IN THE CIRCUIT COURT OF COLE COUNTY
STATE OF MISSOURI

EMILY NOE, individually and as next friend and on behalf of her minor child, NICHOLAS NOE, et al.,	)	
Plaintiffs,	)	
v.	)	No. 23AC-CC04530
MICHAEL L. PARSON, in his official capacity as Governor for the State of Missouri, et al.,	)	
Defendants.	)	

BRIEF OF AMICI CURIAE ALABAMA, ARKANSAS, TENNESSEE, ALASKA, GEORGIA, IOWA, KANSAS, KENTUCKY, LOUISIANA, MISSISSIPPI, MONTANA, NEBRASKA, OKLAHOMA, SOUTH CAROLINA, UTAH, AND WEST VIRGINIA SUPPORTING DEFENDANTS AND DENIAL OF PLAINTIFFS' MOTION FOR PRELIMINARY INJUNCTION

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INTRODUCTION AND INTERESTS OF AMICI CURIAE[1]

Amici curiae are the States of Alabama, Arkansas, Tennessee, Alaska, Georgia, Iowa, Kansas, Kentucky, Louisiana, Mississippi, Montana, Nebraska, Oklahoma, South Carolina, Utah, and West Virginia.

Amici regulate healthcare. They have done so for as long as they have existed. *See Dent v. West Virginia*, 129 U.S. 114, 121-24 (1889) (explaining how this was a power of States "from time immemorial"); *Abigail Alliance For Better Access to Developmental Drugs v. von Eschenbach*, 495 F.3d 695, 703-05 (D.C. Cir. 2007) (en banc) (explaining history of drug regulation). State legislatures have particularly "wide discretion to pass legislation in areas where there is medical and scientific uncertainty." *Gonzales v. Carhart*, 550 U.S. 124, 163 (2007).

When the fact that these practices put children's health at stake is added to the medical uncertainty, the State's police power is likely at its zenith. "The State plainly has authority, in truth a responsibility, to look after the health and safety of its children." *L.W. v. Skrmetti*, 73 F.4th 408, 419 (6th Cir. 2023). States like Missouri, therefore, "could rationally take the side of caution before permitting irreversible medical treatments of its children." *Id.* (granting stay pending appeal of preliminary injunction enjoining enforcement of similar Tennessee law).

[1] No party's counsel authored, and no one other than *amici* and its counsel contributed money for, this brief. Defendants have consented to the filing of this brief, and Plaintiffs have stated that they do not oppose the filing.

Rather than accord Missouri's "health and welfare laws" a "strong presumption of validity," *Dobbs v. Jackson Women's Health Org.*, 142 S. Ct. 2228, 2284 (2022) (citation omitted), Plaintiffs ask this court to treat certain medical interest groups as the *real* regulators, authoring standards that no mere State could contradict. "[E]very medical association in the country agrees" with the Standards of Care promulgated by the World Professional Association for Transgender Health (WPATH) and the Endocrine Society's Guidelines, so it is *those* standards the Missouri and Federal Constitutions purportedly mandate. Suggestions at 8.[2]

One could scarcely dream up a more radical organization to outsource the regulation of medicine to than WPATH, whose members almost entirely wrote the Endocrine Society Guidelines. As "Americans are engaged in an earnest and profound debate about" how best to help children suffering from gender dysphoria, *cf. Washington v. Glucksberg*, 521 U.S. 702, 735 (1997), WPATH has taken its gender ideology to the extreme and included in its latest Standards of Care an entire chapter on self-identified "eunuchs"—individuals "assigned male at birth" who "wish to eliminate masculine physical features, masculine genitals, or genital functioning."[3]

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[2] Plaintiffs bring solely Missouri law claims but rely extensively on federal court precedents interpreting equivalent provisions in the U.S. Constitution. *E.g.*, Suggestions at 24, 42. Amici States, therefore, similarly focus on federal precedents.

[3] E. Coleman et al., *WPATH Standards of Care for the Health of Transgender & Gender Diverse People, Version 8*, INT'L J. OF TRANSGENDER HEALTH (Sept. 15, 2022), S88 ("SOC 8").

Because eunuchs "wish for a body that is compatible with their eunuch identity," the Standards say, some will need "castration to better align their bodies with their gender identity."[4] WPATH thus deems castration "medically necessary gender-affirming care" for eunuchs to "gain comfort with their gendered self."[5]

And how did WPATH learn that castration constitutes "medically necessary gender-affirming care"? From the Internet of course—specifically from a "large online peer-support community" called the "Eunuch Archive," which WPATH says hosts "the greatest wealth of information about contemporary eunuch-identified people."[6] WPATH curiously did not include the fact that the Eunuch Archive also hosts thousands of stories that "focus on the eroticization of child castration" and "involve the sadistic sexual abuse of children."[7] Just as with eunuchs, WPATH's Standards consider sterilizing gender-modification procedures to be medically necessary "gender-affirming care" for *minors* suffering from gender dysphoria.[8] This is the stuff of nightmares or farce, not constitutional law.

Even the American Academy of Pediatrics—which has aggressively lobbied against laws such as Missouri's—acknowledged earlier this month that there are no

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[4] *Id.* at S88-89.
[5] *Id.* at S88-89.
[6] *Id.* at S88.
[7] Genevieve Gluck, *Top Trans Medical Association Collaborated With Castration, Child Abuse Fetishists*, REDUXX (May 17, 2022), https://perma.cc/5DWF-MLRU.
[8] *See* SOC 8, *supra*, at S43-S66.

systematic reviews supporting the treatments Missouri has prohibited.[9] Several European countries *have* conducted systematic reviews and, based on those reviews' findings, effectively banned these treatments outside controlled research settings.[10] Plaintiffs would substitute WPATH's year-old Standards—rejected abroad and in numerous States—for the judgment of Missouri's legislature.

Thankfully, the Missouri and Federal Constitutions do not put WPATH in charge of regulating medicine in Missouri or any other State. The government regulates the medical profession, not the other way around. *See Glucksberg*, 521 U.S. at 731. Amici write in support of States' well-established authority to enact health and welfare laws—even ones that conflict with WPATH's horrifying Standards.

The most recent appellate court to consider a similar law rejected those plaintiffs' request to substitute WPATH's judgment for that of Tennessee and, after a month of additional deliberation, Kentucky. *L.W.*, 73 F.4th at 413; *Doe 1 v. Thornbury*, No. 23-5609, 2023 WL 4861984, at *1 (6th Cir. July 31, 2023). Plaintiffs try to bury the Sixth Circuit's *L.W.* decision in a footnote, Suggestions at 30 n.13, and completely ignore that five Eighth Circuit judges have already announced they are "skeptical" about the equal protection arguments Plaintiffs advance here. *Brandt v.*

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[9] Azeen Ghorayshi, *Medical Group Backs Youth Gender Treatments, but Calls for Research Review*, N.Y. TIMES (Aug. 3, 2023), https://perma.cc/N3BJ-TB9J.

