#### No. 23-5609

## IN THE UNITED STATES COURT OF APPEALS FOR THE SIXTH CIRCUIT

JANE DOE, et al.,

Plaintiffs-Appellees,

v.

WILLIAM C. THORNBURY, JR., MD,

Defendants,

and

COMMONWEALTH OF KENTUCKY *ex rel.*ATTORNEY GENERAL DANIEL CAMERON, *Intervenor-Appellant.* 

On Appeal from the United States District Court for the Western District of Kentucky, No. 3:23-cv-230, Hon. David. J. Hale

## PLAINTIFF-APPELLEES' EMERGENCY MOTION TO LIFT STAY OF PRELIMINARY INJUNCTION

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### **INTRODUCTION**

On June 28, 2023, the district court preliminarily enjoined Sections 4(2)(a) and (b) of Kentucky Senate Bill 150 ("SB 150"), which forbid all healthcare providers in Kentucky from providing medically necessary treatments, including hormone therapy and puberty blockers, to transgender adolescents (the "Treatment Ban"). Plaintiffs are transgender youth and their parents who live in Kentucky and will imminently suffer serious irreparable harm from enforcement of SB 150.

On July 8, 2023, this Court stayed a preliminary injunction preventing enforcement of a similar healthcare ban in Tennessee. L. W. v. Skrmetti, — F.4th —, 2023 WL 44106576, at \*8 (6th Cir. July 8, 2023). On July 14, 2023, the district court granted Attorney General Cameron's motion for an emergency stay, based on L.W. The district court found that "this case is distinguishable from L.W. with respect to the balance of harms" because, unlike SB 150, the Tennessee law "allows existing treatments to continue until March 31, 2024," a provision the L.W. motions-panel majority concluded 'lessens the harm to those minors who wish to continue receiving treatment." Exhibit A (Order Staying Preliminary Injunction) at 2 (quoting L.W., 2023 WL 4410576, at \*8). Nonetheless, the district court granted Cameron's motion to stay because, "notwithstanding [its] difference of opinion as to the strength of the plaintiffs' claims under relevant Supreme Court and Sixth Circuit precedent," it was compelled by the L.W. motions-panel majority's preliminary conclusions regarding

"a substantially similar statute" that "Smith and Bostock [are] inapplicable" and that "the L.W. plaintiffs—and, by extension, Plaintiffs here—are unlikely to succeed on appeal." Id.

The result is devastating, especially for transgender youth who were receiving care: SB 150 has gone into effect and is causing the irreparable harm the preliminary injunction was issued to prevent. Kentucky doctors are prohibited from continuing to provide standard, recommended, and necessary care to transgender minors, who will suffer severe psychological and physical harm. Plaintiffs now ask the Court to lift the stay and restore the district court's preliminary injunction to protect Plaintiffs from this avoidable harm, or at a minimum, like their counterparts in Tennessee, allow Kentucky providers to continue to provide that care to those individuals who have already started this recommended treatment.

The Court evaluates requests for stays pending appeal, like other forms of injunctive relief, under familiar equitable factors: likelihood of success on the merits, harm to the movant, harm to the nonmovant, and the public interest. *Kentucky v. Beshear*, 981 F.3d 505, 508 (6th Cir. 2020). These factors "must be balanced together," so a greater showing on one will permit a lesser showing on another. *Id.* "The strength of the likelihood of success on the merits that needs to be demonstrated is inversely proportional to the amount of irreparable harm that will be suffered if" relief is denied. *Id.* The movant "must demonstrate at least serious questions going

to the merits and irreparable harm that decidedly outweighs the harm that will be inflicted on others" if the relief is granted. *Baker v. Adams Cnty/Ohio Valley Sch. Bd.*, 310 F.3d 927, 928 (6th Cir. 2002). Thus, a party who makes a strong showing of irreparable harm is "not required to make as a strong a showing of a likelihood of success on the merits." *Stein v. Thomas*, 672 F. App'x 565, 569 (6th Cir. 2016); *see Mich. Coal. of Radioactive Material Users v. Griepentrog*, 945 F.2d 150, 153 (6th Cir. 1991) ("high probability of success" unnecessary if irreparable harm to movant "decidedly outweighs any potential harm to" nonmovant).

