UNITED STATES DISTRICT COURT
MIDDLE DISTRICT OF NORTH CAROLINA

AMY BRYANT, MD, Plaintiff, v. JOSHUA H. STEIN, in his official capacity as Attorney General for the State of North Carolina, *et al.*, Defendants, and TIMOTHY K. MOORE and PHILIP E. BERGER, Intervenors.	Case No.: 1:23-cv-00077-WO-LPA

MEMORANDUM OF LAW IN OPPOSITION TO INTERVENORS' MOTION TO DISMISS

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INTRODUCTION

Out of the many thousands of drugs that have been approved by the federal Food and Drug Administration, a few dozen are subject to extraordinary federal oversight in the form of a Risk Evaluation and Mitigation Strategy, commonly known as a REMS. Congress charged FDA with determining whether any REMS restrictions on distribution are needed, and if they are, ensuring that such restrictions are "commensurate with" the drug's identified risks, are "not unduly burdensome on patient access," and are designed to "minimize the burden on the health care delivery system." 21 U.S.C. § 355-1(f)(2).

This case presents a straightforward question: When FDA, pursuant to its congressionally delegated REMS authority, determines that a particular mix of regulatory controls is commensurate with a drug's risks, may a State impose additional restrictions on that drug, including restrictions that FDA has determined are unwarranted and inappropriate? The answer is no. Such additional, state-imposed restrictions are preempted because they would "upset the careful regulatory scheme established by federal law." *Geier v. Am. Honda Motor Co.*, 529 U.S. 861, 870 (2000) (quotation marks omitted).

The drug at issue in this case is mifepristone, which is FDA-approved for termination of pregnancy in the first 10 weeks. Under the Mifepristone REMS, a healthcare practitioner certified under the REMS, who need not be a physician, can prescribe mifepristone to a patient either in person or through telemedicine; the patient can obtain the medication either directly from the prescriber or from a pharmacy certified under the REMS; and the patient can take the medication at home or at another place of the patient's choosing. FDA has also imposed requirements designed to standardize the information patients receive about the risks of

mifepristone and ensure that the patient has given informed consent. Exercising its congressionally delegated authority, FDA has concluded that this specific mix of regulatory controls is, in the agency's view, commensurate with the risks of mifepristone and sufficient to ensure its safe use while not unduly burdening patient access or the healthcare delivery system. *See generally* Ex. A.[1] FDA has also denied multiple citizen petitions from anti-abortion groups challenging aspects of the Mifepristone REMS. *See, e.g.*, Exs. E & P.

In defiance of FDA's regulatory judgments, North Carolina has imposed a tangle of additional restrictions on mifepristone that conflict with the federal REMS and interfere with Congress's decision to entrust these matters to FDA. For example, North Carolina dictates that mifepristone may only be provided in person by a physician in a specialized healthcare facility and may not be obtained from a pharmacy—even a pharmacy that is certified to dispense the drug under FDA's REMS. North Carolina also imposes informed-consent requirements that are inconsistent with those under the Mifepristone REMS, and it requires an ultrasound in circumstances where FDA has deemed such a requirement inappropriate.

Plaintiff, Dr. Amy Bryant, is certified to prescribe mifepristone in accordance with the federal REMS, and she contends that North Carolina's efforts to prevent her from doing so are preempted. "[A]fter review and analysis," the North Carolina Department of Justice has "concluded that Plaintiff's preemption arguments are legally correct." Doc. 30-1 at 1. All named defendants answered the complaint, and intervenors alone moved to dismiss. Their

[1] Citations in the form "Ex. __" refer to the exhibits attached to the complaint (Doc. 1) and the page numbering added by the CM/ECF system.

arguments are unpersuasive.

First, intervenors claim that the "major questions doctrine" prevents this Court from finding preemption of any state law that even touches on the topic of abortion. But where, as here, a federal agency's statutory authority is undisputed, the major questions doctrine does not interfere with the ordinary working of obstacle preemption. Moreover, this case does not involve a question of "vast economic and political significance." *West Virginia v. EPA*, 142 S. Ct. 2587, 2605 (2022) (quotation marks omitted). Dr. Bryant is not claiming here that North Carolina is displaced from regulating abortion at all (for example, she is not challenging the State's 20-week abortion ban). Her position in this case is only that longstanding precedent prevents the State from imposing restrictions on one particular drug that conflict with the federal regulatory scheme.

Second, intervenors claim that the Mifepristone REMS only establishes a regulatory "floor" upon which States are free to layer additional restrictions, even restrictions that FDA has expressly rejected. They base that argument primarily on a misreading of the Supreme Court's decision in *Wyeth v. Levine*, 555 U.S. 555 (2009). The reasons the Court gave for not finding preemption there—including that FDA "did not consider and reject" the requirement the State sought to impose, *id.* at 580-81 & n.14—point to precisely the opposite conclusion here, where FDA, performing the role Congress assigned to it under the REMS program, *did* consider and expressly reject the very same restrictions North Carolina seeks to impose on mifepristone.

