No. 24-40568

United States Court of Appeals for the Fifth Circuit

STATE OF TEXAS; STATE OF MONTANA,

Plaintiffs-Appellees,

v.

ROBERT F. KENNEDY, JR., SECRETARY, U.S. DEPARTMENT OF HEALTH AND HUMAN SERVICES; MELANIE FONTES RAINER, DIRECTOR; CENTERS FOR MEDICARE AND MEDICAID SERVICES; UNITED STATES DEPARTMENT OF HEALTH AND HUMAN SERVICES,

Defendants-Appellants.

On Appeal from the United States District Court
for the Eastern District of Texas
No. 6:24-cv-211, Hon. Jeremy D. Kernodle

BRIEF FOR *AMICUS CURIAE* AMERICAN COLLEGE OF PEDIATRICIANS IN SUPPORT OF APPELLEES AND AFFIRMANCE

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SUPPLEMENTAL STATEMENT OF INTERESTED PERSONS

No. 24-40568

State of Texas, et al. v. Kennedy, et al.

Pursuant to 5th Cir. R. 29.2, the undersigned counsel of record hereby certifies that, in addition to the persons and entities listed in the parties' and *amici*'s Certificates of Interested Persons, the following listed persons and entities as described in the fourth sentence of Rule 28.2.1 have an interest in the outcome of this case. These representations are made in order that the judges of this court may evaluate possible disqualification or recusal.

Amicus Curiae:
American College of Pediatricians

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In accordance with Federal Rule of Appellate Procedure 26.1, *amicus curiae* American College of Pediatricians states that it is not publicly traded and has no parent corporation. No publicly traded corporation owns 10% or more of *amicus*.

/s/ Edward H. Trent
Edward H. Trent

Counsel of Record for Amicus Curiae

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IDENTITY AND INTEREST OF *AMICUS CURIAE* AND SOURCE OF AUTHORITY TO FILE BRIEF

While a significant segment of the international medical community has backed off hormonal and surgical interventions for children following the comprehensive review of the medical evidence by Dr. Hilary Cass for the National Health Services England ("Cass Review"), the U.S. Department of Health and Human Services ("HHS") through its Section 1557 Regulations at issue here seeks to force doctors and medical providers to provide aggressive experimental medical interventions for "gender transition" beginning at the onset of puberty or even earlier. Such interventions include puberty blockers and cross-sex/wrong-sex hormonal intervention followed by radically invasive surgeries for minors experiencing what studies show is most often a temporary issue in young people who are often experiencing other forms of mental distress. And, as the growing number of "detransitioners" attests, their permanent scars and resulting infertility from these unproven interventions cannot be undone, no matter how great their regret.

These developments are of great concern to *Amicus,* the American College of Pediatricians ("the College" or "ACPeds"), a national

organization of nearly 500 board-certified pediatricians or related specialists in 47 states, all dedicated to the health and well-being of children. Formed in 2002, the College is a scientific medical association committed to producing policy recommendations based on the best available scientific research. The College strives to ensure that all children reach their optimal physical and emotional health and well-being.

The College's members provide high-quality medical services to children and all patients without discrimination based on sex or any other characteristic prohibited by law. Based on the Hippocratic Oath and on science, the College categorically excludes providing medical interventions or referrals for "gender transition" procedures because they inherently harm children. *Amicus* has a direct interest in the outcome of this case because it affects the vulnerable population it serves, and the medical services the College's members provide.

Amicus is authorized to file this brief by Fed. R. App. P. 29(a)(2) because all parties have consented to its filing.

RULE 29(a)(4)(e) STATEMENT

Amicus hereby states that no party's counsel authored this brief in whole or in part; that no party or party's counsel contributed money that was intended to fund the preparation or submission of the brief; and that no person other than *amicus* or its counsel contributed money that was intended to fund the preparation or submission of the brief.

SUMMARY OF ARGUMENT

Treatment of children and adolescents with gender incongruity and dysphoria should be based on sound scientific evidence. Addressing the underlying mental health issues is critical, especially before placing them on hormones that permanently alter their bodies causing sterility and a host of other physical and psychological problems, and prior to altering their natural anatomy. Yet, the HHS Regulations to Section 1557 of the Affordable Care Act, 42 U.S.C. §18116, require just the opposite—forcing doctors to prescribe puberty blockers and perform surgery for the "purpose of gender transition" if used or offered for other, medically appropriate reasons. *See* 45 C.F.R. §92.206(b)(4).

I. Scientific research shows that children with gender incongruence or dysphoria almost always have significant mental health struggles and adverse childhood events that contribute to if not cause their dysphoria. And multiple studies show that these children almost always grow out of or desist from such gender incongruity while going through puberty if not "affirmed" of being of the opposite sex. Yet when children are placed on puberty blockers and/or cross-sex hormones, they

almost always persist in their dysphoria which can lead to "gender transition" surgeries—all with life-long adverse consequences.

II. When it comes to puberty blockers, cross-sex hormones, and "gender transition" surgeries, moreover, these interventions have severe adverse health consequences and do nothing to treat the underlying mental health struggles these children face. Just as alarming is that these children—often 11 years old or even younger—are incapable of consenting to such life-altering decisions.

III. The Section 1557 Regulations are inconsistent with sound medical practice. The appropriate medical treatment is to address the child's underlying mental health issues while allowing the child to go through natural puberty. That is what their bodies were meant to do. Yet the Regulations do not allow a doctor to deny medical interventions on this basis thus denying the child the chance to simply grow up.

