IN THE SUPREME COURT OF THE STATE OF MONTANA

Case No. DA 23-0572

SCARLET VAN GARDEREN, et al.,
Plaintiffs-Appellees,

v.

STATE OF MONTANA, et al.,
Defendants-Appellants,

On Appeal from the Montana Fourth Judicial District Court, Missoula County
Cause No. DV 2023–541, the Honorable Jason Marks, Presiding

Brief of *Amici Curiae* GLBTQ Legal Advocates & Defenders and National Center for Lesbian Rights in Support of Plaintiffs-Appellees

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INTEREST OF *AMICI CURIAE*

Amici are GLBTQ Legal Advocates & Defenders ("GLAD") and the National Center for Lesbian Rights ("NCLR" and, together with GLAD, "*Amici*"). *Amici* have strong interests and deep expertise in issues concerning the civil rights of LGBTQ+ people and are committed to ensuring that all people, including LGBTQ+ people, can live their lives free from discrimination, including the freedom to access the health care they need. *Amici* seek to eliminate discriminatory barriers to health care for LGBTQ+ people, particularly transgender people, across the United States through impact litigation, education, and public policy work. *Amici* fully support the arguments made by Plaintiffs and write to provide the Court with additional guidance on the multiple reasons this Court should apply strict scrutiny to laws—like the Montana statute at issue here—that discriminate against transgender people.

SUMMARY OF ARGUMENT

SB 99 (the "Act"), codified at Mont. Code Ann. §§ 50-4-1001–1006 (eff. Oct. 1, 2023), forbids health care providers from offering medical treatment to transgender minors if—and only if—the purpose of that treatment is to allow those minors to live lives consistent with their gender identities. The Act's prohibitions on health care for minors are broad and ban doctors from prescribing puberty blockers, hormones, and surgery. *Id.* § 50-4-1004(1)(a), (b). Yet the Act specifically allows these same treatments for all "other purposes" and prohibits them solely when

"knowingly provided to address a female minor's perception that her gender or sex is not female or a male minor's perception that his gender or sex is not male." *Id.* § 50-4-1004(1)(c). The Act places transgender adolescents at grave risk of physical and psychological harm while violating their rights under the Montana Constitution.

The District Court correctly issued a preliminary injunction enjoining the Act's ban on gender-affirming care. Doc. 131. Because the Act targets transgender people, it facially discriminates on the basis of sex in violation of Montana's Equal Protection Clause. The District Court's reasoning is supported by the Supreme Court, which has held that laws and policies that target transgender people inherently discriminate based on sex. *See Bostock v. Clayton Cnty.*, 140 S. Ct. 1731, 1753–54 (2020). The Supreme Court's reasoning in *Bostock* applies with even greater force here because the Montana Constitution "provides for even more individual protection" than the federal Constitution. *Cottrill v. Cottrill Sodding Serv.*, 229 Mont. 40, 42, 744 P.2d 895, 897 (1987).

Under federal law, because the Act discriminates on the basis of sex, it would be subject to heightened scrutiny. *Craig v. Boren*, 429 U.S. 190 (1976). Because Montana's strict scrutiny test "better mimics the federal 'heightened scrutiny' test," the District Court correctly applied strict scrutiny under Montana law. Doc. 131 at 27. The District Court also correctly held that the Act infringed on the Plaintiffs'

fundamental right to obtain otherwise lawful medical treatment, separately subjecting the Act to strict scrutiny. *Id*. at 36–40.

On appeal, the State argues that rational basis review is warranted because the Act does not discriminate based on sex, but purportedly distinguishes minors with "psychological conditions" from those with "physical conditions." *See* Appellants' Opening Brief ("Br.") at 28–29. That reasoning is flawed—the Act permits treatment for *every* psychological and physical condition *except* when a transgender minor seeks gender-affirming care—and the Act cannot be applied without first determining the sex and transgender status of the individual.

