UNITED STATES DISTRICT COURT
MIDDLE DISTRICT OF NORTH CAROLINA
DURHAM DIVISION

AMY BRYANT, MD, Plaintiff, v. JOSHUA H. STEIN, *et al.*, Defendants, and PHILIP E. BERGER, *et al.*, Intervenors-Defendants.	**Case No. 1:23-cv-00077** **INTERVENOR-DEFENDANTS' SUPPLEMENTAL BRIEF**

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INTRODUCTION

The States have long worked in tandem with the federal Food and Drug Administration to protect American consumers from dangerous drugs. Mifepristone is a drug with known serious risks. For this reason, its FDA approval is subject to minimum safety requirements to ensure safe use. North Carolina has chosen to protect the health and safety of its citizens by enacting additional safety measures above the federal floor set by the FDA. These requirements are consistent with Congress's health and safety objectives.

Yet Plaintiff argues that North Carolina's health and safety laws conflict with federal law. It is uncontested that no provision of federal law expressly preempts the challenged state laws and that nothing prevents Dr. Bryant from complying with both federal and state requirements. She nevertheless argues that the state requirements somehow stand as an obstacle to Congress's health and safety objective because the FDA has chosen not to adopt such requirements. Plaintiff can point to no federal statutory text supporting that argument and this Court should uphold the State's health and safety requirements.

LEGAL STANDARD

At the hearing on the Legislative Leaders' Motion to Dismiss, this Court converted the motion and briefing to cross-motions for summary judgment.[1] "Summary judgment is appropriate when 'there is no genuine dispute as to any material fact and the movant is entitled to judgment as a matter of law.'" *Reyes v. Waples Mobile Home Park Ltd. P'ship*, No. 22-1660, 2024 WL 236286, at *3 (4th Cir. Jan. 24, 2024) (quoting Fed. R. Civ. P. 56(a)). All parties agree that there is no genuine dispute of material fact in this case. Tr. of Jan. 17, 2024 Mot. Hr'g 38:12–14, 40:14, 100:24–101:2. This Court should grant judgment to the Legislative Leaders as a matter of law.

[1] Intervenors do not object to holding the converted cross-motions for summary judgment in abeyance pending the Supreme Court's decision in *Food & Drug Admin. v. All. for Hippocratic Med.*, No. 23-235 (U.S.). If Respondents prevail on their challenge to the removal of REMS safeguards even in part, that ruling will narrow the scope of the issues presented here.

ARGUMENT

I. North Carolina's health and safety regulations are not preempted by the Food, Drug, and Cosmetic Act.

Under the Supremacy Clause, "federal law preempts—or bars—claims under state law that either interfere with or are contrary to federal law." *Guthrie v. PHH Mortg. Corp.*, 79 F.4th 328, 336 (4th Cir. 2023). However, a court "must not presume federal law preempts state law," *id.*, especially where, as here, Congress legislates "in a field which the States have traditionally occupied," *Wyeth v. Levine*, 555 U.S. 555, 565 (2009). Instead, "any analysis of preemption begins 'with the basic assumption that Congress did not intend to displace state law.'" *Guthrie*, 79 F.4th at 336.

This presumption against preemption can be overcome where "'state law [] stand[s] as an obstacle to the accomplishment and execution of the full purposes and objectives of Congress.'" *Id.* at 337.[2] But "[i]mplied preemption analysis

[2] Obstacle preemption is unsupported by the Supremacy Clause and inconsistent with separation of powers principles because it permits the elevation of "abstract and unenacted legislative desires above state law." *See, e.g., Virginia Uranium, Inc. v. Warren*, 139 S. Ct. 1894, 1907–08 (2019) (plurality opinion written by Gorsuch, J., and joined by Thomas, J., and Kavanaugh, J.) While the Fourth Circuit has

does not justify a 'freewheeling judicial inquiry into whether a state statute is in tension with federal objectives.'" *Chamber of Com. of U.S. v. Whiting*, 563 U.S. 582, 607 (2011). On the contrary, Supreme Court "precedents 'establish that a high threshold must be met if a state law is to be preempted for conflicting with the purposes of a federal Act.'" *Id.*

In the Fourth Circuit, "[d]etermining whether a state law 'stands as an obstacle' to federal law is a two-step process." *Guthrie*, 79 F.4th at 338. First, a court must "determine Congress's 'significant objectives' in passing the federal law." *Id.* Second, it must determine "whether the state law stands 'as an obstacle to the accomplishment of a significant federal regulatory objective.'" *Id.* Because North Carolina's health and safety regulations do not stand as an obstacle to Congress's purpose of protecting the health and safety of consumers, the challenged laws are not preempted by the FDCA.