The lack of an evidence-based foundation for the Section 1557 Regulations renders them without any rational justification. Further, these regulations are actually dangerous to the vulnerable children who will be subjected to such procedures. That is why states such as Texas

and Montana chose the opposite approach and banned such procedures for minors.

ARGUMENT

By requiring the use of puberty blockers, cross-sex hormones, and surgical interventions for the purpose of "gender transition," the Section 1557 Regulations improperly require that treatment of children with gender incongruence be based on blatantly political concerns untethered to biological reality and contrary to valid scientific evidence. The scientific evidence demonstrates not just a lack of benefit to these children from such interventions but clearly points to the significant and life-long harms to children subjected to such efforts to change their sex.[1] The decision of the United States District Court for the Eastern District

[1] The American College of Pediatricians, other medical organizations representing over 75,000 physicians and healthcare providers, and over 5,200 individual signatories, recently issued a declaration—the Doctors Protecting Children Declaration—stating that "Medical decision making should respect biological reality and the dignity of the person by compassionately addressing the whole person. … [Yet,] [g]ender ideology seeks to affirm thoughts, feelings and beliefs, with puberty blockers, hormones, and surgeries that harm healthy bodies, rather than affirm biological reality." Decl., Doctors Protecting Children (2024), https://doctorsprotectingchildren.org/.

of Texas staying the implantation of the Section 1557 Regulations should be affirmed.

I. The Section 1557 Regulations are Based on a Tragic Misunderstanding of Gender Incongruence and Dysphoria In Children.

To understand why many states prohibit the experimental medical procedures the Section 1557 Regulations require, it is helpful to briefly establish a foundation on what is known about gender incongruence in children.

A. "Transitioning" to a Different Sex Is Biologically Impossible.

We begin with the reality that sex is a biological, immutable characteristic—a scientific fact, not a social construct. As ACPeds has previously pointed out, "[f]rom a purely scientific standpoint, human beings possess a biologically determined sex and innate sex differences. No [physician or surgeon] could actually change a person's genes through hormones and surgery. Sex change is objectively impossible."[2]

[2] Am. Coll. of Pediatricians (ACPeds), *Mental Health in Adolescents with Incongruence of Gender Identity and Biological Sex* 2 (2024), https://tinyurl.com/2s3aa6a9 [hereinafter, ACPeds, *Mental Health*] (citing extensive scientific research).

The scientific term that best describes the condition of concern here is gender dysphoria. While rare,[3] gender dysphoria in children is "a psychological condition in which they experience marked incongruence between their experienced gender and the gender associated with their biological sex. They often express the belief that they are the opposite sex."[4]

And as explained in detail below, efforts to "transition" a child using "gender-affirming care," 45 C.F.R. §92.206(b)(4), is a misnomer—as such procedures are specifically designed to *entrench* a mental health condition of gender incongruence while leaving a child permanently sterile and without relief from the underlying mental health issues that contributed to the dysphoria in the first place.

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[3] Am. Coll. of Pediatricians (ACPeds), *Gender Dysphoria in Children* 1 (Nov. 2018), https://tinyurl.com/4znwftd2 [hereinafter, ACPeds, *Gender Dysphoria*]. Indeed, "[f]or natal adult males, prevalence ranges from 0.005% to 0.014%, and for natal females, from 0.002% to 0.003%." Am. Psych. Ass'n, *Diagnostic and statistical manual of mental disorders: DSM-5,* at 454 (5th ed. 2013).

[4] ACPeds, *Gender Dysphoria*, *supra* note 3, at 1.

B. Gender Incongruence and Dysphoria are Mental Health Issues, Not Body Issues.

It follows that gender dysphoria (GD) or, equivalently gender identity disorder (GID), is a problem that resides in the mind, not in the body.

1. As ACPeds has elsewhere explained: “Children with GD do not have a disordered body—even though they feel as if they do. Similarly, a child’s distress over developing secondary sex characteristics does not mean that puberty should be treated as a disease to be halted, because puberty is not, in fact, a disease.”[5] Unsurprising, such dysphoria is associated with a variety of “diverse psychiatric problems.”[6] Accordingly,

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[5] *Id.* at 9.

[6] Pien Rawee et al., *Development of Gender Non-Contentedness During Adolescence and Early Adulthood*, 53 Archives of Sexual Behav. 1813, 1822 (2024) (internal citations omitted), doi.org/10.1007/s10508-024-02817-5; *see also* ACPeds, *Mental Health*, *supra* note 2, at 3 (“Using five independent cross-sectional datasets consisting of 641,860 individuals, researchers found ‘transgender and gender-diverse individuals have, on average, higher rates of autism, other neurodevelopmental and psychiatric diagnoses’”); Riittakerttu Kaltiala-Heino et al., *Two years of gender identity service for minors: overrepresentation of natal girls with severe problems in adolescent development*, 9 Child & Adolescent Psych. & Mental Health art. 9, at 5 (2015) (75% of adolescents seen for gender identity services were or had been undergoing psychiatric treatment for reasons other than GD); Gunter Heylens et al., *Psychiatric characteristics in transsexual individuals: multicentre study in four European countries*, 204 Brit. J. Psych. 151, 152 & tbl. 2 (2014), doi:10.1192/bjp.bp.112.

treating gender dysphoria, especially in children, as a mental health disorder is the appropriate focus for medical providers.

