No. 23-477

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

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BRIEF OF *AMICUS CURIAE* AMERICAN PRINCIPLES PROJECT IN SUPPORT OF RESPONDENTS

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INTEREST OF AMICUS[1]

American Principles Project (APP) is a national non-profit organization engaging in research, public education, and advocacy on behalf of the institution of the family. It evaluates public policy, legislation, culture, and social and political trends as those factors affect parents, children, communities, and the health, welfare, and liberties of the American citizenry. It also files legal briefs as amicus in cases that implicate those issues. APP has advocated for measures protecting children from exposure to harmful content online and testified before state legislatures in that regard. APP recently published a research paper on the subject of "gender-affirming-care" (GAC), evaluating that fast-evolving industry and analyzing both the supposed benefits it promises to American youth, as well as more importantly, the actual risks that it poses to them, issues that lie at the heart of this case.

SUMMARY OF THE ARGUMENT

The correct standard of review for the law in question, TENN. CODE ANN. §§ 68-33-101 *et seq*. (SB1), is rational basis, and not any form of heightened scrutiny.

The question presented concerns U.S. Const. Amend. XIV, § 1 (Equal Protection Clause), rather than 42 U.S.C. 2000e-2(a)(1) (Title VII), a statute construed in *Bostock v. Clayton Cnty.*, 590 U.S. 644 (2020). Yet the *Bostock* case is cited several times by Petitioner United States (Government). The attempt by the Government to equate that statute with the constitutional guarantee of equal protection under an alleged commonality of

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[1] Rule 37 Statement: No part of this brief was authored by any party's counsel, and no person or entity other than *amicus* funded its preparation or submission.

sex discrimination fails for several reasons, including the substantial differences between that statute and the Equal Protection Clause, distinguishable by their differences in text, underlying context, and purposes.

Nor does "gender identity" qualify as a "suspect class" or a quasi-suspect class. The Government argues that the medical practices prohibited to minors under SB1 are necessary for minors with "gender dysphoria." Brief of Pet. ("Br.") 2-7, 9-10, 18, 26-27, 33, 36-38, 39-43, 45, 47-48. However, that condition is not an immutable, organic or physical condition, but is a psychological one, consisting of a mental or emotional "incongruence" between the sex with which such minors self-identify and their biological sex and thus is defined by mental and psychological factors. Mental conditions or disabilities cannot create a suspect class. *City of Cleburne v. Cleburne Living Ctr., Inc.*, 473 U.S. 432 (1985). It follows, then, that intentions or perceptions regarding one's own personal gender identity do not create a suspect or quasi-suspect class.

Neither is the text of SB1 "sex-based" or "gender-based." As the Court made clear in *Dobbs v. Jackson Women's Health Org.*, 597 U.S. 215 (2022), medical regulations, even those directly impacting only one sex (as in state regulations of abortion), are not deemed to be based on sex but are "health and safety" statutes subject to rational basis review and not heightened scrutiny. Additionally, there is no evidence here for applying the specific exception in *Dobbs* where a law is a product of *pretext* (or *targeting* as the Government phrases it), because neither are present in SB1 which treats minors of both sexes the same.

Tennessee's SB1 does not enforce "gender conformity," as the Government contends. The text of the law when taken in context seeks to avoid the negative effects of

minor's gender transition procedures that are "*harmful,*" or "e*xperimental*," or "*unsupported by high-quality or long-term studies*." TENN. CODE ANN. § 68-33-101(m) (emphasis added). The statute rests upon Tennessee's legitimate interest in protecting minors from being subjected to medical treatments falling into any of those three categories.

First, there are indeed *harmful* aspects of "gender-affirming care" (GAC) for minors: temporary or even permanent infertility from long-term use of cross-sex hormones; developmental harms in bone maturation and bone mineral density; benefits are largely "unknown" due to insufficient studies on the degree of psychosocial improvement for females, while there is demonstrated lack of improvement for males regarding the very symptoms, like depression and anxiety, that drive the use of GAC; plus, potential risks to minors exist with long-term use of cross-sex hormones in light of serious complications for adults after lengthy hormone use. See, *infra*, Sections II. C. - E.

Second, the Sixth Circuit determined the procedures the Government defends are "in truth still experimental," Pet. App. 48a, directly related to an objective in § 68-33-101(m).

Third, the rapidly growing "gender affirming care" (GAC) industry lacks both long-term studies and rigorous trials of any kind regarding the efficacy and safety of the procedures for minors at issue here.

The methodological deficiencies are many that taint the medical justification for GAC for the young. Amicus APP's own report documents: (1) stringent protocols are lacking to determine the best health alternatives for minors seeking GAC; (2) puberty blockers are often pushed by practitioners at the very

first appointment; and (3) parents are too often pressured into GAC for their children with the unsurprising result that lawsuits brought by former child patients and their parents are increasing because of gender-transition-regret connected to the rush-to-judgment professional culture surrounding GAC. In a peer-reviewed study of 100 GAC patients who decided to "detransition" after GAC, more than half reported they did not receive adequate evaluation from a doctor or mental health professional before starting the transition process.

Only two national studies on the potential risks and efficacy of GAC for minors have been conducted by independent experts *not* already advocating for, or already performing GAC. One was commissioned by the United Kingdom's National Health Service, and the other was authorized by the health service of Finland. Their findings show a plethora of unreasonable risks to youth, including: (1) unstudied areas of harm such as impact on brain maturation, (2) a failure of data to support expectations of success or efficacy, and (3) the resulting inability to provide adequate medical data for a truly informed consent from minor patient or parents.

