

**IN THE UNITED STATES DISTRICT COURT
EASTERN DISTRICT OF ARKANSAS
CENTRAL DIVISION**

**DYLAN BRANDT, by and through his mother,
Joanna Brandt, *et al.*,**

PLAINTIFFS,

v.

No. 4:21-CV-00450-JM

**LESLIE RUTLEDGE, in her official capacity as
the Arkansas Attorney General, *et al.*,**

DEFENDANTS.

**DEFENDANTS' COMBINED BRIEF IN OPPOSITION TO
PLAINTIFFS' MOTION FOR PRELIMINARY INJUNCTION;
AND REPLY IN SUPPORT OF DEFENDANTS' MOTION TO DISMISS**

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INTRODUCTION

Reading Plaintiffs' filings in this case leaves a false impression. Contrary to the story that Plaintiffs tell, there is no scientific consensus that children ought to undergo the irreversible, experimental gender-transition procedures regulated by the Save Adolescents from Experimentation (SAFE) Act. Indeed, there is no dispute that the procedures at issue here are entirely experimental: They have *never* been approved—or evaluated—by the Food and Drug Administration as a method of gender transition in children. But to create the misleading impression that there is a consensus about the experimental, dangerous procedures at issue, Plaintiffs entirely omit that fact. Nor do they discuss any of the countless studies over the last few years casting serious doubt on the evidentiary basis for the guidelines produced by advocacy groups like the World Professional Association for Transgender Health (WPATH) and the Endocrine Society. And though Plaintiffs assiduously avoid acknowledging it, there are now countless studies undermining those groups' specious claims and an ever growing body of scientific data that those claims rest on manipulated data, counterfactual claims, and political bias. In the face of that growing scientific evidence, it would be irresponsible for Arkansas to defer to those groups' views.

Nor in any event are the people of Arkansas or their elected representatives required to defer to those groups' views. Rather, the people of Arkansas are entitled to set public policy based on science and data, not politics. That's precisely what the SAFE Act does.

The scientific evidence supporting the SAFE Act is clear. Most children (80-98%) who suffer gender discordance will desist from gender discordance prior to adulthood. Indeed, the evidence demonstrates that's only not the case where they are subject to the kind of experimental, medically unnecessary procedures at issue here. Despite that, WPATH, the Endocrine Society, and Plaintiffs advocate the widespread use of irreversible gender-transition procedures.

Indeed, when they're used as a method of gender transition, puberty blockers reduce bone density, can reduce brain functioning, and can cause sex organs to remain permanently immature, although Plaintiffs ignore these facts. Similarly, when used as a method of gender transition in children, cross-sex hormones result in permanent sterilization. Against that backdrop, it's hardly surprising that the FDA has never approved what Plaintiffs ask this Court to grant them. And the consequences of gender-reassignment surgery like a double mastectomy are devastatingly obvious: complete destruction of functional breasts, including losing the ability to ever breastfeed.

Yet one might be tempted to think—as Plaintiffs claim—that despite those devastating consequences, such procedures surely must be worth it for a subset of children who struggle daily with their bodies. Plaintiffs, for instance, repeatedly invoke the specter of suicide, noting the tragically high rate of suicide among those who identify as transgender. But contrary to Plaintiffs' claim, there is no evidence whatsoever that such procedures are beneficial. Instead, a leading study found that those who went through a full complement of gender-transition procedures actually had an *increased* risk of suicide as compared to the control group. And study after study has searched through the available data for evidence that gender-transition procedures benefit those who undergo them. Yet no evidence of benefit has been found.

Based on this scientific record, the gender-transition procedures at issue are, at best, experimental treatments for gender dysphoria. And no one has a constitutional right to conduct or undergo experimental medicine. As explained more fully below, this Court should therefore deny Plaintiffs' motion for a preliminary injunction and dismiss this case with prejudice.

BACKGROUND

A. Sex, Gender, and Gender Discordance

A person's sex is determined by DNA. (Decl. of Dr. Stephen Levine ¶ 9.) ("Levine Decl.")¹ In every person, every cell in his or her body that has a nucleus is chromosomally encoded as either female or male: two X chromosomes for females; one X and one Y chromosome for males. (*See id.*)

While sex is genetic, there are people who have normal, healthy sex organs but experience gender discordance. (*Id.*) When that sense of discordance brings on "clinically significant distress," a person may receive a diagnosis of gender dysphoria. (*Id.* ¶ 17.) The current version of the *Diagnostic & Statistical Manual*, the DSM-5, divides gender dysphoria into two categories based on age of onset.² Early-onset and late-onset gender dysphoria differ in diagnostic criteria.³ In children, the DSM-5 diagnostic criteria are as follows:

A marked incongruence between one's experienced/expressed gender and assigned gender, lasting at least 6 months, as manifested by at least six of the following (one of which must be the first criterion):

1. A strong desire to be of the other gender or an insistence that one is the other gender (or some alternative gender different from one's assigned gender)
2. In boys (assigned gender), a strong preference for cross-dressing or simulating female attire; or in girls (assigned gender), a strong preference for wearing only typical masculine clothing and a strong resistance to the wearing of typical feminine clothing
3. A strong preference for cross-gender roles in make-believe play or fantasy play

¹ Dr. Levine's declaration is simultaneously filed with this brief as Exhibit 1.

² Am. Psychiatric Ass'n, *Diagnostic and Statistical Manual of Mental Disorders* 452 (5th ed. 2013) [hereinafter, "DSM-5"]. Excerpts from the DSM-5 are simultaneously filed with this brief as Exhibit 24.

³ *Id.* at 452-53.

4. A strong preference for the toys, games or activities stereotypically used or engaged in by the other gender
5. A strong preference for playmates of the other gender
6. In boys (assigned gender), a strong rejection of typically masculine toys, games, and activities and a strong avoidance of rough-and-tumble play; or in girls (assigned gender), a strong rejection of typically feminine toys, games, and activities
7. A strong dislike of one's sexual anatomy
8. A strong desire for the physical sex characteristics that match one's experienced gender⁴

Using those metrics, then, merely playing with toys stereotypically associated with children of the opposite sex, pretending to be fictional characters of the opposite sex, and having opposite-sex friendships may be evidence of early-onset gender dysphoria.

Perhaps unsurprisingly given that threshold, WPATH—whose guidelines Plaintiffs rely on for nearly all of their arguments about why early intervention is necessary—acknowledges the “relatively *low* persistence rates of childhood gender dysphoria.”⁵ Yet Plaintiffs ask this Court to require Arkansas to sanction subjecting children to experimental medical procedures that will render them forever sterile.

Additionally, and perhaps just as unsurprising given that criteria, none of these sources equate gender dysphoria with transgender status. Nor do they treat those who identify as transgender as a unified class that shares defining characteristics. Both the Endocrine Society and WPATH explain that “transgender” is “an umbrella term” that includes “a *diverse* group of

⁴ *Id.* at 452.

⁵ WPATH, *Standards of Care for the Health of Transsexual, Transgender, and Gender-Non-conforming People* 17 (7th ed.) (2012) (emphasis added), <https://www.wpath.org/publications/soc> [hereinafter “WPATH Guidelines”]. The WPATH Guidelines are simultaneously filed with this brief as Exhibit 19.

individuals.”⁶ And that diverse group includes, for example, those who “experience themselves as having both a male and female gender identity,” those who “experienc[e] a continuous and rapid involuntary alternation between a male and female identity,” and those “who do not experience themselves as men but do not want to live as women.”⁷ Indeed, the umbrella term “transgender” includes anyone who does “not conform to a binary understanding of gender as limited to the categories of man or woman, male or female.”⁸ The diversity of this group—and its lack of any defining characteristic—is reflected in the multiplicity of more specific terms that fall within it. To name just a few: “boygirl,” “girlboy,” “genderqueer,” “eunuch,” “bigender,” “pangender,” “androgyn[e],” “genderless,” “gender neutral,” “neutrois,” “agender,” “genderfluid,” “third gender.”⁹

These same sources also make clear that “gender identity,” and transgender status in particular, is not necessarily a biologically determined characteristic. Those sources state that a person’s “gender identity” is not biologically fixed but necessarily indexed to “culturally defined categories of gender,”¹⁰ or that it reflects “environmental” and “cultural factors.”¹¹ And being

⁶ Wylie C. Hembree, et al., *Endocrine Treatment of Gender-Dysphoric/Gender-Incongruent Persons: An Endocrine Society Clinical Practice Guideline*, 102 *J. Clinical Endocrinology & Metabolism* 3869, 3875 (Nov. 2017) [hereinafter, “ES Guidelines”]; see WPATH Guidelines, *supra*, at 97. The ES Guidelines are simultaneously filed with this brief as Exhibit 21.

⁷ ES Guidelines, *supra*, at 3873.

⁸ WPATH Guidelines, *supra*, at 96.

⁹ See *id.*; Am. Psych. Ass’n, *Guidelines for Psychological Practice with Transgender and Gender Nonconforming People*, 70 *Am. Psychologist* 832, 862 (2015) [hereinafter, “APA Guidelines”]. The APA Guidelines are simultaneously filed with this brief as Exhibit 22.

¹⁰ WPATH Guidelines, *supra*, at 97.

¹¹ ES Guidelines, *supra*, 3874; see Jason Rafferty, Am. Acad. of Pediatrics, *Ensuring Comprehensive Care and Support for Transgender and Gender-Diverse Children and Adolescents*, 142 *Pediatrics* 1, 4 (Oct. 2018) [hereinafter, “AAP Guidelines”]. The AAP Guidelines are simultaneously filed with this brief as Exhibit 23.

“transgender” is also said to include each person whose mere “name, pronouns, clothing, haircut, behavior, voice, or body characteristics” (*i.e.*, a person’s so-called “gender expression”) differ “from what is typically associated with their sex designated at birth”—*regardless* of how such persons identify themselves.¹² Thus, being transgender does not require even identifying in a way at odds with one’s sex. Rather than being rooted in biology as Plaintiffs claim, WPATH says that being transgender is based on “what is normative” regarding categories of masculine and feminine “in a given culture and historical period.”¹³

More than that, in any particular person, these advocacy organizations posit that gender identity can toggle between various options at different times. As WPATH says, “for some transgender individuals, gender identity may remain somewhat fluid for many years.”¹⁴ Along similar lines, the American Psychological Association says some people “experience their gender identity as fluid.”¹⁵ And the Endocrine Society goes even further, stating that some are said to have “a continuous and rapid involuntary alternation between a male and female identity.”¹⁶ In fact, according to the Endocrine Society, a person *can switch* between being transgender or not literally by simply changing her “clothing, haircut, [or] behavior.”¹⁷

¹² ES Guidelines, *supra*, at 3875.

¹³ WPATH Guidelines, *supra*, at 96-97.

¹⁴ WPATH, *Position Statement on Medical Necessity of Treatment, Sex Reassignment, and Insurance Coverage in the U.S.A.* 1 (2016) [hereinafter, “WPATH’s Med. Nec. Stmt.”]. (*See* Compl. ¶ 154 n.11 (citing WPATH’s Med. Nec. Stmt.).)

¹⁵ APA Guidelines, *supra*, at 836.

¹⁶ ES Guidelines, *supra*, at 3873.

¹⁷ *See* ES Guidelines, *supra*, at 3875.

Ultimately and critically for the legal analysis here, the above discussion demonstrates that—contrary to Plaintiffs’ claims here—these organizations all recognize that transgender status is not immutable. As the DSM-5 makes clear, “[t]ransgender refers to the *broad* spectrum of individuals who *transiently or persistently* identify with a gender different from their natal gender.”¹⁸ And the WPATH guidelines concede that “[i]n children and adolescents, a rapid and dramatic developmental process (physical, psychological, and sexual) is involved and there is greater fluidity and variability in outcomes.”¹⁹ Not only does the Endocrine Society agree with WPATH’s concession, it also highlights that “we cannot predict the psychosexual outcome for any specific child,” which is to say we do not know which children will desist from suffering gender dysphoria.²⁰ In fact, as the broad diagnostic criteria outlined above would suggest, “[i]n *most children*, gender dysphoria will disappear before, or early in, puberty.”²¹ And “[s]ome identity beliefs in adolescents may become firmly held and strongly expressed, giving *a false impression of irreversibility*.”²² This is perhaps why the American Psychological Association maintains the category of “gender-questioning” youth as those for whom questioning merely “*may lead*” to a transgender identity.²³ In any event, “[i]t is . . . important that parents explicitly let the child know that *there is a way back*.”²⁴

¹⁸ DSM-5, *supra*, at 451 (emphasis altered).

¹⁹ WPATH Guidelines, *supra*, at 10-11.

²⁰ ES Guidelines, *supra*, at 3876.

²¹ WPATH Guidelines, *supra*, at 12 (emphasis added); *see id.* at 17 (recognizing that children’s desire to transition can reflect “other forces” than “gender identity”).

²² *Id.* at 18 (emphasis added).

²³ APA Guidelines, *supra*, at 841 (emphasis added).

²⁴ WPATH Guidelines, *supra*, at 17 (emphasis added); *see* APA Guidelines, *supra*, at 843 (“*Emphasizing* to parents the importance of allowing their child the freedom to return to a gender

B. Treatment Models for Gender Dysphoria

The mental-health community has developed three primary treatment models for gender dysphoria: watchful waiting, psychotherapy, and affirmation. (*See* Levine Decl. ¶¶ 27-42.) Under the watchful-waiting model, the mental health professional takes a cautious approach to interventions. (*Id.* ¶ 28-29.) Watchful-waiting treatment is often combined with the second treatment model, psychotherapy. (*Id.* ¶¶ 30-35.) Here, the mental health professional uses established psychotherapeutic techniques to alleviate the distress experienced by the person with gender dysphoria. (*Id.*) This approach makes sense because the data shows that an overwhelming majority of the time, a child’s gender dysphoria will desist on its own and in the absence of any other intervention. (*See id.* ¶ 58 (reporting on studies finding desistence rate of 80-98%).) This finding has held true across many different follow-up studies: A majority of children suffering gender dysphoria will, by the time they reach puberty, stop wanting to transition. (*Id.*)

Other mental health professionals follow an “affirmation therapy” model. Under that model, a child experiencing gender dysphoria must be unquestioningly affirmed and encouraged to pursue a transgender identity. (*Id.* ¶¶ 36-42.) This model often encourages children to socially transition first, then to medically transition through the use of drugs, and eventually even to surgically transition. These are not neutral choices. Even social transition is associated with a much higher rate of persistent, long-lasting gender dysphoria in children. (*See id.* ¶ 58 (discussing one study that found fewer than 20% of boys who partially or completely transitioned prior to puberty desisted by age 15); *id.* (discussing different study finding that social transition was correlated with persistence in boys but not girls).)

identity that aligns with sex assigned at birth . . . cannot be overstated, particularly given the research that suggests that not all young gender nonconforming children will ultimately express a gender identity different from that assigned at birth.”).

The lasting effects of medical and surgical transition are even more permanent. The first step of a medical transition is often to place a child on puberty blockers. When used as a gender-transition procedure to indefinitely halt the normal progression of puberty in a child, puberty blockers are *not* FDA approved. (Decl. of Dr. Paul Hruz at p. 76.) (“Hruz Decl.”)²⁵ That is, the use of such drugs as a gender-transition procedure on children is experimental and unsupported by data. They are only FDA-approved as a treatment for precocious puberty—a fundamentally different treatment that doesn’t carry even remotely the same risks or consequences. (See Decl. of Dr. Mark Regnerus ¶¶ 50-51.) (“Regnerus Decl.”)²⁶ The long-term effects of using puberty blockers as a gender-transition procedure are not well studied. (See Regnerus Decl. ¶ 33 (“It remains the fact that little is understood about the long-term physical effects of puberty blockers and cross-sex hormones, especially when they are administered during those years that are critical for biological and brain development.”).) But it is known that children placed on puberty blockers have slower rates of growth in height, and an elevated risk of low bone density. (Hruz Decl. at p. 76.) Additionally, because “the contribution of sex hormones should not be ignored” “when examining brain development,” it may alter the normal maturation of adolescents’ brains to cause them to miss normally timed puberty—and the sex hormones that come with it.²⁷ And because puberty blockers prevent the maturation of a child’s sexual organs, some children placed on puberty blockers as a gender-transition procedure will never develop the capability to orgasm, although data on the likelihood of this consequence have not yet been published. (Levine Decl. ¶ 83.)

²⁵ Dr. Hruz’s Declaration is simultaneously filed with this brief as Exhibit 3.

²⁶ Dr. Regnerus’s Declaration is simultaneously filed with this brief as Exhibit 2.

²⁷ Mariam Arain, et al., *Maturation of the Adolescent Brain*, 9 *Neuropsychiatric Disease & Treatment* 449, 452 (cited by Hruz Decl. at p. 76).

Data also indicate that putting a child on puberty blockers as a gender-transition procedure leads almost invariably to cross-sex hormones for that child. (*See* Regnerus Decl. ¶ 77 (“Rather than pressing a pause button for time to think, 98 percent of the adolescents put on puberty blockers at the UK’s Tavistock clinic proceeded to cross-sex hormones, thereby triggering irreversible effects.” (footnotes omitted)).) This phenomenon may arise from the fact that “[a]fter an extended period of pubertal suppression one cannot ‘turn back the clock’ and reverse changes in the normal coordinated pattern of adolescent psychological development and puberty.” (Hruz Decl. at p. 77.) In other words, children placed on puberty blockers may face the choice of remaining in a prepubertal body for their entire lives, or taking cross-sex hormones to induce the development of cross-sex secondary sex characteristics.

As with puberty blockers, cross-sex hormones are *not* approved by the FDA for use as a gender-transition procedure. (Regnerus Decl. ¶ 50.) As above, the use of such drugs on children is wholly experimental and results in a variety of irreversible consequences. In girls who take testosterone, this can include a permanently deepened voice; in boys on estrogen, permanent loss of muscle mass. (Levine Decl. ¶ 84.) Cross-sex hormones also lead to a variety of negative health outcomes. (*See, e.g.*, Hruz Decl. at p. 72 (“Other potential adverse effects include disfiguring acne, high blood pressure, weight gain, abnormal glucose tolerance, breast cancer, liver disease, thrombosis, and cardiovascular disease.”).) Perhaps most troublingly, cross-sex hormones result in permanent and irreversible sterilization. (*Id.* at 71.)

Finally, some pursue surgery as a gender-transition procedure. Where such surgery is performed on a patient’s genitals the primary irreversible effects are obvious. (*See* Decl. of Clifton Francis Burleigh, Jr. ¶ 7 (describing profuse bleeding after a “penile inversion” surgery); Decl. of Walt Heyer ¶ 7 (discussing his penile-inversion surgery, which “consist[ed] of removing

the testicles while retaining the penis, but surgically inverting the penis into a pouch”).²⁸ Plaintiffs bring no claims, however, regarding genital gender-reassignment surgery. They focus instead on the use of double mastectomies as a gender-transition procedure. (*See, e.g.*, Br. in Supp. of Plfs.’ Mot. for a Prelim. Inj., Dkt. No. 12 (“PI Br.”) at 7-8.) In this gender-transition procedure, otherwise healthy breasts are removed, thereby permanently destroying functioning organs. (Decl. of Dr. Patrick Lappert ¶¶ 17, 30-35.) (“Lappert Decl.”)²⁹ A girl who undergoes a double mastectomy will permanently lose the ability to breastfeed. (*Id.* ¶¶ 34-35.) And because the most commonly performed procedure for gender-reassignment mastectomies removes the nipples and severs the fourth intercostal nerve, it permanently destroys the erotic sensibility of the nipples. (*Id.*)

Each of the gender-transition procedures at issue in this case permanently destroys the biological function of otherwise healthy sex and reproductive organs. And the experimental use of drugs that are designed to address fundamentally different conditions runs the risk of creating a lifetime of mental and physical conditions that children cannot fully comprehend. Many of the children who undergo these procedures have other psychological problems, like attention deficit hyperactivity disorder and autism. (Levine Decl. ¶ 18.)

C. Science-Based Criticism of WPATH and the Endocrine Society

Plaintiffs ignore the existence of any treatment model for gender discordance other than affirmation and transition. To claim that gender-transition procedures are “well-established” and

²⁸ Mr. Burleigh’s and Mr. Heyer’s declarations are simultaneously filed with this brief as Exhibits 27 and 28.

²⁹ Dr. Lappert’s Declaration is simultaneously filed with this brief as Exhibit 4.

“medically necessary,” Plaintiffs rely on guidelines published by WPATH and the Endocrine Society. (*See, e.g.*, PI Br. 4-5 & nn.1-2; Compl. ¶¶ 32-40.) These sources cannot bear the weight that Plaintiffs place on them. They have faced serious scientific criticism for years.

First off, these guidelines do not establish what Plaintiffs claim they establish. The Endocrine Society guidelines expressly recognize that they “cannot . . . establish a standard of care.”³⁰ And WPATH “acknowledges that despite the misleading name, WPATH Standards of Care 7 are *practice guidelines*, not standards of care.”³¹ The American Psychological Association agrees that the WPATH and Endocrine Society documents are merely “treatment guidelines”—not “standards of care.”³²

While clinical guidelines have increasingly become a familiar part of clinical practice, “[u]nlike standards of care, which should be authoritative, unbiased consensus positions designed to produce optimal outcomes, practice guidelines are suggestions or recommendations to improve care that, depending on their sponsor, may be biased.”³³ Indeed, because guidelines represent a political, consensus-seeking process (*i.e.*, voting)—a process with no known error

³⁰ ES Guidelines, *supra*, at 3895.

³¹ William J. Malone, et al., *Letter to the Editor from William J. Malone et al: Proper Care of Transgender and Gender-diverse Persons in the Setting of Proposed Discrimination: A Policy Perspective* 1 (2021), <https://doi.org/10.1210/clinem/dgab205> (citing *WPATH Statement Regarding Medical Affirming Treatment including Puberty Blockers for Transgender Adolescents*, https://www.wpath.org/media/cms/Documents/Public%20Policies/2020/FINAL%20Statement%20Regarding%20Informed%20Consent%20Court%20Case_Dec%2016%202020.docx.pdf?_t=1608225376); *see* WPATH Guidelines, *supra*, at 1 (“The overall goal of the [WPATH guidelines] is to provide clinical guidance.”). (*See* Levine Decl. ¶ 15 n.9 (citing Malone, *supra*).)

³² American Psychological Association, *Guidelines for Psychological Practice with Transgender and Gender Nonconforming People*, 70 *Am. Psychologist* 832, 833 (Dec. 2015).

³³ Malone, *supra*, at 1.

rate—as opposed to an evidence-seeking scientific research process, they have never been accepted by the scientific community as establishing what practices are or are not experimental. (See Hruz Decl. at pp. 46-48; Levine Decl. ¶ 52.)

Recommendations provided by guidelines “are influenced by the opinions and clinical experience and composition of the guideline development group. Tests and treatments that experts believe are good for patients may in practice be inferior to other options, ineffective, or even harmful.”³⁴ Guidelines may recommend “sub-optimal” treatments to “serve societal needs, or protect special interests (those of doctors, risk managers, or politicians, for example).”³⁵ Worse, they are “subject to misuse by proponents and advocacy groups giving the public (and health professionals) the wrong impression about . . . the effectiveness of interventions.”³⁶ Guidelines can “compromis[e] the quality of care” by “encourag[ing] ineffective, harmful, or wasteful interventions,” leading “[n]aïve consumers” to “accept official recommendations on face value, especially when they carry the imprimatur of prominent professional groups.”³⁷

There is also no doubt that the WPATH guidelines encourage harmful medical interventions. For example, the current version of the WPATH guidelines removed the previously existing requirement that persons suffering gender dysphoria receive psychotherapy *before* undergoing aggressive and experimental hormone therapy or surgery. (Levine Decl. ¶¶ 50-53.)³⁸ Thus,

³⁴ Steven H. Woolf, et al., *Potential Benefits, Limitations, and Harms of Clinical Guidelines*, 318 *Brit. Med. J.* 527, 529 (1999). (See Hruz Decl. at p. 19 (citing Woolf, *supra*, in discussion of deficiencies of clinical guidelines).)

³⁵ Woolf, *supra*, at 529.

