presentation of recommendations. *J Clin Epidemiol*. 2013;66(7):719-725.

<sup>&</sup>lt;sup>18</sup> Andrews JC, Schünemann HJ, Oxman AD, et al. GRADE guidelines: 15. Going from evidence to recommendation-determinants of a recommendation's direction and strength. *J Clin Epidemiol*. 2013;66(7):726-735.

(both Class 1 and Class 3 Harm), 48 (84%) are based on "limited data" or "expert opinion." Table 1 (Exhibit B).

31. Clinicians cannot tell their patients to come back later after randomized controlled trials have been conducted. Clinicians must make decisions based on the best, currently available evidence, which may be observational studies or expert opinion. The lack of randomized controlled trials and reliance on "low" quality evidence does not mean that there is not reasonable support for a clinical practice guideline recommendation or that a treatment is not medically necessary.

### Clinical Practice Guidelines for the Treatment of Adolescents with Gender Dysphoria

- 32. Gender dysphoria is a medical diagnosis contained in the American Psychiatric Association's (APA's) *Diagnostic and Statistical Manual of Mental Disorders*. This diagnosis is defined by "a marked incongruence between one's experienced/expressed gender and their assigned gender, lasting at least 6 months" which is "associated with clinically significant distress or impairment in social, occupational, or other important areas of functioning."<sup>20</sup>
- 33. Gender-affirming care for minors is not experimental in the sense of new or novel. The first reference to the use of GnRH analogs for the treatment of gender dysphoria in the medical literature was in 1998, over 25 years ago.<sup>21</sup> In the same year, the World Professional Association

<sup>&</sup>lt;sup>19</sup> Topjian AA, Raymond TT, Atkins D, et al. Part 4: Pediatric basic and advanced life support: 2020 American Heart Association guidelines for cardiopulmonary resuscitation and emergency cardiovascular care. *Circulation*. 2020;142(16\_suppl\_2):S469-S523. These clinical practice guidelines use different terminology than the GRADE approach for describing the quality of the evidence and the strength of recommendations.

<sup>&</sup>lt;sup>20</sup>American Psychiatric Association. Gender Dysphoria. In: *Diagnostic and Statistical Manual of Mental Disorders*. 5th ed., text rev. American Psychiatric Publishing; 2022.

<sup>&</sup>lt;sup>21</sup> Cohen-Kettenis PT, van Goozen SH. Pubertal delay as an aid in diagnosis and treatment of a transsexual adolescent. *Eur Child Adolesc Psychiatry*. 1998;7(4):246-248. See also Gooren L, Delemarre-van de Waal H. The feasibility of endocrine interventions in juvenile transsexuals. *J Psychol Human Sex*. 1996;8(4):69-74.

for Transgender Health (WPATH), then called the Harry Benjamin International Gender Dysphoria Association, included recommendations regarding gender-affirming hormones for adolescents in its Standards of Care (SOC). <sup>22</sup> Providers at Children's Hospital Boston began treating minors with gender-affirming hormones at this time. <sup>23</sup> Prospective observational trials of GnRH analogs began recruiting participants in 2000. <sup>24</sup> In 2007, Boston Children's Hospital established its Gender Management Service which provided treatment with GnRH analogs, in addition to gender-affirming hormones. <sup>25</sup> The Endocrine Society published its first clinical practice guideline for gender-affirming medical care, which recommended treatment with GnRH analogs, in 2009<sup>26</sup> and WPATH added recommendations about GnRH analogs in the 7<sup>th</sup> edition of its Standards of Care in 2012. <sup>27</sup>

34. The Endocrine Society published its updated clinical practice guideline for the treatment of gender-dysphoric/gender-incongruent persons, including pubertal suppression, sex

<sup>&</sup>lt;sup>22</sup> Levine SB, Brown G, Coleman E, et al. The standards of care for gender identity disorders. *Int J Transgend*. 1998;2(2). Gender identity disorders is the prior terminology for gender dysphoria. This is the 5<sup>th</sup> edition of the Standards of Care.

<sup>&</sup>lt;sup>23</sup> Spack NP, Edwards-Leeper L, Feldman HA, et al. Children and adolescents with gender identity disorder referred to a pediatric medical center. *Pediatrics*. 2012;129(3):418-425.

<sup>&</sup>lt;sup>24</sup> de Vries AL, Steensma TD, Doreleijers TA, Cohen-Kettenis PT. Puberty suppression in adolescents with gender identity disorder: A prospective follow-up study. *J Sex Med*. 2011;8(8):2276-2283.

<sup>&</sup>lt;sup>25</sup> Spack NP, Edwards-Leeper L, Feldman HA, et al. Children and adolescents with gender identity disorder referred to a pediatric medical center. *Pediatrics*. 2012;129(3):418-425.

<sup>&</sup>lt;sup>26</sup> Hembree WC, Cohen-Kettenis P, Delemarre-van de Waal HA, et al. Endocrine treatment of transsexual persons: An Endocrine Society clinical practice guideline. *J Clin Endocrinol Metab*. 2009;94(9):3132-3154.

<sup>&</sup>lt;sup>27</sup> World Professional Association for Transgender Health. Standards of Care for the Health of Transsexual, Transgender, and Gender Nonconforming People. 7<sup>th</sup> Version. Accessed August 3, 2024. Available at

 $https://www.wpath.org/media/cms/Documents/SOC\%20v7/SOC\%20V7\_English.pdf.$ 

hormone treatment, and surgery for gender confirmation, in 2017.<sup>28</sup> WPATH's Standards of Care is currently in its 8<sup>th</sup> version.<sup>29</sup> The treatments outlined in these guidelines are also endorsed by other medical professional associations including the American Academy of Family Physicians,<sup>30</sup> the AAP,<sup>31</sup> the American College of Obstetricians and Gynecologists,<sup>32</sup> the American Medical

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<sup>&</sup>lt;sup>28</sup> Hembree WC, Cohen-Kettenis PT, Gooren L, et al. Endocrine treatment of gender-dysphoric/gender-incongruent persons: An Endocrine Society clinical practice guideline. *J Clin Endocrinol Metab*. 2017;102(11):3869-3903.

<sup>&</sup>lt;sup>29</sup> Coleman E, Radix AE, Bouman WP, et al. Standards of care for the health of transgender and gender diverse people, version 8. *Int J Transgend Health*. 2022;23(Suppl 1):S1-S259.

American Academy of Family Physicians. Care for the transgender and gender nonbinary patient. December 2023. Accessed August 3, 2024. Available at https://www.aafp.org/about/policies/all/transgender-nonbinary.html#:~:text=The%20American%20Academy%20of%20Family,patients%2C%20incl uding%20children%20and%20adolescents.

<sup>&</sup>lt;sup>31</sup> Rafferty J, Committee on Psychosocial Aspects of Child and Family Health, Committee on Adolescence, Section on Lesbian, Gay, Bisexual, and Transgender Health and Wellness. Ensuring comprehensive care and support for transgender and gender-diverse children and adolescents. *Pediatrics*. 2018;142(4):e20182162.

American College of Obstetricians and Gynecologists. ACOG Committee Opinion Number 823: Health care for transgender and gender diverse individuals. March 2021. Accessed August 3, 2024. Available at https://www.acog.org/clinical/clinical-guidance/committee-opinion/articles/2021/03/health-care-for-transgender-and-gender-diverse-individuals/; American College of Obstetricians and Gynecologists' Committee on Gynecologic Practice and Committee on Health Care for Underserved Women. Health care for transgender and gender diverse individuals: ACOG Committee Opinion, Number 823. *Obstet Gynecol*. 2021;137(3):e75-e88.

Association,<sup>33</sup> the APA,<sup>34</sup> the American Psychological Association,<sup>35</sup> and the Pediatric Endocrine Society.<sup>36</sup>

- 35. Gender-affirming medical care is also not experimental in the sense of unproven. The Endocrine Society clinical practice guideline includes 28 recommendations: 3 (11%) are based on "moderate" and 19 (68%) are based on "low" or "very low" quality evidence. The remaining 6 (21%) recommendations are Ungraded Good Practice Statements.<sup>37</sup> Table 2 (Exhibit C). Ungraded Good Practice Statements draw attention to general principles, like shared decision-making, for which direct evidence is unavailable or not systematically apprised.
- 36. The quality of the evidence supporting these recommendations is similar to the quality of the evidence supporting the recommendations in the AHA clinical practice guideline described above and in other Endocrine Society guidelines for the pediatric population. For

<sup>&</sup>lt;sup>33</sup> American Medical Association. Removing financial barriers to care for transgender patients H-185.950. 2022. Accessed August 3, 2024. Available at https://policysearch.ama-assn.org/policyfinder/detail/H-185.950?uri=%2FAMADoc%2FHOD.xml-0-1128.xml; Madara JL. Letter to Mr. Bill McBride. April 26, 2021. Accessed August 3, 2024. Available at https://searchlf.ama-assn.org/letter/documentDownload?uri=%2Funstructured%2Fbinary%2Fletter%2FLETTERS%2

assn.org/letter/documentDownload?uri=%2Funstructured%2Fbinary%2Fletter%2FLETTERS%2F2021-4-26-Bill-McBride-opposing-anti-trans-bills-Final.pdf.

<sup>&</sup>lt;sup>34</sup> American Psychiatric Association. Position statement on treatment of transgender (trans) and gender diverse youth. July 2020. Accessed August 3, 2024. Available at https://www.psychiatry.org/File%20Library/About-APA/Organization-Documents-Policies/Position-Transgender-Gender-Diverse-Youth.pdf.

<sup>&</sup>lt;sup>35</sup> American Psychological Association. Transgender, gender identity, and gender expression non-discrimination. August 2008. Accessed August 3, 2024, Available at https://www.apa.org/about/policy/transgender.pdf.

<sup>&</sup>lt;sup>36</sup> Endocrine Society and Pediatric Endocrine Society. Transgender health: Position statement. December 2020. Accessed August 3, 2024. Available at https://www.endocrine.org/-/media/endocrine/files/advocacy/position-statement/position statement transgender health pes.pdf.

<sup>&</sup>lt;sup>37</sup> Hembree WC, Cohen-Kettenis PT, Gooren L, et al. Endocrine treatment of gender-dysphoric/gender-incongruent persons: An Endocrine Society clinical practice guideline. *J Clin Endocrinol Metab*. 2017;102(11):3869-3903.

example, none of the Endocrine Society's 84 recommendations in its two other guidelines that focus on the pediatric population—guidelines on pediatric obesity and congenital adrenal hyperplasia—is based on "high" quality evidence. Twenty-four (29%) of the recommendations are based on "moderate," and 49 (58%) on "low" or "very low" quality evidence. The remaining recommendations (11, 13%) are Ungraded Good Practice Statements.<sup>38</sup> Table 2 (Exhibit C).

- 37. With respect to GnRH analogs, the Endocrine Society specifically "suggest[s] that adolescents who meet diagnostic criteria for [gender dysphoria]/gender incongruence, fulfill criteria for treatment, . . . and are requesting treatment should initially undergo treatment to suppress pubertal development." The evidence for this recommendation includes a longitudinal study of a group of 70 transgender adolescents who were evaluated using objective measures prior to both pubertal suppression and sex hormone treatment. The mean length of time between the start of pubertal suppression and sex hormone treatment was 1.88 years and ranged from 0.42 to 5.06 years. The study showed statistically significant decreases in behavioral and emotional problems and depressive symptoms, and increases in general functioning. 40
- 38. This is the same level of evidence as supports the use of GnRH analogs for the treatment of central precocious puberty which the Ban permits. Central precocious puberty is the

<sup>&</sup>lt;sup>38</sup> Speiser PW, Arlt W, Auchus RJ, et al. Congenital adrenal hyperplasia due to steroid 21-hydroxylase deficiency: An Endocrine Society clinical practice guideline. *J Clin Endocrinol Metab*. 2018;103(11):4043-4088; Styne DM, Arslanian SA, Connor EL, et al. Pediatric obesity-assessment, treatment, and prevention: An Endocrine Society clinical practice guideline. *J Clin Endocrinol Metab*. 2017;102(3):709-757.

<sup>&</sup>lt;sup>39</sup> Hembree WC, Cohen-Kettenis PT, Gooren L, et al. Endocrine treatment of gender-dysphoric/gender-incongruent persons: An Endocrine Society clinical practice guideline. *J Clin Endocrinol Metab*. 2017;102(11):3880.

<sup>&</sup>lt;sup>40</sup> de Vries AL, Steensma TD, Doreleijers TA, Cohen-Kettenis PT. Puberty suppression in adolescents with gender identity disorder: A prospective follow-up study. *J Sex Med*. 2011;8(8):2276-2283.

premature initiation of puberty, before 8 years of age in people assigned female at birth and before 9 in people assigned male, by the central nervous system. The potential negative effects of precocious puberty include impairment of final adult height as well as antisocial behavior and lower academic achievement. There are no randomized trials evaluating the adult height of treated and untreated individuals. Most studies are observational and compare pretreatment predicted final height with actual final height. These studies have additional limitations including small sample sizes. This "low" quality evidence nonetheless is sufficient to support the use of GnRH analogs as treatment for central precocious puberty. <sup>41</sup> The Ban therefore subjects the use of GnRH analogs to a double standard. There are no randomized clinical trials for the use of GnRH analogs to treat precocious puberty or gender dysphoria, but the evidence is deemed sufficient for the former but not the latter.

- 39. The evidence supporting the guideline's recommendations regarding gender-affirming hormone treatment in adolescents include Annelou L. C. de Vries and colleagues' longer-term follow-up of individuals after pubertal suppression through sex hormone and gender-affirming surgical treatment. Participants' mean age at their initial assessment was 13.6 years and their mean age at their final assessment was 20.7 years. The researchers report the resolution of gender dysphoria and improvement in psychological functioning.<sup>42</sup>
  - 40. As a result of these studies and healthcare providers' subsequent experience,

<sup>&</sup>lt;sup>41</sup> Mul D, Hughes IA. The use of GnRH agonists in precocious puberty. *Eur J Endocrinol*. 2008;159(Suppl 1):S3-S8.

<sup>&</sup>lt;sup>42</sup> See de Vries AL, McGuire JK, Steensma TD, Wagenaar EC, Doreleijers TA, Cohen-Kettenis PT. Young adult psychological outcome after puberty suppression and gender reassignment. *Pediatrics*. 2014;134(4):696-704. Additional longitudinal studies of the psychosocial effects of pubertal suppression to treat gender dysphoria include Costa R, Dunsford M, Skagerberg E, Holt V, Carmichael P, Colizzi M. Psychological support, puberty suppression, and psychosocial functioning in adolescents with gender dysphoria. *J Sex Med*. 2015;12(11):2206-2214 and

randomized, placebo-controlled trials (trials that compare pharmacological treatment to no pharmacological treatment) of gender-affirming medical care are currently unethical. Potential investigators do not have equipoise between pharmacological treatment and no pharmacological treatment; they believe that pharmacological treatment is superior. It is also highly unlikely that a sufficient number of participants would enroll in randomized controlled trials for them to be informative.<sup>43</sup>

41. Even if such studies could be conducted ethically, they would provide a lower quality of evidence because of intrinsic limitations in their design. For example, it would be impossible to blind/mask the investigators or the participants to whether the participants were receiving the active treatment or a placebo. They would know if participants were in the intervention or the control arm of the study due to the physical changes in their bodies, or the lack thereof, over time. This might bias their perception of the outcomes and lower the rating of the study's quality.<sup>44</sup>

#### OFF-LABEL USE DOES NOT SUPPORT THE BAN

42. The fact that GnRH analog and gender-affirming hormone treatment are not approved by the US Food and Drug Administration (FDA) for the treatment of gender dysphoria does not support a ban. Off-label use of FDA-approved medications is legal, common, and often

Carmichael P, Butler G, Masic U, et al. Short-term outcomes of pubertal suppression in a selected cohort of 12 to 15 year old young people with persistent gender dysphoria in the UK. *PLoS One.* 2021;16(2):e0243894.

<sup>&</sup>lt;sup>43</sup> Chew D, Anderson J, Williams K, May T, Pang K. Hormonal treatment in young people with gender dysphoria: A systematic review. *Pediatrics*. 2018;141(4):e20173742; Reisner SL, Deutsch MB, Bhasin S, et al. Advancing methods for US transgender health research. *Curr Opin Endocrinol Diabetes Obes*. 2016;23(2):198-207.

<sup>&</sup>lt;sup>44</sup> Browner WS, Newman TB, Cummings SR, et al. *Designing Clinical Research*. 5th ed. Wolters Kluwer; 2022; Atkins D, Best D, Briss PA, et al. Grading quality of evidence and strength of recommendations. *BMJ*. 2004;328(7454):1490.

evidence-based. FDA approval is not required for each and every use of a medication. Once the FDA has approved a medication for one indication, <sup>45</sup> thereby agreeing that it is safe (i.e., its benefits outweigh its potential risks) and effective for this intended use, as is the case with the medications at issue here, prescribers are generally free to prescribe it for other indications. <sup>46</sup> The AAP Committee on Drugs states, "[i]t is important to note that the term 'off-label' does not imply an improper, illegal, contraindicated, or investigational use" and "[t]he administration of an approved drug for a use that is not approved by the FDA is not considered research and does not warrant special consent or review if it is deemed to be in the individual patient's best interest." It further states "in no way does a lack of labeling signify that therapy is unsupported by clinical experience or data in children."<sup>47</sup> There are several reasons why, even if there is substantial

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<sup>&</sup>lt;sup>45</sup> According to the FDA, an indication includes several factors: the particular disease or condition or the manifestation or symptoms of the disease or condition for which the drug is approved; whether the drug is approved for treatment, prevention, mitigation, cure, or diagnosis; and the population, including age group, for which the drug is safe and effective. U.S. Department of Health and Human Services, Food and Drug Administration, Center for Drug Evaluation and Research, Center for Biologics Evaluation and Research. Indications and Usage Section of Labeling for Human Prescription Drug and Biological Products—Content and Format: Guidance for Industry. July 2018. Accessed August 3, 2024. Available at https://www.fda.gov/files/drugs/published/Indications-and-Usage-Section-of-Labeling-for-Human-Prescription-Drug-and-Biological-Products-%E2%80%94-Content-and-Format-Guidance-for-Industry.pdf. A medication approved for the treatment of asthma in adults would, for example, be prescribed off label if used to treat a different disease, like pneumonia, or a different age group, like children.

<sup>&</sup>lt;sup>46</sup> U.S. Food & Drug Administration. Understanding Unapproved Use of Approved Drugs "Off Label." February 5, 2018. Accessed August 3, 2024. Available at https://www.fda.gov/patients/learn-about-expanded-access-and-other-treatment-options/understanding-unapproved-use-approved-drugs-label.

<sup>&</sup>lt;sup>47</sup> Frattarelli DA, Galinkin JL, Green TP, et al. Off-label use of drugs in children. *Pediatrics*. 2014;133(3):563-567. Quotations appear on pages 563, 565, and 564 respectively.

evidence of safety and efficacy for a new indication, a sponsor may not seek FDA approval for it.

These reasons include that seeking approval may not be economically beneficial for the sponsor. 48

43. "Off-label" use of drugs is common in many areas of medicine, including pediatrics. A recent study of children's hospitals found that in 28.1% of encounters, at least one off-label drug was prescribed. Examples of medications used off-label in this study included: albuterol, which is used to treat asthma; morphine, which is used to treat pain; and lansoprazole (Prevacid®), which is used to treat gastroesophageal reflux.<sup>49</sup> The rate of off-label use may be significantly higher in certain age groups, categories of drugs, and clinical settings.<sup>50</sup>

# GENERALLY APPLICABLE PRINCIPLES OF INFORMED CONSENT APPLY TO PEDIATRIC GENDER-AFFIRMING MEDICAL CARE

### **Principles of Informed Consent**

44. Before performing any medical intervention, a healthcare provider must generally obtain an adult patient's informed consent. Informed consent is a process in which the provider discloses information, elicits the patient's preferences, offers medical advice, and seeks explicit authorization. In order to participate in the informed consent process, a patient must have medical decision-making capacity. If an adult patient lacks capacity, a proxy decision-maker is generally appointed. The healthcare provider's disclosure should include the nature of the intervention and the reasons for it, as well as its potential benefits, risks, and alternatives, including the alternative of not undergoing the intervention. The patient or the patient's proxy must understand and

<sup>&</sup>lt;sup>48</sup> Wittich CM, Burkle CM, Lanier WL. Ten common questions (and their answers) about off-label drug use. *Mayo Clin Proc.* 2012;87(10):982-990.

<sup>&</sup>lt;sup>49</sup> See Yackey K, Stukus K, Cohen D, Kline D, Zhao S, Stanley R. Off-label medication prescribing patterns in pediatrics: An update. *Hosp Pediatr*. 2019;9(3):186-193.

<sup>&</sup>lt;sup>50</sup> Maltz LA, Klugman D, Spaeder MC, Wessel DL. Off-label drug use in a single-center pediatric cardiac intensive care unit. *World J Pediatr Congenit Heart Surg.* 2013;4(3):262-266.

appreciate this information and express a decision. For the informed consent to be valid, the authorization must be voluntary. Exceptions to the requirement to obtain informed consent exist, such as in the case of an emergency.<sup>51</sup>

- 45. Medical decision-making and informed consent in pediatrics is more complex than in adult medicine because it involves both minor patients and their parents or legal guardians. Parents and guardians are afforded substantial, but not unlimited, discretion in making medical decisions for their minor children based on their assessment of the individual child's best interest. They generally care about their children and best understand their children's unique needs.<sup>52</sup>
- 46. Healthcare providers also have an ethical obligation to include children in medical decision-making to the extent that it is developmentally appropriate. For example, a provider examining a toddler for a possible ear infection should not ask a toddler for permission to look in the child's ear because the provider intends to look even if the child says no. The provider could, however, ask the toddler which ear the child would like to have looked in first. As a minor becomes older, the minor should participate more actively in medical decision-making and the minor's assent should be sought. In early adolescence, individuals typically have developed a sense of identity, individual values and preferences, and are developing medical decision-making capacity. Capacity entails the ability to (i) understand the indications and the potential benefits, risks, and alternatives to a treatment, including declining treatment; (ii) appreciate the implications of a treatment decision for their own lives; (iii) evaluate the potential benefits and risks; and

<sup>&</sup>lt;sup>51</sup> Beauchamp TL, Childress JF. *Principles of Biomedical Ethics*. 6th ed. Oxford University Press; 2009.

<sup>&</sup>lt;sup>52</sup> Diekema DS. Parental refusals of medical treatment: The harm principle as threshold for state intervention. *Theor Med Bioeth.* 2004;25(4):243-264.

(iv) express a preference.<sup>53</sup> Adolescents generally possess comparable medical decision-making capacity to adults. Louis A. Weithorn and Susan B. Campbell, for example, found that 14-year-olds performed similarly to adults with respect to their ability to understand and reason about treatment information.<sup>54</sup>

47. The current treatment paradigm for treating gender dysphoria in minors is consistent with general ethical principles instantiated in the practices of informed consent and assent. The Endocrine Society clinical practice guideline extensively discusses the potential benefits, risks, and alternatives to treatment, and its recommendations regarding the timing of interventions are based in part on the treatment's potential risks and the adolescent's decision-making capacity. The guideline recommends that the informed consent process for GnRH analogs and sex hormones include a discussion of the implications for fertility and options for fertility preservation. The Endocrine Society clinical practice guideline also advises delaying gender-affirming hormone treatment, which results in partly irreversible physical changes, until an adolescent is developmentally capable of providing informed consent. Lieke J. J. J. Vrouenraets and colleagues found most adolescents with gender dysphoria have sufficient medical decision-making capacity to make decisions regarding GnRH analogs. The practice of the providing informed consent of the implications in minors is adolescent to the providing informed consent.

<sup>&</sup>lt;sup>53</sup> Katz AL, Webb SA, Committee on Bioethics. Informed consent in decision-making in pediatric practice. *Pediatrics*. 2016;138(2):e20161485; Kon AA, Morrison W. Shared decision-making in pediatric practice: A broad view. *Pediatrics*. 2018;142(Suppl 3):S129-S132.

<sup>&</sup>lt;sup>54</sup> Weithorn LA, Campbell SB. The competency of children and adolescents to make informed treatment decisions. *Child Dev.* 1982;53(6):1589-1598.

<sup>&</sup>lt;sup>55</sup> See Hembree WC, Cohen-Kettenis PT, Gooren L, et al. Endocrine treatment of gender-dysphoric/gender-incongruent persons: An Endocrine Society clinical practice guideline. *J Clin Endocrinol Metab.* 2017;102(11):3869-3903.

<sup>&</sup>lt;sup>56</sup> Vrouenraets LJJJ, de Vries ALC, de Vries MC, van der Miesen AIR, Hein IM. Assessing medical decision-making competence in transgender youth. *Pediatrics*. 2021;148(6):e2020049643.

### Pediatric Gender-Affirming Medical Care's Benefits, Risks, and Alternatives

- 48. The potential benefits of gender-affirming medical care in minors include improved physical and psychological outcomes. Starting pubertal suppression in early puberty prevents adolescents with gender dysphoria from developing secondary sex characteristics inconsistent with their gender identity, which can be extremely distressing for them, and that may be difficult, if not impossible, to eliminate once the characteristics have fully developed. Sex hormone therapy results in the development of secondary sex characteristics consistent with an individual's gender identity. Potential psychological benefits include increased quality of life and decreased depression, suicidal ideation and suicide attempts, and anxiety.<sup>57</sup>
- 49. As with all medical treatments, gender-affirming medical care entails risks. One of the potential risks is negative effects on fertility, but this risk should not be overstated. GnRH analogs do not, by themselves, permanently impair fertility. Children with central precocious puberty are routinely treated with GnRH analogs and have typical fertility in adulthood. <sup>58</sup> GnRH analogs are also used for fertility preservation in individuals being treated for cancer. <sup>59</sup>
- 50. While treatment for gender dysphoria with gender-affirming hormones may impair fertility, this is not universal and may also be reversible. There are transgender men who became

<sup>&</sup>lt;sup>57</sup> See, for example, Baker KE, Wilson LM, Sharma R, Dukhanin V, McArthur K, Robinson KA. Hormone therapy, mental health, and quality of life among transgender people: A systematic review. *J Endocr Soc.* 2021;5(4):1-16.

<sup>&</sup>lt;sup>58</sup> Lazar L, Meyerovitch J, de Vries L, Phillip M, Lebenthal Y. Treated and untreated women with idiopathic precocious puberty: Long-term follow-up and reproductive outcome between the third and fifth decades. *Clin Endocrinol* (Oxf). 2014;80(4):570-576.

<sup>&</sup>lt;sup>59</sup> Valsamakis G, Valtetsiotis K, Charmandari E, Lambrinoudaki I, Vlahos NF. GnRH analogues as a co-treatment to therapy in women of reproductive age with cancer and fertility preservation. *Int J Mol Sci.* 2022;23(4):2287.

pregnant while on or after discontinuing testosterone therapy. <sup>60</sup> Transgender men and women are also capable of producing eggs and sperm respectively both during and after the discontinuation of gender-affirming hormone treatment. <sup>61</sup>

- 51. Additionally, the clinical practice guidelines discussed above recommend that healthcare providers offer individuals considering gender-affirming medical care methods to potentially preserve their fertility.<sup>62</sup>
- 52. The risk of infertility is also not unique to treatment for gender dysphoria. For example, parents and legal guardians consent to the treatment of medical conditions for their minor children, including some nonmalignant rheumatologic disorders and hematologic conditions, which may impair fertility.<sup>63</sup>
- 53. While transgender adolescents have higher rates of depression, anxiety, suicidal ideation, and suicide attempts, there are no studies indicating that those higher rates are caused or exacerbated by gender-affirming medical care. <sup>64</sup> Rather, contributing factors include conflict

<sup>&</sup>lt;sup>60</sup> Light AD, Obedin-Maliver J, Sevelius JM, Kerns JL. Transgender men who experienced pregnancy after female-to-male gender transitioning. *Obstet Gynecol*. 2014;124(6):1120-1127.

<sup>&</sup>lt;sup>61</sup> Leung A, Sakkas D, Pang S, Thornton K, Resetkova N. Assisted reproductive technology outcomes in female-to-male transgender patients compared with cisgender patients: A new frontier in reproductive medicine. *Fertil Steril*. 2019;112(5):858-865; de Nie I, van Mello NM, Vlahakis E, et al. Successful restoration of spermatogenesis following gender-affirming hormone therapy in transgender women. *Cell Rep Med*. 2023;4(1):100858.

<sup>&</sup>lt;sup>62</sup> Hembree WC, Cohen-Kettenis PT, Gooren L, et al. Endocrine treatment of gender-dysphoric/gender-incongruent persons: An Endocrine Society clinical practice guideline. *J Clin Endocrinol Metab*. 2017;102(11):3869-3903.

<sup>&</sup>lt;sup>63</sup> Delessard M, Saulnier J, Rives A, Dumont L, Rondanino C, Rives N. Exposure to chemotherapy during childhood or adulthood and consequences on spermatogenesis and male fertility. *Int J Mol Sci.* 2020;21(4):1454; Blumenfeld Z. Chemotherapy and fertility. *Best Pract Res Clin Obstet Gynaecol.* 2012;26(3):379-390; Hirshfeld-Cytron J, Gracia C, Woodruff TK. Nonmalignant diseases and treatments associated with primary ovarian failure: An expanded role for fertility preservation. *J Womens Health (Larchmt).* 2011;20(10):1467-1477.

<sup>&</sup>lt;sup>64</sup> Haas AP, Eliason M, Mays VM, et al. Suicide and suicide risk in lesbian, gay, bisexual, and

between one's appearance and identity, stigma, and rejection.<sup>65</sup> As discussed above, the available evidence indicates that gender-affirming care improves, rather than worsens, psychological outcomes.

- 54. Finally, not knowing all potential harmful effects associated with a medication is not a sufficient reason for the FDA to not approve a medication, let alone for a state to ban it. The FDA requires post-marketing surveillance of medications' adverse effects because the clinical trials on which the approvals are based cannot identity all possible side effects.<sup>66</sup>
- 55. In determining whether the benefits of treatment outweigh the risks, medical providers and patients must also consider the potential alternatives including not providing or receiving the treatment. As stated above, prior to the initiation of gender-affirming medical care, many minors with gender dysphoria have significant, unresolved symptoms that treatment improves. Without medical treatment, these symptoms would persist. The assertion that psychotherapy alone is sufficient to treat gender dysphoria in adolescents is only supported by anecdotal evidence.<sup>67</sup>

# The Risks and Benefits of Gender-Affirming Medical Care are Comparable to Those of Other Medical Care to which Parents and Guardians May Consent

56. Medical care for minors can require weighing potential benefits and risks in the face of uncertainty. There is nothing unique about gender-affirming medical care that justifies

transgender populations: Review and recommendations. J Homosex. 2011;58(1):10-51.

<sup>&</sup>lt;sup>65</sup> Bauer GR, Scheim AI, Pyne J, Travers R, Hammond R. Intervenable factors associated with suicide risk in transgender persons: A respondent driven sampling study in Ontario, Canada. *BMC Public Health*. 2015;15:525.

<sup>&</sup>lt;sup>66</sup> U.S. Food & Drug Administration. Postmarketing Surveillance Programs. April 2, 2020. Accessed August 3, 2024. Available at https://www.fda.gov/drugs/surveillance/postmarketing-surveillance-programs.

<sup>&</sup>lt;sup>67</sup> See, for example, Levine SB. Transitioning back to maleness. *Arch Sex Behav*. 2018;47(4):1295-1300.

singling out this medical care for prohibition based on concern for adolescents' inability to assent or parents or guardians' inability to consent. Medical decisions regarding treatment for gender dysphoria should continue to be left to the discretion of adolescents, their parents or guardians, and their healthcare providers.

- 57. The potential risks of gender affirming medical care are comparable to the risks parents and adolescents are permitted to assume in numerous other treatment decisions, including decisions explicitly authorized by this legislation. As described above, parents can choose treatments that have some chance of damaging their children's gonads and impairing their fertility. Individuals with some types of differences of sex development (DSDs), such as complete androgen insensitivity syndrome, are treated with sex hormones, which have comparable risks to the use of these treatments in persons with gender dysphoria. Parents of children with some types of DSDs may even choose to have their children's gonads removed due to the possible elevated risk of malignancy, which causes infertility. It is also my understanding that the Ban permits genderaffirming medical treatment of individuals with DSDs, which has similar risks to the use of this treatment in individuals who do not have DSDs.
- 58. As discussed above, the potential benefits of gender-affirming medical care, including improved psychological outcomes, frequently outweigh the potential risks.

#### Potential Regret Does Not Support the Ban

59. Patients experiencing regret as a result of any medical treatment is profoundly unfortunate and such individuals should be provided support and additional treatment as needed.

<sup>&</sup>lt;sup>68</sup> Lanciotti L, Cofini M, Leonardi A, Bertozzi M, Penta L, Esposito S. Different clinical presentations and management in complete androgen insensitivity syndrome (CAIS). *Int J Environ Res Public Health*. 2019;16(7):1268.

<sup>&</sup>lt;sup>69</sup> Abacı A, Çatlı G, Berberoğlu M. Gonadal malignancy risk and prophylactic gonadectomy in disorders of sexual development. *J Pediatr Endocrinol Metab*. 2015;28(9-10):1019-1027.

Patients expressing regret over having received a certain kind of medical care, gender-affirming or other medical care, however, does not justify banning that medical care.