The Government and its experts rely extensively on information from the World Professional Association of Transgender Health (WPATH). But as the Sixth Circuit noted, WPATH has continued to lower its restrictions and standards regarding GAC for minors despite the increase of professional disagreement over gender transition protocols for children. The United Kingdom's National Health Service has now distanced itself from WPATH regarding GAC for minors. According to expert witness Dr. James Cantor, Ph.D., the WPATH-commissioned study failed to study minors' safety, it

contained "discrepancies" and "misleading ambiguities," and WPATH's guidelines are not "evidence-based" at all. J.A. 373, ¶¶ 93-94; 377, ¶ 97; 377,¶ 103.

The risks and the potential dangers for minors are sufficiently real to justify SB1 as a reasonable method to protect them.

ARGUMENT

I. THE RATIONAL BASIS TEST APPLIES TO SB1.

A. *Bostock* Does Not Apply.

The Government's hailing of *Bostock v. Clayton Cnty.*, 590 U.S. 644 (2020), does nothing to benefit its case. Br. 13, 22, 28. *Bostock* was a Title VII case, not an equal protection case, and the substantial distinctions between the two have been cited by Justices Alito and Kavanaugh in *Bostock*, and by Justice Gorsuch in a more recent case regarding a related statute. We urge the Court to resist any "gravitational pull in constitutional cases" like this one that would diminish and devalue the "important differences between the Fourteenth Amendment and Title VII." *Bostock*, 590 U.S. at 733 (Alito, J., dissenting). In fact, relatedly, "Not a single Justice [in the Court's sexual orientation cases] stated or even hinted that sexual orientation discrimination was just a form of sex discrimination and therefore entitled to the same heightened scrutiny under the Equal Protection Clause." *Id*. at 798 (Kavanaugh, J., dissenting). Likewise, in a case involving Title VI of the same civil rights statute, Justice Gorsuch referenced the many "obvious differences" between Title VI and the Equal Protection Clause." *Students for Fair Admissions, Inc. v. President & Fellows of Harvard Coll.*, 600 U.S. 181, 308 (2023) (Gorsuch, J., concurring).

The Court should reject the Government's attempt to boot-strap the *Bostock* ruling about a mid-twentieth century federal civil rights statute to the Equal Protection Clause that was adopted a hundred years earlier, with a different text and in a different context, and for different reasons.

B. "Gender Identity" Is Not a Suspect Classification.

The Government's argument that SB1 classifies based on sex and discriminates against "transgender individuals," Br. 18, incorrectly assumes the existence of a "suspect" or "quasi-suspect" class here. In fact, *no* Supreme Court precedents support such a class.

If the factor of immutable characteristics is applied here as in past decisions of the Court, deciding whether gender identity is a new suspect class is even more straightforward. *See Frontiero v. Richardson*, 411 U.S. 677, 686 (1973) ("[S]ex, like race and national origin, is an immutable characteristic determined solely by the accident of birth"). *See also Craig v. Boren*, 429 U.S. 190, 212, n.2 (1976) (Stevens, J., concurring) (citing *Frontiero).*

In the context of equal protection, sex means an aspect of human nature determined objectively by means of natural biology, rather than by cosmetic appearance, medicine, surgery, or one's own ideation. External physical anatomy results *from* one's objective, biological sex status, rather than vice-versa. By contrast, determining a person's "gender" by how that person *identifies* becomes a purely subjective and malleable inquiry, the opposite of immutability, a fact that patient *detransition* illustrates; and which the Six Circuit recognized. Pet. App. 46a. *See also infra*, Section II. E. 4.

The Sixth Circuit rightly noted the absence of any Court precedents for the creation of a new suspect, or quasi-suspect class for gender identity, and the "high" bar to do so -

> [N]either the Supreme Court nor this Court has recognized transgender status as a suspect class. Until that changes, rational basis review applies.
>
> The bar for recognizing a new suspect class is a high one. The Supreme Court "has not recognized any new constitutionally protected classes in over four decades, and instead has repeatedly declined to do so." *Ondo [v. City of Cleveland]*, 795 F.3d [597,] 609 [(6th Cir. 2015)]; *see City of Cleburne,* 473 U.S. at 442 (mental disability is not a suspect class); [*Mass. Bd. of Ret. v.*] *Murgia*, 427 U.S. [307,] 313–14 [(1976)] (age is not a suspect class).

Pet. App. 44a.

C. Psychological Conditions Do Not Make a Suspect Class.

The Government argues that the State law here (and similar laws) "classify based on sex and discriminate against transgender individuals … by denying medical treatments … to treat a serious medical condition." Br. 18. Not to be missed is the Government's emphasis on the word "medical." While the treatments at issue can be categorized as "medical" (indeed they are administered by medical staff), the condition of "gender dysphoria" is not medical. Rather, it is a psychological condition, as the Government seemingly admits —- having defined it as a condition "characterized by clinically significant distress resulting from incongruence between a person's gender identity

and sex assigned at birth." Br. 3. Mental or emotional "incongruence" about sex is plainly psychological and psychiatric in nature.

The American Psychiatric Association has similarly defined the condition of "gender dysphoria" as "*psychological* distress that results from an incongruence between one's sex … and one's … psychological sense of [his or her] gender" (emphasis added).[2] So has the American Psychological Association, which more importantly uses the term "gender identity" to mean "[a]n *internal sense* of being male, female or something else." *A Glossary: Defining Transgender Terms*, 49 AM. PSYCH. ASS'N, MONITOR ON PSYCH. 32 (Sept. 2018), https://www.apa.org/monitor/2018/09/ce-corner-glossary, *cited in Bostock*, 590 U.S. at 715 n.29 (2020) (Alito, J., dissenting) (emphasis added). The condition that the Government designates for heightened constitutional protection is, ultimately, a person's malleable "internal sense" of his or her sex.