[10] *See, e.g.*, *L.W. v. Skrmetti*, No. 3:23-cv-00376, Cantor Decl. ¶¶16-35, 2023 WL 3778750 (M.D. Tenn. May 19, 2023); *L.W. v. Skrmetti*, Román Decl. ¶33, 2023 WL 3778753 (M.D. Tenn. May 19, 2023).

Rutledge, 2022 WL 16957734, at *1 n.1 (8th Cir. Nov. 16, 2022) (en banc) (Stras, J., joined by Gruender, Erickson, Grasz, Kobes, JJ., dissental). This Court should similarly reject Plaintiffs' newest attempt to constitutionalize WPATH's shoddy Standards.

ARGUMENT

The Missouri Save Adolescents from Experimentation (SAFE) Act is a valid exercise of Missouri's police power. Missouri, like many other States, became concerned that healthcare providers were risking the long-term health and well-being of gender dysphoric children with unproven hormonal and surgical treatments. The Missouri legislature responded by prohibiting the prescription or administration of cross-sex hormones or puberty-blocking drugs "for the purpose of a gender transition" or performing "a gender transition surgery" on minors. Mo. Stat. §191.1720. Such treatments stunt children's pubertal and mental development, lower their bone density, and gamble away their ability to have children as adults.

Plaintiffs' request for a preliminary injunction is flawed for two main reasons. First, they assume that heightened scrutiny applies to any healthcare regulation that "speaks in explicitly gendered terms" or even acknowledges that boys and girls are not biologically the same. Statement at 26. Second, they insist that any healthcare regulation that conflicts with the WPATH's 2022 Standards of Care and American medical interest groups "fails any level of review," even rational basis. Statement at

39. But the Constitution does not cast such a skeptical eye on health and welfare laws, even if they regulate gender transition treatments. And States do not need to seek approval from WPATH before banning experimental procedures that leave children sterilized. The Court should deny Plaintiffs' request for an injunction.

I. Laws Prohibiting Pediatric Gender Transition Procedures Do Not Trigger Heightened Scrutiny.

The fundamental goal of the SAFE Act is the same as laws many of Amici States have enacted: to prohibit healthcare providers from performing surgeries on and administering hormones to gender dysphoric minors in the name of WPATH-encouraged gender transition. The SAFE Act "does not prefer one sex to the detriment of the other." *L.W.*, 73 F.4th at 419. In regulating these unproven treatments, the SAFE Act mentions the word "gender." "But how could it not? That is the point of the existing hormone treatments—to help a minor transition from one gender to another." *Id.* References to gender or to the biological differences between the two sexes do not trigger heightened scrutiny. "If a law restricting a medical procedure that applies only to women does not trigger heightened scrutiny, as in *Dobbs*, a law equally applicable to all minors, no matter their sex at birth, does not require such scrutiny either." *Id.*

Nor should this Court dramatically expand *Bostock*'s hiring-and-firing Title VII reasoning to Missouri's equal protection clause. Even the author of *Bostock* has called such a move "implausible on its face." *Students for Fair Admissions, Inc. v.*

President & Fellows of Harv. Coll., 143 S. Ct. 2141, 2220 (2023) (Gorsuch, J., concurring). Transgender status is not a quasi-suspect class. As with "other health and welfare laws," rational-basis review applies. *Dobbs*, 142 S. Ct. at 2284.

A. Laws Prohibiting Pediatric Gender-Modification Procedures Do Not Discriminate Based on Sex.

Rejecting the equal protection analysis of the Sixth Circuit, Plaintiffs want this Court to follow the erroneous reasoning of an Eighth Circuit preliminary injunction panel that five Eighth Circuit judges—half of all participating judges—wanted to rehear en banc and another three judges wanted to reconsider after a trial that would "conclude in less than a month." *Brandt*, 2022 WL 16957734, at *1 (Colloton, J., joined by Smith, C.J., and Benton, J., concurring). According to Plaintiffs, any law, regulation, or policy that uses the words sex, gender, male, female, man, woman, boy, or girl automatically triggers heightened review. Statement at 26.

That cannot be. If such were enough to warrant heightened review, the Constitution would look askance at any public hospital offering testicular exams only to men or c-sections only to women. It would also mean that a law restricting abortions would face heightened scrutiny. The U.S. Supreme Court squarely rejected this reasoning, explaining that "[t]he regulation of a medical procedure that only one sex can undergo does not trigger heightened constitutional scrutiny unless the regulation is a 'mere pretext designed to effect an invidious discrimination against members of one sex or the other.'" *Dobbs*, 142 S. Ct. at 2245-46 (cleaned up) (quoting *Geduldig*

v. Aiello, 417 U.S. 484, 496 n.20 (1974)). It could hardly be otherwise: Plaintiffs have produced no evidence that the Fourteenth Amendment was originally understood to be suspicious of any recognition that males and females are biologically different. No special blessing from a court is needed, for example, before a government enforces a ban on female genital mutilation. *See, e.g.*, 18 U.S.C. §116. That remains true even if a medical interest group like the American Academy of Pediatrics encourages doctors to participate in female genital mutilation by offering a "ritual nick" of girls' clitoral skin in contravention of such laws.[11]

Plaintiffs try to get around this truth by asserting that, unlike with abortions, both boys and girls can take hormones to transition, yet the law "does not prevent a minor assigned male at birth from receiving testosterone, nor does it prevent a minor assigned female at birth from receiving estrogen." Statement at 27. This pathway doesn't evade *Dobbs* either. For healthy development, males naturally need higher levels of testosterone than females, and females need higher levels of estrogen than males. Plaintiffs' comparison is like subjecting an abortion regulation to heightened scrutiny because men can access "reproductive healthcare," while only women's access to abortion is restricted. It defines the procedure at too high a level of generality (though there would be no asymmetry here because neither boys *nor* girls can be

[11] AAP Policy Statement, *Ritual Genital Cutting of Female Minors*, 125 PEDIATRICS 1088, 1092 (2010).

prescribed gender-transition procedures). What matters are the individual procedures at issue.