Similarly, the State argues that the Act does not infringe on the fundamental right of privacy because it does not involve a "constitutionally protected medical procedure," but merely regulates a "particular medication" under the State's police powers. Br. 36–39. But the Act is not an ordinary regulation of a "particular medication"—indeed, it refers to *no* medication by name—but rather constitutes a broad prohibition on the medically accepted treatment of gender dysphoria. This Court has repeatedly held that the Montana Constitution gives individuals a broad fundamental right to obtain lawful medical treatment. The Act violates that fundamental right.

The Act cannot withstand strict scrutiny. The State cannot justify a targeted ban on health care treatment for transgender minors. As the District Court found,

based on the voluminous factual record before it, the Act fails to serve the State's purported interest in protecting the well-being of minors because it bans precisely those treatments that the leading medical associations have endorsed as the appropriate standard of care for treating gender dysphoria. This Court should affirm the District Court's preliminary injunction and preserve the rights of Montana teenagers, parents, and doctors to make medically appropriate health care decisions.

ARGUMENT

I. The Act Is Subject to Strict Scrutiny Because It Discriminates Based on Sex.

When laws such as the Act target transgender people, they inherently discriminate on the basis of sex. Here, the District Court determined that the Act discriminates between minors based on their transgender status and sex and correctly applied strict scrutiny. Doc. 131 at 20–34.

A. The Act Involves Similarly Situated Classes Distinguished by Sex and Transgender Status.

The first step of an equal protection challenge is to determine whether the Act distinguishes two otherwise similarly situated classes in terms of the challenged characteristic. *Snetsinger v. Mont. Univ. Sys.*, 2004 MT 390, ¶ 27, 325 Mont. 148, 104 P.3d 445. "If the two groups are equivalent in all respects other than the isolated factor, then they are similarly situated." *Hensley v. Mont. State Fund*, 2020 MT 317, ¶ 21, 402 Mont. 277, 477 P.3d 106. Here, the District Court correctly found the Act

takes a "similarly situated" class of minors seeking identical medical treatment and divides them into two groups based on their transgender status and sex: transgender minors who are denied the treatment and all other minors who may receive it. Doc. 131 at 20–23. The Act thus involves similarly situated classes.

The State denies these facts by claiming the Act classifies minors into those seeking treatment for "physical conditions like precocious puberty" and those seeking treatment for the "psychological condition of gender dysphoria." Br. 28–29. But, in fact, the Act identifies a single set of "medical treatments" and then distinguishes between transgender minors seeking gender-affirming care (who cannot receive that treatment) and *every other minor* (who can receive that treatment). *See* Mont. Code Ann. § 50-4-1004(1)(a)–(c). The Act is thus focused *exclusively* on the denial of gender-affirming care to transgender minors and explicitly permits the proscribed treatments for any "other purposes," including *any* "psychological" or *any* "physical" condition except gender dysphoria. *Id*. § 50-4-1004(1)(c). The Act takes two groups of similarly situated minors, both seeking the same lawful treatment, and provides or withholds that treatment solely on the basis of those minors' sex and transgender statuses.

The State also argues that the Act does not discriminate based on transgender status because "not all transgender-identifying minors seek 'gender-affirming' treatments or procedures." Br. 29. But this ignores the fact that *every* minor denied

care under the Act will be transgender—and that, crucially, the Act denies such care precisely *because* the minor is transgender. *See, e.g.*, § 50-4-1004(1)(a) (prohibiting treatment "to a female minor to address the minor's perception that her gender or sex is not female"). Transgender status is not incidentally implicated by the Act, as the State claims, but explicitly written into its terms. The fact that some transgender minors might not seek medical treatment for gender dysphoria is irrelevant and does nothing to free the Act from the taint of discrimination. *See United States v. Virginia*, 518 U.S. 515, 542 (1996) (rejecting the argument that heightened scrutiny does not apply because "most women would not choose VMI's adversative method" and so would never apply for admission, finding the question is "whether [the State] can constitutionally deny to women who have the will and capacity . . . the opportunities that VMI uniquely affords").[1]

B. Strict Scrutiny Applies to the Act Because It Discriminates on the Basis of Sex.

Because the Act addresses two similarly situated classes, the next step is to determine what level of scrutiny should be applied. *Snetsinger*, ¶ 17. "Strict scrutiny

