In the Supreme Court of the United States

UNITED STATES OF AMERICA,

Petitioner,

v.

JONATHAN THOMAS SKRMETTI, ATTORNEY GENERAL AND REPORTER FOR TENNESSEE, ET AL.,

Respondents.

ON WRIT OF CERTIORARI TO THE UNITED STATES COURT OF APPEALS FOR THE SIXTH CIRCUIT

Brief of Amici Curiae of Fifty-Six Physicians in Support of Respondents

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IDENTITY & INTEREST OF AMICI CURIAE¹

Amici are fifty-six physicians (all of whom are named in the accompanying appendix) who treat adolescent patients across the country. Each one has taken an oath to "do no harm." In their practices diagnosing and treating children, this oath requires them to do what is in the best interest of the child. But in recent years, the popular approach to treating and diagnosing children with gender dysphoria has increasingly ignored the physical and mental health and well-being of adolescent patients while elevating the interests of activists, interest groups, and politicians. Amici submit this brief so the Court may more fully understand how Senate Bill 1 continues the centuries-long tradition of ensuring children receive medical care that is in their best interest.

¹ Pursuant to Supreme Court Rule 37.6, no counsel for any party authored this brief in whole or in part. Do No Harm, a nonprofit membership organization committed to ensuring that the practice of medicine is driven by scientific evidence, funded the preparation and submission of this brief on behalf of Amici.

INTRODUCTION & SUMMARY OF THE ARGUMENT

Since the days of Hippocrates, physicians have taken an oath to "do no harm." That includes acting in the best interest of the patient. And that is particularly true for children. Biologically, children undergo profound physical changes throughout adolescence that cause treatments to affect them differently than adults. Consequently, it is paramount that physicians use extreme caution when prescribing treatments for children, particularly treatments with life-altering effects. The primary way physicians do this is by ensuring all adolescent treatments are in the child's best interest.

Lawmakers likewise have hewn to this best-interest standard for centuries. Indeed, states have historically regulated under their "independent interest in the well-being of [their] youth." *Ginsberg v. New York*, 390 U.S. 629, 640 (1968). States routinely legislate limits on certain activities that may pose significant harms or create life-altering effects for youth, like underage drinking or getting tattoos. And for centuries, the American legal system has used the best-interest-of-the-child standard to determine the outcome of custody determinations.

Senate Bill 1 continues this centuries-long commitment to protecting the best interests of children. It regulates two—and only two—treatments for gender dysphoria: puberty blockers and cross-sex hormones. Puberty blockers suppress an adolescent patient's natural puberty. Cross-sex hormones—administering testosterone to biological females and estrogen to biological males—induce the adolescent

patient to undergo some (but not all) aspects of the opposite sex's puberty. These treatments physically and permanently change a patient's body to conform more to their gender identity.

Given the little that modern science can inform us about gender dysphoria in children and adolescents, combined with the gravity inherent in prescribing irreversible treatment to a potentially misdiagnosed patient, Senate Bill 1 accords with every conceivable notion of medical ethics to which Amici are aware.

patients often suffer Adolescent comorbidities such as anxiety, depression, and even autism, all of which present psychological distress like gender dysphoria. This makes it treacherously difficult to determine whether a child experiencing psychological distress would do best with permanent. life-changing intervention, or may instead improve with a less-drastic treatment aimed at a comorbidity. Moreover, puberty blockers and cross-sex hormones present concerning risks, particularly to adolescent patients. Cardiovascular disease, impaired brain development, sexual disfunction, infertility, increased risk of cancer, and decreased bone-mineral density have all been observed in patients receiving puberty blockers and cross-sex hormones. These are all enduring negative side effects that should be avoided in adolescent patients at all costs. And medical researchers agree that the purported benefits of puberty blockers and cross-sex hormones on mentalhealth outcomes in adolescents with dvsphoria backed by limited are data methodologically questionable studies. Even the often-cited World Professional Association

Transgender Health ("WPATH") and Endocrine Society standards recognize these limitations.