Here, there are three procedures that Plaintiffs concern themselves with. The first is puberty blocker transitioning treatment. Puberty blockers work the same way in males and females. Sex has no bearing on their prescription or dosage for transitioning or for conditions, such as precocious puberty, that they are actually approved to treat.[12] So banning their use in gender-modification procedures does not draw any line based on sex. Girls and boys are treated identically: both may receive puberty blockers to treat precocious puberty, but not to transition. Rational-basis review applies.

The second treatment is testosterone transitioning treatment. Unlike puberty blockers, testosterone transitioning treatments can be used *only* in females. That is, giving testosterone to a female can be a transitioning treatment because it will lead to approximations of male characteristics, while giving testosterone to a male *cannot* be a transitioning treatment because it will *not* lead to female characteristics. While the same drug may be used in *other* treatments for males (like treating a testosterone deficiency), no amount of testosterone can cause a male to develop female characteristics. If a male wants to transition, he must use estrogen, not testosterone.

[12] *See* Victoria Pelham, *Puberty Blockers: What You Should Know*, Cedars Sinai (Jan. 16, 2023), https://perma.cc/H83F-4ZR7; Mayo Clinic, *Precocious Puberty*, https://perma.cc/58SA-ESRV (last visited May 12, 2023).

The third treatment is estrogen transitioning treatment, which works the inverse as testosterone transitioning treatment. It can be given only to males to transition. Giving estrogen to a female won't lead to transitioning; testosterone is needed to do that.

Because biology dictates that only males can take estrogen *to transition*, and only females can take testosterone *to transition*, testosterone transitioning treatments and estrogen transitioning treatments are "medical procedure[s] that only one sex can undergo." *Dobbs*, 142 S. Ct. at 2245-46. Rational-basis review thus applies to laws regulating the procedures. *Id.*

It does not matter that Missouri allows these same drugs—puberty blockers, testosterone, and estrogen—to be used for some purposes but not for transitioning. The distinctions Missouri drew make sense because the different uses of the drugs have different diagnoses, different goals, and different risks. That makes them different treatments. This distinction is normal. States routinely allow drugs to be used for some treatments (morphine to treat a patient's pain) but not others (morphine to assist a patient's suicide). *E.g.*, *McMain v. Peters*, 2018 WL 3732660, at *4 (D. Or. Aug. 2, 2018) (prisoner seeking testosterone for PTSD not similarly situated to prisoner with Klinefelter Syndrome); *Titus v. Aranas*, 2020 WL 4248678, at *6 (D. Nev. June 29, 2020) (prisoner seeking testosterone to treat low levels not similarly situated to female prisoner taking testosterone to transition). Indeed, distinguishing

between treatments that use the same drug is not just rational, but necessary. To the diabetic patient, injecting insulin is lifesaving. To the hypoglycemic patient, it can be life ending. Same drug, different treatments.

Consider puberty blockers again. Puberty blockers are ordinarily prescribed to treat precocious puberty, in which a child begins puberty at an unusually early age.[13] Unlike gender dysphoria, precocious puberty is a physical abnormality that can be diagnosed through medical tests.[14] And the goal of using puberty blockers to treat precocious puberty is to ensure children develop at "the normal age of puberty"[15]—the exact opposite goal as when doctors use them to treat gender dysphoria by *halting* normal puberty. This distinction alters the risk calculus as well: because doctors prescribe blockers to dysphoric children well beyond the normal age, using puberty blockers to treat gender dysphoria may risk diminished bone growth and social development.[16]

The same distinctions hold for the hormones barred by Missouri. Males and females normally have very different amounts of naturally occurring testosterone

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[13] Mayo Clinic, *Precocious Puberty*, *supra*.
[14] *See* NIH, *How Do Healthcare Providers Diagnose Precocious Puberty & Delayed Puberty?*, https://perma.cc/3LGJ-TSV4 (last visited May 12, 2023).
[15] Mayo Clinic, *Precocious Puberty*, *supra*.
[16] *See* Nat'l Inst. for Health & Care Excellence (NICE), *Evidence review: Gonadotrophin releasing hormone analogues for children and adolescents with gender dysphoria*, (Mar. 11, 2021), https://perma.cc/93NB-BGAN, at 26-32 ("NICE Puberty Blocker Evidence Review").

and estrogen.[17] And these hormones serve very different purposes in the different sexes. In females, excess testosterone can *cause* infertility[18]; in males, testosterone is prescribed to *alleviate* fertility problems.[19] The inverse is true of estrogen. When prescribed at an excess level to males, estrogen can *cause* infertility and sexual dysfunction[20]; for females, estrogen is usually prescribed to *treat* problems with sexual development.[21] This makes the use of the same hormones in the different sexes different treatments.

Plaintiffs' attempt to turn the equal protection clauses into a prohibition on the use of "explicitly gendered terms" runs headlong into *Dobbs*. Statement at 26. Virtually every abortion regulation, including the one at issue in *Dobbs*, uses gendered terms or references the unique characteristics of the female reproductive system. *See* Miss. Code Ann. § 41-41-191 (calculating gestational age "from the first day of the last menstrual period of the pregnant woman"). Or say that plastic surgeons started using TikTok to market to minors an experimental surgery that uses

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[17] *E.g.*, Claire Sissions, *Typical Testosterone Levels in Males and Females*, MEDICAL NEWS TODAY (Jan. 6, 2023), https://perma.cc/M98N-4WG4.
[18] Jayne Leonard, *What Causes High Testosterone in Women?*, MEDICAL NEWS TODAY (Jan. 12, 2023), https://perma.cc/BT38-L79X.
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[20] Anna Smith Haghighi, *What To Know About Estrogen in Men*, MEDICAL NEWS TODAY (Nov. 9, 2020), https://perma.cc/B358-S7UW.
[21] Karen O. Klein, *Review of Hormone Replacement Therapy in Girls and Adolescents with Hypogonadism*, 32 J. PEDIATRIC & ADOLESCENT GYNECOLOGY 460 (2019), https://perma.cc/WU36-5889.

skin grafts to change one's racial appearance. (Disturbingly, not a far cry from current trends like #NipRevealFriday and "Yeet the Teet" that some surgeons use to sell gender-modification mastectomies to children.[22]) If Missouri enacted a law prohibiting doctors from providing skin grafts to minors for the purpose of changing their racial appearance, would strict scrutiny apply simply because the statute uses "racial terms"? Of course not. Such a law would not impose a suspect race-based classification under the Equal Protection Clause. So too here: States can ban experimental pediatric gender transition procedures without triggering heightened scrutiny because such laws do not impose a sex-based classification.