As explained below, intervenors' remaining arguments fare no better. Dr. Bryant therefore respectfully requests that the Court deny intervenors' motion to dismiss.

BACKGROUND

A. The Statutory Scheme: Assuring Access to REMS Drugs

Under the Federal Food, Drug, and Cosmetic Act ("FDCA"), a drug manufacturer cannot introduce a new drug into interstate commerce unless FDA determines that the drug is safe and effective under the conditions of use prescribed in the drug's labeling. 21 U.S.C. § 355. For a small number of drugs, Congress directed FDA to impose additional controls in the form of a Risk Evaluation and Mitigation Strategy, or "REMS." *See* Food and Drug Administration Amendments Act of 2007 ("FDAAA"), Pub. L. No. 110-85, § 901, 121 Stat. 823, 926 (enacting 21 U.S.C. § 355-1). A REMS may include requirements such as (i) a medication guide or patient package insert; (ii) a communication plan; or (iii) packaging and disposal requirements. *Id.* § 355-1(e).

FDA can also require that a REMS include Elements to Assure Safe Use, or "ETASU." These elements may require that (i) healthcare providers who prescribe the drug have particular training or experience or be specially certified; (ii) pharmacies, practitioners, or healthcare settings that dispense the drug be specially certified; (iii) the drug be dispensed only in certain settings; (iv) the drug be dispensed only with documentation of safe-use conditions, such as laboratory test results; or (v) patients using the drug be monitored or enrolled in a registry. *Id.* § 355-1(f)(3). In a provision titled "Assuring Access and Minimizing Burden," Congress charged FDA with ensuring that any REMS restrictions are "commensurate with" specific identified risks of the drug, are "not … unduly burdensome on patient access to the drug," and "minimize the burden on the health care delivery system" of complying with the restrictions. *Id.* § 355-1(f)(2). In determining what restrictions are appropriate, FDA is required

to "seek input from patients, physicians, pharmacists, and other healthcare providers" about how to design the requirements so as to avoid unduly burdening patients and providers. *Id.* § 355-1(f)(5)(A).

Congress also charged FDA with continued monitoring and periodic reassessment of REMS and ETASU to ensure that they continue to reflect the least restrictive set of requirements necessary to ensure safety while protecting patient access. Every REMS thus includes a timetable for periodic assessments. *Id.* § 355-1(c)(1), (d). In addition, FDA must "periodically evaluate" ETASU to assess whether they are necessary to assure safe use, "are not unduly burdensome on patient access to the drug," and "minimize the burden on the health care delivery system." *Id.* § 355-1(f)(5)(B). And FDA must "modify" the ETASU "as appropriate" in light of the evaluations and input received from patients, physicians, pharmacists, and other healthcare providers. *Id.* § 355-1(f)(5)(C). FDA also may require modification of a REMS whenever necessary to "minimize the burden on the health care delivery system." *Id.* § 355-1(g)(4)(B).

B. FDA's Regulation of Mifepristone Under the REMS Statute

Twenty-three years ago, FDA approved mifepristone for use in medication abortion and found that access to mifepristone was "important to the health of women." Ex. D at 5.[2] Mifepristone is FDA-approved for use in a regimen with a second drug, misoprostol, which is taken 24 to 48 hours later. Serious complications are extremely rare, "occurring in no more

[2] FDA initially approved mifepristone under the brand name Mifeprex; the agency approved a generic version in 2019. Ex. P at 3, 5. References to mifepristone in this brief include both the branded and generic versions.

than a fraction of a percent of patients"—which makes mifepristone as safe as "commonly used prescription and over-the-counter medications," such as aspirin, ibuprofen, and commonplace antibiotics. Nat'l Acads. of Scis., Eng'g, & Med., The Safety and Quality of Abortion Care in the United States 55, 58 (2018); *see* Ex. P at 8, 21.[3]

FDA's approval of mifepristone included distribution restrictions under regulations that predated the REMS statute. Ex. D at 7. When Congress created the REMS program in 2007, it deemed mifepristone and 15 other drugs to have an approved REMS, and it required those drugs' sponsors to submit proposed REMS for approval under the new REMS provision of the FDCA. *See* FDAAA § 909(b), 121 Stat. at 950-51; Identification of Drug and Biological Products Deemed to Have Risk Evaluation and Mitigation Strategies for Purposes of the Food and Drug Administration Amendments Act of 2007, 73 Fed. Reg. 16,313 (Mar. 27, 2008).