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recognized obstacle preemption, the Legislative Leaders reserve the right to argue the doctrine is unsupported by the Supremacy Clause.

A. Congress passed the FDCA to protect the public health by ensuring that drugs are safe and effective.

In 1938, Congress enacted the Food, Drug, and Cosmetic Act (FDCA) to "protect the public health by ensuring that . . . drugs are safe and effective." 21 U.S.C. § 393(b)(2); *Wyeth*, 555 U.S. at 574 ("Congress enacted the FDCA to bolster consumer protection against harmful products."). But "Congress did not intend FDA oversight to be the exclusive means of ensuring drug safety and effectiveness." *Wyeth*, 555 U.S. at 575. In 1962, it "added a saving clause, indicating that a provision of state law would only be invalidated upon a 'direct and positive conflict' with the FDCA." *Id.* at 567. "The 'direct and positive conflict' language . . . simply restates the principle that state law is superseded in cases of an actual conflict with federal law such that 'compliance with both federal and state regulations is a physical impossibility.'" *S. Blasting Servs., Inc. v. Wilkes Cnty.*, 288 F.3d 584, 591 (4th Cir. 2002). "And when Congress enacted an express pre-emption provision for medical devices in 1976, . . . it declined to enact such a provision for prescription drugs." *Wyeth*, 555 U.S. at 567.

In 2007, Congress passed the Food and Drug Administration Amendments Act (FDAAA), which amended the FDCA to subject medications with "serious safety concerns" to additional restrictions. Pub. L. No. 110-85, 121 Stat. 823 (2007). Counsel for Dr. Bryant argued at the hearing that the FDAAA added two additional objectives: minimizing burdens on patient access to dangerous drugs, Tr. 41:1–23, and minimizing burdens on "the healthcare system," Tr. 40:23–24. But the FDAAA's language concerning patient access and burdens "is plainly a limitation on the FDA's *own restrictions* on a drug, rather than a command that the FDA assure access for all patients." *GenBioPro, Inc. v. Sorsaia*, No. CV 3:23-0058, 2023 WL 5490179, at *6 (S.D.W. Va. Aug. 24, 2023). Dr. Bryant's counsel acknowledged as much at the hearing. Tr. 41:24–42:3 ("Now, it's true that this statute is directed to the FDA. It's talking about the burdens of the REMS. It's not—it doesn't say in so many words that state law is preempted.").

Therefore, as another district court in this circuit recently held, "Congress's purpose in directing the FDA to consider burden and access when promulgating REMS with

elements to assure safe use was to ensure that the elements *themselves* would not be unduly burdensome upon patient access," *GenBioPro*, 2023 WL 5490719, at *6, not to give the FDA freewheeling authority to preempt state laws it considers "unduly burdensome."[3] The Supreme Court's decision in *Geier v. American Honda Motor Co., Inc.*, 529 U.S. 861 (2000), does not require otherwise. In that case, the Court held that the federal National Traffic and Motor Vehicle Safety Act preempted a state common-law tort action where the auto manufacturer was in compliance with federal regulations. *Id.* at 865. The Court relied on the fact that the relevant federal statute contained both an express preemption clause and a savings clause, which canceled each other out, *id.* at 867–74, and Department of Transportation's statement "that a tort suit such as this one would 'stand as an obstacle to the accomplishment and execution' of [the statute's] objectives," *id.* at 874–75, 882.

[3] Although the *GenBioPro* court ultimately found that West Virginia's telehealth provision was preempted, it did so under impossibility preemption. *Id.* at *11. Plaintiffs here have not raised impossibility preemption.

In contrast, FDA has "long maintained that state law offers an additional, and important, layer of consumer protection that complements FDA regulation." *Wyeth*, 555 U.S. at 579. Indeed, FDA specifically acknowledges on its website that States may impose additional restrictions beyond the mifepristone REMS. Exhibit 3, FDA Q&A on Mifepristone at 11. And again, the FDCA contains an express savings clause. That's why the Attorney General concedes that "state law traditionally 'offers an additional, and important, layer of consumer protection that complements FDA regulation." Defs.' Mem. 3, ECF No. 86.