Plaintiffs do not even try to justify the performance of gender transition surgeries on children. Gesturing only at the 2017 Endocrine Society Guidelines, Petition ¶84, Plaintiffs try to keep this Court in the dark about how WPATH now sets no minimal age for any gender transition surgery—including mastectomy, breast augmentation, hysterectomy, orchiectomy, or vaginoplasty—other than phalloplasty.[23] Only females undergo mastectomies, hysterectomy, or phalloplasty to transition. And only males undergo breast augmentation, orchiectomy, or vaginoplasty to transition. That makes sense because, for example, no male has a uterus for doctors to remove, and no female has testicles for doctors to remove. Yet, under

[22] *See* Azeen Ghorayshi, *More Trans Teens Are Choosing "Top Surgery,"* N.Y. TIMES (Sept. 26, 2022), https://perma.cc/2K79-A7S8.
[23] SOC 8, *supra*, at S125.

Plaintiffs' theory, if parents sign off on castrating a son so that he can sing with an unnaturally high vocal range as an adult, Missouri would be powerless to stop it—especially if the boy asserts the WPATH approved gender identity of "eunuch." *Cf. Whipping & Castration as Punishments for Crime*, 8 YALE L.J. 371, 382 (1899) (citing the existence of *castrati* in the 1800s in Italy, not in the United States, to justify eugenic sterilization). The drafters of the Missouri Constitution did not smuggle in such an absurd restriction on the legislature's power through the Constitution's equal protection clause.

B. *Bostock* Does Not Control.

Nor does *Bostock v. Clayton County*, 140 S. Ct. 1731 (2020), say otherwise. First, *Bostock* concerned only Title VII's prohibition on sex-based employment discrimination. The Supreme Court expressly cabined *Bostock*'s reasoning to that context. *See id.* at 1753; *see also Pelcha v. MW Bancorp, Inc.*, 988 F.3d 318, 324 (6th Cir. 2021); *Meriwether v. Hartop*, 992 F.3d 492, 510 n.4 (6th Cir. 2021). That is particularly true when it comes to the Equal Protection Clause, which "predates Title VII by nearly a century, so there is reason to be skeptical that [their] protections" are coextensive. *Brandt*, 2022 WL 16957734, at *1 n.1 (Stras, J., dissental); *accord Washington v. Davis*, 426 U.S. 229, 239 (1976) (declining to hold that Title VII's race discrimination standards are "identical" to the Fourteenth Amendment's). Justice Gorsuch, the author of *Bostock*, recently agreed with this conclusion, explaining

why interpretations of Title VII, "enacted at the same time by the same Congress" as Title VI, go "beyond the Equal Protection Clause." *Students for Fair Admissions, Inc.*, 143 S. Ct. at 2216, 2221 (Gorsuch, J., concurring).

Second, even if *Bostock*'s reasoning applied to the Equal Protection Clause, Plaintiffs' claims still would fail. In *Bostock*, the Supreme Court held that an employer that "penalizes a person identified as male at birth for traits or actions that it tolerates in an employee identified as female at birth" discriminates based on sex under Title VII. 140 S. Ct. at 1741. At the core of the Court's reasoning was a "simple test": "if changing the employee's sex would have yielded a different choice by the employer," the employer has treated the employee differently "because of sex." *Id.*

Bostock applied this test to hiring and firing decisions in the workplace based on gender stereotypes. It makes no sense to apply it to medicine, where males and females are *not* similarly situated. *See Cleburne v. Cleburne Living Ctr.*, 473 U.S. 432, 439 (1985) ("The Equal Protection Clause … is essentially a direction that all persons similarly situated should be treated alike."). Take in vitro fertilization. A fertility clinic would not discriminate on the basis of sex by deciding to implant fertilized eggs only in females, even though "changing the [patient's] sex would have yielded a different choice by the [clinic]." *Bostock*, 140 S. Ct. at 1741. There is no equal protection problem because there is no stereotype or inequality in the

clinic's policy; implanting the egg in a male would be a different procedure altogether.

The same is true for gender transition procedures, which also depend on biology, not stereotype. Administering testosterone to bring a boy's levels into a normal range is not the same treatment as ramping up a young girl's testosterone levels to that of a healthy boy—or, for that matter, as providing the hormone to a Tour de France cyclist seeking a yellow jersey. The laws at issue use sex only to determine who would benefit from certain drugs and who would not. And States may regulate testosterone wherever it is administered, be it a pediatrician's office, a gender clinic, or a cyclist training center. To put it in *Bostock*'s terms, it is *not* true that but for a child's sex he or she could be given gender-modification hormones to transition, because *no one* is allowed to receive the drug that transitions *them*. More particularly, because puberty blockers work the same for boys and girls, changing the child's sex changes nothing. Testosterone transitioning treatments and estrogen transitioning treatments, on the other hand, are "medical procedure[s] that only one sex can undergo," *Dobbs*, 142 S. Ct. at 2245-46—unlike Aimee Stephens's desire to wear a dress, which anyone of either sex can do, *see Bostock*, 140 S. Ct. at 1738. *Bostock* does not apply.

Ironically, Plaintiffs lean heavily on misreadings of Sixth Circuit precedents about stereotypes in the workplace, Statement at 28, even though the Sixth Circuit

itself has squarely ruled that those precedents "do[] not move the needle" when it comes to healthcare regulations similar to the SAFE Act, *L.W.*, 73 F.4th at 420-21 (rejecting plaintiffs' invocation of *Smith v. City of Salem*, 378 F.3d 566 (6th Cir. 2004)). "[W]hether someone's body is male or female" simply is not a stereotype. *Id.* at 420. The physical differences between the two sexes are "enduring." *United States v. Virginia*, 518 U.S. 515, 533 (1996). They define sex itself. At the Fourteenth Amendment's ratification, "sex" meant the "physical difference between male and female." Webster, *An American Dictionary of the English Language* (1865). A female is an "individual of the sex among animals which conceives and brings forth young," while a male is of the "sex that begets or procreates young, as distinguished from the female." *Id.*; *see also* Worcester, *A Dictionary of the English Language* (1860) (providing similar definitions for female, male, and sex). Such biologically focused definitions remain the common understanding of those terms today. *See, e.g.*, *The American Heritage Dictionary of the English Language* (5th ed. 2022 online update) (defining "sex" as "[e]ither of the two divisions, designated female and male, by which most organisms are classified on the basis of their reproductive organs and functions").

