

IN THE SUPREME COURT OF THE STATE OF MONTANA
DA 23-0572

SCARLETT VAN GARDEREN, et al.,

Plaintiffs and Appellees,

v.

STATE OF MONTANA, et al.,

Defendants and Appellants.

AMICUS CURIAE BRIEF OF THE MONTANA FAMILY FOUNDATION

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INTRODUCTION

The Montana Family Foundation (“MFF”) is deeply concerned about the use of puberty blockers, cross-sex hormones, and surgical interventions for children with gender dysphoria. Systematic reviews have shown insufficient evidence to support these practices. Many studies even suggest these interventions are dangerous. As a result, many European nations and American states forbid puberty blockers, cross-sex hormones, and surgical interventions for children with gender dysphoria. MFF believes such caution is best, given the high stakes and unsettled science.

Montana seeks to protect children from unproven drug treatments and irreversible surgical interventions that risk permanent harm. Senate Bill 99 (“SB 99”) was enacted to regulate puberty blockers, cross-sex hormones, and surgical interventions for children experiencing gender dysphoria. (Doc. 102). After examining the medical literature and best practices around the world, Montana found such drug use and elective surgery was harmful—it causes irreversible sterility, increases a child’s risk of disease and illness, and sparks adverse and sometimes fatal psychological consequences. At minimum, the State found that these medical interventions are reckless because they are experimental, unsupported by high-quality evidence, and pose unknown risks.

The district court enjoined these protections for children and suggested that children have a constitutional right to inject themselves with experimental drugs or sterilize themselves through surgery. (Doc. 131 at 46). That ruling wrongly assumed

that all individuals who suffer from gender dysphoria identify as transgender, and it ignored principles of evidence-based medicine—valuing low-quality anecdote over high-quality systematic reviews. The court should have found instead that no high-quality evidence supports puberty blockers, cross-sex hormones, or surgical intervention to treat children with gender dysphoria, and multiple studies suggest that these interventions are potentially dangerous.

Courts give legislatures wide discretion to pass legislation when there is medical and scientific uncertainty. In 2022, the Supreme Court reversed a 50-year-old precedent constitutionalizing a right to abortion, recognizing it had improperly withheld judicial restraint on a critical social issue, causing great turmoil. This Court should not repeat that error here by constitutionalizing a new right to unproven medical interventions.

Accordingly, MFF asks this Court to reverse the ruling below and allow Montana to protect children from these dangerous, irreversible interventions.

ARGUMENT

An injunction is “an extraordinary remedy not available as a matter of right.” *Netzer Law Office, P.C. v. State*, 2022 MT 234, ¶ 17, 410 Mont. 513, 520 P.3d 335 (citations omitted); see also *Winter v. Nat. Res. Def. Council, Inc.*, 555 U.S. 7, 24 (2008). If a preliminary injunction “will not accomplish its *limited* purpose, then it should not issue.” *Id.* (emphasis supplied). This is particularly true when plaintiffs seek to enjoin the “enforcement of a presumptively valid state statute.” *Brown v.*

Gilmore, 122 S. Ct. 1, 1 (2001) (Rehnquist, C.J., in chambers). Such a request “demands” unusually strong “justification.” *Lux v. Rodrigues*, 561 U.S. 1306, 1307 (2010) (Roberts, C.J., in chambers).

To obtain a preliminary injunction, Plaintiffs must prove, among other things, that they are “likely to succeed on the merits.” *Winter*, 555 U.S. at 20. Plaintiffs have not done so here. Plaintiffs are unlikely to succeed because only rational-basis review applies to their claims and SB 99 satisfies even intermediate scrutiny by reasonably protecting children from unproven drugs and surgical interventions.