B. North Carolina's health and safety regulations are not an obstacle to accomplishment of Congress's health and safety objective.

Nothing in the challenged laws conflicts with Congress's (or FDA's) ability to protect the public health by ensuring that drugs are safe and effective. On the contrary, North Carolina imposes additional safeguards above the floor set by the mifepristone REMS.

The *Zogenix* cases, which upheld provisions of state law very much like those challenged here, illustrate the point. In *Zogenix I*, the district court held that the State's

emergency order banning a REMS drug approved by FDA was preempted because it effectively required the drug manufacturer "to return to the FDA and seek approval of a drug different from the one that FDA has already deemed safe." *Zogenix, Inc. v. Patrick* (*Zogenix I*), No. CIV.A. 14-11689-RWZ, 2014 WL 1454696, at *2 (D. Mass. Apr. 15, 2014).

However, in *Zogenix II*, the same court upheld revised regulations which "removed" "the obstacle." *Zogenix, Inc. v. Patrick* (*Zogenix II*), No. CIV.A. 14-11689-RWZ, 2014 WL 4273251, at *3 (D. Mass. Aug. 28, 2014). Those regulations imposed additional requirements—including an assessment of patient risk factors, a discussion of the medication's risks and benefits, a pain management treatment agreement, and a letter of medical necessity—above and beyond FDA requirements. *Zogenix, Inc. v. Baker* (*Zogenix III*), No. CIV.A. 14-11689-RWZ, 2015 WL 1206354, at *2 n. 7 (D. Mass. Mar. 17, 2015). And in *Zogenix III*, the district court applied the motion to dismiss standard accepting as true allegations that certain pharmacy regulations would mean the drug was not stocked by pharmacies at all resulting in an "effective ban" on the REMS drug. *Zogenix III*, 2015 WL 1206354, at *2. These

cases demonstrate that reasonable safety measures above the floor set by REMS are not preempted by the FDCA unless they functionally ban an FDA-approved drug.

Yet neither Dr. Bryant nor the Attorney General argued that the challenged laws prevent the FDA from ensuring that mifepristone is safe and effective. Nor have they argued that the challenged laws effectively ban mifepristone.

Instead, recognizing the broad preemptive effect of Plaintiff Bryant's access-plus-burden-on-provider theory, counsel for the Attorney General suggested at oral argument that "where a requirement has been imposed and then withdrawn, . . . preemption becomes obvious." Tr. 99:24–25. But the Attorney General pointed to no statutory text supporting this theory. And none exists. The FDAAA does not suggest that preemption suddenly obtains when FDA removes a requirement. *See* Tr. 94:13–95:17 (Plaintiff arguing against limiting theory).

Again, the object of the FDCA is to ensure drugs are safe and effective, not to minimize burdens on patient access. And for good reason. If this Court accepts Dr. Bryant's invitation to view the 2007 FDAAA amendments as having expanded the

purpose of the FDCA to "minimiz[e] burden on the healthcare system," as well as "burdens" on providers then any state law that touches upon the medical field will be subject to preemption challenge.

There are currently 67 REMS drugs, a category which includes the highest-risk drugs on the market. Exhibit 7, FDA REMS Public Dashboard. These are drugs like opioids, which States have a legitimate and important interest in making sure are prescribed and distributed safely. Dr. Bryant's theory would mean that States can do virtually nothing at the prescriber level to combat the opioid crisis. Plaintiff's theory would declare unconstitutional laws limiting prescribing authority to as little as three days, *see* Ky. Rev. Stat. Ann. § 218A.205(3)(b); limiting dosages that prescribers can give patients, *see* 12-5 Vt. Code R. § 53; and requiring prescribers to obtain a controlled substances certificate from the State, *see* Ala. Code § 20-2-51; *see also* Exhibit 8, Opioid Regulations: State by State Guide. Many States currently enforce such laws even though the FDA declined to adopt dosage and time limits for prescribing

opioids in 2013. Exhibit 9, Delia Stubbs, *Where experts go to learn about FDA*, FDA Law Blog (2013).