This standard decisively favors granting Plaintiffs relief from the stay. Plaintiffs have shown, and the district court found, that they will suffer severe, irreparable harm if SB 150 goes into effect, and that immediate harm decidedly outweighs any harm to Kentucky from a temporary delay. Moreover, there can be no doubt that Plaintiffs have demonstrated at least "serious questions" going to the merits. While the motions-panel majority initially determined that the *L.W.* plaintiffs are not likely to succeed on the merits, the motions-panel majority acknowledged that this initial determination "may be wrong" and is contrary to the opinions of all "other courts and judges" who have evaluated similar treatment bans for transgender adolescents. *L.W.*, 2023 WL 4410576, at \*8; *Brandt v. Rutledge*, 47 F.4th 661 (8th Cir. 2022); *Brandt v. Rutledge*, 2023 WL 4073727 (E.D. Ark. 2023); *K.C. v. Individual Members of Med. Licensing Bd.*, 2023 WL 4054086 (S.D. Ind. 2023);

Doe v. Ladapo, 2023 WL 3833848 (N.D. Fla. 2023); Eknes-Tucker v. Marshall, 603 F. Supp. 3d 1131 (M.D. Ala. 2022). Accordingly, Plaintiffs respectfully ask the Court to take account of the specific circumstances of this case, including the inability of transgender youth in Kentucky to maintain their current medical treatments while this appeal proceeds, and to grant the relief Plaintiffs seek.

### **ARGUMENT**

# I. PLAINTIFFS HERE WILL SUFFER IRREPARABLE HARM BECAUSE, UNLIKE TENNESSEE'S BAN, SB 150 HAS NO PROVISION FOR CONTINUING CARE.

The *L.W.* motions-panel majority granted a stay in part because it found that Tennessee's "continuing care exception" "lessen[ed] the harm to ... [Tennessee] minors" by "permit[ting] [them] to continue their existing treatments until March 31, 2024." *L.W.*, 2023 WL 4410576, at \*8. SB 150 is different. It requires doctors to reduce or stop patients' ongoing treatments. *See* SB 150 § 4(6) (doctors must cease treatment outright or "systematically reduce" it to none); *see also* PI Order, R.61, PageID#2311 (finding Ban will "eliminate" treatments); Ex. A at 2 ("[T]his case is distinguishable from *L.W.* with respect to the balance of harms.").

Because of this material difference from *L.W.*, and as explained further below, the risk of harm to Plaintiffs here substantially outweighs any abstract risk of harm to Kentucky. *See, e.g.*, JD3 Decl., R.17-6, PageID#288 (attesting that Jane Minor Doe 3's "endocrinologist has informed us she will no longer be able to treat [Jane

Minor] Doe 3 once the Treatment Ban goes into effect"). Lifting the stay is necessary to protect Plaintiffs from this immediate, irreparable harm.

#### A. The District Court Found Plaintiffs Will Suffer Irreparable Harm.

The district court properly found that Plaintiffs will suffer imminent, irreparable harm if the Treatment Ban takes effect, PI Order, R.61, PageID#2311, and such findings merit significant deference by this Court. *U.S. Student Ass'n Found. v. Land*, 546 F.3d 373, 380 (6th Cir. 2008) (district court reviews factual findings reviewed only for "clear error"). The district court's finding is amply supported by the record, which shows that the Treatment Ban will cause potentially severe psychological and emotional harm to the Minor Plaintiffs, including anxiety, depression, self-harm, and suicidal ideation. JD1 Decl., R.17-4, PageID#280-82; JD2 Decl., R.17-5, PageID#283-85; JD3 Decl., R.17-6, PageID#286-88; JD5 Decl., R.17-7, PageID#289-91.