For all these reasons, Senate Bill 1 is plainly reasonable and entirely in line with the applicable standard of medical care—doing what is in the best interest of the adolescent patient. So much so that even European countries that were once all-in on "gender-affirming care" have pressed the brakes, taking similar action to limit puberty blockers and cross-sex hormones as treatments for adolescent patients. Moreover, Senate Bill 1's focus on regulating treatments for a specific diagnosis tracks with decades of medical treatment regulation; it is not evidence of any class-based distinction.

This Court should not, by constitutional fiat, bind states' ability to continue the centuries-long tradition of ensuring children receive only that medical care that is in their best interest. Accordingly, the Court should affirm the Sixth Circuit's judgment.

ARGUMENT

I. Physicians and lawmakers must consider the best interests of the child when prescribing and regulating adolescent treatments.

According to tradition, a contemporary of Socrates penned the earliest oath of medical ethics known to the Western world. From that time—roughly twenty-five-hundred years ago—through the present, physicians have been required to swear or affirm that they will abide by Hippocrates's tenets before they begin their vocation of tending to the needs of others.

Among the most important affirmations in the Hippocratic oath is the following: "I will use those...regimens which will benefit my patients according to my greatest ability and judgment, and I will do no harm or injustice to them."

Another way of promising to "do no harm" is to swear that the best interest of the patient will always take precedence. The importance of this principle should be self-evident; were it otherwise, the patient would likely be better off not seeing a physician at all. And indeed, the best-interest standard is the vernacular used by modern medical-ethics codes to get at the same principle that Hippocrates pronounced in the 5th Century BCE.

Similarly self-evident is the notion that what is in the best interest of one might not be in the best interest of another, given—as is particularly relevant here—the age of the patient. Modern medicine recognizes this point (perhaps implicitly) by codifying different ethical codes for children and adults. An example of the former is the American Academy of Child & Adolescent Psychiatry's Code of Ethical Principles, which states that "[t]he welfare and needs of the child should be paramount."

One reason (among others) that treatment for children differs from treatment for adults is that children undergo a profound developmental transition when they reach puberty. Interrupting or

² AM. ACAD. OF CHILD & ADOLESCENT PSYCHIATRY, AACAP CODE OF ETHICAL PRINCIPLES, Principle II, available at https://www.aacap.org/aacap/Member_Resources/Ethics/Found ation/AACAP_Code_of_Ethical_Principles.aspx.

altering that tremendously complicated biological process can have a cornucopia of unintended, cascading consequences. For that reason, American Medical Association requires physicians to base "treatment recommendations on the best available evidence and general in prefer[s] alternatives that will not foreclose important future choices by the adolescent and adult the patient will become."3 Doing so advances a physician's "obligation to promote the optimal wellbeing, functioning and development of youth," which, given the undeniable influence that peers have on each other, must "be prioritized over . . . societal pressures."4

These ethical standards have informed and shaped laws for centuries. And, given a sovereign's obligation to legislate for purposes of public health (the lodestar of the police powers) and to protect the rights of all its citizens, the best-interest-of-the-child standard has permeated legal codes and decisions worldwide. For example, in the United States, for nearly the entire history of the Republic, the bestinterest standard has stood tall as the central precept of American family law. Tennessee, like every other state, requires custody determinations to "be made on the basis of the best interest of the child." Tenn. Code Ann. § 36-6-106(a). Lawmakers are regularly tasked with articulating factors that may determine what action is in a child's best interest, and courts routinely apply these factors to real-life circumstances. Indeed,

³ Am. MED. ASS'N, CODE OF MED. ETHICS, Op. 2.2.1, *Pediatric Decision Making*, available at https://code-medical-ethics.ama-assn.org/ethics-opinions/pediatric-decision-making.

 $^{^4\,\}mathrm{Am}.$ Acad. of Child & Adolescent Psychiatry, supra note 2.

Tennessee law articulates sixteen factors to determine what custody determination is in a child's best interest, including the child's relationship with their parents, each parent's willingness and ability to perform parental responsibilities, and each parent's ability to provide the child with necessary care. *Id*.

