UNITED STATES DISTRICT COURT
FOR THE MIDDLE DISTRICT OF NORTH CAROLINA

AMY BRYANT, MD, *Plaintiff*, v. JOSHUA H. STEIN *et al.*, *Defendants*, and PHILIP E. BERGER, *et al.*, *Intervenor- Defendants.*	No. 1:23-cv-77

DEFENDANT ATTORNEY GENERAL JOSHUA H. STEIN'S SUPPLEMENTAL MEMORANDUM OF LAW IN SUPPORT OF SUMMARY JUDGMENT

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DEFENDANT ATTORNEY GENERAL JOSHUA H. STEIN'S SUPPLEMENTAL MEMORANDUM OF LAW IN SUPPORT OF SUMMARY JUDGMENT

Attorney General Joshua H. Stein respectfully submits this supplemental memorandum in response to this Court's January 17, 2024 order converting Legislative Defendants' motion to dismiss, D.E. 83, into cross-motions for summary judgment. For the reasons set out below and in the Attorney General's prior briefing, D.E. 86, the Attorney General respectfully requests that this Court grant summary judgment to Plaintiff and enjoin the enforcement of the challenged state-law restrictions on the provision of mifepristone because they are in conflict with, and therefore preempted by, federal law.

INTRODUCTION

For more than two decades, the Food and Drug Administration has allowed the use of mifepristone, a drug used for the medical termination of early pregnancy, pursuant to certain conditions. These conditions, known as the Risk Evaluation and Mitigation Strategy, have been imposed by the FDA under its express statutory authority to: (1) decide which drugs carry risks that require a REMS, (2) impose conditions that appropriately mitigate any risks of taking these drugs, and (3) ensure that the burdens that the REMS conditions impose do not unnecessarily impede public access to the drugs or cause unnecessary burdens on the healthcare system. 21 U.S.C § 355-1(a)(1), (f).

When the FDA approved mifepristone in 2000, the FDA imposed a number of conditions it deemed necessary to ensure safe use. Since that time, the FDA has regularly modified the drug's REMS based on evidence that has been compiled across two decades of use. As part of these modifications, the agency has rescinded a number of conditions that, in its expert scientific judgment, are no longer necessary to ensure the drug's safety

and instead cause unnecessary burdens on access and delivery.

North Carolina law reimposes some of the very same restrictions on mifepristone that the FDA has withdrawn. Plaintiff challenges seven of those requirements. Under well-settled preemption principles, these requirements violate the Supremacy Clause because they frustrate the careful balance struck by the FDA pursuant to its express statutory authority. As a result, this Court should hold that the mifepristone REMS preempts the challenged North Carolina laws to the extent that those laws impose restrictions on mifepristone that the FDA previously required, but ultimately removed.

ARGUMENT

I. THE CHALLENGED STATE LAWS ARE PREEMPTED BECAUSE THEY UNLAWFULLY INTERFERE WITH THE CAREFUL BALANCE THE FDA STRUCK IN PROVIDING ACCESS TO MIFEPRISTONE.

Since approving mifepristone for use in 2000, the FDA has continued to calibrate the optimal balance between the risks of the drug and the need to minimize burdens on patient access and the healthcare system. 21 U.S.C. § 355-1(f)(2). The state laws that Plaintiff challenges here impose the same restrictions on mifepristone that the FDA had once adopted but has since deliberately rescinded. The reimposition of these restrictions under state law frustrates the delicate balance that Congress charged the FDA alone to strike. As a result, these state-law restrictions must yield to the FDA's considered judgment.

A. Federal Law Preempts State Laws That Impose Restrictions That the FDA Has Implemented and Subsequently Retracted Under Its REMS Authority.

Protecting public health and safety is "primarily, and historically, a matter of local concern." *Hillsborough Cnty. v. Automated Med. Labs. Inc.*, 471 U.S. 707, 719 (1985). But federal law may nonetheless preempt state police-powers legislation in certain limited circumstances—including, as relevant here, when state law "prevent[s] or frustrate[s] the accomplishment of a federal objective." *Geier v. Am. Honda Motor Co.*, 529 U.S. 861, 873 (2000); *see also* AG Br., D.E. 86 at 15-17. A state law frustrates a federal objective when there is a strong federal interest with which the state law conflicts. *Hillman v. Maretta*, 569 U.S. 483, 491 (2013); *see also* AG Br., D.E. 86 at 16-19. The Supreme Court has long recognized a strong federal interest when Congress authorizes an expert federal agency to comprehensively regulate complex or technical subject matter by balancing "difficult (and often competing) objectives." *Buckman Co. v. Plaintiffs' Legal Comm.*, 531 U.S. 341, 349 (2001).

