IN THE UNITED STATES DISTRICT COURT
FOR THE MIDDLE DISTRICT OF NORTH CAROLINA

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| AMY BRYANT, M.D., Plaintiff, | ) | |
| v. | ) | 1:23-CV-77 |
| JOSHUA H. STEIN, in his official capacity as Attorney General for the State of North Carolina, et al., Defendants. | ) | |

**MEMORANDUM OPINION AND ORDER**

Catherine C. Eagles, Chief District Judge.

Under the Food, Drug, and Cosmetic Act, the Food and Drug Administration is responsible for evaluating the safety and efficacy of prescription drugs and setting restrictions on their lawful use and distribution within the United States. Outside the terms of FDA approval, such drugs cannot be distributed legally in this country. Under the 2007 amendments to that Act, Congress increased and expanded the FDA's duties, and, as is most relevant here, imposed extensive obligations and responsibilities that the FDA must meet when it evaluates and sets restrictions on higher-risk drugs.

The State of North Carolina has imposed additional requirements beyond what the FDA requires on the distribution of one of these drugs and what must occur before such distribution. The plaintiff, a medical doctor who prescribes this medication, contends that these additional requirements are preempted by federal law. The defendant-intervenors, North Carolina state legislative leaders, contend in part that without the additional state

requirements the drug is not safe, and as to some of the requirements, they point to other state interests supported by the state laws.

This case thus raises the question of whether and when a state can impose additional requirements on the distribution of an FDA-approved drug. While this case concerns the distribution of a drug used to terminate a pregnancy, a similar case could arise over any drug, from FDA-approved thyroid or diabetes medications, drugs for cancer treatment, vaccinations, contraceptives, or opioids for pain management.

The Court finds and concludes that to the extent North Carolina law imposes safety restrictions on the distribution of the drug that the FDA has implemented and then later affirmatively rejected and removed, those laws frustrate the congressional goal of establishing a comprehensive regulatory framework under which the FDA determines conditions for safe drug distribution that do not create unnecessary burdens on the health care system or patient access. The provisions of the North Carolina law that prohibit health care providers other than physicians from prescribing the drug, require in-person prescribing, dispensing, and administering, mandate the scheduling of an in-person follow-up appointment, and require non-fatal adverse event reporting to the FDA stand as obstacles to Congress' purpose and are preempted.

But to the extent North Carolina law imposes requirements that have not been expressly considered and rejected by the FDA or that focus more on the practice of medicine and a patient's informed consent, these provisions do not interfere with Congress' purpose and are not preempted. This includes the state's requirements for an

in-person advance consultation, use of an ultrasound, an in-person examination, blood type testing, and adverse event reporting to state health authorities.

Summary judgment will be entered accordingly.

## I. Introduction

The FDA approved Mifeprex, the brand name of mifepristone, for distribution in 2000, subject to numerous restrictions and label requirements. *See generally* Doc. 82-4. Mifepristone is taken in a regimen with another drug to terminate a pregnancy. *See* Doc. 100-11 at 19. When the FDA approved Mifeprex, it included conditions on distribution to assure safe use of the drug under Subpart H of the FDA's regulations. *See* Doc. 82-4 at 7; *see also* 21 C.F.R. §§ 314.500–314.560.[1]

In 2007, Congress enacted the Food and Drug Administration Amendments Act ("FDAAA" or "the 2007 amendments"). *See* Pub. L. No. 110-85, 121 Stat. 823 (2007). These amendments made major changes to the Food, Drug, and Cosmetic Act and to the responsibilities and duties of the FDA. One such change was the addition of a requirement that for certain categories of drugs, the FDA must create risk evaluation and mitigation strategies ("REMS") when "necessary to ensure that the benefits of [a] drug outweigh the risks of the drug." 21 U.S.C. § 355-1(a)(1). Congress deemed drugs already approved with safety conditions under Subpart H of the FDA's regulations to

[1] The FDA approves drugs under Subpart H if it finds the drugs "can be safely used only if distribution or use is restricted." 21 C.F.R. § 314.520(a) (2023). Any restrictions must be "commensurate with the specific safety concerns" of the drug. § 314.520(b).

have a REMS in effect under the 2007 amendments and required those responsible for these approved drugs to submit a proposed REMS to the FDA. *See* 121 Stat. at 950–51.

At a minimum, a REMS must include a timeline for periodic reassessment of the REMS strategy. *See* §§ 355-1(c)–(d). It can also contain two other types of requirements outlined in statute: (1) "additional potential elements of strategy," if the FDA decides that such elements mitigate a serious risk of the drug, *see* § 355-1(e), and (2) elements to assure safe use ("ETASUs") for drugs with "inherent toxicity or potential harmfulness." *See* § 355-1(f). If the FDA includes an ETASU, it must make sure that the element mitigates "a specific serious risk listed in the labeling of the drug," § 355-1(f)(3), and is not "unduly burdensome on patient access to the drug." § 355-1(f)(2)(C). To the extent possible, the FDA should also implement an ETASU in a way that "minimize[s] the burden on the health care delivery system." § 355-1(f)(2)(D).

The manufacturers of Mifeprex submitted proposed REMS restrictions to the FDA pursuant to the FDAAA. *See* Doc. 82-9 at 2. In 2011, the FDA adopted a REMS program for the drug that incorporated the original Subpart H restrictions. *See id.* at 2, 5; Doc. 82-8 at 2–4 (2011 Mifeprex REMS).[2] The REMS included a number of ETASUs, discussed in more detail *infra* pp. 13–17.

As required by statute, *see* § 355-1(d), the FDA has reevaluated the mifepristone REMS elements periodically. Several times since 2000, it has altered and reduced the restrictions and ETASUs on Mifeprex and its generic equivalent mifepristone.