2. Further, children experiencing gender incongruity are two to three times more likely to have suffered from an adverse childhood event such as sexual abuse, emotional neglect, emotional abuse, or a family member with mental illness.[7] Additionally, "studies suggest that social reinforcement, parental psychopathology, family dynamics, and social contagion facilitated by mainstream and social media, all contribute to the development and/or persistence of GD in some vulnerable children."[8] Accordingly, the available, credible science suggests that mental health

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121954 (Four nation European study found almost 70% of people with gender identity disorder had "a current and lifetime diagnosis."); Tracy A. Becerra-Culqui et al., *Mental Health of Transgender and Gender Nonconforming Youth Compared With Their Peers*, 141 Pediatrics e20173845 (2018) (study finding teens with gender non-conformity significantly more likely to have underlying psychiatric disorders, psychiatric hospitalizations, and suicidal ideation than peers).

[7] ACPeds, *Mental Health*, *supra* note 2, at 5 (citing, among others, Anna Austin et al., *Adverse childhood experiences related to poor adult health among lesbian, gay, and bisexual individuals*, 106 Am. J. Pub. Health 314 (2016); Shelley L. Craig et al., *Frequencies and patterns of adverse childhood events in LGBTQ+ youth*, 107 Child Abuse & Neglect 104623 (2020)).

[8] ACPeds, *Gender Dysphoria*, *supra* note 3, at 6 (citing, among others, Kenneth J. Zucker & Susan J. Bradley, *Gender Identity and Psychosexual Disorders*, 3 FOCUS 598 (2005)).

treatment should be the focus for children expressing gender incongruence and not hormonal or surgical interventions mandated by HHS. Indeed, avoiding invasive, dangerous, and irreversible medical interventions is what will benefit children and save them from serious and life-long harms.

C. In Natural Puberty, Gender Dysphoria Generally Desists On Its Own, Without Intervention.

Fortunately, it has long been recognized that "80-95% of the prepubertal children with GID will no longer experience a GID in adolescence."[9] In a recent study, Pien Rawee and colleagues followed a study group beginning at age 11 through age 25. According to the study, "children and adolescents referred for gender dysphoric feelings had a more negative self-concept compared to the standardization sample of the questionnaire."[10] However, while that was the case early in puberty, any "gender non-contentedness … decreased with age."[11] And overall, the

[9] Peggy T. Cohen-Kettenis et al., *The Treatment of Adolescent Transsexuals: Changing Insights*, 5 J. Sexual Med. 1892, 1893 (2008); Devita Singh et al., *A Follow-Up Study of Boys With Gender Identity Disorder*, 12 Frontiers in Psych. 632784, at 1, 8 (2021), doi:10.3389/fpsyt.2021.632784 (finding 87.8% desistance in "largest sample to date of boys clinic-referred for gender dysphoria.").

[10] Rawee, *supra* note 6, at 1814.

[11] *Id*. at 1818.

scientific evidence is that the vast majority of children who express discomfort with their sex at the start of puberty overwhelmingly express no gender discomfort after going through puberty.[12]

Equally important, while natural desistance predominates, children in such studies who socially "transitioned"[13] in early childhood were more likely (often between 96% and 100% of the time) to have persistent feelings of gender dysphoria.[14] The same is true for children who are started on puberty blockers to address gender confusion.[15]

In other words, the Section 1557 Regulations force children at age 11 or even younger onto a pathway that will result in life-long hormone interventions and sterilization, and without improved mental health

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[12] *Ibid*.

[13] Social transitioning "consists of first affirming the child's false self-concept by instituting name and pronoun changes, and facilitating the impersonation of the opposite sex within and outside of the home." ACPeds, *Gender Dysphoria*, *supra* note 3, at 11.

[14] Rawee, *supra* note 6, at 1814 (citation omitted); *see also* ACPeds, *Mental Health*, *supra* note 2, at 7.

[15] ACPeds, *Gender Dysphoria*, *supra* note 3, at 12 (study of 70 pre-pubertal candidates to receive puberty suppression showed that every child "eventually embraced a transgender identity and requested cross-sex hormones"); Hilary Cass for NHS England, The Cass Review, Final Report 176, §14.24 (2024), https://tinyurl.com/ysew5cbu [hereinafter, Cass Review].

concerns as noted below. Yet, when allowed to go through natural puberty, children overwhelmingly desist such incongruence and accept their biological sex.[16] Inexplicably, that is what the Regulations forbid.

Accordingly, the evidence-based approach is to simply allow a child to grow up without being "affirmed" in an incongruent gender identity. This is critical since there is no test to determine which small minority of children experiencing gender incongruence will persist in such feelings into adulthood unless forced onto that path by medical intervention or social affirmation.[17]

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[16] Ironically, the American Psychological Association in their *Handbook of Sexuality and Psychology* states that "[p]remature labeling of gender identity should be avoided. Early social transition (i.e., change of gender role, …) should be approached with caution to avoid foreclosing this stage of (trans)gender identity development." Walter O. Bockting, *Chapter 24: Transgender Identity Development, in* 1 Am. Psych. Ass'n, *APA Handbook of Sexuality and Psychology* 744 (Deborah L. Tolman & Lisa M. Diamond eds., 2014).

[17] *See* Doctors Protecting Children Decl., *supra* note 1, ¶4; Cass Review, *supra* note 15, at 193, §16.8; ACPeds, *Gender Dysphoria*, *supra* note 3, at 11-12 ("puberty is suppressed via GnRH agonists as early as age 11 years, and then finally, patients may graduate to cross-sex hormones at age 16 in preparation for sex-reassignment surgery as an older adolescent or adult").