Other laws, if not expressly adopting the bestinterest standard, are at least informed by it. For example, states routinely restrict minors from engaging in certain activities based on the unique risks they pose to children. In Tennessee, minors cannot possess, consume, or purchase alcohol. Id. §§ 39-15-404, 57-5-301. The state also limits their ability get a tattoo or body piercing. Id. §§ 62-38-211, 62-38-305. And this Court long ago held that states may restrict children's access to sexually explicit materials that the state could not restrict for adults. Ginsberg, 390 U.S. at 637–43. That is because "[t]he well-being of its children is of course a subject within the State's constitutional power to regulate," and "[t]he State also has an independent interest in the well-being of its youth." *Id.* at 639–40.

In other words, there is nothing new about states legislating in the best interest of the child. States must do so, and indeed, have done so for centuries.

To know what in fact is in an adolescent patient's best interest requires eliminating as many unknown variables as possible. That, however, is far easier said than done. Diagnosing a child, particularly in the realm of psychiatry and psychology, is far more fraught than diagnosing a fully developed adult, especially as social, peer, and even parental pressure amplifies. And given this murkiness, the risks of

providing adult-intended treatment to children swell precipitously, especially when the treatment produces changes that cannot be reversed. For this reason, sometimes the best interest of the child demands circumspection.

II. Senate Bill 1 continues the twomillennia-long tradition of ensuring that physicians act in the best interests of their adolescent patients.

Amici, fifty-six physicians who treat adolescent patients across the country, speak in unison. Given the little that modern science can inform us about gender dysphoria in children and adolescents, combined with the gravity of prescribing irreversible treatment to a potentially misdiagnosed patient, Senate Bill 1 accords with every conceivable notion of medical ethics to which Amici are aware. It regulates treatments—and only two treatments commonly prescribed for those experiencing gender dysphoria: puberty blockers and cross-sex hormones. The former stymy natural pubertal development while the latter induce some aspects of pubertal development of the opposite sex. Given the permanent changes that these treatments produce, the natural fickleness of children compared to adults, and the dearth of reliable data showing that puberty blockers and cross-sex hormones in fact serve the best interest of a child who might (or might not) be experiencing psychological distress caused by gender dysphoria, Senate Bill 1 is plainly reasonable and entirely in line with the applicable standard of medical care.

A. Adolescent patients often experience treatable psychological distress from conditions other than gender dysphoria.

To diagnose an individual with gender dysphoria. a physician must determine that the patient is experiencing severe psychological distress resulting from an incongruence between their biological sex gender identity. But children regularly experience severe psychological distress conditions other than gender dysphoria. And this psychological distress does not always reflect an inherent, gender-nonconforming identity. This makes it increasingly complex to determine whether a child's psychological distress can be successfully treated using puberty blockers and cross-sex hormones, or whether more traditional treatments would be more successful. As a result, extreme caution is warranted in prescribing these life-altering treatments.

Current medicine understands sex to be based on biology and anatomy, while gender comprises culturally constructed attributes associated with masculinity or femininity. Gender identity, in turn refers to a person's psychological sense of their gender, which can change throughout one's life. If gender identity diverges from biological sex in a way that causes severe discomfort or distress, a gender-dysphoria diagnosis may follow. Critically, however, permanence of these feelings is not a prerequisite for a gender-dysphoria diagnosis. Neither is a determination that the discomfort is driven by something other than social or peer pressure.

Sometimes, children younger than seven years old experience symptoms that may suggest gender dysphoria.⁵ *Eighty percent*, however, see their symptoms abate with the onset of puberty.⁶ For these reasons, medical professionals have warned against early interventions to treat gender dysphoria prior to or during the early stages of puberty. And this makes sense; if the symptoms of gender dysphoria fluctuate, a treatment that produces irreversible changes makes little sense.