[1] The State's reliance on *Adams by & through Kasper v. School Board of St. Johns County*, 57 F.4th 791, 809 (11th Cir. 2022) (en banc), is misplaced because—as the very language quoted by the State explains—that case involved a bathroom-use policy that "d[id] not facially discriminate on the basis of transgender status." Br. 30. Here, the Act facially discriminates on the basis of both transgender status and sex.

applies if a suspect class or fundamental right is affected." *Id*. Here, following a careful analysis of relevant Montana and federal decisions on sex discrimination, the District Court correctly found that strict scrutiny applied to the Act because it discriminates based on sex and transgender status and separately infringes on the fundamental right of privacy. Doc. 131 at 23–28.

On its face, the Act discriminates on the basis of sex. Under the Act, a person may not knowingly provide the specified medical treatments "to a female minor to address the minor's perception that her gender or sex is not female." Mont. Code Ann. § 50-4-1004(1)(a), (b). Nor can those medical treatments be provided "to a male minor to address the minor's perception that his gender or sex is not male." *Id*. The Act also separately defines "Female," "Male," "Gender," and "Sex," as those terms are essential for the Act's operation. *See id.* § 50-4-1003(1), (2), (5), (9). "Sex" is thus literally baked into the statutory text—appearing eighteen times—with "male," "female," and "gender" together appearing thirty-one times.

Consider a Montana seventeen-year-old who, with the consent and support of their parents and under the guidance of a licensed doctor, receives a prescription for estrogen treatment. If the minor's assigned sex at birth were male, the Act would apply and the treatment would be denied. But if the minor were assigned female at birth, the Act would not apply and the treatment would be permitted. In each case,

the minor's sex is outcome-determinative. The Act on its face classifies based on sex. Its application rests directly on a court discerning the sex of the minor.

The State seeks to ignore these facts by arguing the Act "does not prefer one sex to the other" or otherwise treat the two sexes differently because "[n]o minor—regardless of sex—can obtain the experimental treatments to transition." Br. 31–32. But applying a sex-based rule to both sexes does not immunize the classification. In *Loving v. Virginia*, which struck down state bans on interracial marriage, the Supreme Court rejected precisely such an "equal application" argument, holding that so long as the challenged statute operated on the basis of a prohibited classification, the "fact of equal application does not immunize the statute from the very heavy burden of justification" required by the Fourteenth Amendment's strict scrutiny analysis. 388 U.S. 1, 9 (1967). The Act undeniably operates on the basis of sex.

Recently, in *Bostock*, the Supreme Court repudiated the same reasoning advanced by the State. The Supreme Court rejected an interpretation of Title VII of the Civil Rights Act of 1964 that "would require [the Court] to consider the employer's treatment of groups rather than individuals, to see how a policy affects one sex as a whole versus the other as a whole," instead explaining that "our focus should be on individuals, not groups." 140 S. Ct. at 1740. As Justice Gorsuch explained: "An employer musters no better a defense by responding that it is equally happy to fire male and female employees who are homosexual or transgender. . . .

Instead, the law makes each instance of discriminating against an individual employee because of that individual's sex an independent violation of Title VII." *Id*. at 1742. So, too, here, the fact that the Act prohibits medically necessary treatment to transgender minors who are biologically male and female does not mean the Act does not discriminate based on sex in each instance. And while *Bostock* addressed sex discrimination under Title VII, this same analysis applies to the Equal Protection Clause. It is hornbook law that the Equal Protection Clause embodies the very same "basic principle" as Title VII: it "protect[s] *persons*, not *groups*." *See Adarand Constructors, Inc. v. Pena*, 515 U.S. 200, 227 (1995).

As this Court has repeatedly held, the Montana Constitution "provides for even more individual protection" than the federal Constitution. *Cottrill*, 229 Mont. at 42, 744 P.2d at 897. Accordingly, the Supreme Court's reasoning in *Bostock* applies with even greater force here. The State's arguments are unavailing. The Act is subject to strict scrutiny because it discriminates based on sex.