I. Rational-basis review applies, and SB 99 easily satisfies both rational-basis and intermediate scrutiny.

Statutory classifications are typically valid if they rationally advance a legitimate interest. *San Antonio Indep. Sch. Dist. v. Rodriguez*, 411 U.S. 1, 55 (1973). Closer scrutiny applies when laws implicate suspect or quasi-suspect classes. *Reed v. Reed*, 404 U.S. 71, 76 (1971). Laws that implicate sex or other quasi-suspect classifications must advance an “important” goal through “substantially related” means. *Tuan Anh Nguyen v. INS*, 533 U.S. 53, 60 (2001). But a perfect fit is not required; only a “reasonable” one. *Tyler v. Hillsdale Cnty. Sheriff’s Dep’t*, 837 F.3d 678, 693 (6th Cir. 2016). Rational-basis review applies here because SB 99 does not target a suspect or quasi-suspect class as it regulates interventions used on minors of both sexes. Regardless, SB 99 satisfies even intermediate scrutiny.

A. SB 99 protects children from unproven drug and surgical interventions no matter how they identify.

Montana enacted the Youth Health Protection Act “to enhance the protection of minors,” irrespective of how they identify. (Doc. 102). SB 99 protects children from “any form of pressure to receive harmful, experimental” drugs and hormones or to “undergo irreversible, life-altering surgical procedures.” *Id.* at § 2. SB 99 also prohibits public funding or facilitation of the proscribed interventions and creates a private right of action for children who are harmed by the proscribed interventions. *Id.* at §§ 3-10.¹

The district court found that SB 99 targets individuals “based on transgender status,” and further, that “[r]estricting access to gender-affirming medical care for adolescents is not based in science and will raise the risk of poor mental health and suicidality among transgender adolescents.” (Doc. 131 at pp. 45-46). Inherent to the district court’s reasoning is the notion that a child cannot experience gender dysphoria without identifying as transgender. Not so. Gender dysphoria is a recognized mental health condition. Am. Psychiatric Ass’n, *Diagnostic & Statistical Manual of Mental Disorders*, 512 (5th ed. 2013). It requires six-month “marked

¹ Plaintiffs lack standing to seek relief that would prevent the filing of private lawsuits against providers who violate the provisions of SB 99. *See Whole Woman’s Health v. Jackson*, 142 S. Ct. 522, 532 (2021); *Arizonans for Official English v. Arizona*, 520 U.S. 43, 66 & n. 21 (1997); *Hope Clinic v. Ryan*, 249 F.3d 603, 605 (7th Cir. 2001) (en banc) (“[P]laintiffs lack standing to contest ... statutes authorizing private rights of action”). Thus, it is not clear how a judgment that restrains state officials from enforcing SB 99 will cause providers to continue the prohibited treatments when they remain exposed to private lawsuits and potentially ruinous liability.

incongruence between one’s experienced/expressed gender and assigned gender” that is “associated with clinically significant distress.” *Id.* In contrast, transgender *identification* is not a mental disorder: individuals can identify as transgender without suffering from gender dysphoria.²

Adolescent gender dysphoria often does not lead to adult transgender identification. Until recently, most minors presenting with gender dysphoria were pre-pubescent males.³ The Dutch protocol analyzed this population. (Appx. 94). With psychotherapy (but not social or medical transition practices), the study showed that most children ceased to experience gender dysphoria during adolescence and identified with their natal sex as an adult. (Appx. 464, 726). On the other hand, children subject to medical intervention are far more likely to *persist* in experiencing gender dysphoria than those who aren’t. (Appx. 521). In other words, transitioning children is “not a neutral act.”⁴ Against this backdrop, SB 99 provides a space for children’s gender dysphoria to resolve.

This space is critical because a new population dominates gender clinics: females in mid-adolescence with gender discordance *without* a childhood history of such. (Appx. 615). Early research did not study this population, (Appx. 94), and

² *Expert Q&A: Gender Dysphoria*, Am. Psychiatric Ass’n, <https://perma.cc/3YJ4-F2A2> (last accessed April 2, 2024).

³ The Cass Review, *Independent review of gender identity services for children and young people: Interim report 32* (2022), <https://perma.cc/9CT5-J6NU> (last accessed April 2, 2024).

⁴ Cass Review 38, 62-63.

modern research lags because this group is newly developing.⁵ Nothing suggests this population will necessarily identify as transgender in adulthood. So, caution is critical.

Montana enacted SB 99 to protect the health and safety of children no matter how they identify. SB 99 thus does not distinguish based on a suspect or quasi-suspect classification. Moreover, the goal of protecting children is both legitimate and “compelling.” *New York v. Ferber*, 458 U.S. 747, 756-57 (1982).