- 60. While there are individuals who received gender-affirming medical care as minors who express regret, the available studies report that rates of regret regarding gender-affirming medical care are very low. For example, Chantal M. Wiepjes and colleagues report that 0.6% of transgender women and 0.3% of transgender men experienced regret. Similarly, R. Hall and colleagues report regret was specifically documented in 1.1% of adult gender-diverse patients. Banning gender-affirming medical care to prevent regret in a small minority of patients would result in harm to the majority of patients who benefit. The potential for regret should nonetheless be disclosed in the informed consent process, and support and services should be provided to individuals who experience regret.
- 61. The potential for regret is also not unique to gender-affirming medical care. Ironically, at the same time that South Carolina prohibits gender-affirming medical care for minors, the statute expressly allows doctors to perform irreversible genital surgeries on infants and children with DSDs at ages when they are unable to meaningfully participate in medical decision-making. The evidence base for these surgeries is poor and they are highly controversial when performed at such an early age. 72 Parents of children who have undergone feminizing genitoplasty

<sup>&</sup>lt;sup>70</sup> Wiepjes CM, Nota NM, de Blok CJ, et al. The Amsterdam Cohort of Gender Dysphoria Study (1972-2015): Trends in prevalence, treatment, and regrets. *J Sex Med*. 2018;15(4):582-590. This study analyzes all individuals who presented to the clinic, whether they presented as minors or adults. Regret was assessed in individuals who had undergone gender-affirming surgery that included removal of the gonads. This surgery was only performed on adults.

<sup>&</sup>lt;sup>71</sup> Hall R, Mitchell L, Sachdeva J. Access to care and frequency of detransition among a cohort discharged by a UK national adult gender identity clinic: Retrospective case-note review. *BJPsvch Open.* 2021;7(6):e184.

<sup>&</sup>lt;sup>72</sup> Jesus LE. Feminizing genioplasties: Where are we now? *J Pediatr Urol.* 2018;14(5):407-415; Frader J, Alderson P, Asch A, et al. Health care professionals and intersex conditions. *Arch* 

and hypospadias repair have experienced regret over their decisions.<sup>73</sup> For example, Rachel S. Fisher and colleagues found that 38% of caregivers of infants with congenital adrenal hyperplasia reported some level of regret about their child's genital surgery.<sup>74</sup>

## THE INCREASED PREVALENCE OF GENDER-AFFIRMING CARE DOES NOT SUPPORT THE BAN

62. The increased number of transgender individuals and those receiving medical treatment does not justify the Ban. The causes of these changes are likely to be multifactorial including increased social acceptance of transgender individuals and availability of gender-affirming medical care. The Changes in demographics are not unique to gender dysphoria and have been seen in other conditions such as autism spectrum disorder and childhood-onset type 1 diabetes. These changes are a justification for further research on gender-affirming medical care rather than prohibiting these treatments and thereby preventing further research on them.

Pediatr Adolesc Med. 2004;158(5):426-428.

<sup>&</sup>lt;sup>73</sup> Fisher RS, Espeleta HC, Baskin LS, et al. Decisional regret about surgical and non-surgical issues after genitoplasty among caregivers of female infants with CAH. *J Pediatr Urol*. 2022;18(1):27-33; Vavilov S, Smith G, Starkey M, Pockney P, Deshpande AV. Parental decision regret in childhood hypospadias surgery: A systematic review. *J Paediatr Child Health*. 2020;56(10):1514-1520.

<sup>&</sup>lt;sup>74</sup> Fisher RS, Espeleta HC, Baskin LS, et al. Decisional regret about surgical and non-surgical issues after genitoplasty among caregivers of female infants with CAH. *J Pediatr Urol*. 2022;18(1):27-33.

<sup>&</sup>lt;sup>75</sup> Wiepjes CM, Nota NM, de Blok CJM, et al. The Amsterdam Cohort of Gender Dysphoria Study (1972-2015): Trends in prevalence, treatment, and regrets. *J Sex Med*. 2018;15(4):582-590.

<sup>&</sup>lt;sup>76</sup> Christensen DL, Maenner MJ, Bilder D, et al. Prevalence and characteristics of autism spectrum disorder among children aged 4 years - Early Autism and Developmental Disabilities Monitoring Network, seven sites, United States, 2010, 2012, and 2014. *MMWR Surveill Summ*. 2019;68(2):1-19; DIAMOND Project Group. Incidence and trends of childhood type 1 diabetes worldwide 1990-1999. *Diabet Med*. 2006;23(8):857-866.

#### TREATMENT PROTOCOLS IN EUROPE DO NOT SUPPORT THE BAN

- 63. Some have pointed to the actions of several European health authorities (discussed below) as support for banning gender-affirming medical care. It is difficult to evaluate some of these actions because the relevant material is not available in official English translations. While several of these authorities have conducted systematic reviews of the evidence, none have developed a formal clinical practice guideline. While both systematic reviews and clinical practice guidelines ideally grade the quality of the evidence, only clinical practice guidelines make recommendations and grade their strength. Of the documents by European health authorities that do make treatment recommendations, none rate the quality of the evidence and the strength of the recommendations.
- 64. Critically, none of the European health authorities has prohibited gender-affirming medical care for minors as does South Carolina. The only categorical prohibition of a form of gender-affirming medical care appears to be the Finnish Council for Choices in Health Care's statement, "[s]urgical treatments are not part of the treatment methods for dysphoria caused by gender-related conflicts in minors (2)."<sup>77</sup> (It is not clear whether surgical treatments as used in this statement includes masculinizing chest surgery.) Pubertal suppression and gender affirming hormone treatment are permitted for minors in Finland.<sup>78</sup>

5-8c35-8492-59d6-b3de1c00de49/Summary\_minors\_en+(1).pdf?t=1631773838474.

Palveluvalikoima. Summary: Medical treatment methods for dysphoria associated with variations in gender identity in minors – recommendations. June 16, 2020. Accessed August 3, 2024.

Available at https://palveluvalikoima.fi/documents/1237350/22895008/Summary\_minors\_en+(1).pdf/fa2054c

Palveluvalikoima. Summary: Medical treatment methods for dysphoria associated with variations in gender identity in minors – recommendations. June 16, 2020. Accessed August 3, 2024.

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

- 65. Gender-affirming medical care for minors is not banned in Sweden. While the Swedish National Board of Health and Welfare states, "Treatment with GnRH analogues, gender-affirming hormones, and mastectomy can be administered in exceptional cases (3),"<sup>79</sup> it clarifies that by exceptional cases it means the criteria used by the "Dutch protocol" which is the basis for the Endocrine Society and WPATH clinical practice guidelines. The Board also "recommends that these treatments [puberty suppressing and gender-affirming hormone therapy] be provided in the context of research" and previously stated that this research need not be randomized, controlled trials. <sup>81</sup>
- 66. National Health Service (NHS) England's recent policy changes do not ban gender-affirming medical care for minors. On March 12, 2024, NHS England announced that it will not make GnRH analogs available as "a routine commissioning treatment option" for treating minors with gender dysphoria. 82 However, GnRH analogs to treat adolescents with gender dysphoria are anticipated to be available through the NHS England in a clinical study that is currently being

<sup>&</sup>lt;sup>79</sup> Socialstyrelsen: The National Board of Health and Welfare. Care of children and adolescents with gender dysphoria: Summary of national guidelines. December 2022. Accessed August 3, 2024. Available at https://www.socialstyrelsen.se/globalassets/sharepoint-dokument/artikelkatalog/kunskapsstod/2023-1-8330.pdf.

<sup>&</sup>lt;sup>80</sup> Socialstyrelsen: The National Board of Health and Welfare. Care of children and adolescents with gender dysphoria: Summary of national guidelines. December 2022. Accessed August 3, 2024. Available at https://www.socialstyrelsen.se/globalassets/sharepoint-dokument/artikelkatalog/kunskapsstod/2023-1-8330.pdf.

<sup>&</sup>lt;sup>81</sup> Socialstyrelsen. Care of children and adolescents with gender dysphoria: Summary. 2022. Accessed June 28, 2023. Available at https://www.socialstyrelsen.se/globalassets/sharepoint-dokument/artikelkatalog/kunskapsstod/2022-3-7799.pdf.

<sup>&</sup>lt;sup>82</sup> NHS England. Clinical Policy: Puberty suppressing hormones (PSH) for children and young people who have gender incongruence / gender dysphoria [1927]. March 12, 2024. Accessed August 3, 2024. Available https://www.england.nhs.uk/wp-content/uploads/2024/03/clinical-commissioning-policy-gender-affirming-hormones-v2.pdf.

designed and is expected to begin in late 2024.<sup>83</sup> Moreover, NHS England announced on March 21, 2024 that gender-affirming hormones are available as "a routine commissioning treatment option" around individuals' 16th birthday.<sup>84</sup> The recommendations contained in Dr. Hilary Cass's final report, issued on April 10, 2024,<sup>85</sup> are largely consistent with the NHS clinical policies pertaining to GnRH analogs and gender-affirming hormone treatment. On May 29, 2024, the Secretary of State for Health and Social Care and the Minister for Health made a temporary prohibition on the private prescription of GnRH analogs to minors for the treatment of gender

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NHS England. Consultation report for the clinical policy on puberty suppressing hormones for children and adolescents who have gender incongruence / gender dysphoria. March 11, 2024. Accessed August 3, 2024. Available at https://www.england.nhs.uk/publication/clinical-policy-puberty-suppressing-hormones/ under "Puberty suppressing hormones consultation report 11 March 2024." See also NHS England. Child and Young People's Gender Dysphoria Research Oversight Board. Accessed August 3, 2024. Available at https://www.england.nhs.uk/commissioning/spec-services/npc-crg/gender-dysphoria-clinical-programme/implementing-advice-from-the-cass-review/cyp-gender-dysphoria-research-oversight-board/.

<sup>&</sup>lt;sup>84</sup> NHS England. Clinical Commissioning Policy: Prescribing of gender affirming hormones (masculinising and feminising hormones) as part of the Children and Young People's Gender Service. March 21, 2024. Accessed August 3, 2024. Available at https://www.england.nhs.uk/wp-content/uploads/2024/03/clinical-commissioning-policy-prescribing-of-gender-affirming-hormones.pdf.

<sup>&</sup>lt;sup>85</sup> Cass H. The Cass Review: Independent review of gender identity services for children and young people. April 2024. Accessed August 3, 2024. Available at https://cass.independent-review.uk/home/publications/final-report/.

Following the release of the Case Review's Final Report, NHS Scotland announced a "pause" in new prescriptions for GnRH analogs and a minimum age of 18 years for new prescriptions of gender affirming hormones. See Sandyford. Gender Service for Young People at Sandyford: Important service update – Young Person's Gender Service. Accessed August 3, 2024. Available at https://www.sandyford.scot/sexual-health-services/gender-service-at-sandyford/gender-young-people-service/. NHS Scottland's Chief Medical Officer Professor Sir Gregor Smith subsequently submitted recommendations to make the services provided by NHS Scottland consistent with those of NHS England and the Cass Review. Scottish Government. Cass Review – implications for Scotland: letter from Chief Medical Officer. July 4, 2024. Accessed August 3, 2024. Available at https://www.gov.scot/publications/cass-review-implications-for-scotland-letter-from-chief-medical-officer-professor-sir-gregor-smith/.

dysphoria to provide consistency between the public and private healthcare systems in the U.K.<sup>86</sup>

67. None of these European health authorities have prohibited all gender-affirming medical care for minors as South Carolina has.

#### THE BAN UNDERMINES THE INTEGRITY OF THE MEDICAL PROFESSION

- 68. The Ban violates the integrity of the medical profession and coerces medical professionals to violate their integrity and ethical duties. The medical profession has processes by which it evaluates treatments and determines whether they are safe and effective. The Ban intervenes in these processes replacing medical professionals' judgement with the judgment of the legislature.
- 69. Healthcare providers have an ethical obligation to promote their patients' well-being and to protect them from harm. When providers believe that the potential benefits of gender-affirming medical care outweigh the potential risks for a particular patient, prohibiting them from providing this treatment forces them to violate their ethical obligations to their patients or risk losing their licenses and incurring financial penalties.

# THE FUNDING AND MEDICAID RESTRICTIONS LACK MEDICAL OR ETHICAL JUSTIFICATION

70. There is no medical or ethical basis for treating gender-affirming medical or surgical care differently from other care covered by public funds or Medicaid. Gender-affirming medical care is consistent with generally accepted professional medical standards and is not experimental or investigational. It is endorsed by evidence-based clinical practice guidelines that

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<sup>&</sup>lt;sup>86</sup> Legislation.gov.uk. The Medicines (Gonadotrophin-Releasing Hormone Analogues) (Emergency Prohibition) (England, Wales, and Scotland) Order 2024. May 29, 2024. Accessed August 3, 2024. Available at https://www.legislation.gov.uk/uksi/2024/727/made.

are themselves based on studies published in the peer-reviewed literature demonstrating that it improves individuals' health outcomes.

- 71. As described above, gender-affirming medical care is not experimental in the sense of new or novel. Gender-affirming medical and surgical care of adults substantially predates that of minors. Hormone treatment for gender dysphoria began after estrogen and testosterone became commercially available in the 1930s. The first documented male to female gender-affirming genital surgery was performed in 1931, and Christine Jorgensen famously underwent gender-affirming surgery in 1952.<sup>87</sup> WPATH developed in original SOC in 1979.<sup>88</sup>
- 72. As discussed earlier in this report, gender-affirming medical and surgical care is also not experimental in the sense of unproven. It is evidence-based and is supported by clinical practice guidelines developed my medical professional organizations including the Endocrine Society<sup>89</sup> and the WPATH.<sup>90</sup> The evidence base for gender-affirming medical care in adults does include randomized, double-blind, placebo-controlled trials. One trial compared the effect of testosterone combined with a 5alpha-reductase inhibitor or placebo on muscle strength.<sup>91</sup> It is important to note that this trial compared one form of gender-affirming hormone treatment to another, rather than comparing gender-affirming hormone treatment to no treatment at all. The

<sup>&</sup>lt;sup>87</sup> Stryker S. Transgender History. 2nd ed. Seal Press; 2017.

<sup>&</sup>lt;sup>88</sup> Coleman E, Radix AE, Bouman WP, et al. Standards of care for the health of transgender and gender diverse people, version 8. *Int J Transgend Health*. 2022;23(Suppl 1):S1-S259.

<sup>&</sup>lt;sup>89</sup> Hembree, WC, Cohen-Kettenis PT, Gooren L, et al. Endocrine treatment of gender-dysphoria/gender-incongruent persons: An Endocrine Society clinical practice guideline. *J Clin Endocrinol Metab.* 2017;102(11):3869-3903.

<sup>&</sup>lt;sup>90</sup> Coleman E, Radix AE, Bouman WP, et al. Standards of care for the health of transgender and gender diverse people, version 8. *Int J Transgend Health*. 2022;23(Suppl 1):S1-S259.

<sup>&</sup>lt;sup>91</sup> Gava G, Armillotta F, Pillastrini P, et al. A randomized double-blind placebo-controlled pilot trial on the effects of testosterone undecanoate plus dutasteride or placebo on muscle strength, body composition, and metabolic profile in transmen. *J Sex Med.* 2021;18(3):646-655.

evidence base for gender-affirming surgical care is generally observational studies. WPATH SOC-8, for example, cites five prospective observational studies of gender-affirming chest surgery in individuals assigned female at birth and 8 prospective observational studies of gender-affirming vaginoplasty in individuals assigned male at birth.

- 73. As described above, the use of GnRH analogs, estrogen, and testosterone "off-label" in gender-affirming medical care also does not inherently imply that this use is experimental.
- 74. The Funding and Medicaid Restrictions do not provide a sound basis for excluding coverage of gender-affirming medical care and treating it differently from other comparable medical interventions. For example, H 4624 does not exclude coverage for the use of GnRH analogs to treat central precocious puberty, but prohibits coverage for its use to treat gender dysphoria, even though its use to treat both conditions is supported by comparable levels of evidence.
- 75. Additionally, while the Funding and Medicaid Restrictions would eliminate coverage of chest surgery for the treatment of gender dysphoria for individuals with state-funded health insurance or for Medicaid beneficiaries, individuals with those kinds of health insurance are provided coverage for comparable surgeries, such as those for gynecomastia. Gynecomastia in the proliferation of ductal or glandular breast tissue, as opposed to adipose tissue or fat, in individuals who sex assigned at birth is male. While surgeries to treat gynecomastia may at times be performed to lessen pain, they are commonly performed to reduce psychosocial distress. Surgery affirms patients' gender identity, that is, to help someone assigned male at birth feel more typically masculine. Risks associated with the procedure include bruising, bleeding, infection, scarring, poor

cosmetic outcome, and loss of sensation.<sup>92</sup> There is nothing unique about chest surgery for gender dysphoria that justifies singling this treatment, or other medical or surgical treatments for gender dysphoria, out for non-coverage.

#### **CONCLUSION**

- 76. Treating adolescents with gender dysphoria with gender-affirming medical care under clinical practice guidelines, like the Endocrine Society's, is evidence-based; its potential benefits outweigh its potential risks for many patients; and these risks are well within the range of other medical decisions that adolescents and their parents or guardians have the discretion to make in consultation with their healthcare professionals.
- 77. Based on my research and experience as a pediatrician and bioethicist, there is no sound medical or ethical basis to prohibit healthcare professionals from providing gender-affirming medical care to minors. Doing so puts clinicians in the untenable position of having to harm their patients and violate their integrity and ethical obligations due to the threat of administrative and civil penalties.
- 78. There is not a sound medical or ethical basis for excluding gender-affirming medical or surgical care for minors or adults from coverage by public funds or Medicaid. Care for adults is evidence-based and is not experimental. Excluding coverage for gender-affirming medical and surgical care is also inconsistent with the program's other coverage decisions.

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<sup>&</sup>lt;sup>92</sup> Nordt CA, DiBVasta AD. Gynecomastia in adolescents. *Curr Opin Pediatr.* 2008;20(4):375-382.

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

Executed on AUGUST8, 2024

ARMAND H. MATHENY ANTOMMARIA, MD, PhD

#### **EXHIBIT A**

#### **Curriculum Vitae**

Last Updated: August 3, 2024

## PERSONAL DATA

Armand H. Matheny Antommaria, MD, PhD, FAAP, HEC-C

Birth Place: Pittsburgh, Pennsylvania Citizenship: United States of America

## **CONTACT INFORMATION**

Address: 3333 Burnet Ave, ML 15006, Cincinnati, OH 45229

Telephone Number: (513) 636-4939

Electronic Mail Address: armand.antommaria@cchmc.org

#### **EDUCATION**

1983-1987	BSEE	Valparaiso University, with High Distinction
		Valparaiso, IN
1983-1987	BS	Valparaiso University (Chemistry), with High Distinction
		Valparaiso, IN
1987-1989	MD	Washington University School of Medicine
1998-2000		Saint Louis, MO
1989-2000	PhD	The University of Chicago Divinity School (Religious Ethics)
		Chicago, IL
2000-2003	Resident	University of Utah (Pediatrics)
		Salt Lake City, UT
2005-2006	Certificate	Conflict Resolution Certificate Program, University of Utah
		Salt Lake City, UT

#### **BOARD CERTIFICATION**

2019 Pediatric Hospital Medicine, American Board of Pediatrics

2019 Healthcare Ethics Consultant-Certified, Healthcare Ethics Consultation Certification Commission

2004 General Pediatrics, American Board of Pediatrics

#### **PROFESSIONAL LICENSES**

2012-Present	Doctor of Medicine, Ohio
2006-2010	Alternative Dispute Resolution Provider—Mediator, Utah
2001-2014	Physician and Surgeon, Utah
2001-2014	Physician and Surgeon Controlled Substance, Utah

#### **PROFESSIONAL EXPERIENCE**

#### **Full Time Positions**

2019-Present Professor

Cincinnati Children's Hospital Medical Center, Cincinnati, OH

Department of Surgery

2019-Present	Professor of Clinical-Affiliated
	University of Cincinnati, Cincinnati, OH
2017 D	Department of Surgery
2017-Present	· ·
	Cincinnati Children's Hospital Medical Center, Cincinnati, OH
	Division of Pediatric Hospital Medicine
2017-Present	Professor of Clinical-Affiliated
	University of Cincinnati, Cincinnati, OH
	Department of Pediatrics
2016-2017	Associate Professor of Clinical-Affiliated
	University of Cincinnati, Cincinnati, OH
	Department of Pediatrics
2012-2017	Associate Professor
	Cincinnati Children's Hospital Medical Center, Cincinnati, OH
	Division of Pediatric Hospital Medicine
2012-Present	Lee Ault Carter Chair in Pediatric Ethics
	Cincinnati Children's Hospital Medical Center
2012-2016	Associate Professor-Affiliated
	University of Cincinnati, Cincinnati, OH
	Department of Pediatrics
2010-2012	Associate Professor of Pediatrics (with Tenure)
	University of Utah School of Medicine, Salt Lake City, UT
	Divisions of Inpatient Medicine and Medical Ethics
2010-2012	Adjunct Associate Professor of Medicine
	University of Utah School of Medicine, Salt Lake City, UT
	Division of Medical Ethics and Humanities
2004-2010	Assistant Professor of Pediatrics (Tenure Track)
	University of Utah School of Medicine, Salt Lake City, UT
	Divisions of Inpatient Medicine and Medical Ethics
2004-2010	Adjunct Assistant Professor of Medicine
	University of Utah School of Medicine, Salt Lake City, UT
	Division of Medical Ethics and Humanities
2003-2004	Instructor of Pediatrics (Clinical Track)
	University of Utah School of Medicine, Salt Lake City, UT
	Divisions of Inpatient Medicine and Medical Ethics
2003-2004	Adjunct Instructor of Medicine
	University of Utah School of Medicine, Salt Lake City, UT
	Division of Medical Ethics

## **Part Time Positions**

2024-Present Expert Witness, Report

Van Garderen, et al., v. Montana, et al., Montana Fourth Judicial District Court, Missoula County. Cause No. DV 2023-541.

2024-Present Expert Witness, Report, Deposition, and Testimony

Moe, et al., v. Yost, et al., Court of Common Pleas, Franklin County, Ohio. Case No. 24-CV-002481.

2024-Present	Expert Witness, Report and Deposition Noe, et al., v. Parson, et al., Circuit Court of Cole County State of Missouri. Case
	No. 23AC-CC04530.
2023-Present	Expert Witness, Report
	Voe, et al., v. Mansfiled, et al., United States District Court, Middle District of North Carolina. Case No. 1:23-CV-864-LCB-LPA
2023-Present	Expert Witness, Report and Deposition Zayre-Brown v. The North Carolina Department of Public Safety, et al., United States District Court, Western District of North Carolina, Case No. 3:22-CV- 01910-MOC-DCK
2023-Present	Expert Witness, Report Poe, et al., v. Drummond, et al., United States District Court, Northern District of
2022 Progent	Oklahoma, Case No. 23-cv-00177-JFH-SH
2025-Pieseiii	Expert Witness, Report L.W., et al., v. Skrmetti, et al., United States District Court, Middle District of
	Tennessee, Case No. 3:23-cv-00376.
2022-2023	Expert Witness, Report, Deposition, and Testimony
	Dekker, et al., v. Marstiller, et al., United States District Court, Northern District
	of Florida, Case No. 4:22-cv-oo325-RH-MAF
2022- Present	Expert Witness, Report, Deposition, and Testimony
	Boe, et al., and United States, v. Marshall, et al., United States District Court,
	Middle District of Alabama Northern Division, Case No. 2:22-cv0-184-LCB.
2022	Expert Witness, Report
	Jeffrey Walker, et al., v. Steven Marshall, et al., United States District Court, Middle District of Alabama Northern Division
2022-Present	Expert Witness, Report and Testimony
	Jane Doe, et al., v. Greg Abbott, et al., District Court of Travis County, Texas 353 <sup>rd</sup> Judicial District, Case No. D-1-GN-22-000977
2021-2022	Expert Witness, Reports, Deposition, and Testimony
	Dylan Brandt, et al., v. Leslie Rutledge, et al., United States District Court, Eastern District of Arkansas, Case No.: 5:21-CV-00450-JM-1
2021	Consultant
	Proctor & Gamble, Cincinnati, OH
2019	Consultant
	Sanofi Genzyme, Cambridge, MA
2018-2023	Consultant
	Center for Conflict Resolution in Healthcare, Memphis, TN
2017-2020	Consultant
2017	Amicus Therapeutics, Cranbury, NJ
2017	Expert Witness, Report
	Robert J. Klickovich, MD, PLLC v. Tristate Arthritis & Rheumatology, PSC, <i>et al.</i> , Commonwealth of Kentucky, Boone Circuit Court, Division III, Civil Action No. 16-CI-01690
2017	Consultant
	Sarepta Therapeutics, Cambridge, MA

2014 Consultant

Genzyme, A Sanofi Company, Cambridge, MA

## **Editorial Experience**

**Editorial Board** 

2020-Present Pediatrics, Associate Editor for Ethics Rounds and Member of the Executive

**Editorial Board** 

2015-2020 Journal of Clinical Ethics

2009-2020 Journal of Medical Humanities

**Guest Academic Editor** 

2017 PLOS|ONE

Ad Hoc Reviewer: Academic Medicine, Academic Pediatrics, AJOB Primary Research, American Journal of Bioethics, American Journal of Law & Medicine, American Journal of Medical Genetics, American Journal of Transplantation, Archives of Disease in Childhood, BMC Medical Ethics, BMJ Open, Canadian Journal of Bioethics, CHEST, Clinical Transplantation, European Journal of Human Genetics, European Journal of Pediatrics, Frontiers in Genetics, Hospital Medicine, International Journal of Health Policy and Management, International Journal of Nursing Studies, Journal of Adolescent and Young Adult Oncology, Journal of Clinical Ethics, Journal of Empirical Research on Human Research Ethics, Journal of General Internal Medicine, Journal of Healthcare Leadership, Journal of Hospital Medicine, Journal of the Kennedy Institute of Ethics, Journal of Law, Medicine & Ethics, Journal of Medical Ethics, Journal of Medical Humanities, Journal of Medicine and Life, Journal of Palliative Care, Journal of Pediatrics, Journal of Pediatric Surgery, Mayo Clinic Proceedings, Medicine, Healthcare and Philosophy, Molecular Diagnosis & Therapy, New England Journal of Medicine, Patient Preference and Adherence, Pediatrics, Pediatrics in Review, Personalized Medicine, PLOS ONE, Risk Management and Healthcare Policy, Saudi Medical Journal, SSM - Qualitative Research in Health, and Theoretical Medicine and Bioethics

## SCHOLASTIC AND PROFESSIONAL HONORS

Member, Sigma Xi: The Scientific Research Honor Society, Research Triangle
Park, NC
Digital Health Award, Bronze Medal in the Digital Health Media/Publications
category for Pediatric Collections: Ethics Rounds: A Casebook in Pediatric
Bioethics Part II, Health Information Resource Center, Libertyville, IL
Hidden Gem Award, Cincinnati Children's Hospital Medical Center, Cincinnati,
ОН
Presidential Citation, American Society for Bioethics and Humanities, Chicago,
IL
Laura Mirkinson, MD, FAAP Lecturer, Section on Hospital Medicine, American
Academy of Pediatrics, Elk Grove Village, IL
Certificate of Excellence, American Society for Bioethics and Humanities,
Glenview, IL
Senior Resident Division Teaching Award, Cincinnati Children's Hospital
Medical Center, Cincinnati, OH

2012	Role Model, Quality Review Committee, Primary Children's Medical Center, Salt
	Lake City, UT
2011	Member, Society for Pediatric Research, The Woodlands, TX
2011	Presidential Citation, American Society for Bioethics and Humanities, Glenview,
	IL
2009	Role Model, Quality Review Committee, Primary Children's Medical Center, Salt
	Lake City, UT
2008	Nominee, Physician of the Year, Primary Children's Medical Center, Salt Lake
	City, UT
2005-2006	Fellow, Medical Scholars Program, University of Utah School of Medicine, Salt
	Lake City, UT
1995-1997	Doctoral Scholar, Crossroads, A Program of Evangelicals for Social Action,
	Philadelphia PA
1989-1992	Fellow, The Pew Program in Medicine, Arts, and the Social Sciences, University
	of Chicago, Chicago, IL

## **ADMINISTRATIVE EXPERIENCE**

## **Administrative Duties**

Manifeliari	ve Buttes
2023-2024	Chair, Literature Selection Technical Review Committee, National Library of
	Medicine, Bethesda, MD
2019-Present	Chair, Oversight Committee, Cincinnati Fetal Center, Cincinnati, OH
2014-Present	Chair, Ethics Committee, Cincinnati Children's Hospital Medical Center,
	Cincinnati, OH
2012-Present	Director, Ethics Center, Cincinnati Children's Hospital Medical Center,
	Cincinnati, OH
2012-Present	Chair, Ethics Consultation Subcommittee, Cincinnati Children's Hospital
	Medical Center, Cincinnati, OH
2010	Co-Chair, Ethics Subcommittee, Work Group for Emergency Mass Critical Care
	in Pediatrics, Centers for Disease Control and Prevention, Atlanta, GA
2009	Chair, Ethics Working Group, H1N1 and Winter Surge, Primary Children's
	Medical Center, Salt Lake City, UT
2005-2012	Chair, Ethics Committee, Primary Children's Medical Center, Salt Lake City, UT
2005-2012	Chair, Ethics Consultation Subcommittee, Primary Children's Medical Center,
	Salt Lake City, UT
2003-4	Chair, Clinical Pertinence Committee, Primary Children's Medical Center, Salt

## **Professional & Scientific Committees**

Lake City, UT

Professional & Scientific Committees		
Committees		
2023-Present	Member, Expert Committee, Humanitarian Access Program, Alnylam	
	Pharmaceuticals, Cambridge, MA	
2021	Member, EMCO Capacity Collaboration, Ohio Hospital Association, Columbus,	
	ОН	
2020-2021	Member, Allocation of Scarce Resources Work Group, Ohio Hospital	
	Association, Columbus, OH	

2020-2024	Member, Literature Selection Technical Review Committee, National Library of
2020	Medicine, Bethesda, MD  Member, Crisis Standards of Care Workgroup, The Health Collaborative,
_0_0	Cincinnati, OH
2019-2023	Member, Healthcare Ethics Consultant Certification Commission, Oak Park, IL
2019	Member, Expert Panel, Pediatric Oncology End-of-Life Care Quality Markers, Institute for Cancer Outcomes & Survivorship, University of Alabama at Birmingham, Birmingham, AL
2018	Member, Resource Planning and Allocation Team Implementation Task Force, Ohio Department of Health, Columbus, OH
2012-2022	Member, Gaucher Initiative Medical Expert Committee, Project HOPE, Millwood, VA
2009-2014	Member, Clinical Ethics Consultation Affairs Committee, American Society for Bioethics and Humanities, Glenview, IL
2005-2011	Member, Committee on Bioethics, American Academy of Pediatrics, Oak Park, IL
Data Cafatra	ud Manitanina Danda
	nd Monitoring Boards  Member, Data and Safety Monitoring Board, Sickle Cell Domestic Trials,
2017 11656110	National Heart, Lung, and Blood Institute, Bethesda, MD
2018-2019	Member, Standing Safety Committee for P-188-NF (Carmeseal-MD <sup>TM</sup> ) in
	Duchenne Muscular Dystrophy, Phrixus Pharmaceuticals, Inc., Ann Arbor, MI
2017-Present	, , , , , , , , , , , , , , , , , , ,
	Observational Monitoring Board, National Heart, Lung, and Blood Institute, Bethesda, MD
2016-2018	Member, Observational Study Monitoring Board, Long Term Effects of
	Hydroxyurea in Children with Sickle Cell Anemia, National Heart, Lung, and
	Blood Institute, Bethesda, MD
Reviewer	
2020-Present	Abstract Reviewer, American Society for Bioethics and Humanities Annual
	Meeting
2020	Grant Reviewer, The Croatian Science Foundation, Hvatska zaklada za znanost
2018	(HRZZ)  Book Proposal Reviewer, Elsevier
2018-2019	Category Leader, Religion, Culture, and Social Sciences, American Society for
2010 2019	Bioethics and Humanities Annual Meeting
2017	Timekeeper, American Society for Bioethics and Humanities Annual Meeting
2017-Present	Abstract Reviewer, Pediatric Academic Societies Annual Meeting
2016-2021	Workshop Reviewer, Pediatric Academic Societies Annual Meeting
2016	Grant Reviewer, Innovation Research Incentives Scheme, The Netherlands Organisation for Health Research and Development
2016-2017	Abstract Reviewer, American Society for Bioethics and Humanities Annual
	Meeting
2014, 2016	External Peer Reviewer, PSI Foundation, Toronto, Ontario, Canada

2014	Member, Scientific Committee, International Conference on Clinical Ethics and
2013	Consultation  Abstract Reviewer, American Society for Bioethics and Humanities Annual
	Meeting
2013	Reviewer, Open Research Area Plus, Agence Nationale de la Research, Deutsche Forschungsgemeinschaft, Economic and Social Research Council, National Science Foundation, and Organization for Scientific Research
2011-2012	Abstract Reviewer, Pediatric Academic Societies Annual Meeting
2011-2013	Workshop Reviewer, Pediatric Academic Societies Annual Meeting
2011-2014	Abstract Reviewer, Pediatric Hospital Medicine Annual Meeting
2011-2012	Religious Studies Subcommittee Leader, Program Committee, American Society
2011 2012	for Bioethics and Humanities Annual Meeting
2010	Abstract Reviewer, American Society for Bioethics and Humanities Annual
2010	Meeting
	Meeting
Other	
2023	Marshay Student Depar Committee American Society for Directhics and
2023	Member, Student Paper Committee, American Society for Bioethics and Humanities
2021	
2021 2021	Timekeeper, American Society for Bioethics and Humanities Annual Meeting
2021	Mentor, Early Career Advisor Professional Development Track, American
2021	Society for Bioethics and Humanities.
2021	Mentor, Early Career Advisor Paper or Project Track, American Society for Bioethics and Humanities.
2100	
2109	Mentor, Early Career Advising Program, American Society for Bioethics and
2010	Humanities  Province Print December 11 and Health and Ethica Control Continue 1
2018	Passing Point Determination, Healthcare Ethics Consultant-Certified
2010	Examination, Healthcare Ethics Consultant Certification Commission
2018	Member, Examination Committee, Healthcare Ethics Consultant-Certified
2010	Examination, Healthcare Ethics Consultant Certification Commission
2018	Item Writer, Healthcare Ethics Consultant-Certified Examination, Healthcare
	Ethics Consultant Certification Commission
	Y COMMUNITY ACTIVITIES
	hildren's Hospital Medical Center
	Member, Artificial Intelligence Governance Council
	Member, Executive Committee, Discover Together Biobank
	Member, Faculty Diversity and Inclusion Steering Committee
2020-2022	Member, Medical Management of COVID-19 Committee
2020-2021	Member, Caregiver Refusal Team
2020-2021	Member, COVID-19 Vaccine Allocation Committee
2020	Member, Personal Protective Equipment Subcommittee of the COVID-19
	Steering. Committee
2018-2019	Member, Planning Committee, Center for Clinical & Translational Science &
	Training Research Ethics Conference
2017 Present	Mambar Donor Selection Committee

Member, Employee Emergency Fund Review Committee

2017-Present Member, Donor Selection Committee

2017-2020

2017	Member, Root Cause Analysis Team
2016-2017	Member, Planning Committee, Center for Clinical & Translational Science &
	Training Research Ethics Conference
2015-2019	Member, Destination Excellence Medical Advisory Committee
2015-Present	Member, Disorders of Sexual Development Case Review Committee
2015-2019	Member, Destination Excellence Case Review Committee
2014-2018	Member, Genomics Review Group, Institutional Review Board
2014-2017	Member, Center for Pediatric Genomics Leadership Committee
2013-2017	Member, Genetic Testing Subcommittee, Health Network
2013-2016	Member, Schwartz Center Rounds Planning Committee
2013-2014	Member, Genomics Ad Hoc Subcommittee, Board of Directors
	Member, Cincinnati Fetal Center Oversight Committee
2012-Present	Member, Ethics Committee
2012-Present	Member, G-23
2012-2016	Member, Integrated Solid Organ Transplant Steering Committee
University of	
2009-2012	Member, Consolidated Hearing Committee
•	Utah School of Medicine
2010-2012	Member, Medical Ethics, Humanities, and Cultural Competence Thread
	Committee
2008-2010	Member, Fourth Year Curriculum Committee
TT	
•	Utah Department of Pediatrics
2010-2011	Member, Planning Committee, 25 <sup>th</sup> Annual Biological Basis of Children's Health
2000 2012	Conference, "Sex, Gender, and Sexuality"
2009-2012	Member, Medical Executive Committee

2010-2011	Member, Planning Committee, 25 <sup>th</sup> Annual Biological Basis of Children's Health
	Conference, "Sex, Gender, and Sexuality"
2009-2012	Member, Medical Executive Committee
2005-2012	Member, Retention, Promotion, and Tenure Committee
2004-2012	Interviewer, Residency Program
2003-2012	Member, Education Committee

## **Intermountain Healthcare**

2009-2012	Member, System-Wide Bioethics Resource Service
2009-2012	Member, Pediatric Guidance Council

## **Primary Children's Medical Center**

2012-2012	Member, Shared Accountability Organization Steering Committee
2009	Member, H1N1 and Winter Surge Executive Planning Team
2005-2010	Member, Continuing Medical Education Committee
2005-2010	Member, Grand Rounds Planning Committee
2003-2012	Member, Ethics Committee

# <u>ACTIVE MEMBERSHIPS IN PROFESSIONAL SOCIETIES</u> 2012-Present Association of Bioethics Program Directors

2011-Present Society for Pediatric Research

2000-Present American Academy of Pediatrics

1999-Present American Society of Bioethics and Humanities

**FUNDING** 

**Past Grants** 

2015-2019 "Better Outcomes for Children: Promoting Excellence in Healthcare Genomics to

Inform Policy." Percent Effort: 9%

National Human Genome Research Institute

Grant Number: 1U01 HG008666-01

Role: <u>Investigator</u>

2015-2016 "Ethics of Informed Consent for Youth in Foster Care"

Direct Costs: \$10,000

Ethics Grant, Center for Clinical and Translational Science and Training

University of Cincinnati Academic Health Center

Role: Co-Investigator

2014-2015 "Extreme Personal Exposure Biomarker Levels: Engaging Community Physicians

and Ethicists for Guidance" Direct Costs: \$11,640

Center for Environmental Genetics

University of Cincinnati College of Medicine

Role: Investigator

2014-2015 "Child, Adolescent, and Parent Opinions on Disclosure Policies for Incidental

Findings in Clinical Whole Exome Sequencing"

Direct Costs: \$4,434

Ethics Grant, Center for Clinical and Translational Science and Training,

University of Cincinnati Academic Health Center

Role: Principal Investigator

2013-2014 "Better Outcomes for Children: GWAS & PheWAS in eMERGEII

Percent Effort: 5%

National Human Genome Research Institute Grant Number: 3U01HG006828-0251

Role: <u>Investigator</u>

2004-2005 "Potential Patients' Knowledge, Attitudes, and Beliefs Regarding Participating in

Medical Education: Can They be Interpreted in Terms of Presumed Consent?"