II. The Section 1557 Regulations Harm Children.

It is against this background that the Section 1557 Regulations mandating "gender-affirming care" for minors needs to be evaluated. As shown below, each of the medical interventions used to "transition" a minor to a different sex poses enormous risks in this context, has not been shown to reduce other risks associated with gender dysphoria such as suicide, and cannot be ethically administered to a child who is incapable of making permanent, life-altering decisions such as the decision to become permanently sterile.

A. Puberty Blockers Harm Children.

The first medical intervention recommended by "gender affirming care" proponents is hormonal—specifically, delaying or preventing natural puberty with puberty blockers and then moving on to cross-sex hormones.

1. Puberty blockers interrupt the normal process of sexual development in children. The issue here is not the short-term use of puberty blockers for precocious or early onset puberty, for which they have been approved, but the long-term effects of the off-label use of these drugs for "gender transition" purposes. Significantly, these drugs were

never intended or approved for "gender transition" purposes[18] and using them for that purpose is "very different" from use when treating precocious puberty.[19]

Indeed, these drugs have serious side-effects and should thus be used sparingly: "In addition to preventing the development of secondary sex characteristics, GnRH agonists arrest bone growth, decrease bone accretion, prevent the sex-steroid dependent organization and maturation of the adolescent brain, and inhibit fertility by preventing the development of gonadal tissue and mature gametes for the duration of treatment."[20]

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[18] Ainhoa Gomez-Lumbreras & Lorenzo Villa-Zapata, *Exploring Safety in Gender-Affirming Hormonal Treatments: An Observational Study on Adverse Drug Events Using the Food and Drug Administration Adverse Event Reporting System Database*, Annals of Pharmacotherapy 1, 4 (2024), doi:10.117/10600280241231612.

[19] Cass Review, *supra* note 15, at 173, §14.6.

[20] ACPeds, *Gender Dysphoria*, *supra* note 3, at 12 (referencing Lauren Schmidt & Rachel Levine, *Psychological outcomes and reproductive issues among gender dysphoric individuals,* 44 Endocrinology & Metabolism Clinics N. Am. 773 (2015); Sheila Jeffreys, *The transgendering of children: gender eugenics*, 35 Women's Studies Int'l F. 384 (2012); Sara B. Johnson et al., *Adolescent maturity and the brain: the promise and pitfalls of neuroscience research in adolescent health policy,* 45 J. Adolescent Health 216 (2009)); *see* Jonas F. Ludvigsson et al., *A Systematic Review of Hormone Treatment for Children with Gender*

Moreover, when it comes to using puberty blockers as "treatment" for gender dysphoria, the Cass Review correctly noted, "[b]locking this experience [of puberty] means that young people have to understand their identity and sexuality based only on their discomfort about puberty and a sense of their gender identity developed at an early stage of the pubertal process. Therefore, there is no way of knowing whether the normal trajectory of the sexual and gender identity may be permanently altered."[21] This is so because, when placing pre-teens on puberty blockers "[t]heir experience of puberty will then be based on their identified gender, which may have permanent neuropsychological effects."[22] As noted above, this denies the child the opportunity to naturally grow out of the discomfort they feel with their sex at age 11, a desistance that is the norm if they are not "affirmed" in their incongruent identity at such a young age.

2. While blocking a child's natural development, puberty blockers have not been shown to benefit the child psychologically, which

Dysphoria and Recommendations for Research, 112 Acta Pediatrica 2279, 2280, 2286-2290 (2023).

[21] Cass Review, *supra* note 15, at 178, §14.37.

[22] *Id.* at 194, §16.19.

is at the heart of gender dysphoria. Rather, studies demonstrate "there is insufficient and/or inconsistent evidence about the effects of puberty suppression on psychological or psychosocial health" of young people.[23] Indeed, as the Cass Review noted, the fact that only very modest and inconsistent improvements in mental health were seen makes it all the more important to assess whether other treatments may have a greater effect on the distress that young people with gender dysphoria are suffering during puberty.[24]

This lack of scientific research also extends to the long-term effects these drugs have on children. As ACPeds has previously noted, "[t]here is not a single large, randomized, controlled study that documents the alleged benefits and potential harms to gender-dysphoric children from pubertal suppression and decades of cross-sex hormone use. Nor is there a single long-term, large, randomized, controlled study that compares the outcomes of various psychotherapeutic interventions for childhood GD

[23] *Id.* at 176, §14.28.

[24] *Id.* at 177, §14.29; *see also id.* at 180, §14.55.

with those of pubertal suppression followed by decades of toxic synthetic steroids."[25]

But beyond this, "[t]here are serious long-term risks associated with the use of social transition, puberty blockers, masculinizing or feminizing hormones, and surgeries, not the least of which is potential sterility."[26] And as if that were not enough, the Cass Review noted another effect of puberty blockers is that "brain maturation may be temporarily or permanently disrupted by the use of puberty blockers, which could have a significant impact on the young person's ability to make complex risk-laden decisions, as well as having possible longer-term neuropsychological consequences."[27]

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[25] ACPeds, *Gender Dysphoria*, *supra* note 3, at 10; *see also* ACPeds, *Mental Health*, *supra* note 2, at 8 (referencing McMaster University Department of Health Research Methods systematic review done at request of the Florida Agency for Health Care Administration); Cass Review, *supra* note 15, at 194, §16.14.

[26] Doctors Protecting Children Decl., *supra* note 1, ¶5 (citing numerous sources); *see also*, ACPeds, *Gender Dysphoria*, *supra* note 3, at 13 (citing Schmidt & Levine, *supra* note 20).