In June 2011, FDA approved the first Mifepristone REMS, which carried forward the restrictions FDA had imposed 11 years earlier. Ex. P at 2-3. The 2011 REMS required, among other things, that mifepristone be provided by a specially certified physician with enumerated qualifications who signed an FDA-approved Prescriber's Agreement. Ex. H at 2-3, 8. The REMS also stated that mifepristone could be dispensed "only in certain health care settings, specifically clinics, medical offices, and hospitals." *Id.* at 3. The REMS did not require that that

[3] Intervenors misleadingly claim that "[o]ne in five women suffers complications from chemical abortions," citing a study of abortions in Finland in the early 2000s. Doc. 54, Mem. in Supp. of Mot. to Dismiss at 12 n.8 (hereinafter "MTD"). But as FDA noted, that figure includes women who reported bleeding, a normal side effect. Ex. P at 38-39. One of the study's authors recently called its use by anti-abortion groups "pure nonsense." Amy Schoenfeld Walker et al., *Are Abortion Pills Safe? Here's the Evidence.*, N.Y. Times (Apr. 1, 2023), https://www.nytimes.com/interactive/2023/04/01/health/abortion-pill-safety.html.

every patient have an ultrasound, as FDA had "carefully considered" the question and determined that whether to perform an ultrasound should be left "to the medical judgment of the physician." Ex. D at 6. In addition, patients had to sign the FDA-approved Patient Agreement and receive a copy of the FDA-approved Medication Guide. *Id.* at 2-3, 5-7, 10-11. The Patient Agreement stated, among other things, that the patient would "take Mifeprex in [the] provider's office." *Id.* at 10.

Five years later, FDA revisited the Mifepristone REMS and determined that it had to be modified "to minimize the burden on the healthcare delivery system." Ex. J at 3. Among other changes, FDA decided that qualified healthcare providers other than physicians should be allowed to become certified to prescribe mifepristone. Ex. N at 6; Ex. P at 9-11. The 2016 REMS continued to require that the drug be dispensed in person in a clinic, medical office, or hospital. Ex. N at 3-4. However, FDA revised the Patient Agreement to no longer state that mifepristone would be administered in person in the provider's office. Ex. N at 8; Ex. M at 3.

The in-person dispensing REMS requirement remained in place until July 2020, when a district court preliminarily enjoined FDA from enforcing it during the COVID-19 pandemic. *Am. Coll. of Obstetricians & Gynecologists v. FDA*, 472 F. Supp. 3d 183, 217 (D. Md. 2020). The Supreme Court stayed that injunction six months later, with the Chief Justice emphasizing that courts owe "significant deference" to FDA's expert judgment. *FDA v. Am. Coll. of Obstetricians & Gynecologists*, 141 S. Ct. 578, 579 (2021) (concurring op.). But two Justices urged FDA to reconsider the in-person dispensing requirement. They pointed out that the requirement was "irrational" because the REMS already "allow[ed] patients to receive all physician consultations for a medication abortion virtually and to take [mifepristone] at home without

medical supervision." *Id.* at 579 (dissenting op.). And they noted that the in-person requirement had "been suspended for six months, yet the Government ha[d] not identified a single harm experienced by women who ha[d] obtained mifepristone by mail or delivery." *Id.* at 584.

In the wake of these court decisions and other litigation challenging the REMS, FDA announced that it would not enforce the in-person dispensing requirement during the COVID-19 public health emergency, and that it would undertake "a full review of the Mifepristone REMS program." Ex. P at 7. Following that review, on December 16, 2021, FDA determined that this requirement was "no longer necessary to ensure the benefits of mifepristone outweigh the risks" and that "[r]emoval of the requirement for in-person dispensing" was "necessary" to "minimize the burden on the healthcare delivery system." Ex. R at 2-3; *see* Ex. P at 6.

In January 2023, FDA approved a REMS modification that effectuated these changes by removing the in-person dispensing requirement and adding a certification requirement for pharmacies to dispense the drug. Ex. S at 4; Ex. A at 2-5. As modified, the REMS states that mifepristone can be dispensed "by or under the supervision of certified prescribers, or by certified pharmacies on prescriptions written by certain prescribers." Ex. A at 2. FDA concluded that with these changes, the REMS "will continue to ensure the benefits of mifepristone for medical abortion outweigh the risks while minimizing the burden imposed

by the REMS on healthcare providers and patients." Ex. T at 14.[4]

C. North Carolina's Restrictions on Mifepristone

Plaintiff, Dr. Amy Bryant, is a licensed physician with a medical practice in Orange County, North Carolina, and is certified to prescribe mifepristone under the federal REMS. Doc. 1 ¶ 14. North Carolina law, however, imposes unnecessary and burdensome restrictions on her practice that are inconsistent with the federal REMS—including the same in-person requirement that FDA specifically rejected.