³⁶ *Id.*

³⁷ *Id.* at 529-30.

³⁸ See WPATH Guidelines, *supra*, at 28 (“Psychotherapy is Not an Absolute Requirement for Hormone Therapy and Surgery”).

unlike under the previous guidelines, adolescents don't need to see anyone with professional experience in addressing developmental forces shaping identity and behavior and experience identifying and diagnosing psychiatric comorbidities that could underlie their gender dysphoria before undergoing life-altering procedures. (*Id.* ¶ 50.) Instead, the revised guidelines focus only on confirming dysphoria, not what may have caused that condition or how it can best be addressed. (*See id.* ¶ 33.)

Underscoring the point, Dr. Stephen B. Levine, former Chairman of the WPATH Standards of Care Committee, reluctantly resigned from WPATH after concluding that it had become driven by politics and ideology rather than by scientific methodology and evidence. (*Id.* ¶ 46.) Questions concerning the benefits of gender-transition procedures are not well tolerated in discussions within the organization and skeptical voices have been literally shouted down by large numbers of unlicensed transgender activists who attend its biennial meetings—an unusual thing for what purports to be a professional organization. (*Id.* ¶¶ 47-48.) WPATH expressly acknowledges that its “mission is to promote . . . advocacy” and “public policy” concerning transgender-related issues.³⁹ Indeed, WPATH has issued statements advocating for the removal of gender-identity-related disorders from the DSM and other publications.⁴⁰ These statements concerning the existence of such disorders are not based on any evidence, data, or science, but are designed merely to combat what WPATH's Board of Directors calls “stigma” created by “prejudice and discrimination.”⁴¹ (*See* Levine Decl. ¶ 52 (discussing the unscientific nature of this statement).)

³⁹ WPATH Guidelines, *supra*, at 1.

⁴⁰ *See* WPATH Board of Directors, *De-Psychopathologisation Statement* (May 26, 2010), available at <https://www.wpath.org/policies>; G. DeCuypere et al., *Response of the World Professional Association for Transgender Health to the Proposed DSM 5 Criteria for Gender Incongruence* (May 25, 2010), available at <https://www.wpath.org/policies>.

⁴¹ *See* WPATH De-Psychopathologization Statement.

Although WPATH claims to speak for the profession, it represents only a self-selected subset of it along with many non-professional activists. (*Id.* ¶ 51.) Indeed, most psychiatrists and psychologists who treat patients seeking inpatient psychiatric care for gender dysphoria are not members of WPATH. (*Id.*)

Unlike the WPATH guidelines, the more recent Endocrine Society guidelines attempt to grade the quality of the evidence for each of their recommendations. They use the Grading of Recommendations, Assessment, Development and Evaluations (GRADE) system.⁴² Notably, “[t]he only data that reached the level of ‘moderate’ quality were related to adverse medical outcomes.”⁴³ And the Endocrine Society guidelines *strongly* “recommend *against* puberty blocking and gender-affirming hormone treatment in prepubertal children with [gender dysphoria].”⁴⁴ For youth who reach puberty, the guidelines are unable even to “recommend” puberty blockers, instead merely “suggest[ing]” their use.⁴⁵ By the guidelines’ own terms, the weakness of this statement indicates—contrary to Plaintiffs’ unqualified assurances that children will benefit from them—doubt that those “who receive [puberty blockers] will derive, on average, more benefit than harm.”⁴⁶ The guidelines similarly recognize that there is only “very low-quality” or, at best, “low quality” evidence supporting the use either of puberty blockers or cross-sex hormones.⁴⁷ “By definition, these designations mean that there is a high likelihood that the attainment of new

⁴² See G.H. Guyatt, et al., *GRADE: An Emerging Consensus on Rating Quality of Evidence and Strength of Recommendations*, 336 *British Md. J.* 924 (2008).

⁴³ Paul W. Hruz, *Deficiencies in Scientific Evidence for Medical Management of Gender Dysphoria*, 87 *Linacre Quarterly* 34, 37 (2020).

⁴⁴ ES Guidelines, *supra*, at 3879; *see id.* at 3872 (explaining strength and quality-of-evidence indicators)).

⁴⁵ *Id.* at 3880.

⁴⁶ *Id.* at 3872.

⁴⁷ *Id.*

data will necessitate changes to the guidelines provided.”⁴⁸ The guidelines upon which Plaintiffs rely likewise recognize that “[t]here is *insufficient evidence* to recommend a specific age requirement” for mastectomies.⁴⁹

The guidelines published by WPATH and the Endocrine Society, which are essentially the only evidence that Plaintiffs offer, have not withstood the serious scientific criticism leveled against them in recent years and, in any event, don’t support their claims.

D. Recent Boom in Gender Discordance

A number of surprising demographic trends have occurred in the past decade among those who identify as transgender.

Chief among them is a sudden, rapid increase in that self-identification. (*See* Levine Decl. ¶ 15 (describing a 4,000% increase over the course of a few years).) Because of the nature of the American healthcare system, U.S. data are not well standardized. But some data suggest that the number of those who identify as transgender ballooned from 0.3% of the population in 2011 to 0.6% in 2016—doubling in just 5 years. (Regnerus Decl. ¶ 13.) Since 2016, the pace has only quickened. Estimates of those who identify as transgender now range from 1.8% to just under 3%. (*Id.*) Even taking the low end of that range means that transgender self-identifications have tripled in the last five years. Countries with nationalized healthcare have more robust data sets that confirm this trend. For example, the primary gender-transition facility for minors in the United Kingdom has documented a precipitous rise in patients since 2009. (*Id.* ¶ 14.) For the period from 2009 to 2010, that facility saw 32 females and 40 males. (*Id.*) Five years later,

⁴⁸ Hruz, *supra*, at 37.

⁴⁹ ES Guidelines, *supra*, at 3894 (emphasis added).

those numbers were 399 females and 250 males. (*Id.*) And in the 2018-2019 period, the facility saw 1,740 females and 624 males. (*Id.*)

These numbers from the United Kingdom document a related demographic trend. The sex ratio of those who identify as transgender has suddenly flipped. Throughout the 20th century, that ratio was around three or four males experiencing gender discordance for every one female, a 3:1 or 4:1 ratio of males over females. (Levine Decl. ¶ 15.) Many clinics now report a sex ratio of 7:1, females over males. (*Id.*) Driving this reversal, along with the general uptick in transgender self-identification, is an increase in gender-dysphoria diagnoses amongst females. The U.K. numbers, for example, show that females' diagnoses have risen nearly 50-fold over the last five years. (*See* Regnerus Decl. ¶¶ 13-17; Lappert Decl. ¶ 70.)

These shifting demographics of course raise a question: Why? The reasons are not yet known. (*See* Regnerus Decl. ¶¶ 23, 28.) The suddenness of this shift is inconsistent with the theory that gender dysphoria and transgender identity have a biological basis. (Levine Decl. ¶ 15.) And because the surge in dysphoria has been limited to adolescents, it “cannot be simplistically attributed to ‘pent-up demand.’” (Regnerus Decl. ¶ 22.) The pent-up-demand theory would result in a “parallel and documentable rise in gender dysphoria among, say middle-aged adults,” which “has not been observed.” (*Id.*)

As an alternative thesis, some in this field have developed a theory of “social contagion” or “social influence.” (*See* Levine Decl. ¶ 15; Regnerus Decl. ¶¶ 24-25.) This theory arose in part based on the observation of a connection between increasing self-identifications as transgender and the rise of an internet subculture regarding transgender issues. (*See* Levine Decl. ¶ 15 (“I have not seen a trans adolescent who has not spent countless hours on trans Inter-

net sites.”.) As a result, healthcare providers around the world have documented a trend in patients arriving for gender-transition procedures with preconceived notions about their need to transition—notions based on their own online research. (*See* Regnerus Decl. ¶¶ 35-37.)

The explosion in those identifying as transgender has led to a concomitant explosion in gender-transition facilities. (*Id.* ¶¶ 65-70.) Many facilities practice a “patient-driven, on-demand” model, often referred to as an “informed consent” model of gender-transition services. (*Id.* ¶ 69.) Under this model, if the patient indicates that she understands and accepts possible side effects, practitioners offer “no gatekeeping at all.” (*Id.*; *see id.* (“I had a prescription in my hand the same day I went in.”).)

This lack of “gatekeeping” is unfortunate, given that “[r]egret following transition is not an infrequent phenomenon.” (Levine Decl. ¶¶ 94-99.) Billy Burleigh and Walt Heyer each have stories of post-transition regret. From an early age, both men wished they were girls, and later, women. (*See* Burleigh Decl. ¶¶ 3-4; Heyer Decl. ¶¶ 2-6.) As a young man, Mr. Burleigh began to take testosterone blockers and estrogen. (Burleigh Decl. ¶ 6.) Three years later, he surgically transitioned, with “a penile inversion, an Adam’s apple shave, and a brow shave.” (*Id.* ¶ 7.) Post-surgery, Mr. Burleigh bled profusely and had to remain in the hospital for three weeks. (*Id.*) He lived as a woman for seven years. Then, “[d]epression began to set back in and suicide was again coming to seem like more of an option.” (*Id.* ¶ 9.) In the end, Mr. Burleigh chose to detransition, a process that took him two or three years. (*Id.* ¶ 10.)

Mr. Heyer’s story is similar, though he transitioned later in life. As a young man, he married and had two children. (Heyer Decl. ¶ 4.) Then, still plagued by gender dysphoria, Mr. Heyer chose to pursue gender-reassignment surgery. (*Id.* ¶ 6.) After his genital surgery, his wife divorced him, and he began to live as a woman. (*Id.* ¶ 7.) Mr. Heyer lived eight years as a

woman, but his gender dysphoria returned. (*Id.* ¶ 8.) His psychological distress deepened, and he eventually attempted suicide as a result. (*Id.* ¶¶ 10-12.) Only with counseling and psychotherapy was Mr. Heyer eventually able to move past his gender dysphoria. (*Id.* ¶ 13.) And although, with time, Mr. Heyer detransitioned, his body will always bear the markers of his gender-transition procedures. (*Id.* ¶¶ 14-15.)

Laura Perry also detransitioned after gender-reassignment surgery. (*See* Decl. of Laura Perry ¶¶ 10-13.) (“Perry Decl.”)⁵⁰ Her gender dysphoria began at a young age, when her mother made it known she wished Ms. Perry were a boy. (*Id.* ¶ 2.) Then, as an eight-year-old, Ms. Perry was sexually abused. (*Id.* ¶ 3.) In her mid-20s, Ms. Perry began to present herself as a man and to take cross-sex hormones. (*Id.* ¶¶ 4-5, 7-8.) She changed her legal name and birth certificate. (*Id.* ¶ 9.) And she underwent a hysterectomy. (*Id.* ¶ 11.) After researching phalloplasty—a surgery that converts female genitalia into the shape of male genitalia, using “donor muscle from [the patient’s] arm”—Ms. Perry realized that she could not afford genital surgery. (*Id.* ¶¶ 12-13.) Then, in her early 30s, Ms. Perry began to doubt whether she should go on living as a man. (*Id.* ¶ 19.) During the detransitioning process, she confronted the underlying psychological problems left from her childhood. (*Id.* ¶¶ 20-21.) According to Ms. Perry, “[t]he only intervention that has ever helped [her] without hurting [her] far worse is psychological counseling.” (*Id.* ¶ 22.)

If adults like Mr. Burleigh, Mr. Heyer, and Ms. Perry—all of whom could trace their gender dysphoria to a young age, and for whom their dysphoria persisted into adulthood—can find themselves regretting their gender-transition procedures and detransitioning years later, it seems

⁵⁰ Ms. Perry’s declaration is simultaneously filed with this brief as Exhibit 29.

all the more likely that adolescents, with their reduced capacity to consider long-term consequences, will often regret these procedures later in life. (*See* Regnerus ¶¶ 86-90 (discussing medical associations’ positions on diminished decisional capacity of minors); Levine Decl. ¶ 55 (“It is not yet known how to distinguish those children who will desist from that small minority whose trans identity will persist.”).)

E. International Criticism of Lack of Evidence Supporting Gender-Transition Procedures

The dramatic rise over the last decade in transgender self-identifications among children and concomitant presentations for gender-transition procedures has led to a swell of international concern about the state of the gender-transition industry.

In 2019, the Swedish government commissioned a review of the scientific literature on gender dysphoria in children and adolescents.⁵¹ (*See* Hruz Decl. at p. 9-10; Levine Decl. ¶¶ 67(b), 126.) That study found a lack of evidence for hormonal and surgical treatments and a lack of explanation for the recent sharp increase in the numbers of adolescents presenting with gender dysphoria.⁵² Then, the Karolinska Hospital in Sweden issued a new guideline effective May 1, 2021, that banned the use of puberty blockers and cross-sex hormones on patients under 18.⁵³ The existing studies on these gender-transition procedures, Sweden concluded, “provid[e]

⁵¹ Swedish Agency for Health Tech. Assessment and Assessment of Soc’l Servs., *Gender Dysphoria in Children and Adolescents: An Inventory of the Literature*, <https://www.sbu.se/en/publications/sbu-bereder/gender-dysphoria-in-children-and-adolescents-an-inventory-of-the-literature/>. A copy of this document is simultaneously filed with this brief as Exhibit 6.

⁵² *Id.*

⁵³ *Guideline Regarding Hormonal Treatment of Minors with Gender Dysphoria at Tema Barn - Astrid Lindgren Children’s Hospital (ALB)*, <https://segm.org/sites/default/files/Karolinska%20Guideline%20K2021-4144%20April%202021%20%28English%2C%20unofficial%20translation%29.pdf> [hereinafter, “Swedish Guideline”].

low quality evidence that the treatments have the desired effect”—namely, the reduction of distress associated with gender dysphoria—and “we have very little knowledge about their safety in the long term.”⁵⁴ The Swedish guideline cited the same irreversible consequences discussed above, including osteoporosis and infertility.⁵⁵ Having found little evidence of benefit but strong evidence of significant harms, the Karolinska Institute placed an absolute ban on hormonal treatments for children under 16 and banned all treatments for patients between 16 and 18 outside of clinical trial settings approved by the Swedish Institutional Review Board.⁵⁶ (See Regnerus Decl. ¶ 97.)

Finland reached a similar conclusion in June 2020. Prompted by the increase in the number of minors referred for treatment of gender dysphoria, the Council for Choices in Healthcare in Finland published guidelines that govern medical treatments of gender dysphoria.⁵⁷ (See Levine Decl. ¶¶ 67(a), 126 & n.85; Regnerus Decl. ¶ 42, 97.) Those guidelines noted that *no* gender-

The Society for Evidence Based Gender Medicine published online the Swedish guideline and policy statement (discussed below) both in Swedish and in English translation. See *Sweden’s Karolinska Ends All Use of Puberty Blockers and Cross-Sex Hormones for Minors Outside of Clinical Studies*, https://segm.org/Sweden_ends_use_of_Dutch_protocol.

⁵⁴ Swedish Guideline, *supra*.

⁵⁵ *Id.*

⁵⁶ *Id.*; see *Policy Change Regarding Hormonal Treatment of Minors with Gender Dysphoria at Tema Barn - Astrid Lindgren Children’s Hospital*, https://segm.org/sites/default/files/Karolinska%20_Policy_Statement_English.pdf. A copy of the Karolinska policy change is simultaneously filed with this brief as Exhibit 7.

⁵⁷ Palveluvalikoima, *Recommendation of the Council for Choices in Health Care in Finland (PALKO / COHERE Finland)*, https://segm.org/sites/default/files/Finnish_Guidelines_2020_Minors_Unofficial%20Translation.pdf (hereinafter, “Finnish Guideline”).

An English translation of the Finnish Guideline is simultaneously filed with this brief as Exhibit 5. The original Finnish text is available from the health service’s website, <https://palveluvalikoima.fi/documents/1237350/22895623/Muunsukupuolinen+suositus.pdf/058ac8f5-560d-da00-7b03-20644f97674a/Muunsukupuolinen+suositus.pdf>.

reassignment “surgeries are performed on minors” in Finland.⁵⁸ And although the guidelines permitted some interventions (as long as they are reversible), they recognized that, “[i]n light of available evidence, gender reassignment of minors is an experimental practice.”⁵⁹ “As far as minors are concerned,” they noted, “there are no medical treatment[s] that can be considered evidence-based.”⁶⁰

Importantly, Finland broke with the WPATH guidelines, recognizing that for adolescents who experience gender dysphoria, “[t]he first-line treatment . . . is psychosocial support and, as necessary, psychotherapy and treatment of possible comorbid psychiatric disorders.”⁶¹ The Finnish guidelines recognized that because “reduction of psychiatric symptoms cannot be achieved with hormonal and surgical interventions,” it “is not a valid justification for gender reassignment.”⁶² They noted a worrisome 18-month study that showed adolescents who received psychological interventions alone improved more quickly in global psychosocial function than adolescents who received both puberty blockers and psychological interventions.⁶³

Similarly, in the United Kingdom, concern about gender-transition procedures has been growing since at least 2019. In February of that year, a prominent Oxford-based researcher and

⁵⁸ Finnish Guideline, *supra*, at 5.

⁵⁹ *Id.* at 7.

⁶⁰ *Id.* at 6.

⁶¹ *Id.* at 5, 8.

⁶² *Id.* at 7.

⁶³ *Id.* at 6.

editor of the *British Medical Journal's Evidence Based Medicine Spotlight* raised serious concerns with the quality of the evidence for puberty blockers and cross-sex hormones.⁶⁴ (See Regnerus Decl. ¶ 33 & n.27.) Because of “significant problems with how the evidence for Gender-affirming cross-sex hormone has been collected and analysed,” he concluded that such “treatments for under 18 gender dysphoric children and adolescents remain largely experimental.”⁶⁵ “The current evidence base,” he said, “does not support informed decision making and safe practice in children.”⁶⁶

Then, in March 2019, an Oxford sociologist raised serious concerns about a trial of puberty blockers that the U.K. National Health Service’s Tavistock Gender Identity Development Service (the “Tavistock clinic”) had begun in 2010.⁶⁷ Although the Tavistock clinic’s director, Dr. Polly Carmichael, announced in May 2014 that the trial was complete, no results were published.⁶⁸ Unpublished results became publicly available, however. Most concerning was that youth undergoing gender-transition procedures experienced a significant increase in attempts “to hurt or kill self.”⁶⁹ Additionally, the Tavistock clinic’s results showed that, after one year on puberty blockers, children “continue[d] to report an increase in internalising problems and body

⁶⁴ Carl Heneghan, *Gender-affirming Hormone Treatment in Children and Adolescents*, BMJ Blog (Feb. 25, 2019), <https://blogs.bmj.com/bmjebmspotlight/2019/02/25/gender-affirming-hormone-in-children-and-adolescents-evidence-review/>.

⁶⁵ *Id.*

⁶⁶ *Id.*

⁶⁷ See Michael Biggs, *The Tavistock’s Experiment with Puberty Blockers* (Jul. 29, 2019), https://users.ox.ac.uk/~sfos0060/Biggs_ExperimentPubertyBlockers.pdf. (See also Hruz Decl. at pp. 12-13 (discussing Biggs’s writing).) A copy of Biggs’s report on Tavistock is simultaneously filed with this brief as Exhibit 17.

⁶⁸ Biggs, *supra*, at 5.

⁶⁹ *Id.* at 6.

dissatisfaction, especially natal girls.”⁷⁰ The data found no statistically significant difference in outcomes between children who were given puberty blockers and those who were not.⁷¹

In March 2021, the U.K. National Institute for Health and Care Excellence (NICE) published two systematic reviews of the evidence concerning whether puberty blockers and cross-sex hormones were effective for treatment of minors with gender dysphoria. The review of studies of puberty blockers found that they were “all small, uncontrolled observational studies, which are subject to bias and confounding, and all the results are of very low certainty using modified GRADE. They all reported physical and mental health comorbidities and concomitant treatments very poorly.”⁷² (See Hruz Decl. at pp. 11-12 (discussing findings of NICE evidence review); Levine Decl. ¶¶ 67(c), 126 & nn.50-51, 85 (same); Regnerus Decl. ¶¶ 42, 45 (same).) As the review explained, “Studies that found differences in outcomes could represent changes that are either of questionable clinical value, or the studies themselves are not reliable and changes could be due to confounding, bias or chance.”⁷³ In any case, examining those poor-quality studies, the review found “little change . . . from baseline to follow-up” on “the critical outcomes of gender dysphoria and mental health (depression, anger and anxiety), and the important outcomes of body image and psychosocial impact (global and psychosocial functioning).”⁷⁴

⁷⁰ *Id.* (emphasis omitted).

⁷¹ *Id.* at 7.

⁷² Nat’l Inst. Health & Care Excellence, *Evidence Review: Gonadotrophin Releasing Hormone Analogues for Children and Adolescents with Gender Dysphoria*, at 13 (Mar. 11, 2021), <https://www.evidence.nhs.uk/document?id=2334888&returnUrl=search%3fq%3dtransgender%26s%3dDate>. A copy of this NICE evidence review is simultaneously filed with this brief as Exhibit 9.

⁷³ *Id.*

⁷⁴ *Id.*

The NICE review of studies of cross-sex hormones identified similar shortcomings. It again found that all of the studies “are uncontrolled observational studies, which are subject to bias and confounding and were of very low certainty using modified GRADE.”⁷⁵ “A fundamental limitation of all the uncontrolled studies,” the review found, “is that any changes in scores from baseline to follow-up could be attributed to a regression-to-the-mean.”⁷⁶ Further, “no study reported concomitant treatments in detail,” meaning that “it is not clear whether any changes observed were due to gender-affirming hormones or other treatments the participants may have received,” including “mental health support.”⁷⁷ Finally, the review concluded that “[a]ny potential benefits of treatment [with cross-sex hormones] must be weighed against the largely unknown long-term safety profile of these treatments.”⁷⁸

⁷⁵ Nat’l Inst. Health & Care Excellence, *Evidence Review: Gender-affirming Hormones for Children and Adolescents with Gender Dysphoria*, at 47 (Mar. 11, 2021), <https://www.evidence.nhs.uk/document?id=2334889&returnUrl=search%3ffrom%3d2021-03-10%26q%3dEvidence%2bReview%26to%3d2021-04-01>. A copy of this NICE evidence review is simultaneously filed with this brief as Exhibit 10.

⁷⁶ *Id.*

⁷⁷ *Id.* at 48.

⁷⁸ *Id.* at 50.

Around this same time, in November 2020, Cochrane⁷⁹ published a systematic review that “aimed to assess the efficacy and safety of hormone therapy” for male-to-female transitioners.⁸⁰ Cochrane’s researchers exhausted the available literature.⁸¹ Despite their extensive research, however, they concluded, starkly: “This systematic review has shown that well-designed, sufficiently robust randomised controlled trials (RCTs) and controlled-cohort studies *do not exist*.”⁸² Although gender-transition practitioners had spent “more than four decades” trying “to improve the quality of hormone therapy,” Cochrane “found that no RCTs or suitable cohort studies have yet been conducted to investigate the efficacy and safety of hormonal treatment approaches.”⁸³ Due to the absence of studies, Cochrane was unable to rigorously analyze the safety and effectiveness of cross-sex hormones as a gender-transition procedure.⁸⁴ Cochrane thus agreed with the “repeatedly emphasised” problem of “a gap between current clinical practice and clinical research.”⁸⁵ In other words, there was no research to support current clinical practice.

⁷⁹ Cochrane is an international network of 50,000 researchers in 130 countries headquartered in the UK that conducts rigorous, systematic reviews of evidence for treatment safety and efficacy independent of pharmaceutical conflicts of interest. Cochrane, *About Us*, <https://www.cochrane.org/about-us>.

⁸⁰ Claudia Haupt, et al., *Antiandrogen or Estradiol Treatment or Both during Hormone Therapy in Transitioning Transgender Women*, Cochrane Database of Systematic Reviews (Nov. 28, 2020), at 1. (See Hruz Decl. at pp. 16-17 (discussing findings of Cochrane review).) A copy of this Cochrane review is simultaneously filed with this brief as Exhibit 11.

⁸¹ See *id.* at 5-7, 10 (describing their research efforts).