Direct Costs: \$8,000

Interdisciplinary Research in Applied Ethics and Human Values, University

Research Committee, University of Utah

Role: Principal Investigator

#### TEACHING RESPONSIBILITIES/ASSIGNMENTS

#### **Course and Curriculum Development**

2003-2012 Medical Ethics, Internal Medicine 7560, University of Utah School of Medicine, Taught 1 time per year, Taken by medical students, Enrollment 100

#### **Course Lectures**

2018, 2021- Introduction to Biotechnology, "Ethics and Biotechnology" and "Clinical Ethics," BIOL

Present 3027, University of Cincinnati, Taught 1 time per year, Taken by undergraduate students, Enrollment 25.

2018-Present Biomedical Ethics, "Conscientious Objection in Healthcare" and "Ethical Issues in the Care of Transgender Adolescents," MEDS 4035 & MEDS 4036, University of Cincinnati College of Medicine, Taught 1 time per year, Taken by senior undergraduate students, Enrollment 52.

Foundations of Healthcare Ethics and Law, "Clinical Ethics," HESA 390, Xavier University.

2014-2020 Physicians and Society, "Transfusion and the Jehovah's Witness Faith," "Obesity Management: Ethics, Policy, and Physician Implicit Bias," "Embryos and Ethics: The Ethics of Designer Babies," "Ethics and Genetic Testing," and "Ethics and Direct to Consumer Genetic Testing," 26950112 and 26950116, University of Cincinnati School of Medicine, Taken by first and second year medical students, Enrollment 100.

2014-Present Ethical Issues in Health Care, "Ethical Issues in Managing Drug Shortages: The Macro, Meso, and Micro Levels," HESA 583, College of Social Sciences, Health, and Education Health Services Administration, Xavier University, Taken by health services administration students, Enrollment 25.

Physical Diagnosis II, Internal Medicine 7160, University of Utah School of Medicine, Taught 1 time per year, Taken by medical students, Enrollment 100
 Medical Ethics, Internal Medicine 7560, University of Utah School of Medicine,

Taught 1 time per year, Taken by fourth year medical students, Enrollment 100

#### **Small Group Teaching**

Clinical Ethics Consortium Tutorial B, BETH 731B, Harvard Medical School, Taught 1 time, Taken by Master of Science in Bioethics students.

2018-Present Ethics in Research, GNTD 7003-001, University of Cincinnati School of Medicine, Taught 1 time per year, Taken by fellows, MS, and PhD students, Enrollment 110.

2007 Physical Diagnosis I, Internal Medicine 7150, University of Utah School of Medicine, Taught 1 time per year, Taken by medical students, Enrollment 100

2003-2012 Medical Ethics, Internal Medicine 7560, University of Utah School of Medicine, Taught 1 time per year, Taken by fourth medical students, Enrollment 100

2003 Pediatric Organ System, Pediatrics 7020, University of Utah School of Medicine,

Taught 1 time per year, Taken by medical students, Enrollment 100

#### **Graduate Student Committees**

2018-2022	Chair, Scholarship Oversight Committee, William Sveen, Pediatric Critical Care
	Fellowship, Cincinnati Children's Hospital Medical Center, Cincinnati, OH
2018-2020	Member, Scholarship Oversight Committee, Anne Heuerman, Genetic
	Counseling, University of Cincinnati, Cincinnati, OH
2017-2019	Chair, Scholarship Oversight Committee, Bryana Rivers, Genetic Counseling,
	University of Cincinnati, Cincinnati, OH
2013-2015	Mentor, Sophia Hufnagel, Combined Pediatrics/Genetics Residency, Cincinnati
	Children's Hospital Medical Center, Cincinnati, OH
2013-2015	Co-Chair, Scholarship Oversight Committee, Andrea Murad, Genetic Counseling,
	University of Cincinnati, Cincinnati, OH
2013-2014	Member, Scholarship Oversight Committee, Grace Tran, Genetic Counseling,
	University of Cincinnati, Cincinnati, OH
2011-2012	Chair, Scholarship Oversight Committee, Kevin E. Nelson, MD, PhD, Pediatric
	Inpatient Medicine Fellowship, University of Utah, Salt Lake City, UT

## **Continuing Education Lectures**

- 2008 Choosing Healthplans All Together (CHAT) Exercise Facilitator, 18<sup>th</sup> Annual Intermountain Medical Ethics Conference, "Setting Priorities for Healthcare in Utah: What Choices are We Ready to Make?," Salt Lake City, Utah, October 3.
- 2007 *Speaker*, Infant Medical Surgical Unit, Primary Children's Medical Center, "Withholding and Withdrawing Artificial Nutrition and Hydration: Can It Be Consistent With Care?," Salt Lake City, Utah, September 6.
- 2007 Faculty Scholar-in Residence, Summer Seminar, "The Role of Religion in Bioethics," Utah Valley State College, Orem, Utah, May 1.
- 2006 *Workshop Leader*, Faculty Education Retreat, "Publications and Publishing in Medical Education," University of Utah School of Medicine, Salt Lake City, Utah, September 15.
- 2006 Breakout Session, 16<sup>th</sup> Annual Intermountain Medical Ethics Conference, "Donation after Cardiac Death: Evolution of a Policy," Salt Lake City, Utah, March 28.

#### **Other Educational Activities**

- 2008 Instructor, Contemporary Ethical Issues in Medicine and Medical Research, Osher Lifelong Learning Institute, University of Utah, "Religion and Bioethics: Religiously Based Demands for and Refusals of Treatment," Salt Lake City, Utah, February 7.
- 2007 *Speaker*, Biology Seminar, Utah Valley State College, "Is He Dead?: Criteria of the Determination of Death and Their Implications for Withdrawing Treatment and Recovering Organs for Transplant," Orem, Utah, September 21.

#### PEER-REVIEWED JOURNAL ARTICLES

- 1. <u>Armand H. Matheny Antommaria</u>. (2024) "Decision Making for Adolescents with Gender Dysphoria." *Perspectives in Biology and Medicine*. 67: 244-60. PMID: 38828602.
- 2. Erica K. Salter, D. Micah Hester, Lou Vinarcsik, <u>Armand H. Matheny Antommaria</u>, Johan Bester, Jeffrey Blustein, Ellen Wright Clayton, Douglas S. Diekema, Ana S. Iltis, Loretta M. Kopelman, Jay R. Malone, Mark R. Mercurio, Mark C. Navin, Erin Talati Paquette, Thaddeus Mason Pope, Rosamond Rhodes, and Lainie F. Ross, (2023) "Pediatric Decision Making: Consensus Recommendations," *Pediatrics*. 152: e2023061832. PMID: 37555276.

- 3. William N. Sveen, <u>Armand H. Matheny Antommaria</u>, Stephen Gilene, and Erika L. Stalets. (2023) "Adverse Events During Apnea Testing for the Determination of Death by Neurologic Criteria: A Single Center, Retrospective Pediatric Cohort." *Pediatric Critical Care Medicine*. 24: 399-405. PMID: 36815829.
- 4. Erica K. Salter, Jay R. Malone, Amanda Berg, Annie B. Friedrich, Alexandra Hucker, Hillary King, and <u>Armand H. Matheny Antommaria</u>. (2023) "Triage Policies at U.S. Hospitals with Pediatric Intensive Care Units." *AJOB Empirical Bioethics*. 14: 84-90. PMID: 36576201.
- 5. <u>Armand H. Matheny Antommaria</u>, Elizabeth Lanphier, Anne Housholder, and Michelle McGowan. (2023). "A Mixed Methods Analysis of Requests for Religious Exemptions to a COVID-19 Vaccine Requirement." *AJOB Empirical Bioethics*. 14: 15-22. PMID: 36161802.
- 6. Anne C Heuerman, Danielle Bessett, <u>Armand H. Matheny Antommaria</u>, Leandra. K. Tolusso, Nicki Smith, Alison H. Norris and Michelle L. McGowan (2022). "Experiences of Reproductive Genetic Counselors with Abortion Regulations in Ohio." *Journal of Genetic Counseling*. 31: 641-652. PMID: 34755409.
- 7. <u>Armand H. Matheny Antommaria</u> and Ndidi I. Unaka. (2021) "Counterpoint: Prioritizing Health Care Workers for Scarce Critical Care Resources is Impractical and Unjust. *Journal of Hospital Medicine*. 16: 182-3. PMID 33617445.
- 8. Gregory A. Grabowski, <u>Armand H. Matheny Antommaria</u>, Edwin H. Kolodny, and Pramod K. Mistry. (2021) "Gaucher Disease: Basic and Translational Science Needs for More Complete Therapy and Management." *Molecular Genetics and Metabolism.* 132: 59-75. PMID: 33419694.
- 9. <u>Armand H. Matheny Antommaria</u>, Laura Monhollen, and Joshua K. Schaffzin. (2021) "An Ethical Analysis of Hospital Visitor Restrictions and Masking Requirements During the COVID-19." *Journal of Clinical Ethics*. 32(1): 35-44. PMID 33416516.
- 10. <u>Armand H. Matheny Antommaria</u> (2020) "The Pediatric Hospital Medicine Core Competencies: 4.05 Ethics." *Journal of Hospital Medicine*. 15(S1): 120-121.
- 11. <u>Armand H. Matheny Antommaria</u>, Tyler S. Gibb, Amy L. McGuire, Paul Root Wolpe, Matthew K. Wynia, Megan K. Applewhite, Arthur Caplan, Douglas S. Diekema, D. Micah Hester, Lisa Soleymani Lehmann, Renee McLeod-Sordjan, Tamar Schiff, Holly K. Tabor, Sarah E. Wieten, and Jason T. Eberl for a Task Force of the Association of Bioethics Program Directors (2020) "Ventilator Triage Policies During the COVID-19 Pandemic at U.S. Hospitals Associated With Members of the Association of Bioethics Program Directors." *Annals of Internal Medicine*. 173(3): 188-194. PMID: 32330224.
- 12. <u>Armand H. Matheny Antommaria</u> (2020) "Conflicting Duties and Reciprocal Obligations During a Pandemic." *Journal of Hospital Medicine*. 5:284-286. PMID: 32379030.
- 13. Mary V. Greiner, Sarah J. Beal, and <u>Armand H. Matheny Antommaria</u> (2020) "Perspectives on Informed Consent Practices for Minimal-Risk Research Involving Foster Youth." *Pediatrics*. 45:e20192845. PMID: 32156772.
- 14. Jennifer deSante-Bertkau, Michelle McGowan, and <u>Armand H. Matheny Antommaria</u> (2018) "Systematic Review of Typologies Used to Characterize Clinical Ethics Consultations." *Journal of Clinical Ethics*. 29:291-304. PMID: 30605439.

- 15. Andrew J. Redmann, Melissa Schopper, <u>Armand H. Matheny Antommaria</u>, Judith Ragsdale, Alessandro de Alarcon, Michael J. Jutter, Catherine K. Hart, and Charles M. Myer. (2018) "To Transfuse or Not to Transfuse? Jehovah's Witnesses and PostOperative Hemorrhage in Pediatric Otolaryngology." *International Journal of Pediatric Otorhinolaryngology*. 115:188-192. PMID: 30368384.
- 16. <u>Armand H. Matheny Antommaria</u>, Kyle B. Brothers, John A. Myers, Yana B Feygin, Sharon A. Aufox, Murray H. Brilliant, Pat Conway, Stephanie M. Fullerton, Nanibaa' A. Garrison, Carol R. Horowitz, Gail P. Jarvik, Rongling Li, Evette J. Ludman, Catherine A. McCarty, Jennifer B. McCormick, Nathaniel D. Mercaldo, Melanie F. Myers, Saskia C. Sanderson, Martha J. Shrubsole, Jonathan S. Schildcrout, Janet L. Williams, Maureen E. Smith, Ellen Wright Clayton, Ingrid A. Holm. (2018) "Parents' Attitudes toward Consent and Data Sharing in Biobanks: A Multi-Site Experimental Survey." *AJOB Empirical Research*. 21:1-15. PMID: 30240342.
- 17. <u>Armand H. Matheny Antommaria</u> and Cynthia A. Prows. (2018) "Content Analysis of Requests for Religious Exemptions from a Mandatory Influenza Vaccination Program for Healthcare Personnel" *Journal of Medical Ethics*. 44: 389-391. PMID: 29463693.
- 18. <u>Armand H. Matheny Antommaria</u> (2017) "May Medical Centers Give Nonresident Patients Priority in Scheduling Outpatient Follow-Up Appointments?" *Journal of Clinical Ethics*. 28: 217-221. PMID: 28930708.
- 19. Andrea M. Murad, Melanie F. Myers, Susan D. Thompson, Rachel Fisher, and <u>Armand H. Matheny Antommaria</u> (2017) "A Qualitative Study of Adolescents' Understanding of Biobanks and Their Attitudes Toward Participation, Re-contact, and Data Sharing." *American Journal of Medical Genetics: Part A.* 173: 930-937. PMID: 28328120.
- 20. Saskia Sanderson, Kyle Borthers, Nathaniel Mercaldo, Ellen Wright Clayton, <u>Armand Antommaria</u>, Sharon Aufox, Murray Brillant, Diego Campos, David Carrell, John Connolly, Pat Conway, Stephanie Fullerton, Nanibaa Garrison, Carol Horowitz, Gail Jarvik, David Kaufman, Terrie Kitchner, Rongling Li, Evette Ludman, Cahterine McCarty, Jennifer McCormick, Valerie McManus, Melanie Myers, Aaron Scrol, Janet Williams, Martha Shrubsole, Jonathan Schildcrout, Maureen Smith, and Ingrid Holm (2017) "Public Attitudes Towards Consent and Data Sharing in Biobank Research: A Large Multisite Experimental Survey in the US." *The American Journal of Human Genetics*. 100: 414-427. PMID: 28190457.
- 21. Maureen E. Smith, Saskia C Sanderson, Kyle B Brothers, Melanie F Myers, Jennifer McCormick, Sharon A Aufox, Martha J Shrubsole, Nanibaa' A Garrison, Nathaniel D Mercaldo, Jonathan S Schildcrout, Ellen Wright Clayton, <u>Armand H. Matheny Antommaria</u>, Melissa Basford, Murray Brilliant, John J Connolly, Stephanie M Fullerton, Carol R Horowitz, Gail P Jarvik, Dave Kaufman, Terrie Kitchner, Rongling Li, Evette J Ludman, Catherine McCarty, Valerie McManus, Sarah C Stallings, Janet L Williams, and Ingrid A Holm (2016) "Conducting a Large, Multi-Site Survey about Patients' Views on Broad Consent: Challenges and Solutions." *BMC Medical Research Methodology*. 16: 162. PMID: 27881091.
- 22. Angela Lorts, Thomas D. Ryan, <u>Armand H. Matheny Antommaria</u>, Michael Lake, and John Bucuvalas (2016) "Obtaining Consensus Regarding International Transplantation Continues to be Difficult for Pediatric Centers in the United States." *Pediatric Transplant*. 20: 774-777. PMID: 27477950.

- 23. Sophia B. Hufnagel, Lisa J. Martin, Amy Cassedy, Robert J. Hopkin, and <u>Armand H. Matheny Antommaria</u> (2016) "Adolescents' Preferences Regarding Disclosure of Incidental Findings in Genomic Sequencing That Are Not Medically Actionable in Childhood." *American Journal of Medical Genetics Part A.* 170: 2083-2088. PMID: 27149544.
- 24. Nanibaa' A. Garrison, Nila A. Sathe, <u>Armand H. Matheny Antommaria</u>, Ingrid A. Holm, Saskia Sanderson, Maureen E. Smith, Melissa McPheeters, and Ellen Wright Clayton (2016) "A Systematic Literature Review of Individuals' Perspectives on Broad Consent and Data Sharing in the United States." *Genetics in Medicine*. 18: 663-71. PMID: 26583683.
- 25. Kyle B. Brothers, Ingrid A. Holm Janet E. Childerhose, <u>Armand H. Matheny Antommaria</u>, Barbara A. Bernhardt, Ellen Wright Clayton, Bruce D. Gelb, Steven Joffe, John A. Lynch, Jennifer B. McCormick, Laurence B. McCullough, D. William Parsons, Agnes S. Sundaresan, Wendy A. Wolf, Joon-Ho Yu, and Benjamin S. Wilfond (2016) "When Genomic Research Participants Grow Up: Contact and Consent at the Age of Majority." *The Journal of Pediatrics* 168: 226-31. PMID: 26477867.
- 26. Erin E. Bennett, Jill Sweney, Cecile Aguayo, Criag Myrick, <u>Armand H. Matheny</u> <u>Antommaria</u>, and Susan L. Bratton (2015) "Pediatric Organ Donation Potential at a Children's Hospital." *Pediatric Critical Care Medicine*. 16: 814-820. PMID: 26237656.
- 27. Anita J. Tarzian, Lucia D. Wocial, and the ASBH Clinical Ethics Consultation Affairs Committee (2015) "A Code of Ethics for Health Care Ethics Consultants: Journey to the Present and Implications for the Field." *American Journal of Bioethics*. 15: 38-51. PMID: 25970392.
- 28. <u>Armand H. Matheny Antommaria</u>, Christopher A. Collura, Ryan M. Antiel, and John D. Lantos (2015) "Two Infants, Same Prognosis, Different Parental Preferences." *Pediatrics*, 135: 918-923. PMID: 25847802.
- 29. Stefanie Benoit, <u>Armand H. Matheny Antommaria</u>, Norbert Weidner, and Angela Lorts (2015) "Difficult Decision: What should we do when a VAD supported child experiences a severe stroke?" *Pediatric Transplantation* 19: 139-43. PMID: 25557132.
- 30. Kyle B. Brothers, John A. Lynch, Sharon A. Aufox, John J. Connolly, Bruce D. Gelb, Ingrid A. Holm, Saskia C. Sanderson, Jennifer B. McCormick, Janet L. Williams, Wendy A. Wolf, <u>Armand H. Matheny Antommaria</u>, and Ellen W. Clayton (2014) "Practical Guidance on Informed Consent for Pediatric Participants in a Biorepository." *Mayo Clinic Proceedings*, 89: 1471-80. PMID: 25264176.
- 31. Sophia M. Bous Hufnagel and <u>Armand H. Matheny Antommaria</u> (2014) "Laboratory Policies on Reporting Secondary Findings in Clinical Whole Exome Sequencing: Initial Uptake of the ACMG's Recommendations." *American Journal of Medical Genetics Part A*, 164: 1328-31. PMID: 24458369.
- 32. Wylie Burke, Armand H. Matheny Antommaria, Robin Bennett, Jeffrey Botkin, Ellen Wright Clayton, Gail E. Henderson, Ingrid A. Holm, Gail P. Jarvik, Muin J. Khoury, Bartha Maria Knoppers, Nancy A. Press, Lainie Friedman Ross, Mark A. Rothstein, Howard Saal, Wendy R. Uhlmann, Benjamin Wilfond, Susan M. Wold, and Ron Zimmern (2013) "Recommendations for Returning Genomic Incidental Findings? We Need to Talk!" *Genetics in Medicine*, 15: 854-859. PMID: 23907645.
- 33. <u>Armand H. Matheny Antommaria</u> (2013) "An Ethical Analysis of Mandatory Influenza Vaccination of Health Care Personnel: Implementing Fairly and Balancing Benefits and Burdens," *American Journal of Bioethics*, 13: 30-37. PMID: 23952830.

- 34. Joseph A. Carrese and the Members of the American Society for Bioethics and Humanities Clinical Ethics Consultation Affairs Standing Committee (2012) "HCEC Pearls and Pitfalls: Suggested Do's and Don't's for Healthcare Ethics Consultants," *Journal of Clinical Ethics*, 23: 234-240. PMID: 23256404.
- 35. Christopher G Maloney, <u>Armand H Matheny Antommaria</u>, James F Bale Jr., Jian Ying, Tom Greene and Rajendu Srivastiva (2012) "Factors Associated with Intern Noncompliance with the 2003 Accreditation Council for Graduate Medical Education's 30-hour Duty Period Requirement," *BMC Medical Education* 12: 33. PMID: 22621439.
- 36. <u>Armand H. Matheny Antommaria</u>, Jill Sweney, and W. Bradley Poss (2010) "Critical Appraisal of: Triaging Pediatric Critical Care Resources During a Pandemic: Ethical and Medical Considerations," *Pediatric Critical Care Medicine*, 11:396-400. PMID: 20453611.
- 37. <u>Armand H. Matheny Antommaria</u>, Karen Trotochaud, Kathy Kinlaw, Paul N. Hopkins, and Joel Frader (2009) "Policies on Donation After Cardiac Death at Children's Hospitals: A Mixed-Methods Analysis of Variation," *Journal of the American Medical Association*, 301: 1902-8. PMID: 19436017.
- 38. Kristine M. Pleacher, Elizabeth S. Roach, Willem Van der Werf, <u>Armand H. Matheny</u> <u>Antommaria</u>, and Susan L. Bratton (2009) "Impact of a Pediatric Donation after Cardiac Death Program," *Pediatric Critical Care Medicine*, 10: 166-70. PMID: 19188881.
- 39. Flory L. Nkoy, Sarah Petersen, <u>Armand H Matheny Antommaria</u>, and Christopher G. Maloney (2008) "Validation of an Electronic System for Recording Medical Student Patient Encounters," *AMIA [American Medical Informatics Association] Annual Symposium Proceedings*, 6: 510-14. PMID: 18999155. Nominated for the Distinguished Paper Award
- 40. <u>Armand H. Matheny Antommaria</u>, Sean D. Firth, and Christopher G. Maloney (2007) "The Evaluation of an Innovative Pediatric Clerkship Structure Using Multiple Outcome Variables including Career Choice" *Journal of Hospital Medicine*, 2: 401-408. PMID: 18081170.
- 41. <u>Armand H. Matheny Antommaria</u> (2006) "Who Should Survive?: One of the Choices on Our Conscience: Mental Retardation and the History of Contemporary Bioethics." *Kennedy Institute of Ethics Journal*, 16: 205-224. PMID: 17091558.
- 42. <u>Armand H. Matheny Antommaria</u> (2004) "Do as I Say Not as I Do: Why Bioethicists Should Seek Informed Consent for Some Case Studies." *Hastings Center Report*, 34 (3): 28-34. PMID: 15281724.
- **43.** <u>Armand H. Matheny Antommaria</u> (2004) "A Gower Maneuver: The American Society for Bioethics and Humanities' Resolution of the 'Taking Stands' Debate." *American Journal of Bioethics*, 4 (Winter): W24-27. PMID: 15035934.

#### NON PEER-REVIEWED JOURNAL ARTICLES

- 1. Katherine Wade and <u>Armand H. Matheny Antommaria</u> (2016) "Inducing HIV Remission in Neonates: Children's Rights and Research Ethics." *Journal of Medicine and Biology*, 58(3): 348-54. PMID 27157354.
- 2. <u>Armand H. Matheny Antommaria</u> (2014) "Response to Open Peer Commentaries on 'An Ethical Analysis of Mandatory Influenza." *American Journal of Bioethics*, 14(7): W1-4. PMID: 24978422.
- 3. <u>Armand H. Matheny Antommaria</u> and Brent D. Kaziny (2012) "Ethical Issues in Pediatric Emergency Medicine's Preparation for and Response to Disasters." *Virtual* Mentor, 14: 801-4. PMID: 23351860.

- 4. <u>Armand H. Matheny Antommaria,</u> Tia Powell, Jennifer E. Miller, and Michael D. Christian (2011) "Ethical Issues in Pediatric Emergency Mass Critical Care," *Pediatric Critical Care Medicine*, 12(6 Suppl): S163-8. PMID: 22067926.
- 5. <u>Armand H. Matheny Antommaria</u> and Emily A. Thorell (2011) "Non-Pharmaceutical Interventions to Limit Transmission of a Pandemic Virus: The Need for Complementary Programs to Address Children's Diverse Needs." *Journal of Clinical Ethics*, 22: 25-32. PMID: 21595352.
- 6. <u>Armand H. Matheny Antommaria</u> (2010) "Conscientious Objection in Clinical Practice: Notice, Informed Consent, Referral, and Emergency Treatment." *Ave Maria Law Review*, 9: 81-99.
- 7. <u>Armand H. Matheny Antommaria</u> (2008) "Defending Positions or Identifying Interests: The Uses of Ethical Argumentation in the Debate over Conscience in Clinical Practice," *Theoretical Medicine and Bioethics*, 29: 201-12. PMID: 18821078.
- 8. <u>Armand H. Matheny Antommaria</u> (2008) "How can I give her IV antibiotics at home when I have three other children to care for?: Using Dispute System Design to Address Patient-Provider Conflicts in Health Care." *Hamline Journal of Public Law & Policy*, 29: 273-86.
- 9. <u>Armand H. Matheny Antommaria</u> (2007) "Alternative Dispute Resolution and Pediatric Clinical Ethics Consultation: Why the Limits of Ethical Expertise and the Indeterminacy of the Best Interests Standard Favor Mediation." *Ohio State Journal on Dispute Resolution*, 23: 17-59.
- 10. <u>Armand H. Matheny Antommaria</u> (2006) "Jehovah's Witnesses, Roman Catholicism, and Calvinism: Religion and State Intervention in Parental, Medical Decision-Making," *Journal of Law and Family Studies*, 8: 293-316.
- 11. <u>Armand H. Matheny Antommaria</u> and James F. Bale, Jr. (2002) "Ethical Issues in Clinical Practice: Cases and Analyses," *Seminars in Pediatric Neurology* 9: 67-76. PMID: 11931129.

#### **REVIEW ARTICLES**

<u>Armand H. Matheny Antommaria</u> (2010) "Conceptual and Ethical Issues in the Declaration of Death: Current Consensus and Controversies." *Pediatrics in Review* 31: 427-430. PMID: 20889737.

#### **BOOKS**

- 1. <u>Armand H. Matheny Antommaria</u>, ed. (2022) *Ethics Rounds: A Casebook in Pediatric Bioethics Part II*. Itasca, IL: American Academy of Pediatrics.
- 2. <u>Armand H. Matheny Antommaria</u> (1998) A Retrospective, Political and Ethical Analysis of State Intervention into Parental Healthcare Decisions for Infants with Disabilities. Wynnewood, Pennsylvania: Evangelicals for Social Action.

#### **BOOK CHAPTERS**

- 1. <u>Armand H. Matheny Antommaria</u> (2018) "Against Medical Advice Discharges: Pediatric Considerations." In *Against-Medical-Advice Discharges from the Hospital: Optimizing Prevention and Management to Promote High-Quality, Patient-Centered Care.* David Alfandre. New York, Springer: 143-157.
- 2. <u>Armand H. Matheny Antommaria</u> (2016) "Conscientious Objection in Reproductive Medicine." In *The Oxford Handbook of Reproductive Ethics*. Leslie Francis. Oxford, Oxford University Press: 209-225.

- 3. <u>Armand H. Matheny Antommaria</u> (2011) "Patient Participation in Medical Education." In *Clinical Ethics in Pediatrics: A Case-based Approach*. Douglas Diekema, Mark Mercurio, and Mary Beth Adam. Cambridge, Cambridge University Press: 221-225.
- 4. <u>Armand H. Matheny Antommaria</u> (2011) "State Intervention in Parental Decision Making: *Gone Baby Gone.*" In *The Picture of Health: Medical Ethics and the Movies.* Henri Colt, Silvia Quadrelli, and Lester Friedman. Oxford, Oxford University Press: 308-12.
- 5. <u>Armand H. Matheny Antommaria</u> (2009) "Managing Conflicts of Interest: A Perspective from a Pediatrician." In *Professionalism in Medicine: The Case-Based Guide for Medical Students*. John Spandorfer, Charles Pohl, Thomas Nasca and Susan Lee Rattner. Cambridge, Cambridge University Press: 376-7.
- 6. <u>Armand H. Matheny Antommaria</u> (2007) "Do-Not-Resuscitate Orders." In *Comprehensive Pediatric Hospital Medicine*. L. B. Zaoutis and V. W. Chiang. Philadelphia, Mosby Elsevier: 1200-4.