Similarly, North Carolina's laws governing mifepristone are hardly unique. On the contrary, twenty-four other States require a waiting period before prescribing mifepristone.[4] Twenty-one States require the reporting of complications from chemical abortion.[5] Eighteen States require some sort of in-

[4] Ala. Code § 26-23A-4(a)(48 hours); Ariz. Rev. Stat. Ann. § 36-2153(A)(1)(24 hours); Fla. Stat. § 390.0111(3)(a)(1)(24 hours); Ga. Code Ann. § 31-9A-3(1)(24 hours); Idaho Code Ann. § 18-609(4) (24 hours); Ind. Code § 16-34-2-1.1(a)(1)(18 hours); Iowa Code § 146A.1(1) (24 hours); Kan. Stat. Ann. § 65-6716(c)(1) (24 hours); Ky. Rev. Stat. Ann. § 311.7735(1) (24 hours); La. Rev. Stat. Ann. § 40:1061.17(B)(3)(a) (72 hours); Mich. Comp. Laws § 333.17015(3) (24 hours); Miss. Code Ann. § 41-41-33(1)(a) (24 hours); Mo. Rev. Stat. § 188.027(1) (72 hours); Neb. Rev. Stat. § 28-327(1)(24 hours); N.D. Cent. Code § 14-02.1-02 (24 hours); Ohio Rev. Code Ann. § 2317.56(B)(1) (24 hours); 18 Pa. Cons. Stat. § 3205(a)(1) (24 hours); S.C. Code. Ann. § 44-41-330(C) (24 hours); S.D. Codified Laws § 34-23A-56 (72 hours); Tenn. Code Ann. § 39-15-202(d)(1) (48 hours); Tex. Health & Safety Code Ann. § 171.012(a)(4) (24 hours); Utah Code Ann. § 76-7-305(2) (72 hours); W. Va. Code § 16-2I-2(a) (24 hours); Wis. Stat. § 253.10(3)(c)(1) (24 hours).

[5] Ariz. Rev. Stat. Ann. § 36-2162; Ark. Code. Ann. § 20-16-1505; Conn. Agencies Regs. § 19-13-D54(b); Idaho Code Ann. § 39-9504; Ill. Admin. Code tit. 77, § 505.40(b); Ind. Code § 16-34-2-4.7; Ky. Rev. Stat. Ann. § 311.7736(2); La. Rev. Stat. Ann. § 40:1061.11(D); Minn. Stat. § 145.4131(b)(5); Miss. Code Ann. § 41-41-109(1)(b); Mo. Rev. Stat. § 188.052(2); Neb. Rev. Stat. § 28-343; N.D. Cent. Code § 14-02.1-07; Ohio Rev. Code Ann. § 2919.123(C)(1); Okla. Stat.

person visit to the clinic.[6] Seventeen States prevent non-physicians from prescribing mifepristone.[7] And eleven require an ultrasound before a chemical abortion.[8] Many of these

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tit. 63, § 1-756.8(D)-(E); Or. Rev. Stat. § 435.496(2); 18 Pa. Cons. Stat. § 3214(h); S.D. Codified Laws § 34-23A-34(24)(a); Tex. Health & Safety Code Ann. § 171.063(g); Wis. Stat. § 69.186(1)(i); Wyo. Stat. Ann. § 35-6-131(a)(iii).

[6] Ariz. Rev. Stat. Ann. § 36-2153; Ark. Code. Ann. § 20-16-1504(c)(1); Fla. Stat. § 390.0111(3)(a)(1); Ind. Code § 16-34-2-1(a)(1); Ky. Rev. Stat. Ann. § 311.7734(2); La. Rev. Stat. Ann. § 40:1061.11(A); Miss. Code Ann. § 41-41-107(2)-(3); Mo. Rev. Stat. § 188.021(1); Neb. Rev. Stat. § 28-335(2); N.D. Cent. Code § 14-02.1-03.5(5); Ohio Rev. Code Ann. § 2919.124(B); Okla. Stat. tit 63 § 1-729.1; S.C. Code Ann. § 44-41-330(A)(1)(a); S.D. Codified Laws § 34-23A-56; Tenn. Code Ann. § 39-15-202(b); Tex. Health & Safety Code Ann. § 171.063(c)(1); Utah Code Ann. § 76-7-305(3)(a); Wis. Stat. Ann. § 253.105(2).