Further, adolescent patients often suffer from multiple diagnoses at once, which necessarily cloud their subjective understanding and make it even tougher to assess whether their distress is attributable to gender dysphoria or to something else. Indeed, studies suggest that between one-third and three-quarters of adolescents with gender dysphoria "display clinically significant psychopathology to the same extent as adolescents referred to mental health services *due to other reasons.*"

This complication cannot be overstated. Depression, anxiety, self-harm, and suicidal ideation are common in children who are examined for gender and studies have suggested dysphoria. adolescents with gender dysphoria experience autism-spectrum disorders at higher rates than their

⁵ Michael Zaliznyak et al., Age at First Experience of Gender Dysphoria Among Transgender Adults Seeking Gender-Affirming Surgery, JAMA NETWORK OPEN, Mar. 2020, at 3.

⁶ Riittakerttu Kaltiala-Heino et al., Gender Dysphoria in Adolescence: Current Perspectives, 9 Adolescent Health, Med. & Therapeutics 31, 33 (2018).

⁷ *Id.* (emphasis added) (collecting studies).

peers.⁸ Each of these conditions can drive the sort of psychological distress that might incorrectly be attributable to gender dysphoria, especially in a population that may not have the age-evolved sense to know why they do not feel okay the way they are.

B. Puberty blockers and cross-sex hormones pose concerning risks to adolescent patients.

The foregoing makes it treacherously difficult to determine whether a child experiencing psychological distress would do best with permanent, life-changing intervention, or may instead improve with a less-drastic treatment aimed at a comorbidity. Physicians (including Amici) know this. So too, does Tennessee. That's why it enacted Senate Bill 1.

To reiterate, Senate Bill 1 regulates only two treatments, both of which have lasting effects: puberty blockers and cross-sex hormones. Puberty blockers suppress an adolescent patient's natural puberty. Cross-sex hormones—administering testosterone to biological females and estrogen to biological males—induce the adolescent patient to undergo some (but not all) aspects of the opposite sex's puberty. Ninety-eight percent of adolescent patients with gender dysphoria who receive puberty blockers later receive cross-sex hormones.⁹ These treatments physically and permanently change a

⁸ Id. at 34.

⁹ Maria Anna Theodora Catherina van der Loos et al., Continuation of Gender Affirming Hormones in Transgender People Starting Puberty Suppression in Adolescence: A Cohort Study in the Netherlands, 6 LANCET CHILD & ADOLESCENT HEALTH 869 (2022).

patient's body to conform more to their gender identity. Once puberty ends, the effects of these treatments cannot be reversed. Starting this treatment, then, is a profoundly difficult and weighty decision that will have consequences for the rest of a child's life.

The risks do not end with the distress a patient may eventually feel after a gender-dysphoria misdiagnosis and irreversible bodily changes. The phrase "gender-affirming care" masks a host of these treatments' pernicious, well-documented side effects. Cardiovascular disease, impaired brain development, sexual dysfunction, an increased risk of cancer, and decreased bone-mineral density have all been observed in patients receiving puberty blockers and cross-sex hormones. Infertility is also possible, particularly in biological males. Indeed. transgender-care provider counsels patients that "it is best to assume that within a few months of starting [cross-sex hormones] you could permanently and irreversibly lose the ability to create sperm." 10 But despite the United States' suggestion that patients simply freeze their sperm or eggs for future assisted reproduction, U.S. Br. 44, doing so is an obviously cold comfort for a person who may have had a childhood. tremendously difficult but nonetheless grew up desiring to have children without the added difficulty of assisted fertilization.

¹⁰ Dr. Maddie Deutsch, *Overview of Feminizing Hormone Therapy*, UCSF TRANSGENDER CARE (July 2020), https://transcare.ucsf.edu/article/information-estrogen-hormone-therapy.

And that is a staggeringly complex and unnecessary decision to ask a 12, 13, or 14-year-old child to make.