North Carolina law provides that any abortion, including a medication abortion with mifepristone, is lawful only "when the procedure is performed by a qualified physician ... in a hospital or clinic certified by the Department of Health and Human Services to be a suitable facility for the performance of abortions." N.C. Gen. Stat. § 14-45.1(a). Locations the State deems "suitable" are limited to (a) facilities attached to or operated by licensed hospitals; and (b) freestanding abortion clinics, which must meet a host of onerous and medically unnecessary facility requirements. *Id.*; *see generally* 10A N.C. Admin. Code subchapter 14E. North Carolina law also provides that "[t]he physician prescribing, dispensing, or otherwise providing any drug or chemical for the purpose of inducing an abortion shall be physically present in the same room as the patient when the first drug or chemical is administered to the

[4] Recently, a single district judge in Texas purported to "stay" all of FDA's regulatory actions regarding mifepristone, from the 2000 approval forward. That order was itself stayed pending appeal by the Supreme Court, so the Mifepristone REMS remains in effect. *See Danco Labs., LLC v. All. for Hippocratic Med.*, 2023 WL 3033177 (U.S. Apr. 21, 2023); *see also GenBioPro, Inc. v. Sorsaia*, No. 3:23-cv-58 (S.D. W. Va. Apr. 21, 2023), Doc. 52 (noting that the Texas order "has been met with broad criticism from legal commentators" and according it "little weight").

patient." N.C. Gen. Stat. § 90-21.82(1)(a). In addition, North Carolina requires that the patient receive specific, state-mandated information at least 72 hours before an abortion—including statements that are inconsistent with the Mifepristone REMS—and mandates an ultrasound for "any patient who is scheduled for an abortion procedure" in a non-hospital-affiliated clinic. *Id.* §§ 90-21.82, 90-21.90; 10A N.C. Admin. Code § 14E.0305(d).

North Carolina threatens severe consequences for a physician who fails to comply with these restrictions, including criminal prosecution, civil penalties, and suspension or revocation of the physician's medical license. *See* N.C. Gen. Stat. §§ 14-44, 14-45, 90-14(a)(2), 90-21.82. These restrictions prevent Dr. Bryant from prescribing mifepristone to her patients in a manner consistent with the federal REMS and her professional judgment.

ARGUMENT

I. The complaint plausibly alleges that North Carolina's restrictions on mifepristone are preempted.

In our federal system, state law must yield to federal law, which is "the supreme Law of the Land." U.S. Const. art. VI, cl. 2. For preemption purposes, relevant federal law includes both statutes enacted by Congress and actions taken by "a federal agency acting within the scope of its congressionally delegated authority." *La. Pub. Serv. Comm'n v. FCC*, 476 U.S. 355, 369 (1986). Accordingly, "agency actions taken pursuant to the FDA's congressionally delegated authority" can preempt state law. *Merck Sharp & Dohme Corp. v. Albrecht*, 139 S. Ct. 1668, 1679 (2019).

One circumstance in which state law is preempted is when it "stands as an obstacle to the accomplishment of the full purposes and objectives of federal law." *Anderson v. Sara Lee*

Corp., 508 F.3d 181, 191-92 (4th Cir. 2007) (quoting *Worm v. Am. Cyanamid Co.*, 970 F.2d 1301, 1305 (4th Cir. 1992)). The Supreme Court's decision in *Geier v. American Honda Motor Co.*, 529 U.S. 861 (2000), is a classic illustration of obstacle preemption. There, the Court held that a state law requiring auto manufacturers to equip every car with a driver-side airbag was preempted because it would conflict with a federal agency's decision not to require airbags for all vehicles. *Id.* at 874-75, 881-82. Acting under the National Traffic and Motor Vehicle Safety Act, the Department of Transportation had promulgated a Federal Motor Vehicle Safety Standard that "deliberately sought variety" by "allowing manufacturers to choose among different passive restraint mechanisms," including seatbelts. *Id.* at 878. The agency had specifically rejected a proposed "all airbag" standard as inconsistent with its goals. *Id.* at 879. The Supreme Court held that a state-law airbag requirement "would have presented an obstacle to the variety and mix of devices that the federal regulation sought" and "upset the careful regulatory scheme established by federal law." *Id.* at 870, 881 (quotation marks omitted).[5]

A straightforward application of *Geier* shows that Dr. Bryant's complaint states at least a "plausible" claim that North Carolina's restrictions on mifepristone are preempted. *Ashcroft v. Iqbal*, 556 U.S. 662, 678 (2009) (quotation marks omitted). In crafting the Mifepristone REMS, FDA has identified the specific mix of regulatory controls that, in the agency's view,

[5] Citing only a separate opinion by Justice Thomas, intervenors claim that obstacle preemption is "disfavored." MTD at 21-22. But the Supreme Court has held that obstacle preemption is among the "ordinary principles of preemption" and is "well-settled." *Arizona v. United States*, 567 U.S. 387, 406 (2012).