The Government wants suspect classification protection for the relatively opaque workings of an "internal" mental state of "identification," and not a process that can be studied through objective, established medical tests. The novel issue in this matter is far from diagnostically-honed conditions such as autism that, although involving cognitive and behavioral factors, can be reliably documented by rigorous "objective measurements," a vivid contrast to the condition

[2] AMERICAN PSYCHIATRIC ASSOCIATION, "WHAT IS GENDER DYSPHORIA?" accessed at https://www.psychiatry.org/patients-families/gender-dysphoria/what-is-gender-dysphoria (last accessed Oct. 11, 2024), *quoted in* SARAH PARSHALL PERRY & THOMAS JIPPING, HERITAGE FOUNDATION, *States May Protect Minors by Banning "Gender-Affirming Care* 1 (Dec. 6, 2023).

presented here that centers on feelings of "distress" or sexual "incongruence."[3]

Suspect class status should not be applied to one's personal choices or internal decision-making. If it were, the Equal Protection Clause would become meaningless through unbounded expansion, giving heightened scrutiny protection to nearly every decision, choice, or "internal sense" that any group of persons might experience about anything. The psychological nature of a minor aspiring to a different sex because of personal "distress" – no matter how severe or sympathetically expressed – is itself a compelling reason to reject the Government's revolutionary argument.

The Court's ruling in *City of Cleburne v. Cleburne Living Ctr., Inc.*, 473 U.S. 432 (1985), is significant. Because the *Cleburne* Court denied suspect class status for persons challenged with mental retardation, it would be illogical to apply suspect status to a "condition" here that is dependent on the potentially fluctuating state-of-mind of minors. In *City of Cleburne,* the Court reasoned that State or local laws directly affecting those with mental disabilities did not warrant heightened scrutiny, because they are

> very much a task for legislators guided by qualified professionals, and not by the perhaps ill-informed opinions of the judiciary. Heightened scrutiny inevitably involves

[3] Contrast gender dysphoria with autism, a condition that can be verified by "objective" measurement: *e.g.,* the recent study testing autism diagnosis by tracking eye movement patterns using "eye-tracking data … collected using near infrared video-based measurements." Warren Jones, Ph.D., *et al., Development and Replication of Objective Measurements of Social Visual Engagement to Aid in Early Diagnosis and Assessment of Autism*, JAMA NETWORK OPEN 5 (Sept. 5, 2023) (emphasis added).

> substantive judgments about legislative decisions, and we doubt that the predicate for such judicial oversight is present regarding mental disabilities like retardation.

City of Cleburne, 473 U.S. at 443. Under the Government's theory, courts would be free to treat an obvious equal application of law for two distinct but related categories (*i.e.,* the opposite biological sexes of minors subject to identical state law provisions) as constitutionally *unequal* if the law burdens the minor citizen's *self-perception*. No matter how potentially harmful, experimental, or poorly substantiated a medical procedure is, if it purports to affirm a youth's GAC decision, state legislatives would be powerless to intervene.

D. The Regulations Are Not "Sex-Based" or "Gender-Based."

1. Applying the Dobbs Test.

The Government relies extensively on the argument that the Tennessee law classifies from a "sex-based" position sufficient to trigger higher scrutiny. Br. 19 – 30.

The Government misses the fact that regulations here relate to medical treatments and procedures. Medical regulations, as the *Dobbs* opinion instructs, do not implicate heightened scrutiny. *Dobbs*, 597 U.S. at 236 ("it is squarely foreclosed by our precedents."). Comparing the equal treatment of both males and females under the statute at issue, to abortion procedures that are directly applicable only to females, prompts even more straightforward application of the *Dobbs* test in this case. As a public health and safety law, SB1 is subject to rational basis analysis rather than suspect or quasi-suspect class treatment.

In *Dobbs,* the Court spoke clearly that an Equal Protection Clause attack was meritless regarding abortion — a procedure performed by doctors only on women but not on men. Such a disparity did not violate equal protection, because that argument was "squarely foreclosed by our precedents, which establish that a State's regulation of abortion is not a sex-based classification and is thus not subject to the 'heightened scrutiny' that applies to such classifications." *Dobbs*, 597 U.S. at 236 n.17 (citing *Sessions v. Morales-Santana*, 582 U.S. 47, 58-59 (2017)).

The *Dobbs* reference to *Sessions* is instructive. Writing for the Court in *Sessions*, Justice Ginsburg noted the disparity of *benefits* "based on sex" between male and female parents under a federal naturalization and citizenship statute. That resulted in heightened scrutiny because "[l]aws granting or denying benefits '*on the basis of the sex* of the qualifying parent,' our post-1970 decisions affirm, *differentiate on the basis of gender*, and therefore attract heightened review …" *Id*. (emphasis added) (citations omitted).

The *Sessions* holding was a government benefits decision. The Court found support for heightened scrutiny/quasi-suspect classification from past "benefits" cases. 582 U.S. at 58-59. The present case deals, not with state benefits where the metrics of disparate treatment are fairly recognizable, but with a general health and safety regulation for minors. The latter subject is distinctly one that requires the legislative weighing and balancing of risks to public safety against interests of public welfare. Or, in the words of the Court in *City of Cleburne*, "very much a task for legislators guided by qualified professionals, and not by the perhaps ill-informed opinions of the judiciary." 473 U.S. at 443. The rational basis standard is appropriate.