Moreover, growing evidence suggests that "[p]uberty blockers may actually *cause* depression and other emotional disturbances related to suicide," rather than alleviate them. ¹¹ In fact, Lupron, the most-prescribed puberty blocker in the United States, now "lists 'emotional instability' as a side effect and warns prescribers to '[m]onitor for development or worsening of psychiatric symptoms during treatment." ¹²

None of this is reversible. While endogenous puberty may resume if puberty blockers are discontinued without cross-sex hormones, most patients who take puberty blockers later receive cross-sex hormones. And once cross-sex hormones are administered, it becomes increasingly difficult to reverse the resulting changes in the patient's physical characteristics. Even if the physical changes induced by these treatments were reversible, the risks themselves are not. Infertility, weakened bone density, and the risk of cancer will all follow the child for the rest of his or her life.

Of note, gender-dysphoria treatment (particularly in children) is not binary. Effective, less-risky treatments exist. Traditional therapeutic treatments may alleviate psychological distress until the gender dysphoria subsides or the adolescent patient can

¹¹ Transgender Interventions Harm Children, AM. COLL. OF PEDIATRICIANS (last visited Oct. 14, 2024) (emphasis added), https://acpeds.org/transgender-interventions-harm-children.

 $^{^{12}}$ *Id*.

make a fully informed decision about more drastic treatments. And because less than one-third of adolescents experiencing gender dysphoria continue to do so after they reach adulthood, is circumspection remains in the best interest of the child.

C. The purported benefits of puberty blockers and cross-sex hormones are backed by limited data and methodologically questionable studies.

Exacerbating these concerns is that the benefits of puberty blockers and cross-sex hormones are backed by limited data and methodologically questionable studies. For example, many argue that these treatments are necessary to prevent suicide and suicidal ideation. But all current studies on these treatments' impact on suicidality suffer from methodological errors. Most gloss over other psychiatric diagnoses; the presence, type, and timing of psychiatric treatment; or comorbid substance abuse. These failures impair the validity and robustness of current suicidality studies' results. And at least one of those studies found that incidence of mental healthcare visits for suicidality *increased* following the initiation of cross-sex hormones. If

¹³ Pien Rawee, et al., Development of Gender Non-Contentedness During Adolescence and Early Adulthood, 53 Archives of Sexual Behav. 1813 (2024).

¹⁴ Daniel Jackson, Suicide-Related Outcomes Following Gender-Affirming Treatment: A Review, 15(3) CUREUS 11–13 (2023).

¹⁵ *Id.*

¹⁶ *Id.* at 9.

Even the often-cited WPATH and Endocrine Society standards of care recognize the current limitations on benefits of puberty blockers and cross-sex hormones. For example, WPATH admits that "formal epidemiologic studies on gender dysphoria—in children, adolescents, and adults—are lacking. Additional research is needed to refine estimates of its prevalence and persistence in different populations worldwide."¹⁷

The Endocrine Society's guidelines are even more explicit. It uses a grading system to rate the evidence quality for a treatment recommendation: evidence is either high, moderate, low, or very low quality. Every recommended gender-dysphoria treatment for adolescents is backed by low- or very low-quality evidence. Not a single recommendation is backed by high- or moderate-quality evidence. This includes the following recommendations: 19

 "[T]hat adolescents who meet diagnostic criteria for [gender dysphoria], fulfill criteria for treatment, and are requesting treatment

¹⁷ World Prof. Ass'n for Transgender Health, Standards of Care for the Health of Transsexual, Transgender, and Gender Nonconforming People 11 (7th ver. 2012).

¹⁸ ENDOCRINE SOCIETY, ENDOCRINE SOCIETY GUIDELINE METHODOLOGY 2 (2022), available at https://www.endocrine.org/-

[/]media/endocrine/files/cpg/methodology-page-refresh/endocrine_society_guideline_methodology_links.pdf.

¹⁹ Wylie C. Hembree et al., Endocrine Treatment of Gender-Dysphoric/Gender-Incongruent Persons: An Endocrine Society Clinical Practice Guideline, 102 J. CLINICAL ENDOCRINOLOGY & METABOLISM 3869, 3871 (2017).

should initially undergo treatment to suppress pubertal development." (Low quality).