protects patient safety without unduly burdening patient access or the healthcare system. North Carolina seeks to upset that regulatory balance by imposing restrictions that go beyond the federal REMS, including restrictions that FDA has specifically concluded are unwarranted and inappropriate. For example, North Carolina requires that mifepristone be provided in person in a specialized facility, even though FDA determined that "prescribers do not have to be physically present with the patient" and that removing "the requirement that mifepristone be dispensed only in certain healthcare settings" was "necessary" to assure appropriate patient access and eliminate undue burdens on the healthcare system. Ex. P at 7, 13; *see also id.* at 22-23, 26-37. North Carolina requires that mifepristone be provided by a physician, even though FDA determined that mifepristone "is safe and effective when prescribed by midlevel providers, such as physician assistants and nurse practitioners." *Id.* at 9-11. North Carolina mandates an ultrasound for every patient who receives abortion care from a non-hospital-affiliated clinic, even though FDA "carefully considered the role of ultrasound" and concluded it would be "inappropriate" to "mandate" an ultrasound in every case. Ex. E at 19; *see* Ex. D at 6; Ex. P at 12-13. And although FDA developed a Patient Agreement Form and Medication Guide to "standardiz[e] the medication information on the use of mifepristone that prescribers communicate to their patients," Ex. T at 12, North Carolina deems those materials inadequate and requires that a patient receive additional, state-mandated information at least 72 hours

before the abortion, including statements that contradict the federal materials.[6]

In sum, North Carolina's restrictions are preempted because they "represent[] an effort by the state to directly override [FDA's] explicit policy choice[s]." *PPL EnergyPlus, LLC v. Nazarian*, 753 F.3d 467, 479 (4th Cir. 2014), *aff'd sub nom. Hughes v. Talen Energy Mktg., LLC*, 578 U.S. 150 (2016); *see United States v. Locke*, 529 U.S. 89, 110 (2000) (a state requirement is obstacle-preempted where a federal agency "has decided that no such requirement should be imposed"); *Sperry v. Florida ex rel. Fla. Bar*, 373 U.S. 379, 385 (1963) (a State may not "impose upon the performance of activity sanctioned by federal license additional conditions not contemplated by Congress"). And allowing North Carolina to enforce those restrictions would upset "the complex balancing of interests and concerns" reflected in the REMS provisions of the FDCA and in FDA's Mifepristone REMS. *City of Charleston v. A Fisherman's Best, Inc.*, 310 F.3d 155, 172-73 (4th Cir. 2002).

II. The "major questions doctrine" is not relevant here.

Intervenors' lead argument is that the Court should invoke the "major questions doctrine" to hold that Congress did not authorize FDA to "set national abortion policy." MTD at 17. The Court should reject this argument for at least two reasons.

First, the major questions doctrine is a tool for deciding whether an agency has

[6] For example, North Carolina's written materials tell medication-abortion patients that they "will need to return for another visit 12 to 18 days later to make sure that [they] have passed all the tissue." N.C. Dep't of Health & Hum. Servs., A Woman's Right to Know 18 (Sept. 2015), https://www.ncdhhs.gov/awomansrighttoknow-web-1/open. But FDA "disagree[s] that medical abortion always requires in-person follow-up with a healthcare provider" and maintains that "appropriate follow-up after medical termination of a pregnancy may be accomplished in multiple ways and not all require an in-clinic visit." Ex. P at 14-16.

authority to take some challenged action; it does not affect whether a concededly valid agency action gives rise to obstacle preemption. In every case where the Supreme Court has applied the doctrine, a party was challenging some regulatory action taken by the agency and arguing that it exceeded the agency's statutory authority. *See West Virginia*, 142 S. Ct. at 2608-09 (surveying cases). Here, however, there is no dispute that Congress authorized FDA to promulgate the Mifepristone REMS. Because the existence of statutory authority for FDA's actions is not challenged, the only question is whether North Carolina's restrictions on mifepristone "stand[] as an obstacle" to the federal regulatory scheme. *Sara Lee*, 508 F.3d at 191-92 (quoting *Worm*, 970 F.2d at 1305). With respect to that question, intervenors cite no authority suggesting that the major questions doctrine alters the well-established rule that "express congressional authorization to displace state law" is not required for obstacle preemption. *Fid. Fed. Sav. & Loan Ass'n v. de la Cuesta*, 458 U.S. 141, 154 (1982); *see Nat'l Home Equity Mortg. Ass'n v. Face*, 239 F.3d 633, 637 (4th Cir. 2001) ("Even when Congress's intent is unclear, state law must nevertheless yield when it conflicts with federal law.").