⁸² *Id.* at 11 (emphasis added).

⁸³ *Id.* at 10.

⁸⁴ *Id.* at 8-9.

⁸⁵ *Id.* at 10.

In an effort to rectify the complete absence of longitudinal research on treatment outcomes for gender-transition procedures, two researchers, Richard Bränström and John E. Pachankis, published the very first long-term treatment-outcome study in the *American Journal of Psychiatry*.⁸⁶ The authors presented their data as supporting claims that gender-transition procedures improve long-term mental health outcomes.⁸⁷ But the data were not as the authors had presented them. The study's methodological blunders prompted multiple devastating letters from prominent researchers to the editor of the *American Journal of Psychiatry* that highlighted its shortcomings.⁸⁸ Besides coding errors that excluded lithium and other antipsychotic medications from (but included antihistamines in) the category of treatments for mood disorders,⁸⁹ the study excluded cases in which the subjects actually committed suicide, attempted suicide without being hospitalized, had health care visits for other psychological issues, and more.⁹⁰ Letters noted that the data in fact showed “a spike in suicide attempts” in the year after surgery.⁹¹ Another ex-

⁸⁶ Richard Bränström and John E. Pachankis, *Reduction in Mental Health Treatment Utilization among Transgender Individuals after Gender-affirming Surgeries: A Total Population Study*, 177 *Am. J. of Psychiatry* 727 (2020).

⁸⁷ *See id.* (“In this first total population study of transgender individuals with a gender incongruence diagnosis, the longitudinal association between gender-affirming surgery and reduced likelihood of mental health treatment lends support to the decision to provide gender-affirming surgeries to transgender individuals who seek them.”).

⁸⁸ These letters and the *Journal*'s response are simultaneously filed with this brief as Exhibits 12 and 13.

⁸⁹ Henrik Anckarsäter and Christopher Gillberg, *Methodological Shortcomings Undercut Statement in Support of Gender-Affirming Surgery*, 177 *Am. J. Psychiatry* 764, 765 (Aug. 2020).

⁹⁰ Andre Van Mol, et al., *Gender-Affirmation Surgery Conclusion Lacks Evidence*, 177 *Am. J. Psychiatry* 765, 765 (Aug. 2020).

⁹¹ David Curtis, *Study of Transgender Patients: Conclusions Are Not Supported by Findings*, 177 *Am. J. Psychiatry* 766, 766 (Aug. 2020); see Mikael Landén, *The Effect of Gender-Affirming Treatment on Psychiatric Morbidity Is Still Undecided*, 177 *Am. J. Psychiatry* 767 (Aug. 2020).

plained that “the data also could be interpreted as showing that masculinizing or feminizing surgeries were the actual cause of increased mental health utilization.”⁹² In fact, “the risk of being hospitalized for a suicide attempt was 2.4 times higher if they had undergone gender-corrective surgery than if they had not.”⁹³

An extraordinary comment published by the *Journal*'s editor explained that after receiving the letters, the *Journal* enlisted two statistical experts to review the letters and the original article.⁹⁴ It published a “Correction to Bränström and Pachankis,” which explained that “the results demonstrated no advantage of surgery in relation to subsequent mood or anxiety disorder-related health care visits or prescriptions or hospitalizations following suicide attempts in that comparison.”⁹⁵ The *Journal* also published a statement from Bränström and Pachankis in which the authors admitted that “individuals diagnosed with gender incongruence who had received gender-affirming surgery were more likely to be treated for anxiety disorders compared with in-

⁹² William J. Malone and Sven Roman, *Calling Into Question Whether Gender-Affirming Surgery Relieves Psychological Distress*, 177 *Am. J. Psychiatry* 766, 766 (Aug. 2020).

⁹³ Agnes Wold, *Gender-Corrective Surgery Promoting Mental Health in Persons With Gender Dysphoria Not Supported by Data Presented in Article*, 177 *Am. J. Psychiatry* 768, 768 (Aug. 2020).

In addition to the letters already cited, see Avi Ring and William J. Malone, *Confounding Effects on Mental Health Observations After Sex Reassignment Surgery*, 177 *Am. J. Psychiatry* 768 (Aug. 2020).

⁹⁴ Ned H. Kalin, *Reassessing Mental Health Treatment Utilization Reduction in Transgender Individuals After Gender-Affirming Surgeries: A Comment by the Editor on the Process*, 177 *Am. J. Psychiatry* 764, 764 (Aug. 2020), <https://ajp.psychiatryonline.org/doi/10.1176/appi.ajp.2020.20060803>.

⁹⁵ *Correction to Bränström and Pachankis*, 177 *Am. J. Psychiatry* 734 (Aug. 2020), <https://ajp.psychiatryonline.org/doi/10.1176/appi.ajp.2020.1778correction>.

dividuals diagnosed with gender incongruence who had not received gender-affirming surgery.”⁹⁶ Consequently, the only long-term treatment-outcome study of gender-transition procedures to date is inconclusive at best, and, at worst, demonstrates actual harm to the mental health of persons undergoing gender-transition surgery.

Amidst the swirling gender-transition debate, the U.K courts stepped in. On December 1, 2020, the Administrative Court of the United Kingdom’s High Court of Justice of England and Wales issued its decision in *Bell v. Tavistock and Portman National Health Service Foundation Trust*, [2020] EWHC (Admin) 3274.⁹⁷ The claimants in that proceeding sought judicial review of the Tavistock clinic’s use of puberty blockers as a gender-transition procedure for minors. *Id.* ¶ 2. At the heart of the case was whether children ever are competent to consent to that experimental use of puberty-blocking drugs. *Id.* ¶ 6. The High Court decided that children usually cannot give informed consent to puberty-blocking drugs. *See id.* ¶¶ 151-53.

The High Court rejected the Tavistock clinic’s evidence. It defended its practice of prescribing puberty blockers to children under 18 by claiming compliance “with the international frameworks of WPATH and the Endocrine Society.” *Id.* ¶ 97. Examining the evidence, however, the High Court recognized that “the history of the use of puberty blockers relied upon” by WPATH and the Endocrine Society was misleading. *Id.* ¶ 60. Those organizations relied only

⁹⁶ Richard Bränström and John E. Pachankis, *Toward Rigorous Methodologies for Strengthening Causal Inference in the Association Between Gender Affirming Care and Transgender Individuals’ Mental Health: Response to Letters*, 177 *Am. J. of Psychiatry* 769, 771 (Aug. 2020).

⁹⁷ <https://www.judiciary.uk/judgments/r-on-the-application-of-quincy-bell-and-a-v-tavistock-and-portman-nhs-trust-and-others/>.

on history pertaining to “the treatment of *precocious puberty*”—“a different condition from gender dysphoria,” to say the least.⁹⁸ *Id.* (emphasis altered). The High Court also doubted the claim that puberty blockers are fully reversible. *See id.* ¶ 64 (noting that puberty blockers “stop the physical changes in the body when going through puberty”); *id.* ¶ 137 (“[T]he use of puberty blockers is not itself a neutral process by which time stands still for the child on puberty blockers, whether physically or psychologically.”). It also highlighted the fact that the U.K. National Health Service had, in June 2020, removed from its website a statement that puberty blockers are “fully reversible.” *Id.* ¶ 67.

The High Court credited evidence that “in statistical terms once a child or young person starts on puberty blockers, they are on a very clear clinical pathway to cross-sex hormones.” *Id.* ¶ 68; *see id.* ¶ 136 (describing puberty blockers and cross-sex hormones as “two stages of one clinical pathway and once on that pathway it is extremely rare for a child to get off it”); *id.* ¶ 137 (“[T]he statistical correlation between the use of puberty blockers and cross-sex hormones supports the case that it is appropriate to view puberty blockers as a stepping stone to cross-sex hormones.”). And there is no real dispute that “cross-sex hormones are to a very significant degree not reversible.” *Id.* ¶ 68. Given the long-term effects of placing minors on puberty blockers and, most likely, cross-sex hormones, the High Court found that “children of this age cannot understand” the irreversible risks they face, “such as the loss of the ability to orgasm, the potential need to construct a neo-vagina, or the loss of fertility.” *Id.* ¶ 93. It stated unequivocally that “[t]here is no age appropriate way to explain to many of these children what losing their fertility or full sexual function may mean to them in later years.” *Id.* ¶ 144.

⁹⁸ The *Tavistock* opinion often shortens “gender dysphoria” to “GD”, “puberty blockers” to “PBs”, and “cross-sex hormones” to “CSH.” *See* ¶¶ 3, 4, 15. For consistency and clarity, this brief’s quotations from *Tavistock* expand those abbreviations.

F. The SAFE Act

About two months after the *Tavistock* decision, the Save Adolescents from Experimentation (SAFE) Act was introduced during the Arkansas General Assembly’s 2021 session. *See* 2021 Ark. Act 626 (bill filed Feb. 25, 2021) (to be codified at Ark. Code 20-9-1501 through -1504). The General Assembly did not deny that there are children who experience psychological distress with their bodies. *See id.*, sec. 2(2), (4). But it also noted that this distress often has underlying causes and comorbidities, and that experimental endocrine and surgical interventions—such as the use of puberty blockers and cross-sex hormones—leave the underlying issues unaddressed. *Id.*; *see id.*, sec. 2(6)-(7).

In the SAFE Act’s findings, the General Assembly echoed much of the international body of research that has sprung up over the last 18 to 24 months. It highlighted lack of evidence demonstrating the safety of puberty blockers to indefinitely halt normal pubertal development. *Id.*, sec. 2(6). And it emphasized the known irreversible consequences of cross-sex hormones. *See id.*, sec. 2(7)-(8). Noting with concern that referrals of children for experimental gender-reassignment surgeries are increasing, *id.*, sec. 2(9), 13(B), the General Assembly also discussed the consequences of such surgeries: the alteration or destruction of biological functions. *Id.*, sec. 2(10)-(12).

Based on this scientific evidence, the General Assembly concluded that “[t]he risks of gender transition procedures far outweigh any benefit at this stage of clinical study on these procedures.” *Id.*, sec. 2(15). Therefore, in light of the experimental nature of endocrine and surgical interference with children’s normal biological development and functioning, along with its known dangers, the SAFE Act prohibits practitioners from performing gender-transition procedures on children or referring them for such procedures. *Id.*, sec. 3 (Ark. Code Ann. 20-9-

1502(a) through (b)); *see id.* secs. 3-4 (enacting Ark. Code Ann. 20-9-1503 and 23-79-164) (prohibiting additionally public expenditures on or insurance reimbursements for such procedures on children). The Act defines “gender transition procedures” as “any medical or surgical service . . . including . . . puberty-blocking drugs, cross-sex hormones, . . . or genital or nongenital gender reassignment surgery performed for the purpose of assisting an individual with a gender transition.” *Id.*, sec. 3 (enacting Ark. Code Ann. 20-9-1501(6)(A)). Crucially, the SAFE Act does *not* prohibit gender-transition procedures for anyone 18 years old or above. *Id.* (enacting Ark. Code Ann. 20-9-1502(a)). Finally, the SAFE Act does not prohibit—rather, it encourages—the provision of mental health services to children to address the comorbidities and underlying causes of their distress. *Id.*, sec. 2(4).

Plaintiffs filed suit on May 25, 2021, asking the Court to require Arkansas to permit the performance of untested, experimental procedures with irreversible and long-term consequences on distressed and vulnerable children. That is, they ask this Court to require Arkansas to sanction the use of procedures that the FDA has not approved, for which the benefits have not been established, and that will undisputedly destroy a child’s functional sex organs (or prevent the child from ever developing them). Determining that these known risks outweigh the unknown benefits, Arkansas has made the decision that doctors in this State cannot, consistent with established principles of medical ethics, continue performing these procedures on children.

LEGAL STANDARD

Plaintiffs do not state the correct standard for a preliminary-injunction motion like theirs. As in any other case, they must satisfy the *Dataphase* factors, showing that: (1) they are likely to succeed on the merits; (2) they are likely to suffer irreparable harm in the absence of preliminary relief; (3) the balance of equities tips in their favor; and (4) an injunction is in the public interest. *Dataphase Sys., Inc. v. CL Sys., Inc.*, 640 F.2d 109, 114 (8th Cir. 1981) (en banc); *see Winter v.*

Nat. Res. Def. Council, 555 U.S. 7, 24-25 (2008). And they bear the burden of making “a clear showing” that they have satisfied those factors. *Winter*, 555 U.S. at 22.

Yet Plaintiffs do not discuss an additional burden they face. Because their requested preliminary injunction would prevent “implementation of a duly enacted state statute,” they must make a “*more rigorous* showing” than usual “that [they are] ‘likely to prevail on the merits.’” *Planned Parenthood Ark. & E. Okla. v. Jegley*, 864 F.3d 953, 957-58 (8th Cir. 2017) (emphasis added) (quoting *Planned Parenthood Minn., N.D., S.D. v. Rounds*, 530 F.3d 724, 732-33 (8th Cir. 2008) (en banc)); see *Richland/Wilkin Joint Powers Auth. v. U.S. Army Corps of Eng’rs*, 826 F.3d 1030, 1040 (8th Cir. 2016) (“[U]nder *Rounds*, the court must sometimes apply a more stringent standard of ‘likely to prevail.’”). That requirement guards against attempts to “thwart a state’s presumptively reasonable democratic processes.” *Rounds*, 530 F.3d at 733. “A more rigorous standard ‘reflects the idea that government policies implemented through legislation or regulations developed through presumptively reasoned democratic processes are entitled to a higher degree of deference and should not be enjoined lightly.’” *Id.* at 732 (quoting *Able v. United States*, 44 F.3d 128, 131 (2d Cir. 1995) (per curiam)).

Another feature of Plaintiffs’ requested preliminary injunction further increases their burden. Granting their requested preliminary injunction would “give [them] substantially the relief [they] would obtain after a trial on the merits.” *Dakota Indus., Inc. v. Ever Best Ltd.*, 944 F.2d 438, 440 (8th Cir. 1991). As a result, their burden “is a heavy one.” *Id.*

A preliminary injunction is always an extraordinary remedy. See *Winter*, 555 U.S. at 24. Plaintiffs cannot meet their heavy burden of making a more rigorous showing than is typically required that they are likely to succeed on the merits. Nor have they made the necessary clear showing of their entitlement to relief on any of the other factors.

SUMMARY OF ARGUMENT

Because Plaintiffs lack scientific evidence to undermine Arkansas's interests here, this Court should deny their pending motion for a preliminary injunction, and instead grant Defendants' motion to dismiss the complaint with prejudice. As an initial matter, Plaintiffs lack standing to challenge certain provisions of the SAFE Act because, as even they concede, their claims do not implicate those provisions. Just as importantly, the practitioners who are Plaintiffs here lack standing to assert the rights of their non-party patients. Arguing otherwise, Plaintiffs ask this Court to expand current third-party-standing doctrine, creating a blanket exception for doctors to assert their patients' rights. Such an expansion is unwarranted under binding precedent.

In addition to their standing problems, Plaintiffs are not likely to succeed on the merits of their claims. They first challenge the SAFE Act's prohibition under the Equal Protection Clause. Because the Act draws classifications on the basis of age and medical procedure, however, their equal-protection claim receives only rational-basis scrutiny, which the SAFE Act easily satisfies. Even intermediate scrutiny, the highest level of equal-protection scrutiny that Plaintiffs seek to apply, would not be a problem for the Act. Arkansas's compelling interests here, in protecting children and enforcing medical ethics, are essentially undisputed. And the SAFE Act prohibits practitioners from performing experimental gender-transition procedures for which there is a total lack of evidence that they lead to any benefit whatsoever. That prohibition is at least substantially related to Arkansas's compelling interests.

Plaintiffs are equally unlikely to succeed on their other claims. Parents have no fundamental right under substantive-due-process doctrine to choose non-FDA-approved experimental gender-transition procedures for their children. And the SAFE Act's prohibition on referrals—*i.e.*, sending children to other practitioners (presumably outside Arkansas) for prohibited procedures—regulates only the professional conduct of practitioners, not anyone's speech. In any

event, because the SAFE Act is narrowly tailored to Arkansas’s compelling interests, it would survive even strict scrutiny. There is no alternative means of pursuing Arkansas’s interests but to prohibit the gender-transition procedures that are harming those interests. And if Arkansas allowed its practitioners to continue referring children elsewhere for these procedures, the SAFE Act’s protections for children would be practically ineffective.

Without proving they are likely to succeed on their claims, Plaintiffs cannot obtain a preliminary injunction. Yet here, their injunction request also fails for an additional reason. An injunction would itself harm Arkansas children. If this Court grants a preliminary injunction, additional children in Arkansas will undergo irreversible changes to their bodies while this case proceeds to judgment—changes that result in the permanent destruction of their once-healthy sex and reproductive organs.

As explained below, and in the brief in support of Defendants’ motion to dismiss, this Court should deny the preliminary-injunction motion, and dismiss this case with prejudice.

ARGUMENT

I. Relying on inapposite precedent, much of it from the abortion context, Plaintiffs have failed to establish their standing.

A. Plaintiffs concede that certain SAFE Act provisions are not implicated by their claims, so they lack standing to challenge those provisions.

Plaintiffs’ allegations do not implicate the provisions of the SAFE Act prohibiting gender-reassignment surgery on minors and creating a private right of action. In response to Defendants’ motion to dismiss, Plaintiffs do not claim otherwise. (*See* MTD Opp’n 7-10.) Instead, they argue that this Court should allow them to challenge those provisions anyway and opine that they violate the Constitution. That would be the very definition of an advisory opinion, one that resolves a “hypothetical or abstract dispute.” *TransUnion LLC v. Ramirez*, No. 20-297, — S.

Ct. —, 2021 WL 2599472, at *6 (June 25, 2021). So this Court should dismiss Plaintiffs' claims as to these provisions for lack of standing.

I. According to the Complaint, none of the practitioners in this case perform gender-reassignment surgery on children, and none of the children seek to undergo gender-reassignment surgery before their eighteenth birthday. (*See generally* Compl. ¶¶ 13-14, 65-126.) Yet Plaintiffs seek an injunction that would block even the SAFE Act's prohibition on performing gender-reassignment surgeries on children. (*See id.* at 46, Prayer for Relief ¶ ii; *see also id.* ¶ 1 (defining the SAFE Act in its entirety as the "Health Care Ban").) Plaintiffs admit that the SAFE Act does not injure them insofar as it prohibits gender-reassignment surgery on children. Enjoining this part of the SAFE Act, therefore, would violate the rule that they must have standing not just for "each claim they bring" but also "for *each form of relief* they seek." *Webb ex rel. K.S. v. Smith*, 936 F.3d 808, 814 (8th Cir. 2019) (emphasis added).

Plaintiffs argue that their lack of standing to obtain an injunction of the SAFE Act as to gender-reassignment surgery does not matter because the Act prohibits it in the same section in which it prohibits other gender-transition procedures. (*See* MTD Opp'n 7.) This argument ignores the substance of the prohibition. The SAFE Act prohibits a *variety* of procedures by defining them as "gender transition procedures." SAFE Act, sec. 3 (enacting Ark. Code Ann. 20-9-1501(6)(A), 20-9-1502(a) through (b)). Just as easily, the Act could have instead banned each of these procedures in separate provisions. Arkansas's choice to instead simplify the language of the SAFE Act by placing gender-reassignment surgery and other procedures within the umbrella term "gender transition procedures" should not change the analysis. However drafted, the SAFE Act prohibits gender-reassignment surgery on minors—a point Plaintiffs cannot dispute.

In any event, the Supreme Court has rejected this sort of standing theory. It is not enough that “all claims for relief” in the Complaint “derive from a ‘common nucleus of operative fact.’” *DaimlerChrysler Corp. v. Cuno*, 547 U.S. 332, 352 (2006). Thus in *Cuno*, although the plaintiffs had standing to challenge a tax exemption, that did not suffice to give them standing to challenge a related tax credit. *Id.* at 350-51. Here, that principle means that Plaintiffs cannot bootstrap themselves into standing for an injunction against conduct they agree is not harming them—*i.e.*, a prohibition on surgeries that they don’t intend to get—by pointing to their claim that they have standing to challenge other conduct. This Court should dismiss Plaintiffs’ claims insofar as they relate to the SAFE Act’s prohibition of gender-reassignment surgery.

2. Separately, Plaintiffs cannot challenge the SAFE Act’s private right of action, because they do not allege that any private action has been brought against them. *See* SAFE Act, sec. 3 (enacting Ark. Code Ann. 20-9-1504(b) through (c)). Even if there were a private action pending against Plaintiffs, they would lack standing to challenge that action in a lawsuit against Defendants. Any injury caused by the private right of action would not be fairly traceable to Defendants, who are exclusively state officials sued in their official capacities, nor would it be redressable by an order of this Court. (*See* MTD Br. 12-13.)

Plaintiffs do not cite—let alone distinguish—the decisions from other courts that have rejected similar challenges to private rights of action. *See Hope Clinic v. Ryan*, 249 F.3d 603, 605 (7th Cir. 2001) (“[P]laintiffs lack standing to contest the statutes authorizing private rights of action, not only because the defendants cannot cause the plaintiffs injury by enforcing the private-action statutes, but also because any potential dispute plaintiffs may have with future private plaintiffs could not be redressed by an injunction running only against public prosecutors.”); *Okpalobi v. Foster*, 244 F.3d 405, 427 (5th Cir. 2001) (en banc) (holding that state officials in their

official capacity “cannot prevent purely private litigants from filing and prosecuting a cause of action”); *Planned Parenthood of Greater Tex. Surgical Health Servs. v. City of Lubbock, Tex.*, — F. Supp. 3d —, No. 5:21-CV-114-H, 2021 WL 2385110, at *1 (N.D. Tex. June 1, 2021) (“Because plaintiffs fail to show that any relief provided by this Court is likely to redress the injury at issue—citizen suits brought in state court—the Court lacks jurisdiction.”).

Defendants here cannot bring a private right of action against a practitioner, nor do Defendants otherwise have authority to enforce those provisions creating a private right of action. Therefore, the Court should hold that Plaintiffs lack standing to challenge the law’s private right of action.

3. On a slightly unrelated note about standing, the Plaintiffs who are parents and their children lack standing, because they allege no *facts* demonstrating that the children fall outside the SAFE Act’s exemptions. (*See* MTD Br. 13.) They merely assert the conclusion that they seek prohibited gender-transition procedures. (*See* Compl. ¶¶ 9-12.) Even on a motion to dismiss, this Court need not accept as true all the conclusory statements in the Complaint—never mind a preliminary-injunction motion. *See Ashcroft v. Iqbal*, 556 U.S. 662, 678 (2009). The Dennises lack standing for an additional reason: The Complaint admits that their child is not undergoing any prohibited gender-transition procedure. (*See* MTD Opp’n 8 n.1.) They allege no “certainly impending” injury, only that, at this point in time, their plan for some indefinite point in the future is to have their child undergo gender-transition procedures. *Carson v. Simon*, 978 F.3d 1051, 1058 (8th Cir. 2020) (quotation marks omitted). The Dennises may change their mind before their child begins puberty, when the prohibited gender-transition procedures would become available. Like all the parents and children, the Dennises lack standing.

B. The practitioners have standing only to assert their own rights—not their patients’ rights.

1. Other than abortion cases, Plaintiffs do not cite a single decision allowing doctors to assert their patients’ rights.