#### **OTHER**

## **Policy Statements and Technical Reports**

- 1. American Academy of Pediatrics Committee on Bioethics. <u>Armand H. Matheny Antommaria</u> Lead Author. (2013) "Conflicts between Religious or Spiritual Beliefs and Pediatric Care: Informed Refusal, Exemptions, and Public Funding." *Pediatrics*. 132: 962-965. PMID: 24167167.
- 2. American Academy of Pediatrics Committee on Bioethics. <u>Armand H. Matheny Antommaria</u> Lead Author. (2013) "Ethical Controversies in Organ Donation After Circulatory Death." *Pediatrics*. 131: 1021-1026. PMID: 23629612.
- 3. American Academy of Pediatrics Committee on Bioethics and Committee on Genetics and the American College of Medical Genetics and Genomics Social, Ethical, and Legal Issues Committee (2013) "Policy Statement: Ethical and Policy Issues in Genetic Testing and Screening of Children." *Pediatrics*. 131: 620-622. PMID: 23428972.
- 4. Lainie Friedman Ross, Howard M. Saal, Karen L. David, Rebecca R. Anderson and the American Academy of Pediatrics Committee on Bioethics and Committee on Genetics and the American College of Medical Genetics and Genomics Social, Ethical, and Legal Issues Committee (2013) "Technical Report: Ethical and Policy Issues in Genetic Testing and Screening of Children." *Genetics in Medicine*. 15: 234-245. PMID: 23429433.
- 5. American Academy of Pediatrics Committee for Pediatric Research and Committee on Bioethics (2012) "Human Embryonic Stem Cell (hESC) and Human Embryo Research." *Pediatrics* 130: 972-977. PMID: 23109685.
- 6. American College of Obstetricians and Gynecologists, Committee on Ethics and American Academy of Pediatrics, Committee on Bioethics (2011) "Maternal-Fetal Intervention and Fetal Care Centers," *Pediatrics* 128; e473-e478. PMID: 21788223.
- 7. American Academy of Pediatrics Committee on Pediatric Emergency Medicine and Committee on Bioethics (2011) "Consent for Emergency Medical Services for Children and Adolescents." *Pediatrics* 128: 427-433. PMID: 21788221.
- 8. Council on School Health and Committee on Bioethics. Robert Murray and <u>Armand H. Matheny Antommaria</u> Lead Authors. (2010) "Honoring –Do-Not-Attempt Resuscitation Requests in Schools." *Pediatrics* 125; 1073-1077. PMID: 20421255.
- 9. Committee on Bioethics (2010) "Ritual Genital Cutting of Female Minors." *Pediatrics* 125; 1088-1093. PMID: 20421257.

- 10. Committee on Bioethics. (2010) "Children as Hematopoietic Stem Cell Donors," *Pediatrics* 125; 392-40. PMID: 20100753.
- 11. Committee on Bioethics. <u>Armand H. Matheny Antommaria</u> Lead Author. (2009) "Physician Refusal to Provide Information or Treatment Based on Claims of Conscience." *Pediatrics*. 124; 1689-93. PMID: 19948636.
- 12. Committee on Bioethics (2009) "Pediatrician-Family-Patient Relationships: Managing the Boundaries." *Pediatrics* 124; 1685-8. PMID: 19948635.
- 13. Douglas S. Diekema, Jeffrey R. Botkin, and Committee on Bioethics (2009) "Forgoing Medically Provided Nutrition and Hydration in Children." *Pediatrics* 124; 813-22. PMID: 19651596.
- 14. Lainie Friedman Ross, J. Richard Thistlethwaite, Jr., and the Committee on Bioethics (2008) "Minors as Living Solid-Organ Donors." *Pediatrics* 122: 454-61. PMID: 18676567.
- 15. Mary E. Fallat, John Hutter, and Section on Hematology Oncology and Section on Surgery the Committee on Bioethics (2008) "Preservation of Fertility in Pediatric and Adolescent Patients with Cancer." *Pediatrics* 121: 1461-9. PMID: 18450888.
- 16. Marcia Levetown and Bioethics and the Committee on Bioethics (2008) "Communicating With Children and Families: From Everyday Interactions to Skill in Conveying Distressing Information." *Pediatrics* 121: 1441-60. PMID: 18450887.
- 17. American Academy of Pediatrics. Committee on Bioethics (2007) "Professionalism in Pediatrics: Statement of Principles." *Pediatrics* 120:895-7. PMID: 17908776.

#### **Ethics Rounds**

- 1. Imogen Clover-Brown, Bryanna More, Christina G. Andrews, and <u>Armand H. Matheny</u> <u>Antommaria.</u> (2023) "Ethical Issues With Patient-Provider Interactions in an Evolving Social Media Landscape." *Pediatrics.* 151: e2022060066. PMIC 3765789.
- 2. Maeghann S. Weaver, Marianne E. M. Yee, Courtney E. Lawrence, <u>Armand H. Matheny Antommaria</u>, and Ross M. Fasano. (2023) "Requests for Directed Blood Donations." *Pediatrics*. 151: e2022058183. PMID: 36897227.
- 3. Erwin Jiayuan Khoo, Devan M. Duenas, Benjamin S. Wilfond, Luke Gelinas, <u>Armand H. Matheny Antommaria</u>. (2023) "Incentives in Pediatric Research in Developing Countries: When Are They Too Much?" *Pediatrics*. 141: e2021055702. PMID: 36660851.
- 4. Kim Mooney-Doyle, Kimberly A. Pyke-Grimm, Ashley Foster Lanzel, Kathleen E. Montgomery, Jamila Hassan, Anisha Thompson, Rebecca Rouselle, and <u>Armand H. Matheny Antommaria</u>. (2022) "Balancing Protection and Progress in Pediatric Palliative Care Research: Stakeholder Perspectives." *Pediatrics*. 150: e2022057502. PMID: 36069137.
- 5. Megan H. Pesch, Phoebe Dazinger, Lainie Friedman Ross, and <u>Armand H. Matheny Antommaria</u>. (2022) "An Ethical Analysis of Newborn Congenital Cytomegalovirus Screening." *Pediatrics*. 149: e2021055368. PMID: 35641472.
- 6. Ian D. Wolfe, Don Brunnquell, Rena Sorensen, and <u>Armand H. Matheny Antommaria</u>. (2022) "Should Tactile Defensiveness Exclude a Life-Sustaining Intervention in an Adolescent With Autism?" *Pediatrics*. 149: e2021054469. PMID: 35229117.
- 7. Jennifer E. deSante-Bertkau, Timothy K. Knilans, Govind Persad, Patricia J. Zettler, Holly Fernandez Lynch, and <u>Armand H. Matheny Antommaria</u>. (2021) "Off-Label Prescription of COVID-19 Vaccines in Children: Clinical, Ethical, and Legal Issues." *Pediatrics*. 149: e2021054578. PMID: 34615694.

- 8. Jamilah M. Hackworth, Meera Kotagal, O. N. Ray Bignal, 2<sup>nd</sup>, Ndidi Unaka, and <u>Armand H. Matheny Antommaria.</u> (2021) "Microaggressions: Privileged Observers' Duty to Act and What They Can Do." *Pediatrics*. 148: e2021052758. PMID: 34417286.
- 9. Elizabeth Lanphier, Luke Mosley, and <u>Armand H. Matheny Antommaria.</u> (2021) "Assessing Visitor Policy Exemption Requests During the COVID-19 Pandemic." *Pediatrics.* 148: e2021051254. PMID: 33990461.
- 10. Natalie Lanocha, Tyler Tate, Erica Salter, Nanette Elster, and <u>Armand H. Matheny</u> <u>Antommaria.</u> (2021) "Can Parents Restrict Access to Their Adolescent's Voice?: Deciding About a Tracheostomy." *Pediatrics*. 147: e2021050358. PMID 33785636.
- 11. Timothy Crisci, Zeynep N. Inanc Salih, Ndidi Unaka, Jehanna Peerzada, and <u>Armand H. Matheny Antommaria.</u> (2021) "What Should an Intern Do When She Disagrees With the Attending?" *Pediatrics*. 147: e2020049646. PMID 33627371.
- 12. Liza-Marie Johnson, Erica C. Kaye, Kimberly Sawyer, Alex M. Brenner, Stefan J. Friedrichsdorf, Abby R. Rosenberg, <u>Armand H. Mathey Antommaria</u>. (2021) "Opioid Management in the Dying Child With Addiction." *Pediatrics* 147: e2020046219. PMID 33446508.

## **Continuing Medical Education**

- 1. Armand H. Matheny Antommaria (2014) Authored 4 questions. NEJM Knowledge+ Family Medicine Board Review. NEJM Group.
- 2. Armand H. Matheny Antommaria (2009) "Hot Topics: Ethics and Donation After Cardiac Death [online course]. PediaLink. American Academy of Pediatrics. October 24. http://ethics.ht.courses.aap.org/. Accessed December 14. 2009.

#### **Editorials**

- 1. <u>Armand H. Matheny Antommaria</u>, Chris Feudtner, Mary Beth Benner, and Felicia Cohn on Behalf of the Healthcare Ethics Consultant-Certified Certification Commission (2020) "The Healthcare Ethics Consultant-Certified Program: Fair, Feasible, and Defensible, But Neither Definite Nor Finished," *American Journal of Bioethics* 20:1-5. PMID: 32105202.
- 2. <u>Armand H. Matheny Antommaria</u> and Pamela W. Popp (2020) "The Potential Roles of Surrogacy Ladders, Standby Guardians, and Medicolegal Partnerships, in Surrogate Decision Making for Parents of Minor Children," *Journal of Pediatrics* 220:11-13. PMID 31952849.

#### **Commentaries**

- 1. Jerry Schwartz, Dawn Nebrig, Laura Monhollen, and <u>Armand H. Matheny Antommaria.</u> (2023) "Transforming Behavior Contracts into Collaborative Commitments with Families." *American Journal of Bioethics.* 23(1): 73-75. PMID: 36594997.
- 2. <u>Armand H. Matheny Antommaria</u> and Elizabeth Lanphier. (2022) "Supporting Marginalized Decision-Marker's Autonom(ies)." *American Journal of Bioethics*. 22(6):22-24. PMID: 35616965.
- 3. Mary V. Greiner and Armand H. Matheny Antommaria. (2022) "Enrolling Foster Youth in Clinical Trials: Avoiding the Harm of Exclusion." *American Journal of Bioethics*. 22(4):85-86. PMID: 35420526. Reprinted in (2024) *Challenging Cases in Clinical Research Ethics*. Benjamin S. Wilfond, Liza-Marie Johnson, Devan M. Duenas, and Holly A. Taylor. Boca Raton, FL, CRC Press: 166-167.

- 4. William Sveen and <u>Armand H. Matheny Antommaria.</u> (2020) "Why Healthcare Workers Should Not Be Prioritized in Ventilator Triage." *American Journal of Bioethics*. 20(7): 133-135. PMID: 32716811.
- 5. <u>Armand H. Matheny Antommaria</u>, William Sveen, and Erika L. Stalets (2020) "Informed Consent Should Not Be Required for Apnea Testing and Arguing It Should Misses the Point," *American Journal of Bioethics*. 20: 25-27. PMID: 32441602.
- 6. <u>Armand H. Matheny Antommaria</u> (2019) "Relational Potential versus the Parent-Child Relationship," *Hastings Center Report.* 49(3): 26-27. PMID: 31269255.
- 7. <u>Armand H. Matheny Antommaria</u>, Robert A. Shapiro, and Lee Ann E. Conard (2019) "Psychological Maltreatment and Medical Neglect of Transgender Adolescents: The Need for Recognition and Individualized Assessment." *American Journal of Bioethics*. 19: 72-74. PMID: 31543011.
- 8. <u>Armand H. Matheny Antommaria</u> (2018) "Accepting Things at Face Value: Insurance Coverage for Transgender Healthcare." *American Journal of Bioethics*. 18: 21-23. PMID: 31159689.
- 9. <u>Armand H. Matheny Antommaria</u> and Judith R. Ragsdale (2018) "Shaken, not Stirred: What are Ethicists Licensed to Do?" *American Journal of Bioethics* 18: 56-58. PMID: 29697345.
- 10. <u>Armand H. Matheny Antommaria</u> (2017) "Issues of Fidelity and Trust Are Intrinsic to Uncontrolled Donation after Circulatory Determination of Death and Arise Again with Each New Resuscitation Method," *American Journal of Bioethics* 17: 20-22. PMID: 28430053.
- 11. <u>Armand H. Matheny Antommaria</u> (2016) "Conscientious Objection: Widening the Temporal and Organizational Horizons," *The Journal of Clinical Ethics* 27: 248-250. PMID: 27658282.
- 12. <u>Armand H. Matheny Antommaria</u> and Ron King. (2016) "Moral Hazard and Transparency in Pediatrics: A Different Problem Requiring a Different Solution." *American Journal of Bioethics* 16: 39-40. PMID: 27292846.
- 13. Armand H. Matheny Antommaria and Richard F. Ittenabch (2016) "Quality Attestation's Portfolio Evaluation Is Feasible, But Is It Reliable and Valid?" *American Journal of Bioethics* 16: 35-38. PMID: 26913658.
- 14. <u>Armand H. Matheny Antommaria</u> and Kristin Stanley Bramlage (2015) "Enrolling Research Participants in Private Practice: Conflicts of Interest, Consistency, Therapeutic Misconception, and Informed Consent." *AMA Journal of Ethics*. 17:1122-1126. PMID: 26698585.
- 15. Armand H. Matheny Antommaria (2015) "Characterizing Clinical Ethics Consultations: The Need for a Standardized Typology of Cases." *American Journal of Bioethics* 15: 18-20. PMID: 25970383.
- 16. <u>Armand H. Matheny Antommaria</u> (2015) "Intensified Conflict Instead of Closure: Clinical Ethics Consultants' Recommendations' Potential to Exacerbate Ethical Conflicts." *American Journal of Bioethics* 15: 52-4. PMID: 25562231.
- 17. Lainie Friedman Ross and <u>Armand H. Matheny Antommaria</u> (2014) "The need to promote all pediatric stem cell donors' understanding and interests." *Pediatrics* 133: e1356-e1357. PMID: 24777208.
- 18. <u>Armand H. Matheny Antommaria</u> (2014) "Pubertal Suppression and Professional Obligations: May a Pediatric Endocrinologist Refuse to Treat an Adolescent with Gender Dysphoria." *American Journal of Bioethics* 13: 43-46. PMID: 24422933.

- 19. <u>Armand H. Matheny Antommaria (</u>2012) "Empowering, Teaching, and Occasionally Advocating: Clinical Ethics Consultants' Duties to All of the Participants in the Process." *American Journal of Bioethics* 12 11-3. PMID: 22852533.
- 20. <u>Armand H. Matheny Antommaria (</u>2010) "Dying but not Killing: Donation after Cardiac Death Donors and the Recovery of Organs." *Journal of Clinical Ethics* 21: 229-31. PMID: 21089993.
- 21. <u>Armand H. Matheny Antommaria</u> and Julie Melini (2010) "Is it Reasonable to Refuse to be Seen by a Nurse Practitioner in the Emergency Department?" *American Journal of Bioethics* 10: 15-17. PMID: 20694899.
- 22. William Meadow, Chris Feudtner, <u>Armand H. Matheny Antommaria</u>, Dane Sommer, John Lantos (2010) "A Premature Baby with Necrotizing Enterocolitis Whose Parents Are Jehovah's Witnesses." *Pediatrics*. 216: 151-155. PMID: 20566607.
- 23. C. C. Weitzman, S. Schlegel, Nancy Murphy, <u>Armand H. Matheny Antommaria</u>, J. P. Brosco, Martin T. Stein (2009) "When Clinicians and a Parent Disagree on the Extent of Medical Care." *Journal of Developmental and Behavioral Pediatrics*. 30: 242-3. PMID: 19525718. Reprinted as (2010) *Journal of Developmental and Behavioral Pediatrics*. 31: S92-5. PMID: 20414087
- 24. <u>Armand H. Matheny Antommaria</u> and Susan Bratton (2008) "Nurses' Attitudes toward Donation after Cardiac Death: Implications for Nurses' Roles and Moral Distress." *Pediatric Critical Care Medicine*, 9: 339-40. PMID: 18446100.
- 25. <u>Armand H. Matheny Antommaria and Nannette C. Dudley (2007)</u> "Should Families Be Present During CPR?" *AAP Grand Rounds*, 17: 4-5.
- 26. <u>Armand H. Matheny Antommaria</u> (2006) "The Proper Scope of Analysis of Conscientious Objection in Healthcare: Individual Rights or Professional Obligations" *Teaching Ethics*, 7: 127-31.
- 27. <u>Armand H. Matheny Antommaria</u> and Rajendu Srivastava (2006) "If Cardiologists Take Care of Patients with Heart Disease, What do Hospitalists Treat?: Hospitalists and the Doctor-Patient Relationship." *American Journal of Bioethics*, 6: 47-9. PMID: 16423793.
- 28. <u>Armand H. Matheny Antommaria</u> (2003) "I Paid Out-of-Pocket for My Son's Circumcision at Happy Valley Tattoo and Piercing: Alternative Framings of the Debate over Routine Neonatal Male Circumcision," *American Journal of Bioethics* 3: 51-3. PMID: 12859817.

#### Letters

Benjamin S. Wilfond, David Magnus, <u>Armand H Matheny Antommaria</u>, Paul Appelbaum, Judy Aschner, Keith J. Barrington, Tom Beauchamp, Renee D. Boss, Wylie Burke, Arthur L. Caplan, Alexander M. Capron, Mildred Cho, Ellen Wright Clayton, F. Sessions Cole, Brian A. Darlow, Douglas Diekema, Ruth R. Faden, Chris Feudtner, Joseph J. Fins, Norman C. Fost, Joel Frader, D. Micah Hester, Annie Janvier, Steven Joffe, Jeffrey Kahn, Nancy E. Kass, Eric Kodish, John D. Lantos, Laurence McCullough, Ross McKinney, Jr., William Deadow, P. Pearl O'Rourke, Kathleen E. Powderly, DeWayne M. Pursley, Lainie Friedman Ross, Sadath Sayeed, Richard R. Sharp, Jeremy Sugarman, William O. Tarnow-Mordi, Holly Taylor, Tom Tomlison, Robert D. Truog, Yoram T. Unguru, Kathryn L. Weise, David Woodrum, Stuart Youngner (2013) "The OHRP and SUPPORT," *New England Journal of Medicine*, 368: e36. PMID: 23738513.

- 2. Lainie Friedman Ross and <u>Armand H. Matheny Antommaria</u> (2011) "In Further Defense of the American Academy of Pediatrics Committee on Bioethics 'Children as Hematopoietic Stem Cell Donors' Statement." *Pediatric Blood & Cancer*. 57: 1088-9.
- 3. <u>Armand H. Matheny Antommaria</u> (2011) "Growth Attenuation: Health Outcomes and Social Services." *Hastings Center Report*, 41(5): 4. PMID: 21980886.
- 4. Susan Bratton and <u>Armand H. Matheny Antommaria</u> (2010) "Dead Donor Rule and Organ Procurement: The Authors Reply." *Pediatric Critical Care Medicine*, 11: 314-5.
- 5. <u>Armand H. Matheny Antommaria</u> and Joel Frader (2009) "Policies of Children's Hospitals on Donation After Cardiac Death—Reply." *Journal of the American Medical Association*, 302: 845.

#### **Case Reports**

Armand H. Matheny Antommaria (2002) "Case 4.9: Inappropriate Access to a Celebrity's Medical Records." In *Ethics and Information Technology: A Case-Based Approach to a Health Care System in Transition*, James G. Anderson and Kenneth W. Goodman, 79-80. New York: Springer-Verlag.

#### **Book Reviews**

- 1. <u>Armand H. Matheny Antommaria</u> (2024) Review of *Mormonism, Medicine, and Bioethics,* by Courtney S. Campbell. *Mormon Studies Review* 11: 182-8.
- 2. <u>Armand H. Matheny Antommaria</u> (2023) "An Ambitious Goal: A Grounded, Informed, and Compelling Theological Bioethics." Review of *Disability's Challenge to Theology: Genes, Eugenics, and the Metaphysics of Modern Medicine* by Devan Stahl. *Hastings Center Report* 53(2): 44-45.
- 3. <u>Armand H. Matheny Antommaria</u> (2021) Review of *When Harry Became Sally: Responding to the Transgender Moment*, by Ryan T. Anderson. *Journal of Medical Humanities* 42: 195-9. PMID 31808021.
- 4. <u>Armand H. Matheny Antommaria</u> (2012) Review of *The Ethics of Organ Transplantation*, by Steven J. Jensen, ed., *Journal of the American Medical Association* 308: 1482-3.
- 5. <u>Armand H Matheny Antommaria</u> (2012) Review of *The Soul of Medicine: Spiritual Perspectives and Clinical Practice*, by John R. Peteet and Michael N. D'Ambra, ed., *Journal of the American Medical Association* 308: 87.
- 6. <u>Armand H. Matheny Antommaria</u> (2009) Review of *Conflicts of Conscience in Health Care: An Institutional Compromise*, by Holly Fernandez Lynch. *American Journal of Bioethics* 9: 63-4.
- 7. <u>Armand H. Matheny Antommaria</u> (2008) Review of *A Practical Guide to Clinical Ethics Consulting: Expertise, Ethos, and Power*, by Christopher Meyers. *American Journal of Bioethics* 8: 72-3.
- 8. <u>Armand H. Matheny Antommaria</u> (2004) Review of *Children, Ethics, and Modern Medicine*, by Richard B. Miller. *American Journal of Bioethics* 4: 127-8.
- 9. <u>Armand H. Matheny Antommaria</u> (2002) Review of *Ward Ethics: Dilemmas for Medical Students and Doctors in Training*, by Thomasine Kushner and David Thomasma, ed. *American Journal of Bioethics* 2: 70-1. PMID: 22494193.
- 10. <u>Armand H. Matheny Antommaria</u> (1999) Review of *Human Cloning: Religious Responses*, by Ronald Cole-Turner, ed. *Prism* 6 (March/April): 21.

- 11. <u>Armand H. Matheny Antommaria</u> (1999) Review of *Christian Theology and Medical Ethics:* Four Contemporary Approaches, by James B. Tubbs, Jr. *Journal of Religion* 79 (April): 333-5.
- 12. <u>Armand H. Matheny Antommaria</u> (1997) Review of *Body, Soul, and Bioethics*, by Gilbert C. Meilaender. *Prism* 4 (May/June): 28.

#### **Newspaper Articles**

- 1. W. Bradley Poss and <u>Armand H. Matheny Antommaria</u> (2010) "Mass casualty planning must incorporate needs of children." *AAP News* 31 (July): 38.
- 2. Robert Murray and <u>Armand H. Matheny Antommaria</u> (2010) "Pediatricians should work with school nurses to develop action plans for children with DNAR orders." *AAP News* 31 (May): 30..
- 3. <u>Armand H. Matheny Antommaria</u> (2009) "Addressing physicians' conscientious objections in health care." *AAP News* 30 (December): 32.

#### UNPUBLISHED POSTER PRESENTATIONS

- 1. <u>Armand H. Matheny Antommaria.</u> (2018) "Ethical Issues in the Care of International Patients: A Case Study." International Conference on Clinical Ethics and Consultation, Oxford, United Kingdom.
- 2. Jill S Sweney, Brad Poss, Colin Grissom, Brent Wallace, and <u>Armand H Matheny</u> <u>Antommaria</u>, (2010) "Development of a Statewide Pediatric Pandemic Triage Plan in Utah." Pediatric Academic Societies Annual Meeting, Vancouver, Canada. E-PAS20103713.147.
- 3. Christopher G. Maloney, <u>Armand H. Matheny Antommaria</u>, James F. Bale, Thomas Greene, Jian Ying, Gena Fletcher, and Rajendu Srivastava (2010) "Why Do Pediatric Interns Violate the 30 Hour Work Rule?" Pediatric Academic Societies Annual Meeting, Vancouver, Canada. E-PAS20101500.596
- 4. <u>Armand H. Matheny Antommaria</u> and Edward B. Clark (2007) "Resolving Conflict through Bioethics Mediation." 3<sup>rd</sup> International Conference on Ethics Consultation and Clinical Ethics, Toronto, Canada.
- 5. Elizabeth Tyson, Tracy Hill, <u>Armand Antommaria</u>, Gena Fletcher, and Flory Nkoy (2007) "Physician Practice Patterns Regarding Nasogastric Feeding Supplementation and Intravenous Fluids in Bronchiolitis Patients." Pediatrics Academic Societies Annual Meeting, Toronto, Canada. E-PAS2007:61300.

#### **ORAL PRESENTATIONS**

## **Keynote/Plenary Lectures**

## <u>International</u>

- 1. 2021, *Panelist*, Partnership for Quality Medical Donations, Charitable Access Programming for Rare Diseases, "Ethical Issues," Webinar, April 6.
- 2. 2017, *Invited Speaker*, Spina Bifida Fetoscopic Repair Study Group and Consortium, "Ethics of Innovation and Research in Fetal Surgery," Cincinnati, Ohio, October 26.
- 3. 2014, *Invited Speaker*, CIC 2013 CCI: Canadian Immunization Conference, "Condition-of-Service Influenza Prevention in Health Care Settings," Ottawa, Canada, December 2.
- 4. 2014, *Invited Speaker*, National Conference of the Chinese Pediatric Society, "A Brief Introduction to Pediatric Research and Clinical Ethics," Chongqing, China, September 12.

#### National

- 1. 2020, *Panelist*, Children's Mercy Bioethics Center, "Ethical Issues in the COVID Pandemic at Children's Hospitals," Webinar, March 2.
- 2. 2019, *Invited Speaker*, North American Fetal Therapy Network (NAFTnet), "Ethics of Innovation," Chicago, Illinois, October 12.
- 3. 2019, *Panelist*, National Society of Genetic Counselors Prenatal Special Interest Group, "Fetal Intervention Ethics," Webinar, September 12.
- 4. 2017, *Invited Participant*, American College of Epidemiology Annual Meeting, Preconference Workshop, "Extreme Personal Exposure Biomarker Levels: Guidance for Study Investigators," New Orleans, Louisiana, September 24.
- 5. 2016, *Invited Speaker*, American Academy of Pediatrics National Conference & Exhibition, Joint Program: Section on Hospital Medicine and Section on Bioethics, "Resource Allocation: Do We Spend Money to Save One Patient with Ebola or Over a 1,000?" San Francisco, California, October 23.
- 6. 2016, *Invited Speaker*, 26<sup>th</sup> Annual Specialist Education in Extracorporeal Membrane Oxygenation (SEECHMO) Conference, "Ethical Issues in ECMO: The Bridge to Nowhere," Cincinnati, Ohio, June 5.
- 7. 2015, *Invited Speaker*, Extracorporeal Life Support Organization (ELSO) 26<sup>th</sup> Annual Conference, "ECMO-Supported Donation after Circulatory Death: An Ethical Analysis," Atlanta, Georgia, September 20.
- 8. 2014, *Invited Speaker*, Pediatric Evidence-Based Practice 2014 Conference: Evidence Implementation for Changing Models of Pediatric Health Care, "Ethical Issues in Evidence-Based Practice," Cincinnati, Ohio, September 19.
- 9. 2014, *Invited Speaker*, 6<sup>th</sup> Annual David Kline Symposium on Public Philosophy: Exploring the Synergy Between Pediatric Bioethics and Child Rights, "Does Predictive Genetic Testing for Adult Onset Conditions that Are Not Medically Actionable in Childhood Violate Children's Rights?" Jacksonville, Florida, March 6.
- 10. 2010, *Invited Speaker*, Quest for Research Excellence: The Intersection of Standards, Culture and Ethics in Childhood Obesity, "Research Integrity and Religious Issues in Childhood Obesity Research," Denver, Colorado, April 21.
- 11. 2010, *Invited Speaker*, Symposium on the Future of Rights of Conscience in Health Care: Legal and Ethical Perspectives, J. Reuben Clark Law School at Brigham Young University and the Ave Maria School of Law, "Conscientious Objection in Clinical Practice: Disclosure, Consent, Referral, and Emergency Treatment," Provo, Utah, February 26.
- 12. 2009, *Invited Speaker*, Pediatric Organ Donation Summit, "Research Findings Regarding Variations in Pediatric Hospital Donation after Cardiac Death Policies," Chicago, Illinois, August 18.
- 13. 2008, *Meet-the-Experts*, American Academy of Pediatrics National Conference & Exhibition, "Physician Refusal to Provide Treatment: What are the ethical issues?" Boston, Massachusetts, October 11.
- 14. 2008, *Invited Conference Faulty*, Conscience and Clinical Practice: Medical Ethics in the Face of Moral Controversy, The MacLean Center for Clinical Medical Ethics at the University of Chicago, "Defending Positions or Identifying Interests: The Uses of Ethical Argumentation in the Debate over Conscience in Clinical Practice," Chicago, IL, March 18.

- 15. 2007, *Symposium Speaker*, Alternative Dispute Resolution Strategies in End-of-Life Decisions, The Ohio State University Mortiz College of Law, "The Representation of Children in Disputes at the End-of-Life," Columbus, Ohio, January 18.
- 16. 2005, *Keynote Speaker*, Decisions and Families, *Journal of Law and Family Studies* and The University of Utah S.J. Quinney College of Law, "Jehovah's Witnesses, Roman Catholicism, and Calvinism: Religion and State Intervention in Parental, Medical Decision-Making," Salt Lake City, Utah, September 23.

#### Regional/Local

- 1. 2024, *Case Expert Commentator*, Center for Bioethics Clinical Ethics Consortium, Harvard Medical School, "Can he be his mother's keeper?", Boston, Massachusetts, February 2.
- 2. 2023, *Speaker*, Yale Ethics Program, Yale School of Medicine, "Gender-Affirming Care," New Haven, Connecticut, March 8.
- 3. 2021, *Panelist*, Pediatric Residency Noon Conference, University of Tennessee Health Science Center, "Bioethics Rounds—Ethical Issues in the Care of Transgender Adolescents," Memphis, Tennessee, September 21.
- 4. 2020, *Keynote Speaker*, 53<sup>rd</sup> Annual Clinical Advances in Pediatrics, "Referral to a Fetal Care Center: How You Can Help Patients' Mothers Address the Ethical Issues," Kansas City, Kansas, September 16.
- 5. 2019, *Speaker*, Patient and Family Support Services, Primary Children's Hospital, "Ethical Issues in the Care of Trans Adolescents," Salt Lake City, Utah, December 5.
- 6. 2019, *Speaker*, Evening Ethics, Program in Medical Ethics and Humanities, University of Utah School of Medicine, "Patients, Parents, and Professionals: Ethical Issues in the Treatment of Trans Adolescents," Salt Lake City, Utah, December 4.
- 7. 2019, *Speaker*, Pediatric Hospital Medicine Board Review Course, "Ethics, Legal Issues, and Human Rights including Ethics in Research," Cincinnati, Ohio, September 8.
- 8. 2019, *Speaker*, Advances in Fetology, "Evolving Attitudes Toward the Treatment of Children with Trisomies," Cincinnati, Ohio, September 6.
- 9. 2019, *Speaker*, Half-Day Ethics Training: Ethics Consultation & Ethics Committees, "Navigating the Rapids of Clinical Ethics Consultation: Intake, Recommendations, and Documentation," Salt Lake City, Utah, June 1.
- 10. 2019, *Speaker*, Scientific and Ethical Underpinnings of Gene Transfer/Therapy in Vulnerable Populations: Considerations Supporting Novel Treatments, BioNJ, "What Next? An Ethical analysis of Prioritizing Conditions and Populations for Developing Novel Therapies," Cranbury, New Jersey, March 7.
- 11. 2018, *Panelist*, Periviability, 17<sup>th</sup> Annual Regional Perinatal Summit, Cincinnati, Ohio, October 12.
- 12. 2018, *Speaker*, Regional Advance Practice Registered Nurse (APRN) Conference, "Adults are Not Large Children: Ethical Issues in Caring for Adults in Children's Hospitals," Cincinnati, Ohio, April 26.
- 13. 2018, *Speaker*, Southern Ohio/Northern Kentucky Sigma Theta Tau International Annual Conference, "Between Hope and Hype: Ethical Issues in Precision Medicine," Sharonville, Ohio, March 2.
- 14. 2017, *Speaker*, Advances in Fetology 2017, "Ethics of Innovation and Research: Special Considerations in Fetal Therapy Centers," Cincinnati, Ohio, October 27.

- 15. 2016, *Speaker*, End-of-Life Pediatric Palliative Care Regional Conference, "Ethical/Legal Issues in Pediatric Palliative Care," Cincinnati, Ohio, September 15.
- 16. 2016, *Speaker*, 26<sup>th</sup> Annual Bioethics Network of Ohio (BENO) Conference, "When Does Parental Refusal of Medical Treatment for Religious Reasons Constitute Neglect?" Dublin, Ohio, May 29.
- 17. 2014, *Speaker*, Cincinnati Comprehensive Sickle Cell Center Symposium: Research Ethics of Hydroxyurea Therapy for Sickle Cell Disease During Pregnancy and Lactation, "Ethical Issues in Research with Pregnant and Lactating Women," Cincinnati, Ohio, October 30.
- 18. 2014, *Speaker*, Advances in Fetology 2014, "The 'Miracle Baby' and Other Cases for Discussion," Cincinnati, Ohio, September 26.
- 19. 2014, *Speaker*, Advances in Fetology 2014, "Can you tell me ...?": Achieving Informed Consent Given the Prevalence of Low Health Literacy," Cincinnati, Ohio, September 26.
- 20. 2014, *Panelist*, Center for Clinical & Translational Science & Training, Secrets of the Dead: The Ethics of Sharing their Data, Cincinnati, Ohio, August 28.
- 21. 2014, *Speaker*, Office for Human Research Protections Research Community Forum: Clinical Research ... and All That Regulatory Jazz, "Research Results and Incidental Findings: Do Investigators Have a Duty to Return Results to Participants," Cincinnati, Ohio, May 21.
- 22. 2013, *Opening Presentation*, Empirical Bioethics: Emerging Trends for the 21<sup>st</sup> Century, University of Cincinnati Center for Clinical & Translational Science & Training, "Empirical vs. Normative Ethics: A Comparison of Methods," Cincinnati, Ohio, February 21.
- 23. 2012, *Videoconference*, New York State Task Force on Life and the Law, "Pediatric Critical Care Triage," New York, New York, March 1.
- 24. 2011, *Presenter*, Fall Faculty Development Workshop, College of Social Work, University of Utah, "Teaching Ethics to Students in the Professions," Salt Lake City, Utah, November 14.
- 25. 2011, *Speaker*, 15<sup>th</sup> Annual Conference, Utah Chapter of the National Association of Pediatric Nurse Practitioners, "Ethical Issues in Pediatric Practice," Salt Lake City, Utah, September 22.
- 26. 2011, *Speaker*, Code Silver! Active Shooter in the Hospital, Utah Hospitals & Health Systems Association, Salt Lake City, Utah, March 21.
- 27. 2009, *Speaker*, Medical Staff Leadership Conference, Intermountain Healthcare, "The Ethics of Leadership," Park City, Utah, October 30.
- 28. 2008, *Speaker*, The Art and Medicine of Caring: Supporting Hope for Children and Families, Primary Children's Medical Center, "Medically Provided Hydration and Nutrition: Ethical Considerations," Salt Lake City, Utah, February 25.
- 29. 2005, *Speaker*, Utah NAPNAP (National Association of Pediatric Nurse Practitioners) Chapter Pharmacology and Pediatric Conference, "Immunization Update," Salt Lake City, Utah, August 18.
- 30. 2005, *Keynote Speaker*, 17th Annual Conference, Utah Society for Social Work Leadership in Health Care, "Brain Death: Accommodation and Consultation," Salt Lake City, March 18.
- 31. 2004, *Continuing Education Presentation*, Utah NAPNAP (National Association of Pediatric Nurse Practitioners), "Febrile Seizures," Salt Lake City, Utah, April 22.
- 32. 2004, *Speaker*, Advocacy Workshop for Primary Care Providers, "Ethics of Advocacy," Park City, Utah, April 3.