- "[T]hat clinicians begin pubertal hormone suppression after girls and boys first exhibit physical changes of puberty." (Low quality).
- "[T]hat there may be compelling reasons to initiate sex hormone treatment prior to the age of 16 years in some adolescents with [gender dysphoria], even though there are minimal published studies of gender-affirming hormone treatments administered before age 13.5 to 14 years." (Very low quality).

Given these concerns, it is abundantly reasonable for physicians and lawmakers to conclude that the purported benefits of puberty blockers and cross-sex hormones are not outweighed by the known risks and are therefore not in the best interest of adolescent patients.

III. National and global medical consensus supports reasonable restrictions on using puberty blockers and cross-sex hormones to treat gender dysphoria.

For all these reasons, a growing chorus of physicians and lawmakers in the United States and across the globe have called for reasonable restrictions on using puberty blockers and cross-sex hormones to treat gender dysphoria, particularly in adolescent patients.

In recent years, the global consensus on puberty blockers and cross-sex hormones has turned. Countries that once liberally promoted access to "gender-affirming care" have either recommended caution or nixed the treatments altogether. For example, in March 2024, the United Kingdom's National Health Service ("NHS") decommissioned the use of puberty blockers to treat gender dysphoria in adolescent patients.²⁰ This followed the release of a years-long report commissioned by NHS, concluding that "[o]ur current understanding of the long-term health impacts of hormone interventions is limited and needs to be better understood."²¹

Other countries have reached similar conclusions:

• Sweden: In 2022, Sweden's National Board of Health and Welfare released updated guidelines for treating minors with gender dysphoria, encouraging "[c]aution in the use of hormonal and surgical treatment" for minor patients, and instead directing practitioners to employ lower-risk measures like "[s]exology counselling and treatment."22 The Board

²⁰ NHS England, Clinical Policy: Puberty Suppressing Hormones (PSH) for Children and Young People Who Have Gender Incongruence/Gender Dysphoria (Mar. 12, 2024), https://www.england.nhs.uk/wp-

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 $^{^{21}}$ Hilary Cass et al., Independent Review of Gender Identity Services for Children and Young People: Final Report 22 (2024).

²² Care of Children and Adolescents with Gender Dysphoria, SOCIALSTYRELSEN: NAT'L BD. OF HEALTH & WELFARE (2022), https://www.socialstyrelsen.se/globalassets/sharepoint-dokument/artikelkatalog/kunskapsstod/2023-1-8330.pdf.

recognized that "the risks of puberty-inhibiting and gender-affirming hormone treatment for those under 18 currently outweigh the possible benefits for the group as a whole."²³

- France: The French National Academy of Medicine noted in 2022 that "great medical caution must be taken in children and adolescents. given the vulnerability, particularly psychological, of this population and the many undesirable effects, and even serious complications, that some of the available therapies can cause."24 The Academy concluded that "the greatest reserve is required" in the use of puberty blockers and cross-sex hormones, "given the side effects such as impact on growth, bone fragility, risk of sterility, emotional and intellectual and, girls, consequences for symptoms reminiscent of menopause."25
- **Finland:** In 2020, Finland's Council for Choices in Health Care placed restrictions on

²³ Thomas Linden, *Updated Recommendations for Hormone Therapy for Gender Dysphoria in Young People*, SOCIALSTYRELSEN: NAT'L BD. OF HEALTH & WELFARE (Feb. 22, 2022), https://www.socialstyrelsen.se/omsocialstyrelsen/pressrum/press/uppdateraderekommendationer-for-hormonbehandling-vid-konsdysfori-hosunga/.

²⁴ Medicine and Gender Transidentity in Children and Adolescents, FRENCH NAT'L ACADEMY OF MED. (Feb. 25, 2022), https://www.academie-medecine.fr/la-medecine-face-a-la-transidentite-de-genre-chez-les-enfants-et-les-adolescents/?lang=en.