The present case facts are substantially more favorable than those relied upon by the legislature in *Craig v. Boren*, 429 U.S. 190, 202 (1976), the Court case that yielded a quasi-suspect class. In *Boren*, *maleness* was the failed "proxy" for the risks of drinking and driving that resulted in the law's different treatment of the sexes. By contrast, the record here has ample medical and expert support for SB1's safety concerns, so the "fit" between the law's solutions and the law's objectives is far from "tenuous." 429 U.S. at 204.

Finally, while *Dobbs* noted limited exceptions for laws guilty of targeting and "pretext," they are inapplicable to this case.

2. No Targeting Exists.

In the context of regulating medical procedures, classifications that reference males and females "do[] not trigger heightened constitutional scrutiny unless the regulation is a 'mere pretex[t] *designed* to effect an invidious discrimination against members of one sex or the other.'" *Dobbs*, 597 U.S. at 236 (quoting *Geduldig v. Aiello*, 417 U. S. 484, 496, n.20 (1974)) (emphasis added). There is no evidence that the Tennessee law *targets* male or female minors, nor is it a "mere pretext" to discriminate against "members of one sex or the other."

The Government's response is a broadside that misses the mark. It argues that the law "'expressly and exclusively *targets*' transgender individuals," Br. 28-29 (emphasis added). But that argument shifts quickly, without elaboration on the supposed "targeting" to a discussion of the factors that the Court has applied to the limited categories that can constitute a suspect class. Br. 29.

The Government presumably finds "targeting" within the text of the Tennessee law. But if that were true, this Court in *Dobbs* would not have rejected out of hand as it did, the suggestion of *amici* in the *Dobbs* case that abortion restrictions somehow implicate heightened scrutiny under the Equal Protection Clause. The Court held that such medical measures are simply "governed by the same standard of review as other health and safety measures." 597 U.S. at 237.

Dobbs held that abortion restrictions restricting the medical choices of women do not, by reason of that fact, *target* them so as to require heightened scrutiny. Similarly, the Court should conclude that the Tennessee law does not "target[ ] transgender individuals" simply by restricting the choices of both sexes before they become adults.

3. No Pretext for Discrimination.

There is no indication that the statute by its text is "designed" to discriminate. Rather, the design of the law is obvious: to protect all minors of both sexes equally from "medical procedures that are harmful, unethical, immoral, experimental, or unsupported by high-quality or long-term studies, or that might encourage minors to become disdainful of their sex." TENN. CODE ANN. § 68-33-101(m)

Statutory references to sex or gender do not automatically signal mere "pretext" for discrimination, nor do they determine that a gender distinction is the "basis" of a law. The question is whether a law actually discriminates against anyone "on the basis of sex." The Tennessee statute simply does not discriminate between biological males and females because it makes no distinction "on the basis of sex." See *infra* Section I.E. The law at issue treats male and female minors "alike"

in the same way the immigration law in *Sessions,* 582 U.S. at 56, treated children "alike," as opposed to their parents: "Because §1409 treats sons and daughters "*alike*," Morales Santana [the child] does not suffer discrimination on the basis of *his* gender." *Id.* (emphasis in original).

E. No Actual Discrimination.

The Government misconstrues the Sixth Circuit opinion regarding the assertion of "transgender status" discrimination in the case. It assumes that discrimination has been established, asserting that "The Sixth Circuit did not question the district court's conclusion that SB1 discriminates based on transgender status." Br. 13.

To the contrary, the Court of Appeals specifically found that *sex-based discrimination* (the only relevant category applicable here, and one cited repeatedly by the Government) had *not* occurred: "no such form of discrimination occurs in either law. The laws regulate sex-transition treatments for all minors, regardless of sex." Pet. App. 32. In other words, both biological minor males and biological minor females are "treat[ed] … alike," *Sessions*, 582 U.S. at 56.

The Government would have this Court first recognize a novel, unsupported "transgender status" category as suspect and then, they argue, it should decide that the law, as seen through that slanted lens, fails the heightened scrutiny test. But that argument is simply another version of the Government's failed transgender *targeting*-by-implication assertion, treating as "suspect" any regulatory burden on those who "identify" with another sex.

Nor does the actual equality among females and males within SB1 evaporate simply because the L.W.

Plaintiffs or others are subjected to a state's "health and safety" laws, as they are here. *Dobbs,* 597 U.S. at 237. Were it otherwise, equal protection simply becomes a by-word for creating new rights for any group desiring a novel medical outcome at odds with a regulatory statute.

F. No Fundamental Rights or Forced "Gender Conformity."

The *Dobbs* Court applied a rational basis standard of review to a state prohibition that, except for two narrow exceptions, prohibited all abortions for a pregnant woman at a probable gestational age of 15 weeks or more. Despite an abortion law that affected only women in a direct and physical way, the Court nevertheless held that fundamental rights were not implicated and the State law merited no heightened scrutiny. The Court, applied the rational basis test, and found the regulation was "for legitimate reasons." *Dobbs,* 597 U.S. at 221. In the light of *Dobbs*, it would be incongruent to convert into a fundamental constitutional right the desires of minors to seek potentially harmful procedures in order to change their physical appearance, solely in an effort to assist their emotional state.

The Government charges Tennessee with a "deliberate" plan to force gender conformity, asserting that its "focus on sex and gender conformity is deliberate: SB1 declares that its very purpose is to 'encourag[e] minors to appreciate their sex' and to ban treatments 'that might encourage minors to become disdainful of their sex.' [TENN. CODE ANN.] § 68-33-101(m). That is sex discrimination." Br. 16. It argues that the State is engaged "in discouraging people from being transgender or encouraging them to present as their sex assigned at birth." Br. 33.