33. 2002, *Speaker*, 16<sup>th</sup> Annual Biologic Basis of Pediatric Practice Symposium, "Stem Cells: Religious Perspectives," Deer Valley, Utah, September 14.

#### **Meeting Presentations**

#### International

- 1. 2024, *Panelist*, International Conference on Clinical Ethics and Consultation, "Clinical Ethicists as Expert Witnesses: A Workshop Based on the Experiences of Clinical Ethicists and Lawyers in Pediatrics," Montreal, Canada, May 31.
- 2. 2023, *Speaker*, International Conference on Clinical Ethics and Consultation, "Addressing Ethical and Conceptual Issues in Gender-Affirming Medical Care Outside of the Hospital," Rome, Italy, June 8.
- 3. 2018, *Speaker*, International Conference on Clinical Ethics and Consultation, "A Systematic Review of Typologies Used to Characterize Clinical Ethics Consultations," Oxford, United Kingdom, June 21.

#### National

- 1. 2024, Srinivasan Suresh, Sriram Ramgopal, Judith Dexheimer, and <u>Armand H. Matheny</u> <u>Antommaria</u>. *Workshop Presenter*, Pediatric Academic Societies Annual Meeting, "ChatGPT for Pediatricians: You've Heard About It. Noe Learn How to Use It!" Toronto, May 6.
- 2. 2023, *Speaker*, American Society for Bioethics and Humanities Annual Meeting, "Addressing Restrictions on Gender-Affirming Medical Care in New Spaces: State Houses and Courtrooms," Baltimore, Maryland, October 13.
- 3. 2023, Kelsey S. Ryan, Rakhi Gupta Bassuray, Leela Sarathy, Sharon Ostfeld, <u>Armand H. Matheny Antommaria</u>, Erin Rholl, Steven R. Leuthner, and Christy L. Cummings. *Workshop Presenter*, Pediatric Academic Societies Annual Meeting, "How Can Newborn Toxicology Testing be Equitable?" Washington, DC, April 30.
- 4. 2022, *Speaker*, American Society for Bioethics and Humanities Annual Meeting, "A Mixed Methods Analysis of Requests for Religious Exemptions to a COVID-19 Vaccine Requirement." Portland, Oregon, October 27.
- 5. 2022, *Panelist*, American Society for Bioethics and Humanities Annual Meeting, Pediatric Ethics Affinity Group, "When Ethical Healthcare Is Prohibited By Law, How Do We Respond?" Portland, Oregon, October 27.
- 6. 2022, *Speaker*, APPD/PAS Fellow Core Curriculum Workshop, Pediatric Academic Societies Annual Meeting, "From Idea to Implementation: Navigating the Ethical Landscape of Pediatric Clinical Research," Denver, Colorado, April 22.
- 7. 2021, *Panelist*, Pediatric Endocrine Society Annual Meeting, Difference of Sex Development Special Interest Group, Virtual Conference, April 29.
- 8. 2020, *Speaker*, American Society for Bioethics and Humanities Annual Meeting, "Is This Child Dead? Controversies Regarding the Neurological Criteria for Death," Virtual Conference, October 17.
- 9. 2020, *Speaker*, American Society for Bioethics and Humanities Annual Meeting, "Contemporary Ethical Controversy in Fetal Therapy: Innovation, Research, Access, and Justice," Virtual Conference, October 15.
- 10. 2020, *Speaker*, American Society for Bioethics and Humanities Annual Meeting, "K-12 Schools and Mandatory Public Health Programs During the COVID-19 Pandemic," Virtual Conference, October 15.

- 11. 2019, *Speaker*, American Society for Bioethics and Humanities Annual Meeting, "Ethical Issues in Translating Gene Transfer Studies Involving Children with Neurodegenerative Disorders," Pittsburgh, Pennsylvania, October 26.
- 12. 2019, *Moderator*, Pediatric Academic Societies Annual Meeting, Clinical Bioethics, Baltimore, Maryland, April 28.
- 13. 2018, *Presenter*, American Society for Bioethics and Humanities Annual Meeting, "Looking to the Past, Understanding the Present, and Imaging the Future of Bioethics and Medical Humanities' Engagement with Transgender Health," Anaheim, California, October 19.
- 14. 2018, *Speaker*, American Society for Bioethics and Humanities Annual Meeting, "Should Vaccination Be a Prerequisite for Sold Organ Transplantation?" Anaheim, California, October 18.
- 15. 2018, Lindsey Douglas, <u>Armand H. Matheny Antommaria</u>, Derek Williams. *Workshop Presenter*, Pediatric Hospital Medicine Annual Meeting, "IRB Approved! Tips and Tricks to Smooth Sailing through the Institutional Review Board (IRB)." Atlanta, Georgia, July 20.
- 16. 2018, Alan Schroeder, <u>Armand H. Matheny Antommaria</u>, Hannah Bassett, Kevin Chi, Shawn Ralston, Rebecca Blankenburg. *Workshop Speaker*, Pediatric Hospital Medicine Annual Meeting, "When You Don't Agree with the Plan: Balancing Diplomacy, Value, and Moral Distress," Atlanta, Georgia, July 20.
- 17. 2018, Alan Schroeder, Hannah Bassett, Rebecca Blankenburg, Kevin Chi, Shawn Ralston, <u>Armand H. Matheny Antommaria.</u> *Workshop Speaker*, Pediatric Academic Societies Annual Meeting, "When You Don't Agree with the Plan: Balancing Diplomacy, Value, and Moral Distress," Toronto, Ontario, Canada, May 7.
- 18. 2017, *Speaker*, American Society for Bioethics and Humanities Annual Meeting, "Tensions in Informed Consent for Gender Affirming Hormone Therapy and Fertility Preservation in Transgender Adolescents," Kansas City, Missouri, October 19.
- 19. Lindsey Douglas, <u>Armand H. Matheny Antommaria</u>, and Derek Williams. 2017, *Workshop Leader*, PHM[Pediatric Hospital Medicine]2017, "IRB Approved! Tips and Tricks to Smooth Sailing through the Institutional Review Board (IRB) Process," Nashville, Tennessee, July 21.
- 20. 2016, *Speaker*, American Society for Bioethics and Humanities Annual Meeting, "Ethical Challenges in the Care of International Patients: Organization, Justice, and Cultural Considerations," Washington, DC, October 9.
- 21. 2015, *Coauthor*, The American Society of Human Genetics Annual Meeting, "Adolescents' Opinions on Disclosure of Non-Actionable Secondary Findings in Whole Exome Sequencing," Baltimore, Maryland, October 9.
- 22. 2012, *Speaker*, American Society for Bioethics and Humanities Annual Meeting, "A Public Health Ethics Analysis of the Mandatory Immunization of Healthcare Personnel: Minimizing Burdens and Increasing Fairness," Washington, DC, October 21.
- 23. <u>Armand H. Matheny Antommaria</u>, Valerie Gutmann Koch, Susie A. Han, Carrie S. Zoubul. 2012, *Moderator*, American Society for Bioethics and Humanities Annual Meeting, "Representing the Underrepresented in Allocating Scarce Resources in a Public Health Emergency: Ethical and Legal Considerations," Washington, DC, October 21.
- 24. 2012, *Platform Presentation*, Pediatric Academic Societies Annual Meeting, "Qualitative Analysis of International Variation in Donation after Circulatory Death Policies and Rates," Boston, Massachusetts, April 30. Publication 3150.4.

- 25. 2011, *Speaker*, American Society for Bioethics and Humanities Annual Meeting, "The Intersection of Policy, Medicine, and Ethics during a Public Health Disaster: Special Considerations for Children and Families," Minneapolis, Minnesota, October 13.
- 26. <u>Armand H. Matheny Antommaria</u> and Joel Frader. 2010, *Workshop Leader*, Pediatric Academic Societies Annual Meeting, "Conscientious Objection in Health Care: Respecting Conscience and Providing Access," Vancouver, British Columbia, Canada. May 1. Session 1710.
- 27. 2009, *Workshop Leader*, American Society for Bioethics and Humanities Annual Meeting, "Advanced Clinical Ethics Consultation Skills Workshop: Process and Interpersonal Skills," Washington, DC, October 15.
- 28. 2009, *Platform Presentation*, Pediatric Academic Societies Annual Meeting, "Qualitative Analysis of Donation after Cardiac Death Policies at Children's Hospitals," Baltimore, Maryland, May 2. Publication 2120.6.
- 29. 2008, *Speaker*, American Society for Bioethics and Humanities Annual Meeting, "Qualitative Analysis of Donation After Cardiac Death (DCD) Policies at Children's Hospitals," Cleveland, Ohio, October 26.
- 30. 2007, *Participant*, Hamline University School of Law Biennial Symposium on Advanced Issues in Dispute Resolution, "An Intentional Conversation About Conflict Resolution in Health Care," Saint Paul, Minnesota, November 8-10.
- 31. 2007, Speaker, American Society of Bioethics and Humanities Annual Meeting, "Bioethics Consultation and Alternative Dispute Resolution: Opportunities for Collaboration," Washington, DC, October 21.
- 32. 2007, *Speaker*, American Society of Bioethics and Humanities Annual Meeting, "DNAR Orders in Schools: Collaborations Beyond the Hospital," Washington, DC, October 18.
- 33. <u>Armand H. Matheny Antommaria</u> and Jeannie DePaulis. 2007, *Speaker*, National Association of Children's Hospitals and Related Institutions Annual Meeting, "Using Mediation to Address Conflict and Form Stronger Therapeutic Alliances," San Antonio, Texas, October 9.
- 34. 2006, *Speaker*, American Society of Bioethics and Humanities Annual Meeting, "Bioethics Mediation: A Critique," Denver, Colorado, October 28.
- 35. 2005, *Panelist*, American Society of Bioethics and Humanities Annual Meeting, "How I See This Case: 'He Is Not His Brain," Washington, DC, October 20.
- 36. 2005, *Paper Presentation*, Pediatric Ethics: Setting an Agenda for the Future, The Cleveland Clinic, "'He Is Not His Brain:' Accommodating Objections to 'Brain Death,'" Cleveland, Ohio, September 9.
- 37. 2004, *Speaker*, American Society for Bioethics and Humanities Spring Meeting, "Verification and Balance: Reporting Within the Constraints of Patient Confidentiality," San Antonio, Texas, March 13.
- 38. 2002, *Panelist*, American Society for Bioethics and Humanities Annual Meeting, "Who Should Survive?:' Mental Retardation and the History of Bioethics," Baltimore, Maryland, October 24.

#### **Invited/Visiting Professor Presentations**

1. 2013, Visiting Professor, "How to Listen, Speak and Think Ethically: A Multidisciplinary Approach," Norton Suburban Hospital and Kosair Children's Hospital, Louisville, Kentucky, May 22.

2. 2010, Visiting Professor, Program in Bioethics and Humanities and Department of Pediatrics, "What to Do When Parents Want Everything Done: 'Futility' and Ethics Facilitation," University of Iowa Carver College of Medicine, Iowa City, Iowa, September 10.

#### **Grand Round Presentations**

- 1. 2023, Harvey and Bernice Jones Lecture in Pediatric Ethics, "Too Far or Not Far Enough? Assessing Possible Changes in Determining Death and Procuring Organs," Arkansas Children's Hospital, Little Rock, November 16.
- 2. 2019, David Green Lectureship, "Establishing Goals of Care and Ethically Limiting Treatment," Primary Children's Hospital, Salt Lake City, Utah, December 5.
- 3. 2018, "The Ethics of Medical Intervention for Transgender Youth," El Rio Health, Tucson, Arizona, September 29.
- 4. 2018, Pediatrics, "Patient Selection, Justice, and Cultural Difference: Ethical Issues in the Care of International Patients," Cleveland Clinic, Cleveland, Ohio, April 10.
- 5. 2018, Bioethics, "Reversibility, Fertility, and Conflict: Ethical Issues in the Care of Transgender and Gender Nonconforming Children and Adolescents," Cleveland Clinic, Cleveland, Ohio, April 9.
- 6. 2017, Heart Institute, "Have you ever thought about what you would want—if god forbid—you became sicker?': Talking with adult patients about advance directives," Cincinnati Children's Hospital Medical Center, Cincinnati, Ohio, October 16.
- 7. 2017, Pediatrics, "Respectful, Effective Treatment of Jehovah's Witnesses," with Judith R. Ragsdale, PhD, MDiv and David Morales, MD, Cincinnati Children's Hospital Medical Center, Cincinnati, Ohio, March 14.
- 8. 2017, Pediatrics, "Ethical Dilemmas about Discharging Patients When There Are Disagreements Concerning Safety," Seattle Children's Hospital, Seattle, Washington, January 19.
- 9. 2015, Pediatrics, "Nonbeneficial' Treatment: What must providers offer and what can they withhold?," Greenville Health System, Greenville, South Carolina, May 10.
- 10. 2014, Advance Practice Providers, "Common Ethical Issues," Cincinnati Children's Hospital Medical Center, Cincinnati, Ohio, August 13.
- 11. 2014, Respiratory Therapy, "Do-Not-Resuscitate (DNR) Orders," Cincinnati Children's Hospital Medical Center, Cincinnati, Ohio, July 15.
- 12. 2013, Heart Institute, "No Not Months. Twenty-Two *Years*-Old: Transiting Patients to an Adult Model of Care." Cincinnati Children's Hospital Medical Center, Cincinnati, Ohio, October 21.
- 13. 2013, Division of Neonatology, "This Premature Infant Has a *BRCA1* Mutation!?: Ethical Issues in Clinical Whole Exome Sequencing for Neonatologists." Cincinnati Children's Hospital Medical Center, Cincinnati, Ohio, October 11.
- 14. 2013, Department of Pediatrics, "Adults are Not Large Children: Ethical Issues in Caring for Adults in Children's Hospitals," Cincinnati Children's Hospital Medical Center, Cincinnati, Ohio, February 26.
- 15. 2012, "Mandate or Moratorium?: Persisting Ethical Controversies in Donation after Circulatory Death," Cedars-Sinai Medical Center, Los Angeles, California, May 16.
- 16. 2011, Division of Pediatric Neurology Friday Lecture Series, "Inducing or Treating 'Seizures' with Placebos: Is It Ever Ethical?," University of Utah, Salt Lake City, Utah, October 7.

- 17. 2011, Department of Surgery, "DNR Orders in the OR and other Ethical Issues in Pediatric Surgery: Case Discussions," Primary Children's Medical Center, Salt Lake City, Utah, October 3.
- 18. 2009, Department of Pediatrics, "What to Do When Parents Want Everything Done: 'Futility' and Bioethical Mediation," Primary Children's Medical Center, Salt Lake City, Utah, September 17.
- 19. 2008, Division of Pulmonology and Critical Care, "Futility: May Clinicians Ever Unilaterally Withhold or Withdraw Medical Treatment?" Utah Valley Regional Medical Center, Provo, Utah, April 17.
- 20. 2007, Division of Otolaryngology-Head and Neck Surgery, "Advance Directives, Durable Powers of Attorney for Healthcare, and Do Not Attempt Resuscitation Orders: Oh My!," University of Utah School of Medicine, Salt Lake City, Utah, June 20.

#### **Outreach Presentations**

- 1. 2019, *Panelist*, Cincinnati Edition, WVXU, "The Ethics of Human Gene Editing," Cincinnati, Ohio, June 13.
- 2. 2019, *Speaker*, Adult Forum, Indian Hill Church, "Medical Ethics," Indian Hill, Ohio, March 24.
- 3. 2016, *Speaker*, Conversations in Bioethics: The Intersection of Biology, Technology, and Faith, Mt. Washington Presbyterian Church, "Genetic Testing," Cincinnati, Ohio, October 12.
- 4. 2008, *Speaker*, Science in Society, Co-sponsored by KCPW and the City Library, "Death—Choices," Salt Lake City, Utah, November 20.
- 5. 2003, *Panelist*, Utah Symposium in Science and Literature, "The Goodness Switch: What Happens to Ethics if Behavior is All in Our Brains?" Salt Lake City, Utah, October 10.
- 6. 2002, *Respondent*, H. Tristram Englehardt, Jr. "The Culture Wars in Bioethics," Salt Lake Community College, Salt Lake City, Utah, March 29.

#### **Podcasts**

- 1. 2021, "Ethics of COVID Vaccines in Kids," PHM from Pittsburgh, August 12.
- 2. 2020, COVID Quandaries: Episode 1, "Is Getting Sick Just Part of the Job?" Hard Call, October 6.

#### **EXHIBIT B**

TABLE 1: Level (Quality) of Evidence and Class (Strength) of Recommendation<sup>1</sup> and in 2020 American Heart Association Guideline for Pediatric Basic and Advanced Life Support

	Class 1	Class 2a	Class 2b	Class 3	Class 3	Total
	(Strong)	(Moderate)	(Weak)	No Benefit	Harm	
	Benefit >>>	Benefit >>	Benefit >=	(Moderate)	(Strong)	
	Risk	Risk	Risk	Benefit =	Risk >	
				Risk	Benefit	
Level A	1 (0.8%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	1 (0.8%)
Level B-R	1 (0.8%)	2 (1.5%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	3 (2.3%)
(Randomized)						
Level B-NR	5 (3.8%)	9 (6.9%)	3 (2.3%)	0 (0.0%)	2 (1.5%)	19 (14.6%)
(Nonrandomized)						
Level C-LD	24 (18.5%)	22 (16.9%)	21 (16.2%)	1(0.8%)	2 (1.5%)	70 (53.8%)
(Limited Data)						
Level C-EO	22 (16.9%)	9 (6.9%)	6 (4.6%)_	0 (0.0%)	0 (0.0%)	37 (28.5%)
(Expert Opinion)						
Total	53 (40.8%)	42 (32.3%)	30 (23.1%)	1 (0.8%)	4 (3.1%)	130 (100%)

1. Level (Quality) of Evidence

#### Level A

- High-quality evidence from more than 1 [Randomized Controlled Trial (RCT)]
- Meta-analyses of high-quality RCTs
- One or more RCTS corroborated by high-quality registry studies

#### Level B-R (Randomized)

- Moderate-quality evidence from 1 or more RCTS
- Meta-analyses of moderate-quality RCTs

## Level B-NR (Nonrandomized)

- Moderate-quality evidence from 1 or more well-designed, well-executed nonrandomized studies, observational studies, or registry studies
- Meta-analyses of such studies

#### Level C-LD (Limited Data)

- Randomized or nonrandomized observational or registry studies with limitations of design or execution
- Meta-analyses of such studies
- Psychological or mechanistic studies in human subjects

#### Level C-EO (Expert Opinion)

• Consensus of expert opinion based on clinical experience

Topjian AA, Raymond TT, Atkins D, et al. Part 4: Pediatric basic and advanced life support: 2020 American Heart Association guidelines for cardiopulmonary resuscitation and emergency cardiovascular care. Circulation. 2020;142(16 suppl 2):S469-S523.

#### **EXHIBIT C**

TABLE 2: Strength of Recommendation and Quality of Evidence in Recommendations Made by the Endocrine Society

Strength of the Recommendation/ Quality of the Evidence <sup>1</sup>	Endocrine Treatment of Gender-Dysphoric/Gender- Incongruent Persons	Pediatric Obesity- Assessment, Treatment, and Prevention	Congenital Adrenal Hyperplasia Due to Steroid 21-Hydroxylase Deficiency
Strong High	$0(0)^2$	0 (0)	0 (0)
Strong Moderate	3 (11)	4 (13)	18 (33)
Strong Low	5 (18)	6 (20)	13 (25)
Strong Very Low	2 (7)	1 (3)	1 (2)
Weak High	0 (0)	0 (0)	0 (0)
Weak Moderate	0 (0)	0 (0)	2 (4)
Weak Low	9 (32)	5 (17)	4 (7)
Weak Very Low	3 (11)	12 (40)	7 (13)
Ungraded Good	6 (21)	2 (7)	9 (17)
Practice			
Statement <sup>3</sup>			
Either Low or	19 (68)	24 (80)	25 (46)
Very Low			
Total	28	30	54

<sup>&</sup>lt;sup>1</sup> Quality of the Evidence

High: "Consistent evidence from well-performed RCTs [Randomized Controlled Trials] or exceptionally strong evidence from unbiased observational studies"

Moderate: "Evidence from RCTs with important limitations (inconsistent results, methodological flaws, indirect or imprecise evidence), or unusually strong evidence from unbiased observational studies"

Low: "Evidence for at least one critical outcomes from observational studies, from RCTs with serious flaws, or indirect evidence"

Very Low: "Evidence for at least one of the critical outcomes from unsystematic clinical observations or very indirect evidence"

See Swiglo BA, Murad MH, Schünemann HJ, et al. A case for clarity, consistency, and helpfulness: State-of-the-art clinical practice guidelines in endocrinology using the grading of recommendations, assessment, development, and evaluation system. *J Clin Endocrinol Metab*. 2008;93(3):666-73.

<sup>&</sup>lt;sup>2</sup> n (%)

<sup>3</sup>Ungraded Good Practice Statement: "Direct evidence for these statements was either unavailable or not systematically appraised and considered out of the scope of this guideline. The intention of these statements is to draw attention to these principles." See Hembree WC, Cohen-Kettenis PT, Gooren L, et al. Endocrine treatment of gender-dysphoric/gender-incongruent persons: An Endocrine Society clinical practice guideline. *J Clin Endocrinol Metab*. 2017;102(11):3869-3903.

#### Guidelines:

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

Styne DM, Arslanian SA, Connor EL, et al. Pediatric obesity-assessment, treatment, and prevention: An Endocrine Society clinical practice guideline. *J Clin Endocrinol Metab*. 2017;102(3):709-757.

Speiser PW, Arlt W, Auchus RJ, et al. Congenital adrenal hyperplasia due to steroid 21-hydroxylase deficiency: An Endocrine Society clinical practice guideline. *J Clin Endocrinol Metab.* 2018;103(11):4043-4088.

## IN THE UNITED STATES DISTRICT COURT FOR THE DISTRICT OF SOUTH CAROLINA Charleston Division

STERLING MISANIN, et al.,	
Plaintiffs,	Case No.
v.	
ALAN WILSON, in his official capacity as the Attorney General of South Carolina, et al.,	
Defendants.	

### EXPERT DECLARATION OF DANIEL SHUMER, M.D.

- I, Daniel Shumer, M.D., hereby declare and state as follows:
- 1. I have been retained by counsel for Plaintiffs as an expert in connection with the above-captioned litigation.
- 2. I have actual knowledge of the matters stated herein. If called to testify in this matter, I would testify truthfully and based on my expert opinion.

# I. <u>BACKGROUND AND QUALIFICATIONS</u>

#### A. Qualifications

3. I am a Pediatric Endocrinologist, Associate Professor of Pediatrics, and the Clinical Director of the Child and Adolescent Gender Clinic at Mott Children's Hospital at Michigan Medicine. I am also the Medical Director of the Comprehensive Gender Services Program at Michigan Medicine, University of Michigan.

- 4. I am Board Certified in Pediatrics and Pediatric Endocrinology by the American Board of Pediatrics and licensed to practice medicine in the state of Michigan.
- 5. I received my medical degree from Northwestern University in 2008. After completing a Residency in Pediatrics at Vermont Children's Hospital, I began a Fellowship in Pediatric Endocrinology at Harvard University's Boston Children's Hospital. Concurrent with the Fellowship, I completed a Master of Public Health from Harvard's T.H. Chan School of Public Health. I completed both the Fellowship and the MPH degree in 2015.
- 6. I have extensive experience in working with and treating children and adolescents with endocrine conditions including differences in sex development (DSD) (also referred to as intersex conditions), gender dysphoria, type 1 diabetes, thyroid disorders, growth problems, and delayed or precocious puberty. I also see patients over the age of 18 as they transition into accessing care as adults. I have been treating patients with gender dysphoria since 2015.
- 7. A major focus of my clinical, teaching, and research work pertains to the assessment and management of transgender adolescents.
- 8. I have published extensively on the topic of gender identity in pediatrics and the treatment of gender dysphoria, as well as reviewed the peer-reviewed literature concerning medical treatments for gender dysphoria, the current standards of care for the treatment of gender dysphoria, and research articles on a variety of topics with a focus on mental health in transgender adolescents.
- 9. I am involved in the education of medical trainees. I am the Fellowship Director in the Division of Pediatric Endocrinology, Education Lead for the Division of Pediatric Endocrinology, and Course Director for a medical student elective in Transgender Medicine. My

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additional academic duties as an Associate Professor include teaching several lectures, including those entitled "Puberty," "Transgender Medicine," and "Pediatric Growth and Development."

- 10. As a Fellow at Harvard, I was mentored by Dr. Norman Spack. Dr. Spack established the Gender Management Services Clinic (GeMS) at Boston Children's Hospital. While working and training at GeMS, I became a clinical expert in the field of transgender medicine within Pediatric Endocrinology and began conducting research on gender identity, gender dysphoria, and the evaluation and management of gender dysphoria in children and adolescents.
- 11. Based on my work at GeMS, I was recruited to establish a similar program assessing and treating gender diverse and transgender children and adolescents at the C.S. Mott Children's Hospital in Ann Arbor. In October 2015, I founded the hospital's Child and Adolescent Gender Services Clinic.
- 12. The Child and Adolescent Gender Services Clinic has treated over 600 patients since its founding. The clinic provides comprehensive assessment, and when appropriate, treatment with pubertal suppression and hormonal therapies, to patients diagnosed with gender dysphoria. I have personally evaluated and treated over 400 patients with gender dysphoria. The majority of the patients receiving care range between 10 and 21 years old. Most patients attending clinic live in Michigan or Ohio. As the Clinical Director, I oversee the clinical practice, which currently includes 4 physicians (including 1 psychiatrist), 1 nurse practitioner, 2 social workers, 1 research coordinator, as well as nursing and administrative staff. I also actively conduct research related to transgender medicine, gender dysphoria treatment, and mental health concerns specific to transgender youth.
- 13. I also provide care in the Differences/Disorders of Sex Development (DSD) Clinic at Michigan Medicine at Mott Children's Hospital. The DSD Clinic is a multidisciplinary clinic

focused on providing care to infants and children with differences in the typical path of sex development, which may be influenced by the arrangement of sex chromosomes, the functioning of our gonads (i.e. testes, ovaries), and our bodies' response to hormones. The clinic is comprised of members from Pediatric Endocrinology, Genetics, Psychology, Urology, Gynecology, Surgery, and Social Work. In this clinic I have assessed and treated over 100 patients with DSD. In my role as Medical Director of the Comprehensive Gender Services Program (CGSP), I lead Michigan Medicine's broader efforts related to transgender services. CGSP is comprised of providers from across the health system including pediatric care, adult hormone provision, gynecologic services, adult surgical services, speech/language therapy, mental health services, and primary care. I run monthly meetings with representatives from these areas to help coordinate communication between Departments. I coordinate strategic planning aimed to improve care within the health system related to our transgender population. I also serve as the medical representative for CGSP in discussions with health system administrators and outside entities.

- 14. I have authored numerous peer-reviewed articles related to treatment of transgender youth. I have also co-authored chapters of medical textbooks related to medical management of transgender patients. I have been invited to speak at numerous hospitals, clinics, and conferences on topics related to clinical care and standards for treating transgender children and youth.
- 15. The information provided regarding my professional background, experiences, publications, and presentations is detailed in my curriculum vitae, a true and correct copy of the most up-to-date version of which is attached as **Exhibit A**.

#### **B.** Prior Testimony

16. In the past four years, I have been retained as an expert and provided testimony at trial or by deposition in the following cases: *Roe et al. v. Herrington et al.*, 4:20-cv-00484 (D.

Ariz.); Dekker v. Weida, No. 4:22-cv-00325-RH-MAF (N.D. Fla.); Boe v. Marshall, No. 2:22-cv-00184-LCB-CWB (M.D. Ala.); Roe v. Utah High Sch. Activities Ass'n, No. 220903262 (3d Jud. Dist. in and for Salt Lake County, Utah); Doe et al. v. Ladapo et al., 4:23-cv-00114-RH-MAF (N.D. Fla.); K.C. et al v. Medical Licensing Board of Indiana, 1:23-CV-595 (S.D. Ind.); Koe et al. v. Noggle et al., 1:23-cv-02904-SEG (N.D. Geo.); Noe et al. v. Parson et al., (Cole County, MO); Loe et al. v. Texas et al., (Travis County, TX).

## C. Compensation

17. I am being compensated at an hourly rate for the actual time that I devote to this case, at the rate of \$400 per hour for any review of records, preparation of reports, and declarations, and a flat rate of \$3,200 per day for any deposition or trial testimony. My compensation does not depend on the outcome of this litigation, the opinions that I express, or the testimony that I provide.

#### D. Bases for Opinions

- 18. In preparing this declaration, I reviewed the text of House Bill 4624.
- 19. I have also reviewed the materials listed in the bibliography attached as **Exhibit B** to this report, as well as the materials listed within my curriculum vitae, which is attached as **Exhibit A**. The sources cited therein include authoritative, scientific peer-reviewed publications. They include the documents specifically cited as supportive examples in particular sections of this report. I may rely on these materials as additional support for my opinions.
- 20. In addition, I have relied on my scientific education, training, and years of clinical and research experience, and my knowledge of the scientific literature in the pertinent fields.

- 21. The materials I have relied upon in preparing this report are the same types of materials that experts in my field of study regularly rely upon when forming opinions on these subjects.
- 22. To the best of my knowledge, I have not met or spoken with the Plaintiffs in this matter. My opinions are based solely on my extensive background and experience treating transgender patients.
- 23. I may wish to supplement or revise these opinions or the bases for them due to new scientific research or publications or in response to statements and issues that may arise in my area of expertise.

#### II. <u>EXPERT OPINIONS</u>

# A. MEDICAL AND SCIENTIFIC BACKGROUND ON SEX AND GENDER IDENTITY

- 24. Sex is comprised of several components, including, among others, internal reproductive organs, external genitalia, chromosomes, hormones, gender identity, and secondary sex characteristics (IOM, 2011).
- 25. Gender identity is the medical term for a person's internal, innate sense of belonging to a particular sex. Everyone has a gender identity. Diversity of gender identity and incongruence between assigned sex at birth and gender identity are naturally occurring sources of human biological diversity (IOM, 2011). The term *transgender* refers to individuals whose gender identity does not align with their sex assigned at birth (Shumer, et al., 2013).
- 26. The terms *gender role* and *gender identity* refer to different things. *Gender roles* are behaviors, attitudes, and personality traits that a particular society considers masculine or feminine, or associates with male or female social roles. For example, the convention that girls

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wear pink and have longer hair, or that boys wear blue and have shorter hair, are socially constructed gender roles from a particular culture and historical period. By contrast, *gender identity* does not refer to socially contingent behaviors, attitudes, or personality traits. It is an internal and largely biological phenomenon, as reviewed below. Living consistent with one's gender identity is critical to the health and well-being of any person, including transgender people (Hidalgo, et al., 2013; Shumer, et al., 2013; White Hughto, et al., 2015).

- A person's understanding of their gender identity may evolve over time in the natural course of their life, however, attempts to "cure" transgender individuals by forcing their gender identity into alignment with their birth sex has been found to be both harmful and ineffective. In one study, transgender adults who recall previous attempts from healthcare professionals to alter their gender identity reported an increase in lifetime suicide attempts and higher rates of severe psychological distress in the present (Turban, et al., 2020a). In another study, exposure to these types of attempts were found to increase the likelihood that a transgender adolescent will attempt suicide by 55% and more than double the risk for running away from home (Campbell, et al., 2002). Those practices have been denounced as unethical by all major professional associations of medical and mental health professionals, such as the American Medical Association, the American Academy of Pediatrics, the American Psychiatric Association, and the American Psychological Association, among others (Fish, et al., 2022).
- 28. Scientific research and medical literature across disciplines demonstrates that gender identity, like other components of sex, has a strong biological foundation. For example, there are numerous studies detailing the similarities in the brain structures of transgender and non-transgender people with the same gender identity (Luders, et al., 2009; Rametti, et al., 2011; Berglund, et al., 2008; Savic, et al., 2011). In one such study, the

volume of the bed nucleus of the *stria terminalis* (a collection of cells in the central brain) in transgender women was equivalent to the volume found in non-transgender women (Chung, et al., 2002).