In Plaintiffs’ telling, it is “well-established” that doctors invariably have third-party standing to assert their patients’ rights. (MTD Opp’n 11.) But they don’t cite a single case reaching that conclusion. Instead, they rely exclusively on cases holding that abortion practitioners *generally* satisfy the test for third-party standing when they file lawsuits asserting the rights of women seeking abortions. That is, Plaintiffs ask this Court to expand the holding of decisions granting third-party standing to abortion practitioners so that it covers all doctors. But such an expansion of abortion doctrine outside the abortion context would violate the view among Supreme Court Justices and the lower courts “that there is constitutional law and then there is the aberration of constitutional law relating to abortion.” *W. Ala. Women’s Ctr. v. Williamson*, 900 F.3d 1310, 1314 (11th Cir. 2018). Because this is not an abortion case, there is no reason to “apply here . . . the aberration.” *Id.*

Before detailing why this Court should decline to expand the third-party standing exception the Supreme Court has applied to abortion practitioners, a short rebuttal is necessary of Plaintiffs’ attempted explanation of their standing to assert third-party rights under 42 U.S.C. 1983. (See MTD Opp’n 11.) It is a non sequitur to say “that ‘[t]here is no language in the statute that supports [Defendants’] argument.’” (*Id.* (quoting *Hopkins v. Jegley*, No. 4:17-CV-00404, 2021 WL 41927, at *50 (E.D. Ark. Jan. 5, 2021), *appeal pending*, No. 21-1068 (8th Cir. docketed Jan. 11, 2021)) (first alteration in original).) That is precisely the point: There is no language in Section 1983 that extends to the practitioners in this case the ability to assert third-party claims. See *Rizzo v. Goode*, 423 U.S. 362, 370-71 (1976) (“The plain words of the statute im-

pose liability whether in the form of payment of redressive damages or being placed under an injunction *only for* conduct which ‘subjects, or causes to be subjected’ *the complainant* to a deprivation of a right secured by the Constitution and laws.” (emphasis added) (citation omitted)).

And it makes no difference that the Supreme Court has—without analyzing the question whether abortion practitioners may bring third-party claims under Section 1983—ruled on the merits of such third-party claims. (See MTD Opp’n 11.) For the Court has also said that “drive-by jurisdictional rulings of this sort . . . have no precedential effect.” *Steel Co. v. Citizens for a Better Env’t*, 523 U.S. 83, 91 (1998). This Court should conclude that Plaintiffs cannot assert third-party claims under Section 1983. (See MTD Br. 15.)

Along with the statutory barrier to third-party standing, the practitioners here cannot avoid the principle that they “generally must assert [their] own legal rights and interests, and cannot rest [their] claim[s] to relief on the legal rights or interests of third parties.” *Kowalski v. Tesmer*, 543 U.S. 125, 129 (2004) (quotation and citation omitted). Here, they argue for a per se rule that doctors have a sufficiently close relationship with their patients to assert claims on behalf of those patients. (MTD Opp’n 11.) But the Supreme Court has never recognized such a rule.

The closest it came was in *Singleton v. Wulff*, 428 U.S. 106 (1976), where it held that abortion practitioners often may bring a lawsuit on behalf of women seeking abortion challenging any “governmental interference with the abortion decision.” *Id.* at 118. Supreme Court Justices have for decades recognized that *Singleton*’s rule is about abortion, not medical care. See, e.g., *June Med. Servs. LLC v. Russo*, 140 S. Ct. 2103, 2118 (2020) (“We have long permitted *abortion* providers to invoke the rights of their actual or potential patients in challenges to *abortion-related* regulations.” (emphasis added)) (collecting citations to abortion cases on third-party

standing); *Whole Woman’s Health v. Hellerstedt*, 136 S. Ct. 2292, 2322 (2016) (Thomas, J., dissenting) (“Above all, the Court has been especially forgiving of third-party standing criteria for one particular category of cases: those involving the purported substantive due process right of a woman to abort her unborn child.”).⁹⁹

There is no general exception to the rule against third-party standing for doctors. And the practitioners here have shown neither a “close relationship” with their patients, nor that the patients face the sort of “hindrance” to asserting their own rights that would justify third-party standing. *Kowalski*, 543 U.S. at 130 (quotation marks omitted).

Regarding their lack of a close relationship with their patients, the key point is that they have a conflict of interest. (*See* MTD Br. 16-18.) Practitioners will always have an interest in reducing the number of legal requirements with which they must comply. Here, that means the practitioners have an interest in avoiding compliance with the SAFE Act. But their patients have an interest in seeing the Act enforced, because it exists to protect them from harmful procedures. Thus, the practitioners’ interests conflict with their patients’. But more than that, the evidence shows that performing gender-transition procedures is a lucrative (and growing) business. (*See* Regnerus Decl. ¶¶ 67-72.) The SAFE Act would greatly reduce the scope of this business in Arkansas. And against that backdrop, the Court does not need to “ascribe[] grotesque motivations” to the practitioners (MTD Opp’n 12) to conclude that the practitioners’ and patients’ interests are, at least, “potentially in conflict,” *Elk Grove Unified Sch. Dist. v. Newdow*, 542 U.S. 1, 15 (2004). That suffices to defeat third-party standing.

⁹⁹ Even assuming those abortion cases were correctly decided, gender-transition procedures present different issues than abortion. Part of the reason for the Court’s holding in *Singleton* was “the imminent mootness, at least in the technical sense, of any individual woman’s claim.” 428 U.S. at 117. Children seeking gender-transition procedures do not face the same mootness problem faced by pregnant women.

Add to the conflict of interest that the practitioners seek to invoke third-party standing not just on behalf of particular children currently undergoing gender-transition procedures at Arkansas Children’s Hospital but also on behalf of all future, hypothetical children who might seek such procedures. *See Kowalski*, 543 U.S. at 134. That is because they seek to facially invalidate the SAFE Act. (*See Compl.* at 46, Prayer for Relief.) And a facial injunction, by blocking the Act in all its applications, would effectively grant the practitioners third-party standing to assert the rights of entirely hypothetical, future patients. *See United States v. Salerno*, 481 U.S. 739, 745 (1987) (“A facial challenge to a legislative Act is, of course, the most difficult challenge to mount successfully, since the challenger must establish that no set of circumstances exists under which the Act would be valid.”). Regardless of whether the practitioners may assert third-party standing on behalf of their current patients, they certainly lack the standing to assert claims on behalf of hypothetical, future patients.

In addition to an inability to show a close relationship, the practitioners also cannot assert third-party standing because they have not established that potential plaintiffs face any hindrance to pursuing their own claims. *See Kowalski*, 543 U.S. at 130. Indeed, the participation of *four* families in this lawsuit belies the notion that such a hindrance exists. (*See Compl.* ¶¶ 9-12.) It makes no difference that other patients chose not to join in this lawsuit. (*See MTD Opp’n* 13.) Plaintiffs do not discuss a single third-party standing case—even in the abortion context—analogue to this one, where a party seeks to assert third-party standing on behalf of another plaintiff *in the same lawsuit*.

The practitioners meet neither of the required elements for third-party standing. To allow them to assert it, this Court would have to expand abortion-specific precedent and grant third-party standing to all doctors on behalf of their patients. Under Plaintiffs’ theory, an eye surgeon

could challenge state-law limitations on the performance of experimental eye surgery on behalf of her patients, even though the limitation was designed to protect the patients from experimentation. Because such an expansion of third-party standing would be inappropriate, the Court should dismiss the practitioners' third-party claims.

2. The practitioners lack first-party standing to bring their equal-protection claim.

Plaintiffs do not claim that the practitioners have a fundamental right to perform experimental gender-transition procedures, nor that such practitioners are a suspect classification. (MTD Opp'n 14-15.) The Eighth Circuit rejected a similar claim just last year. *See Birchansky v. Clabaugh*, 955 F.3d 751, 755 (8th Cir. 2020). Insofar as the practitioners have first-party standing to sue under the Equal Protection Clause, therefore, their claim receives only rational-basis review. *Id.* at 757. As explained later in this brief, they cannot show that the SAFE Act is not reasonably related to a legitimate end.¹⁰⁰

II. Plaintiffs are not likely to succeed on the merits of their Equal Protection Claim.

By default, the SAFE Act, like any other state law, “is accorded a strong presumption of validity.” *Heller v. Doe ex rel. Doe*, 509 U.S. 312, 319 (1993). For a rule other than the default rule to apply, Plaintiffs must establish that the SAFE Act “involv[es] fundamental rights” or “proceed[s] along suspect lines.” *Id.* The SAFE Act does neither of those things.

¹⁰⁰ Plaintiffs fail to mention relevant subsequent history of the case they cite in this section of their opposition to Defendants' motion to dismiss. (MTD Opp'n 14 (citing *Am. Coll. of Obstetricians & Gynecologists v. U.S. FDA*, 472 F. Supp. 3d 183 (D. Md. 2020)).) The district court in that case granted a preliminary injunction, but the Supreme Court stayed that injunction pending appeal, after the FDA filed an emergency application seeking a stay. *See FDA v. Am. Coll. of Obstetricians & Gynecologists*, 141 S. Ct. 578 (2021). After President Biden's inauguration, the FDA changed its position in that litigation, and the plaintiffs subsequently dismissed the claims voluntarily. *See Am. Coll. of Obstetricians & Gynecologists v. U.S. FDA*, No. 8:20-CV-01320 (D. Md.), Joint Status Rep., ECF 156 at 1-2 (May 6, 2021), and Order, ECF 158 at 1 (May 13, 2021).

In fact, as it pertains to the Equal Protection Clause, Plaintiffs do not claim that the SAFE Act involves any fundamental right of the children or practitioner plaintiffs. (*See* PI Br. 24-25; *see also* Compl. ¶¶ 155-71.) And in any event, such a fundamental-rights claim under the Equal Protection Clause would be unlikely to succeed, because there is no fundamental right to perform or to undergo a gender-transition procedure (a point discussed in more detail when this brief turns to Plaintiffs’ substantive-due-process claim, *see infra* pp. 88-94). *Cf., e.g., Planned Parenthood of Mid-Mo. & E. Kan., Inc. v. Dempsey*, 167 F.3d 458, 464 (8th Cir. 1999) (rejecting “the notion that physicians and clinics have a fundamental constitutional right to provide abortion services”). Even a hypothetical fundamental right to undergo gender-transition procedures would not help the practitioner plaintiffs, for they may not “use their patients’ due process rights as a means of elevating the standard of review for their own equal protection rights.” *Birth Control Ctrs., Inc. v. Reizen*, 743 F.2d 352, 358 (6th Cir. 1984).

Pressing no fundamental right under the Equal Protection Clause, Plaintiffs also fail to show that the SAFE Act draws lines according to a suspect classification. Therefore, only rational-basis review applies to the Act, and it is constitutional “so long as it bears a rational relation to some legitimate end.” *Vacco v. Quill*, 521 U.S. 793, 799 (1997) (citation omitted). The SAFE Act clears that low bar. Plaintiffs are thus unlikely to succeed on the merits of their equal-protection claim unless they can show that the Act would fail intermediate scrutiny—the only heightened equal-protection standard they argue should apply. (*See* PI Br. 32-43.) But the SAFE Act would survive intermediate scrutiny, too. Under either equal-protection standard, Plaintiffs cannot prevail and this Court should deny the preliminary-injunction motion and dismiss the complaint with prejudice.

A. The SAFE Act receives only rational-basis review, not heightened scrutiny.

On its face, the SAFE Act draws distinctions on only two bases: age and medical procedure. Neither of those is among the “suspect or quasi-suspect classifications” that courts have thus far identified; namely, race, immigrant status, national origin, illegitimacy, and sex. *Gallagher v. City of Clayton*, 699 F.3d 1013, 1018 (8th Cir. 2012); see *Clark v. Jeter*, 486 U.S. 456, 461 (1988). So Plaintiffs ask this Court to add transgender status as a new suspect classification, despite the fact that neither the Supreme Court nor the Eighth Circuit have even suggested that such an addition is an appropriate interpretation of the Equal Protection Clause. (See PI Br. 25-30.) This Court ought not get ahead of those courts and identify an entirely new suspect classification without their guidance.

Nor should this Court adopt Plaintiffs’ misreading of the Supreme Court’s decisions regarding sex discrimination and the Equal Protection Clause. (See PI Br. 30-32.) They claim those decisions require heightened scrutiny of any law for which sex is at all relevant—even if that law, like the SAFE Act, in no way disadvantages one sex as compared to the other. That is not the correct constitutional analysis. Because the SAFE Act draws no distinctions based on suspect classifications, it is only subject to rational-basis review.

1. The SAFE Act does not draw distinctions on the basis of any suspect classifications.

Neither age nor medical procedure are suspect classifications that receive heightened scrutiny under the Equal Protection Clause. Because these are the only distinctions that the SAFE Act draws between Arkansans, the Act is subject to rational-basis review. It easily survives that review.

- i. The SAFE Act draws lines based on a patient's age, and age-based distinctions are only subject to rational-basis review.*

First, the SAFE Act clearly distinguishes between Arkansans who are over 18 and “any individual under eighteen (18) years of age.” SAFE Act, sec. 3 (enacting Ark. Code Ann. 20-9-1502(a)). The Act only prohibits practitioners from performing covered experimental procedures on minors; it leaves all adults free to undergo these same procedures. Under the Act, a practitioner cannot perform a gender-transition procedure on a young woman one month *before* her eighteenth birthday. But that same practitioner can perform that same gender-transition procedure on that same young woman one month *after* her eighteenth birthday. This holds true for both sexes and for those who identify as transgender: A person of either sex who identifies as transgender can obtain any available gender-transition procedure once that person turns eighteen. The SAFE Act’s clear demarcation between children (those *under* eighteen) and adults (those *over* eighteen) undermines any suggestion that the Act classifies Arkansans based on transgender status or sex. (*See, e.g.*, PI Br. 26-32; Compl. ¶¶ 165-66.)

Plaintiffs cannot deny the age classification at the heart of the SAFE Act’s prohibition. Their filings in this case are shot through with age-based language. Throughout their briefing and their complaint—even their declarations—Plaintiffs consistently describe this as a case about “youth,” “adolescents,” or “minors.” (*See, e.g.*, PI Br. 1-4, 6-7, 9, 11-12, 20-21, 24-27, 30-31, 33-39, 41-46, 49, 51, 56, 58-59; Compl. ¶¶ 1-3, 5-6, 8, 22 (and heading for Subpart IV.A), 32, 35-37, 40, 46-48, 50-51, 55, 107, 127-28, 131, 133, 135, 137-38, 140, 144, 146-48 (and heading for Part VI), 153-54, 156, 163-64, 168, 170, 175-77; Adkins Decl. ¶¶ 2, 4, 28, 31, 33, 35-36, 38 (heading), 40, 42, 45, 47-48, 50-51 (and heading); Antommara Decl. ¶¶ 2-3, 28-30, 32-34, 44-46, 48, 50.) Plaintiffs’ own statements leave no doubt that the SAFE Act does not affect adults—only children. Its key provision, therefore, classifies Arkansans on the basis of age.

The Supreme Court “has said repeatedly that age is not a suspect classification under the Equal Protection Clause.” *Gregory v. Ashcroft*, 501 U.S. 452, 470 (1991); accord *City of Cleburne v. Cleburne Living Ctr., Inc.*, 473 U.S. 432, 441 (1985); *Vance v. Bradley*, 440 U.S. 93, 97 (1979); *Mass. Bd. of Ret. v. Murgia*, 427 U.S. 307, 313-14 (1976) (per curiam). Put another way by the Eighth Circuit, a “classification by age,” as in the SAFE Act, “does not define a ‘discrete and insular’ group, in need of ‘extraordinary protection from the majoritarian political process.’” *Stiles v. Blunt*, 912 F.2d 260, 264 (8th Cir. 1990) (citation omitted) (quoting *Murgia*, 427 U.S. at 313); see *United States v. Carolene Prods. Co.*, 304 U.S. 144, 152-53 n.4 (1938). Arkansas “need therefore assert only a rational basis for its age classification” in the SAFE Act. *Gregory*, 501 U.S. at 470. As will be explained below, see *infra* pp. 71-74, it has done so.

- ii. *Additionally, the SAFE Act distinguishes on the basis of medical procedure, and this distinction is also subject to rational-basis review.*

Second, the SAFE Act classifies on the basis of medical procedure. The only procedures it prohibits for children are experimental, non-FDA-approved gender-transition procedures. SAFE Act, sec. 3 (enacting Ark. Code Ann. 20-9-1502(a)). Contrary to Plaintiffs’ arguments, the covered procedures are not “the very same treatments” as other procedures that the SAFE Act continues to allow minors to undergo. (See PI Br. 35-37.) The experimental procedures prohibited by the SAFE Act are distinct from the other, permitted procedures on which Plaintiffs rely. Even the U.S. Food and Drug Administration recognizes as such: For example, the FDA has approved puberty blockers for use in children diagnosed with precocious puberty—but *not* as a gender-transition procedure. (Hruz Decl. at p. 76; Regnerus Decl. ¶¶ 50-51.) And a state law may draw distinctions between different medical procedures without becoming subject to heightened scrutiny.

Plaintiffs' central fallacy here is to assert that the SAFE Act allows "the same health care treatments" for some minors that "the law prohibits when provided to transgender adolescents for the purpose of 'gender transition.'" (PI Br. 1-2; *see id.* at 26 (calling it "the exact same medical care").) Merely using the same medicine, or performing a similar surgical procedure, however, isn't the same treatment. The gender-transition procedures prohibited by the SAFE Act and the unrelated procedures that Plaintiffs identify may have some similarities, but they are not the *same* procedures.

Thus, it is true that the practitioner plaintiffs use the same puberty-blocking drugs for gender-transition procedures that doctors use elsewhere to treat precocious puberty. (*See* PI Br. 35.) But puberty blockers have been studied—and approved by the FDA—only as a treatment for precocious puberty. (Hruz Decl. at p. 76; Regnerus Decl. ¶¶ 50-51.) The practitioner plaintiffs use these drugs to indefinitely stop puberty in children who would—absent the practitioners' intervention—begin puberty normally. (*See* Hruz Decl. at p. 62-63, 76-77.) The long-term effects of indefinitely postponing puberty on children's bone density, brain maturation, and other development are not known. (Hruz Decl. at p. 76.) By contrast, when doctors use these same drugs to treat precocious puberty, the goal is to delay the onset of puberty only *temporarily*, so the child begins puberty normally. (*See id.* at p. 77.) In such cases, puberty blockers are used to treat a verifiable physiological disorder with the goal of restoring normal, biological functioning.

Far from being the same treatments, using puberty blockers for gender transition and for treating precocious puberty are at cross-purposes. *See Tavistock*, [2020] EWHC 3274, ¶ 60 (re-marking that precocious puberty "is a different condition from gender dysphoria, and where puberty blockers are used in a very different way"). Practitioners like plaintiffs here use puberty

blockers to indefinitely prevent children from progressing normally through puberty, in the absence of any physiological disorder. Doctors use puberty blockers to facilitate children in progressing normally through puberty when a physiological disorder would otherwise prevent it.

The differences are still more striking between cross-sex hormone procedures that the SAFE Act prohibits and those it permits. It is true that adolescent males experiencing delayed puberty are permitted by the Act to receive testosterone therapy to initiate puberty. (*See* Hruz Decl. at p. 22; *see also* PI Br. 36.) Such testosterone therapy allows the male to develop normally, when a verifiable physiological disorder like delayed puberty or low testosterone is preventing it. (Hruz Decl. at p. 22.) But testosterone therapy in an adolescent female, even one who identifies as a “transgender boy” (PI Br. 36), will halt her development, resulting in nearly certain infertility (Hruz Decl. at pp. 71-74). It is undertaken even in adolescent females with no verifiable physiological disorders that are disrupting normal pubertal development. (*See id.* at p. 62.) The same principle applies to the use of estrogen therapy in adolescent females versus its use in adolescent males as a gender-transition procedure. (*Id.* at p. 22.) And while testosterone suppressants may reduce facial hair growth in adolescent females with polycystic ovarian syndrome, Plaintiffs do not claim that these drugs pose the same fertility and sexual-development risks for females that they pose for adolescent males who use them as a gender-transition procedure. (*See id.*) Nor do they claim that such males suffer from a physiological disorder that requires testosterone suppression to allow normal development. (*See id.* at p. 62.)

In each case, using hormones as a gender-transition procedure both prevents the normal, biological development of functioning sexual and reproductive organs in a child, and poses high risks of permanent infertility. And they are not approved by the FDA for that purpose. Plaintiffs offer no evidence whatsoever that the other hormone-based procedures they identify lead to these

same consequences. These other procedures are not the “same treatment” as hormonal gender-transition procedures.

A similar analysis applies to Plaintiffs’ claim that the treatment of gynecomastia in adolescent boys is the same procedure as a double mastectomy performed on adolescent girls. (*See* PI Br. 36-37.) Gynecomastia is an “objectively diagnosed” condition, involving “female type breast gland tissue” in a male patient. (Lappert Decl. ¶ 30.) For males, this condition can be painful “and sometimes disfiguring.” (*Id.*) Removal of this abnormal, female-type tissue from a male patient does not destroy any biological function of his breasts. By contrast, performing a double mastectomy on a female patient—which Plaintiffs euphemistically call “chest reconstructive surgery” (PI Br. 7)—invariably destroys the biological function of her breasts. She will never be able to breastfeed a child. (Lappert Decl. ¶¶ 34-35.) And she will almost certainly have lost any erotic sensation in her nipples. (*See id.* ¶ 35 (“[T]here will never be erotic sensation because the particular branch of the fourth intercostal nerve which communicates with particular centers in the brain responsible for oxytocin release and erotic provocation will have been permanently severed.”).) As a result, when double mastectomy is used as a gender-transition procedure “breast function [is] completely and irreversibly sacrificed for the sake of producing a cosmetic result.” (*Id.*) Removing abnormal tissue from a boy’s chest is not even similar to—let alone the *same* procedure as—performing a double mastectomy on a girl.

Plaintiffs also make the inverse claim that breast augmentation on a female is the same procedure as the creation of the appearance of breast on a male. (*See* PI Br. 37.) But the purposes of the procedures distinguish them. All sides agree that breast augmentation in girls is a cosmetic procedure.¹⁰¹ (*See* Lappert Decl. ¶¶ 51-58 (distinguishing reconstructive and cosmetic

¹⁰¹ *See* WPATH Guidelines, *supra*, at 58.

surgery).) According to Plaintiffs, however, boys seeking breast augmentation as a gender-transition procedure do so in order “to reduce psychosocial distress.” (PI Br. 37.) Often, “the only way of distinguishing cosmetic breast surgery from ‘medically indicated’ surgery is based upon the diagnosis of underlying pathology.” (Lappert Decl. ¶ 39.) In other words, a procedure performed according to the well-settled guidelines governing cosmetic procedures is not the same procedure as one performed according to the disputed premise that gender-transition procedures relieve psychological distress. (*See id.* ¶¶ 16-20 (discussing the evidence that gender-reassignment surgery actually leads to worse outcomes, including increased suicide risk).)

With all of the procedures that Plaintiffs identify, the SAFE Act allows continued use of drugs in an FDA-approved manner to treat verifiable physiological disorders and to foster normal development of a child’s biological functions. And it allows continued performance of established surgeries on children, without destroying any biological function. The SAFE Act prohibits only experimental gender-transition procedures, which use drugs in a manner that has never been approved by the FDA. These prohibited procedures use these drugs and, at times, surgeries in an effort to treat a condition without any physiologically verifiable symptoms. And these procedures disrupt the normal development of—in some cases, *destroy*—the biological function of a child’s sexual and reproductive organs, among other consequences.¹⁰²

The procedures that the SAFE Act permits and prohibits are not the same procedures. Laws that distinguish between disparate medical procedures do not receive heightened scrutiny. That is because people seeking a particular medical procedure are not a protected class. *Cf. Bray*

¹⁰² Despite Plaintiffs’ repeated references to those with intersex conditions, procedures performed on minors with such conditions present issues beyond the scope of this case. (*See, e.g.*, PI Br. 37.) Medical treatment for children born with intersex conditions, which are verifiable physiological conditions, requires consideration of many factors beyond those considered for gender-transition procedures. (*See Hruz Decl.* at pp. 32-34.)

v. Alexandria Women’s Health Clinic, 506 U.S. 263, 269 (1993) (holding that “[w]omen seeking abortion’ is not a qualifying class” for purposes of the civil-rights conspiracy statute, 42 U.S.C. 1985(3)). Laws like the SAFE Act that distinguish between dissimilar medical procedures do not “treat anyone differently from anyone else or draw any distinctions between persons.” *Vacco*, 521 U.S. at 800. The Act simply prohibits certain procedures for minors and permits certain other procedures, much like the laws in *Vacco* prohibited “assisting suicide” but “permitt[ed] patients to refuse medical treatment.” *Id.* As in *Vacco*, therefore, the SAFE Act receives only rational-basis scrutiny, *see id.* at 799, which it easily survives, *see infra* pp. 71-74.