Here, there is a strong federal interest in giving the FDA the latitude to set and revise the rules for how and when drugs subject to REMS may be prescribed and administered. In the 2007 amendments to the Food, Drug, and Cosmetic Act, Congress created a regulatory scheme that gave the FDA a unique degree of control over a specific subset of drugs subject to REMS. 21 U.S.C. § 355-1. The statute's text shows that Congress's purpose in giving the FDA special authority over these kinds of drugs was two-fold: (1) to "allow[ ] safe access to drugs with known serious risks" and (2) to

"assur[e] access and minimiz[e] burden." *Id.* §§ 355-1(f)(1), (2).

To accomplish these twin goals, Congress allowed the FDA to include in the REMS for certain drugs "such elements as are necessary to assure safe use." *Id.* § 355-1(f). Congress specifically authorized the FDA to consider certain restrictions in particular, including requiring healthcare providers to have specific training or special certification to prescribe the drug or requiring pharmacies and healthcare professionals to dispense the drug in particular ways. *Id.* §§ 355-1(f)(3), (e)(2).

But Congress also required the FDA to calibrate these safety restrictions against the burden that they may impose, ensuring that the safety restrictions are "commensurate with the specific serious risk," are not "unduly burdensome on patient access," and "minimize the burden on the health care delivery system." *Id.* § 355-1(f)(2). Congress also directed the FDA to conduct periodic assessments of the REMS to ensure that the requirements continue to adequately balance both safety and access concerns. *Id.* §§ 355-1(d), (f)(5), (g).

These latter provisions undermine Legislative Defendants' effort to characterize the REMS statutory regime as being exclusively about drug and patient safety. *See, e.g.*, Hrg. Tr. 8:19–9:2. To the contrary, Congress directed the FDA to carefully calibrate each REMS using a variety of tools to ensure *both* safe use of the drug *and* patient access.

Having identified this federal interest, the next step of the analysis is to determine whether the challenged state laws "prevent or frustrate" that interest. *Geier*, 529 U.S. at 873. When Congress charges a federal agency with balancing competing considerations

and, as part of that balancing, the agency expressly rejects regulations of the kind that state law attempts to impose, the state law frustrates a federal interest and is preempted.

As the Attorney General explained in his opposition to the Legislative Defendants' motion to dismiss, AG Br., D.E. 86 at 16-19, this rule flows directly from the Supreme Court's decision in *Geier*. There, the Court held that federal law preempted state tort lawsuits that would have required all cars to have airbags because such lawsuits would have frustrated the Department of Transportation's reasoned decision to allow a range of different passive-restraint systems. *Geier*, 529 U.S. at 876-82. Indeed, the Department had "*rejected*" a proposed "'all airbag' standard because of safety concerns (perceived or real) associated with airbags, which concerns threatened a 'backlash' more easily overcome 'if airbags' were 'not the only way of complying.'" *Id.* at 879 (quoting 49 Fed. Reg. 28990, 29001 (1984)). Against that historical backdrop, state tort law could not seek to impose the same all-airbag rule that the Department had considered and rejected. *Id.* at 881; *cf. Arizona v. United States*, 567 U.S. 387, 404-06 (2012) (holding that Congress's deliberate choice not to impose criminal penalties on immigrants for pursuing employment preempted state law criminalizing the same behavior).

To be sure, the Supreme Court's precedent in this area may sometimes raise difficult questions about whether an agency has sufficiently "considered" and then "rejected" a particular regulation, such that a state law has been preempted. *See, e.g.*, Hrg. Tr. 57:8-25. But there can be no question that an agency has considered and rejected a regulation when the agency has affirmatively implemented and then

deliberately rescinded the rule. In that context, *Geier* clearly applies, and the preemption conclusion is obvious.

This is that easy case. Here, as discussed below, the FDA did not merely consider and reject the mifepristone restrictions at issue. Rather, the agency *affirmatively implemented* and *deliberately rescinded* the restrictions, acting under its express statutory obligation to reevaluate REMS restrictions on an ongoing basis. 21 U.S.C. § 355-1(f)(5), (g)(4). That unique regulatory history makes the preemption in this case crystal clear. State laws cannot overrule the FDA's expert judgment and reinstitute restrictions that the agency included and then deliberately removed from a drug's REMS plan.

B. The Challenged State Laws and Regulations Frustrate the FDA's Regulatory Scheme and Are Preempted.

Plaintiff challenges seven requirements under North Carolina law. All of these requirements are preempted by the mifepristone REMS because the FDA once implemented each of them but has since explicitly rejected them. North Carolina's imposition of the same requirements frustrates the carefully calibrated REMS designed by the FDA and thus violates the Supremacy Clause.