But that claim takes the statute's text substantially out of context, which is clear by looking at the full statutory section:

> This state has a legitimate, substantial, and compelling interest in encouraging minors to *appreciate their sex, particularly as they undergo puberty*. This state has a legitimate, substantial, and compelling interest in protecting the integrity of the medical profession, including by prohibiting *medical procedures* that are *harmful, unethical, immoral, experimental, or unsupported by high-quality or long-term studies*, or that might encourage minors to become disdainful of their sex.

TENN. CODE ANN. § 68-33-101(m) (emphasis added). The phrase "disdainful of their sex" must be viewed in the context of the entire text and its two goals. One goal is to protect children approaching "puberty" from choosing experimental procedures occasioned by serious complications and possible heart-breaking regret. The other is to "protect[ ] the integrity of the medical profession" by lessening the demand for experimentation on minors driven by improper motives, or professional rushes to judgment about the minor's best interests fueled by cultural, personal, or professional pressures.

Both goals, supporting children's healthy "appreciation of their sex" as well as promoting the medical profession's "integrity," are undermined by procedures and treatments that are "harmful, unethical, immoral, experimental, or unsupported by high-quality or long-term studies." Flawed procedures and treatments have the capacity to cause inappropriate "encourage[ing] [of] minors to become disdainful of their sex," whatever the sex.

Statutory construction principles support this. Text is informed by its relation to accompanying terms, like those above. *See United States v. Williams*, 553 U.S. 285, 294 (2008) ("the common sense canon of *noscitur a sociis* . . . counsels that a word is given more precise content by the neighboring words with which it is associated"); *Massachusetts v. Morash*, 490 U.S. 107, 114-15 (1989) ("expounding a statute … [is] not . . . guided by a single sentence or member of a sentence, but look[s] to the provisions of the whole law, and to its object and policy") (quoting *Pilot Life Ins. Co. v. Dedeaux,* 481 U.S. 41, 51 (1987)).

The goal of the statutory text is not gender "conformity," but to give minors breathing room to achieve adulthood before choosing controversial medical experimentation. Obviously, "unethical" or "experimental" treatments can lead a child to unduly "become disdainful of their sex." The stronger such treatments are urged by third parties, the more it delivers the message to the minor that their biological sex was "wrong" for them, a message agnostic to the fact that young GAC patients may later conclude, too late, that in fact it was not.

This is evidenced by lawsuits filed by those who, after submitting to youthful GAC, experience deep regret and negative outcomes.[4] That the State seeks to

[4] AMERICAN PRINCIPLES PROJECT, THE GENDER INDUSTRIAL COMPLEX 2-5, 22 (2024) https://americanprinciplesproject.org/wp-content/uploads/2024/06/Gender-Industrial-Complex-Full-Report.pdf, (citing lawsuits: *Cole v. Kaiser Found. Hosps., Inc.*, No. STK-CV-UMM-2023-1612 (Cal. Super. Ct. San Joaquin Cnty. Feb. 2, 2023), https://s3.documentcloud.org/documents/23693707/chloe-complaint-clean.pdf.; *Lovdahl v. Kaiser Found. Hosps., Inc.,* No. STK-CV-UMM-2023-6100 (Cal. Super. Ct. San Joaquin Cnty. June 14, 2023), https://libertycenter.org/wp-content/uploads/2023/06/1.-Complaint-1.pdf ; *Mosley v. Emerson*, No. 23-CVS-2375 (N.C. Super. Ct. Gaston Cnty. July 17, 2023), https://www.docu

protect its youth from those outcomes is far from forcing gender "conformity."

G. The "Sex-Based" Cases Cited by the Government Do Not Apply.

None of the three cases cited by the Government regarding "sex-based classification," Br. 25, has any application to the factual and legislative context of Tennessee's law. In *Nguyen v. INS*, 533 U.S. 53, 64 (2001), birth mothers and male biological fathers were subjected to *different rules* that triggered heightened scrutiny, albeit a differential that still satisfied the heightened test. 533 U.S. at 60. In contrast, SB1 treats males and females seeking GAC under the same, and not "different," rules.

Citation to *Miller v. Albright*, 523 U.S. 420 (1998), illustrates the same error. Br. 25. The challenged INS rules *applied differently* to each sex, invoking heightened scrutiny, although sufficiently justified: "The biological differences between single men and single women provide a relevant basis for *differing rules* …" *Id*. at 445 (emphasis added). Again, "differing rules" are the key, because SB1 does not have rules differing between boys or girls.[5]

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mentcloud.org/documents/23882834-prisha-mosley-complaint; *Aldaco v. Perry*, No. 067-343803-23 (Dist. Ct. Tarrant Cnty., Tex. July 21, 2023), https://www.scribd.com/document/660451210/Aldaco-Gender-Modification-Suit#fullscreen&from_embed; *Hein v. UNMC Physicians*, No. D01CI23007381 (Dist. Ct. Douglas Cnty., Neb. Sept. 13, 2023), https://libertycenter.org/wp-content/uploads/2023/09/Luka-Hein-District-Court-Complaint-9-13-23-filed.pdf

[5] While the SB1 rules are equal in practical impact for boys and girls, the State is also right, Resp. Br. 28-31, that the two sexes are "not similarly situated" biologically regarding, for instance, testosterone for boys if administered to girls.

Moreover, the Court in *Miller* merely assumed *arguendo* that even if heightened scrutiny applied, the standard was satisfied in any event: "*Even if*, as petitioner and her amici argue, the heightened scrutiny that normally governs gender discrimination claims applied in this context," that test was met. *Miller,* 523 U.S. at 435 (emphasis added).