2. The SAFE Act does not discriminate on the basis of transgender status, which is not, in any event, a suspect class.

i. The SAFE Act applies neutrally, regardless of transgender status.

The distinction between which medical procedures a child may undergo and which she may not does not depend, as Plaintiffs claim, on whether she identifies as transgender. (*See, e.g.*, PI Br. 26, 35-37.) They argue that the Act prohibits the use of puberty blockers and cross-sex hormones, and the performance of double mastectomies on, children “solely because a patient’s gender identity does not align with” his or her sex. (*Id.* at 1.) But this argument rests on the untenable assertion that these gender-transition procedures are “the exact same medical care” as well-established treatments for physiologically verifiable disorders like precocious puberty or hypogonadotropic hypogonadism. (*Id.* at 26; *see id.* at 35-36.) As just explained, it would be a fallacy to conflate such FDA-approved treatments with the gender-transition procedures covered by the SAFE Act. In reality, a child who identifies as transgender can receive the same medical care as any other child. Because the SAFE Act distinguishes on the basis of medical procedure, it does not distinguish on the basis of transgender status.

Plaintiffs attempt to avoid that conclusion by claiming the SAFE Act creates a classification based on transgender status since the Act prohibits procedures that “only transgender people undergo.” (*Id.* at 26; *see* Compl. ¶¶ 163-64.) But the Supreme Court has rejected precisely this sort of argument in the equal-protection context. “[M]any [laws] affect certain groups unevenly, even though the law itself treats them no differently from all other members of the class described by the law.” *Pers. Adm’r of Mass. v. Feeney*, 442 U.S. 256, 271-72 (1979). Thus, for example, a veterans’ preference statute was not a sex-based classification even though 98% of veterans were male. *See id.* at 270, 274. Likewise, the Court has held that a legislative classification concerning pregnancy is not a sex-based classification. *Geduldig v. Aiello*, 417 U.S. 484, 494, 496-97 (1974). “‘While it is true,’ [the Court] said, ‘that only women can become pregnant, it does not follow that every legislative classification concerning pregnancy is a sex-based classification.’” *Bray*, 506 U.S. at 271 (quoting *Geduldig*, 417 U.S. at 496 n.20). Similarly, here, even if only children suffering gender dysphoria sought procedures the SAFE Act prohibits, it does not follow that the law classifies based on transgender status.

That final point suggests another reason why the SAFE Act does not draw any classifications based on transgender status. It is not true that the category “children identifying as transgender” is equivalent to the categories “children suffering from gender dysphoria,” or “children seeking gender-transition procedures.” By conflating these categories, Plaintiffs ask this Court to treat the category “children seeking gender-transition procedures” as a proxy for the category “children identifying as transgender.” But “the transgender community is not a monolith in which every person wants to take steps necessary to live in accord with his or her preferred gender (rather than his or her biological sex).” *Doe 2 v. Shanahan*, 917 F.3d 694, 722 (D.C. Cir. 2019) (Williams, J, concurring in the result); *see id.* at 701 (Wilkins, J., concurring) (noting that

the transgender classification “include[s] persons who identify with another gender but who do not wish to live or work in accordance with that preferred gender”).

Plaintiffs first conflate children-identifying-as-transgender with the distinct category of children-suffering-from-gender-dysphoria. (*See* Compl. ¶ 162 (alleging that “gender dysphoria” is “a condition that *only* transgender people suffer from” (emphasis added)).) But many children with gender dysphoria do *not* identify as transgender but rather seek to overcome their psychiatric condition so that they are comfortable in their own bodies. (*See* Hiatt Decl. ¶¶ 21-28.) Conversely, not all children who identify as transgender suffer from gender dysphoria. As Plaintiffs concede, only “*some* transgender people” experience gender dysphoria. (Compl. ¶ 30 (emphasis added).) This concession is consistent with WPATH’s position that “[o]nly *some* gender-non-conforming people experience gender dysphoria at *some* point in their live.”¹⁰³ Even among those who do, only “[s]ome people experience gender dysphoria at such a level that the distress meets criteria for a formal diagnosis.”¹⁰⁴

Having conflated those two categories of children, Plaintiffs next conflate them with a third, children-seeking-gender-transition-procedures. (*See, e.g.*, Compl. ¶ 162 (alleging that “[t]reatment . . . is *always* aimed at affirming a gender identity that differs” from the child’s biological sex (emphasis added)).) But, again, these are not the same class: Many children with gender dysphoria and even many who identify as transgender have no desire to go through the experimental procedures covered by the SAFE Act—or even to pass as members of the opposite sex. (*See* Hiatt Decl. ¶¶ 21-28.) Indeed, Plaintiffs’ guidelines themselves concede this point.¹⁰⁵

¹⁰³ WPATH Guidelines, *supra*, at 5.

¹⁰⁴ *Id.*

¹⁰⁵ *See* ES Guidelines, *supra*, at 3875 (“Not all transgender individuals seek treatment.”); WPATH Guidelines, *supra*, at 8 (noting that some people with gender dysphoria “need neither” hormone therapy nor surgery to “alleviate their gender dysphoria”).

As a purely factual matter, it is not correct that the category of children-seeking-gender-transition-procedures is a reliable proxy for children-identifying-as-transgender. But Plaintiffs' arguments here miss another point. Even some children who suffer gender dysphoria or identify as transgender will seek procedures that the SAFE Act does not prohibit. The Act does not prohibit procedures unless they change a child's "physical," "physiological," or "anatomical characteristics." SAFE Act, sec. 3 (enacting Ark. Code Ann. 20-9-1501(6)(A)). Other procedures remain available. A practitioner might engage in "watchful waiting," for example, which involves conducting therapy with a child while waiting to see whether the child—like the vast majority of children—will desist from experiencing gender dysphoria or identifying as transgender. (*See* Levine Decl. ¶¶ 27-35, 58.) Alternatively, a child might progress to socially transitioning, which the SAFE Act does not prohibit. *See* SAFE Act, sec. 3 (enacting Ark. Code Ann. 20-9-1501(6)(A)) (prohibiting only "medical or surgical service[s]"). (*See also* Levine Decl. ¶¶ 54-63 (describing consequences of social transition).)

Contrary to Plaintiffs' allegations, knowing whether a child suffers from gender dysphoria or identifies as transgender tells us little about whether he or she would seek the experimental gender-transition procedures the SAFE Act prohibits. The same guidelines on which Plaintiffs rely admit that "[o]ften with the help of psychotherapy, some individuals . . . do not feel the need to feminize or masculinize their body."¹⁰⁶ And according to WPATH, others desire nothing more than social transition, finding that "changes in gender role and expression are sufficient to alleviate gender dysphoria."¹⁰⁷ Because not all children who identify as transgender will seek

¹⁰⁶ WPATH Guidelines, *supra*, at 8.

¹⁰⁷ *Id.* at 8-9.

gender-transition procedures—nor will all children who seek gender-transition procedures identify as transgender—it would be inappropriate to treat the SAFE Act’s prohibition on gender-transition procedures as a proxy for a classification based on transgender status.

This final point illustrates why this Court ought to follow the reasoning of the court in *Hennessy-Waller v. Snyder*, No. CV-20-00335, 2021 WL 1192842 (D. Ariz. Mar. 30, 2021). The plaintiffs there were 15- and 17-year-old girls taking testosterone, whose healthcare providers recommended they receive “‘male chest reconstruction surgery’—that is, the permanent removal of their breasts.” *Id.* at *1. They challenged the exclusion of gender-reassignment surgery from Arizona’s Medicaid program under the Equal Protection Clause and moved for a preliminary injunction. *Id.* Among other things, the plaintiffs there, like Plaintiffs here, argued that the program facially discriminated based on transgender status because it would cover the surgery “for other medically necessary reasons, such as to treat breast cancer or traumatic injury, but refuses to do so for the treatment of gender dysphoria.” *Id.* at *8. The court rejected that argument because Arizona’s Medicaid program “does not exclude coverage for *all* gender dysphoria treatments.” *Id.* at *9 (emphasis added). Like Arkansas, Arizona had simply distinguished between treatments—those the State had determined were “safe and effective for adolescents,” and those for which the State had not made such a determination. *Id.*

Like the Arizona program, the SAFE Act prohibits only experimental procedures and permits other healthcare for gender dysphoria. In fact, the SAFE Act expressly *encourages* the provision of mental health services to children suffering from gender dysphoria. SAFE Act, sec. 2(4). There is no “invidious” purpose to discriminate. *Feeney*, 442 U.S. at 274. Indeed, Plaintiffs offer no evidence of an invidious discriminatory purpose. (*See* PI Br. 26-30.) And the

SAFE Act is certainly not, as Plaintiffs claim, a ban on healthcare for children with gender dysphoria. Therefore, this Court should conclude that the SAFE Act does not classify on the basis of transgender status.

- ii. Because transgender status is not a suspect classification, it cannot be the basis for applying heightened scrutiny.*

Even if the SAFE Act did classify based on transgender status, such a classification is not subject to heightened scrutiny. Neither the Supreme Court nor the Eighth Circuit has treated transgender status as a suspect classification under the Equal Protection Clause, a point that Plaintiffs acknowledge. (*See* PI Br. 27.) Not only that, “no Court within the Eighth Circuit has yet examined this question.” (U.S. Br. 13; *see id.* at 11-17.) And there is no reason for this Court, as the first court in this Circuit to consider this question, to create a novel suspect classification based on transgender status.

a. The Supreme Court’s application of the Equal Protection Clause to laws related to homosexuality suggests that this Court should refuse Plaintiffs’ invitation to invent a suspect classification. Although the Supreme Court has considered equal-protection challenges to a variety of laws relating to homosexuality, it “has never ruled that sexual orientation is a suspect classification for equal protection purposes.” *Citizens for Equal Prot. v. Bruning*, 455 F.3d 859, 866 (8th Cir. 2006), *abrogated on other grounds by Obergefell v. Hodges*, 576 U.S. 644 (2015). The Eighth Circuit, “like many other[] [courts], has previously rejected the notion that homosexuality is a suspect classification.” *Price-Cornelison v. Brooks*, 524 F.3d 1103, 1113 n.9 (10th Cir. 2008) (collecting citations to other courts). And although the Supreme Court abrogated the bottom-line holding of cases like *Bruning* (upholding Nebraska’s law defining marriage as between a man and a woman), *Obergefell* did not address the holding of *Bruning* or any other case that homosexuality is not a suspect classification. *Obergefell* held only “that *the right to marry is a*

fundamental right inherent in the liberty of the person, and under the Due Process and Equal Protection Clauses of the Fourteenth Amendment couples of the same-sex may not be deprived of that right and that liberty.” 576 U.S. at 675 (emphasis added).

Over the course of decades, the Supreme Court has forgone multiple opportunities in addition to *Obergefell* to hold that homosexuality is a suspect classification under the Equal Protection Clause. Cf. *Lawrence v. Texas*, 539 U.S. 558, 574-75, 578-79 (2003) (invalidating criminal prohibition of sodomy under substantive-due-process analysis, despite challenger’s alternative argument under Equal Protection Clause); *Romer v. Evans*, 517 U.S. 620, 631-32 (1996) (applying rational-basis scrutiny under Equal Protection Clause to law that affected homosexuals); *Richenberg v. Perry*, 97 F.3d 256, 260 n.5 (8th Cir. 1996) (“The Supreme Court applied rational basis review in reviewing a state constitutional amendment adversely affecting homosexuals in [*Romer*].”). To be sure, the Supreme Court’s prior forbearance to add homosexuality as a suspect classification does not bind this Court here. But it does suggest that Plaintiffs face long odds in ultimately prevailing on their claim that those who identify as transgender are a novel suspect classification.

b. In any event, none of the four factors relevant to the analysis favor creating this novel classification. First, Plaintiffs have merely asserted—not shown that they are likely to prove—that people who identify as transgender have “been subjected to discrimination.” *Lyng v. Castillo*, 477 U.S. 635, 638 (1986). Second, similarly, Plaintiffs simply assert without argument that these people share a defining characteristic with “no relation to [their] ability to perform or contribute to society.” *Cleburne Living Ctr.*, 473 U.S. at 441 (quoting *Frontiero v. Richardson*, 411 U.S. 677, 686 (1973)). But the problem with the second point is more than simply a failure of proof, because, third, the evidence shows that Plaintiffs cannot establish that people who identify

as transgender in fact share any “obvious, immutable, or distinguishing characteristics that define them as a discrete group.” *Lyng*, 477 U.S. at 638. Fourth and finally, they are not likely to show that those people are “politically powerless.” *Id.*

First, Plaintiffs have not established that those who identify as transgender have suffered a history of discrimination. Although Plaintiffs offer a handful of statistics about the difficulties these people face—drawn entirely from statements made in decisions by out-of-Circuit courts, not from evidence submitted in this case—they never connect any of these statistics to discrimination. (*See* PI Br. 28.) The United States similarly cites material from *other cases*—not evidence in this one. (U.S. Br. 13-14.) And much of what both Plaintiffs and the United States cite on this point amounts to unsupported assertions. It is not enough for Plaintiffs to assert or even prove that “the treatment of” those who identify as transgender “in this Nation has not been wholly free of discrimination.” *Murgia*, 427 U.S. at 313. Rather, they must prove the existence of “a ‘history of purposeful unequal treatment.’” *Id.*

Plaintiffs have not even alleged such a history. The Complaint generically recites the legal test but offers no factual support. (*See* Compl. ¶ 160.) As a result, they have failed even to plead—let alone *prove*—the first element necessary for this Court to create a novel suspect classification of those who identify as transgender.

Second, Plaintiffs similarly assert that those who identify as transgender share a “defining characteristic” without any evidence of what that characteristic is, or why such a characteristic would be unrelated to Arkansas’s interests. (PI Br. 29; *see* U.S. Br. 15-16 (citing series of district court decisions in other Circuits and a single, vague APA position statement—but no evidence).) *Cf. Cleburne Living Ctr.*, 473 U.S. at 441 (refusing to create new suspect classification “where individuals in the group affected by a law have distinguishing characteristics relevant to

interests the State has the authority to implement”). Elsewhere, Plaintiffs would define “transgender” as “people who have a gender identity that does not align with their sex assigned at birth.” (PI Br. 11.) But Plaintiffs’ own evidence undermines the idea that those who identify as transgender share any defining characteristic whatsoever.

For one thing, Plaintiffs fail to explain the shared defining characteristics of those suffering from “early-onset” and “late-onset” gender dysphoria. (*See, e.g.*, PI Br. 11-12.) Treating those two types of gender dysphoria as the same category fails to account for their differences, which even Plaintiffs’ cited guidelines acknowledge. Late- and early-onset gender dysphoria differ in diagnostic criteria and symptoms.¹⁰⁸ They also differ in persistence rates, with “relatively low persistence rates of childhood gender dysphoria.”¹⁰⁹ Unsurprisingly, as a result of these differences, the two types of gender dysphoria differ in treatment recommendations.¹¹⁰ Despite these differences, Plaintiffs fail to explain why the Court should treat these two divergent conditions as sharing a defining characteristic. (*See* PI Br. 29.)

In addition to that failure, Plaintiffs fail to mention that none of the guidelines they cite treat “transgender individuals” as a clearly delineated group sharing defining characteristics. These sources treat “transgender” as “an umbrella term” that includes “a *diverse* group of individuals.”¹¹¹ Within that diverse group, are those who “experienc[e] a continuous and rapid involuntary alternation between a male and female identity.”¹¹² According to WPATH, the term

¹⁰⁸ DSM-5, *supra*, at 452-53, 456.

¹⁰⁹ WPATH Guidelines, *supra*, at 17.

¹¹⁰ *See, e.g.*, ES Guidelines, *supra*, at 3879; APA Guidelines, *supra*, at 843.

¹¹¹ ES Guidelines, *supra*, at 3875 (emphasis added); WPATH Guidelines, *supra*, at 97.

¹¹² ES Guidelines, *supra*, at 3873.

“transgender” broadly covers anyone who does “not conform to a binary understanding of gender as limited to the categories of man or woman, male or female.”¹¹³ Thus, the term “transgender” covers people who identify with any of the following gender identities: “boygirl,” “girlboy,” “genderqueer,” “eunuch,” “bigender,” “pangender,” “androgynous,” “genderless,” “gender neutral,” “neutrois,” “agender,” “genderfluid,” and “third gender,” among many others.¹¹⁴ Plaintiffs nowhere attempt to synthesize “a defining characteristic” shared by this diverse group who identifies as transgender. (PI Br. 29.)

These same sources belie Plaintiffs’ claim that transgender status is biologically determined. Although Plaintiffs seek to pin transgender status to how a person identifies him- or herself, according to the Endocrine Society, being transgender does not require even identifying in a way at odds with one’s sex. (*See* PI Br. 26; Adkins Decl. ¶ 19.) Regardless of how a person self-identifies, transgender status is said to depend on whether a person’s “name, pronouns, clothing, haircut, behavior, voice, or body characteristics” (*i.e.*, a person’s so-called “gender expression”) differ “from what is typically associated with their sex designated at birth.”¹¹⁵ As a result of this definition, the Endocrine Society holds that a person *can switch* between being transgender or not literally by simply changing her “clothing, haircut, [or] behavior.”¹¹⁶

These official statements are from the same organizations to which Plaintiffs ask this Court to defer. And they demonstrate that the members of Plaintiffs’ purported class of “transgender individuals” share no “defining characteristic”—let alone a characteristic unrelated

¹¹³ WPATH Guidelines, *supra*, at 96.

¹¹⁴ *Id.*; APA Guidelines, *supra*, at 862.

¹¹⁵ ES Guidelines, *supra*, at 3875.

¹¹⁶ *See id.*

to the purposes of the SAFE Act. Therefore, this Court should not create a novel suspect classification based on transgender status. *See Cleburne Living Ctr.*, 473 U.S. at 441.

Third, Plaintiffs have no evidence that individuals who identify as transgender constitute a discrete group with *immutable* characteristics. Here, Plaintiffs are content simply to assert immutability in a single sentence, with a single citation. (PI Br. 29.) Content to offer conclusory quotations from nonbinding decisions of other courts, neither they nor the United States independently analyze the question of immutability. (*See* U.S. Br. 16.) Contrary to their assertions, young people identifying as transgender do not “share[] ‘an immutable characteristic determined solely by the accident of birth.’” *Gallagher*, 699 F.3d at 1018 (quoting *Frontiero*, 411 U.S. at 686). For one thing, the well-documented boom in self-identifications as transgender over the last decade—over the last five years at a still-more accelerated pace—“should be enough to dissuade anyone from the idea that transgender self-identification is a biologically determined condition.” (Lappert Decl. ¶ 71; *see* Regnerus Decl. ¶¶ 19-30.)

Plaintiffs’ own evidence also establishes that identifying as transgender is not an immutable characteristic determined at birth. For one thing, Plaintiffs allege that biology—that is, “the accident of birth,” *Gallagher*, 699 F.3d at 1018—is, at most, only one “component to gender identity.” (Compl. ¶ 24.) But their problems go deeper than just that statement. Plaintiffs’ evidence is incompatible with the assertion that “gender identity” is “immutable,” “innate,” and grounded in biology. (*See* PI Br. 3, 29; Adkins Decl. ¶¶ 16, 21.)

As an initial matter, Plaintiffs make no attempt to account for young people who desist in their gender dysphoria or transgender identity. This phenomenon is well documented. (*See* Regnerus Decl. ¶¶ 76-78, 96; Hiatt Decl. ¶ 27; Levine Decl. ¶ 58.) Plaintiffs’ sources agree. For instance, the DSM-5 asserts that “[t]ransgender refers to the *broad* spectrum of individuals who

transiently or persistently identify with a gender different from their natal gender.”¹¹⁷ And the WPATH guidelines concede that “[i]n children and adolescents, a rapid and dramatic developmental process (physical, psychological, and sexual) is involved and there is greater fluidity and variability in outcomes.”¹¹⁸ Not only does the Endocrine Society agree with WPATH’s characterization, it also emphasizes that “we cannot predict the psychosexual outcome for any specific child,” which is to say we do not know which children will desist from suffering gender dysphoria.¹¹⁹ In fact, there is no dispute that “[i]n *most children*, gender dysphoria will disappear before, or early in, puberty.”¹²⁰ And “[s]ome identity beliefs in adolescents may become firmly held and strongly expressed, giving *a false impression of irreversibility*.”¹²¹

The phenomenon of desistance undermines the idea that transgender status is an immutable characteristic. So, too, does the recent rapid rise in cases. (*See* Regnerus Decl. ¶ 30.) A sharp uptick like the one witnessed around the western world is inconsistent with a biological basis for transgender status. (*See* Levine Decl. ¶ 15.)

Beyond ignoring the reality of desistance and the import of the recent surge in gender discordance, Plaintiffs’ own sources argue that transgender status is culturally, rather than biologically, determined. WPATH says this explicitly: A person’s “gender identity” is necessarily indexed to “culturally defined categories of gender.”¹²² The Endocrine Society similarly says that

¹¹⁷ DSM-5, *supra*, at 451 (emphasis altered).

¹¹⁸ WPATH Guidelines, *supra*, at 10-11.

¹¹⁹ ES Guidelines, *supra*, at 3876.

¹²⁰ WPATH Guidelines, *supra*, at 12 (emphasis added); *see id.* at 17 (recognizing that children’s desire to transition can reflect “other forces” than “gender identity”).

¹²¹ *Id.* at 18 (emphasis added).

¹²² *Id.* at 97.

it is linked to “environmental” and “cultural factors.”¹²³ Rather than being rooted in biology, Plaintiffs’ sources maintain that being transgender is based on “what is normative” regarding categories of masculine and feminine “in a given culture and historical period.”¹²⁴ More than that, WPATH elsewhere posits that “for some transgender individuals, gender identity may remain somewhat fluid for many years.”¹²⁵ Along similar lines, the American Psychological Association says some people “experience their gender identity as fluid.”¹²⁶ And the Endocrine Society takes its comments about fluidity even further, stating that some are said to have “a continuous and rapid involuntary alternation between a male and female identity.”¹²⁷

Thus, according to the very organizations to which Plaintiffs argue this Court must defer (WPATH, the Endocrine Society, and the APA), “gender identity” is culturally determined, can remain “fluid” for many years, and can even rapidly toggle between different identities. This is the opposite of “an immutable characteristic determined solely by the accident of birth.” *Gallagher*, 699 F.3d at 1018 (quoting *Frontiero*, 411 U.S. at 686). As WPATH puts it: “It is . . . important that parents explicitly let the child know that *there is a way back*.”¹²⁸ The upshot is that, even considering only Plaintiffs’ evidence, the record establishes that those who identify as transgender are not a class that shares “an immutable characteristic determined solely by the ac-

¹²³ ES Guidelines, *supra*, at 3874; see AAP Guidelines, *supra*, at 4 (“In a GACM [i.e., gender-affirmative care model] the following messages are conveyed: . . . gender identity evolves as an interplay of biology, development, socialization, and culture.”).

¹²⁴ WPATH Guidelines, *supra*, at 96-97.

¹²⁵ WPATH Med. Nec. Stmt., *supra*, at 1. (See Compl. ¶ 154 n.11 (citing WPATH Med. Nec. Stmt.).)

¹²⁶ APA Guidelines, *supra*, at 836.

¹²⁷ ES Guidelines, *supra*, at 3873.

¹²⁸ WPATH Guidelines, *supra*, at 17 (emphasis added).

cident of birth.” *Gallagher*, 699 F.3d at 1018. At very least, Plaintiffs are not likely to prove immutability, so this Court should not create a new suspect classification based on transgender status. *See Cleburne Living Ctr.*, 473 U.S. at 445 (withholding protected status from the purported class in part because they were an “amorphous” group).