In-person examination, administration, and dispensing requirements: When the FDA first approved mifepristone, it required a physician to examine the patient and dispense the medication in person. FAC, Ex. H (D.E. 82-8). In addition, the patient was required to take the medication in the presence of a physician. *Id.* Now, however, the FDA has expressly removed the requirement that a patient be examined in person, and mifepristone can be dispensed by certified pharmacies. The FDA has also made clear

that a physician need not be present when the patient takes the drug. FAC, Ex. L (D.E. 82-12), FAC, Ex. R (D.E. 82-18). But North Carolina law seeks to override the FDA's expert judgment and reinstitute the requirements that a qualified physician examine the patient and dispense the medication in person, and that the patient take the medication in the presence of a physician. N.C. Gen. Stat. §§ 90-21.83A(b)(2)a, 90-21.83B(a).

In-person 72-hour consultation requirement: When the FDA first approved mifepristone, it required a physician to inform the patient of the risks and benefits of mifepristone in person. FAC, Ex. H (D.E. 82-8). Now, however, the FDA has determined that a healthcare professional can "fully explain the risks of the mifepristone treatment regimen, and answer any questions, as in any consent process, without physical proximity." FAC, Ex. P (D.E. 82-16). But North Carolina law seeks to override the FDA's expert judgment and reinstitute the requirement that a physician consult with the patient in person before prescribing mifepristone. N.C. Gen. Stat. §§ 90-21.83A(b)(1), (5), 90-21.90(a).

In-person fourteen-day follow-up requirement: When the FDA first approved mifepristone, it required patients to return for an in-person follow-up appointment approximately fourteen days after taking the drug. FAC, Ex. H (D.E. 82-8). Now, however, the FDA has determined that this mandatory, in-person follow-up appointment is unnecessary and has rescinded the requirement. FAC, Ex. P (D.E. 82-16). But North Carolina law seeks to override the FDA's expert judgment and reinstitute the fourteen-day, in-person follow-up requirement. N.C. Gen. Stat. §§ 90-21.83A(b)(4)*l*, 90-

21.83B(b), 90-21.93(8)-(9).

Physician-only restriction: When the FDA first approved mifepristone, it required that a physician prescribe the medication. FAC, Ex. H (D.E. 82-8). Now however, mifepristone may be prescribed by a range of "health care providers," including nurse practitioners, certified midwives, and physician assistants. FAC, Ex. P (D.E. 82-16). But North Carolina law seeks to override the FDA's expert judgment and reinstitute the physician-only restriction. N.C. Gen. Stat. §§ 90-21.83A(b)(2)a, 90-21.93(b)(1).

Ultrasound requirement: The FDA has expressly rejected the need to give the patient an ultrasound before prescribing mifepristone and indeed no longer requires the patient to be examined in person at all. FAC, Ex. P (D.E. 82-16). But North Carolina law seeks to override the FDA's expert judgment and require that the patient receive an ultrasound—that is, an in-person examination—before being prescribed mifepristone. N.C. Gen. Stat. §§ 90-21.83A(b)(2)b, 90-21.93(b)(6), 10A Admin. Code § 14E.0305(d).

Blood-type determination requirement: The FDA has expressly rejected the need to administer a blood test before prescribing mifepristone to the extent that a blood test requires in-person examination of the patient. FAC, Ex. L (D.E. 82-12), FAC, Ex. R (D.E. 82-18). As discussed, the FDA originally required patients to be examined in person prior to taking mifepristone, but rescinded any such in-person requirement in recent years. But North Carolina law seeks to override the FDA's expert judgment and require an in-person examination during which the patient must receive a blood test before being prescribed mifepristone. N.C. Gen. Stat. § 90-21.83(B)(a)(2).

Nonfatal-complication reporting requirement: When the FDA first approved mifepristone, it required physicians to report a variety of nonfatal complications. FAC, Ex. H (D.E. 82-8). Now, however, physicians need only report fatal complications. FAC, Ex. N (D.E. 82-14). But North Carolina law seeks to override the FDA's expert judgment and reinstitute the nonfatal-complication reporting requirement. N.C. Gen. Stat. §§ 90-21.93(b)(1), (c).

* * *

Each of these North Carolina laws directly contradicts the careful balance that the FDA—at Congress's direction—has reached with respect to mifepristone access. They impose restrictions that the FDA initially included as part of mifepristone's REMS, but ultimately rescinded, based on the agency's considered judgment. Because well-settled preemption principles prohibit States from attempting to override the FDA's reasoned decisions about how to balance patient safety against patient access, the state laws at issue in this case must yield. *See Buckman Co.*, 531 U.S. at 348; *see also Geier*, 529 U.S. at 878-82.