C. Strict Scrutiny Also Applies to the Act Because It Discriminates on the Basis of Transgender Status.

In addition, the Act discriminates based on transgender status, which is inherently discrimination based on sex. In *Bostock*, the U.S. Supreme Court held that "it is impossible to discriminate against a person for being . . . transgender without discriminating against that individual based on sex." 140 S. Ct. 1731 at 1741. As the *Bostock* Court explained: "[T]ake an employer who fires a transgender

person who was identified as a male at birth but who now identifies as a female. If the employer retains an otherwise identical employee who was identified as female at birth, the employer intentionally penalizes a person identified as male at birth for traits or actions that it tolerates in an employee identified as female at birth." *Id.* at 1741. And if the policy discriminates equally against both transgender men and transgender women, it "doubles rather than eliminates" the discrimination. *Id.* at 1742–43.

The State tries to deny the applicability of *Bostock* by claiming its reasoning applies solely to Title VII and is inapplicable to the Equal Protection Clause. Br. 33–34. There is no principled distinction between the standard articulated in *Bostock* for Title VII and the Equal Protection Clause. Title VII and the Equal Protection Clause both bar sex discrimination. Why would a law that constitutes sex discrimination under Title VII transform into a law that does not constitute sex discrimination under the Constitution?[2] *Bostock* explained that it is arbitrary to distinguish discrimination based on sex stereotyping from discrimination against transgender people: If an employer who "fires men who do not behave in a

[2] The State claims that *Bostock*'s reasoning does not extend from Title VII to the Equal Protection Clause because they are "such differently worded provisions," Br. 34, without actually identifying those differences or why they would matter. In fact, Plaintiffs note in their brief that the Montana Constitution's language more closely resembles the text of Title VII by prohibiting discrimination "on account of . . . sex," Mont. Const. art. II, § 4. *See* Plaintiffs/Appellees' Response at 26.

sufficiently masculine way" engages in sex discrimination, why should courts "roll out a new and more rigorous standard" when "that same employer discriminates against . . . persons identified at birth as women who later identify as men"? 140 S. Ct. at 1749. That arbitrariness does not go away when considering discrimination under the Equal Protection Clause. For this reason, the Fourth, Seventh, Eighth, and Ninth Circuits have all found that *Bostock*'s reasoning extends beyond Title VII. *See, e.g.*, *Grimm v. Gloucester Cnty. Sch. Bd.*, 972 F.3d 586, 616 (4th Cir. 2020), as amended (Aug. 28, 2020) (Title IX); *A.C. by M.C. v. Metro. Sch. Dist. of Martinsville*, 75 F.4th 760, 772 (7th Cir. 2023), cert. denied sub nom. *Metro. Sch. Dist. of Martinsville v. A. C.*, 144 S. Ct. 683 (2024) (Title IX); *Sch. of the Ozarks, Inc. v. Biden*, 41 F.4th 992, 1001 (8th Cir. 2022), cert. denied sub nom. *The Sch. of the Ozarks, Inc. v. Biden*, 143 S. Ct. 2638 (2023) (Fair Housing Act); *Doe v. Snyder*, 28 F.4th 103, 113–14 (9th Cir. 2022) (Title IX and Section 1557 of the Affordable Care Act); *Grabowski v. Ariz. Bd. of Regents*, 69 F.4th 1110, 1116 (9th Cir. 2023) (Title IX).[3]

[3] The State's reliance on *L.W. by and through Williams v. Skrmetti*, 73 F.4th 408 (6th Cir. 2023), *see* Br. 32, is misplaced for the same reason. *Skrmetti* avoided the Supreme Court's reasoning in *Bostock* (finding that policies discriminating against transgender people constitute sex discrimination) by arguing "that reasoning applies only to Title VII," *id.* at 420, which the State also relies upon in attempting to distinguish *Bostock*. Br. 33.