Fourth, and finally, Plaintiffs’ own evidence disproves the notion that people identifying as transgender warrant “extraordinary protection from the majoritarian political process.” *Gallagher*, 699 F.3d at 1018. Plaintiffs offer no evidence that such people have been subjected to “a history of purposeful unequal treatment,” suffered from “political powerlessness,” or had such disabilities imposed upon them as to implicate the “traditional indicia of suspectness.” *San Antonio Indep. Sch. Dist. v. Rodriguez*, 411 U.S. 1, 28 (1973). Instead, they simply refer to the same general statistics they have already cited about problems this group faces. (*See* PI Br. 30.) They offer no evidence that those problems are caused by political powerlessness. Nor do Plaintiffs or the United States connect any of these problems with their assertion—unsupported by any evidence in this case—that among elected officials at all levels of government, those who identify as transgender are underrepresented. (*See id.* at 29-30; U.S. Br. 17.) More fundamentally, they cite no authority for the proposition that a minority group satisfies the political-powerlessness prong so long as the group’s representation among all elected offices in the Nation falls below perfect proportionality. That sort of proportionality test has been rejected in other contexts, and this Court should reject it here. *Cf.*, *e.g.*, 52 U.S.C. 10301(b) (rejecting any right under the Voting Rights Act for a group to have representation “in numbers equal to their proportion in the population”).

Moreover, the facts of this case refute Plaintiffs’ political-powerlessness argument. The federal government, 19 political organizations, and a group of prominent Arkansas business leaders—including the Arkansas Chamber of Commerce and the Walton Family Foundation—stand alongside Plaintiffs and against Arkansas here. (See U.S. Br. 1-3; *Amici Br. of Political Orgs.*, Dkt. No. 30, at 22-28 (appendix listing political-organization *amici*); *Amici Br. of Business Leaders*, Dkt. No. 43, at 1-3 (identifying business-leader *amici*.) Indeed, the crux of Plaintiffs’ claims in this case is that Arkansas disagrees with WPATH, the Endocrine Society, and other major political organizations about what sorts of experimental procedures are appropriate to perform on minors. (See, e.g., Compl. ¶¶ 32-40, 154.) Not only that, the President and his administration have made it a political priority to join in cases regarding laws that have a claimed effect on those identifying as transgender. (See U.S. Br. 2 (describing recent executive order to that effect).) On Inauguration Day, President Biden issued Executive Order No. 13,988—one of his first actions as President—announcing the federal government’s political support for people identifying as transgender. See Exec. Order No. 13,988, 86 Fed. Reg. 7023 (issued Jan. 20, 2021; published Jan. 25). And the President has made it a political priority to nominate those who identify as transgender for Senate-confirmed offices. See, e.g., Press Release, White House Briefing Room, *Fact Sheet: 100 Days In, Biden-Harris Administration Makes History with Presidential Appointees* (Apr. 29, 2021).¹²⁹

As this makes clear, those who identify as transgender are not the sort of politically powerless minority that the Supreme Court treats as a suspect classification. Cf. *Cleburne Living Center*, 473 U.S. at 472 n.24 (minors “might be considered politically powerless to an extreme

¹²⁹ <https://www.whitehouse.gov/briefing-room/statements-releases/2021/04/29/fact-sheet-100-days-in-biden-harris-administration-makes-history-with-presidential-appointees/>.

degree” but are not a protected class). Because Plaintiffs are unlikely to meet this or any other prong for establishing a new suspect classification, this Court should apply rational-basis review to the SAFE Act.

3. The SAFE Act does not discriminate based on sex.

Given their inability to justify the creation of a new suspect classification, Plaintiffs try another strategy to subject the SAFE Act to heightened scrutiny. According to them, the SAFE Act “treats similarly situated people differently” on the basis of sex. (PI Br. 30.) But they cannot identify any sex-based distinction that appears on the face of the Act. As already discussed in other contexts, a girl who receives testosterone suppressants to treat polycystic ovarian syndrome is not undergoing the same procedure as a boy who receives testosterone suppressants as a gender-transition procedure. *See supra* pp. 47-52. In both cases, one result may be “to reduce facial hair” (PI Br. 30), but Plaintiffs do not claim that the girl faces the same sexual-development risks as the boy. (*See Hruz Decl.* at pp. 22, 76-77; *Levine Decl.* ¶¶ 80-87.)

Thus, the SAFE Act allows certain procedures for children of either sex and prohibits different procedures for children of either sex. It contains no sex classifications, only medical-procedure classifications. But Plaintiffs and the United States maintain that such classifications between medical procedures, based as they are in “our most basic biological differences,” amount to nothing more than sex stereotypes. *Tuan Anh Nguyen v. INS*, 533 U.S. 53, 73 (2001). (*See* PI Br. 31-32; U.S. Br. 7-8.) Such “[m]echanistic classification of all our differences as stereotypes,” however, “obscure[s] those misconceptions and prejudices that are real.” *Tuan Anh Nguyen*, 533 U.S. at 73. In other words, laws do not necessarily raise constitutional problems simply because they, at some level, implicate the biological realities of sex. Rather, they merely reflect the fact—as the case law says—that boys and girls aren’t similarly situated.

Plaintiffs’ only apparent response to that fact amounts to little more than an assertion that the SAFE Act’s references to “biological sex” means it must be subject to heightened scrutiny. *See* SAFE Act, sec. 3 (enacting Ark. Code Ann. 20-9-1501(6)(A)). (*See also* PI Br. 30-31; U.S. Br. 8-9.) But this argument rests on an overly broad interpretation of the Supreme Court’s holding in *Bostock v. Clayton County, Georgia*, 140 S. Ct. 1731 (2020). There, the Court interpreted specific language in Title VII: “discriminate against any individual . . . because of such individual’s . . . sex.” *Id.* at 1738 (quoting 42 U.S.C. 2000e-2(a)(1)). That “starkly broad” language, it held, *id.* at 1753, required “a sweeping standard” for causation under Title VII, *id.* at 1739. Under that sweeping standard, the Court said that “fir[ing] someone simply for being homosexual or transgender” amounted to “discriminat[ion] against that individual ‘because of such individual’s sex.’” *Id.* at 1753.

As an initial matter, this represents a radical change in position for the United States. (*See* Regnerus Decl. ¶¶ 101-03.) On January 17, 2021, the Department of Justice issued a memorandum explaining, among other things, why “*Bostock* has no bearing on the proper interpretation of the Constitution.”¹³⁰ Five days later—the day after President Biden’s inauguration—the Department cancelled that memorandum and purged it from the Internet.¹³¹ (Regnerus Decl. ¶ 102.) And the United States now asserts a totally different position here. The timing of that flip-flop suggests that politics—not legal analysis—was the primary driver of the Department’s change in position. (*See* Regnerus ¶ 103 (“The DOJ Civil Rights Division’s direct contradiction

¹³⁰ John B. Daukas, Dep’t of Justice, Civ. Rights Div., Memorandum re: Application of *Bostock v. Clayton County* (Jan. 17, 2021), <https://web.archive.org/web/20210120125231/https://www.justice.gov/crt/page/file/1356531/download>.

¹³¹ Gregory B. Friel, Dep’t of Justice, Civ. Rights Div., Memorandum (Jan. 22, 2021), <https://www.justice.gov/crt/page/file/1373621/download>.

of the precise legal position that it took only a few months ago renders undeniable the politically-charged nature of matters bearing on individuals who identify as transgender.”.)

Beyond the political nature of the Department’s flip-flop, there is simply no reason to think the Court would import *Bostock*’s statutory causation standard into the constitutional analysis. For one thing, *Bostock* expressly cautioned against extending its reasoning beyond the text of Title VII. *See* 140 S. Ct. at 1753 (refusing to “prejudge” similar arguments under “other federal or state laws that prohibit sex discrimination”). And the broad language that drove the reasoning in *Bostock* does not appear in the Equal Protection Clause. That explains why the Supreme Court has not equated the standards for finding discrimination under Title VII and the Constitution. *See Washington v. Davis*, 426 U.S. 229, 239 (1976) (“We have never held that the constitutional standard for adjudicating claims of invidious racial discrimination is identical to the standards applicable under Title VII, and we decline to do so today.”); *see also Fitzgerald v. Barnstable Sch. Comm.*, 555 U.S. 246, 256-58 (2009) (detailing the distinctions between the standards for liability under Title IX and the Equal Protection Clause).

Neither Plaintiffs nor the United States cite any Supreme Court or Eighth Circuit decisions requiring heightened constitutional scrutiny for laws that, at some level, refer to sex. Decisions from those courts have held that sex discrimination under the Equal Protection Clause exists when members of one sex are disadvantaged as compared to the other sex. *United States v. Virginia*, 518 U.S. 515, 519-20 (1996), is of course the paradigmatic example of this, where the State ran a military school that wholly barred women from attending. But other cases finding sex discrimination under the Constitution had similarly clear one-way, sex-based disadvantages. *See, e.g., Sessions v. Morales-Santana*, 137 S. Ct. 1678, 1686, 1689 (2017) (longer physical-presence requirement for men to pass citizenship to their children than for women); *Craig v.*

Boren, 429 U.S. 190, 191-92 (1976) (higher drinking age for men than for women); *Frontiero*, 411 U.S. at 678-79 (more difficult standard for servicewomen to prove spousal dependency than for servicemen); *Reed v. Reed*, 404 U.S. 71, 73-75 (1971) (preference for men over women when administering estates).

All of those cases involve *unequal treatment* of one sex as compared to the other sex. In other words, a similarly situated woman is somehow disadvantaged when compared to a similarly situated man, or vice versa. The SAFE Act does not treat similarly situated people differently on the basis of sex. As already discussed in detail, *see supra* pp. 47-52, a child taking puberty blockers to treat precocious puberty is not similarly situated to a child taking them as a gender-transition procedure. These two different procedures have dramatically different consequences for the child. (Hruz Decl. at pp. 76-77.) And a boy taking testosterone to jump-start normal pubertal development is not similarly situated to a girl taking testosterone as a gender-transition procedure. Only the girl faces the prospect of life-long infertility as a result of the testosterone. (*Id.*) The same is true of a boy on estrogen versus a girl on estrogen. (*See id.* at p. 22.) And the difference is obvious between a double mastectomy performed on a girl—resulting in the permanent destruction of all functionality in her previously healthy breasts—and the removal of abnormal breast tissue in a boy. (*E.g.*, Lappert Decl. ¶ 35.)

This reflects the reasoning of the district court in *Hennessy-Waller*, which rejected *Bostock*-based arguments like Plaintiffs' arguments here. Recall that *Hennessy-Waller* involved a challenge to Arizona's refusal to provide Medicaid coverage for "'male chest reconstruction surgery'—that is, the permanent removal of their breasts." 2021 WL 1192842, at *1. The plaintiffs there brought an equal-protection challenge, among other claims. *Id.* Relying on *Bostock*, much like Plaintiffs here, they argued that Arizona had discriminated based on transgender status and

sex because it would cover the surgery “for other medically necessary reasons, such as to treat breast cancer or traumatic injury, but refused to do so for the treatment of gender dysphoria.” *Hennessey-Waller*, 2021 WL 1192842, at *8. But the court there rejected those arguments. Among other things, it found that mastectomies as a gender-transition procedure were not the “same” as chest surgeries performed as other treatments. *See id.* at *7 (discussion whether these were “the same services” for purpose of Medicaid Act). As a result, the court concluded that those plaintiffs “ha[d] not clearly shown” that Arizona “denies coverage on the basis of sex and not on the basis of some other permissible rationale.” *Id.* at *9.

Like *Hennessey-Waller*, this Court should find that the SAFE Act does not classify on the basis of transgender status or sex. Therefore, this Court ought to apply rational-basis review to the SAFE Act. *See Romer*, 517 U.S. at 632.

B. The SAFE Act satisfies rational-basis review.

Because the SAFE Act is only subject to rational-basis review, “if any state of facts reasonably may be conceived to justify” the SAFE Act, then it is constitutional. *McGowan v. Maryland*, 366 U.S. 420, 426 (1961). It must be only “rationally related to a legitimate state interest.” *Kimel v. Fla. Bd. of Regents*, 528 U.S. 62, 83 (2000). Plaintiffs do not dispute Arkansas’s legitimate interests in protecting minors, *see Reno v. ACLU*, 521 U.S. 844, 869 (1997), and the vulnerable more generally, *see Washington v. Glucksberg*, 521 U.S. 702, 731 (1997). Nor do they dispute Arkansas’s interest in promoting ethics in the medical profession. *See Gonzales v. Carhart*, 550 U.S. 124, 157 (2007). Plaintiffs do briefly suggest that prohibiting gender-transition procedures for minors is not rationally related to those interests. But their argument on this point rests on the incorrect notion that gender-transition procedures are “the same treatments” as other procedures. (PI Br. 44.) As already discussed, *see supra* pp. 47-52, these are not the same treatments.

The main thrust of Plaintiffs' argument is that the SAFE Act is irrational, because "it was enacted for an impermissible purpose." (MTD Opp'n 31.) Chiefly, they argue that the SAFE Act was "the result of a rushed and anomalous legislative process." (*Id.* at 33.) But the supposedly "anomalous" process that resulted in the SAFE Act is simply the gubernatorial-veto procedure in the Arkansas Constitution. *See* Ark. Const., art. 6, sec. 15 (allowing majority of each house in the Arkansas General Assembly to override a gubernatorial veto). And there was nothing unusual about the General Assembly's handling of testimony from gender-transition practitioners. (*See* PI Br. 45-46 (suggesting that it "ignored testimony from Arkansas doctors"); MTD Opp'n 33 (same).)

Plaintiffs' arguments to the contrary rest entirely on a misrepresentation of the testimony that the General Assembly heard. They are simply incorrect when they allege that "[n]ot a single doctor with experience treating transgender youth testified in support of the bill." (Compl. ¶ 51.) Among others, the General Assembly heard testimony in support of the SAFE Act from Dr. Roger Hiatt, a psychiatrist practicing in Arkansas who has treated dozens of patients with gender dysphoria, and Dr. Charles Lewis, another Arkansas psychiatrist with experience treating gender dysphoria. (Hiatt Decl. ¶¶ 4-5, 9, 12.) Later, still another Arkansas psychiatrist with experience treating gender dysphoria, Dr. Melanie Conway (who is certified by the American Board of Psychiatry and Neurology), addressed legislators to voice her support for the SAFE Act. (*Id.* ¶ 10.) After this, Drs. Conway, Hiatt, and Lewis were joined by more Arkansas doctors in a letter urging the General Assembly to pass the Act. (*Id.* ¶ 11.)

The upshot is that the General Assembly heard conflicting testimony from practitioners who opposed the SAFE Act and from doctors who supported the SAFE Act. Choosing whom to

credit when faced with conflicting medical testimony is precisely the sort of choice the Constitution leaves to the state legislatures. *See Gonzales*, 550 U.S. at 163 (“The Court has given state and federal legislatures wide discretion to pass legislation in areas where there is medical and scientific uncertainty.”). “[T]he context surrounding the [SAFE Act’s] passage” shows only that the General Assembly chose to follow the advice of certain Arkansas doctors and not others. (MTD Opp’n 32.) That hardly suffices to demonstrate that it was enacted “for the purpose of disadvantaging the group burdened by the law.” *Romer*, 517 U.S. at 633.

The treatment of those who identify as transgender elsewhere in Arkansas law also undermines the assertion that the State has acted out “of animosity toward the class of persons affected.” *Id.* at 634. According to a 2014 administrative directive, the Arkansas Division of Correction will under certain circumstances initiate gender-transition procedures for Arkansas inmates. (See Administrative Directive 14-19, attached as Exhibit A to Declaration of Christine Cryer.)¹³² This Court has itself acknowledged this effect of AD 14-19. *See Prowse v. Kelley*, No. 5:19-CV-00115, 2019 WL 2606890, at *1 (E.D. Ark. June 25, 2019), *vacated & dismissed as moot sub nom. Prowse v. Payne*, 984 F.3d 700 (8th Cir. 2021); *see also id.* at 702 (dismissing Prowse’s appeal as moot because ADC had provided cross-sex hormones). Yet no court required ADC to adopt AD 14-19. To the contrary, the Eighth Circuit has held—repeatedly and for decades—that prison officials need not necessarily provide gender-transition procedures to

¹³² Ms. Cryer’s declaration is simultaneously filed with this brief as Exhibit 26.

inmates diagnosed with gender dysphoria, referring to it as “transsexualism,” then-current terminology under the DSM. *See White v. Farrier*, 849 F.2d 322, 327-28 (8th Cir. 1988) (following decisions that held “inmates do not have a constitutional right to hormone therapy”).¹³³

That Arkansas provides gender-transition procedures to certain inmates belies Plaintiffs’ allegation that the State bears ill will towards those who identify as transgender. So Plaintiffs resort to religion-based *ad hominem* attacks against members of the Arkansas General Assembly. (*See* MTD Opp’n 33.) Shockingly, the United States describes how its staff hunted through the Facebook posts of state legislators looking to bolster Plaintiffs’ argument. (*See, e.g.*, U.S. Br. 21.) But pointing to stray social media comments by a couple legislators does not carry Plaintiffs’ burden of proof to rebut “the presumption of legislative good faith.” *Abbott v. Perez*, 138 S. Ct. 2305, 2324 (2018). That is because “[w]hat motivates one legislator to make a speech about a statute”—or to post on Facebook about current events—“is not necessarily what motivates scores of others to enact it.” *United States v. O’Brien*, 391 U.S. 367, 384 (1968).

“The only direct evidence” is that the “Legislature’s intent was legitimate,” given the focus in the legislative findings on safety concerns. *Abbott*, 138 S. Ct. at 2327. The SAFE Act “appl[ies] evenhandedly to all” children, protecting them from harmful experimentation. *Vacco*, 521 U.S. at 800. As a result, it singles out no one and satisfies rational-basis review.

¹³³ *See also, e.g., Reid v. Griffin*, 808 F.3d 1191, 1192-93 (8th Cir. 2015) (holding that qualified immunity barred claims that prison had inappropriately refused cross-sex hormones); *Long v. Nix*, 86 F.3d 761, 765-66 (8th Cir. 1996) (reviewing Eighth Amendment challenge to prison’s refusal to provide cross-sex hormones, among other procedures, and holding that “[p]risoners do not have a constitutional right to any particular type of treatment”); *Dex v. Kelley*, No. 5:17-CV-00040, 2017 WL 2874627, at *3-4 (E.D. Ark. June 19) (relying on such Eighth Circuit decisions to recommend dismissal of Eighth Amendment claim seeking cross-sex hormones), *recommendation adopted*, 2017 WL 2874314 (July 5, 2017).

C. The SAFE Act would additionally pass heightened scrutiny.

Plaintiffs nowhere claim that the Equal Protection Clause subjects the SAFE Act to strict scrutiny. (*Compare, e.g.*, PI Br. 32-47, *with id.* at 50-51.) For a law like the SAFE Act—one with distinctions that are clearly rooted in “our most basic biological differences,” even if Plaintiffs dislike the distinctions it draws—the greatest equal-protection scrutiny it can receive is intermediate scrutiny. *Tuan Anh Nguyen*, 533 U.S. at 73. That is because, in Justice Ginsburg’s memorable words for the Court, “[p]hysical differences between men and women . . . are enduring.” *Virginia*, 518 U.S. at 533.

The SAFE Act survives intermediate scrutiny, because it is “substantially related” to Arkansas’s “important governmental objectives” of protecting children and regulating the medical profession. *Id.* at 524; *see Reno*, 521 U.S. at 869 (discussing “compelling interest in protecting the physical and psychological well-being of minors” (quoting *Sable Commc’ns of Cal., Inc. v. F.C.C.*, 492 U.S. 115, 126 (1989))).

Plaintiffs do not dispute that Defendants have important—indeed, compelling—interests at stake here. In general, “the State has an interest in protecting vulnerable groups . . . from abuse, neglect, and mistakes.” *Glucksberg*, 521 U.S. at 731. And the Supreme Court has made clear that the States have a compelling interest in protecting the well-being of children, in particular. *See Reno*, 521 U.S. at 869. Separately, “[t]here can be no doubt the government ‘has an interest in protecting the integrity and ethics of the medical profession.’” *Gonzales*, 550 U.S. at 157 (quoting *Glucksberg*, 521 U.S. at 731). This interest is not derivative of the State’s interest in protecting children. (*See* MTD Opp’n 24 n.8.) Instead, it is rooted in the State’s “power to regulate, reasonably and rationally, all facets of the medical field, even to excluding certain professions or specialists or schools . . . by expressly outlawing them.” *England v. La. State Bd. of*

Med. Examiners, 263 F.2d 661, 674 (5th Cir. 1959) (denying rehearing and explaining that the Louisiana state medical board may refuse to issue medical licenses to chiropractors).

1. The SAFE Act is substantially related to Arkansas’s important interests in protecting minors and safeguarding the medical profession.

Here, Arkansas has left open avenues for treatment of gender dysphoria while prohibiting only dangerous and experimental gender-transition procedures. The prohibited procedures are performed on children’s bodies and are, in key respects, irreversible. *See Tavistock*, [2020] EWHC 3274, ¶ 137 (“[T]he use of puberty blockers is not itself a neutral process by which time stands still for the child on puberty blockers, whether physically or psychologically.”). Add to those grave physical effects the fact that there is “very limited evidence as to its efficacy.” *Id.* ¶ 134. This combination of profound physical effects and limited evidence of benefit means that gender-transition procedures are “properly described as experimental treatment.” *Id.*; *see Hennesy-Waller*, 2021 WL 1192842, at *6 (noting that the *Tavistock* “decision regarding puberty-suppressing medication being experimental suggests the irreversible surgery Plaintiffs seek here is also experimental”).

Arkansas has prohibited the experimental gender-transition procedures that threaten its objectives of protecting children from harm and regulated the medical profession by preventing practitioners from inflicting harm. Given the limited nature of this prohibition, the SAFE Act substantially furthers Arkansas’s important objectives. Therefore, Plaintiffs have failed to state a claim under the Equal Protection Clause, and this Court should dismiss.

i. The long-term, irreversible harms of gender-transition procedures are well documented in the scientific community.

Plaintiffs do not dispute the irreversible consequences of the gender-transition procedures that they seek. Instead, to attempt to undermine Arkansas’s interests in the SAFE Act’s prohibition of gender-transition procedures for minors, Plaintiffs claim “[t]here is nothing unique about

the risks associated with” them. (PI Br. 38.) But they have offered no evidence that the other procedures they discuss lead to the same irreversible consequences as gender-transition procedures.

A key problem with puberty blockers used as a gender-transition procedure is the lack of studies on their long-term effects. (*See* Regnerus Decl. ¶ 31-49.) But it is established that they lead to slower growth in children and lower bone density. (Hruz Decl. at p. 76-77.) And because puberty blockers used for gender transition indefinitely halt pubertal development, they possibly alter the normal maturation of an adolescent’s brain. (*Id.* at p. 76.) Finally, a child who never goes through puberty will never develop mature sex organs, meaning that child will likely never develop the capability to orgasm. (Levine Decl. ¶ 83.) Plaintiffs do not discuss another “medical intervention” that “carries” these particular “potential risks.” (PI Br. 38.)

Once a child has indefinitely halted normal pubertal development, that child is almost invariably going to proceed to cross-sex hormone therapy. Unlike that child’s peers, the child’s body will not have experienced the “changes in the normal coordinated pattern of adolescent psychological development and puberty.” (Hruz Decl. at p. 77.) As a result, practically speaking, since the inception of the “affirmative care” model, puberty blockers have become irreversible because research is beginning to show that children placed on puberty blockers almost invariably proceed to cross-sex hormones. (Regnerus Decl. ¶ 77.) Thus, in the Tavistock clinic they found that 98% of the children put on puberty blockers proceeded to cross-sex hormones. (*Id.*) And the irreversible effects of cross-sex hormones are well established. (*See, e.g.*, Levine Decl. ¶ 84 (describing how cross-sex hormones can lead to permanently having secondary sex characteristics of the opposite sex); Hruz Decl. at p. 72 (“Other potential adverse effects include disfiguring acne, high blood pressure, weight gain, abnormal glucose tolerance, breast cancer, liver

disease, thrombosis, and cardiovascular disease.”.) Worst of all these effects, cross-sex hormones result in lifetime sterilization. (Hruz Decl. at p. 76.) Plaintiffs point to no other permanently sterilizing, experimental procedures that the SAFE Act allows.