Last, the Government cites *Michael M. v. Superior Ct.*, 450 U.S. 464, 471-473 (1981) (plurality opinion). The *Michael M.* majority recognized that the "Court has had some difficulty in agreeing upon the proper approach and analysis in cases involving challenges to gender-based classification." *Id.* at 468. A decision adopting the Government's novel theory of "gender-based classification" poses a high risk of obfuscating that proper approach and analysis, rather than clarifying it.

The Tennessee law does not restrict treatment choices for adults, but only for minors. In doing so, the statute does not demean those minors or their parents, any more than it demeans underage teens when it prohibits them from buying alcohol, or elementary school children from buying cigarettes, or youthful would-be drivers from the dangers of automobile travel until they obtain a license at a stated age. Protection of minors may be debatable, but it does not constitute a diminishment of equality under the law.

II. THE RATIONAL BASIS TEST IS SATISFIED.

A. Empirical Data Is Not Required for Rational Basis.

There are studies, data and professional opinions in this case supporting the rationality of SB1 (see *infra*, Section II.E. 1-4). However, the common sense behind the law should satisfy the rational basis inquiry. Indeed, empirical data is not a prerequisite:

> … under rational scrutiny, a statute may be defended based on generalized classifications unsupported by empirical evidence. *See Heller v. Doe,* 509 U.S. 312, 320 (1993) ("[A] classification must be upheld against equal protection challenge if there is any reasonably conceivable state of facts that could provide a rational basis for the classification. A State, moreover, has no obligation to produce evidence to sustain the rationality of a statutory classification" (internal quotation marks and citations omitted)).

Miller v. Albright, 523 U.S. 420, 452 (1998) (O'Connor, J., concurring).

B. The Law's Exceptions are Reasonable and Consistent with Federalism.

The Government admits that girls, for example, are "commonly treated with estrogen to bring on puberty in non-GAC cases. Pet. App. 266a," Br. 23. *See also* Br. 45. That practice finds support in established, professionally documented standards of care in biological-sex-consistent usage, which is why the statute permits that practice while barring the experimental and controversial use of cross-sex hormones. SB1's medical exceptions, attacked by the Government, Br. 43-44, are reasonable, non-arbitrary and acknowledged standard of care. *See Watson v. Maryland*, 218 U.S. 173, 179-180 (1910) (no equal protection violation in the non-arbitrary exceptions in State's medical regulation).

Further, the reasonableness of SB1 in its framing of restrictions and exceptions is clear. The State restricts the use of experimental and potentially harmful GAC methods for youth but not for adults, and prohibits *experimental cross-sex* hormones for minors, but does not restrict hormones for medical use when consistent

with long-established medical use of hormones under an *undisputed* standard of care, which is the case when administered consistent with biological sex.

Respect for that legislative balancing act by a State in the interests of public safety is also a hallmark of another constitutional principle, that of federalism. The Court has recognized "the role of the States as laboratories for devising solutions to difficult legal problems." *Oregon v. Ice*, 555 U.S. 160, 171 (2009). Even more to the point, "[T]he States may perform their role as laboratories for experimentation to devise various solutions where the best solution is far from clear." *United States v. Lopez*, 514 U.S. 549, 581 (1995) (Kennedy, J., concurring). Further, "the [constitutionally] reserved powers of the States are sufficient to enact those measures" that protect children. *Id*. (safety of children in schools).

As research shows, the experimental use of GAC for youth and children lacks clear efficacy, and though potential harmfulness from GAC is also very real, the full extent of those harms is still "far from clear," *Lopez,* 514 U.S. at 581, primarily because of the inadequacy of studies conducted thus far. That should be reason enough to leave it to the States to be the "laboratories" for possible legislative "solutions," rather than wielding the Equal Protection Clause to ban State authority.

C. The Sixth Circuit Rightly Notes GAC is "Experimental."

Expert witness Dr. James Cantor states flatly that those procedures that the Government wants fully available for minors are "experimental," and that the international medical community has generally agreed with that designation. J.A. 408-411.

That "experimental" designation was adopted by the Court of Appeals as well. Pet. App. 48a. The Government's merits brief does not refute the Court of Appeal's conclusion that GAC is experimental. Nor, for that matter, do the Respondents in Support of Petitioner ("LW Plaintiffs") directly attack it in their merits brief.

Instead, they argue the existence of a standard that relies on the policies of the World Professional Association of Transgender Health (WPATH), citing it as "the leading association of medical professionals treating transgender individuals." Br. 3; Pet. Cert. 4, 12. WPATH is also cited as authoritative in the merits brief of the L.W. Plaintiffs. Brief of Resps. L.W. *et al.*, 5, 6, 44. However, basing standards on WPATH presents more problems than answers.

D. WPATH's Credibility Problems.

The Government's experts are deeply entrenched in WPATH and its guidelines. Dr. Susan Lacy relies on those guidelines. J.A. 99, ¶ 14. Dr. Shayne Sebold Taylor is a member of WPATH, J.A. 254, ¶ 10, as is also Dr. Cassandra C. Brady, J.A. 273, ¶ 5. In his letter, C. Wright Pinson, M.D., MBA, states that he follows the WPATH guidelines. J.A. 277.

The first problem is that the changes in WPATH standards ignore questions of efficacy and risk and have trended in only one direction: a consistent lowering of standards and elimination of preconditions in its guidelines for GAC procedures for minors, a trend noted by the Sixth Circuit. Pet. App. 6a.