[27] Cass Review, *supra* note 15, at 178, §14.38; Dick Mul et al., *Psychological Assessments Before and After Treatment of Early Puberty in Adopted Children*, 90 Acta Paediatrica 965, 970 (2001) (finding 7 point drop in intelligence quotient after one year on puberty blockers).

These are some of the reasons the Swedish National Board of Health and Welfare concluded that "the risks of hormonal interventions for gender dysphoric youth outweigh the potential benefits."[28] In short, as the renowned Swedish psychiatrist Dr. Christopher Gillberg has said, pediatric transition is "possibly one of the greatest scandals in medical history," which is why he also called for "an immediate moratorium on the use of puberty blocker drugs because of their unknown long-term effects."[29]

B. Cross-Sex Hormones Harm Children.

Cross-sex hormone interventions, often the next step in childhood "gender transition," are equally dangerous, subjecting a young person to high doses of hormones never intended for their bodies. By themselves, these hormones often result in infertility, cardiovascular disease, and

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[28] *Summary of Key Recommendations from the Swedish National Board of Health and Welfare (Socialstyrelsen/NBHW), February 2022 update,* Soc'y for Evidence-Based Gender Med. (Feb. 27, 2022), https://tinyurl.com/2je6phjv.

[29] Jonathon Van Maren, *World-renowned child psychiatrist calls trans treatments "possibly one of the greatest scandals in medical history"*, The Bridgehead (Sept. 25, 2019), https://tinyurl.com/34eya7y8; Am. Coll. of Pediatricians (ACPeds), *Transgender Interventions Harm Children,* https://tinyurl.com/586zp6wh (last visited Mar. 4, 2025); *see also* Cass Review, *supra* note 15, at 179, §14.49.

other chronic illnesses—all visited upon children who are barely teenagers. For example, as one researcher has described, females attempting "gender transition" are typically given testosterone to achieve levels "6 to 100 times above normal female circulating testosterone levels"—levels "generally only seen among patients with rare conditions such as benign or malignant androgen producing tumors of the adrenal gland or ovaries or those who misuse androgens in bodybuilding and other sports."[30] And there are no studies demonstrating that such doses in children is safe or reversible,[31] but there is evidence of their harm.

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[30] Michael Laidlaw & Sarah Jorgensen, Comment, *Exploring Safety in Gender-Affirming Hormonal Treatments: An Observational Study on Adverse Drug Events Using the Food and Drug Administration Adverse Event Reporting System Database*, Annals of Pharmacotherapy 1, 1 (2024), doi:10.1177/10600280241278913.

[31] "In fact, the package insert for Lupron, the number one prescribed puberty blocker in America, lists 'emotional instability' as a side effect and warns prescribers to 'Monitor for development or worsening of psychiatric symptoms during treatment.'" ACPeds, *Transgender Interventions*, *supra* note 29. Indeed, such negative adverse reactions are no surprise to WPATH where one doctor noted, "*I have one transition friend/collegue [sic] who, after about 8-10 years of [testosterone] developped [sic] hepatocarcinoma. To the best of my knowledge, it was linked to his hormone treatment … it was so advanced that he opted for palliative care and died a couple of months later.*" Env't Progress, *WPATH Files Excerpts: Exposing the Realities of Gender Medicine* 7 (underscore added), https://tinyurl.com/w23aar2n (last accessed Mar. 4, 2025) [hereinafter, *WPATH Files*].

In their recent study, Ainhoa Gomez-Lumbreras, MD, PhD, and Lorenzo Villa-Zapata, PharmD, PhD, found there were significant adverse drug reactions to "gender transition" hormone therapy, noting that the drugs used were "unintended for their recipient gender."[32] Indeed, "drugs such as testosterone and spironolactone frequently used in gender-affirming therapies exhibit divergent ADR [adverse drug reaction] patterns in transgender individuals compared with cisgender counterparts."[33]

Finally, those receiving these interventions continue to have serious mental health concerns. For example, a recent Finnish study "demonstrated that transgender individuals who underwent medical transition had increased needs for specialist-level psychiatric care compared to those transgender individuals who presented for care but

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[32] Gomez-Lumbreras & Villa-Zapata, *supra* note 18, at 1.

[33] *Id.* at 8; *see also id.* at 4 ("The ADRs for hormone treatments are described on the drug labels, but they typically pertain to the opposite sex of those transitioning for gender reassignment."). A study from the University Medical Center in Amsterdam followed 2,260 transwomen (men) receiving estrogen and found a 46-fold increase in breast cancer compared to natal Dutchmen. Christel J.M. de Blok et al., *Breast Cancer Risk in Transgender People Receiving Hormone Treatment: Nationwide Cohort Study in the Netherlands*, 365 BMJ l1652, at 1, 3 (2019).

did not receive medical interventions."[34] In short, these hormonal treatments permanently harm children and make their psychological conditions worse.

C. "Gender Transition" Surgery Harms Children

So-called "gender transition" surgeries are even more harmful to children. The concept of surgically altering minors suffering from gender dysphoria became accepted in the Netherlands in the early 1980s. It was surmised, wrongly, that transitioning patients earlier would benefit their psychological well-being and make the surgical changes in a patient's secondary sex characteristics easier. Unsurprisingly, neither of these two suppositions, that had no scientific foundation to begin with, proved true.