Moreover, the rationale for applying strict scrutiny applies with full force here. Heightened scrutiny exists to "smoke out" improper legislative rationales, such as hostility to those who may be marginalized by parts of society. *City of Richmond v. J.A. Croson Co.*, 488 U.S. 469, 493 (1989). Although the State contends that it is trying merely to protect minors from "experimental" medical treatments, this justification is pretext to permit the unequal treatment of transgender individuals. In fact, the Act is merely one of many Montana laws enacted primarily to discriminate against transgender people, including recent state legislation that prohibits individuals from changing the sex on their birth certificates except in limited circumstances,[4] defines "sex" in state laws in exclusively chromosomal terms,[5] permits medical practitioners to deny health care to transgender persons based on the practitioners' religious beliefs,[6] and prevents transgender women and girls from competing in school sports teams.[7] Remarks by Montana elected officials about the Act illustrate that it was motivated not by any actual concern for the mental and physical well-being of transgender youth, but by discriminatory animus. During

[4] S.B. 280, codified at Mont. Code Ann. § 50-15-224 (eff. Apr. 30, 2021).

[5] S.B. 458, codified at Mont. Code Ann. § 1-1-201 (and elsewhere) (eff. Oct. 1, 2023).

[6] H.B. 303, codified at Mont. Code Ann. §§ 50-4-1101–1107 (eff. Oct. 1, 2023).

[7] H.B. 112, codified at Mont. Code Ann. §§ 20-7-1305–1307 (eff. July 1, 2021).

debate on the proposed Act, Senator Manzella stated that "you cannot change your sex" because "the Creator has reserved that for Himself," while the primary sponsor of the Act, Senator Fuller, objected to providing hormone treatments to transgender individuals because he believed it was not "natural" and that "transgender ideology" is a "spiritual dogma" and that "medicine cannot make a man into a woman or a woman into a man." *See* Doc. 60, ¶ 69. Other senators described gender-affirming treatments as "mutilation" and "disfigurement."[8] *Id*. ¶ 70. These discriminatory remarks are precisely the type of statements that warrant courts to examine legislative intent in order to "smoke[s] out" illicit motives, such as hostility toward marginalized groups. *J.A. Croson Co.*, 488 U.S. at 493. This provides even further reason to apply strict scrutiny and conduct a "searching analysis" into the justifications for the Act. *Virginia*, 518 U.S. at 536.

II. The Act Is Also Subject to Strict Scrutiny Because It Infringes on the Right to Privacy.

Strict scrutiny should also be applied to the Act because it infringes on the fundamental right of privacy established in the Declaration of Rights of the Montana Constitution. This Court has held that the right to privacy is "fundamental," *Weems*

[8] These statements are contradicted by the vast majority of medical professionals, who recognize gender dysphoria as a legitimate diagnosis set forth by the *DSM-5* for which gender-affirming care may be medically necessary. *See* Doc. 131 at 6, 8-11.

v. State by & through Knudsen (Weems II), 2023 MT 82, ¶ 36, 412 Mont. 132, 529 P.3d 789, and that "[s]trict scrutiny applies if a fundamental right is affected," *Snetsigner*, ¶ 17. This Court has held that the right to privacy "guarantees each individual the right to make medical judgments affecting her or his bodily integrity and health in partnership with a chosen health care provider free from government interference." *Armstrong v. State*, 1999 MT 261, ¶ 14, 296 Mont. 361, 989 P.2d 364. Here, the District Court correctly found that the Act violated Plaintiffs' right to privacy by unconstitutionally limiting their ability to obtain otherwise lawful medical treatment constituting the accepted standard of care for gender dysphoria. Doc. 131 at 36–40.