Doctors who specialize in the treatment of transgender adolescents submitted detailed declarations that confirm the medical legitimacy of the Parent Plaintiffs' fears. Shumer Decl., R.17-1, PageID#171-72 (SB 150 could lead "to a staggering increase in mental health problems including suicidality"); Janssen Decl., R.17-2, PageID#215 (SB150 will make transgender adolescents "suffer" and cause their mental health to "deteriorate"); Kingery Decl., R.17-3, PageID#251-53 (SB 150 "will worsen . . . mental health outcomes"). Based on this evidence, the district court

correctly found that Plaintiffs would be irreparably harmed because the Treatment Ban will "eliminate [the] treatments that have already significantly benefited" them. PI Order, R.61, PageID#2311.

SB 150's provision permitting a "health care provider [to] institute a period during which the minor's use of the [medications] is systematically reduced" does not mitigate these serious and irreparable harms. See SB 150 § 4(6). Just as the harm caused by a prohibition of diabetes treatment would not be mitigated by allowing physicians to taper a diabetic child off insulin, the irreparable harm from a prohibition of medical treatment for transgender adolescents is not mitigated by allowing physicians to taper them off their medicines. A transgender minor who has been receiving and benefitting from these medications and who is then required to stop taking them (either immediately or over time) "will suffer and their mental health will deteriorate." Janssen Decl., R.17-3, PageID#215.

### B. The Balance of Harms and Public Interest Favor Lifting the Stay.

Against these severe, irreparable, and specific harms to real people, the only countervailing harm to Kentucky is a constructive form of harm from delaying SB 150's effective date. Such harm does not outweigh the concrete, irreparable physical and psychological harms that actual children and their parents will suffer from being denied the medical care they have relied on and need.

Moreover, unlike in *L.W.*, Defendants here disagree over whether Kentucky will be harmed by a preliminary injunction or will benefit from it. Defendants Thornbury and Denker, the Kentucky officials responsible for enforcing the Treatment Ban, agreed that it would "behoove ... licensees and their patients for the Court to grant the injunction and maintain the status quo pending final ruling on the merits of the suit, to avoid potentially unnecessary cost, time, and harmful exposure should Plaintiffs be successful." Response to Emergency Motion for Stay, R.69, PageID#2439. The Attorney General's office has no role in enforcing SB 150, so delay in enforcing the Treatment Ban imposes no practical requirements on Cameron. Because the Treatment Ban imposes obligations on Thornbury and Decker, their views merit greater weight in connection with the balance of harms.

For the same reasons, lifting the stay is in the public interest. In *L.W.*, the motions-panel majority held that "Tennessee's interests in applying the law to its residents and in being permitted to protect its children from health risks weigh heavily in favor of the State at this juncture." *L.W.*, 2023 WL 4410576, at 15. A similar determination is not warranted here because Plaintiffs are immediately barred from receiving recommended care and because the Defendants charged with enforcing SB 150 agree that it should be preliminarily enjoined. Moreover, as the *L.W.* motions-panel majority acknowledged, there are, at a minimum, serious questions about SB 150's constitutionality.

# II. AT A MINIMUM, PLAINTIFFS HAVE RAISED SERIOUS QUESTIONS ON THE MERITS OF THEIR EQUAL PROTECTION CLAIMS.

The district court determined that heightened scrutiny applied to Plaintiffs' claims and that SB 150 likely failed that standard. While the motions-panel majority reached a different, preliminary conclusion in *L.W.*, Plaintiffs respectfully submit that the *L.W.* analysis did not adequately consider the full weight of controlling authority supporting Plaintiffs' equal protection claims. *L.W.*, 2023 WL 4410576, at \*6. At a minimum, this Court should find that Plaintiffs have raised serious questions on the merits warranting the relief requested, considering that the *L.W.* panel majority acknowledged the possibility that it "may be wrong" and that its conclusions may change upon consideration of the full record and argument. *Id.* at \*8.

# A. The District Court Correctly Found That SB 150 Is Subject To Heightened Scrutiny.

By facially targeting transgender people, SB 150 makes a sex-based classification and is therefore subject to intermediate scrutiny under the Equal Protection Clause. PI Order, R.61, PageID#2303. The district court's decision on the preliminary injunction is consistent with controlling Supreme Court and Sixth Circuit authority. In *Bostock v. Clayton Cnty.*, 140 S. Ct. 1731, 1741 (2020), the

Supreme Court held that it is "impossible to discriminate against a person for being . . . transgender without discriminating against that individual based on sex."