B. SB 99 reasonably advances its important goal of protecting children from risky interventions.

1. The Endocrine Society guidelines and WPATH standards of care lack evidence-based support.

Rejecting Montana’s concerns about the use of experimental drugs and irreversible surgery for children, the district court invoked the “WPATH standard of care” to preliminarily enjoin SB 99. (Doc. 131 at p. 30). However, “optimal clinical decision making requires” support “from systematic summaries” based on high-quality evidence.⁶ The WPATH standards lack such evidentiary support.

The GRADE method is widely accepted for rating available medical evidence.⁷ High-quality evidence means the “true effect [of medical intervention] lies close to that of the estimate.” (Appx. 461) Moderate-quality evidence means the

⁵ Lisa Littman, *Parent reports of adolescents and young adults perceived to show signs of a rapid onset of gender dysphoria* 3, PLOS ONE (2018), <https://perma.cc/E8ZH-FWP6>.

⁶ Gordon Guyatt et al., *Users’ Guides to the Medical Literature* 10 (McGraw Hill Education, 3rd ed. 2015).

⁷ *Id.* at 16.

“true effect is likely to be close to the estimate... but there is a possibility that it is substantially different.” *Id.* Low-quality evidence means the “true effect may be substantially different from the estimate.” *Id.* Very-low-quality evidence means the “true effect is likely to be substantially different from the estimate.” *Id.* When applied correctly, the GRADE method “achieves explicit and transparent judgment” by requiring evaluators to disclose all evidence and reasons supporting their rating. (Appx. 455). Generally, strong recommendations should *not* be made based on low-quality evidence—only when “a panel would have a low level of regret if [later] evidence showed that their recommendation was misguided.” (Appx. 490).

WPATH admits that its standards lack support from systematic reviews of available evidence and the group does not rate the quality of evidence.⁸ Per WPATH, “a systematic review” of evidence “is not possible,” but a co-developer of evidence-based medicine says such reviews “are always possible,” and WPATH would “violat[e] standards of trustworthy guidelines” by making “a recommendation without one.” (Appx. 497). It turns out that others *have* systematically reviewed the evidence, and as shown below, the results are disturbing.

2. Systematic reviews have shown insufficient evidence to use puberty blockers, cross-sex hormones, and surgical interventions to treat minors with gender dysphoria.

⁸ E. Coleman et al., *Standards of Care for the Health of Transgender and Gender Diverse People, Version 8*, 23 Int’l J. Transgender Health S1, S42 (2022), <https://www.wpath.org/publications/soc>.

Swedish and Finnish authorities have systematically reviewed the evidence to conclude that its quality is insufficient to justify using puberty blockers, cross-sex hormones, or surgical intervention for children with gender dysphoria.⁹ Similar systematic reviews have led England’s National Health Service to prohibit the use of puberty blockers for children. (Appx. 57; 151-306; 307-437; & 537). While European nations that forbid clinical use are still allowing research to continue, it does not mean that drug or surgical interventions are safe.

McMaster University, where evidence-based medicine originated, systematically reviewed the “[e]ffects of gender affirming therapies in people with gender dysphoria” and concluded that (1) “there is great uncertainty about the effects of puberty blockers, cross-sex hormones, and surgeries in young people with gender dysphoria” and (2) available evidence “is not sufficient to support ... using these treatments.” (Appx. 623). The Cochrane Library agrees, finding *not a single study* sufficiently rigorous to warrant inclusion in its systematic review. (Appx. 26-47).

Last summer, 21 clinicians and researchers from 9 countries publicly warned that treating gender-dysphoric minors with puberty blockers and cross-sex hormones “is not supported by the best available evidence,” criticizing the WPATH and Endocrine Society’s claims to the contrary.¹⁰ Per this report, “[e]very systematic

⁹ *Medical treatment methods for dysphoria associated with variations in gender identity in minors—recommendation 1*, Council for Choices in Health Care in Finland (2020).