C. Legislative Defendants' Contrary Arguments Are Unpersuasive.

Legislative Defendants fall short in seeking to argue that the challenged provisions are not preempted by the unique federal regulatory scheme at issue here.

First, Legislative Defendants argue that individual States should have the freedom to more strictly regulate REMS drugs than the FDA. Hrg. Tr. 35:8-19. Citing the Supreme Court's decision in *Wyeth*, Legislative Defendants argue that REMS are a

"floor," but not a ceiling. *Id.* 33:6-9.

This argument misunderstands both preemption analysis generally and *Wyeth* specifically. *Wyeth*, it is true, explains that state law generally "offers an additional, and important, layer of consumer protection that complements FDA regulation." *Wyeth v. Levine*, 555 U.S. 555, 579 (2009). But the word "*complements*" is critical in that statement from the Court: Under well-settled preemption principles, state laws that *complement* federal laws or interests pose no problem under the Supremacy Clause. *Id.* at 578. State laws that *contradict* or *frustrate* federal laws or interests, however, cannot stand. *Geier*, 529 U.S. at 906.

In *Wyeth*, the state tort suit that the plaintiff sought to bring posed no obstacle to a federal objective. 555 U.S. at 578. To the contrary, the state tort suit sought to promote the same federal interest as the relevant provisions in the Federal Food, Drug, and Cosmetic Act: the protection of consumers through labels that adequately warn of a drug's safety risks. The Court explained that nothing about tort suits holding manufacturers accountable for their warning labels was inconsistent with federal law: federal law places "responsibility for the content of [a drug's] label" squarely on the shoulders of manufacturers "at all times" and obligates manufacturers to update their labels whenever they acquire new safety information that necessitates a revision. *Id.* at 568-71. The Court emphasized that it would have been different had the manufacturer attempted to change the drug's label and been rebuffed by the FDA. *Id.* at 571. In that case, a state tort suit would no longer have been complementary of an agency's judgment,

but rather would have run counter to it.

This case, by contrast, presents the equivalent scenario to the FDA rejecting a proposed drug label change. Congress has granted the FDA authority to weigh competing factors and set the rules for how a certain subset of drugs can be prescribed and dispensed. Manufacturers have no authority to override the FDA's judgment. And the FDA has explicitly considered and rejected the inclusion of the restrictions that North Carolina state law seeks to impose as part of the mifepristone REMS. In that situation, *Wyeth* counsels in favor of finding preemption, not against it, as Legislative Defendants claim.

Second, Legislative Defendants argue that the "savings clause" in the FDCA confirms that States can pass restrictions on a drug's use in addition to those in the drug's REMS. Hrg. Tr. 9:23-10:1, 25:3-10. Legislative Defendants are again incorrect. The savings clause that Legislative Defendants cite was part of the 1962 amendments to the FDCA and states that "[n]othing in the amendments made by this Act . . . shall be construed as invalidating any provision of State law . . . unless there is a direct and positive conflict between such amendments and such provision of State law." Drug Amendments of 1962, § 202, 76 Stat. 793. The 2007 amendments to the FDCA—the ones that established the REMS regulatory scheme—included no such savings clause. And even if they had, such a clause could not save the state laws at issue here. After all, those state laws *are* in "direct and positive conflict" with the mifepristone REMS that the FDA has devised, since they impose restrictions that the FDA has deliberately rescinded.

Finally, Legislative Defendants argue that North Carolina must be permitted to reinstitute the challenged requirements because they purportedly improve "safety" and are "minimally burdensome." Hrg. Tr. at 28:23-32:19. But these justifications have been directly contradicted by the FDA's expert judgment in revising the mifepristone REMS. Congress has authorized that particular agency to decide whether certain restrictions are necessary to ensure a drug's safety or whether such restrictions are instead unduly burdensome. By withdrawing the same restrictions that North Carolina state law now seeks to impose, the FDA has made clear that those restrictions are either unnecessary for safe mifepristone use, unduly burdensome on patients or doctors, or both. That reasoned decision is conclusive in light of the Supremacy Clause.

CONCLUSION

For the foregoing reasons, the North Carolina laws that impose restrictions that the FDA once included in the mifepristone REMS, but later withdrew, are preempted and should be enjoined.

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Respectfully submitted,

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CERTIFICATE OF COMPLIANCE

I hereby certify that the foregoing brief complies with this Court's January 17, 2024 order (D.E. 95) because, excluding the parts of the brief exempted by Rule 7.3(d) (cover page, caption, signature lines, and certificates of counsel), this brief contains fewer than 3,000 words. This brief also complies with Local Rule 7.1(a).

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