 $^{^{25}}$ *Id*.

using puberty blockers and cross-sex hormones to treat gender dysphoria and recommended psychotherapy as the primary treatment.²⁶ The Council noted that "[t]he reliability of the existing studies with no control groups is highly uncertain, and because of this uncertainty, no decisions should be made that can permanently alter a still-maturing minor's mental and physical development."²⁷

• Australia & New Zealand: The Royal Australian and New Zealand College of Psychiatrists notes that "[d]istress associated with gender may in some situations be related to a range of psychosocial issues or mental health conditions" and that "[t]here are methodological limitations in studies which assess the effectiveness of all models of treatment on the mental health of children adolescents with Gender Dysphoria."28

²⁶ PALVELUVALIKOIMA, RECOMMENDATION OF THE COUNCIL FOR CHOICES IN HEALTH CARE IN FINLAND: MEDICAL TREATMENT METHODS FOR DYSPHORIA RELATED TO GENDER VARIANCE IN MINORS 7 (2020), https://segm.org/sites/default/files/Finnish_Guidelines_2020_Minors_Unofficial%20Translation.pdf.

²⁷ *Id.* at 7.

²⁸ The Royal Australian & New Zealand Coll. Of Psychiatrists, Position Statement, The Role of Psychiatrists in Working with Trans and Gender Diverse People (Dec. 2023), https://www.ranzcp.org/clinical-guidelines-publications/clinical-guidelines-publications-library/role-of-psychiatrists-working-with-trans-gender-diverse-people.

In America too, the "[o]pinion on the use of puberty blockers... is turning." Even courts have recognized that "[a]ny claim to 'consensus' in the medical community [regarding these treatments]—never a claim that reflected reality—seems to be crumbling quickly, even on its own terms." State v. Loe, 692 S.W.3d 215, 241 n.5 (Tex. 2024) (Blacklock, J., concurring).

It is against this backdrop that Tennessee—and nearly half of all U.S. states³⁰—chose to reasonably regulate puberty blockers and cross-sex hormones as treatments for gender dysphoria. Like Senate Bill 1, these other state laws regulate or prohibit these

²⁹ Opinion on the Use of Puberty Blockers in America is Turning, ECONOMIST (Oct. 16, 2021), https://www.economist.com/united-states/2021/10/16/opinion-on-the-use-of-puberty-blockers-in-america-isturning?utm_medium=cpc.adword.pd&utm_source=google&ppc campaignID=17210591673&ppcadID=&utm_campaign=a.22bra nd_pmax&utm_content=conversion.direct-response.anonymous&gad_source=1&gclid=EAIaIQobChMI7bz 2vID4iAMVA4daBR0yZi5XEAMYASAAEgJeRPD_BwE&gclsrc=aw.ds.

 $^{^{30}}$ E.g., Ala. Code § 26-26-4; Ark. Code Ann. § 20-9-1502; Ga. Code Ann. § 31- 7-3.5; Idaho Code § 18-1506C; Ind. Code § 25-1-22-13; Iowa Code § 147.164; La. Stat. Ann. § 40:1098; Miss. Code Ann. § 41-141-1-9; Mo. Rev. Stat. Ann. § 191.1720; Neb. Rev. Stat. § 72-7301-07; N.D. Cent. Code. § 12.1-36.1-02; Okla. Stat. tit. 63, § 2607.1; Tex. Health & Safety Code § 161.702(3); Utah Code Ann. § 58-68-502(1)(g); W. Va. Code § 30-3-20; see also Elliott Davis, Jr., States That Have Restricted Gender-Affirming Care for Trans Youth, U.S. News (Aug. 27, 2024), https://www.usnews.com/news/best-states/articles/2023-03-30/what-is-gender-affirming-care-and-which-states-have-restricted-it-in-2023#flor (listing twenty-four states that have banned puberty blockers and cross-sex hormones through legislation or other government action) .

treatments for adolescent patients, citing the growing consensus that the risks of such treatments dwarf the purported benefits. And courts have repeatedly upheld these laws, noting they represent "a permissible, rational policy choice," *Loe*, 692 S.W.3d at 223 (upholding Texas law), and are based on "record evidence," *Eknes-Tucker v. Governor of Ala.*, 80 F.4th 1205, 1225 (CA11 2023) (upholding Alabama law).