Again, the irreversible effects of gender-reassignment surgery are clear. When a double mastectomy is performed as a gender-transition procedure, otherwise healthy breasts are removed, thereby permanently destroying functioning organs. (Lappert Decl. ¶¶ 34-35.) A girl who undergoes a double mastectomy will have permanently lost the ability to breastfeed. (*Id.*) And because the most commonly performed procedure for gender-reassignment mastectomies removes the nipples and severs the fourth intercostal nerve, it will permanently destroy the erotic sensibility of the nipples. (*Id.*)

ii. There is no scientifically valid evidence that gender-transition procedures benefit recipients.

Apart from falsely claiming the gender-transition procedures present the same risks as other procedures, Plaintiffs portray the evidence supporting their theory as so overwhelming that Arkansas simply could not credit other evidence. (*See* PI Br. 40-42.) But just the opposite is true: Medical authorities around the world have concluded that there is no reliable evidence demonstrating any benefits from gender-transition procedures.

Central to Plaintiffs’ arguments here is their experts’ unfounded assertion that gender-transition procedures “can be lifesaving treatment.” (Adkins Decl., Dkt. No. 11-11 ¶ 50.) The basis for this claim tends to be the heightened suicide risk faced by those who identify as transgender. As an initial matter, the “estimates of suicidal ideation and attempts among transgender-identifying adolescents vary notably.” (Regnerus Decl. ¶ 107.) And though suicide rates are tragically elevated among those who identify as transgender, suicide “remains ‘ex-

tremely rare’ among dysphoric youth.” (*Id.* ¶ 108.) More fundamentally, insofar as gender-transition procedures affect patients’ suicide rates, the evidence is mounting that these procedures actually *increase* the risk of suicide. The best data on this come from a follow-up study of a group who had completely transitioned, including surgically. (Levine Decl. ¶ 74.) This study demonstrated that the risk of completed suicide increased significantly after full transition by natal females.¹³⁴ (*See id.* (discussing study that “found a suicide rate in the post-sex reassignment surgery population 19.1 times greater than that of the control[]” group”).) Thus, Plaintiffs are wrong that “sufficient medical evidence support[s]” gender-transition procedures. (PI Br. 40.) The best medical evidence further demonstrates the harm caused by these procedures.

Plaintiffs are also more broadly wrong about the medical evidence. Since 2019, study after study has come out, around the world, finding that there is no good evidence of the claimed benefits of gender-transition procedures. That was the finding of the Swedish government in 2019. (*See* Hruz Decl. at pp. 10-11; Levine Decl. ¶ 126 & n.85.) It found a lack of evidence for hormonal and surgical treatments.¹³⁵ Then, earlier this year, a major Swedish hospital banned the use of puberty blockers and cross-sex hormones on patients under 18, as a general matter.¹³⁶ The existing studies on these gender-transition procedures “provid[e] low quality evidence that the treatments have the desired effect”—namely, the reduction of distress associated with gender

¹³⁴ *See* Cecilia Dhejne, et al., *Long-Term Follow-Up of Transsexual Persons Undergoing Sex Reassignment Surgery: Cohort Study in Sweden*, 6 PLoS ONE Feb. 2011, at 1, 7 (“This study found substantially higher rates of overall mortality, death from cardiovascular disease and suicide, suicide attempts, and psychiatric hospitalisations in sex-reassigned transsexual individuals compared to a healthy control population.”).

¹³⁵ Swedish Agency for Health Tech. Assessment & Assessment of Soc. Servs., *Gender Dysphoria in Children and Adolescents: An Inventory of the Literature*, <https://www.sbu.se/en/publications/sbu-bereder/gender-dysphoria-in-children-and-adolescents-an-inventory-of-the-literature/>.

¹³⁶ Swedish Guideline, *supra*.

dysphoria—and “we have very little knowledge about their safety in the long term.”¹³⁷ (*See* Regnerus Decl. ¶ 97.)

Finland reached a similar conclusion in June 2020. (Levine Decl. ¶ 126 & n.85; Regnerus Decl. ¶¶ 42, 97.) The Finnish guidelines permitted some reversible interventions but recognized that, “[i]n light of available evidence, gender reassignment of minors is an experimental practice.”¹³⁸ “As far as minors are concerned,” they noted, “there are no medical treatment[s] that can be considered evidence-based.”¹³⁹ Beyond these evidentiary concerns, Finland broke with WPATH’s guidelines by recognizing the benefits of psychotherapeutic treatment models, as opposed to affirmative models.¹⁴⁰ The Finnish guidelines recognized that because “reduction of psychiatric symptoms cannot be achieved with hormonal and surgical interventions,” it “is not a valid justification for gender reassignment.”¹⁴¹ They noted a worrisome 18-month study that showed adolescents who received psychological interventions alone improved more quickly in global psychosocial function than adolescents who received both puberty blockers and psychological interventions.¹⁴²

Controversy in the United Kingdom led to two systematic reviews from NICE late last year. (*See* Hruz Decl. at pp. 11-12 (discussing findings of NICE evidence review); Levine Decl. ¶¶ 67(c), 126 & nn.50-51, 85 (same); Regnerus Decl. ¶¶ 42, 45 (same).) One looked at the efficacy of puberty blockers as a gender-transition procedure. NICE criticized the poor data quality

¹³⁷ Swedish Guideline, *supra*.

¹³⁸ Finnish Guideline, *supra*, at 8.

¹³⁹ *Id.* at 6.

¹⁴⁰ *Id.* at 5, 7.

¹⁴¹ *Id.* at 7.

¹⁴² *Id.* at 6.

used in the studies purporting to find benefits.¹⁴³ In any event, examining those poor-quality studies, the review found “little change . . . from baseline to follow-up” on “the critical outcomes of gender dysphoria and mental health (depression, anger and anxiety), and the important outcomes of body image and psychosocial impact (global and psychosocial functioning).”¹⁴⁴ The NICE review of studies of cross-sex hormones identified similar shortcomings. It again found that all of the studies “are uncontrolled observational studies, which are subject to bias and confounding and were of very low certainty using modified GRADE.”¹⁴⁵ Thus, the review concluded that “[a]ny potential benefits of treatment [with cross-sex hormones] must be weighed against the largely unknown long-term safety profile of these treatments.”¹⁴⁶ The prestigious research group, Cochrane, also concluded around this time in a systematic review that the evidence is lacking that gender-transition procedures have any benefits.¹⁴⁷ (*See* Hruz Decl. at pp. 16-17 (discussing Cochrane review).) The High Court’s findings in *Tavistock* resemble these scientific findings. *See, e.g., Tavistock*, [2020] EWHC 3274, ¶ 134.

Plaintiffs’ only counter to the weight of this evidence comes from Dr. Antommaria. He essentially claims that obtaining better evidence of benefit through placebo-controlled studies is not possible because researchers already “believe that pharmacological treatment is superior.”

¹⁴³ *See* Nat’l Inst. For Health & Care Excellence, *Evidence Review: Gonadotrophin Releasing Hormone Analogues for Children and Adolescents with Gender Dysphoria*, at 13 (Mar. 11, 2021), <https://www.evidence.nhs.uk/document?id=2334888&returnUrl=search%3fq%3dtransgender%26s%3dDate>.

¹⁴⁴ *Id.*

¹⁴⁵ Nat’l Inst. For Health & Care Excellence, *Evidence Review: Gender-affirming Hormones for Children and Adolescents with Gender Dysphoria*, at 47 (Mar. 11, 2011), <https://www.evidence.nhs.uk/document?id=2334889&returnUrl=search%3ffrom%3d2021-03-10%26q%3dEvidence%2bReview%26to%3d2021-04-01>.

¹⁴⁶ *Id.* at 50.

¹⁴⁷ Haupt, *supra*, at 1, 8-11.

(Antommara Decl. ¶ 37.) He goes so far as to suggest that seeking additional data would “be unethical.” (*Id.* ¶ 22.) But this view “is based not on longitudinal medical and social science research but on media-fostered patient demand and premature professional organizational claims and pressure.” (Regnerus Decl. ¶ 54.) The “lack of equipoise is more a psychological or cultural than a scientific development. (*Id.*) What’s more, Dr. Antommara casts aside without explanation research other than placebo-controlled studies. (*Id.* ¶ 55.) As he acknowledges, longitudinal studies are one other reliable option. (*See* Antommara Decl. ¶ 35.) But he does not address the fact that, in response to longitudinal, population-based data, “the Tavistock Institute in London and the Karolinska Institute Hospital in Sweden—in a dramatic change—have restricted the use of puberty blockers, cross-sex hormones, and transgender surgery in minors.” (Lappert Decl. ¶ 81 (emphasis omitted).) Dr. Antomarra never explains how his opinions—based only on practitioners’ preconceived, nonscientific treatment opinions—fit with the growing, international consensus against gender-transition procedures for minors.

Like nations around the world, Arkansas has decided that the lack of evidence of the supposed benefits of gender-transition procedures, compared to the undisputed, irreversible consequences of these procedures, means that they should not be performed on children. A prohibition of the specific procedures that implicate Arkansas’s interests is substantially related to those interests. Because that describes the SAFE Act, Plaintiffs are not likely to succeed on the merits.

2. Plaintiffs’ contrary arguments do not address the scientific literature but are based on scientifically unsound positions taken by advocacy organizations.

The crux of Plaintiffs’ claims is that groups like WPATH and the Endocrine Society do not agree with the position Arkansas has taken based on its review of the scientific evidence. (*See, e.g.*, Compl. ¶¶ 22-47.) Dr. Adkins bases many of her opinions on the guidelines published by these organizations. (*See, e.g.*, Adkins Decl. ¶¶ 27-39.) And these same guidelines play a

central role in Dr. Antommaria's opinions. (*See, e.g.*, Antommaria Decl. ¶ 31.) But Plaintiffs cite nothing to support the proposition that States must outsource their science-based policymaking to advocacy organizations. The truth is quite to the contrary.

In other areas, the Supreme Court has made clear that States get to make their own policy judgments about appropriate medical care. *Gonzales*, 550 U.S. at 163; *see Kansas v. Hendricks*, 521 U.S. 346, 360 n.3 (1997) (“[W]hen a legislature ‘undertakes to act in areas fraught with medical and scientific uncertainties, legislative options must be especially broad and courts should be cautious not to rewrite legislation.’” (quoting *Jones v. United States*, 463 U.S. 354, 370 (1983))). The Court itself has rejected the positions taken by advocates like WPATH and the Endocrine Society. *See EMW Women’s Surgical Ctr., P.S.C. v. Beshear*, 920 F.3d 421, 438-39 (6th Cir. 2019) (explaining that in both *Casey* and *Gonzales*, the Supreme Court upheld laws that “conflicted with official positions of ACOG,” the American College of Obstetricians and Gynecologists).

Nothing requires the FDA, Arkansas, or any governmental entity to defer to the policy judgments of an advocacy organization. *See City of Akron v. Akron Ctr. for Reprod. Health, Inc.*, 462 U.S. 416, 456 (1983) (O’Connor, J., dissenting) (criticizing rule requiring courts “to revise [their] standards every time [ACOG] or [a] similar group revises its views about what is and what is not appropriate”); *Stenberg v. Carhart*, 530 U.S. 914, 1018 (2000) (same) (Thomas, J., dissenting). And neither the FDA nor Arkansas has done so.

But in addition to the fact that Arkansas isn’t required to defer to an advocacy organization’s view of what is medically required, Plaintiffs’ reliance on advocacy pieces from WPATH and the Endocrine Society is misplaced since nothing in their guidelines undermines Arkansas’s justifications for the SAFE Act. As already discussed, these guidelines themselves acknowledge

that they “cannot . . . establish a standard of care.”¹⁴⁸ The distinction between a clinical guideline—like WPATH’s or the Endocrine Society’s—and a standard of care is more than semantic. “Unlike standards of care, which should be authoritative, unbiased consensus positions designed to produce optimal outcomes, practice guidelines are suggestions or recommendations to improve care that, depending on their sponsor, may be biased.”¹⁴⁹

Because guidelines represent a political, consensus-seeking process (*i.e.*, voting)—a process with no known error rate—as opposed to an evidence-seeking, scientific research process, they have never been accepted by the scientific community as establishing what practices are or are not experimental. (*See* Hruz Decl. at pp. 46-48; Levine Decl. ¶ 52.) The guideline-production process is “influenced by the opinions and clinical experience of the guideline development group.”¹⁵⁰ They serve purposes other than merely following the scientific evidence. At times, guidelines may recommend “sub-optimal” treatments to “serve societal needs, or protect special interests (those of doctors, risk managers, or politicians, for example).”¹⁵¹ Similarly, “proponents and advocacy groups” can “misuse” guidelines to “giv[e] the public (and health professionals) the wrong impression about . . . the effectiveness of interventions.”¹⁵² Although guidelines

¹⁴⁸ ES Guidelines, *supra*, at 3895; *see* WPATH Guidelines, *supra*, at 1 (“The overall goal of the [WPATH guidelines] is to provide clinical guidance.”); *see also* Malone, *supra*, at 1 (noting that WPATH “acknowledges that despite the misleading name, WPATH Standards of Care 7 are [merely] *practice guidelines*, not standards of care”); APA Guidelines, *supra*, at 833 (agreeing that the WPATH and Endocrine Society documents are merely “treatment guidelines”—not “standards of care”).

¹⁴⁹ Malone, *supra*, at 1.

¹⁵⁰ Woolf, *supra*, at 529.

¹⁵¹ *Id.*

¹⁵² *Id.*

“carry the imprimatur of prominent professional groups,” they can “compromis[e] the quality of care” by “encourag[ing] ineffective, harmful, or wasteful interventions.”¹⁵³

These problems with the guideline-production process are also on clear view here, particularly as it relates to WPATH. It openly admits that “advocacy” and “public policy” are its “mission.”¹⁵⁴ (*See* Levine Decl. ¶¶ 45-53.) Indeed, despite holding itself out as a profession organization, WPATH’s meetings are increasingly dominated by activists who, at times, literally shout down discussions of scientific evidence. (*Id.* ¶ 47-48.) And though it claims to speak for the profession, most psychiatrists and psychologists who treat patients seeking inpatient psychiatric care for gender dysphoria are not members of WPATH. (*Id.* ¶ 51.)

Acting as a public-policy advocate, WPATH has issued statements advocating for the removal of gender dysphoria from the DSM and other publications, on the basis of perceived “stigma” or “prejudice and discrimination”—not on the basis of science.¹⁵⁵ Related to this effort to remove gender dysphoria from the DSM, the current version of WPATH’s guidelines removed the former requirement of psychotherapy prior to gender-transition procedures.¹⁵⁶ Rather than undergoing care from an experienced professional with the expertise to identify and treat psychiatric comorbidities, WPATH’s current guidelines focus only on confirming gender dysphoria—indifferent to *the reason* the patient is suffering that dysphoria—before shunting the patient off for irreversible gender-transition procedures. (*See* Levine Dec. ¶¶ 50-53 (discussing this change in policy).)

¹⁵³ *Id.* at 529-30.

¹⁵⁴ WPATH Guidelines, *supra*, at 1.

¹⁵⁵ *See* WPATH De-Psychopathologization Statement, *supra*; WPATH Reaction to DSM-V Criteria for Gender Incongruence, *supra*.

¹⁵⁶ *See also* WPATH Guidelines, *supra*, at 28 (“Psychotherapy is Not an Absolute Requirement for Hormone Therapy and Surgery”).

Unlike the WPATH guidelines, the more recent Endocrine Society guidelines at least attempt to grade the quality of the evidence for each of their recommendations. Overall, the data quality was very poor. The best data the Endocrine Society could find was related to “adverse medical outcomes,” and even that only “reached the level of ‘moderate’ quality.”¹⁵⁷ The guidelines found only “very low quality” or, at best, merely “low quality” evidence supporting the use either of puberty blockers or cross-sex hormones.¹⁵⁸ It doubted that those “who receive [puberty blockers] will derive, on average, more benefit than harm.”¹⁵⁹ Because of these data-quality problems, the Endocrine Society was unable even to “recommend” puberty blockers for pubertal children, instead merely “suggest[ing]” their use.¹⁶⁰ The guidelines likewise recognize that “[t]here is *insufficient evidence* to recommend a specific age requirement” for mastectomies.¹⁶¹ “By definition, these designations mean that there is a high likelihood that the attainment of new data will necessitate changes to the guidelines provided.”¹⁶²

So far, researchers have failed to obtain new data supporting the views of WPATH and the Endocrine Society. Most notorious was the Bränström and Pachankis incident discussed above. *See supra* pp. 27-29. They published in the *American Journal of Psychiatry* a study pur-

¹⁵⁷ Hruz, *supra*, at 37.

¹⁵⁸ ES Guidelines, *supra*, at 3872 (emphasis added).

¹⁵⁹ *Id.*

¹⁶⁰ *Id.* at 3880.

¹⁶¹ ES Guidelines, *supra*, at 3894 (emphasis added).

¹⁶² Hruz, *supra* at 37.

porting to demonstrate that gender-transition procedures improved long-term mental-health outcomes.¹⁶³ But a large number of distinguished medical researchers then submitted a series of letters to the editor of the *Journal* picking apart Bränström and Pachankis’s data, bit by bit.¹⁶⁴ As those letters laid out, the data actually demonstrated that gender-transition procedures led to an *increase* in adverse outcomes. These letters were so devastating that the *Journal* published a correction.¹⁶⁵

Given these serious deficiencies in Plaintiffs’ scientific evidence, they have not met their burden of establishing that this Court may consider the evidence of their putative experts. *Polski v. Quigley Corp.*, 538 F.3d 836, 841 (8th Cir. 2008). When considering this evidence, this Court must exercise “its role as a gatekeeper” and screen out unreliable evidence. *Miller v. Baker Implement Co.*, 439 F.3d 407, 412 (8th Cir. 2006); *see Daubert v. Merrell Dow Pharms., Inc.*, 509 U.S. 579, 593-95 (1993). In particular, they have made no effort to show “what the known rate of error is” for the evidence they cite in support of the supposed benefits of gender-transition procedures. *Miller*, 439 F.3d at 412. Nor have they shown that “the concept[s]” central to their claims are “generally accepted by the community.” *Id.*

To the contrary, the guidelines produced by groups like WPATH and the Endocrine Society are advocacy pieces—not scientific evidence. (*See, e.g.*, Regnerus Decl. ¶ 63 (“[D]espite the fact that American professional associations have endorsed the ‘affirmative’ approach to treating dysphoric adolescents, there is no wide, international consensus about its superiority.”).) The

¹⁶³ Richard Bränström and John E. Pachankis, *Reduction in Mental Health Treatment Utilization among Transgender Individuals after Gender-affirming Surgeries: A Total Population Study*, 177 *Am. J. Psychiatry* 727 (2020).

¹⁶⁴ Those letters to the editor are simultaneously filed with this brief as Exhibit 13.

¹⁶⁵ *Correction to Bränström and Pachankis*, 177 *Am. J. Psychiatry* 734 (Aug. 2020), <https://ajp.psychiatryonline.org/doi/10.1176/appi.ajp.2020.1778correction>.

“consensus-seeking” methodology these groups employ is “not a reliable[,]valid scientific methodology.” (Levine Decl. ¶ 52; *see* Hruz Decl. at pp. 46-48.)

Plaintiffs thus have “not offer[ed] the results of any testing to demonstrate that [their] theory” is “accurate”—*i.e.*, that gender-transition procedures sufficiently benefit children to offset the indisputable, irreversible harms they cause. *Smith v. Cangieter*, 462 F.3d 920, 924 (8th Cir. 2006). “[A]nd where there is no testing, there cannot be a known rate of error for the district court to consider.” *Id.* Despite years of performing gender-transition procedures, their benefits have “not been scrutinized by the scientific community.” *Id.* What research there is does not support the conclusions of Plaintiffs’ experts, nor Plaintiffs’ arguments based on those conclusions. Therefore, this Court should find that Plaintiffs’ evidence “does not meet the reliability requirements of Rule 702” and should not rely on it. *Id.* at 925; *see, e.g., Pro Serv. Auto., L.L.C. v. Lenan Corp.*, 469 F. 3d 1210, 1215-16 (8th Cir. 2006) (affirming exclusion of expert who “provided no testing or engineering analysis to support his causation opinion”).

Whether this Court formally rejects Plaintiffs’ evidence, or simply agrees that Defendants’ evidence is more persuasive, Plaintiffs are not likely to succeed on their equal-protection claim. This Court should deny the preliminary-injunction motion and dismiss this claim with prejudice.

III. The parents are not likely to succeed on their substantive-due-process claim.

Plaintiffs make no effort to rebut the clearly established principle that—even for terminally ill patients—there is no substantive-due-process right of affirmative access to experimental procedures. (*See* MTD Opp’n 35-37; MTD Br. 33-36.) That is likely because the courts of appeals have so clearly rejected claims that such a right exists. *See, e.g., Morrissey v. United States*, 871 F.3d 1260, 1269 (11th Cir. 2017); *Raich v. Gonzales*, 500 F.3d 850, 864 (9th Cir. 2007); *Abigail All. for Better Access to Developmental Drugs v. von Eschenbach*, 495 F.3d 695,

710 n.18 (D.C. Cir. 2007) (en banc); *Rutherford v. United States*, 616 F.2d 455, 456 (10th Cir. 1980). Thus, it is undisputed by Plaintiffs that children—including the children who are parties to this lawsuit—have no substantive-due-process right of affirmative access to experimental, gender-transition procedures.

That explains Plaintiffs’ decision to bring only a parental-rights substantive-due-process claim. But their arguments frame the parental-rights question in terms that are too generic. To assert a substantive-due-process claim based on an allegedly fundamental right, Plaintiffs must provide “a careful description” of the putative right. *Glucksberg*, 521 U.S. at 721 (quotation marks omitted). It will not suffice to say that parents have a “right to make decisions regarding the ‘care, custody, and control’ of their children,” or even a “right to seek and to follow medical advice.” (MTD Opp’n 34.) What Plaintiffs assert is a right to choose particular experimental medical procedures for their children, notwithstanding Arkansas’s reasoned judgment, based on medical evidence, that these particular procedures should not be carried out on minors. Such a right does not exist. And even it did, the SAFE Act would survive Plaintiffs’ substantive-due-process claim, no matter what level of scrutiny applies.

A. Although the Constitution protects parental rights, it does not include a right to subject a child to experimental medical procedures.

Given that children themselves have no substantive-due-process right to access gender-transition procedures, it is difficult to understand how their parents have a substantive-due-process right to access these procedures on behalf of their children. It cannot be true that “parents’ right to the care, custody, and control of their children” independently empowers parents to make any choice whatsoever for their children. (MTD Opp’n 35-36.) Indeed, it is not true. Plaintiffs cite no authority supporting their vision for parental rights.

Plaintiffs’ theory of a “right of parents to seek and follow medical advice for their minor children” would be a significant expansion of current substantive-due-process doctrine. (*Id.* at 35.) A hypothetical example helps illustrate the novelty of Plaintiffs’ argument. Take medical marijuana. *Cf.* Ark. Const., amend. 98, Medical Marijuana Amend. of 2016. In Arkansas, minors may, under certain, circumstances obtain medical marijuana. *See* Ark. Admin. Code 007.16.4-IV(C). But minors have no constitutional right to medical marijuana. *Cf. Gonzales v. Raich*, 545 U.S. 1, 15-22 (2005) (upholding Congress’s ban of even medicinal marijuana use under the Commerce Clause); *Raich*, 500 F.3d at 864-66 (holding there is no substantive-due-process right to medicinal marijuana use). Under Plaintiffs’ parental-rights theory, if a doctor advises parents to place their child on medical marijuana, then those parents have a substantive-due-process right to do so. Thus, according to Plaintiffs, if the child does not satisfy the conditions for using medical marijuana in Arkansas, the parents may assert a constitutional right to follow that doctor’s advice—even though their child would have no correlative constitutional claim against the State. There is no authority for this understanding of the right to parental autonomy.