Nearly twenty years earlier, this Court similarly held that discrimination against a person who "fails to act and/or identify with his or her" sex designated at birth—that is, against a transgender person—is sex-based discrimination for purposes of the Equal Protection Clause. *Smith v. City of Salem*, 378 F.3d 566, 577 (6th Cir. 2004). All sex-based classifications are subject to heightened scrutiny. *United States v. Virginia*, 518 U.S. 515, 555 (1996).

The *L.W* majority opined that these precedents were inapplicable to Tennessee's ban on care "for minors of both sexes." *L.W.*, 2023 WL 4410576, at 11. That conclusion should be revisited upon full briefing and argument, but for present purposes it is sufficient that Plaintiffs raise serious questions warranting preservation of the status quo while this Court deliberates. As will be argued in full on the merits, that a law applies to members of both sexes does not necessarily mean that it does not discriminate based on sex. For one example, in *J.E.B. v. Alabama ex rel. T.B.*, 511 U.S. 127 (1994), the Supreme Court held that peremptory challenges based on a juror's sex are unconstitutional, even though such challenges can be applied equally to both sexes. The Court held that the Equal Protection Clause protects *each person*—not merely women as a group or men as a group—from disparate treatment based on sex: "individual jurors themselves have a right to nondiscriminatory jury

selection procedures." *Id.* at 140-41. Heightened scrutiny applied because each person faced discrimination based on their sex, even if there was an equal effect on men and women. *Id.* at 141-42.

The Supreme Court reiterated this principle—that a sex-based classification discriminates based on sex regardless of whether it confers a group-based advantage to either sex—in *Bostock*. In that case, the employer argued that it did not violate Title VII's prohibition of sex discrimination because its refusal to employ transgender workers applied equally to both men and woman. *Bostock*, 140 S. Ct. at 1744. The Court unequivocally rejected that argument: "an employer who intentionally fires an individual . . . transgender employee . . . violates the law *even if* the employer is willing to subject all male and female . . . transgender employees to the same rule." *Id*. (emphasis added). "[A]n employer cannot escape liability by demonstrating that it treats males and females comparably as groups." *Id*.

In L.W., the panel majority held that it need not apply that clear holding to Tennessee's law because Bostock concerned Title VII, not the Equal Protection

<sup>1</sup> Reed v. Reed, 404 U.S. 71 (1971) is not to the contrary. In Reed, the law at issue happened to prefer members of one sex over the other, which the Supreme Court noted. However, the Court nowhere held that a sex-based classification *must* confer such a group-based advantage to warrant heightened scrutiny under the Equal Protection Clause, and the Supreme Court's subsequent decisions reject that limitation.

Clause. L.W., 2023 WL 4410576, at \*13. However, as will be argued in full on the merits, that conclusion is subject to serious questions. Both the Supreme Court and the Sixth Circuit have consistently held that the definitions of sex discrimination under Title VII and the Equal Protection Clause are the same. See, e.g., General Electric Co. v. Gilbert, 429 U.S. 125 (1978) (relying on Geduldig v. Aiello, 417 U.S. 484 (1974), an equal protection case, to resolve a sex discrimination claim under Title VII); Boxill v. O'Grady, 935 F.3d 510, 520 (6th Cir. 2019) ("We review § 1983 discrimination claims brought under the Equal Protection Clause using the same test applied under Title VII").<sup>2</sup> The L. W. panel majority did not address these precedents.

The cases on which the L.W. panel majority relied do not compel a different result. See L.W., 2023 WL 4410576, at \*7. In Pelcha v. MW Bancorp, Inc., 988 F.3d 318, 324 (6th Cir. 2021), this Court held that Bostock's analysis of a Title VII plaintiff's evidentiary burden did not apply to a plaintiff's evidentiary burden under a federal law prohibiting age discrimination, but that has nothing to do with what constitutes sex discrimination under Title VII and the Equal Protection Clause.