C. Transgender Individuals Are Not a Suspect Class.

Plaintiffs insist that the SAFE Act "singles out medical care that only transgender people need or seek." Statement at 31. But this notion is refuted by the

growing ranks of detransitioners—individuals who identify as transgender, receive gender transition procedures, and later re-identify with their sex and seek to "detransition."[24] If detransitioners were not transgender, then Plaintiffs are wrong that only transgender people seek such procedures. And if detransitioners *were* transgender but no longer are, then being transgender is not an immutable characteristic.

Regardless, heightened scrutiny doesn't apply simply because people seeking a procedure are disproportionately (or even uniformly) members of a suspect class. *Vacco v. Quill*, 521 U.S. 793, 800 (1997). For instance, classifications based on sex receive intermediate scrutiny, but a classification of "people seeking abortions" does not, even though only women seek abortions. *Dobbs*, 142 S. Ct. at 2245-46.

And in any event, individuals who identify as transgender do not constitute a suspect class to begin with. Aside from the obvious—race, sex, national origin, religion, etc.—the U.S. Supreme Court rarely designates suspect or quasi-suspect classes. *See, e.g.*, *Cleburne*, 473 U.S. at 442-46. Indeed, the Court has rejected suspect classification for disability, age, and poverty. *Id.*; *Mass. Bd. of Retirement v. Murgia*, 427 U.S. 307, 313 (1976); *San Antonio Ind. Sch. Dist. v. Rodriguez*, 411 U.S. 1, 28 (1973). The fact that so few classifications rise to the level of "suspect" itself casts "grave doubt" on the assertion that transgender identity does. *Adams v. Sch. Bd. of*

[24] *E.g.*, Lisa Littman, *Individuals Treated for Gender Dysphoria with Medical and/or Surgical Transition Who Subsequently Detransitioned: A Survey of 100 Detransitioners*, 50 ARCHIVES OF SEXUAL BEHAVIOR 3353 (2021).

St. Johns Cnty., 57 F.4th 791, 803 n.5 (11th Cir. 2022) (en banc). Until the U.S. Supreme Court or the Missouri Supreme Court say otherwise, "rational basis review applies to transgender-based classifications." *L.W.*, 73 F.4th at 419.

Precedent explains why. Classifications are suspect when they single out "distinguishing characteristics" that have historically been divorced from "the interests the State has the authority to implement." *Cleburne*, 473 U.S. at 441. Sex classifications, for example, are suspect because they often "reflect outmoded notions of the relative capabilities of men and women," rather than real differences. *Id.* Same for racial classifications. *Murgia*, 427 U.S. at 313-14. Thus, to be "suspect," a classification must single out a so-called "immutable" characteristic that has historically been the basis for deep discrimination. *See Lyng v. Castillo*, 477 U.S. 635, 638 (1986) (looking for (1) immutable characteristics that define (2) a discrete group, (3) historical discrimination, and (4) political powerlessness).

Transgender status does not check these boxes. For one, it is not "an immutable characteristic determined solely by the accident of birth." *Frontiero v. Richardson*, 411 U.S. 677, 686 (1973). To the contrary, according to Plaintiffs, individuals identify as transgender when their internal perception of who they are departs from the immutable characteristic of their biological sex, a characteristic known since birth. Petition ¶30. Transgender identification necessarily takes place sometime *after* birth. And many individuals who identify as transgender alternate between gender

identifications, whether it's non-binary, gender fluid, third gender, or their natal gender.[25] If a child can hop in and out of the category based on her "fluid" identity, it makes no sense to use the category for equal protection purposes.

Transgender identity falls short on the other suspect-classification factors too. Individuals identifying as transgender as a class look quite "unlike" those individuals who were long denied equal protection because of their race, national origin, or gender. *Murgia*, 427 U.S. at 313-14 (rejecting age as a suspect class because the elderly have not faced discrimination "akin to [suspect] classifications"). States enshrined purposeful race and sex discrimination into their laws for decades; conversely, as the Supreme Court has explained, transgender individuals have been protected by a "major piece of federal civil rights legislation" for nearly a half-century. *Bostock*, 140 S. Ct. at 1753.

And the laws (wrongly) described as discriminating against transgender individuals are recent enactments grappling with tough policy questions about how to protect children from significant harms arising from the recent spike in transgender identification. To the extent that regulating to prevent those harms requires zeroing in on gender dysphoric individuals most likely to be at risk from them, such a classification is a "sensible ground for differential treatment," not the sort of irrelevant grouping that warrants heightened review. *Cleburne*, 473 U.S. at 440.

[25] *See* Littman, *Individuals Treated for Gender Dysphoria*, *supra*.

Finally, no one can look at how the Biden Administration has prioritized "Preventing and Combating Discrimination on the Basis of Gender Identity," Exec. Order No. 13,988, 86 Fed. Reg. 7,023 (Jan. 20, 2021), and make a straight-faced argument that transgender individuals "are politically powerless," *Cleburne*, 473 U.S. at 445. Federal agencies have attempted to impose new gender-identity obligations on the States. *See, e.g.*, *Tennessee v. Dep't of Educ.*, 615 F. Supp. 3d 807, 838-39 (E.D. Tenn. 2022) (rejecting agency attempts to "go[] beyond the holding of *Bostock*"), *appeal argued* No. 22-5807 (6th Cir. Apr. 26, 2023). And President Biden has "appointed a record number of openly LGBTQI+ leaders," including a Senate-confirmed transgender admiral[26] and a nonbinary Deputy Assistant Secretary for the Office of Nuclear Energy.[27] White House, *A Proclamation on Transgender Day of Visibility* (Mar. 30, 2023), perma.cc/VZN6-4ATC.

True, some States have enacted laws like the SAFE Act. Many States have not. *L.W.*, 73 F.4th at 416 (collecting examples). "To permit legislatures on one side of the debate to have their say while silencing legislatures on the other side of the debate" does not further the goals of equal protection. *Id.* Rational basis review applies to the Missouri legislature's choice here.

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[26] U.S. Dep't of Health & Hum. Servs., Admiral Rachel Levine (Oct. 31, 2022), perma.cc/ET5Z-GHFK.

[27] Sands et al., *Top Energy Department official no longer employed after luggage theft accusations*, CNN (Dec. 13, 2022), perma.cc/MJF7-5JPL.

II. Missouri's Law Survives Any Level of Review, Even Heightened Scrutiny.

Even if Plaintiffs were right that heightened scrutiny applies, the SAFE Act would still satisfy that level of review. First, the law is based in biology, not stereotype. Second, pediatric gender-modification procedures are experimental, and States have every reason to wait for the results of the experiments to come in before allowing children to be sterilized. Third, the medical interest groups Plaintiffs rely on are biased participants, not neutral arbiters of science.