1. As noted above, once a child starts on a path of hormonal interventions, it can often lead to surgical procedures either before or after the child's 18th birthday. These surgeries sterilize the child and permanently change the child's development.[35] Examples of "transitioning" surgeries include:

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[34] ACPeds, *Mental Health*, *supra* note 2, at 9; *see also* Cass Review, *supra* note 15, at 185, §15.32; *id.* at 186, §15.34.

[35] ACPeds, *Transgender Interventions*, *supra* note 29.

- Removing healthy breasts, uteruses, or ovaries from females (hysterectomies, mastectomies, and oophorectomies);
- Removing healthy vaginal tissue from females and creating for them a faux or cosmetic penis (phalloplasties and metoidioplasties);
- Removing healthy testicles or scrotums from males (orchiectomies or scrotectomies);
- Performing a procedure known as an inversion vaginoplasty whereby the erectile tissue of the penis is amputated and the outer skin of the penis is inverted into a space created between the bladder and the rectum to form a false vagina;
- Removing healthy internal or external genitals from any person to create a "smooth gender-neutral look" (nulloplasties or nullification surgeries); and
- Performing other procedures sought to make a person resemble the opposite sex or no sex, such as facial, chest, neck, skin, hair, or vocal modification.

There is simply no medical justification for these surgeries. And it goes without saying that "transgendered individuals who undergo sex reassignment surgery and have their reproductive organs removed are rendered permanently infertile."[36] Just as a surgeon should not perform liposuction for anorexia, so also surgery to "transition" a child's sex should be considered unethical, unscientific, and malpractice.

2. Additionally, published data show that the complications of transgender surgery far exceed the complication rates of other cosmetic operations. For example, the largest single-surgeon experience in vaginoplasty is from the Crane Center in San Francisco, who reported a total complication rate of 70%.[37]

The complication rates for phalloplasty are equally disturbing. The most experienced surgeons performing this procedure are in the Netherlands. Yet, 63% of their patients reported being unable to void

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[36] ACPeds, *Gender Dysphoria*, *supra* note 3, at 13 (citing among others Jeffreys, *supra* note 20).

[37] Jonathan P. Massie et al., *Predictors of Patient Satisfaction and Postoperative Complications in Penile Inversion Vaginoplasty*, 141 Plastic Reconstructive Surgery 911e, 915e-916e & tbl. 2 (2018). *See also*, Paulette Cutruzzula Dreher et al., *Complications of the Neovagina in Male-to-Female Transgender Surgery: A Systematic Review and Meta-Analysis with Discussion of Management*, 31 Clinical Anatomy 191, 193-194 & tbl. 1 (2018).

due to scarring in the urethra and required catheterization, and 27-50% reported leaking urine from the base of the false penis, requiring diapers. They also reported a revisional surgery rate of 73%.[38] And it can only be assumed the rates are higher in adolescents who have underdeveloped genitals from years of cross-sex hormones.

Given these widespread complications, in July 2024, the American Society of Plastic Surgeons (representing 90% of board-certified plastic and reconstructive surgeons in the United States and Canada) cautioned that there is "considerable uncertainty as to the long-term efficacy for … chest and genital surgical interventions" for youth.[39] And Dr. Steven Williams, the Society's president has publicly stated he would not "even entertain" surgically transitioning minors because there is a lack of data to support it.[40] Yet, HHS would sanction such an ethical approach to the treatment of gender dysphoric children.

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[38] H. Veerman et al., *Functional Outcomes and Urologic Complications After Genital Gender Affirming Surgery With Urethral Lengthening In Transgender Men*, 204 J. Urology 104, 104, 107 (2020).

[39] Leor Sapir, *A Consensus No Longer*, City J. (Aug. 12, 2024), https://tinyurl.com/2zt898sr.

[40] Rich McHugh, *'No Good Evidence' for Teen Gender Surgery: Plastic Surgeons Head,* NewsNation (Sept. 2, 2024), https://tinyurl.com/bdhr8s39.

3. Indeed, research shows that every medical intervention being offered to minors from puberty blockers to surgical removal of healthy organs, is irreversible and is likely to have serious adverse consequences. In addition to the harms noted above, there is severe ongoing mental distress. Indeed, a Swedish study that followed patients from 1973 to 2003, found that "Sex-reassigned persons … had an increased risk for suicide attempts … and psychiatric inpatient care" with risks "increasing substantially by 15 *years* after surgical reassignment. At 30 years of follow up, the suicide rate was 19 times that of age-matched controls."[41]

D. Puberty Blockers, Cross-Sex Hormones, and "Gender Transition" Surgery Do Not Lower the Risks of Suicide.

Notwithstanding these serious health risks, proponents of hormonal and surgical interventions claim they help reduce the risk of suicide among gender dysphoric children. Indeed, as ACPeds' members have observed, "many parents are specifically told that if they do not accept their children's gender identity via social transition, medical treatment, and surgical operations, they risk losing their children to

[41] Cecilia Dhejne et al., *Long-Term Follow-Up of Transsexual Persons Undergoing Sex Reassignment Surgery: Cohort Study in Sweden*, 6 PLoSOne e16885, e16885 (2011); ACPeds, *Mental Health*, *supra* note 2, at 9-10 (emphasis added).

suicide."[42] Yet the scientific evidence does not support such a claim, which only guilts or scares a parent into authorizing such treatments.