The State tries to evade the application of strict scrutiny by mischaracterizing this Court's prior decisions. The State claims that strict scrutiny applies solely to restrictions of specific "*constitutionally protected*" medical procedures like abortion, while rational basis review applies to all other restrictions because there is no constitutionally protected right "to access a particular drug." Br. 36–37. The State's argument severely distorts this Court's holdings. First, this Court has never cabined the right to make medical decisions to pre-selected "constitutionally protected" procedures. Indeed, *Armstrong* and its progeny have consistently emphasized that the Montana Constitution sets forth "one of the most stringent protections of its citizens' right to privacy in the United States," which includes the right of

individuals to make medical judgments consistent with the Montana Constitution's "protection of a core sphere of personal autonomy and dignity." *Armstrong*, ¶¶ 34, 36; *Weems II*, ¶ 9.[9] There is no "test" the Court applies to first determine if a "medical procedure" is "deserving" (in the State's words) of constitutional protection. Br. 37.

Further, the State argues that the Act does not infringe on the right to privacy because there is no "right to access a particular drug or treatment." Br. 37 (quoting *MCIA*, ¶¶ 28, 32). The State relies heavily on *MCIA*, but that decision addressed the State's ability to regulate the distribution of marijuana for medical purposes given that it remained "unequivocally illegal under the Controlled Substances Act" and without FDA approval for medical use. *Id.*, ¶ 32. By contrast, here, the Act is *not* regulating the distribution of "a particular medication" lacking FDA approval (let alone, which is illegal), but enacting an outright ban on a broad category of medical treatment—including multiple types of medication and twenty-two types of

[9] *See Armstrong*, ¶ 75 ("We hold that the personal autonomy component of this right [to privacy] broadly guarantees each individual the right to make medical judgments affecting her or his bodily integrity and health . . . ."); *Wiser v. State Dep't of Com.*, 2006 MT 20, ¶ 15, 331 Mont. 28, 129 P.3d 133 (affirming "the general proposition that individuals have the right to obtain and reject medical treatment"); *Mont. Cannabis Indus. Ass'n v. State*, 2012 MT 201, ¶ 27, 366 Mont. 224, 286 P.3d 1161 ("*MCIA*") ("[T]he right to health care is a fundamental privacy right, but only to the extent that it protects an individual's right to obtain a particular *lawful* medical procedure.").

surgery—that is otherwise lawful, approved by the FDA, deemed medically necessary by competent and licensed physicians, and representing the medically-accepted standard of care for gender dysphoria in minors.[10] The fact that the Act *permits* the use of these same "medical treatments" by non-transgender minors (regardless of underlying diagnosis or condition) demonstrates that the Act's purpose is not to regulate "a particular drug" (which would otherwise be prohibited for all minors).[11] The Act implicates none of the concerns present in *Wiser* (unlicensed medical practitioners) or *MCIA* (distribution of federal controlled substances lacking FDA approval). Rather, it resembles the Court's recent decision

[10] Indeed, the Act goes far beyond regulating medical treatment by, for instance, prohibiting the use of "state property" to promote "social transitioning," including "the changing of a minor's preferred pronouns or dress and the recommendation to wear clothing or devices, such as binders, for the purpose of concealing a minor's secondary sex characteristics." Mont. Code Ann. § 50-4-1004(7); *id*. § 50-4-1003(10). Clearly, the Act is far more than the regulation of a "particular medication."

[11] The Act's prohibition on gender-affirming care is thus readily distinguished from the cases cited by the State (*see* Br. 37), which involved medications lacking FDA approval. *See Abigail All. for Better Access to Developmental Drugs v. von Eschenbach*, 495 F.3d 695, 703 (D.C. Cir. 2007) (affirming district court's denial of a constitutional right of access to drugs lacking FDA approval that have "not yet been proven effective" or "proven safe"); *Carnohan v. United States*, 616 F.2d 1120 (9th Cir. 1980) (denying right to access a "new drug" not yet submitted to FDA for review or approval). Here, the State admits that the Act prohibits medications that have received FDA approval. *See* Br. 8. Further, *Abigail* and *Carnohan* explicitly recognize the importance of "scientific and medical judgment" in determining what medication should be available—precisely what the Act here rejects in denying the medically recognized standard of care for gender dysphoria.

in *Weems II*, where this Court imposed strict scrutiny on legislation that "interferes with a woman's right of privacy and her decision to obtain lawful healthcare from a qualified provider." *Id.*, ¶ 43. Here, the Act goes even farther than the restrictions in *Weems II* by entirely banning the medically recognized standard of care for gender dysphoria. The Act clearly infringes on Plaintiffs' fundamental right to access otherwise lawful medical treatment in consultation with their parents and licensed physicians, and strict scrutiny should be applied.