<sup>&</sup>lt;sup>2</sup> See also, e.g., Smith, 378 F.3d at 577 (finding that the facts supporting a transgender plaintiff's Title VII "easily constitute[d] a claim of sex discrimination grounded in the Equal Protection Clause"); Kitchen v. Chippewa Valley Schs., 825 F.2d 1004, 1011 (6th Cir. 1987); Daniels v. Bd. of Educ., 805 F.2d 203, 207 (6th Cir. 1986); Grano v. Dept. of Dev., 637 F.2d 1073, 1081-82 (6th Cir. 1980); Lautermilch v. Findlay City Schs., 314 F.3d 271, 275 (6th Cir. 2003).

And in *Meriwether v. Hartop*, 992 F.3d 492, 510 n.4 (6th Cir. 2021), a footnote mentions that Title VII and Title IX differ "in important respects," citing Title IX's express allowances for consideration of sex in allocating athletic scholarships and living facilities. *Meriwether* does not find a substantive distinction between sex discrimination under Title VII and the Equal Protection Clause.

The panel majority in *L.W.* also assumed that laws like SB 150 that prohibit medical care for transgender minors are comparable to the regulation of pregnancy in *Geduldig*, 417 U.S. 484, or of the regulation of abortion in *Dobbs v. Jackson Women's Health Org.*, 142 S. Ct. 2228 (2022). But unlike the laws challenged in those cases, the law here *facially* discriminates based on transgender status and, therefore, on sex. SB 150 prohibits prescribing puberty blockers and hormone therapy if—and only if—the care is provided "to alter the appearance of, or to validate a minor's perception of, the minor's sex, if that appearance or perception is inconsistent with the minor's sex" at birth. SB 150 § 4(2).<sup>3</sup>

Having a "perception" of one's sex that is "inconsistent with one's sex" at birth is precisely what defines a person as transgender. Therefore, puberty blockers and hormone therapy can be prescribed to a non-transgender minor for the purpose of

<sup>&</sup>lt;sup>3</sup> The Ban defines "sex" as "the biological indication of male and female as evidenced by sex chromosomes, naturally occurring sex hormones, gonads, and nonambiguous internal and external genitalia present at birth." *Id.* at § 4(1)(b).

validating the minor's perception of the minor's birth sex—a born male patient can legally receive male hormones. But the same hormones cannot be provided to a transgender patient born female. That is discrimination on the basis of sex.

As SB 150's repeated use of the word "sex" illustrates, classifications on the basis of transgender status "cannot be stated without referencing sex." *Grimm v. Gloucester Cnty. Sch. Bd.*, 972 F.3d 586, 608 (4th Cir. 2020); *see also* PI Order, R.61, PageID#2303-04 ("[T]he minor's sex at birth determines whether or not the minor can receive certain types of medical care under the law") (citing *Brandt*, 47 F.4th at 669); *K.C.*, 2023 WL 4054086, at \*8 ("[W]ithout sex-based classifications, it would be impossible for [Indiana's ban] to define whether a puberty-blocking or hormone treatment involved transition from one's sex (prohibited) or was in accordance with one's sex (permitted)."); *accord Ladapo*, 2023 WL 3833848, at \*8.

SB 150 facially classifies based on sex. This is not a situation like *Geduldig* or *Dobbs*, in which a law classifies based on a physical or medical condition that is merely *correlated* only with one sex. Here, as explained above, the law's reliance on sex appears on the face of the statute and expressly targets transgender minors—*i.e.*, those whose perception of their sex differs from their sex at birth. As the Supreme Court held of a similarly facially sex-based policy in *City of Los Angeles*, "[o]n its face, this [law] discriminates on the basis of sex whereas the General Electric plan [like the plan in *Geduldig*] discriminated on the basis of a special

physical disability." 435 U.S. at 417. In sum, there is a difference between a law that facially relies on sex and one that relies on a physical or medical condition associated only with one sex; while the latter may have a disparate impact based on sex, the former establishes disparate treatment based on sex.