The right that Plaintiffs assert does not resemble the right discussed in decisions like *Pierce v. Society of Sisters*, 268 U.S. 510 (1925). The Court there did not address “the right of the child to influence the parents’ choice of school.” *Id.* at 532. But if the Court had done so, nothing in its reasoning suggests that it would have held that children, unlike their parents, are not empowered to exercise that right to choose to attend a private school. *See id.* at 534-35. In fact, if a child had the right to influence the parents’ schooling decisions, the Court’s reasoning suggests it would have held that children had a correlative right to attend private school. *See id.*

at 535 (“The fundamental theory of liberty upon which all governments in this Union repose excludes any general power of the state to standardize its children by forcing them to accept instruction from public teachers only.”). Similarly, in *Michael H. v. Gerald D.*, 491 U.S. 110 (1989), although the Court declined to decide whether “a child has a liberty interest, symmetrical with that of her parent, in maintaining her filial relationship,” part of the Court’s rationale for rejecting the child’s claim was “that, at best, her claim is the obverse of [her biological father’s] and fails for the same reasons.” *Id.* at 130-31.

Both *Pierce* and *Michael H.* support the idea that, as a general matter, a parent’s substantive-due-process right to make a choice for their children is correlated with the children’s own right to make that choice. Children indisputably lack a constitutional right of affirmative access to gender-transition procedures. Therefore, the parents’ claim here, which “is the obverse of” a hypothetical right-of-affirmative-access claim brought by a child, “fails for the same reason.” *Id.* at 131.

Plaintiffs’ other citations are not to the contrary. (*See* MTD Opp’n 34-35.) Most notably, two decisions they cite are *procedural*-due-process cases, addressing the procedures necessary for a State to interfere with parental rights, rather than outlining the scope of the fundamental right to raise children. In one, the issue was whether New York’s procedures for terminating parental rights were constitutional. *See Santosky v. Kramer*, 455 U.S. 745, 758-68 (1982) (applying test from *Mathews v. Eldridge*, 424 U.S. 319 (1976)). The question in another was whether the State allowed parents *too much autonomy* in making the decision to have their children involuntarily committed. *See Parham v. J.R.*, 442 U.S. 584, 606-07 (1979) (applying *Mathews* test also). Those cases about constitutionally mandated procedures shed little light on the scope of the fundamental right that Plaintiffs assert here.

Plaintiffs also cite precedent that affirmatively undermines their putative right to subject their children to experimental procedures. The Sixth Circuit stated, as a general matter, that a right to choose a child’s medical care exists. *See Kanuszewski v. Mich. Dep’t of Health & Hum. Servs.*, 927 F.3d 396, 419 (6th Cir. 2019). But that court went on to say that “[t]his does not mean that parents’ control over their children is without limit.” *Id.* “Indeed, limitations on parents’ control over their children are particularly salient in the context of medical treatment.” *Id.* Far from supporting Plaintiffs’ theory, the Sixth Circuit in *Kanuszewski* was careful to circumscribe it.

Lastly, nothing in *Troxel v. Granville*, 530 U.S. 57 (2000), supports Plaintiffs’ theory. There the Court considered a “breathtakingly broad” statute that “effectively permit[ted] any third party seeking visitation to subject any decision by a parent concerning visitation of the parent’s children to state-court review.” *Id.* at 67 (plurality opinion). In that way, the statute struck at the heart of the parent–child relationship—usurping the parents’ power to determine who spent time around their children. The Court nowhere there suggested that parents have, by default, the power to choose any experimental medical procedure that a practitioner recommends.

Discussions of parental rights in other contexts also undermine Plaintiffs’ arguments. Chief among them, the Supreme Court has rejected parents’ right to choose whether their children have abortions. *See Planned Parenthood of Cent. Mo. v. Danforth*, 428 U.S. 52, 72 (1976). And the Court held a few years after *Danforth* that the Constitution required the State to establish procedures for bypassing its parental-consent law. *See Bellotti v. Baird*, 443 U.S. 622, 647-48 (1979). In other words, the Constitution *requires* that parents have little-to-no say in a child’s decision to exercise her substantive-due-process right to an abortion. It makes no sense to apply a different rule to the SAFE Act.

B. Whatever level of scrutiny applies to the parents’ substantive-due-process claim, the SAFE Act survives.

Defendants do not concede that strict scrutiny applies to the parents’ substantive-due-process claim. (*Cf.* MTD Opp’n 37.) But this brief has already explained why the SAFE Act satisfies rational-basis review and intermediate scrutiny. *See supra* pp. 71-88. The Act would also satisfy strict scrutiny.

Plaintiffs do not dispute—because they cannot dispute—that Arkansas’s interests in protecting children and safeguarding the medical profession are compelling. *See, e.g., Reno*, 521 U.S. at 869; *Gonzales*, 550 U.S. at 157; *Glucksberg*, 521 U.S. at 731. Nor do Plaintiffs dispute that parents’ rights “can be limited by the state’s compelling interest in protecting a child.” *Swipies v. Kofka*, 348 F.3d. 701, 703 (8th Cir. 2003). But they do not cite a single case holding that parents’ rights can trump the State’s power to regulate which controversial, experimental medical procedures may be performed on minors. Worse than that, the only decision they do cite *rejected* a claim that the State could not require a child to undergo a blood transfusion. *Jehovah’s Witnesses in Wash. v. King Cty. Hosp. Unit No. 1*, 278 F. Supp. 488, 504-05 (W.D. Wash. 1967). Their attempt to distinguish that decision relies on their unsupported assertion that gender-transition procedures are “life-saving medical care.” (PI Br. 50.) But there is no scientifically valid evidence to support that assertion. *See supra* pp. 78-82.

Because the SAFE Act is narrowly tailored to serve Arkansas’s compelling interests, it survives strict scrutiny. *See Glucksberg*, 521 U.S. at 721. The Arkansas General Assembly recited evidence that gave it concerns about the irreversible consequences of and harms caused by certain experimental gender-transition procedures. *See* SAFE Act, sec. 2 (Legislative findings). Its legislative findings are supported by significant scientific evidence. *See supra* pp. 11-16, 20-30, 76-82 (discussing relevant science). And nations around the world have reviewed the same

evidence as the General Assembly and come to the same conclusion: Something is wrong with the current state of affairs regarding minors and gender-transition procedures. *See supra* pp. 20-30 (detailing international scrutiny of the problems with gender-transition procedures).

The only procedures that the SAFE Act prohibits are the particular procedures that implicate Arkansas’s compelling interests in protecting children and the medical profession. Consistent with those interests, it prohibits those particular procedures *only when performed on minors*. And Arkansas has not prohibited any other treatment for gender dysphoria—even for minors—including “watchful waiting,” psychotherapy, or a combination. (*See Levine Decl.* ¶¶ 27-42.) In fact, the SAFE Act expressly *encourages* the provision of mental health services to children suffering from gender dysphoria. SAFE Act, sec. 2(4). Nor does the SAFE Act place any limits on the use of social transition. Of course, “perfect tailoring” is “impossib[le],” but the SAFE Act comes close to perfect. *Williams-Yulee v. Fla. Bar*, 575 U.S. 433, 454 (2015). Therefore, Plaintiffs are not likely to succeed on their substantive-due-process claim, which this Court should dismiss with prejudice.

IV. Plaintiffs are not likely to succeed on their free-speech claim.

Plaintiffs style their free-speech claims as asserting both the practitioners’ right to speak and the families’ “right to hear.” (Compl. ¶ 180.) But “the right to receive speech is ‘entirely derivative’ of the rights of the speaker.” *Pa. Fam. Inst., Inc. v. Black*, 489 F.3d 156, 165 (3d Cir. 2007) (quoting *In re Dow Jones & Co.*, 842 F.2d 603, 608 (2d Cir. 1988)); *see Spargo v. N.Y. State Comm’n on Jud. Conduct*, 351 F.3d 65, 83 (2d Cir. 2003) (holding that “the rights of the recipients of speech . . . derive in the first instance from the primary rights of the speaker”); *cf. Va. State Bd. of Pharm. v. Va. Citizens Consumer Council, Inc.*, 425 U.S. 748, 757 (1976) (holding that whether there is a “right to receive [] advertising” depends on whether “there is a right to

advertise”). The families’ First Amendment claim, therefore, hinges on the prior question whether the practitioners have a valid First Amendment claim.

A. The SAFE Act prohibits sending a child elsewhere for a gender-transition procedure.

They do not, because the SAFE Act regulates conduct and not speech. Its central provision prohibits two types of conduct. Newly enacted subsection 20-9-1502(a) provides that a practitioner “shall not provide gender transition procedures” to a child, while subsection (b) provides that a practitioner “shall not refer” a child “to any healthcare professional for gender transition procedures.” SAFE Act, sec. 3 (creating Ark. Code Ann. 20-9-1502). The SAFE Act’s prohibition of experimental gender-transition procedures would be significantly weakened if practitioners could avoid it simply by outsourcing the actual procedure to an out-of-state practitioner.

Here, again, WPATH’s guidelines undermine Plaintiffs’ arguments. According to Plaintiffs, when practitioners give a referral they are merely “speaking . . . about medically accepted treatments for gender dysphoria.” (PI Br. 52.) WPATH makes clear that a referral is *conduct* and not merely speech about gender-transition procedures.¹⁶⁶ In this context, a referral means to “provide documentation—in the chart and/or referral letter—of the patient’s personal treatment history, progress, and eligibility” for a requested procedure.¹⁶⁷ All that newly enacted subsection 20-9-1502(b) prohibits, therefore, is the conduct of sending a child to another practitioner for a gender-transition procedure, not any speech about gender dysphoria.

This subsection falls squarely within the Supreme Court’s allowance for the States to “regulate professional conduct, even though that conduct incidentally involves speech.” *Nat’l Inst. of Family & Life Advocates v. Becerra* (“NIFLA”), 138 S. Ct. 2361, 2372 (2018). Arkansas

¹⁶⁶ See WPATH Guidelines, *supra*, at 26-28.

¹⁶⁷ See *id.* at 26 (cross-sex hormones); *id.* at 27 (gender-reassignment surgery).

“does not lose its power to regulate” practitioners’ conduct of referring children to others for gender-transition procedures simply because “speech is a component of that activity.” *Ohralik v. Ohio State Bar Ass’n*, 436 U.S. 447, 456 (1978). Here, as in many other cases, the practitioners’ claim receives less-searching First Amendment scrutiny because they claim a right to speak “only as part of the practice of medicine, subject to reasonable licensing and regulation by the State.” *Planned Parenthood of Se. Pa. v. Casey*, 505 U.S. 833, 884 (1992) (plurality opinion); see *Planned Parenthood Minn., N.D., S.D. v. Rounds*, 686 F.3d 889, 893 (8th Cir. 2012) (en banc). Plaintiffs argue that *Casey*’s rule allowing States to regulate the practice of medicine—even when speech is implicated—does not apply because subsection 20-9-1502(b) is not an informed-consent requirement. (MTD Opp’n 44 n.16.) But this ignores the sweep of *Casey*’s rule. The question is whether subsection (b) is “tied to a procedure.” *NIFLA*, 138 S. Ct. at 2373. The law in *NIFLA* was not, so the Court did not apply *Casey*. By contrast, subsection (b) is closely tied to a particular procedure. It only prohibits practitioners from sending their patients elsewhere for a gender-transition procedure. This is exactly the sort of “professional conduct” that States are free to regulate. *Id.*

Whatever incidental speech may be regulated by the SAFE Act, it is the sort of regulation that requires practitioners to “disclose factual, noncontroversial information” that receives “more deferential review.” *Id.* at 2372. Plaintiffs take too limited a view of this principle. (See MTD Opp’n 42.) Practitioners in Arkansas must simply disclose that state law prohibits them from sending a child to another practitioner—presumably outside Arkansas—to undergo a gender-transition procedure. This discloses nothing more than “the terms under which [the practitioner’s] services will be available.” *Zauderer v. Off. of Disciplinary Counsel of Supreme Ct. of*

Ohio, 471 U.S. 626, 651 (1985). Gender-transition practitioners’ “constitutionally protected interest in *not* providing any particular factual information” to their patients “is minimal.” *Id.*

Finally, Plaintiffs misunderstand the relevance of *Rust v. Sullivan*, 500 U.S. 173 (1991). (See MTD Opp’n 43.) Part of the reason the Court upheld the funding restriction in that case was because employees of funding recipients “remain[ed] free . . . to pursue abortion-related activities when they are not acting under the auspices of the [federally funded] project.” *Rust*, 500 U.S. at 198. The law at issue did “not in any way restrict the activities of those persons acting as private individuals.” *Id.* at 199. The SAFE Act leaves gender-transition practitioners with even more freedom than the funding restriction in *Rust*. In the course of treating children with gender dysphoria, practitioners remain free to pursue any model of treatment except for experimental gender-transition procedures. (See (See Levine Decl. ¶¶ 27-42 (discussing various treatment models, including “watchful waiting” and psychotherapy, which the SAFE Act does not prohibit).) And practitioners remain free to *advocate for* the prohibited gender-transition procedure—even in the midst of treating minors. The only thing subsection 20-9-1502(b) prohibits is sending a child to another practitioner for a prohibited procedure.

B. The SAFE Act satisfies any level of scrutiny that applies.

Plaintiffs briefly assert that subsection 20-9-1502(b) fails intermediate scrutiny, but they offer no new arguments on this front. (MTD Opp’n 44.) It satisfies intermediate scrutiny for the same reasons as the rest of the SAFE Act. *See supra* pp. 75-88.

Although they make a handful of arguments about why subsection 20-9-1502(b) fails strict scrutiny, these mostly boil down to variations on familiar themes. (See PI Br. 55-57.) Arkansas does not assert “a free-floating power to restrict *the ideas* to which children may be exposed.” *Brown v. Ent. Merchants Ass’n*, 564 U.S. 786, 794 (2011) (emphasis added). Arkansas asserts instead the compelling governmental interests in protecting children from experimental

gender-transition procedures and safeguarding medical ethics. The Supreme Court has long held that the State has “a compelling interest in protecting the *physical* and psychological well-being of minors.” *Reno*, 521 U.S. at 869 (quoting *Sable Commc 'ns of Cal.*, 492 U.S. at 126) (emphasis added). A more compelling example of protecting the well-being of children could hardly be imagined than a law that protects them from experimental procedures that irreversibly destroy the function of their sex and reproductive organs. (*See* Hruz Decl. at pp. 73-77; Levine Decl. ¶¶ 80-87; Lappert Decl. ¶¶ 34-35.)

As already discussed, the prohibited gender-transition procedures are not “the same treatments” that are allowed in other contexts. (MTD Opp’n 26.) Even when gender-transition procedures rely on similar medications and surgical techniques as other treatments, the prohibited procedures are performed for different purposes, and have singular, irreversible consequences for children’s sexual, reproductive, physiological, and mental development. *See supra* pp. 76-78. Nor is there any evidence that they are “lifesaving.” (*E.g.*, MTD Opp’n 37.) In fact, the best evidence suggests that suicide risk actually *increases* after transition. (*See* Levine Decl. ¶ 74 (discussing evidence demonstrating that post-surgery, the suicide risk is 19.1 times greater than in a control group); *see also* Regnerus Decl. ¶¶ 104-15 (discussing context for suicide rates).) Arkansas has not banned “an entire category of speech.” (PI Br. 57.) In the SAFE Act, it has simply prohibited gender-transition practitioners in Arkansas from outsourcing prohibited procedures to others by sending them children in Arkansas. Without this prohibition, the SAFE Act’s protections for children would be much less effective.

V. Other factors weigh against granting a preliminary injunction here.

A. If this Court preliminarily enjoins the SAFE Act, children in Arkansas will undergo irreversible changes to their sexual and reproductive organs.

Granting a preliminary injunction in this case will mean that additional children in Arkansas will undergo gender-transition procedures. More children will begin taking puberty blockers and experience the loss of bone density and potential for permanently immature sex organs that comes with those drugs. And more children will go on cross-sex hormones and become permanently infertile. A preliminary injunction will irreparably change those children's lives. On this basis, it is not warranted.

Plaintiffs counter that, absent a preliminary injunction, Arkansas children will be forced “to undergo endogenous puberty.” (PI Br. 58.) But they cite no authority for the proposition that a law irreparably harms children by ensuring their sexual and reproductive development proceeds biologically. And they certainly cite no authority supporting the idea that biological pubertal development is so harmful that it outweighs the irreversible consequences of a preliminary injunction. Granting a preliminary injunction will do more harm to children in Arkansas than allowing them to proceed biologically through puberty.

Plaintiffs try to avoid this conclusion by arguing that biological development would “trigger[] severe distress” in them and other children in Arkansas. (PI Br. 58.) The problem with this argument is that it presumes gender-transition procedures would relieve any distress experienced by these children. But there is no evidence that this is true. For one thing, there is scientifically valid evidence suggesting just the opposite—that gender-transition procedures lead to *more significant* distress and other mental-health problems. (*See, e.g.*, Levine Decl. ¶ 74; Hruz Dec. at p. 24 (discussing findings of previously discussed Bränström study).) For another, there is certainly no evidence that granting a preliminary injunction would reduce any particular person's

risk of committing suicide or, more generally, the suicide risk of those in Arkansas who identify as transgender. (*See, e.g.*, Regnerus Decl. ¶¶ 104-15; Levine Decl. ¶ 74.) Worse, because practitioners do “not yet know[] how to distinguish those children who will desist from that small minority whose trans identity will persist,” there is no way to know whether any particular child can even theoretically benefit from a gender-transition procedure. (Levine Decl. ¶ 55.) In other words, practitioners have no way of knowing *ex ante* whether gender-transition procedures will benefit a particular child experiencing gender incongruity.

In the face of such uncertainty, the prudential path is to wait, given the indisputable consequences of allowing practitioners to perform gender-transition procedures on these children. It is no response to say that “the psychological harm of untreated gender dysphoria is severe.” (PI Br. 59.) Arkansas has not prohibited treatment of gender dysphoria in minors. Scientifically valid evidence supports other treatment models, including the so-called “watchful waiting” model and the use of psychotherapy to address other mental-health problems. (*See* Levine Decl. ¶¶ 29-35; *see also* Hiatt Decl. ¶¶ 23-28.) The SAFE Act allows such treatment to continue, even in minors. It is not irreparable harm that Arkansas has prohibited particular experimental gender-transition procedures while leaving open other accepted courses of treatment. *Cf. Reid v. Griffin*, 808 F.3d 1191, 1192-93 (8th Cir. 2015) (rejecting Eighth Amendment claim seeking cross-sex hormones in part because the plaintiff did “not allege any failure to provide general mental health treatment”); *White v. Farrier*, 849 F.2d 322, 327 (8th Cir. 1988) (rejecting claim that there is an Eighth Amendment “right to hormone therapy”).

Finally, the SAFE Act does not require Plaintiffs to “abruptly cut[] off” ongoing gender-transition procedures. (PI Br. 59.) The SAFE Act was enacted on April 6, 2021. (Compl. ¶ 1.) The earliest the Act can take effect is on July 28. (*See* Compl. ¶ 1 n.1.) This provided 113 days

for gender-transition practitioners in Arkansas to safely ramp down children’s cross-sex hormones. The only evidence they cite for this purported harm is Dr. Adkins’s declaration. (*See* PI Br. 59 (citing Adkins Decl. ¶ 54).) But Dr. Adkins says that only around 42 days (“about six weeks”) are needed to take a patient off cross-sex hormones. (Adkins Decl. ¶ 54.) Because they had 113 days between enactment of the SAFE Act and its earliest possible effective date, gender-transition practitioners in Arkansas had over 2.5 times as long as they need for safe withdrawal, according to Plaintiffs’ own evidence. Indeed, practitioners in Arkansas may continue to prescribe cross-sex hormones up to the Act’s effective date, thereby ensuring that their patients are not abruptly cut off.

This fact also highlights a troubling fact about Arkansas’s gender-transition practitioners brought to light by Plaintiffs’ evidence. One child in this lawsuit was *not* already taking cross-sex hormones before enactment of the SAFE Act. (*See* Decl. of Parker Saxton, Dkt. No. 11-7 ¶ 13.) Practitioners started giving this child testosterone on May 27—almost *two months* after the General Assembly passed the Act. (*Id.* ¶ 14.) In other words, with the knowledge that Arkansas law would soon prohibit giving cross-sex hormones to children, gender-transition practitioners proceeded to place this child on cross-sex hormones. Granting Plaintiffs’ preliminary-injunction motion would condone this reckless behavior by the practitioners here.

B. The public interest weighs in favor of denying the preliminary-injunction motion.

Granting a preliminary injunction will harm children in Arkansas. It will also harm the people of Arkansas more generally, who have decided through their elected representatives that the harms of gender-transition procedures outweigh any theoretical benefits when performed on minors.

In particular, a preliminary injunction would irreparably harm all Arkansans. A State’s “inability to enforce its duly enacted plans clearly inflicts irreparable harm on the State.” *Abbott*, 138 S. Ct. at 2324 n.17. A State always suffers irreparable harm when it is “precluded from applying its duly enacted legislation.” *Org. for Black Struggle v. Ashcroft*, 978 F.3d 603, 609 (8th Cir. 2020); *see id.* (“Any time a State is enjoined by a court from effectuating statutes enacted by representatives of its people, it suffers a form of irreparable injury.” (quoting *Maryland v. King*, 567 U.S. 1301, 1303 (2012) (Roberts, C.J., in chambers)) (alteration omitted)). Plaintiffs claim this Court can disregard this interest because they’ve argued the SAFE Act is unconstitutional. (*See* PI Br. 61.) But that approach would make the harm inquiry irrelevant whenever a party seeks to preliminarily enjoin a state law, because the likelihood-of-success inquiry would always decisively resolve the irreparable-harm inquiry. *See Hand v. Scott*, 888 F.3d 1206, 1214 (11th Cir. 2018) (holding that State “would be harmed if it could not apply its own laws . . . now, even if it might later be able to” apply altered version of law). This Court should not ignore the irreparable harm that an injunction would inflict on Arkansas.

Finally, the purpose of a preliminary injunction—preservation of the status quo—supports Defendants on this motion. Indeed, whenever a plaintiff seeks to enjoin duly enacted legislation, “the status quo is that which the People have wrought, not that which unaccountable federal judges impose upon them.” *Planned Parenthood of Blue Ridge v. Camblos*, 116 F.3d 707, 721 (4th Cir. 1997) (Luttig, J., staying injunction in published, single-judge order). In other words, the status quo is that Arkansas law takes effect.

C. Plaintiffs’ requested facial injunction would be too broad.

Plaintiffs ask this Court for a facial injunction of the SAFE Act. (*See* PI Br. 62.) But even generously construing their own allegations, Plaintiffs would not be entitled to facial relief.

To justify a facial injunction, they “must establish that no set of circumstances exists under which the Act would be valid.” *Salerno*, 481 U.S. at 745. Plaintiffs cannot do that because they seek an injunction based on the alleged irreparable harm to the families participating in this case, but offer no evidence that all children in Arkansas who would seek gender-transition procedures would face similar harm. (*See* PI Br. 58-60.) Indeed, granting facial relief based on evidence about only these families is inconsistent with Dr. Adkins’s claim that “[t]he precise treatment for gender dysphoria depends on each person’s individualized need.” (Adkins Decl. ¶ 27.) Thus, even assuming the families in this lawsuit would be harmed by the SAFE Act, that is not enough to justify invalidating the Act in a statewide, facial injunction. *Cf. Brakebill v. Jaeger*, 932 F.3d 671, 678 (8th Cir. 2019) (“[E]ven assuming that a plaintiff can show that an election statute imposes excessively burdensome requirements on *some* voters, that showing does not justify broad relief that invalidates the requirements on a statewide basis as applied to *all* voters.” (quotation marks and citation omitted)).

Further, the inappropriateness of facial relief is particularly clear as to the SAFE Act’s provisions regarding gender-reassignment surgery and a private right of action. Plaintiffs do not dispute that their allegations do not implicate those provisions. (*See* MTD Opp’n 7-10.) Facially enjoining those provisions would, therefore, be an abuse of discretion. *See St. Louis Effort for AIDS v. Huff*, 782 F.3d 1016, 1022-23 (8th Cir. 2015) (holding that “a preliminary injunction must be narrowly tailored to remedy only the specific harms shown by the plaintiffs, rather than to enjoin all possible breaches of the law” (alterations and quotation marks omitted)).

CONCLUSION

For these reasons, Defendants ask that the Court deny Plaintiffs’ motion for a preliminary injunction, and grant Defendants’ motion to dismiss the Complaint with prejudice.

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