- 29. There are also studies highlighting the genetic components of gender identity. Twin studies are a helpful way to understand genetic influences on human diversity. Identical twins share the same DNA, while fraternal twins share roughly 50% of the same DNA, however both types of twins share the same environment. Therefore, studies comparing differences between identical and fraternal twin pairs can help isolate the genetic contribution of human characteristics. Twin studies have shown that if an identical twin is transgender, the other twin is much more likely to be transgender compared to fraternal twins, a finding which points to genetic underpinnings to gender identity development (Heylens, et al., 2012).
- 30. There is also ongoing research on how differences in fetal exposures to hormones may influence gender identity. This influence can be examined by studying a medical condition called congenital adrenal hyperplasia. Female fetuses affected by congenital adrenal hyperplasia produce much higher levels of testosterone compared to fetuses without the condition. While most females with congenital adrenal hyperplasia have a female gender identity in adulthood, the percentage of those with gender dysphoria is higher than that of the general population. This suggests that fetal hormone exposures contribute to the later development of gender identity (Dessens, et al, 2005).
- 31. There has also been research examining specific genetic differences that appear associated with gender identity formation (Rosenthal, 2014). For example, one study examining differences in the estrogen receptor gene among transgender women and non-transgender male

controls found that the transgender individuals were more likely to have a genetic difference in this gene (Henningsson, et al., 2005).

32. The above studies are representative examples of scientific research demonstrating biological influences on gender identity. Gender identity, like other complex human characteristics, is rooted in biology with important contributions from neuroanatomic, genetic and hormonal variation (Roselli, 2018).

# B. RATIONALE FOR MEDICAL TREATMENT OF GENDER DYSPHORIA IN ADOLECENTS AND ADULTS

- 33. All medical interventions, including treatment for gender dysphoria, require rigorous study and evidence base.
- 34. There are several studies demonstrating positive results of gender-affirming care in adolescents (de Vries, et al., 2014; de Vries, et al., 2011; Green, et al., 2022; Smith, et al., 2005; Turban, et al., 2022). These studies consistently demonstrate improvement of gender dysphoria with associated improvement of psychological functioning. A 2014 long-term follow-up study following patients from early adolescence through young adulthood showed that gender-affirming treatment allowed transgender adolescents to make age-appropriate developmental transitions while living as their affirmed gender with positive outcomes as young adults (de Vries, et al., 2014). More recently, Green et al. (2022) describe that gender-affirming hormone therapy is correlated with reduced rates of depression and suicidality among transgender adolescents. Turban et al. (2022) documented that access to gender-affirming hormone therapy in adolescence is associated with favorable mental health outcomes in adulthood, when compared to individuals who desired but could not access hormonal interventions.

# C. ASSESSMENT OF GENDER DYSPHORIA IN CHILDREN, ADOLESCENTS, AND ADULTS

- 35. Due to the incongruence between their assigned sex and gender identity, transgender people experience varying degrees of gender dysphoria, a serious medical condition defined in the American Psychiatric Association's *Diagnostic and Statistical*Manual of Mental Disorders (DSM-5 TR) (APA, 2022). Gender Dysphoria is defined as an incongruence between a patient's assigned sex and their gender identity present for at least six months, which causes clinically important distress in the person's life. This distress is further defined as impairment in social, occupational, or other important areas of functioning (APA, 2022). Additional features may include a strong desire to be rid of one's primary or secondary sex characteristics, a strong desire to be treated as a member of the identified gender, or a strong conviction that one has the typical feelings of identified gender (APA, 2022).
- 36. In children and adolescents, the diagnosis of gender dysphoria is made by a health provider including but not limited to a psychiatrist, psychologist, social worker, or therapist with expertise in gender identity concerns. It is recommended that children and adolescents diagnosed with gender dysphoria engage with a multidisciplinary team of mental health and medical professionals to formulate a treatment plan, in coordination with the parent(s) or guardian(s), with a goal of reduction of gender dysphoria. The *Standards of Care for the Health of Transgender and Gender Diverse People, Version 8* ("SOC 8"), published by the World Professional Association for Transgender Health (WPATH), provides guidance to providers on how to provide comprehensive assessment and care to this patient population based on medical evidence. These standards recommend involving relevant disciplines, including mental health and medical professionals, to reach a decision with families about whether medical interventions are appropriate and remain indicated through the course of treatment. Multidisciplinary clinics, such

as the Child and Adolescent Gender Clinic where I practice, have structured their programs around this model, as guided by the WPATH SOC.

37. In transgender adults, the WPATH SOC recommends that a health care provider assessing and treating a transgender patient should ensure diagnostic criteria are met prior to initiating gender-affirming treatments and ensure that any health conditions that could negatively impact the outcome of treatment are assessed, with risks and benefits discussed, before a decision is made regarding treatment. The capacity of the adult. to consent for the specific treatment should be confirmed prior to initiation (Coleman, et al., 2022).

# D. EVIDENCE-BASED CLINICAL PRACTICE GUIDELINES FOR THE TREATMENT OF GENDER DYSPHORIA IN CHILDREN, ADOLESCENTS, AND ADULTS

- 38. The goal of any intervention for gender dysphoria is to reduce dysphoria, improve functioning, and prevent the harms caused by untreated gender dysphoria.
- 39. Gender dysphoria is highly treatable and can be effectively managed. If left untreated, however, it can result in severe anxiety and depression, eating disorders, substance abuse, self-harm, and suicidality (Reisner, et al., 2015).
- 40. Based on longitudinal data, and my own clinical experience, when transgender adolescents are provided with appropriate medical treatment and have parental and social support, they are more likely to thrive and grow into healthy adults (de Vries, et al., 2014).
- 41. In children and adolescents, a comprehensive biopsychosocial assessment is typically the first step in evaluation, performed by a mental health provider with experience in gender identity. The goals of this assessment are to develop a deep understanding of the young person's experience with gender identity, to consider whether the child or adolescent meets criteria for a diagnosis of gender dysphoria, and to understand what options may be desired and helpful

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for the adolescent (Coleman, et al., 2022; Coleman, et al., 2012; Hembree, et al., 2017; Hembree, et al., 2009).

- 42. For children younger than pubertal age, the only recommended treatments do not involve medications. For adolescents, additional treatments involving medications may be appropriate.
- 43. For pre-pubertal children with gender dysphoria, treatments may include supportive therapy, encouraging support from loved ones, and assisting the young person through elements of a social transition. Social transition may include adopting a new name and pronouns, appearance, and clothing, and correcting identity documents.
- 44. Options for treatment after the onset of puberty include the use of gonadotropinreleasing hormone agonists ("GnRHa") for purposes of preventing progression of pubertal development, and hormonal interventions such as testosterone and estrogen administration. These treatment options are based on robust research and clinical experience, which consistently demonstrate safety and efficacy.
- 45. Clinical practice guidelines have been published by several long- standing and well-respected medical bodies: the World Professional Association for Transgender Health (WPATH) and the Endocrine Society (Coleman, et al., 2022; Coleman, et al., 2012; Hembree, et al., 2017; Hembree, et al., 2009), as well as the UCSF Center for Excellence in Transgender Health (Deutsch (ed.), 2016). The clinical practice guidelines and standards of care published by these organizations provide a framework for treatment of gender dysphoria in adolescents.
- 46. WPATH has been recognized as the standard-setting organization for the treatment of gender dysphoria since its founding in 1979. The most recent WPATH Standards of Care (SOC 8) were published in 2022 and represent expert consensus for clinicians related to medical care for

transgender people, based on the best available science and clinical experience (Coleman, et al., 2022).

- 47. The purpose of the WPATH Standards of Care is to assist health providers in delivering necessary medical care to transgender people, to maximize their patients' overall health, psychological well-being, and self-fulfillment. The WPATH Standards of Care serve as one of the foundations for the care provided in my own clinic.
- 48. The WPATH SOC 8 is based on rigorous review of the best available science and expert professional consensus in transgender health. International professionals were selected to serve on the SOC 8 writing committee. Recommendation statements were developed based on data derived from independent systemic literature reviews. Grading of evidence was performed by an Evidence Review Team which determined the strength of evidence presented in each individual study relied upon in the document (Coleman, et al., 2022).
- 49. The previous version of the WPATH standards of care (SOC 7), published in 2012 (Coleman, et al., 2012), was similar to SOC 8 in the basic tenets of management for transgender adolescents; however, SOC 8 further reinforces these guidelines with data published since the release of SOC 7.
- 50. In addition, the Endocrine Society is a 100-year-old global membership organization representing professionals in the field of adult and pediatric endocrinology. In 2017, the Endocrine Society published clinical practice guidelines on treatment recommendations for the medical management of gender dysphoria, in collaboration with Pediatric Endocrine Society, the European Societies for Endocrinology and Pediatric Endocrinology, and WPATH, among others (Hembree, et al, 2017).

- 51. The Endocrine Society Clinical Guidelines were developed through rigorous scientific processes that "followed the approach recommended by the Grading of Recommendations, Assessment, Development, and Evaluation group, an international group with expertise in the development and implementation of evidence based guidelines." The guidelines affirm that patients with gender dysphoria often must be treated with "a safe and effective hormone regimen that will (1) suppress endogenous sex hormone secretion determined by the person's genetic/gonadal sex and (2) maintain sex hormone levels within the normal range for the person's affirmed gender." (Hembree, et al., 2017).
- 52. The AAP is the preeminent professional body of pediatricians in the United States, with over 67,000 members. The AAP endorses a commitment to the optimal physical, mental, and social health and well-being for youth. The 2018 policy statement titled *Ensuring Comprehensive Care and Support for Transgender and Gender-Diverse Children and Adolescents* further lends support to the treatment options outlined in the WPATH Standards of Care and the Endocrine Society's Clinical Practice Guidelines (Rafferty, et al., 2018).
- 53. Aside from the AAP, the tenets set forth by the Endocrine Society Clinical Practice Guidelines and the WPATH Standards of Care are supported by the major professional medical and mental health associations in the United States, including the American Medical Association, the American Psychological Association, the American Psychiatric Association, and American Academy of Family Physicians, among others (e.g., AMA, 2019; American Psychological Association, 2015; Drescher, et al., 2018 (American Psychiatric Association); Hembree, et al., 2017 (Endocrine Society); Klein, et al., 2018 (AAFP); National Academies, 2020; WPATH, 2016).
- 54. As a board-certified pediatric endocrinologist, I follow the Endocrine Society Clinical Practice Guidelines and the WPATH Standards of Care when treating my patients.

#### E. TREATMENT PROTOCOLS FOR GENDER DYSPHORIA

- 55. Undergoing treatment to alleviate gender dysphoria is commonly referred to as a transition. The transition process in adolescence typically includes (i) social transition and/or (ii) medications, including puberty-delaying medication and hormone therapy. The steps that make up a person's transition and their sequence will depend on that individual's medical and mental health needs and decisions made between the patient, family, and multidisciplinary care team.
- 56. There are no medications considered for transition until after the onset of puberty. Puberty is a process of maturation heralded by production of sex hormones—testosterone and estrogen—leading to the development of secondary sex characteristics. Secondary sex characteristics include testosterone-induced effects such as deepening of the voice, muscular changes, facial and body hair, and estrogen induced effects such as breast development. There is diversity in the age of pubertal onset; however, most adolescents begin puberty between ages 10 and 12 years.
- 57. Central to the guidance from WPATH, the Endocrine Society, and the AAP is the importance of familial love and support. Transgender youth who report high levels of rejection from family have lower self-esteem and higher degrees of isolation. These youth are at very high risk for health and mental health problems when they become young adults. According to the Family Acceptance Project, transgender young people who reported high levels of family rejection are significantly more likely to have attempted suicide, to report high levels of depression, to use illegal drugs, and to be at high risk for HIV and sexually transmitted diseases compared with transgender young people who report no or low levels of rejection by family due to their identity (Ryan, et al., 2010).
- 58. Undergoing treatment to alleviate gender dysphoria is commonly referred to as a transition. The transition process in adolescence typically includes (i) social transition and/or (ii)

medications, including puberty-delaying medication and hormone therapy. The steps that make up a person's transition and their sequence will depend on that individual's medical and mental health needs and decisions made between the patient, family, and multidisciplinary care team.

- 59. Gender exploration in childhood is expected and healthy. The majority of prepubertal children exploring their gender do not develop gender dysphoria and are not expected to become transgender adolescents or adults. In contrast, data and personal experience shows that children whose gender dysphoria persists into adolescence are highly likely to be transgender (van der Loos, et al., 2022). Some individuals in this field misinterpret older studies showing that a large percentage of children diagnosed with gender identity disorder did not grow up to be transgender. Those studies include children who would not fulfill the current diagnostic criteria for gender dysphoria and, in any case, have no relevance to this case because no medications are prescribed to prepubertal children.
- 60. Puberty-delaying medication and hormone-replacement therapy—both individually and in combination—can significantly improve a transgender young person's mental health. These treatments allow for a physical appearance more closely aligning with gender identity and decreases the likelihood that a transgender young person will be incorrectly identified with their assigned sex, further alleviating their gender dysphoria, and bolstering the effectiveness of their social transition.
- 61. At the onset of puberty, adolescents begin to experience the onset of secondary sex characteristics. Adolescents with differences in gender identity may have intensification of gender dysphoria during this time due to development of secondary sex characteristics incongruent with gender identity. 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 (de Vries, et al., 2012).

## i. Treatment with puberty-delaying medications

- 62. Adolescents diagnosed with gender dysphoria who have entered puberty (Tanner Stage 2) may be prescribed puberty-delaying medications (GnRHa) to prevent the distress of developing permanent, unwanted physical characteristics that do not align with the adolescent's gender identity. Tanner Stage 2 refers to the stage in puberty whereby the physical effects of testosterone or estrogen production are first apparent on physical exam. Specifically, this is heralded by the onset of breast budding in an individual assigned female at birth, or the onset of testicular enlargement in an individual assigned male at birth. For individuals assigned male at birth, Tanner Stage 2 typically occurs between age 9-14, and for those assigned female at birth between age 8-12.
- 63. The treatment works by pausing endogenous puberty at whatever stage it is at when the treatment begins, limiting the influence of a person's endogenous hormones on their body. For example, a transgender girl will experience no progression of physical changes caused by testosterone, including facial and body hair, an Adam's apple, or masculinized facial structures. And, in a transgender boy, those medications would prevent progression of breast development, menstruation, and widening of the hips (Coleman, et al., 2022; de Vries, et al., 2012; Deutsch (ed.), 2016; Hembree, et al., 2017; Rosenthal, 2014).
- 64. GnRHa have been used extensively in pediatrics for several decades. Prior to their use for gender dysphoria, they were used (and still are used) to treat precocious puberty. GnRHa work by suppressing the signal hormones from the pituitary gland (luteinizing hormone [LH] and

follicle stimulating hormone [FSH]) that stimulate the testes or ovaries to produce sex hormones. Upon discontinuation of GnRHa, LH and FSH production resume and puberty will also resume.

- 65. GnRHa have no long-term implications on fertility. In transgender youth, it is most typical to use GnRHa from the onset of puberty (Tanner Stage 2) until mid-adolescence. While treating, the decision to continue treatment will be continually evaluated. Should pubertal suppression no longer be desired, GnRHa would be discontinued, and puberty would recommence.
- 66. Prior to initiation of GnRHa, providers counsel patients and their families extensively on potential benefits and risks. The designed benefit of the treatment is to reduce the risk of worsening gender dysphoria and mental health deterioration. Furthermore, development of secondary sex characteristics incongruent with gender identity could result in the future need for surgeries and other body alterations that would not be needed if GnRHa had been used. More specifically, use of GnRHa in transmasculine adolescents allows for decreased chest development, reducing the need for breast binding and surgical intervention in adulthood. For transfeminine adolescents GnRHa limits facial and body hair growth, voice deepening, and masculine bone structure development, which greatly reduce distress both at the time of treatment and later in life and reduce the need for later interventions such as voice therapy, hair removal, and facial feminization surgery.
- 67. The goal in using GnRHa is to minimize the patient's dysphoria related to progression of puberty and allow for later initiation of puberty consistent with gender identity. When a patient presents to care, the provider assesses the patient's pubertal stage, pubertal history, and individual needs. A patient may present prior to the onset of puberty (Tanner Stage 1), at the onset of puberty (Tanner Stage 2), or further along in puberty (Tanner Stages 3-5). The pubertal stage and individual needs of the patient then direct conversations regarding care options. A patient

at Tanner Stage 2 may benefit from GnRHa, while an older patient who has completed puberty may benefit from pubertal initiation with hormones, as described below. I have observed that providing individualized care based on individual patient characteristics, using the WPATH Standards of Care as the foundation of this care, provides significant benefit to patients, minimizes gender dysphoria, and can eliminate the need for surgical treatments in adulthood.

- 68. As an experienced pediatric endocrinologist, I treat patients with these same medications for both precocious puberty and gender dysphoria and in both cases the side effects are comparable and easily managed. And for both patient populations the risks are greatly outweighed by the benefits of treatment.
- 69. In addition, I regularly prescribe GnRHa for patients who do not meet criteria for precocious puberty but who require pubertal suppression. Examples include patients with disabilities who are unable to tolerate puberty at the typical age due to hygienic concerns; minors with growth hormone deficiency who despite growth hormone treatment will have a very short adult height; and young women with endometriosis. As with gender dysphoria, the prescription of GnRHa to treat these conditions is "off-label," yet it is widely accepted within the field of endocrinology and not considered experimental. The same holds true for other common medications used in pediatric endocrinology: using metformin for weight loss; growth hormone for short stature not caused by growth hormone deficiency; countless medications used to control type 2 diabetes which have an adult indication but whose manufacturers have not applied for a pediatric indication.

## ii. Treatment with hormone therapy

70. In mid-adolescence, the patient, their parents, and the patient's care team may discuss the possibility of beginning the use of testosterone or estrogen. In my practice we discuss

these treatments for a patient who is currently receiving GnRHa, or patients who have already gone through their endogenous puberty and either did not have access to, desire, or elect for GnRHa treatment. In adult patients, use of GnRHa is uncommon, but rather medical decisions are focused more on testosterone or estrogen therapy.

- 71. These hormone therapies are used to treat gender dysphoria in adolescents and adults to facilitate development of sex-specific physical changes congruent with their gender identity. For example, a transgender boy prescribed testosterone will develop a lower voice as well as facial and body hair, while a transgender girl prescribed estrogen will experience breast growth, female fat distribution, and softer skin.
- 72. Under the Endocrine Society Clinical Guidelines and SOC 8, hormone therapy is an appropriate treatment for transgender adolescents with gender dysphoria when the experience of dysphoria is marked and sustained over time, the adolescent demonstrates emotional and cognitive maturity required to provide and informed consent/assent for treatment, other mental health concerns (if any) that may interfere with diagnostic clarity and capacity to consent have been addressed, the adolescent has discussed reproductive options with their provider. SOC 8 also highlights the importance of involving parent(s)/guardian(s) in the assessment and treatment process for minors (Coleman, et al., 2022; Hembree, et al., 2017).
- 73. Under the Endocrine Society Clinical Guidelines and SOC 8, hormone therapy is an appropriate treatment for transgender adults with gender dysphoria when the experience of dysphoria is marked and sustained, other possible causes of apparent gender dysphoria are excluded, any mental and physical health conditions that could negatively impact the outcome of treatment are assessed, the adult has capacity to understand risks and benefits of treatment and provide consent for treatment (Coleman, et al., 2022; Hembree, et al., 2017).

- 74. Similar to GnRHa, the risks and benefits of hormone treatment are discussed with patients (and families, if the patient is a minor) prior to initiation of testosterone or estrogen. When treated with testosterone or estrogen, the goal is to maintain the patient's hormone levels within the normal range for their gender. Laboratory testing is recommended to ensure proper dosing and hormonal levels. If starting hormonal care after completing puberty, discussion of egg or sperm preservation prior to starting treatment is recommended.
- 75. Regardless of the treatment plan prescribed, at every encounter with the care team there is a re-evaluation of the patient's gender identity and their transition goals. Should a patient desire to discontinue a medical intervention, the intervention is discontinued. Discontinuation of GnRHa will result in commencement of puberty. Findings from studies in which participants have undergone comprehensive evaluation prior to gender care show low levels of regret (de Vries, et al., 2011; van der Loos, et al., 2022; Wiepjes, et al., 2018).
- 76. Surgical interventions, including but not limited to chest and genital surgery, are indicated in appropriately selected patients. These surgeries are not typically performed in adolescence but rather considered in adulthood. The WPATH SOC 8 outlines the current literature supporting benefits of surgical interventions for patients with gender dysphoria (Coleman, et al., 2022).

# F. SAFETY AND EFFICACY OF PUBERTY-DELAYING MEDICATIONS AND HORMONE THERAPY TO TREAT GENDER DYSPHORIA

77. GnRHa, prescribed for delaying puberty in transgender adolescents, is both a safe and effective treatment. Patients under consideration for treatment are working within a multidisciplinary team of providers all dedicated to making informed and appropriate decisions with the patient and family in the best interest of the adolescent. Physicians providing this intervention are trained and qualified in gender identity concerns and childhood growth and

development and are participating in this care out of a desire to improve the health and wellness of transgender youth and prevent negative outcomes such as depression and suicide.

- 78. GnRHa, including injectable leuprolide and implantable histrelin, have rare side effects which are discussed with patients and families prior to initiation. Mild negative effects may include pain at the injection or implantation site, sterile abscess formation, weight gain, hot flashes, abdominal pain, and headaches. These effects can be seen in patients receiving GnRHa for gender dysphoria, or for other indications such as precocious puberty. I counsel patients on maintaining a healthy diet and promote physical activity, and regularly document height and weight during treatment. Nutritional support can be provided for patients at risk for obesity.
- 79. Risk of lower bone mineral density in prolonged use of GnRHa can be mitigated by screening for, and treating, vitamin D deficiency when present, and by limiting the number of years of treatment based on a patient's clinical course (Rosenthal, 2014). An exceptionally rare but significant side effect, increased intracranial pressure, has been reported in six patients (five treated for precocious puberty, one for transgender care), prompting an FDA warning in July 2022 (AAP, 2022). These cases represent an extremely small fraction of the thousands of patients who have been treated with GnRHa over decades. Symptoms of this side effect (headache, vomiting, visual changes) are reviewed with families and if they occur the medication is discontinued.
- 80. As discussed above, GnRHa do not have long-term implications on fertility. This is clearly proven from decades of use in the treatment of precocious puberty (Guaraldi, et al., 2016; Martinerie, et al, 2021). Progression through natal puberty is required for maturation of egg or sperm. If attempting fertility after previous treatment with GnRHa followed by hormone therapy is desired, an adult patient would withdraw from hormones and allow pubertal progression. Assistive reproduction could be employed if needed (T'Sjoen, et al., 2013).

- 81. Patients who initiate hormones after completing puberty are offered gamete preservation prior to hormonal initiation (Coleman, et al., 2022), but even when not undertaken, withdrawal of hormones in adulthood often is successful in achieving fertility when it is desired (Light, et al., 2014; Knudson, et al., 2017).
- 82. Discussing the topic of fertility is important, and not specifically unique to treatment of gender dysphoria. Medications used for other medical conditions, such as chemotherapeutics used in cancer treatment, can affect fertility. For all medications with potential impacts on fertility, the potential risks and benefits of both treatment and non-treatment should be reviewed and data regarding risk for infertility clearly articulated prior to the consent or assent of the patient. Risk for fertility changes must be balanced with the risk of withholding treatment.
- 83. Review of relevant medical literature clearly supports the benefits of GnRHa treatment on both short-term and long-term psychological functioning and quality of life (e.g., Achille, et al., 2020; Carmichael, et al., 2021; Costa, et al., 2015; de Vries, et al., 2014; de Vries, et al., 2011; Kuper, et al., 2020; Turban, et al., 2020b; van der Miesen, et al., 2020). For example, a 2014 long-term follow-up study following patients from early adolescence through young adulthood showed that gender-affirming treatment allowed transgender adolescents to make age-appropriate developmental transitions while living as their affirmed gender with positive outcomes as young adults (de Vries, et al., 2014).
- 84. In my own practice, adolescent patients struggling with significant distress at the onset of puberty routinely have dramatic improvements in mood, school performance, and quality of life with appropriate use of GnRHa. Side effects encountered are similar to those seen in other patients treated with these medications and easily managed.

- 85. Hormone therapy (testosterone or estrogen) is prescribed to older adolescents with gender dysphoria. As is the case with GnRHa, the need for hormone therapy is not unique to transgender adolescents. Patients with conditions such as delayed puberty, hypogonadism, Turner Syndrome, Klinefelter Syndrome, agonism, premature ovarian failure, and disorders of sex development all require treatment with these hormones, often starting in adolescence and continuing lifelong. Without testosterone or estrogen treatment, these patients would be unable to progress through puberty normally, which would have serious medical and social consequences. Whether used in adolescents to treat gender dysphoria, or to treat any of these other conditions, testosterone and estrogen are prescribed with a goal to raise the testosterone or estrogen level into the normal male or female range for the patient's age. Careful monitoring of blood levels and clinical progress are required. Side effects are rare, but most often related to overtreatment, which can be minimized with this monitoring. Additionally, side effects are considered, discussed, and easily managed in all individuals needing hormone therapy regardless of the diagnosis necessitating these medications.
- 86. Venous thromboembolism (blood clotting) is a known side effect of estrogen therapy in all individuals placed on it including transgender women. Risk is increased in old age, in patients with cancer, and in patients who smoke nicotine. This side effect is mitigated by careful and accurate prescribing and monitoring. In my career, no patient has suffered a thromboembolism while on estrogen therapy.
- 87. Treatment of gender dysphoria with testosterone or estrogen is highly beneficial for both short-term and long-term psychological functioning of adolescents with gender dysphoria and withholding treatment from those who need it is harmful (e.g., Achille, et al., 2020; Allen, et al., 2019; Chen, et al., 2023; de Lara, et al., 2020; de Vries, et al., 2014; Grannis, et al., 2021; Green,

et al., 2022; Kaltiala, et al., 2020; Kuper, et al., 2020). To highlight examples, Green et al. (2022) describe that gender affirming hormone therapy is correlated with reduced rates of depression and suicidality among transgender adolescents. Turban et al. (2022) documented that access to gender-affirming hormone therapy in adolescence is associated with favorable mental health outcomes in adulthood, when compared to individuals who desired but could not access hormonal interventions.

- 88. I treat many patients with gender dysphoria with GnRHa, testosterone, and estrogen. Side effects related to these medications are very rare and can be treated with dose adjustment and/or lifestyle changes.
- 89. The efficacy of hormone treatment in transgender adults is similarly robust. At least 11 longitudinal studies document improvement in various mental health parameters including depression, anxiety, self-confidence, body image and self-image, general psychological functioning (e.g., Colizzi, et al., 2013; Colizzi, et al., 2014; Corda, et al., 2016; Defreyne, et al., 2018; Fisher, et al., 2016; Heylens, et al., 2014; Keo-Meier, et al., 2015; Manieri, et al., 2014; Motta, et al., 2018; Oda, et al., 2017; Turan, et al., 2018).
- 90. In sum, the use of GnRHa and hormones in adolescents, and hormones in adults for the treatment of gender dysphoria is the current standard of care and certainly not experimental. This is due to robust evidence of safety and efficacy. The sum of the data supports the conclusion that treatment of gender dysphoria with these interventions promotes wellness and helps to prevent negative mental health outcomes, including suicidality in adolescents. The data to support these interventions are so strong that withholding such interventions would be negligent and unethical.

# G. HARMS ASSOCIATED WITH PROHIBITING AND DISCONTINUING TREATMENT

- 91. Prohibition of gender-affirming care for adolescents and adults is likely to have devastating consequences. I am concerned such a prohibition might lead to a staggering increase in mental health problems including suicidality for transgender individuals in South Carolina. One study which highlights my concern is a study of over 21,000 patients who report ever desiring gender-affirming hormone care. When comparing those who were able to access this care to those desiring but never accessing care, those able to access care had lower odds of suicidality within the past year. In addition, those individuals where were able to access care in adolescence had lower odds of suicidality compared to those waiting to access until adulthood (Turban, et al., 2022).
- 92. Even more concerning is a situation where patients currently receiving care and thriving would be forced to discontinue this care. Discontinuation of an intervention which is providing benefit is antithetical to the practice of medicine. There is furthermore no evidence-based guidance on titrating down effective medications, nor is this process of down-titration outlined in clinical practice guidelines or standards of care. I am concerned that the process of down-titration and eventual discontinuation of effective therapist will have a profound destabilizing effect on the health and well-being of otherwise thriving individuals.

#### III. <u>CONCLUSION</u>

- 93. In summary, banning gender-affirming care runs counter to evidence-based best practices and standards of care for the treatment of gender dysphoria in adolescence and adulthood.
- 94. Gender dysphoria is a challenging condition, but it is treatable through individualized assessment and treatment, which may include social transition, psychotherapy, pubertal suppression, and hormonal therapy. These treatments are not experimental and are supported by all major medical bodies in the field of transgender medicine and pediatrics.

- 95. Lack of access to these treatments will result in worse outcomes for countless individuals in South Carolina. Furthermore, banning coverage for evidence-based treatment for gender dysphoria sends a message that transgender people are not valid and should be stigmatized.
- 96. In my own clinical practice in Michigan, I have seen an influx of patients from states banning medically proven treatments for gender dysphoria who report not feeling safe living in the community that they have always called home. Adult patients, and parents who love and support their transgender children have described themselves as "refugees" in their own country, moving to avoid discriminatory laws which they know would clearly harm their health or the health of their child.
- 97. Banning coverage of effective treatment for gender dysphoria will not eliminate transgender people, but will, unfortunately, lead to an increase in mental health problems and suicidality in an already vulnerable population.

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

Executed on the 21st day of August, 2024.

Daniel Shumer, M.D.