Accordingly, given the growing national and global consensus against using puberty blockers and cross-sex hormones to treat gender dysphoria in adolescent patients, it is reasonable for physicians and lawmakers to conclude such treatments are not in the best interest of the child.

IV. Senate Bill 1 is a reasonable restriction on particular treatments for a gender-dysphoria diagnosis.

Finally, Senate Bill 1 is a reasonable approach to regulating these treatments because it distinguishes based on diagnosis and no other factor. Such diagnosis-based distinctions are the hallmark approach to regulating medical treatments. Indeed, governments have long prohibited certain treatments for some diagnoses while permitting them for others. And this is particularly true for adolescent patients. This Court should not bind states' ability to work with the medical community to ensure physicians prescribe safe and effective treatments that are in the best interest of their adolescent patients.

While diagnosis-based distinctions may have a greater effect on one class than another, they are not

class-based distinctions. Perhaps the most famous example is thalidomide. Widely marketed during the 1950s as a miracle drug to relieve morning sickness in pregnant women, thalidomide caused severe birth defects in more than 10,000 children. As a result, it was widely banned in the early 1960s. But thalidomide has since been approved as a treatment for other diagnoses, like certain skin disorders and cancers. While the continued ban on thalidomide as a treatment for morning sickness disproportionately affects women, it cannot rationally be considered a sex-based distinction. Moreover, while thalidomide is permitted for other diagnoses suffered by women, it cannot rationally be considered an invidious distinction against pregnant women as a class.

Another example, isotretinoin, commonly known as Accutane, is an oral medication primarily prescribed for treating severe acne. Like thalidomide, it carries a severe risk of birth defects if taken while pregnant. As a result, in the United States, biological women of child-bearing age must enroll in a program in which they pledge to take contraception and routine pregnancy tests while taking isotretinoin. Biological men can obtain an isotretinoin prescription with significantly fewer hurdles. Even so, the regulatory framework that disproportionately burdens female patients cannot rationally be considered a sex-based distinction.

So too, with Senate Bill 1. As lower courts have recognized, puberty blockers and cross-sex hormones are unique in that the treatments themselves depend on sex. *Eknes-Tucker*, 80 F.4th at 1228. "The cross-sex hormone treatments for gender dysphoria are different for males and for females because of

biological differences between males and females—females are given testosterone and males are given estrogen." *Id.* The fact that a treatment itself is sexbased, however, does not transmogrify Senate Bill 1 into an unconstitutional sex-based law.

Similarly, Senate Bill 1 does not discriminate based on transgender status. It is widely recognized in the medical profession that gender dysphoria does not mean that a person is transgender—a gender-dysphoria diagnosis signifies no more than a patient is experiencing distress based on a current belief that the person's biological sex does not correspond with the person's gender identity. Many transgender people live according to their gender identity without experiencing the severe anxiety or stress associated gender dysphoria, and without that distress, the person does not need (and may not want) puberty blockers or cross-sex hormones.

All this is a matter of biology, and not constitutional law. Biological sex plays determinative role in what treatments physicians should prescribe for certain diagnoses and how effective those treatments will be. The inherent differences between the sexes, from reproductive anatomy to hormonal profile, can cause significant variations in how medications are absorbed and side metabolized and how effects manifest. Legislation that accounts for these differences is critical to protecting patient health and ensuring that physicians account for the best interest of their adolescent patients by providing scientifically and ethically appropriate treatments to the patient's biology, regardless of their gender identity.

CONCLUSION

Senate Bill 1 reasonably restricts access to risky, life-altering treatments for adolescents under the centuries-old tradition of ensuring adolescent patients receive only medical care that is in their best interest. Accordingly, the Court should affirm the Sixth Circuit's judgment.

Respectfully submitted,

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