Second, in any event, this is not an "extraordinary case[]" where an agency seeks to regulate matters of "vast economic and political significance." *West Virginia*, 142 S. Ct. at 2605, 2609 (quotation marks omitted). The Supreme Court has applied the major questions doctrine where an agency claimed the power to (i) force a nationwide transition away from the use of coal to generate electricity, *id.* at 2616; (ii) require 84 million Americans to obtain a COVID-19 vaccine, *Nat'l Fed. of Ind. Bus. v. OSHA*, 142 S. Ct. 661, 662 (2022) (per curiam); (iii) impose a nationwide moratorium on evictions, *Ala. Ass'n of Realtors v. Dep't of Health & Hum. Servs.*, 141 S. Ct. 2485, 2486 (2021) (per curiam); (iv) exercise permitting authority over millions of

offices, schools, and churches, *Util. Air Regul. Grp. v. EPA*, 573 U.S. 302, 328 (2014); and (v) ban cigarettes and other tobacco products, *FDA v. Brown & Williamson Tobacco Corp.*, 529 U.S. 120, 130 (2000). Each of these cases involved a "transformative expansion in [the agency's] regulatory authority." *West Virginia*, 142 S. Ct. at 2610 (quotation marks omitted).

Nothing so dramatic is at issue here. Grasping for the broadest and most abstract framing, intervenors say this case involves the question whether FDA can "set national abortion policy." MTD at 17. But this case involves only the modest question of whether, in connection with abortions that are legal in North Carolina, the State can impose specific restrictions on mifepristone that FDA has rejected as unduly burdensome and that interfere with the operation of the federal REMS (*e.g.*, by preventing pharmacies that are federally certified to dispense mifepristone from doing so). The answer to that question is important to patients and their doctors, but it is hardly a matter of such "vast economic and political significance" as to trigger the major questions doctrine.

Intervenors contend that abortion is such a hot-button issue that ordinary preemption principles cannot apply to any case that so much as touches on "the topic of abortion." MTD at 19. In so arguing, intervenors ignore the Supreme Court's instruction that courts should not "engineer exceptions to longstanding background rules" just because a case involves abortion. *Dobbs v. Jackson Women's Health Org.*, 142 S. Ct. 2228, 2276 (2022). This makes intervenors' reliance on *Dobbs* puzzling. *Dobbs* holds only that there is no fundamental constitutional right to abortion; it says nothing whatsoever about whether federal law preempts particular state requirements, and it directs courts to resolve such questions based on ordinary legal principles. So this Court should not shy away from "evenhandedly applying uncontroversial legal

doctrines," including obstacle preemption, "in a case involving state regulation of abortion." *Madsen v. Women's Health Ctr., Inc.*, 512 U.S. 753, 785 (1994) (Scalia, J., concurring in judgment in part) (quotation marks omitted).

III. FDA's actions under the REMS statute have preemptive force.

Intervenors' contention that the Mifepristone REMS "is not an agency regulation capable of preempting state law," MTD at 20, is not even worth the four brief sentences they devote to it. The Supreme Court recently reaffirmed that "agency actions taken pursuant to the FDA's congressionally delegated authority" can preempt state law, and that such actions are not limited to those adopted "by means of notice-and-comment rulemaking" but include "other agency action[s] carrying the force of law." *Merck Sharp*, 139 S. Ct. at 1679. As examples of FDA actions that could have preemptive force, the Court cited statutes and regulations authorizing FDA to communicate labeling decisions through letters to drug sponsors. *Id.*; *see also id.* at 1685 (Alito, J., concurring in judgment). *Merck* eliminates any doubt that FDA's actions at issue here, including its approval and modification of the Mifepristone REMS, are capable of preempting state law.

Intervenors can point to no authority that supports their contrary argument. They first falsely state that "the Supreme Court has held that a REMS is not even 'agency regulation with the force of law [that] can pre-empt conflicting state requirements.'" MTD at 20. In reality, the language quoted by intervenors comes from the Supreme Court's holding that a "mere assertion" in "the preamble to a 2006 FDA regulation" was only "FDA's opinion" and did not carry preemptive force. *Wyeth*, 555 U.S. at 575-76. That case did not involve a REMS at all, nor even a labeling action that FDA had considered and rejected. And a REMS is not some

non-binding opinion in a regulatory preamble; it is formal agency action taken pursuant to an express grant of statutory authority. *See* 21 U.S.C. § 355-1.

Intervenors' only other citation for this point is a 30-year-old out-of-circuit case holding that a "contract between the government and private parties" authorizing snowmobile tours on federal land lacked preemptive force because it was not "adopted according to the procedures embodied in the Administrative Procedures [sic] Act"—presumably meaning notice-and-comment rulemaking. *Anderson v. Eby*, 998 F.2d 858, 863 (10th Cir. 1993). But it is clear that FDA need not act through notice-and-comment rulemaking for its actions to have the force of law. *Merck*, 139 S. Ct. at 1679; *see, e.g.*, *Feikema v. Texaco, Inc.*, 16 F.3d 1408, 1416 (4th Cir. 1994) (consent order entered into by EPA "acting within valid statutory authority" preempts conflicting state law).