[7] Ariz. Rev. Stat. Ann. § 36-2160(A); Ark. Code. Ann. § 20-16-1504(a); Fla. Stat. § 390.0111(2); Idaho Code Ann. § 18-608A; Ind. Code § 16-34-2-1(a)(1)(B); Iowa Code § 707.7(4); Ky. Rev. Stat. Ann. § 311.7733; Miss. Code Ann. § 41-41-107(1); Mo. Rev. Stat. § 188.020; Neb. Rev. Stat. § 28-335(1); Nev. Rev. Stat. § 442.250(1)(a); N.D. Cent. Code § 14-02.1-03.5(2); Ohio Rev. Code Ann. § 2919.123(A); 18 Pa. Cons. Stat. § 3204(a); Tex. Health & Safety Code Ann. § 171.063(a)(1); Utah Code Ann. § 76-7-332(2); Wis. Stat. § 253.105(2).

[8] Ala. Code § 26-23A-4(b)(4); Ariz. Rev. Stat. Ann. § 36-2156(A); Ark. Code Ann. § 20-16-602(c)(2)(A); Fla. Stat. § 390.0111(3)(a)(1)(b); Ind. Code § 16-34-2-1.1(a)(5); Iowa Code § 146A.1(1); Ky. Rev. Stat. Ann. § 311.7735(4)(a); La. Rev. Stat. Ann. §§ 40:1061.17(B)(1), 40:1061.10(C)-(D); Miss. Code Ann. § 41-41-34(1)(a); Tenn. Code Ann. § 39-15-215(b)(3); Tex. Health & Safety Code Ann. § 171.063(c)(3).

commonsense safety measures have been in place for decades and yet Dr. Bryant's rationale would eliminate them all.

There's no question that the challenged provisions make abortion drugs safer. Ectopic pregnancies are common, 1 in every 50 pregnancies, and ACOG says that an ultrasound is the best way to diagnose the condition. Exhibit 10, ACOG Practice Bulletin No. 193. FDA concedes that complications and failure rates increase with gestational age. Ex. E to Am. Compl., ECF No. 82-5 at 9. That's why FDA told the Supreme Court that the in-person dispensing and counseling requirement was necessary in August of 2020. Appl. for Stay 4, *Food and Drug Admin. v. Am. Coll. of Obstetricians and Gynecologists*, No. 20A34 (U.S.).

Even under Dr. Bryant's theory of the FDAAA many of the challenged provisions do not conflict with any access-plus-burden-on-prescriber standard. The requirement that providers report adverse events is consistent with the transparency purpose behind the FDAAA, *see* Tr. 8:4-14, does not impede access, and routine reporting requirements can hardly be considered a burden. The 14-day follow-up does not mandate that women return but merely requires prescribers to schedule

an appointment and follow-up. N.C. Gen. Stat. Ann. § 90-21.83B(b). That is hardly an unreasonable or burdensome requirement for a high-risk drug. As for the blood type requirement, FDA itself calls testing to determine whether a woman is RH-negative, and thus subject to serious complications with future pregnancies, the standard of care. Exhibit 11, FDA Mifeprex Label. That Dr. Bryant wants to avoid this requirement does not make it overly burdensome. And avoiding it would make abortion drugs *less* safe.

Dr. Bryant's interpretation of the FDCA would not only call those laws into question but also result in a state-law-free zone around any REMS drug. Because nothing in the FDAAA requires such sweeping results, this Court should grant judgment to the Legislative Leaders.

CONCLUSION

For these reasons, the Legislative Leaders respectfully ask this Court to grant summary judgment to the Legislative Leaders.

RESPECTFULLY SUBMITTED THIS 5th day of February, 2024.

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*** Special Appearance

CERTIFICATE OF SERVICE

I hereby certify that on February 5, 2024, I electronically filed the foregoing with the Clerk of Court by using the CM/ECF system which will send a notice of electronic filing to all counsel of record.

s/ Erin M. Hawley
Erin M. Hawley

CERTIFICATE OF COMPLIANCE

I hereby certify that the foregoing document complies with L.R. 7.3(d) and contains 2,986 words. I also certify that this document uses 13-point Courier New Font and has a top margin of 1.25" on each page in compliance with L.R. 7.1(a).

s/ Erin M. Hawley
Erin M. Hawley