A. Laws Prohibiting Pediatric Gender Transition Procedures Are Based in Biology, Not Stereotype.

The Equal Protection Clause commands that "all persons *similarly situated* … be treated alike." *Cleburne*, 473 U.S. at 439 (emphasis added). But males and females are not similarly situated with respect to receiving sex hormones or obtaining certain surgeries. *See supra* Section I. So a law targeting the unique problems inherent in providing cross-sex hormones can't ignore those biological realities. *Dobbs*, 142 S. Ct. at 2245-46. Nor does the Constitution require it to. To the contrary, "fail[ing] to acknowledge ... basic biological differences ... risks making the guarantee of equal protection superficial, and so disserving it." *Nguyen v. INS*, 533 U.S. 53, 73 (2001); *see Ballard v. United States*, 329 U.S. 187, 193 (1946). And a transgender identity doesn't obviate sex-based harms. *Accord Adams*, 57 F.4th at 809-10 (upholding single-sex bathroom policy); *B.P.J. v. W.V. State Bd. of Educ.*, 2023 WL

111875, at *7 (S.D.W.V. Jan. 5, 2023) (upholding single-sex sports policy), *enjoined pending appeal*, 2023 WL 2803113 (4th Cir. 2023).

Biological differences are "the driving force behind the Supreme Court's sex-discrimination jurisprudence." *Adams*, 57 F.4th at 803 n.6. Indeed, "the biological differences between males and females are the reasons intermediate scrutiny," not strict, "applies in sex-discrimination cases in the first place." *Id.* at 809. Intermediate scrutiny prevents States from legislating based on "overbroad generalizations about the different talents, capacities, or preferences of males or females"—generalizations that have no basis in biology. *Virginia*, 518 U.S. at 533 . States cannot presume that women don't like competition, that they have less skill in managing or distributing property, or that they mature faster. *See, e.g.*, *id.* at 541; *Kirchberg v. Feenstra*, 450 U.S. 455, 459-60 (1981); *Reed v. Reed*, 404 U.S. 71, 74 (1971); *Craig v. Boren*, 429 U.S. 190, 192 (1976); *Stanton v. Stanton*, 421 U.S. 7, 14 (1975).

But applying intermediate scrutiny, rather than strict, ensures that distinctions based on "enduring" and "[i]nherent differences" between the sexes survive. *Virginia*, 518 U.S. at 533 (internal quotation marks omitted). Such distinctions are, by their nature, substantially related to the relevant governmental interest and have thus been upheld time and again. Consider *Michael M. v. Superior Court*, which upheld a statutory-rape statute that prohibited sex with a minor female only. 450 U.S. 464, 466 (1981). The Court explained that the classification was permissible because

"young men and young women are not similarly situated with respect to the problems and the risks of sexual intercourse. Only women may become pregnant." *Id.* at 471; *accord Nguyen*, 533 U.S. at 58.

In short, biology matters, and legislatures aren't required to ignore differences rooted in biology. When preventing harms unique to one sex, legislatures can and should take sexual differences into account.

Two recent decisions demonstrate that classifications grounded in biological reality survive intermediate scrutiny. In *Adams*, the Eleventh Circuit, sitting en banc, upheld a school's policy separating bathrooms by biological sex. 57 F.4th at 796.[28] That court acknowledged that schools have a legitimate interest in "protecting the privacy interests of students" in "shielding one's body from the opposite sex." *Id.* at 805. Because that interest was grounded in real, physical differences between the sexes, the court concluded that the sex classification satisfied intermediate scrutiny. *Id.* at 807. And the school's interest didn't change even though one student identified as a member of the opposite sex because that student's self-identification could not change the "immutable characteristic[s]" of biological sex that underpinned the school's privacy interests. *Id.* at 803 n.6, 809 (citing *Frontiero*, 411 U.S. at 686). "[S]ex-specific interests … justif[ied] a sex-specific policy." *Id.* at 806.

[28] *See id.* at 803 n.3 (explaining that analysis about sex-based intermediate scrutiny would be the same if transgender individuals were a suspect class).

Similarly, in *B.P.J. v. West Virginia Board of Education*, a district court upheld West Virginia's law prohibiting biological males from playing girls' sports, even if they identify as transgender. 2023 WL 111875, at *7. That's because "[w]hether a person has male or female sex chromosomes," not what gender he or she identifies as, "determines many of the physical characteristics relevant to athletic performance." *Id.* And "males [generally] outperform females because of inherent physical differences between the sexes." *Id.* To further its "interest in providing equal athletic opportunities for females," the State could "legislate sports rules" based on biological sex. *Id.* at *7-8. So too, States can legislate based on sex to prevent sex-based harms.

B. Gender Transition Procedures Are Experimental.

While Plaintiffs and their preferred medical interest groups repeat again and again that pediatric gender-modification procedures are well-supported by the evidence, that is far from the case. In recent years, medical authorities in the United Kingdom, Finland, Sweden, and Norway have all looked at the evidence and determined that such procedures are in fact experimental.

1. United Kingdom. In 2020, Britain's National Health Service (NHS) commissioned Dr. Hilary Cass, the former president of the Royal College of Paediatrics and Child Health, to chair an independent commission examining the use of puberty blockers and cross-sex hormones to treat gender dysphoria in minors. As part of the

review, the National Institute for Care and Excellence (NICE) conducted two systematic reviews of the published scientific literature concerning the safety and efficacy of using gender-modification procedures to treat children and adolescents with gender dysphoria.[29] The results are striking. The literature reviews concluded that there are no "reliable comparative studies" on the "effectiveness and safety of [puberty blockers],"[30] and that the safety of testosterone transitioning treatment and estrogen transitioning treatment was similarly unknown.[31] Dr. Cass determined that "the available evidence was not strong enough to form the basis of a policy position,"[32] and thus called for experiments to *start* being conducted.[33]

On June 9, 2023, NHS published an interim service specification officially adopting many of Dr. Cass's recommendations. Unlike American medical interest groups, NHS now prioritizes psychological—not hormonal or surgical—care for the treatment of gender dysphoria in youth and will consider prescribing puberty blockers to minors *only* as part of a formal research protocol. Recruitment for that research

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[29] *See Evidence review: Gender-affirming hormones for children and adolescents with gender dysphoria*, Nat'l Inst. for Health & Care Excellence (Mar. 11, 2021), https://perma.cc/M8J5-MXVG ("NICE Cross-Sex Hormone Evidence Review"); NICE Puberty Blocker Evidence Review, *supra*.
[30] NICE Puberty Blocker Evidence Review at 12.
[31] NICE Cross-Sex Hormone Evidence Review 14.
[32] Hilary Cass, *The Cass Review: Interim Report* 37 (Feb. 2022), https://perma.cc/RJU2-VLHT.
[33] Hilary Cass, Letter to Director of Specialized Commissioning (Jul. 19, 2022), https://perma.cc/KS4N-V2GX.