IV. The REMS is not a "floor" to which States can add inconsistent requirements.

According to intervenors, the Mifepristone REMS is just a federal "floor" for regulation of mifepristone that leaves states free to impose additional restrictions, including ones FDA has specifically rejected. MTD at 26-28. Intervenors chiefly rely on the Supreme Court's decision in *Wyeth v. Levine*, which they wrongly claim "decided this precise issue." *Id.* at 29. But *Wyeth* supports Dr. Bryant's preemption claim, and intervenors' remaining arguments against obstacle preemption are unpersuasive.[7]

[7] Intervenors also devote several pages to arguing against "impossibility preemption." MTD at 22-26. But Dr. Bryant's claim is based on obstacle preemption. *See Sara Lee*, 508 F.3d at 191-92 (distinguishing between impossibility and obstacle preemption).

A. *Wyeth* supports preemption here.

To start, recall what was at issue in *Wyeth*. That case involved Phenergan, a non-REMS drug. The defendant argued that obstacle preemption barred a state-law tort suit that would have required it to provide an additional warning for Phenergan, above and beyond the warnings already required as part of the drug's FDA-approved label. The trial court found that FDA "had paid no more than passing attention to the question" whether such an additional warning would be appropriate. *Wyeth*, 555 U.S. at 563. The defendant, however, insisted that state law was preempted "regardless of whether there [was] any evidence that the FDA ha[d] considered the stronger warning at issue." *Id.* at 573-74.

The Supreme Court rejected that argument. Distinguishing *Geier*, the Court explained that there the agency's "contemporaneous record … revealed the factors the agency had weighed and the balance it had struck," including its decision to "[r]eject[] an 'all airbag' standard"; whereas in *Wyeth*, the record showed that "FDA did not consider and reject a stronger warning." *Id.* at 580-81 & n.14. The Court also observed that FDA "has limited resources to monitor the 11,000 drugs on the market," so state tort suits could help the agency identify "unknown drug hazards" that otherwise would not come to its attention, as well as serve a "compensatory function" distinct from federal regulation. *Id.* at 578-79.

Applying the Supreme Court's analysis from *Wyeth* to the very different facts at issue in this case confirms that obstacle preemption applies here.

First, whereas *Wyeth* involved only a drug's FDA-approved labeling, this case involves FDA's ongoing, meticulous regulation of a drug under the highly detailed REMS provisions of the FDCA. As *Wyeth* noted, many thousands of drugs have FDA-approved warning labels.

FDA cannot possibly monitor all those drugs to determine whether their labels should be updated in light of new information, so Congress and FDA expect a drug's manufacturer to update the label as needed. *Id.* at 570-71, 578. Consequently, FDA's approval of a drug's label at a particular point in time does not mean the agency has "performed a precise balancing of risks and benefits" and determined that no additional warnings should ever be given. *Id.* at 575; *see Merck*, 139 S. Ct. at 1677 (noting that *Wyeth* rejected the argument that "FDA's power to approve or to disapprove labeling changes, *by itself*, pre-empts state law" (emphasis added)). By contrast, only a few dozen drugs have REMS with ETASU, and Congress specifically directed FDA to monitor those drugs on an ongoing basis and update their REMS as needed to ensure that any restrictions are appropriate and not unduly burdensome. *See* 21 U.S.C. § 355-1(f)(2), (f)(5), (g)(4). With respect to REMS drugs, Congress thus charged FDA with performing the "precise balancing of risks and benefits" that was absent from the routine labeling review at issue in *Wyeth*. 555 U.S. at 575.

Second, as part of fulfilling that statutory responsibility, FDA specifically "consider[ed] and reject[ed]" the very restrictions North Carolina seeks to impose on mifepristone. *Id.* at 581 n.14. For example, after conducting a "full review of the Mifepristone REMS Program," FDA expressly determined that a requirement that mifepristone be provided in person by a physician in a specialized facility is not necessary to ensure patient safety and would unduly burden patient access and the healthcare system. FDA thus concluded that such a requirement would be unwarranted and inappropriate. Ex. P at 6, 10-13, 22-23, 26-37. That further distinguishes this case from *Wyeth*, where the Court emphasized that FDA had *not* considered and rejected the additional warnings required by state law. 555 U.S. at 581 n.14. And it makes

this case akin to *Geier*, where the agency had deliberately rejected the very airbag requirement the State sought to impose. *Id.* at 580; *Geier*, 529 U.S. at 878-79. Nor do North Carolina's restrictions serve any "distinct compensatory function." *Wyeth*, 555 U.S. at 579.[8]

B. Intervenors' remaining arguments lack merit.

Intervenors offer a few other arguments against obstacle preemption, but all are unpersuasive.