¹⁰ Riittakerttu Kaltiala et al., *Youth Gender Transition is Pushed Without Evidence*, Wall St. J., July 13, 2023, <https://perma.cc/5P6X-KNHL>.

review of evidence to date, including one published in the Journal of the Endocrine Society, has found the evidence for mental-health benefits of hormonal interventions for minors to be of low or very low certainty.”¹¹ “By contrast, the risks are significant and include sterility, lifelong dependence on medication and the anguish of regret.”¹²

3. Using puberty blockers, cross-sex hormones, and surgery to treat minors with gender dysphoria has no proven benefits and poses substantial risk.

Bypassing these concerns, the court below downplayed the risks of using drugs and surgery to treat gender dysphoria and said minors who are blocked from receiving such treatment “are at risk of facing severe psychological distress.” (Doc. 131 at p. 41). Yet puberty blockers, cross-sex hormones, and surgical intervention are not proven to prevent psychological stress, and in fact, pose substantial risk.

Start with the supposed benefits. No reliable evidence suggests that drug use reduces the risk of suicide. WPATH’s own commissioned review shows no link between the use of cross-sex hormones and decreased suicide rates in gender-dysphoric individuals. (Appx. 511). Multiple other studies have found high suicide rates before, during , and after attempted gender transition. (Appx. 52; 64; 479). And, more alarmingly, a recent study found that rates of suicidal ideation, suicide attempts, and non-suicidal self-harm *increased* after minors began using puberty blockers and cross-sex hormones. (Appx. 533). Likewise, no reliable evidence

¹¹ *Id.*

¹² *Id.*

shows that drug use improves psychosocial outcomes. Many studies and systematic reviews report no mental health improvement after drug intervention to treat gender dysphoria. (Appx. 19; 122; 576-601; & 607).

Moving to risks, drug intervention may impair cognitive development. Researchers know that “the pubertal and adolescent period is associated with profound neurodevelopment,” which depends heavily on sex-specific hormones; and many academics worry that “pubertal suppression may prevent key aspects of development during a sensitive period of brain organization.” (Appx. 72-73).

Coupled with cognitive risks to minors, drug intervention may increase fertility risk, while surgical intervention almost always guarantees this risk. The Endocrine Society itself admits this. (Appx. 725). Children who persist through their guidelines and take cross-sex hormones in early to mid-adolescence will lack “fertility preservation” options because they never develop fertility. (Appx. 751-752).

Drug interventions may also weaken bone density. For adults, osteoporosis is a “well understood” risk of using cross-sex hormones long-term.¹³ And children face added risks. Because bone mineral density increases during puberty, children undergoing puberty suppression do not experience this full increase. (Appx. 729). Further, evidence suggests these children never catch up. (Appx. 164).

¹³ Cass Review, *supra* n. 2, at 36.

Concerns also exist about cardiovascular health. The Endocrine Society admits that cross-sex hormones detrimentally affect adult lipid profiles. (Appx. 738). This, too, is a “well understood” risk.¹⁴ In the only cardiovascular study of individuals who began cross-sex hormones in adolescence, the results showed statistically significant increases in blood pressure and body mass for both sexes and worsening lipid profiles for natal females. (Appx. 164).

These drug interventions may also limit sexual function. WPATH’s president has reported that “about zero” natal males can achieve orgasm after undergoing early puberty suppression followed by cross-sex hormones and vaginoplasty. (Appx. 566-67). While this issue, among others, needs more study, there are substantial concerns with subjecting prepubertal children to medical interventions that may affect lifelong sexual function in ways that they cannot possibly understand. (Appx. 704).

What’s more, the long-term safety of “treatments in children and adolescents with gender dysphoria” is “largely unknown” because many identified risks tend to manifest later in life—e.g. the risk of cognitive impairment, cardiovascular decline, and osteoporosis. (Appx. 164). Sadly, early studies report substantial *increases* in mortality from suicide, cardiovascular events, and other problems more than ten years after drug and surgical intervention. One study found that suicide rates surged *over 19 times* the rate of controls in this population, and that mortality rates from

¹⁴ Cass Review, *supra* n. 2, at 36.

cardiovascular disease more than doubled. (Appx. 64). Another study found that adults treated with cross-sex hormones faced increased long-term risk of death by suicide, stroke, and ischemic heart disease. Henk Asscheman et al., *A long-term follow-up study of mortality in transsexuals receiving treatment with cross-sex hormones*, 164:4 Eur. J. Endocrinology 635, 635-42 (2011).