1. For example, addressing this very issue, the Cass Review did a detailed analysis of studies on the relationship between gender dysphoria and suicide. The review found that the studies did not support a claim that a "medical pathway … [of] gender-affirming treatment reduces suicide risk."[43]

This point was illustrated in a recent Finnish study among a population of 2,083 "gender-referred adolescents," which revealed that the suicide rate in these adolescents was equal to the suicide rate in 16,643 controls when the groups were matched for underlying mental disorders.[44] In other words, the underlying mental disorder was the cause of the suicide.[45] And, as the Cass Review concluded, "Tragically deaths by suicide in trans people of all ages continue to be above the

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[42] ACPeds, *Mental Health, supra* note 2, at 3.

[43] Cass Review, *supra* note 15, at 186, §15.36; *see generally id.* at 186-187, §§15.36-15.43.

[44] *Id.* at 96, §5.66.

[45] Sami-Matti Ruuska et al., *All-cause and Suicide Mortalities Among Adolescents and Young Adults Who Contacted Specialised Gender Identity Services In Finland In 1996-2019: A Register Study*, 27 BMJ Mental Health 1, 3 & tbl. 1 (2024).

national average, but there is no evidence that gender-affirmative treatments reduce this. Such evidence as is available suggests that these deaths are related to a range of other complex psychosocial factors and to mental illness."[46]

2. Those other factors are clearly borne out in the research, which demonstrates that "gender transition" services generally do not alleviate the underlying mental health and psychosocial issues that contributed to the feelings of gender incongruity in the first place. While those who identify as transgender have "significantly higher rates of suicide attempts, suicide mortality, suicide-unrelated mortality, and all-cause mortality,"[47] studies show that puberty blockers do not address these issues but may actually make them worse.[48]

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[46] Cass Review, *supra* note 15, at 195, §16.22.

[47] ACPeds, *Mental Health*, *supra* note 2, at 10 (citing Annette Erlangsen et al., *Transgender Identity and Suicide Attempts and Mortality in Denmark*, 329 JAMA 2145 (2023)).

[48] ACPeds, *Transgender Interventions*, *supra* note 29 (quoting Oxford University Professor Michael Biggs, "There was no statistically significant difference in psychosocial functioning between the group given blockers and the group given only psychological support. In addition, there is unpublished evidence that after a year on [puberty blockers] children reported greater self-harm, and the girls also experienced more behavioral and emotional problems and expressed

Further, sex reassignment surgery, in the long term, does not result in a level of health equivalent to that of the general population.[49] Taken together, the evidence indicates that "gender transition" services do not give relief of the patient's mental health concerns, but actually makes matters worse.

E. Children are Unable to Give Informed Consent to "Gender Transition" Procedures.

As if the inherent harms and lack of benefits from the procedures themselves were not enough to undermine the Regulations, children with gender incongruence are not even capable of giving informed consent to such interventions.

1. This is obvious when considering the known medical evidence on the development of the juvenile brain. As ACPeds has elsewhere noted, "[t]he immaturity of the adolescent brain has been well described for the past 20 years, and newer research demonstrates how the

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greater dissatisfaction with their body—so *puberty blockers exacerbated gender dysphoria*." (emphasis added)).

[49] ACPeds, *Gender Dysphoria*, *supra* note 3, at 15 (citing Dhejne, *supra* note 41 (finding "considerably lower general health and general life satisfaction" after gender transition services and "the rate of suicide among post-operative transgender adults was nearly twenty times greater than that of the general population.")).

immaturity affects decision-making. Studies confirm that adolescents, when faced with real life decisions, are much more likely to depend upon their emotions and peer pressure, with less use of their cognitive reasoning skills and with less concern for future consequences. The rise of rapid-onset gender dysphoria in adolescent girls who are high users of social media is evidence of this."[50] Indeed, the adolescent brain does not achieve the capacity for full risk assessment until the early to mid-twenties.[51]

2. As a consequence, there is a serious ethical problem with allowing minors to receive life-altering medical interventions when they are incapable of providing informed consent for themselves.[52]

Indeed, because doctors do not know the long-term effects of the drugs they prescribe or of the surgeries they perform for "gender transition" purposes, they cannot even provide the necessary information for a child or their parents to give informed consent. As the Cass Review

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[50] ACPeds, *Mental Health*, *supra* note 2, at 13 (citing Douglas S. Diekema, *Adolescent brain development and medical decision-making*, 146 Pediatrics e20218F (2020)).

[51] ACPeds, *Gender Dysphoria*, *supra* note 3, at 13.

[52] *Id*. at 14.

noted: "The duty of information disclosure is complicated by many 'unknown unknowns' about the long-term impacts of puberty blockers and/or masculinising/feminising hormone during a dynamic developmental period when gender identity may not be settled."[53] In other words, no doctor can obtain genuine, meaningful informed consent from an adolescent to any medical intervention that would render the adolescent infertile for life.[54]

III. Section 1557 Regulations Are Inconsistent With Sound Medical Practice.

Rather than take rational and necessary steps to protect children from a lifetime of severe consequences that do not address the underlying mental health issues that precipitated a child's gender non-contentedness, the Section 1557 Regulations demand doctors perform unproven, harmful medical interventions on gender confused children. 45 C.F.R. §92.206(b). The exponential harm from the Regulations is evident with the dramatic rise of "rapid onset gender dysphoria" seen

[53] Cass Review, *supra* note 15, at 194, §16.18; *see also id.* at 195-96, §§16.25-16.31; *id.* at 196, §16.34. *See also*, Doctors Protecting Children Decl., *supra* note 1, ¶2.