study is expected to *begin* in 2024. Until then, puberty blockers will ordinarily not be prescribed by NHS physicians as a treatment for gender dysphoria.[34]

2. Sweden. In February 2022, following an extensive literature review, Sweden's National Board of Health and Welfare concluded that "the risk of puberty suppressing treatment with GnRH-analogues and gender-affirming hormonal treatment currently outweigh the possible benefits."[35] Concerned that there is no "reliable scientific evidence concerning the efficacy and the safety of both treatments," that "detransition occurs among young adults," and that there has been an "unexplained increase" in minors identifying as transgender, the National Board restricted the use of puberty blockers and cross-sex hormones to strictly controlled research settings or "exceptional cases."[36]

3. Finland. In June 2020, Finland's Council for Choices in Healthcare in Finland also suggested changes to its treatment protocols.[37] Though allowing for some hormonal interventions under certain conditions, the Council lamented the lack of evidence and urged caution in light of severe risks associated with medical

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[34] *See* Azeen Ghorayshi, *Britain Limits Use of Puberty-Blocking Drugs to Research Only*, N.Y. TIMES (June 9, 2023), https://perma.cc/Z74M-ED6R; NHS England, *Interim Service Specification* (June 9, 2023), https://perma.cc/YE3E-AE3H.
[35] Sweden National Board of Health and Welfare Policy Statement, Socialstyrelsen, *Care of Children and Adolescents with Gender Dysphoria: Summary* 3 (2022), https://perma.cc/FDS5-BDF3.
[36] *Id.* at 3-4.
[37] *See* Palveluvalikoima, *Recommendation of the Council for Choices in Health Care in Finland* (2020), https://perma.cc/VN38-67WT.

intervention. "As far as minors are concerned," the Council found, "there are no medical treatment[s] [for gender dysphoria] that can be considered evidence-based," and "it is critical to obtain information on the benefits and risks of these treatments in rigorous research settings."[38] The Council concluded: "[N]o decisions should be made that can permanently alter a still-maturing minor's mental and physical development."

4. Norway. In March 2023, the Norwegian Healthcare Investigation Board (Ukom) released a report finding that its national guidelines for treating gender dysphoria were inadequate.[39] The existing 2020 guidelines had not been based on a literature review, and the new report found "insufficient evidence for the use of puberty blockers and cross sex hormone treatments in young people, especially for teenagers who are increasingly seeking health services."[40] Ukom "recommended that updated guidelines should be based on a new commissioned review or existing international up-to-date systematic reviews, such as those conducted in 2021 by the UK's National Institute for Health and Care Excellence."[41] At present, "Ukom defines such

[38] *Id.*
[39] Jennifer Block, *Norway's Guidance on Paediatric Gender Treatment is Unsafe, Says Review*, THE BMJ (Mar. 23, 2023), https://perma.cc/9FQF-MJJ9.
[40] *Id.*
[41] *Id.*

treatments as utprøvende behandling, or 'treatments under trial,'"[42]—that is, experimental.

C. Plaintiffs Erroneously Rely on American Medical Interest Groups that are Biased Advocates, Not Neutral Experts.

Plaintiffs entirely discount the European experience, suggesting that no European regulator qualifies as a "reputable medical association." Statement at 36 (citation omitted). But how can pediatric treatments that several European countries treat as experimental be definitively "neither harmful nor experimental" for children in Missouri? Statement at 35. While healthcare authorities in Europe have curbed access to pediatric gender transition procedures, American medical organizations have run in the opposite direction: advocating unfettered access to transitioning treatments while quashing members' calls to review the evidence.

In some ways, it is unsurprising that, until the Sixth Circuit's decision in *L.W.*, courts repeatedly deferred to these organizations. One would think that medical societies like the American Academy of Pediatrics (AAP), the Endocrine Society, and WPATH would be honest brokers, reviewing the evidence as Europe has done and responding accordingly. And one would hope that organizations like the American Medical Association—which has not published guidelines on this topic but supports

[42] *Id.*

the WPATH Standards of Care—would use their institutional goodwill, built up over time, to be the voice of reason and put the safety of children first.

Sadly, this has not happened. As with other institutions, American medical organizations have become increasingly "performative," treated by their leaders as platforms for advancing the current moment's cause célèbre.[43] Add to this a replication crisis in scientific literature and the ability of researchers to use statistics to make findings appear significant when they are not,[44] and it is no wonder that medical organizations find it easier to just go with the zeitgeist. (Not to mention that the American interest groups that endorse gender-transition procedures are just that—interest groups, with a strong financial interest in our capitalistic economy to promote the procedures their members make a living by providing.) Science is *hard*, and there is no reward in the current climate for any organization that questions the safety and efficacy of using sterilizing gender-modification procedures on children.

Take AAP, for instance, which has "decried" "as transphobic" a resolution by its members discussing "the growing international skepticism of pediatric gender

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[43] *See generally* Yuval Levin, *A Time to Build: From Family and Community to Congress and the Campus, How Recommitting to our Institutions Can Revive the American Dream* (2020).

[44] *E.g.*, Andrew Gelman & Eric Loken, *The Statistical Crisis in Science*, 102 AMERICAN SCIENTIST 460, 460-65 (2014) (noting "statistical significance" can "be obtained even from pure noise" by various tricks of the trade).

transition" and calling for a literature review.[45] As AAP member Dr. Julia Mason concluded, "AAP has stifled debate" and "put its thumb on the scale … in favor of a shoddy but politically correct research agenda."[46]

Similar concerns have been raised about the Endocrine Society,[47] whose guidelines for treating gender dysphoria the *British Medical Journal* recently exposed as having "serious problems" because—remarkably—the "systematic reviews" the guidelines were based on "didn't look at the effect of the interventions on gender dysphoria itself."[48] The Endocrine Society knows that plaintiffs in cases like this one bandy about its Guidelines to justify the procedures its members profit from. But the fine print at the end of these Guidelines shows how unauthoritative they are: "The Endocrine Society makes no warranty, express or implied, regarding the guidelines," "nor do they establish a standard of care."[49] One member of the Guidelines authoring committee acknowledged, when not testifying in court against the States, that the Endocrine Society did not even have "some little data"—they

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[45] Julia Mason & Leor Sapir, *The American Academy of Pediatrics' Dubious Transgender Science*, WALL ST. JOURNAL (Apr. 17, 2022).
[46] *Id.*
[47] *E.g.*, Roy Eappen & Ian Kingsbury, *The Endocrine Society's Dangerous Transgender Politicization*, WALL ST. JOURNAL (June 28, 2023).
[48] Jennifer Block, *Gender dysphoria in young people is rising—and so is professional disagreement*, THE BMJ (Feb. 23, 2023), https://perma.cc/QKB6-5QCR.
[49] Hembree et al., *Endocrine Treatment of Gender-Dysphoric/Gender-Incongruent Persons: An Endocrine Society Clinical Practice Guideline*, 102 J. CLIN. ENDOCRINOL. METAB. 3869, 3895 (2017).