The above-described risks, along with the lack of medical or scientific consensus regarding treatment of gender-dysphoric youth, have led the Sixth Circuit Court of Appeals to defer this issue to the legislature’s discretion. *L.W. v. Skrmetti*, 83 F.4th 460, 477 (6th Cir. 2023). The *Skrmetti* court wisely reasoned that “it is difficult to gauge the risks to children—whether by physically transitioning as a child or not—making it reasonable for accountable democracies to consider, reconsider, and if need be reconsider again the best approach to these issues.” *Id.* The district court’s decision should be reversed and the protections provided by SB 99 should be restored.

II. The Court should allow state legislatures to decide this difficult medical issue rife with uncertainty and so avoid miring courts further in constitutionalized medicine.

“It is undisputable ‘that a State’s interest in safeguarding the physical and psychological wellbeing of a minor is compelling.’” *Otto v. City of Boca Raton*, 981 F.3d 854, 868 (11th Cir. 2020) (quoting *Ferber*, 458 U.S. at 756-57). And States play a “significant role ... in regulating the medical profession.” *Gonzales v. Carhart*, 550

U.S. 124, 157 (2007). Here, Montana enacted SB 99 to safeguard children from potentially dangerous and experimental drug treatments and irreversible surgical procedures. (Doc. 102). Evidence strongly suggests that Montana’s caution is warranted. Even though the district court recognized the “competing medical evidence,” (Doc. 131 at p. 47), “[m]edical uncertainty does not foreclose the exercise of legislative power,” and the State may reasonably act to protect children. *Gonzales*, 550 U.S. at 161, 164.

Both sides have marshaled experts to support their positions. These experts belong to professional groups, but “their institutional positions cannot define the boundaries of” what the Constitution requires. *Otto*, 981 F.3d at 869. “They may hit the right mark,” or they may “miss it.” *Id.* And sometimes, these professional communities can be wrong “by a wide margin.” *Id.* Indeed, it’s “not uncommon for professional organizations to do an about-face in response to new evidence or new attitudes.” *Id.* That’s happened on the very issue presented here, as European nations are now backtracking and forbidding these drug interventions to treat children with gender dysphoria because new evidence suggests that caution is best.

For this reason, courts give “state and federal legislatures wide discretion to pass legislation in areas where there is medical and scientific uncertainty.” *Gonzales*, 550 U.S. at 163. This restraint is both wise and constitutionally required. Take *Roe v. Wade*, 410 U.S. 113 (1973), a case in which the Court constitutionalized abortion

without textual support or certainty about unborn human life. Courts then struggled for decades to apply an “inherently standardless” rule covering an issue “of great social significance.” *Dobbs v. Jackson Women’s Health Org.*, 142 S. Ct. 2228, 2272, 2284 (2022). Then just two years ago, the Court reversed *Roe*, admitting that precedent had “departed from [the Court’s] normal rule” of legislative deference and regretting the tremendous “turmoil” that deviation inflicted. *Id.* at 2268, 2283. This Court should avoid similar turmoil by deferring to reasonable legislative judgment.

CONCLUSION

This Court should reverse and uphold Montana’s right to protect children consistent with its reasonable legislative judgment. The Court should explicitly condemn the district court’s rejection of evidence-based medicine because that court’s pronouncements might mistakenly lead families to authorize experimental interventions that could result in permanent harm to their children.

DATED this 3rd day of April, 2024.

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Pursuant to Rule 11 of the Montana Rules of Appellate Procedure, I certify that the foregoing Montana Family Foundation *Amicus Curiae* Brief is proportionately spaced, printed with the typeface Times New Roman, 14 point font, is double-spaced, is not longer than 14 pages, and contains 3,169 words excluding cover page, table of contents, table of authorities, certificate of service, certificate of compliance, signature, and any appendices.

DATED this 3rd day of April, 2024.

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