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# **EXHIBIT A**

## **Daniel Shumer**

## Clinical Associate Professor dshumer@umich.edu

## **Education and Training**

**Education** 

08/2000-08/2003 BA, Northwestern University, Evanston, IL

08/2004-05/2008 MD, Northwestern University, Feinberg School of Medicine, Chicago, IL

07/2013-05/2015 MPH, Harvard T.H. Chan School of Public Health, Boston, MA

**Postdoctoral Training** 

06/2008-06/2011 Residency, Pediatrics, Vermont Children's Hospital at Fletcher Allen Health Care,

Burlington, VT

07/2011-06/2012 Chief Resident, Chief Resident, Vermont Children's Hospital at Fletcher Allen

Health Care, Burlington, VT

07/2012-06/2015 Clinical Fellow, Pediatric Endocrinology, Boston Children's Hospital, Boston, MA

## **Certification And Licensure**

Certification

10/2011-Present American Board of Pediatrics, General

<u>Licensure</u>

08/2015-Present Michigan, Medical License 09/2015-Present Michigan, DEA License

09/2015-Present Michigan, Controlled Substance

## Work Experience

## **Academic Appointment**

10/2015-09/2022 Clinical Assistant Professor in Pediatrics - Endocrinology, University of Michigan -

Ann Arbor, Ann Arbor

09/2022-Present Clinical Associate Professor in Pediatrics - Endocrinology, University of Michigan -

Ann Arbor, Ann Arbor

**Administrative Appointment** 

07/2019-01/2023 Fellowship Director - Pediatric Endocrinology, Michigan Medicine, Department of

Pediatrics, Ann Arbor

07/2020-Present Medical Director of the University of Michigan Comprehensive Gender Services

Program, Oversee the provision of care to transgender and gender nonconforming patients at Michigan Medicine, Michigan Medicine, Ann Arbor

07/2020-01/2023 Education Lead - Pediatric Endocrinology, University of Michigan - Department of

Pediatrics, Ann Arbor

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## **Private Practice**

08/2013-09/2015 Staff Physician, Harvard Vanguard Medical Associates, Braintree

#### **Research Interests**

- · Gender dysphoria
- · Prader Willi Syndrome

#### Clinical Interests

- · Gender dysphoria
- · Disorders of Sex Development
- · Prader Willi Syndrome

## **Honors and Awards**

<u>National</u>

2014 Annual Pediatric Endocrine Society Essay Competition: Ethical Dilemmas in

Pediatric Endocrinology: competition winner - The Role of Assent in the Treatment

of Transgender Adolescents

<u>Institutional</u>

2012 - 2015 Harvard Pediatric Health Services Research Fellowship; funded my final two years

of pediatric endocrine fellowship and provided tuition support for my public health

degree

2016 The University of Michigan Distinguished Diversity Leaders Award, awarded by

The Office of Diversity, Equity and Inclusion to the Child and Adolescent Gender

Services Team under my leadership

2019 Lecturer of the Month, Department of Pediatrics, Michigan Medicine

Teaching

Mentorship

Resident

07/2020-Present Rebecca Warwick, Michigan Medicine

Clinical Fellow

07/2017-06/2020 Adrian Araya, Michigan Medicine

12/2020-Present Jessica Jary, Michigan Medicine - Division of Adolescent Medicine

**Medical Student** 

09/2017-06/2020 Michael Ho, Michigan Medicine

07/2019-06/2020 Jourdin Batchelor, University of Michigan

07/2019-06/2020 Hadrian Kinnear, University of Michigan Medical School

**Teaching Activity** 

**Regional** 

08/2018-08-2019 Pediatric Boards Review Course sponsored by U-M: "Thyroid Disorders and

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	Diabetes". Ann Arbor, MI
06/2023-Present	Care for Transgender Children and Adolescents, Wayne State University School of Social Work, Guest Lecturer
10/2023-Present	Care for Transgender Children and Adolescents, Stand With Trans, Guest Lecturer
<u>Institutional</u>	
12/2015-12/2015	Pediatric Grand Rounds: "Transgender Medicine - A Field in Transition". Michigan Medicine, Ann Arbor, MI
02/2016-02/2016	Psychiatry Grand Rounds: "Transgender Medicine - A Field in Transition". Michigan Medicine, Ann Arbor, MI
02/2016-02/2016	Medical Student Education: Panelist for M1 Class Session on LGBT Health, Doctoring Curriculum. Michigan Medicine, Ann Arbor, MI
03/2016-03/2017	Pharmacy School Education: "LGBT Health". University of Michigan School of Pharmacy, Ann Arbor, MI
04/2016-Present	Course Director: Medical Student (M4) Elective in Transgender Medicine. Michigan Medicine, Ann Arbor, MI
04/2016-04/2016	Rheumatology Grand Rounds: "Gender Identity". Michigan Medicine, Ann Arbor, MI
05/2016-05/2016	Lecture to Pediatric Rheumatology Division: "Gender Dysphoria". Michigan Medicine, Ann Arbor, MI
07/2016-07/2016	Internal Medicine Resident Education: "Gender Identity". Michigan Medicine, Ann Arbor, MI
09/2016-09/2016	Presentation to ACU Leadership: "Gender Identity Cultural Competencies". Michigan Medicine, Ann Arbor, MI
10/2016-10/2016	Presentation to Department of Dermatology: "The iPledge Program and Transgender Patients". Michigan Medicine, Ann Arbor, MI
02/2017-02/2017	Presentation at Collaborative Office Rounds: "Transgender Health". Michigan Medicine, Ann Arbor, MI
02/2017-02/2017	Lecture to Division of General Medicine: "Transgender Health". Michigan Medicine, Ann Arbor, MI
02/2017-02/2017	Swartz Rounds Presenter. Michigan Medicine, Ann Arbor, MI
10/2017-10/2017	Family Medicine Annual Conference: "Transgender Medicine". Michigan Medicine, Ann Arbor, MI
12/2017-12/2017	Presenter at Nursing Unit 12-West Annual Educational Retreat: "Gender Identity at the Children's Hospital". Michigan Medicine, Ann Arbor, MI
02/2018-Present	Pediatrics Residency Lecturer: "Puberty". Michigan Medicine, Ann Arbor, MI
02/2019-Present	Doctors of Tomorrow Preceptor: offering shadowing opportunities to students from Cass Technical High School in Detroit. Michigan Medicine, Ann Arbor, MI
02/2019-Present	Medical Student (M1) Lecturer: "Pediatric Growth and Development". Michigan Medicine, Ann Arbor, MI
03/2019-03/2019	Lecture to Division of Orthopedic Surgery: "Transgender Health". Michigan Medicine, Ann Arbor, MI
04/2023-Present	Guest Lecturer in Woman and Gender Studies 400 undergraduate course, University of Michigan
07/2023-Present	Care for Transgender Children and Adolescents, University of Michigan School of Nursing, Pediatric Nurse Practitioner Students, Guest Lecturer
10/2023-Present	Morning Report: Serving as an Expert Witness, Michigan Medicine: Pediatrics Residency Program
10/2023-Present	Care for Transgender Children and Adolescents, University of Michigan School of

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Nursing, Guest Lecturer

## **Memberships in Professional Societies**

2012 - Present Pediatric Endocrine Society

## Committee/Service

## **National**

2014 - 2016 Pediatric Endocrine Society - Ethics Committee, Other, Member

2017 - present Pediatric Endocrine Society - Special Interest Group on Gender Identity, Other,

Member

2018 - 2022 Pediatric Endocrine Society - Program Directors Education Committee, Other,

Member

**Regional** 

2013 - 2015 Investigational Review Board - The Fenway Institute, Boston, MA, Other, Voting

Member

<u>Institutional</u>

2017 - 2019 Department of Pediatrics at Michigan Medicine; Diversity, Equity, and Inclusion

Committee, Other, Fellowship Lead

2017 - 2019 University of Michigan Transgender Research Group, Other, Director

## **Volunteer Service**

## **Volunteer**

2014 Camp Physician, Massachusetts, Served at a camp for youth with Type 1

Diabetes

## **Scholarly Activities**

#### **Presentations**

#### **Extramural Invited Presentation**

#### **Speaker**

1. Grand Rounds, Shumer D, Loyola University School of Medicine, 07/2022, Chicago, Illinois

#### Other

- 1. Gender Identity, Groton School, 04/2015, Groton, MA
- Television Appearance: Gender Identity in Youth, Channel 7 WXYZ Detroit, 04/2016, Southfield, MI
- 3. It Gets Better: Promoting Safe and Supportive Healthcare Environments for Sexual Minority and Gender Non-Conforming Youth, Adolescent Health Initiative: Conference on Adolescent Health, 05/2016, Ypsilanti, MI
- 4. Gender Identity, Humanists of Southeast Michigan, 09/2016, Farmington Hills, MI
- 5. Gender Identity, Pine Rest Christian Mental Health Services, 10/2016, Grand Rapids, MI
- 6. Pediatric Grand Rounds Hormonal Management of Transgender Youth, Beaumont Children's Hospital, 11/2016, Royal Oak, MI
- 7. Transgender Youth: A Field in Transition, Temple Beth Emeth, 11/2016, Ann Arbor, MI
- 8. Transgender Youth: A Field in Transition, Washtenaw County Medical Society, 11/2016, Ann Arbor, MI
- 9. Pediatric Grand Rounds: Transgender Youth A Field in Transition, St. John Hospital, 02/2017, Detroit, MI
- 10. Transgender Medicine, Veterans Administration Ann Arbor Healthcare System, 05/2017, Ann Arbor, MI

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- 11. Gender Identity, Hegira Programs, 05/2017, Detroit, MI
- 12. Care of the Transgender Adolescent, Partners in Pediatric Care, 06/2017, Traverse City, MI
- 13. Conference planner, host, and presenter: Transgender and Gender Non-Conforming Youth: Best Practices for Mental Health Clinicians, Educators, & School Staff; 200+ attendees from fields of mental health and education from across Michigan, Michigan Medicine, 10/2017, Ypsilanti, MI
- 14. Endocrinology Grand Rounds: Transgender Medicine, Wayne State University, 11/2017, Detroit, MI
- 15. Care of the Transgender Adolescent, St. John Hospital Conference: Transgender Patients: Providing Compassionate, Affirmative and Evidence Based Care, 11/2017, Grosse Pointe Farms, MI
- 16. Hormonal Care in Transgender Adolescents, Michigan State University School of Osteopathic Medicine, 11/2017, East Lansing, MI
- 17. Working with Transgender and Gender Non-Conforming Youth, Michigan Association of Osteopathic Family Physicians, 01/2018, Bellaire, MI
- 18. Community Conversations, Lake Orion, 01/2018, Lake Orion, MI
- 19. "I Am Jazz" Reading and Discussion, St. James Episcopal Church, 03/2019, Dexter, MI
- 20. Gender Identity, Michigan Organization on Adolescent Sexual Health, 10/2019, Brighton, MI; Port Huron, MI
- 21. Ask The Expert, Stand With Trans, 05/2020, Farmington Hills, MI (Virtual due to COVID)
- 22. Lets Talk About Hormones, Stand With Trans, 10/2020, Farmington Hills, MI (Virtual due to COVID)
- 23. Transgender Medicine, Michigan Association of Clinical Endocrinologists Annual Symposium, 10/2020, Grand Rapids, MI (Virtual due to COVID)
- 24. Transgender Youth in Primary Care, Michigan Child Care Collaborative (MC3), 10/2020, Ann Arbor, MI (Virtual due to COVID)
- 25. Gender Identity, Universalist Unitarian Church of East Liberty, 04/2021, Virtual due to COVID
- Unconscious Bias, Ascension St. John Hospital, 05/2021, Virtual due to COVID

## **Publications/Scholarship**

(Co-First Author \*; Corresponding author \*\*; Co-Last author \*\*\*)

#### Peer-Reviewed

#### **Journal Article**

- 1. **Shumer DE**, Mehringer JE, Braverman LE, Dauber A: Acquired hypothyroidism in an infant related to excessive maternal iodine intake: food for thought. *Endocr Pract*.19(4): 729-731, 01/2013. PM23512394
- 2. **Shumer DE**, Spack NP: Current management of gender identity disorder in childhood and adolescence: guidelines, barriers and areas of controversy. *Curr Opin Endocrinol Diabetes Obes*.20(1): 69-73, 02/2013. PM23221495
- 3. **Shumer DE**, Thaker V, Taylor GA, Wassner AJ: Severe hypercalcaemia due to subcutaneous fat necrosis: presentation, management and complications. *Arch Dis Child Fetal Neonatal Ed*.99(5): F419-F421, 09/2014. PM24907163
- 4. Tishelman AC, Kaufman R, Edwards-Leeper L, Mandel FH, **Shumer DE**, Spack NP: Serving Transgender Youth: Challenges, Dilemmas and Clinical Examples. *Prof Psychol Res Pr.*46(1): 37-45, 01/2015. PM26807001
- 5. **Shumer DE**, Tishelman AC: The Role of Assent in the Treatment of Transgender Adolescents. *Int J Transgend*.16(2): 97-102, 01/2015. PM27175107
- 6. **Shumer DE**, Roberts AL, Reisner SL, Lyall K, Austin SB: Brief Report: Autistic Traits in Mothers and Children Associated with Child's Gender Nonconformity. *J Autism Dev Disord*.45(5): 1489-1494, 05/2015. PM25358249
- 7. Tishelman AC, Kaufman R, Edwards-Leeper L, Mandel FH, **Shumer DE**, Spack NP: Reply to comment on "Serving Transgender Youth: Challenges, Dilemmas, and Clinical Examples" by Tishelman et al. (2015).

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Prof Psychol Res Pr.46(4): 307, 08/2015. PM26858509

- 8. Guss C, **Shumer D**, Katz-Wise SL: Transgender and gender nonconforming adolescent care: psychosocial and medical considerations. *Curr Opin Pediatr*.27(4): 421-426, 08/2015. PM26087416
- 9. **Shumer DE**, Nokoff NJ, Spack NP: Advances in the Care of Transgender Children and Adolescents. *Adv Pediatr*.63(1): 79-102, 08/2016. PM27426896
- 10. **Shumer DE**, Reisner SL, Edwards-Leeper L, Tishelman A: Evaluation of Asperger Syndrome in Youth Presenting to a Gender Dysphoria Clinic. *LGBT Health*.3(5): 387-390, 10/2016. PM26651183
- 11. **Shumer DE**, Harris LH, Opipari VP: The Effect of Lesbian, Gay, Bisexual, and Transgender-Related Legislation on Children. *J Pediatr*.178: 5-6.e1, 11/2016. PM27575000
- 12. **Shumer DE**, Abrha A, Feldman HA, Carswell J: Overrepresentation of Adopted Adolescents at a Hospital-Based Gender Dysphoria Clinic. *Transgend Health*.2(1): 76-79, 01/2017. PM28861549
- 13. Edwards-Leeper L, **Shumer DE**, Feldman HA, Lash BR, Tishelman AC: Psychological profile of the first sample of transgender youth presenting for medical intervention in a U.S. pediatric gender center. *Psychology of Sexual Orientation and Gender Diversity*.4(3): 374-382, 01/2017
- 14. Tishelman AC, **Shumer DE**, Nahata L: Disorders of Sex Development: Pediatric Psychology and the Genital Exam. *J Pediatr Psychol*.42(5): 530-543, 06/2017. PM27098964
- 15. Strang JF, Meagher H, Kenworthy L, de Vries AL C, Menvielle E, Leibowitz S, Janssen A, Cohen-Kettenis P, **Shumer DE**, Edwards-Leeper L, Pleak RR, Spack N, Karasic DH, Schreier H, Balleur A, Tishelman A, Ehrensaft D, Rodnan L, Kuschner ES, Mandel F, Caretto A, Lewis HC, Anthony LG: Initial Clinical Guidelines for Co-Occurring Autism Spectrum Disorder and Gender Dysphoria or Incongruence in Adolescents. *J Clin Child Adolesc Psychol.*47(1): 105-115, 01/2018. PM27775428
- 16. Mohnach L, Mazzola S, **Shumer D**, Berman DR: Prenatal diagnosis of 17-hydroxylase/17,20-lyase deficiency (17OHD) in a case of 46,XY sex discordance and low maternal serum estriol. *Case Reports in Perinatal Medicine*.8(1)01/2018
- 17. Kim C, Harrall KK, Glueck DH, **Shumer D**, Dabelea D: Childhood adiposity and adolescent sex steroids in the EPOCH (Exploring Perinatal Outcomes among Children) study. *Clin Endocrinol (Oxf)*.91(4): 525-533, 01/2019. PM31278867
- 18. Selkie E, Adkins V, Masters E, Bajpai A, **Shumer D**: Transgender Adolescents' Uses of Social Media for Social Support. *J Adolesc Health*.66(3): 275-280, 03/2020. PM31690534
- 19. Araya AC, Warwick R, **Shumer D**, Selkie E: Romantic Relationships in Transgender Adolescents: A Qualitative Study. *Pediatrics*.147(2)02/2021. PM33468600
- 20. Vengalil N, **Shumer D**, Wang F: Developing an LGBT curriculum and evaluating its impact on dermatology residents. *Int J Dermatol*.61: 99-102, 01/2022. PM34416015
- 21. Warwick RM, Araya AC, **Shumer DE**, Selkie EM: Transgender Youths' Sexual Health and Education: A Qualitative Analysis. *J Pediatr Adolesc Gynecol*.35(2): 138-146, 04/2022. PM34619356
- 22. Warwick RM, **Shumer DE**: Gender-affirming multidisciplinary care for transgender and non-binary children and adolescents. *Children's Health Care*.52(1): 91-115, 01/2023
- 23. Diaz-Thomas AM, Golden SH, Dabelea DM, Grimberg A, Magge SN, Safer JD, **Shumer DE**, Stanford FC: Endocrine Health and Health Care Disparities in the Pediatric and Sexual and Gender Minority Populations: An Endocrine Society Scientific Statement. *J Clin Endocrinol Metab*.108(7): 1533-1584, 06/2023. PM37191578
- 24. Waselewski AC, Klumpner TT, Kountanis JA, Sandberg ES, **Shumer DE**: Dexamethasone for postoperative nausea and vomiting prophylaxis in cesarean delivery and a delayed diagnosis of neonatal congenital adrenal hyperplasia. *International Journal of Obstetric Anesthesia*. Available on line12/2023. PM38195332
- 25. Roszell K, Shumer D, Orringer J, Wang F: Limited health insurance coverage of injectable neurotoxins and fillers for gender affirmation: a cross-sectional study of Affordable Care Act silver and Medicaid plans. *Int J Womens Dermatol.*10(1): e126, 03/2024. PM38313363
- 26. Blaszczak J, Wiener S, Plegue M, **Shumer D**, Shatzer J, Hernandez A: Evaluating the effectiveness of an online curriculum on caring for transgender and nonbinary patients. *Med Educ Online*.29(1): 2311481, 12/2024. PM38320110

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#### **Books**

1. Clara A-V, Bizic M, Bockting WO, Bouman M-B, Bowers ML, Buncamper ME, Capitán L, Castillo M, Chim HW, Colebunders B, Crane C, D'Arpa S, Djordjevic ML, Estes C, Fein LA, Gasgarth R, Hoebeke P, Horne M, Joumblat NR, Kojic S, Levine JP, Lumen N, Meijerink WJ H J, Monstrey SJ, Salgado CJ, **Shumer DE**, Simon D, Sinha VR, Sinha VK, Spack NP, Sputova K, Stanojevic D, Stojanovic B, Tarsha AA, Thomas JP, van der Sluis WB, Volker MK, Weiss RE, Yamaguchi Y, Zhao LC, Zoghbi Y. *Gender Affirmation Medical & Surgical Perspectives*. Thieme, (2017)

## Chapters

- 1. **Shumer D**: Coma. In Schwartz MW *The 5-Minute Pediatric Consult*,6, Lippincott Williams & Wilkins, Philadelphia, PA, (2012)
- 2. **Shumer D**, Spack N: Medical Treatment of the Adolescent Transgender Patient. In Đorđević M, Monstrey SJ, Salgado CJ Eds. *Gender Affirmation: Medical and Surgical Perspectives*, CRC Press/Taylor & Francis, (2016)
- 3. **Shumer DE**, Kinnear HA: Duration of Pubertal Suppression and Initiation of Gender-Affirming Hormone Treatment in Youth. In Finlayson *Pubertal Suppression in Transgender Youth*, Elsevier, (2018)
- 4. **Shumer DE**, Araya A: Endocrinology of Transgender Care Children and Adolescents. In Poretsky, Hembree Ed. *Transgender Medicine: A Multidisciplinary Approach*, Springer, (2019)

#### Non-Peer Reviewed

## Commentary

1. Martin S, Sandberg ES, **Shumer DE**: Criminalization of Gender-Affirming Care - Interfering with Essential Treatment for Transgender Children and Adolescents. *New England Journal of Medicine*.385(7): 579-581, 05/2021. PM34010528

## **Comparative Study**

1. 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*.56(3): 274-279, 03/2015. PM25577670

## **Editorial**

1. **Shumer D**, Roberts SA: Placing a Report of Bicalutamide-Induced Hepatotoxicity in the Context of Current Standards of Care for Transgender Adolescents. *J Adolesc Health*.74(1): 5-6, 01/2024. PM38103922

#### **Editorial comment**

- 1. **Shumer DE**: Health Disparities Facing Transgender and Gender Nonconforming Youth Are Not Inevitable, 01/2018. PM29437859
- 2. Martin S, Sandberg ES, **Shumer DE**: Criminalization of Gender-Affirming Care Interfering with Essential Treatment for Transgender Children and Adolescents, 01/2021

#### **Erratum**

1. Tishelman AC, Kaufman R, Edwards-Leeper L, Mandel FH, **Shumer DE**, Spack NP: Correction to Serving Transgender Youth: Challenges, Dilemmas, and Clinical Examples, [Professional Psychology: Research and Practice, 46(1), (2015) 37-45]. *Professional Psychology: Research and Practice*.46(4): 249, 08/2015

## **Letter**

1. Strang JF, Janssen A, Tishelman A, Leibowitz SF, Kenworthy L, McGuire JK, Edwards-Leeper L, Mazefsky CA, Rofey D, Bascom J, Caplan R, Gomez-Lobo V, Berg D, Zaks Z, Wallace GL, Wimms H, Pine-Twaddell E, **Shumer D**, Register-Brown K, Sadikova E, Anthony LG: Revisiting the Link: Evidence of the Rates of Autism in Studies of Gender Diverse Individuals. *J Am Acad Child Adolesc Psychiatry*.57(11): 885-887, 11/2018. PM30392631

#### Letter to editor

Shumer D: Doctor as environmental steward, 01/2009. PM19364173

#### News

1. **Shumer DE**, Spack NP: Paediatrics: Transgender medicine--long-term outcomes from 'the Dutch model'. *Nat Rev Urol*.12(1): 12-13, 01/2015. PM25403246

## <u>Other</u>

- 1. **Shumer D**: The Effect of Race and Gender Labels in the Induction of Traits. *Northwestern Journal of Race and Gender Criticism*.NA01/2014
- 2. **Shumer D**: A Tribute to Medical Stereotypes. *The Pharos, Journal of the Alpha Omega Alpha Medical Society*.Summer07/2017
- 3. Mohnach L, Mazzola S, **Shumer D**, Berman DR: Prenatal Diagnosis of 17-hydroxylase/17,20-lyase deficiency (17OHD) in a case of 46,XY sex discordance and low maternal serum estriol. *Case Reports in Perinatal Medicine*.8(1)12/2018
- 4. Araya A, **Shumer D**, Warwick R, Selkie E: 37. "I've Been Happily Dating For 5 Years" Romantic and Sexual Health, Experience and Expectations in Transgender Youth. *Journal of Adolescent Health*.66(2): s20, 02/2020
- 5. Araya A, **Shumer D**, Warwick R, Selkie E: 73. "I think sex is different for everybody" Sexual Experiences and Expectations in Transgender Youth. *Journal of Pediatric and Adolescent Gynecology*.33(2): 209-210, 04/2020
- 6. Araya AC, Warwick R, **Shumer D**, Selkie E, Rath T, Ibrahim M, Srinivasan A: Romantic Health in Transgender Adolescents. *Pediatrics*.Pediatrics01/2021

## **Podcast**

1. Gaggino L, Shumer WG D: Pediatric Meltdown: Caring for Transgender Youth with Compassion: What Pediatricians Must Know, 01/2020

#### Abstract/Posters

- 1. **Shumer D**: Overrepresentation of Adopted Children in a Hospital Based Gender Program, World Professional Association of Transgender Health Biennial International Symposium, Amsterdam, The Netherlands, 2016
- 2. **Shumer D**: Mental Health Presentation of Transgender Youth Seeking Medical Intervention, World Professional Association of Transgender Health Biennial International Symposium, Amsterdam, The Netherlands, 2016
- 3. **Shumer D**, Kinnear H, McLain K, Morgan H: Development of a Transgender Medicine Elective for 4th Year Medical Students, National Transgender Health Summitt, Oakland, CA, 2017
- 4. Adkins V, Masters E, **Shumer D**, Selkie E: Exploring Transgender Adolescents' Use of Social Media for Support and Health Information Seeking (Poster Presentation), Pediatric Research Symposium, Ann Arbor, MI, 2017
- 5. Sandberg E, Baines HK, Aye T, Hart-Unger S, Lopez X, Nikita ME, Nokoff NJ, Persky R, **Shumer D**, Harris RM, Roberts SA: National Assessment for the Need of a Comprehensive Pediatric Gender Affirming Care Curriculum, Poster, Pediatric Endocrine Society Meeting, Virtual, 2021

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## **EXHIBIT B - DANIEL SHUMER BIBLIOGRAPHY**

Achille, C., Taggart, T., Eaton, N. R., Osipoff, J., Tafuri, K., Lane, A., & Wilson, T. A. (2020). Longitudinal impact of gender-affirming endocrine intervention on the mental health and well-being of transgender youths: preliminary results. *International journal of pediatric endocrinology*, 2020, 8.

Allen, N. G., Krishna, K. B., & Lee, P. A. (2021). Use of gonadotropin-releasing hormone analogs in children. *Current opinion in pediatrics*, 33(4), 442–448.

Allen, L.R., Watson, L.B., Egan, A.M., & Moser, C.N. (2019). Well-Being and Suicidality Among Transgender Youth After Gender-Affirming Hormones. *Clinical Practice in Pediatric Psychology*, 7(3), 302-311.

American Medical Association and GLMA (2019). Health Insurance Coverage for Gender-Affirming Care of Transgender Patients. <a href="https://www.ama-assn.org/system/files/2019-03/transgender-coverage-issue-brief.pdf">https://www.ama-assn.org/system/files/2019-03/transgender-coverage-issue-brief.pdf</a>

American Psychological Association. (2015). Guidelines for psychological practice with transgender and gender nonconforming people. American Psychologist, 70, 832-864.

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Ashley, F. (2022). The clinical irrelevance of "desistance" research for transgender and gender creative youth. *Psychology of Sexual Orientation and Gender Diversity*, 9(4), 387–397.

Berglund, H., Lindström, P., Dhejne-Helmy, C., & Savic, I. (2008). Male-to-female transsexuals show sex-atypical hypothalamus activation when smelling odorous steroids. *Cerebral cortex* (*New York, N.Y.*: 1991), 18(8), 1900–1908.

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: <a href="http://dx.doi.org/10.2139/ssrn.4180724">http://dx.doi.org/10.2139/ssrn.4180724</a>

Caanen MR, et al. (2017). Effects of long-term exogenous testosterone administration on ovarian morphology, determined by transvaginal (3D) ultrasound in female-to-male transsexuals. Hum Reprod. 32(7):1457-1464.

Carmichael, P., Butler, G., Masic, U., Cole, T. J., De Stavola, B. L., Davidson, S., Skageberg, E. M., Khadr, S., & Viner, R. M. (2021). Short-term outcomes of pubertal suppression in a selected cohort of 12 to 15 year old young people with persistent gender dysphoria in the UK. *PloS one*, *16*(2), e0243894.

Chen D, Berona J, Chan YM, Ehrensaft D, Garofalo R, Hidalgo MA, Rosenthal SM, Tishelman AC, Olson-Kennedy J. (2023). Psychosocial Functioning in Transgender Youth after 2 Years of Hormones. *New England Journal of Med.* 2023 Jan 19;388(3):240-250.

Chung, W. C., De Vries, G. J., & Swaab, D. F. (2002). Sexual differentiation of the bed nucleus of the stria terminalis in humans may extend into adulthood. *The Journal of neuroscience: the official journal of the Society for Neuroscience*, 22(3), 1027–1033.

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## IN THE UNITED STATES DISTRICT COURT FOR THE DISTRICT OF SOUTH CAROLINA Charleston Division

STERLING MISANIN, et al.,	
Plaintiffs,	Case No.
v.	
ALAN WILSON, in his official capacity as the Attorney General of South Carolina, et al.,	
Defendants.	

## **DECLARATION OF NANCY NOE**

- I, Nancy Noe, pursuant to 28 U.S.C. §1746, declare as follows:
- 1. My name is Nancy Noe. I am a Plaintiff in this action. I offer this Declaration in support of Plaintiffs' Motion for a Preliminary Injunction. I have personal knowledge of the facts set forth in this Declaration and could and would testify competently to those facts if called as a witness.
- 2. I am 46 years old. I am the parent of Nina Noe, my 15-year-old daughter, and Nina's three siblings: her twin brother, her older brother, and her older sister. Although I was born in Alabama, I have lived in South Carolina my entire life.
  - 3. I am a medical assistant in a pediatrics office.

<sup>&</sup>lt;sup>1</sup> Nancy Noe is a pseudonym. My family is proceeding under pseudonym to protect our right to privacy and ourselves from discrimination, harassment, and violence, as well as retaliation for seeking to protect our rights.

- 4. My daughter, Nina, was a happy and energetic child. She was creative, sensitive, and confident, and she often enjoyed theatrics and a stage at home and at school. Today, she continues to be outspoken, and loves art and music, and is a great young woman.
- 5. Nina is transgender. She was assigned a male sex at birth, but I knew from a very early age that she was different from her twin brother. Everything about her screamed that she was not a boy. For example, from as early as when she was two or three years old, she often snuck into my room to borrow my makeup and put on my heels. I remember how excited she was when the Maleficent movie came out, and how she was always more interested in the female protagonists in storybooks and movies. At that time, Nina had a teenage sister, and she wanted to do everything with her sister, including shopping for clothing and dressing like her.
- 6. When Nina was seven years old, she began telling me that she had a "girl brain" and a "boy body." Nina would also firmly tell me that she wanted to "be a mommy" one day. At that time, she began going by "she" and "her" pronouns, wore dresses, and felt comfortable living as a girl at home. Nina had not yet socially transitioned at school at that age because she was worried about being bullied by her classmates. I saw that this was causing her distress, toggling between being comfortable and herself at home, and not fully herself at school.
- 7. When Nina was 8 years old and in the third grade, I noticed that her mental health was declining. She was acting out at school and refusing to do schoolwork, which was abnormal for her. She would often say that she could not sleep, and she was embarrassed to wear "boy clothes" outside of our home. I wanted to get her the support she needed as she navigated her feelings around her gender. At the recommendation of a colleague in my office, I took Nina to see an endocrinologist who is knowledgeable in care for transgender children, and to explore medical treatment options to address the distress associated with her gender dysphoria.

- 8. I took Nina to see a pediatric endocrinologist on July 10, 2017, when she was eight years old. We met with a team of doctors who were able to explain how puberty delaying medications and hormone replacement therapy work, and who thoroughly explained the risks and benefits associated with both medications in transgender adolescents. They were very clear with us that Nina was not yet in puberty, and there was no medical treatment necessary or available to Nina until she hit puberty, except for whatever mental health support she needed. The care team recommended that I take Nina to see a mental health provider in the interim, and Nina met with a therapist on July 31, 2017. Nina's therapist diagnosed her with gender dysphoria.
- 9. Given that Nina was not yet in puberty, we had more time to make a decision with respect to pursuing medical care for Nina and it gave Nina some comfort knowing that she had a few years before she would experience the physical effects of male puberty. We did not feel rushed at any step of this process, and doing the best thing for my daughter has always been my guiding principle as a parent.
- 10. During the spring of her third grade, Nina began dressing how she dressed at home and started going by "she" and "her" pronouns at school. By the time Nina started sixth grade, she started going by "Nina" at school, and one of her favorite teachers was able to help her communicate her new name to other school staff and her peers.
- 11. When Nina was acknowledged as a girl at home and at school, I noticed a large decrease in her stress and anxiety levels. It was a "night and day" different in her mood, and her interest in art and music came back. However, in 2021, when Nina was in the seventh grade, she started showing signs of male puberty, including pubic hair, hardening facial features, and cracking in her voice. This had a harmful impact on Nina, who was terrified of physical changes

such as growing facial hair and having a deeper voice. Nina lived as a girl in every aspect of her life, and having a body that did not match her sense of self as a girl—and that other people would see as male—terrified her. At that point, we knew that medical care was the only way for Nina to feel safe in her body.

- 12. In September of 2021, I took Nina back to see her pediatric endocrinologist, and he conducted lab work that verified that Nina had reached puberty. Based on her age (12) and stage of puberty (Tanner Stage 2), it was medically appropriate for her to start hormone treatment. We were advised as to the risks and benefits related to hormone treatment, and Nina and I, with support from Nina's provider, decided that medical care was the appropriate next step for her.
- 13. That same month, Nina began hormone treatment. Nina started on a very low dose of estrogen that increased incrementally over a six-month period so that she would not have a lot of discomfort with the changes in her body. When Nina began noticing physical changes such as the development of breast tissue, she was elated.
- 14. Nina is insured through her father's Medicaid plan. I am able to fill her prescriptions at a local pharmacy and have her care covered fully through her insurance. Without that coverage, our family would experience an unfathomable financial burden in affording her medication.
- 15. Nina has been receiving hormone therapy for three years now, and I am so relieved to see Nina's improved mental health. Nina is outgoing, she is witty, she is confident, and she is visibly happier. My relationship with my daughter is as strong as can be, and I know that this medication has saved her life.

- 16. Now, the state I have called home for over forty years has banned the life-saving health care that allows my child to be who she is. When I first learned about H 4624, I was devastated that my daughter would go back to the dark place she was in before starting treatment. Our only option is to leave the state to get Nina the care that is medically necessary for her. However, this will not be easy. Before H 4624, Nina's gender affirming medical treatment was covered through Medicaid, and that coverage made it possible for our family to access care for her. Without insurance coverage, this care is incredibly expensive. Leaving the state to access it will add additional travel and accommodation costs, in addition to loss of pay for missed work, that, in totality, will put an immense financial strain on our family.
- 17. The most important thing to me is the health and safety of my children. I have watched my daughter bloom into the happy and confident young woman that she is, and I know that it is in large part due to the health care that allows her to live as her authentic self. I do not want to see my daughter, or any other transgender adolescent in our state, lose access to the care that helps them be who they are. I cannot and will not allow Nina to go back to that dark place.

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

Dated: August 27, 2024

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## IN THE UNITED STATES DISTRICT COURT FOR THE DISTRICT OF SOUTH CAROLINA Charleston Division

STERLING MISANIN, et al.,	
Plaintiffs,	Case No.
V.	
ALAN WILSON, in his official capacity as the Attorney General of South Carolina, et al.,	
Defendants.	

## **DECLARATION OF NINA NOE**

- I, Nina Noe, pursuant to 28 U.S.C. §1746, declare as follows:
- 1. My name is Nina Noe.<sup>1</sup> I am a Plaintiff in this action. I offer this Declaration in support of Plaintiffs' Motion for a Preliminary Injunction. I have personal knowledge of the facts set forth in this Declaration and could and would testify competently to those facts if called as a witness.
- 2. I am a 15-year-old girl. I have a twin brother, an older brother, and an older sister. I live in South Carolina, where I have lived my whole life, with my mom, Nancy Noe.
- 3. I am in the tenth grade. When I'm not at school, I like to do anything and everything creative. I make my own music, and I love painting and balloon knitting.
- 4. I am transgender. For me, being a girl was my normal. Growing up, I was obsessed with Disney characters who wore feminine outfits and were strong women. Femininity

<sup>&</sup>lt;sup>1</sup> Nina Noe is a pseudonym. My family is proceeding under pseudonym to protect our right to privacy and ourselves from discrimination, harassment, and violence, as well as retaliation for seeking to protect our rights.

always felt so cool to me. I also loved wearing makeup, and I would sneak into my mom's room and wear her heels around the house.

- 5. When I was seven years old, I would tell my mom that I had a "girl brain" and a "boy body." My mom did some research and asked me to keep letting her know how I was feeling about my body and my gender.
- 6. There was no "coming out" experience for me because I have always known that I am a girl, and my parents, including my stepdad, have always supported me in being who I am. Since the third grade, I have worn dresses, grown out my hair, used "she" and "her" pronouns, and have been comfortable living my life authentically as a girl, first at home with my family and friends, and then at school. Although it took some kids a little while to get my pronouns right, by the end of third grade, it was a known fact, and the other students and teachers were very nice about it.
- 7. The first time I heard the word transgender, it was around 2017 when I was 8 or 9, and I heard it from another kid who was younger than me at our family church. He kept saying that word over and over again when I was trying to explain what was going on with me. I didn't know what it was, so I asked my mom. She told me that transgender is a word that describes how I feel about myself.
- 8. When I realized that I am transgender, I finally got to express how I felt and be who I am. It felt amazing. But I was worried my body would change in ways that did not feel good.
- 9. My mom took me to see a doctor who works with transgender children like me in July of 2017 when I was eight years old. The doctor was very nice and explained everything to me and my mom in a way that made sense. He said there is a medication that young people like

me can take so that they didn't go through changes associated with male puberty, like my voice getting deeper and growing facial hair. I did not want those things to happen to me because I am a girl, and I knew that they would make my gender dysphoria way worse. I was terrified about going through male puberty. Thankfully the doctor said that I was not in puberty and that I had a few years before I needed any medication.