Nor is the *L.W.* majority's acknowledgment of "the fraught context of whether a State may limit irreversible medical treatments to minors facing gender dysphoria," *L.W.*, 2023 WL 4410576, at \*13, a reason to avoid heightened scrutiny. Legislating matters relating to sex often are fraught, which is, in part, why heightened scrutiny is appropriate. As the Supreme Court stressed in *Bostock*, when a law or policy facially discriminates based on sex, there is no unwritten exemption where the group affected happens to be a "disfavored" or "unpopular group." 140 S. Ct. at 1751; *see also Smith*, 378 F.3d at 575. Heightened scrutiny applies here because SB 150 singles out transgender minors because of their gender non-conformity; that the issues are politically fraught provides more, not less, reason for careful consideration of Kentucky's asserted justifications. *C.f. L.W.*, 2023 WL 4410576, at \*7.

Finally, no precedent supports the *L.W.* panel majority's assumption that *Smith*, which held that discrimination because a person is transgender is sex discrimination under the Equal Protection Clause, is inapposite because that case involved adults and employment rather than minors and medical care. *L.W.* 2023 WL 4410576 at \*13. A law either classifies based on sex, or it does not. *See*, *e.g.*,

Craig v. Boren, 429 U.S. 190 (1976) (striking law that imposed different drinking ages for male and female minors). If it does, it is subject to heightened scrutiny. A law may ultimately be found to *survive* heightened scrutiny because of other factors such as age limitations, but that is a different question. Because SB 150 facially draws classifications based on sex, it is subject to heightened scrutiny.

# B. The District Court Correctly Found that Cameron Failed to Present Evidence to Justify the Treatment Ban Under Heightened Scrutiny.

The district court correctly held that SB 150's sex-based classification is not likely to be found to be "substantially related to the achievement of" the stated objectives of "protecting vulnerable" children or preserving "the integrity and ethics of the medical profession." PI Order, R.61, PageID#2306.

With regard to the protection of vulnerable children, the district court concluded that the evidence supporting the safety and efficacy of the banned medicine outweighed the evidence questioning it. PI Order, R.61, PageID#2302. This Court "may not reverse" a district court decision simply because it "would have weighed the evidence differently." *Anderson*, 470 U.S. at 573–74 (1985);*U.S. Student Ass'n Found. v. Land*, 546 F.3d 373, 380 (6th Cir. 2008) (holding that this Court reviews factual findings only for "clear error").

On the record before this Court, the evidence supporting the district court's findings is substantial. The doctors who describe puberty blockers and hormones as

safe and effective are experts in the treatment of gender dysphoria and have extensive experience treating transgender adolescents. E.g., Shumer Decl., R.17-1, PageID#166-71 (describing medicines), PageID#142-47 (describing qualifications); PageID#205-07 Decl., R.17-2, (medicines), PageID#197-201 Janssen (qualifications); Kingery Decl. R.17-3, PageID#236-39 (medicines), PageID#232-36 (qualifications); Goodman Decl., R.52-2, PageID#1724-25 (medicines), PageID#1718-20 (qualifications); Karasic Decl., R.52-4, PageID#1866-72 (medicines), PageID#1856-59 (qualifications). Their views are supported by established standards of care and clinical practice guidelines developed based on the same criteria and clinical practices used to establish treatments for other medical conditions. See generally Brief of Amici Curiae, R.19-2 (describing the widely accepted guidelines for treating adolescents with gender dysphoria).

In contrast, the doctors who disagree with this broad consensus have little or no relevant medical expertise or experience providing care to transgender adolescents. *See* Reply in Further Support of Motion for Preliminary Injunction, R.52, PageID#1677 n.5. The district court did not abuse its discretion or commit clear error in finding that the outlier opinions of these doctors do not outweigh those of specialists and professional medical organizations. *See Edmo v. Idaho Dep't of Corr.*, 358 F. Supp. 3d 1103, 1125–26; *Eknes-Tucker*, 603 F. Supp. 3d at 1131; *C.P.* 

v. Blue Cross Blue Shield, 2022 WL 17092846, at \*4 (W.D. Wash. 2022); Norsworthy v. Beard, 87 F. Supp. 3d 1164, 1188 (N.D. Cal. 2015).