III. The Act Cannot Withstand Strict Scrutiny.

Finally, the Act cannot without strict scrutiny because it is not "narrowly tailored to serve a compelling government interest." *Snetsinger*, ¶ 17. The District Court's own conclusions here are based on an extensive consideration and discussion of the evidence and far from a manifest abuse of discretion. As the District Court found, while the State has a compelling interest in the health and well-being of minors in Montana, the Act does not support that interest (under any level of scrutiny). *See* Doc. 131 at 28–34. Rather than protecting minors, the District Court concluded that the record evidence showed the Act would have the opposite effect. Relying upon the WPATH standard of care "endorsed and cited as authoritative by leading medical organizations, including the American Medical Association, the American Psychological Association, and the American Academy of Pediatrics," the District Court found "[t]hese organizations agree that the

treatments outlined are safe, effective for treating gender dysphoria, and often medically necessary." *Id*. at 30. In response to the State's claim that gender affirming treatments are "experimental" (and thus unsafe) because certain treatments like puberty blockers lack approval from the FDA for the specific treatment of gender dysphoria, the District Court noted that it was common practice, following initial FDA approval of a drug, for health care providers to provide that drug when deemed medically appropriate. *Id*. at 32. The treatments proscribed by the Act are "the accepted standard of care, even when utilized in an 'off-label' way," a conclusion the record evidence demonstrated was well supported through "clinical experience, observational scientific studies, and even some longitudinal studies." *Id.* The District Court's findings are not a manifest abuse of discretion, as they are well supported by both the record evidence and sound reasoning.

The State continues to rely upon its purported concern that the treatment prohibited by the Act has not been specifically approved by the FDA for the treatment of gender dysphoria. *See* Br. 47–48. But this fact does not indicate that these treatments are not safe or effective when used for that purpose. *See Dekker v. Weida*, 2023 WL 4102243, at *19 (N.D. Fla. June 21, 2023) ("That the FDA approved these drugs at all confirms that, at least for one use, they are safe and effective."). If Montana had chosen to ban *all* off-label uses of FDA-approved drugs, an equal protection challenge to such a ban would likely be subject to rational

basis review, even if it had the incidental effect of restricting medical care for transgender people. But that is not the case. Instead, in 2023, the Legislature passed HB 706 explicitly permitting health care providers to offer "off-label use of health care services," including "use of a prescription drug . . . approved by the United States food and drug administration in a manner not specified in the labeling or indications for the product." Mont. Code Ann. §§ 37-2-502(1), 37-2-502(4). The Legislature also passed SB 422, which makes any person, including minors, "eligible for treatment with an investigational drug," subject to certain conditions such as providing informed consent. *Id.* § 50-12-101–110 (eff. Jan. 1, 2024).[12] The Legislature has thus explicitly acted to expand the off-label use of FDA-approved medications (like those identified in the Act) and even permit the use of medications lacking final FDA approval. Such laws further suggest that the State's asserted justification for the Act is pretextual.

CONCLUSION

For the foregoing reasons and those articulated by Plaintiffs, *Amici* respectfully request that this Court affirm the District Court's grant of a preliminary injunction.

[12] Notably, the medical care prohibited by the Act is not "investigational" under SB 422, which defines "investigational drugs" as being "not yet approved for general use" by the FDA. *Id.* § 50-12-102(3).

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Respectfully submitted,

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CERTIFICATE OF COMPLIANCE

Pursuant to Rule 11 of the Montana Rules of Appellate Procedure, I certify that this amicus curiae brief is printed with a proportionately spaced, 14-point Times New Roman font, is double spaced except for footnotes, and the word count calculated by Microsoft Word is 4,779 words, excluding the cover page, tables, and certificates.

Dated: April 12, 2024 */s/ Jordan D. Hershman*
Jordan D. Hershman