- 10. The doctor told me and my mom that, before I started any medication, it would be good for me to see a therapist as well to help me manage my feelings around my gender. That same month, my mom took me to see a therapist who works with transgender kids. My therapist diagnosed me with gender dysphoria.
- 11. When I started sixth grade, I started going by "Nina" and a supportive teacher at school helped let the rest of the school staff know.
- In 2021, when I was in the seventh grade, I started showing more signs of puberty. My mom took me back to see the same doctor I saw a few years before, and he did my bloodwork and let me know that it was the right time for me to begin hormone therapy. The doctor explained to me and my mom what hormone therapy would do and, together with my mom, we decided that going through a female puberty was right for me, since I am a girl and have felt like a girl my whole life.
- 13. I have been receiving hormone therapy for three years now, and this medication has made a big difference in how I feel about myself. I don't feel as scared or worried about my body continuing to change in ways that would make me feel uncomfortable. I have a lot more confidence in myself and am feeling happier and more present in my own life. However, now I am so scared that there is not going to be a way to get my prescriptions.

When I first learned about the law that bans the care that I need, I was terrified. It was one of my last days of school this year, and I remember feeling like my country had betrayed me. I was so hurt. My mom has talked with me about what we will do since the law was passed. We need to leave South Carolina every time I need to access this care, which is really unfair. I will have to take time off school and my mom will have to take time off work to drive me or fly to another state that has a doctor that is able to take care of me. Losing this medication is not an option for me as I do not want to go through male puberty and go back to a place where I do not feel safe in my body, and it scares me that this law is hurting many transgender kids in my state who won't be able to travel to get the care they need.

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

Dated: August 27, 2024

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## IN THE UNITED STATES DISTRICT COURT FOR THE DISTRICT OF SOUTH CAROLINA Charleston Division

STERLING MISANIN, et al.,	
Plaintiffs,	Case No.
v.	
ALAN WILSON, in his official capacity as the Attorney General of South Carolina, et al.,	

## **DECLARATION OF GARY GOE**

I, GARY GOE, hereby declare and state as follows:

Defendants.

- 1. My name is Gary Goe.<sup>1</sup> I am over the age of 18, of sound mind, and in all respects competent to testify. I have personal knowledge of the information contained in this Declaration and would testify completely to those facts if called to do so.
  - 2. I am next friend of my minor child, Grant Goe, who is a Plaintiff in this action.
- 3. I am a South Carolina resident. I live in Anderson County with my wife and my son, Grant.
  - 4. I work as a welder in South Carolina. I have been a welder for almost 20 years.
- 5. Grant is transgender. Although Grant was assigned female at birth, he has known that he is a boy since he was young.

<sup>1</sup> Gary Goe is a pseudonym. My family is proceeding under pseudonym to protect our right to privacy and ourselves from discrimination, harassment, and violence, as well as retaliation for seeking to protect our rights.

- 6. In the summer of 2021, right before Grant started high school, he told my wife and I that he is a boy and asked us to use "he" and "him" pronouns when referring to him.
- 7. When Grant came out to us as transgender, we were not surprised. I knew something was different about Grant since Kindergarten when he first began interacting with other children. Grant always wanted to hang out with the boys and do stereotypically boyish things. He wore his baseball cap all the time. He wanted to go to math camp, science camp, and robot camp. Having raised his older sister, we knew Grant was different. He just wasn't a girly type of person. Before Grant changed his name, he went by a shortened, gender-neutral version of his deadname.
- 8. I was grateful Grant told my wife and I about being transgender. As his parents, our only goal is to love and support Grant, so we felt relieved knowing that by accepting him, he would feel comfortable and happy at home.
  - 9. My natural parental instinct was to do everything I could to keep Grant safe.
- 10. At the time Grant told us he is a boy, he was receiving counseling for his anxiety.

  My wife and I frequently spoke with his therapist after his sessions, with Grant's permission.

  Grant's therapist told us that Grant had brought up being transgender to her.
- 11. After meeting with Grant and his therapist, my wife and I began to research being transgender, gender dysphoria, and gender affirming care. We didn't know anything about it, so our number one priority was educating ourselves. We told Grant that before we did anything, we needed to find a doctor and make sure we were as informed as possible. The next few months were a learning experience for my whole family.
- 12. Grant's therapist referred us to an adolescent medicine specialist, who diagnosed Grant with gender dysphoria. The doctor ran multiple diagnostic tests on Grant, including bloodwork and mental health evaluations.

- 13. After receiving Grant's diagnosis, Grant, my wife, myself, Grant's doctor, and Grant's therapist embarked on a long and thorough examination of all possible treatments, side-effects—temporary and permanent—upsides, and risks. We weighed all the potential downsides of starting Grant on hormone replacement therapy ("HRT") and a menstrual suppressant.
- 14. Once Grant's medical team discussed all the options available to him, we took the information they provided us home to talk through the next steps in Grant's care as a family. All of us, even Grant, wanted to be 100% sure of the choice we made.
- 15. With the support of Grant's medical and mental health team, my wife and I decided the potential improvements to Grant's well-being far outweighed any risks. Although the decision was neither an easy nor a fast one, I know that without HRT, Grant's life was at risk. Looking back, choosing life-saving treatment is a no-brainer, and I am forever grateful we made the choice we did.
- 16. When we told the doctor that we were ready for Grant to start testosterone, the doctor walked us through a document called an informed consent form.
- 17. Between the initial conversation with Grant's doctor and Grant's first testosterone injection, we spoke to the doctor and the rest of his medical team multiple times.
- 18. My wife and I take a holistic approach to Grant's treatment. We know gender-affirming care is more than just hormones and other medicines. We took every step we could to make sure Grant was affirmed, supported, and protected. This has included informing his school of his transition and changing all of his legal documentation. This also includes mental health care through regular therapy visits.

- 19. Once Grant started receiving testosterone and a menstrual suppressant, I saw immediate improvements in his wellbeing. As his voice dropped, he became happier, less anxious, and more confident.
- 20. After 3 months, Grant had to go off testosterone because his fear of needles became debilitating.
- 21. In April of 2024, Grant's doctor informed us that he could receive testosterone topically via a gel. We immediately re-started Grant on testosterone, having seen its benefits even in the short period of time he had been on it before.
- 22. Grant has now been on testosterone for four months. His voice has dropped and his facial hair is beginning to grow in. Grant is happier than I have seen him since he began puberty. There is a night-and-day difference between him now and 2 years ago. He is excited about the things he loves at school. He loves hanging out with his friends. He is, for once, a typical teenager.
- 23. Before Grant started testosterone, he was often too anxious to leave the house. While he has always had a strong friend group, he was sometimes too anxious or too depressed to hang out with them. Now, he goes to the movies and to dinners with them.
- 24. I can tell that the physical changes Grant is experiencing contribute to his boosted confidence. He no longer hides behind his clothes and the walls of our house.
- 25. Grant gets good grades. He loves art. He likes to bake. He has a tight-knit group of friends who bring out the best in him. We are deeply proud of Grant. We, like every other parent, want him to grow and thrive; we want to protect him from harm. We do not understand why the government, which has never met Grant, thinks it knows our son better than the people and doctors who interact with him on a daily, weekly, and monthly basis.

- 26. If Grant was forced to stop his testosterone treatment, he would be crushed. I am scared he would not survive it.
- 27. South Carolina is my family's home. We are part of a community here. We want to stay in South Carolina, where we have built our life and livelihood. But South Carolina's new ban on gender affirming care for minors has forced us to consider moving out of state or making contingency plans to travel out of state so Grant can get the care he so desperately needs. My wife and I do not wish to move if it can be avoided. But our children are the most important thing in our life. I have witnessed first-hand, in ways no parent wants to or should have to, the life-threatening impact of Grant's gender dysphoria. I will not leave his mental and physical health in the hands of ill-informed and ill-intentioned politicians.

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

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Dated: August **28**, 2024

## IN THE UNITED STATES DISTRICT COURT FOR THE DISTRICT OF SOUTH CAROLINA Charleston Division

STERLING MISANIN, et al.,	
Plaintiffs,	Case No.
v.	
ALAN WILSON, in his official capacity as the Attorney General of South Carolina, et al.,	
Defendants.	

## **DECLARATION OF GRANT GOE**

- I, GRANT GOE, pursuant to 28 U.S.C. § 1746, hereby declare and state as follows:
- 1. My name is Grant Goe.<sup>1</sup> I am a plaintiff in the above-captioned action and submit this declaration in support of Plaintiff's Motion for a Preliminary Injunction. I have personal knowledge of the facts set forth in this Declaration and could and would testify competently to those facts if called as a witness.
  - 2. I am a seventeen-year-old boy and I am a senior in high school.
- 3. I live with my dad, Gary Goe, and my mom in South Carolina. I have lived in South Carolina since I was 6 years old.

<sup>1</sup> Grant Goe is a pseudonym. My family is proceeding under pseudonym to protect our right to privacy and ourselves from discrimination, harassment, and violence, as well as retaliation for seeking to protect our rights.

- 4. I am transgender. I was designated female on my birth certificate, but my gender identity is male.
- 5. Being transgender is a core part of who I am, but it is not the only part of who I am. I love doing art, particularly ceramics. This year in my ceramics class I have advanced to throwing pottery on the wheel. In addition to art, my favorite classes are Creative Writing, English Literature, and Science. I have an amazing group of friends in South Carolina, and I am excited to go to prom this year.
- 6. When I began puberty, I experienced a lot of mental hurt. When I saw the boys in my grade getting facial hair and heard their voices dropping, it was extremely painful for me. I didn't feel like I fit in the body I was supposed to.
- 7. When I was 13, I asked my friends to use "he" and "him" pronouns for me, and I realized that I am just Grant, a boy. I told my friends about my gender before I told my family, and they were very accepting. I hid my identity from my parents for a few months after I told my friends because I wanted to make sure that I felt comfortable in my identity before sharing it with my family.
- 8. I was intimidated to tell my parents because I did not know how they would react. I finally built up enough courage the summer before I started high school, when I was thirteen, and told my family that I am a boy. I was relieved that my parents and sister were really cool about it and they accept me for who I am. Once I told my family, I began to tell more people I am Grant.
- 9. Although it was a relief to have my friends and family recognize me for who I am, I continued to feel mental hurt as my body went through changes that did not reflect who I was.
- 10. In 2022, my parents did careful research to identify doctors who work with transgender kids like me in my area. I told the doctor that I am transgender, and my parents and I

asked about the availability of puberty blockers. The doctor we saw did not specifically work with transgender adolescents, so my family and I searched for one that did.

- 11. After that appointment my parents and I did more research on gender dysphoria. We found a clinic several towns from us with a knowledgeable doctor. That doctor diagnosed me with gender dysphoria in 2022. He told me it was too late for me to start puberty blockers because, at my age, I had already nearly finished puberty.
- 12. I talked with the doctor and my parents about starting testosterone and a menstrual suppressant, and we decided I should start taking a menstrual suppressant and receiving testosterone shots.
- 13. After I began receiving testosterone, my voice began to drop. This was the most affirming I had experienced since coming out as transgender. It made me feel so much more like myself and so much happier.
- 14. After about 6 months, my doctor transitioned me to getting testosterone shots in my home. I am very scared of needles, and getting shots in my home made me really anxious and scared. I had to stop testosterone because my fear of needles was so debilitating.
- 15. After researching other options, my parents and I asked the doctor whether I could get my testosterone without using a needle. The doctor told me I could receive testosterone as a gel and I was excited to restart this treatment.
- 16. In April of 2024, I began using testosterone gel. Since then, my voice has continued to drop, and I am getting facial hair and acne. Even though I am not a huge fan of acne, I am still excited to be getting it because it is a sign that my body is beginning to match my mind. I am so much happier now that I am on testosterone, and my mental health is substantially better.

- 17. As a senior in high school, I am looking forward to making decisions about my future. Before I started testosterone, it was almost impossible for me to do that. All I could think about was the disconnect between my body and who I truly am. Since starting testosterone, I feel like I can finally begin to think about what might be next for me.
- 18. Gender-affirming health care saved my life, and the idea of losing it terrifies me. It would be really scary for me if I wasn't able to access my testosterone. Having access to treatment for gender dysphoria is essential to my mental health. If I can't fill my prescription, my family and I would have to seek treatment in another state. We have already begun looking into treatment in my state of birth, Illinois.
- 19. I already had to pause my testosterone once because I was afraid of needles. That time without care was draining and extremely difficult. The mental hurt I began to feel before I started care started to come back, and I didn't feel like myself.
- 20. When I heard South Carolina politicians were trying to take away my health care, I was scared and angry. My family and I have to talk about regularly traveling out of state to get me care, or even moving away from our home. I feel terrible when I think about what that would mean, not just for me, but for my parents.
- 21. Although I would have to leave South Carolina if I couldn't get my prescription, I don't want to. South Carolina is my home. I want to complete my senior year here with my friends like a normal teenager.

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

Dated: August <u>28</u>, 2024

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## IN THE UNITED STATES DISTRICT COURT FOR THE DISTRICT OF SOUTH CAROLINA Charleston Division

STERLING MISANIN, et al.,	
Plaintiffs,	Case No
V.	
ALAN WILSON, in his official capacity as the Attorney General of South Carolina, et al.,	
Defendants.	

### **DECLARATION OF JANE DOE**

I, Jane Doe, hereby declare and state as follows:

- 1. My name is Jane Doe. 1 I am a plaintiff in the above-captioned action and submit this declaration in support of Plaintiffs' Motion for Preliminary Injunction.
- 2. I am over the age of 18, of sound mind, and in all respects competent to testify. I have personal knowledge of the facts set forth in this Declaration and could and would testify competently to those facts if called as a witness.
  - 3. I am 32 years old and a resident of Charleston, South Carolina.
- 4. I moved to South Carolina in 2020 when I received an opportunity to join a residency program at a hospital here in the state. I moved here with my wife, and we have been married for 8 years. We are expecting our first child in February of 2025.

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<sup>&</sup>lt;sup>1</sup> Jane Doe is a pseudonym. I am proceeding under pseudonym to protect my right to privacy and myself from discrimination, harassment, and violence, as well as retaliation for seeking to protect my rights.

- 5. I am a woman who is transgender. Although I was assigned the sex male at birth, my gender identity is female.
- 6. I have been struggling with gender dysphoria my whole life. Growing up in the South, I did not have a safe space to process my feelings of dysphoria or share these feelings with others. I lived in a body that did not feel like my own because coming out as transgender in that space felt like social suicide. Although I continually felt discomfort in my body, I continued to repress my gender identity in fear of how those around me might react. I was particularly worried about my family's reaction. I have always tried to make my parents proud, and I was not sure if they would continue to support me or embrace who I was if I told them that I am a woman.
- 7. It was only in 2020, once I had finally moved away from my family, gained some independence, and felt financially stable, that I was in a position to safely live as myself. My wife was the first person I told about my gender identity, and her support gave me the confidence to open myself up to the idea of accessing gender affirming care. I then decided to seek professional help to alleviate the distress caused by my gender dysphoria.
- 8. I started seeing a licensed professional counselor who diagnosed me with gender dysphoria in early 2021. Later that year, after consulting with a doctor and learning more about gender affirming care, I began hormone therapy (estrogen and progesterone). I have been accessing this treatment for three years now.
- 9. Hormone therapy has improved my life dramatically. When I look at myself today, I see a more authentic version of myself, and people around me recognize me as the woman that I am. Overall, I am a much happier, more complete person.
- 10. I planned to receive surgical care this year to further ease the distress I experience from my gender dysphoria. My medical providers and I decided this is the appropriate next step

in my continuing care. My hope is to access this surgical care before the end of this year because I want and need to be fully recovered before my wife gives birth and we welcome a baby into our lives. I have scheduled my surgery for November 11, 2024, but I will not be able to access surgical care without insurance coverage due to the cost.

- 11. I am an employee of the State of South Carolina. My healthcare plan is administered by the South Carolina Public Employee Benefit Authority ("PEBA") and processed by BlueCross BlueShield. Until recently, this plan has always covered my gender-affirming care, including hormone treatment. It was my understanding that future gender-affirming surgeries or procedures, including my planned surgical care, would also be covered under the plan.
- In July of 2024, I was informed by my health plan administrators that, although my insurance plan has not changed, the state health plan is required to adhere to state law, including H 4624, and this indicated to me that they will not be able to cover the cost of my surgical care. Without insurance coverage, I will not be able to afford surgical care as the out-of-pocket cost would be hundreds of thousands of dollars. I will also be forced to spend hundreds of dollars more per month to continue filling my prescription for hormone therapy.
- 13. This has caused me a great deal of stress. As a medical professional I have always tracked closely and understood the implications of this legislation, and when the bill was signed into law, I was devastated. Learning that I will no longer be able to access the surgical care I need has made me even more anxious about my future well-being and safety.
- 14. Gender-affirming care, including my hormone therapy and prospective surgery, is essential to my well-being, and helps me be myself. Without this necessary medical care, I am afraid my dysphoria will worsen and my family will face significant financial strains. I was looking forward to accessing surgical care before my wife gives birth to our child so that I could fully

recover and support my wife in taking care of our newborn. I am heartbroken that I will have to shoulder an immense financial burden to continue my hormone therapy without insurance assistance given that these payments will draw away from funds that would otherwise go towards taking care of my child. This law has also complicated the plans my wife and I have made to grow our family. We have already spent a great deal of our savings on IVF treatment, and now we will have to also take on the prohibitive cost of paying for my gender-affirming care out-of-pocket.

- 15. As a transgender person and a medical professional, I believe South Carolina's law-makers lack the appropriate understanding of transgender healthcare. In passing this bill, they have disregarded evidence-based medicine and voted in ignorance leading to the approval of a bill that has devalued me and other transgender people and has created an unnecessary barrier to healthcare for a vulnerable population. By signing this bill into law, the state has singled out transgender people and directly contributed to the stigma we face daily.
- 16. Through this law, South Carolina lawmakers have created unnecessary stress and anxiety for me and my family. Access to gender affirming care saves lives and has enabled me to be the best version of myself, which in turn has enabled me to provide the best care for the South Carolinians I have treated as a physician. Transgender healthcare access should be determined by patients and physicians, not the state.

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

Date: August <u>28</u>, 2024

Jane Doe

## IN THE UNITED STATES DISTRICT COURT FOR THE DISTRICT OF SOUTH CAROLINA Charleston Division

STERLING MISANIN, et al.,	
Plaintiffs,	Case No.
V.	
ALAN WILSON, in his official capacity as the Attorney General of South Carolina, et al.,	
Defendants.	

# **DECLARATION OF JILL RAY**

- I, Jill Ray, hereby declare and state as follows:
- 1. My name is Jill Ray. I am a plaintiff in the above-captioned action and submit this declaration in support of Plaintiff's Motion for a Preliminary Injunction.
- 2. I am over the age of 18, of sound mind, and in all respects competent to testify. I have personal knowledge of the information contained in this Declaration and would testify completely to those facts if called to do so.
- 3. I am a South Carolina resident. I live in Richland County with my wife and my son, who is 2 years old. I have lived in South Carolina since November 2013, when I moved here from Hawaii.

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<sup>&</sup>lt;sup>1</sup> Jill Ray is a pseudonym. I am proceeding under pseudonym to protect my right to privacy and myself from discrimination, harassment, and violence, as well as retaliation for seeking to protect my rights.

- 4. Prior to moving to South Carolina, I was in the United States Navy. I served in the Navy for 6 years in the intelligence space. When I left the Navy in 2013, I was a Petty Officer 2nd Class.
- 5. I currently work as an organizer, trainer, and education specialist on issues impacting LGBTQ+ individuals. Prior to my current job I was a teacher at the University of South Carolina, where I taught English to international students.
- 6. My spouse is a teacher at a public school in South Carolina. As an employee of the state, she receives insurance coverage for herself and our family through South Carolina Public Benefit Authority (PEBA).
- 7. As a veteran, I qualify for Veterans Affairs (VA) health care. I also receive insurance coverage as a beneficiary of my wife's PEBA plan.
  - 8. I am a transgender woman.
- 9. I experience and have been diagnosed with gender dysphoria due to the significant distress caused by the disconnect between my sex assigned at birth and my gender identity.
- 10. Before I came out as transgender and began receiving gender affirming care, I was at a low point in my life. I was experiencing such severe depression and anxiety that I did not even feel comfortable leaving my house.
- 11. I came out as transgender three and a half years ago, and the first person I came out to was my spouse. She was not surprised when I told her, and with her affirmation and support, I decided to seek out medical care. Shortly after, I told my primary care doctor at the VA Hospital that I am transgender. My primary care doctor referred me to a psychologist, who diagnosed me with gender dysphoria in May 2021.

- 12. Through working with and receiving care from both my mental health providers and my endocrinologist, I was able to explore my options for medical care to treat my gender dysphoria. After discussing my care options with my providers, and after careful consideration of both the risks and benefits of care, I began undergoing hormone therapy as medically necessary treatment for my gender dysphoria in July 2021. At present, I am being prescribed estrogen, progesterone, and spironolactone for my gender dysphoria. I see my endocrinologist approximately every 6 months, and I fill my prescriptions every 3 months. Accessing gender affirming health care is the best decision I have made for myself. Hormone therapy allows me to live as the woman I am and has given me my life back, but it does not address the totality of my dysphoria.
- 13. In consultation with and under the care of my medical and mental health providers, I have decided to seek gender affirming surgery. I obtained referral letters from my endocrinologist, primary care doctor, and a psychology evaluator at the VA Hospital in South Carolina to receive surgical care.
- 14. Without insurance, based on testimonials I have researched so far, I anticipate that my gender affirming surgery will cost between \$100,000 and \$250,000. I cannot afford to pay for this prohibitively expensive surgery out of pocket.
- 15. The health care I receive through the VA only covers my hormone replacement therapy. The VA Hospital does not provide gender-affirming surgical procedures.
- 16. I planned to rely on my spouse's PEBA insurance plan in order to pay for my gender affirming surgery. Prior to the passage of H 4624, it was my understanding that my PEBA insurance would cover the cost of my gender affirming surgery.
- 17. Being able to obtain hormone therapy in the form of estrogen, progesterone, and spironolactone has made me feel like a whole new person. The impact of the gender-affirming care

I have received on my life and wellbeing cannot be overstated. The care I have received has brought me even closer to my spouse. I have formed meaningful, lasting friendships and community that bring me joy and fulfillment.

- 18. The difference between the person I was before and the woman I am now is—as my wife sometimes reminds me—night and day. Before coming out I could not leave the house and my relationships were suffering. Now, I am involved in my community, thriving, confident, and happy.
- 19. Although my family, who are religious, were at first hesitant when I told them I am a woman, they have since understood and accepted me for who I am. I feel more comfortable in my relationships with them now that I can openly be myself.
- 20. The gender-affirming surgery my medical and mental health providers have referred me for is medically necessary. It will allow me to bring my body more fully into alignment with who I am.
- 21. Without gender affirming surgery, I will continue to experience pain and harm. Although hormone therapy has significantly improved my wellbeing, without gender affirming surgery I am unable to be my most authentic and happiest self, spouse, and parent.
- 22. I understand, however, that the South Carolina legislature has enacted a new law, H 4624, that will prohibit PEBA-insured plans from covering medical services for the treatment of gender dysphoria.
- 23. South Carolina's law prohibiting my wife's PEBA plan from covering gender-affirming care has caused me a great deal of distress and anxiety. When I learned of the law, I had to put all my plans for my gender affirming surgery on hold despite already receiving referrals and selecting a doctor to perform the procedure.

- 24. I simply cannot afford to pay for my medically necessary gender affirming surgery without the coverage I receive through my wife's PEBA plan.
- 25. It is incredibly stressful and debilitating to have to worry about whether I will be able to get the medical care that I need, or whether without gender affirming surgery, I will not feel like myself. I want to feel safe in my body, my home, and in public spaces. Everyone deserves that, and the fact that I and so many other trans people are being denied that right now, by actions like South Carolina's adoption of H 4624, is a burden on both our physical and mental health.
- 26. The actions by the South Carolina government threaten the health and wellbeing of transgender South Carolinians like me, and many transgender individuals and adolescents will be harmed as a result of this law.

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

- Gill Ray

Date: August <u>27</u>, 2024

## IN THE UNITED STATES DISTRICT COURT FOR THE DISTRICT OF SOUTH CAROLINA Charleston Division

STERLING MISANIN, et al.,	
Plaintiffs,	Case No.
v.	
ALAN WILSON in his official capacity	

as the Attorney General of South Carolina, et al.,

Defendants.

#### **DECLARATION OF STERLING MISANIN**

- I, Sterling Misanin, hereby declare and state as follows:
- 1. My name is Sterling Misanin. I am a plaintiff in the above-captioned action and submit this declaration in support of Plaintiff's Motion for a Preliminary Injunction.
- 2. I am over the age of 18, of sound mind, and in all respects competent to testify. I have personal knowledge of the information contained in this Declaration and would testify completely to those facts if called to do so.
- 3. I am a South Carolina resident. I live in Charleston with my dog. I have lived in South Carolina since early August 2021, when I moved here from Madison, Wisconsin.
- 4. I am the USA Learning and Development manager for a global shipping company. I love what I do for work and am skilled at conducting needs gap analyses for our various business divisions, as well as creating, curating and delivering training content to all levels of employees, from new hires to C-Suite. On the weekends, I enjoy working out, running outside, and hanging out with my great group of friends.

- 5. I am a transgender man.
- 6. I have known since a very young age that my sex assigned at birth did not match my gender identity, but I did not have the language to describe who I am like I do today. When I was about five years old, I went by the name "John" and used "he" and "him" pronouns with various individuals in my life. That lasted only one or two years because I did not grow up in the most affirming environment, and I experienced shame from family that told me that my chosen name and pronouns were not something I was allowed to feel good about. I remember reading Pinocchio, and the line "wish upon a star" really resonated with me. I used to think that if I kept wishing that I was a boy, it would magically happen.
- 7. Since elementary school I was always a tomboy, with typical masculine presentation in dress and demeanor. I spent time hanging out with boys in my neighborhood and class, playing pickup games of football and basketball. My dad even used to joke that I was "his favorite son" even though I have a brother because I was the one he would take fishing, hiking and camping.
- 8. I did not have a good understanding of the word "transgender" until 2014, when I was in college. At that stage in my life, I was able to think independently and begin to process the feelings I had when I was younger. Although it felt like the right word to describe what I was feeling, due to my internalized transphobia it took until the COVID-19 pandemic in 2020 to truly feel comfortable in my identity.
- 9. During the pandemic, I was able to have a lot of alone time with just myself and my dog at home. It allowed me to safely think about what my life would be like if I lived it more authentically, and it provided me with the space to prioritize my mental health and my happiness over fearing how my family or other people in this world would react.

- 10. I first came out to after moving to Charleston, South Carolina. The first people I told that I am a man were my friends in Charleston in late October of 2021. By late November, early December I was using "he" and "him" pronouns and going by the name "Sterling" full-time amongst my friends.
- 11. Based on their positive reactions, I began to tell the more progressive members of my family in late December 2021 and early January of 2022, who I knew would love and support me in living my truth. By February 2022, I told my parents as well. My dad was very supportive and told me that he would always support me no matter what. My mom, though she took some time to warm up to this news, was always doing her best to understand me.
- 12. After I started the process of "coming out" as a man to my friends and family, I started seeking medical care to address the distress I experienced between my physical body and my gender identity. My primary care doctor was based at MUSC, so I was initially referred to their endocrinology department in January of 2022 to see if I could meet with a doctor who works with transgender adults to discuss medical care. Unfortunately, at that time, MUSC had a four month wait time for an appointment with an endocrinologist, so I sought out another provider who I would be able to see sooner.
- 13. When I reached out to Planned Parenthood in Charleston, they were able to make me an appointment for March of 2022. My first appointment there was two hours long. At that appointment, I was evaluated for and diagnosed with gender dysphoria. My team of doctors and nurses talked me through medical treatments that are used to alleviate the distress I experience from gender dysphoria. I was informed of the risks, benefits and side effects of hormone replacement therapy (HRT) and was given time to carefully consider pursuing medical treatment.

- 14. Planned Parenthood requires an individual to provide informed consent and be at least 18 years or older to begin HRT. After the initial appointment and fulfilling the informed consent, I began my medical transition. The first time I filled my prescription for testosterone, which is a medically necessary treatment for my gender dysphoria, was in March of 2022. For the first 24-month period, I filled my prescriptions every three months, and now I am able to fill every six months. In order to authorize a refill prescription, I have to undergo bloodwork and attend a formal doctor's visit (either telehealth or in-person), with Planned Parenthood. During the formal visits, the care team performs an intake evaluation that assesses mental health and stability, as well as changes observed as a result of HRT, and if there are any concerns. It is a continuous discussion with the doctor and myself on whether the dosage is correct or should be changed to be more appropriate based on all the factors mentioned.
- 15. I receive health insurance through my employer, which provides its employees with coverage under Aetna and OptumRx. Thankfully, I am able to have my hormone therapy covered by my insurance, but it requires a prior-authorization each time it needs to be filled.
- 16. Starting testosterone was one of the best decisions of my life. When I started noticing the effects of this care, I was elated to see more masculine features appear in my face, body and voice. It brought me a sense of euphoria that I did not realize was possible before. I knew that the next step in my medical care journey was to access top surgery, which is chest masculinization surgery. I had been wearing a binder in excess for over one year, and I began experiencing negative side effects from that binder in the form of back pain and painful rashes. I spoke with my doctors and therapist about the chest dysphoria that I was experiencing, and I researched surgeons through Aetna's approved surgeons list.

- 17. My consultation process for top surgery began around May of 2022. I spoke to several providers, and finally found one that was affirming and used surgery techniques that resonated with how I wanted my chest to look. In August of 2022, I got the surgery, and I cannot remember my body pre-surgery (and will never look back).
- 18. Hormone therapy and top surgery allow me to live and be recognized as the man I am. I feel so much more confident and comfortable with top half of my body, but I knew that there was more to be done to address my bottom dysphoria.
- 19. Through further discussions with my providers at Planned Parenthood, and my doctors at MUSC, and through discussions with family and friends, I knew that the next step in my care journey was to get a hysterectomy, which is required for an eventual phalloplasty, to address my debilitating bottom dysphoria.
- 20. At my visit with MUSC in January of 2024, I was able to schedule my hysterectomy for March 8, 2024. Prior to the surgery, I worked with my employer and my insurance company, Aetna, to complete the prior authorization requirement. Due to an internal issue with my company's insurance policy, I was required to delay my surgery from March 8, 2024 to June 28, 2024. I received prior authorization for the hysterectomy from Aetna on June 13, 2024.
- 21. After prior authorization was secured, and up until four days before my surgery, I was in routine communication with MUSC about my upcoming procedure. I was given no indication at all that there would be any issue in proceeding with my surgery. MUSC provides patients with a surgery date well ahead of time, but their practice is to inform patients of a specific surgery time just a day or two before the procedure. I messaged MUSC through the MyChart portal on the morning of June 24, 2024 in order to confirm pre-operation lab work and post-operation

restrictions. In that interaction, they reconfirmed I could go in to get my blood work done and let me know that they would call me the on June 25, 2024 to provide me with my surgery time.

- 22. What happened instead led to one of the toughest days of my life. I received a phone call from a stranger who asked me if I had a hysterectomy scheduled, to which I responded "yes." She then asked me whether the surgery was a gender-related procedure, to which I also responded, "yes." She then very quickly and abruptly told me that MUSC is canceling my surgery due to South Carolina's law, H 4624, and did not provide me with an opportunity to ask any follow-up questions. She repeatedly advised I needed to talk directly to my surgeon if I had any questions.
- 23. I was devastated when I hung up the phone after that call. I immediately messaged my surgeon at MUSC who was scheduled to perform my hysterectomy to see if she could give me an explanation for why my surgery had been canceled. She called me back within an hour of my message letting me know that MUSC had decided to shut down all gender affirming care, and was very clear that MUSC was the one cancelling on me.
- 24. The next day, on June 25, 2024, I submitted a formal complaint with MUSC's ethics board regarding the abrupt cancellation of my gender affirming procedure. The complaint stated that I was advised by my surgeon that due to my healthcare being directly related to gender-affirming services, MUSC would no longer go through with my surgery, which is discriminatory on the basis of my gender. Within a day, a lawyer from MUSC's ethics committee called me to let me know that they received my complaint and that I would be best served by going either out of state or through a private provider to access the care I need.
- 25. Since June of 2024, I have struggled immensely without accessing the care that I need. I was required to begin the consultation process from scratch, and although I have a new surgery date set with a new provider, I had to go through the prior-authorization all over again.

The pain I have experienced from the delay in accessing this medically necessary care is indescribable. It is also difficult for me to find affirming providers and maintain a continuity of care. The new OBGYN provider I scheduled my hysterectomy with is located in a standalone section where gynecological care is the only type of care provided. I cannot discretely access my care with the privacy I was afforded at MUSC (which had multiple departments on one floor), and I am subjected to uncomfortable stares of women and children who ask me distressing questions, like if I am visiting the doctor with my wife or girlfriend.

- 26. The biggest impact that MUSC's cancellation of my surgery has had is on my work life. I had preplanned my whole year in January to accommodate the time off I would need to take after my surgery in the Spring. I pushed trainings and travel, I asked my coworkers to clear their calendars to cover for me, and then I had my procedure cancelled at no fault of my own. Now, with my new surgery date set for August 23, 2024, I am having to trouble my colleague to return from their paternity leave early to be able to cover for me while I am on medical leave. My work reputation has taken a hit, and I am personally devastated to put my colleagues and my stakeholders in a difficult position as I take great pride in my work.
- 27. Before I came out as transgender and started receiving gender affirming care, I was a different person. I was constantly angry and difficult to deal with, and my body felt completely foreign to me.
- 28. Today, I am so much more myself and have been told by friends and family they can see how much happier and healthier I am. My family continues to be extremely supportive of me living as that man that I am. In Charleston, I have a wonderful community of LGBTQ+ folks who make me feel safe and seen. I am so lucky to be supported and affirmed by so many wonderful people who accept me for who I am.

29. The actions by MUSC have caused me significant harm, and I am devastated that my state has interfered in my access to life-saving health care. I am an adult, and I know myself better than my state does, and I cannot stay silent about the very real harms that this law inflicts on transgender people like me.

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

Date: August 21, 2024

Sterling Misanin

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