In addition, the district court concluded that Cameron "offer[ed] *no evidence*" to support his claim that SB 150 serves the interest of ensuring medicines are ethically prescribed, which Cameron had premised entirely on the unsupported assertion that doctors view puberty blockers and hormone treatments as "huge money makers." PI Order, R.61, PageID#2307 (emphasis added).

In sum, the district court did not abuse its discretion in finding that Cameron failed to present evidence sufficient to satisfy his burden to show that SB 150 is substantially related to any of Kentucky's stated interests. While Plaintiffs contend Cameron does not have a strong likelihood of success on the merits of his appeal from the district court's order granting a preliminary injunction, Plaintiffs have demonstrated at least "serious questions" going to the merits, and the stay of the preliminary injunction should be lifted to allow care to continue while the appeal is pending.

# III. AT A MINIMUM, PLAINTIFFS HAVE RAISED SERIOUS QUESTIONS ON THE MERITS OF THEIR DUE PROCESS CLAIMS.

As the *L.W.* panel majority acknowledged, *L.W.*, 2023 WL 4410576, at \*8, parents' fundamental rights under the Due Process Clause include "the right, coupled with the high duty . . . to recognize symptoms of illness and to seek and follow

medical advice." *Parham v. J. R.*, 442 U.S. 584, 602 (1979); *Kanuszewski v. Mich.*Dep't of Health & Hum. Servs., 927 F.3d 396, 419 (6th Cir. 2019).

Notwithstanding that settled law, the *L.W.* panel majority held that "[n]o Supreme Court case extends it to a general right to receive new medical or experimental drug treatments." *L.W.*, 2023 WL 4410576, at \*8. The *L.W.* panel presupposed a mistaken predicate—that the banned treatments are "new" or "experimental"—that contradicts the district court's factual findings in that case. *L.W. v. Skrmetti*, 2023 WL 4232308, at \*21 (M.D. Tenn. 2023). Indeed, every other court to hear evidence regarding this same issue has reached the same factual conclusions, including two federal district court opinions issued after a full trial on the merits. *E.g.*, *Brandt*, 2023 WL 4073727, at \*35 ("[t]he State failed to provide sufficient evidence that the banned treatments are ineffective or experimental"); *Ladapo*, 2023 WL 3833848, at \*5 (finding that the banned medicines "have been used for decades" and have well known "safety records").

The *L.W.* panel majority's reliance on *Abigail All. For Better Access to Developmental Drugs v. von Eschenbach*, 495 F.3d 695, 710–11 & n.18 (D.C. Cir. 2007), is therefore misplaced. *L.W.*, 2023 WL 4410576, at \*5. Unlike in *Abigail*, the Parent Plaintiffs here do not seek experimental medications—they seek medicines that the "Food and Drug Administration has approved," *Ladapo*, 2023 WL 3833848, at \*5, and that the nation's leading medical and mental health organization have

deemed effective for the treatment of gender dysphoria. *E.g.*, Shumer Decl., R.17-1, PageID#166-71; Janssen Decl., R.17-2, PageID#205-07 Kingery Decl. R.17-3, PageID#236-39 Goodman Decl., R.52-2, PageID#1724-25 Karasic Decl., R.52-4, PageID#1866-72.

While prescribing puberty blockers and hormones for the treatment of gender dysphoria is "off-label," meaning that FDA has not approved them for that particular use, that does not matter to parents' constitutional rights. "Off-label" does not mean "experimental," "unsafe," or "untested"—far from it. As the Supreme Court has recognized, "off-label use is widespread in the medical community and often is essential to giving patients optimal medical care, both of which medical ethics, FDA, [as] most courts recognize." *Buckman Co. v. Plaintiffs' Legal Committee*, 531 U.S. 341, 351 (2001) (citing Beck & Azari, FDA, Off–Label Use, and Informed Consent: Debunking Myths and Misconceptions, 53 Food & Drug L.J. 71, 72 (1998)); *see also* Janssen R-Decl., R.52-3, PageID#1823-24 ("off-label use of medication is common in medicine, especially treatments for children and adolescents").4