Second, WPATH itself is a problematic source for standards regarding minor GAC interventions. As one journalist and researcher notes –

> Despite its grand title, WPATH is neither solely a professional body – a significant

> proportion of its membership are activists – nor does it represent the "world" view on how to care for this group of people. There is no global agreement on best practice … What's more, NHS England has made it clear that WPATH's views are irrelevant to its core recommendation that puberty blockers will no longer be available as part of routine clinical practice. [6]

In fact, NHS has expressly distanced itself from WPATH's positions, having cited WPATH negatively; *i.e*., as a group upon which NHS does "not" base its treatment standards: "NHS England does not commission based upon guidelines or treatment protocols eg WPATH 8.0 …" [7]

Last, Dr. James Cantor, Ph.D., opines that the WPATH-commissioned study failed to study minors' *safety;* it contained "discrepancies" and "misleading ambiguities;" and WPATH guidelines are really not "evidence-based" at all. J.A. 373,¶ 93-94; 377, ¶ 97; 377, ¶ 103.

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[6] Hannah Barnes, *Why Disturbing Leaks from US Gender Group WPATH Ring Alarm Bells in the NHS*, THE GUARDIAN (Mar. 9, 2024), https://www.theguardian.com/commentisfree/2024/mar/09/disturbing-leaks-from-us-gender-group-wpath-ring-alarm-bells-in-nhs.

[7] NHS ENGLAND ENGAGEMENT REP., *Puberty Suppressing Hormones (PSH) for children and adolescents who have gender incongruence/dysphoria* (2024), https://www.engage.england.nhs.uk/consultation/puberty-suppressing-hormones/user_uploads/engagement-report-interim-policy-on-puberty-suppressing-hormones-for-gender-incongruence-or-dysphoria.pdf.

E. The Risks to Minors are Real and Sufficient.

1. Off-Label Problems.

The Government emphasizes that the Food and Drug Administration (FDA) was not required to approve the use of puberty blockers and cross-sex hormone treatments for off-label use approved for other applications, and that off-label (though FDA-unapproved) use is "common" including "puberty blockers and hormones to treat conditions *other than* gender dysphoria." Br. 40 (emphasis added). However, the FDA has given approval to a category of drugs to treat abnormally early ("precocious") puberty in minors.[8]

A closer look at the pediatric practices relied on by the Government yields more of an indictment against those practices than a defense.

There are four serious catches to off-label use for minors that call into question the Government's reliance on common usages of certain drugs in pediatrics generally, to justify specifically their experimental cross-sex use for gender dysphoria. First, as a general proposition, off-label drug use for children is "*potentially harmful.*" Divya Hoon,, *et al., Trends in Off-Label Drug Use in Ambulatory Settings: 2006–2015*, 144 PEDIATRICS 1 (Oct. 2019) (emphasis added).

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[8] Kristof Chwalisz, *Clinical Development of the GnRH Agonist Leuprolide Acetate Depot*, 4 F&S REPORTS 33–39 (2023), https://www.ncbi.nlm.nih.gov/pmc/articles/PMC10201295/pdf/main.pdf, cited in SARAH PARSHALL PERRY & THOMAS JIPPING, HERITAGE FOUNDATION, *States May Protect Minors by Banning "Gender-Affirming Care"* 1 (Dec. 6, 2023), accessible at https://www.heritage.org/gender/report/states-may-protect-minors-banning-gender-affirming-care.

Second, despite the reality of adverse outcomes, off-label drug prescriptions for minors have increased generally: "In both absolute and relative terms, off-label ordering has risen over time, most notably for unapproved conditions." *Id*. at 6.

Third, adverse outcomes to young patients can be related to inadequate "understanding" of both "safety" "or efficiacy;" thus, the "majority of medications used in the care of children have historically been used off label without an adequate understanding of appropriate dosage, safety, or efficacy… off label usage of medications has been associated with *adverse outcomes*." Katelyn Yackey & Rachel Stanley, *Off-Label Prescribing in Children Remains High: A Call for Prioritized Research*, 144 PEDIATRICS 1 (Oct. 2019) (emphasis added).

While FDA approval may not be required for the Government's suggested novel protocols, Congress has prioritized safety of children receiving pediatric drugs: "In 2012, the U.S. Congress passed the Food and Drug Administration Safety and Innovation Act, aiming to ensure that pediatric evaluations are conducted earlier in the drug development process." *Id*. at 1. *See* Food and Drug Administration Safety and Innovation Act, Pub. L. No. 112-114, § 508(b)(1), 126 Stat. 1046 (2012) (authorizing "assessment of the effectiveness" of existing regulations "in improving information about pediatric uses for approved drugs" and "labeling changes" impacting "the health of children").

Fourth, the medical field of pediatrics has been warned that it must focus on this problematic off-label issue: "This highlights the continued need for comprehensive drug development studies evaluating *safety*, *efficacy*, pharmacokinetics, and optimal dosing in pediatric patients [receiving off-label drugs]." Yackey & Stanley, *supra*, at 2 (emphasis added).

Unfortunately, the record shows evidence of *insufficient efficacy* (or inadequate study of efficacy) coupled with actual evidence of foreseeable *harms* at play. Both of those provide a basis for the Tennessee law.

2. Harms to Minors: The Non-Biased National Studies.

Only three comprehensive GAC reviews, two of them national studies, have been authored by experts who are not hampered by a conflict-of-interest in advocating for, or already providing GAC to minors. J.A. 330-332, ¶¶ 11-14. All have recognized the potential harms to minors receiving forms of GAC such as cross-sex hormones or puberty blockers.

The United Kingdom's National Health Service (NHS) issued one of those national studies. Its website flatly states that: "Long-term gender-affirming hormone treatment may cause temporary or even permanent infertility." [9]

The NHS commissioned NIH leading pediatrician Dr. Hillary Cass to study the issue of GAC practices for minors. J.A.334-335, ¶ 19. The Cass interim report ("Cass IR") found serious risks to minors from GAC procedures including administration of cross-sex hormones and hormone blockers which have not been adequately studied. One potential outcome from cross-sex puberty blockers is a detriment to "brain maturation." J.A. 431,¶ 209. Strong evidence for the efficacy of those treatments is also lacking. J.A. 334-335, ¶ 19.