[54] *WPATH Files*, *supra* note 31, at 4 (a Canadian endocrinologist stated: "*So … [m]ost of the kids are nowhere in any kind of a brain space to really talk about [fertility preservation] in a serious way.*").

today, particularly in teenage girls, and provides another reason to avoid a drugs-first approach for these minors. Indeed, with the dramatic rise in claims of gender incongruity, as well as the social transition and "gender-affirming therapy" provided to young adolescents whose brains are not yet mature, there is less long-term data regarding how many individuals later regret their transition decisions.

Accordingly, addressing the underlying mental health issues rather than "affirming" an incongruent identity is the proper standard of care[55]—a standard jettisoned by HHS here. This is clear based on the lack of evidence to support the protocols HHS imposes on vulnerable youth.[56]

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[55] Doctors Protecting Children Decl., *supra* note 1, ¶¶7-9 (citing sources).

[56] Cass Review, *supra* note 15, at Annex A, 1.2; *The Cass Review, Final Report, Overview of Key Findings,* The Cass Review, https://tinyurl.com/ysew5cbu (last visited Mar. 4, 2025)

Consistent with the Cass Review's findings, countries in Europe such as Sweden,[57] Norway,[58] Finland,[59] Germany,[60] Scotland,[61] and others have determined in recent years that there is no solid evidence to support many of these interventions on minors. Additionally, professional groups and governing agencies in Switzerland, New Zealand, Australia, Chile, Netherlands, France, Belgium, and Italy have called for stringent reviews of transgender protocols in their countries.[62] And yet HHS ignored the evidence and doubled down on its dangerous "protocols" by mandating such procedures and manipulating advocacy organizations to publish unscientific guidance to fit its political

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[57] Socialstyrelsen, Swedish Nat'l Bd. of Health & Welfare, *Care of Children and Adolescents with Gender Dysphoria: Summary of National Guidelines* 3-4 (Dec. 2022), https://tinyurl.com/5349b4pk.

[58] Jennifer Block, *Norway's Guidance on Paediatric Gender Treatment is Unsafe, Says Review,* 380 BMJ 697 (2023), doi:10.1136/bmj.p697.

[59] Council for Choices in Health Care [Finland], *Summary of a Recommendation by Council for Choices in Health Care in Finland: Medical treatment methods for dysphoria associated with variations in gender identity in minors—recommendation* 2 (June 16, 2020), https://tinyurl.com/47vraxmh.

[60] Resolution Ic-048, Treatment of gender dysphoria in minors, 128th German Med. Assembly (passed May 2024), https://tinyurl.com/2jkrjazm.

[61] Mary McCool, *Scotland's under-18s gender clinic pauses puberty blockers*, BBC (Apr. 18, 2024), https://tinyurl.com/4fsyxmny.

[62] Christina Buttons, *The Global Response to the Cass Review: June 2024 Update*, buttonslives (May 13, 2024), https://tinyurl.com/y67b8e8k.

narrative.[63] There is no legitimate basis for the Section 1557 Regulations as they concern the treatment of gender dysphoric children.

CONCLUSION

Sound medical ethics alone demands an end to the use of puberty blockers, cross-sex hormones, and sex reassignment surgeries in children and adolescents. Because HHS has mandated such harmful medical experimentation on vulnerable children, the Section 1557 Regulations cannot be allowed to stand.

The judgment of the district court should be affirmed.

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[63] Leaked WPATH emails reveal that, during the preparation of the current version of its Standards of Care (SOC 8), HHS officials successfully pressured WPATH (over WPATH member objections) to remove all age limits from SOC 8 because HHS feared any age limits could support state laws restricting gender-transition procedures for minors. Azeen Ghorayshi, *Biden Officials Pushed to Remove Age Limits for Trans Surgery, Documents Show*, N.Y. Times (June 25, 2024), https://tinyurl.com/yr79bndh; App'x A to Suppl. Expert Rep. of James Cantor, Ph.D., ¶¶138-39, *Boe v. Marshall*, No. 2:22-cv-00184-LCB-CWB (M.D. Ala. June 24, 2024), ECF No. 591-24. Similarly, WPATH attempted to stop Johns Hopkins from publishing its findings from commissioned studies because the results did not support WPATH's predetermined conclusions. Attach. to U.S. Dep't Health & Hum. Servs. Mots. to Seal Resp. at 1, *Voe v. Mansfield*, No. 1:23-cv-00864-LCB-LPA (M.D.N.C. May 13, 2024), ECF No. 100-1.

March 5, 2025

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CERTIFICATE OF SERVICE

Pursuant to Fed. R. App. P. 25(d) and 5th Cir. R. 25.2.5, I hereby certify that on March 5, 2025, the foregoing Brief was filed with the Clerk of the Court for the United States Court of Appeals for the Fifth Circuit by using the Court's CM/ECF system; service on counsel for all parties was accomplished by service through the Court's electronic filing system.

/s/ Edward H. Trent
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CERTIFICATE OF COMPLIANCE

The foregoing brief contains 6,497 words excluding the parts of the brief exempted by Fed. R. App. P. 32(f), and complies with the type volume limitation of Fed. R. App. P. 32(a)(7)(B).

This brief complies with the typeface and type-syle requirements of Fed. R. App. P. 32(a)(5) and (a)(6) because it has been prepared in a proportionally spaced typeface using M.S. Word Office 2016 in 14-point Century Schoolbook font.

I further certify that required redactions have been made in compliance with 5th Cir. R. 25.2.13; and the document has been scanned with M.S. Defender virus detector and is free of viruses.

March 5, 2025

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