<sup>&</sup>lt;sup>4</sup> "From the FDA perspective, once the FDA approves a drug, healthcare providers generally may prescribe the drug for an unapproved use when they judge that it is medically appropriate for their patient." FDA, *Understanding Unapproved Use of Approved Drugs* "Off Label" (Feb. 5, 2018), <a href="https://www.fda.gov/patients/learn-about-expanded-access-and-other-treatment-options/understanding-unapproved-use-approved-drugs-">https://www.fda.gov/patients/learn-about-expanded-access-and-other-treatment-options/understanding-unapproved-use-approved-drugs-</a>

 $<sup>\</sup>frac{label\#:\sim:text=Unapproved\%20use\%20of\%20an\%20approved\%20drug\%20is\%20offten,it\%20to\%20treat\%20a\%20different\%20type\%20of\%20cancer.}$ 

It is also true that a state's efforts to regulate health and welfare are generally entitled to "a strong presumption of validity," *L.W.*, 2023 WL 4410576, at \*8 (internal citation omitted), but that presumption does not hold when such efforts violate a constitutional right. *See, e.g., National Institute of Family & Life Advocates v. Becerra*, 138 S.Ct. 2361, 2371 (2018) (striking down California laws regulating pregnancy centers under the First Amendment). Given that parents have a fundamental right to make medical decisions for their children, there must be some limit on a state's ability to burden that right, or else it would be meaningless.

As will be shown upon full merits briefing, SB 150 unduly burdens that right because it completely bans established medical care that has been administered for more than twenty years, that is widely accepted as the standard of care by the medical profession, and that is supported by substantial research showing it to be safe and effective. The district court's factual findings on these issues are entitled to significant deference, and based on those findings, the district court correctly found that Plaintiffs are likely to succeed on the merits of their Due Process claim.

For the same reasons that Cameron cannot justify the Treatment Ban under heightened scrutiny, he is even less able to do so under the strict scrutiny that applies to laws that substantially burden a fundamental right.

# IV. THE COURT AT LEAST SHOULD EXTEND RELIEF TO PLAINTIFFS.

Finally, while this Court in L.W. found that a statewide injunction similar to the injunction issued by the district court below was overbroad, L.W. 2023 WL 4410576, at \* 3, the district court did not abuse its discretion here by barring enforcement of SB 150. Where a court finds that a law likely is unconstitutional, it is well within its equitable powers to bar the government from enforcing the statute, even if as a consequence non-parties may benefit. See, e.g., Washington v. Reno, 35 F.3d 1093, 1104 (6th Cir. 1994) ("Because relief for the named plaintiffs in the case would also necessarily extend to all federal inmates, the district court did not err in granting wide-ranging injunctive relief."); Mulholland v. Marion Cnty. Elec. Bd., 746 F.3d 811, 819 (7th Cir. 2014) ("[f]acial unconstitutionality as to one means facial unconstitutionality as to all"). In all events, this Court at least should extend relief "to those minors who," like Plaintiffs, "wish to continue receiving treatment . .." L.W., 2023 WL 4410576 at \*8. For all the reasons discussed, action by this Court is necessary to prevent irreparable harm to Plaintiffs because unlike the Tennessee law, SB 150 does not otherwise permit Plaintiffs' care to continue for the duration of this appeal, and the stay should be lifted at least to that extent.

### **CONCLUSION**

The stay of the district court's preliminary injunction should be lifted, or at a minimum lifted to allow those who are receiving such care to continue while this appeal is pending.

Dated: July 18, 2023 Respectfully Submitted,

/s/ Stephanie Schuster
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### **CERTIFICATE OF COMPLIANCE**

The foregoing response was computer-generated in 14-point Times New Roman proportional font and contains 5,033 words, and thus complies with the requirements of Federal Rule of Appellate Procedure 27(d)(1)-(2).

/s/ Stephanie Schuster

### **CERTIFICATE OF SERVICE**

I certify that on July 18, 2023, I electronically filed the foregoing with the Clerk of the Court for the United States Court of Appeals for the Sixth Circuit using the CM/ECF system. I also certify that all participants in the case are registered CM/ECF users and that service will be accomplished by the CM/ECF system.

/s/ Stephanie Schuster