"had none"—to justify the language allowing prescription of cross sex hormones prior to age 16, a change that gave "cover" to doctors to do so.[50]

Then there is WPATH, which at least confesses to being "an advocacy organization[]." *Boe v. Marshall*, No. 2:22-cv-184-LCB (N.D. Ala.), ECF 208. Ample evidence shows just how true that is. In addition to advocating castration as "medically necessary gender-affirming care" for males whose "gender identity" is "eunuch," WPATH recently removed most minimum-age requirements for gender-modification procedures from its Standards of Care.[51] According to the lead author of the chapter on children, WPATH dropped the age requirements to "bridge th[e] considerations" regarding the need for insurance coverage with the desire to ensure that doctors would not be held liable for malpractice if they deviated from the standards.[52]

WPATH has also suppressed dissent, including canceling the presentation of a prominent researcher who dared to question the safety of transitioning young children and censuring a board member who went public with concerns that medical providers in America are transitioning minors without proper safeguards.[53]

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[50] Joshua Safer, *State of the Art: Transgender Hormone Care* (Feb. 15, 2019), https://www.youtube.com/watch?v=m7Xg9gZS_hg (at 5:38-6:18).
[51] *See* SOC 8, *supra*, at S43-79.
[52] Videorecording of Dr. Tishelman's WPATH presentation, https://perma.cc/4M52-WG4X.
[53] Emily Bazelon, *The Battle Over Gender Therapy*, N.Y. TIMES MAGAZINE (June 15, 2022), https://perma.cc/ZMT2-W6DX.

And just recently, WPATH's leaders were successful in having a major scientific publishing house, Springer, retract a published paper that dared to examine the growing phenomenon of groups of adolescents suddenly "declar[ing] a transgender identity after extensive exposure to social media and peer influence."[54] Indeed, WPATH has tried to cancel nearly every researcher that has looked at "Rapid Onset Gender Dysphoria," for the simple reason that, "[e]ven mentioning the possibility that trans identity is socially influenced or a phase threatens [its] claims that children can know early in life they have a permanent transgender identity and therefore that they should have broad access to permanent body-modifying and sterilizing procedures."[55]

There is thus good reason for the U.S. Supreme Court's observation that medical interest groups' position statements do not "shed light on the meaning of the Constitution." *Dobbs*, 142 S. Ct. at 2267 (rejecting reliance on the positions of American medical associations, which also nearly uniformly supported elective abortions of unborn children). The First and Fifth Circuits had it right when they found that "the WPATH Standards of Care reflect not consensus, but merely one side in a sharply contested medical debate." *Gibson v. Collier*, 920 F.3d 212, 221 (5th Cir. 2019); *see Kosilek v. Spencer*, 774 F.3d 63, 90 (1st Cir. 2014). While

[54] Leor Sapir & Colin Wright, *Medical Journal's False Consensus on "Gender-Affirming Care,"* WALL ST. JOURNAL (June 9, 2023), https://perma.cc/SJK7-SGS8.
[55] *Id.*

medical organizations are certainly capable of establishing true, evidence-based standards of care, they have utterly failed to act responsibly when it comes to pediatric gender transition procedures. As a group of respected gender clinicians and researchers from Finland, the UK, Sweden, Norway, Belgium, France, Switzerland, and South Africa recently opined, "medical societies" in the United States should "align their recommendations with the best available evidence—rather than exaggerating the benefits and minimizing the risks."[56] Until they do so, States like Missouri are forced to step in to protect children.

And Plaintiffs read far too much into the fact that the FDA has approved puberty blockers and other drugs for treatment of conditions other than gender dysphoria. Statement at 30 n.13 & 39. Chief Judge Sutton and Judge Thapar were of course aware of how FDA drug approval works when they ruled that it "is well within a State's police power to ban off-label uses" of drugs. *L.W.*, 73 F.4th at 418. FDA approval of a drug for one indication does not grant Plaintiffs a constitutional right to it for an unapproved use. That is not how federal drug approval works. The "FDA regulates the marketing and distribution of drugs in the United States, not the practice of medicine, which is the exclusive realm of individual states," regardless

[56] Riitakerttu Kaltiala et al., *Youth Gender Transition Is Pushed Without Evidence*, WALL ST. JOURNAL (Jul. 14, 2023).

of whether the FDA has approved a drug for one form of treatment. *Planned Parenthood Cincinnati Region v. Taft*, 444 F.3d 502, 505 (6th Cir. 2006).

Missouri could rationally conclude that "off-label use in this area presents unacceptable dangers," even if it allows other drugs to be used off-label for treating conditions markedly different from gender dysphoria. *L.W.*, 73 F.4th at 418. Gender dysphoria, a mental disorder, is not remotely similar to the physical conditions, such as precocious puberty, for which pharmaceutical companies sought and obtained FDA approval. Pharmaceutical companies have *not* conducted the rigorous studies necessary to determine whether puberty blockers and hormones are effective or safe in treating gender dysphoria. The benefit-risk analysis is not the same.

Pharmaceutical companies' business decision not to seek FDA approval is particularly worrisome because, if the drugs really were effective at treating gender dysphoria, then conducting such studies and obtaining FDA approval for the treatment of gender dysphoria would help dispel concerns of European regulators that have restricted their prescription to gender-dysphoric minors. This Court should not endorse pharmaceutical companies' attempt to end-run around the scientific and regulatory process by having WPATH and other medical interest groups preemptively declare gender transition procedures medically necessary. Missouri was right to protect its children from medical experimentation.

CONCLUSION

The Court should deny Plaintiffs' request for a preliminary injunction enjoining enforcement of the SAFE Act.

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Respectfully submitted,

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CERTIFICATE OF SERVICE

I hereby certify that on August 16, 2023, I filed the foregoing with the Clerk through the Court's electronic filing system, which will accomplish service on all counsel.

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