Following the Cass IR, a Cass final report issued this year: THE CASS REVIEW, *Independent review of gender*

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[9] NHS website, *Treatment – Gender dysphoria*, *Puberty blockers and gender-affirming hormones*, https://search.app/zBkrDfUwPFsRbCg27 (last accessed Oct. 11, 2024).

identity services for children and young people (Apr. 2024), available at https://cass.independent-review.uk/home/publications/final-report ("Cass Final"). The report concluded that: "formal diagnosis of gender dysphoria … is not reliably predictive of whether that young person will have longstanding gender incongruence in the future, or whether medical intervention will be the best option for them;" a "poor evidence base" for treatment and prognosis for gender identity conditions makes it "difficult" to provide actual "informed choice" for youth and their parents; as a result, practitioners must "defuse/manage expectations that have been built up by claims about the efficacy of puberty blockers." *Id*. at 34, ¶¶ 98-100.

A second national study without conflict-of-interest is the study by an independent research firm commissioned by Finland's health service. J.A. 336, ¶ 22. It concluded that "medical gender reassignment is not enough to improve functioning and relieve psychiatric comorbidities among adolescents with gender dysphoria." J.A. 336.

The third independent report comes from psychologist and neuroscientist Dr. James Cantor. He notes the well-documented data that adults treating gender dysphoria with cross-sex hormone protocols have experienced resulting cardiovascular problems, osteoporosis, and hormone-dependent cancers. J.A. 436, ¶ 223. This fact raises serious questions about young GAC patients who may be subjected long-term to those same harms, but which have not been studied.

3. Failed Efficacy, Studies Needed, and the Bias Problem.

In a 2023 "Systemic Review," 195 studies were analyzed regarding "the effects on psychosocial and

mental health, cognition, body composition, and metabolic markers of hormone treatment in children with gender dysphoria" J.A. 281. The findings show a rational basis for the legislation attacked here. In the Review:

- Among boys, there was an absence of efficacy from the treatments, in that there was no improvement in "[l]ife satisfaction … depression and anxiety scores." J.A. 305, ¶ 4.
- Psychosocial improvement or lack of improvement *long-term* was deemed to be an unknown: "the long-term effects of hormone therapy on psychosocial health could not be evaluated." J.A. 282.
- Some negative physical outcomes are foreseeable: for instance, use of cross-sex hormones "seems to delay bone maturation and gain in bone mineral density." J.A. 282, ¶ 5.

Corroborating this, Dr. James Cantor opines that gate-way mental health assessments for youth seeking "transition" present a "selection bias" potential, and that studies merely confirm that "insufficient evidence" exists regarding long-term safety of minors who undergo those treatments. J.A. 359, ¶ 69; 359-361; and 361, ¶ 73.

4. "De-transition" and Rush-to-Judgment.

The current professional industry of "medicalized transition in minors" is not based on an acceptable *risk: benefit ratio*. *See* Opinion of psychologist and neuroscientist, Dr. James Cantor, Ph.D., J.A. 352 ¶ 52; 358, ¶ 67; 360, ¶ 71-72; 370 (top); 430 (top) (WPATH president admits potential "big problem" of negative impact on future sexual functions); 436, ¶ 224 (lifetime need for hormones implicated).

This can lead youth who undergo "gender affirming care" to realize the error too late, then having to "detransition." This is a growing phenomenon.

There is often a lack of adequate counseling and evaluation at the beginning point of the minor's entry into the GAC process. One study of 100 patients desiring or attempting "detransition" showed that, "The majority (55.0%) felt that they did not receive an adequate evaluation from a doctor or mental health professional before starting transition." *See* Lisa Littman, *Individuals Treated for Gender Dysphoria with Medical and/or Surgical Transition Who Subsequently Detransitioned: A Survey of 100 Detransitioners*, 50 ARCH. SEX BEHAV. 3353 (2021) (abstract), https://pubmed.ncbi.nlm.nih.gov/34665380/.

This is coupled with the myriad other problems with the growing "transition" medical industry and its practices. This includes a too-often rush-to-judgment:

> At 18 gender clinics across the country, Reuters found that most do not have stringent protocols to determine whether a patient would be best served by undergoing the life-changing process of transitioning. Seven clinics said that, depending on the age of the child, they will begin prescribing puberty blockers based on the first visit if there are no "red flags"… Adults have also reported being pressed to subject their children to transitioning. Reuters interviewed the parents of 39 minors who had sought "gender-affirming care." Of that number, 28 said they felt "pressured or rushed to proceed with treatment" for their kids. Some said their children were recommended for puberty

blockers after consultations lasting just 15 minutes.[10]

All of the foregoing supports more than a rational connection between the State's legitimate goal of protecting youth and the means used in SB1.

CONCLUSION

The decision of the Court of Appeals for the Sixth Circuit should be affirmed.

Respectfully submitted,

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[10] AMERICAN PRINCIPLES PROJECT, THE GENDER INDUSTRIAL COMPLEX 19-20 (2024), https://americanprinciplesproject.org/wp-content/uploads/2024/06/Gender-Industrial-Complex-Full-Report.pdf, citing Chad Terhune, *et al*., "As more transgender children seek medical care, families confront many unknowns," Reuters (Oct. 6, 2022), https://www.reuters.com/investigates/special-report/usatransyouth-care/.