First, intervenors err when they claim that state law can "*only* be invalidated upon a 'direct and positive conflict' with the FDCA." MTD at 27 (quoting *Wyeth*, 555 U.S. at 567). Once again, intervenors are misrepresenting *Wyeth*. The "direct and positive conflict" language comes from a provision in the Drug Amendments of 1962—the law that established FDA's labeling-review authority that was at issue in *Wyeth*. That law provided only that "[n]othing in *the amendments made by this Act*" would preempt state law absent a "direct and positive conflict." Drug Amendments of 1962, Pub. L. No. 87-781, § 202, 76 Stat. 780, 793 (emphasis added). The REMS statute is not among "the amendments made by" the 1962 law; it was not added to the FDCA until 45 years later, when Congress enacted FDAAA in 2007. And FDAAA, unlike the 1962 law, contained no limitation on preemption. *See generally* 121 Stat. at 823-978.[9]

[8] It is notable that even in *Wyeth*, three Justices would have found the state-law warning requirements preempted under *Geier*. *See* 555 U.S. at 604 (Alito, J., joined by Roberts, C.J., and Scalia, J., dissenting). As explained above, the case for preemption is much stronger here.

[9] Indeed, Congress removed similar anti-preemption language from early FDAAA drafts to avoid "formalizing … a collection of State actions that may be contradictory to or inconsistent with FDA actions on safety and effectiveness of FDA-regulated products." *Hearing Before Subcomm. on Health, H. Comm. on Energy & Com.*, 110th Cong. 50 (2007) (statement of Mr. Lutter, FDA Deputy Comm'r).

Second, contrary to intervenors' suggestion, there is nothing "internally inconsistent" (MTD at 27) about concluding that when FDA subjects a drug to more extensive *federal* regulation under the REMS statute, it leaves less room for inconsistent *state* regulation. *Cf. Walker v. Medtronic, Inc.*, 670 F.3d 569, 572, 577 (4th Cir. 2012) (states have less leeway to regulate Class III medical devices, which receive "the highest level of federal oversight," than they do to regulate Class I and II devices, which receive much less federal oversight). And intervenors cannot plausibly describe North Carolina's laws as "[p]arallel" and "complementary" to FDA's regulations. MTD at 27. State laws that impose requirements FDA expressly rejected are neither parallel nor complementary, but contradictory. *Cf. Bates v. Dow Agrosciences LLC*, 544 U.S. 431, 447 (2005) (state requirements are "parallel" to federal law when they are "equivalent to, and fully consistent with," federal requirements).

Third, while intervenors invoke the presumption that federal law does not displace state regulation of matters of health and safety (MTD at 30-31), that presumption is overcome where, as here, state law presents "a sufficient obstacle" to federal law. *Crosby v. Nat'l Foreign Trade Council*, 530 U.S. 363, 374 n.8 (2000). Indeed, the dissent in *Geier* invoked the same presumption, to no avail. 529 U.S. at 894. Nor can intervenors escape preemption by claiming that the challenged laws "promote the same goals as the FDA's regulations." MTD at 26. Even where state and federal law share the same "ultimate goal," state law "stands as an obstacle to … federal law" if it "interferes with the methods" by which federal law pursues that goal. *Gade v. Nat'l Solid Wastes Mgmt. Ass'n*, 505 U.S. 88, 103 (1992) (cleaned up).

Finally, intervenors complain that although the REMS statute directs FDA to consider patient safety, patient access, and burdens on the healthcare system, it does not require the

agency to consider "other important interests" such as eliminating "gruesome or barbaric" medical procedures, preserving the "integrity of the medical profession," mitigating "fetal pain," and preventing discrimination. MTD at 30 (quotation marks omitted). But none of those interests are implicated here. North Carolina has not sought to eliminate medication abortion; the challenged laws have nothing to do with the interests intervenors recite; and Dr. Bryant's professional integrity will not be imperiled by providing mifepristone in full compliance with the terms of her federal prescriber certification. In any event, the "relative importance to the State of its own law is not material when there is a conflict with a valid federal law, for any state law, however clearly within a State's acknowledged power, which interferes with or is contrary to federal law, must yield." *King v. McMillan*, 594 F.3d 301, 309 (4th Cir. 2010) (quoting *Felder v. Casey*, 487 U.S. 131, 138 (1988)).

CONCLUSION

Intervenors' motion to dismiss should be denied.

Respectfully submitted,

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CERTIFICATE OF COMPLIANCE

I certify that the foregoing document complies with Local Rules 7.1(a) and 7.3(d) because it uses 13-point Garamond font; its top margin is not less than 1.25 inches and its bottom, left, and right margins are each one inch; and it contains 6,235 words.

Date: April 28, 2023

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CERTIFICATE OF SERVICE

I hereby certify that on April 28, 2023, the foregoing pleading was filed via the Court's CM/ECF System, which will effect service upon all registered counsel of record.

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