[2] Doc. 82-8 is undated, but the parties do not dispute that it was the 2011 REMS.

In 2023, North Carolina revised its laws governing pregnancy termination in an act entitled "Abortion Laws." *See* 2023 N.C. Sess. Laws 2023-14; N.C. Gen. Stat. §§ 90-21.80–21.99 (2023). As part of those laws, the state imposes many restrictions around the use and distribution of abortion-inducing drugs, including mifepristone. *See* § 90-21.81(1a) (naming mifepristone in the definition of "[a]bortion-inducing drug"); § 90-21.83A; § 90-21.83B. These restrictions include some of the same restrictions that the FDA implemented in the past and later removed. *See* discussion *infra* pp. 34–41.

The plaintiff, Dr. Amy Bryant, contends that some of the state laws that regulate the use and distribution of mifepristone stand as an obstacle to the full purpose and objectives of Congress identified in the 2007 amendments and thus are preempted. The defendant, the Attorney General, generally agrees with the plaintiff. The defendant-intervenors, state legislative leaders Timothy Moore and Philip Berger, contend that the state laws are not preempted and do not impose such an obstacle, relying primarily on a state's traditional authority to pass laws for the health and safety of its citizens. In the alternative, the defendant-intervenors contend that the major questions doctrine precludes implied preemption.

## II. Procedural Background

After the plaintiff filed her amended complaint, Doc. 82, the defendant-intervenors filed a motion to dismiss. Doc. 83. All parties briefed the motion to dismiss, Doc. 84; Doc. 85; Doc. 86; Doc. 88, and the Court held a hearing on the motion on January 17, 2024. *See* Minute Entry 01/17/2024. During that hearing, the Court confirmed with the parties that there were no disputed questions of fact, and with the consent of all parties,

converted the motion to dismiss into cross-motions for summary judgment. *See id.* The parties have since filed additional briefing on the summary judgment motions, Doc. 98; Doc. 99; Doc. 100, and the matter is ripe for resolution.

## III. Preemption

The Supremacy Clause of the Constitution dictates that "the Laws of the United States" are "the supreme Law of the Land." U.S. CONST. art. VI. "[T]his means that 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), *petition for cert. filed*, No. 23-785 (U.S. Jan. 17, 2024); *accord S. Blasting Servs., Inc. v. Wilkes Cnty.*, 288 F.3d 584, 589 (4th Cir. 2002).

Courts "must not presume federal law preempts state law." *Guthrie*, 79 F.4th at 336. Indeed, "in all preemption cases," courts "start with the assumption that the historic police powers of the states are not to be superseded by the federal act unless that was the clear and manifest purpose of Congress." *Wyeth v. Levine*, 555 U.S. 555, 565 (2009) (cleaned up); *see also S. Blasting Servs.*, 288 F.3d at 589–90 (stating any analysis of preemption begins "with the basic assumption that Congress did not intend to displace state law" (quoting *Maryland v. Louisiana*, 451 U.S. 725, 746 (1981))). This presumption against preemption is especially strong when dealing with matters traditionally left to the states, such as public health and safety, the practice of medicine, and the regulation of medical professionals. *See Wyeth*, 555 U.S. at 565.[3]

[3] *See also Hillsborough Cnty. v. Automated Med. Lab'ys Inc.*, 471 U.S. 707, 719 (1985) (stating "the regulation of health and safety matters is primarily, and historically, a matter of local

Preemption can either be express or implied. *See Altria Grp., Inc. v. Good*, 555 U.S. 70, 76 (2008) ("Congress may indicate pre-emptive intent through a statute's express language or through its structure and purpose"). Implied preemption includes conflict preemption, *id.* at 76–77; *Guthrie*, 79 F.4th at 336–37, which can be divided further into impossibility preemption and obstacle preemption. *See Crosby v. Nat'l Foreign Trade Council*, 530 U.S. 363, 372–73 (2000); *Silkwood v. Kerr-McGee Corp.*, 464 U.S. 238, 248 (1984). Obstacle preemption exists "where state law stands as an obstacle to the accomplishment of the full purposes and objectives of Congress." *Silkwood*, 464 U.S. at 248 (cleaned up); *accord Guthrie*, 79 F.4th at 337. While courts often categorize and subdivide the types of preemption, these categories "are not rigidly distinct." *Va. Uranium, Inc. v. Warren*, 139 S. Ct. 1894, 1901 (2019) (quoting *Crosby*, 530 U.S. at 372 n.6).

In this case, the plaintiff contends that the challenged state laws present an obstacle to the accomplishment of Congress' objectives.[4] When courts evaluate obstacle

concern"); *Watson v. Maryland*, 218 U.S. 173, 176 (1910) (holding that "[i]t is too well settled to require discussion at this day that the police power of the states extends to the regulation of certain trades and callings, particularly those which closely concern the public health" and discussing licensing of medical practitioners); *Gonzales v. Carhart*, 550 U.S. 124, 157 (2007) ("Under our precedents it is clear the State has a significant role to play in regulating the medical profession."); *Barsky v. Bd. of Regents*, 347 U.S. 442, 451 (1954) (indicating that the state has "legitimate concern for maintaining high standards of professional conduct" in the practice of medicine); *Buckman Co. v. Plaintiffs' Legal Comm.*, 531 U.S. 341, 348 (2001) (identifying "historic primacy of state regulation of matters of health and safety").

[4] All parties and the defendant-intervenors agree that Congress has not explicitly preempted state regulation of pharmaceutical drugs. The plaintiff does not contend that there is field preemption or that it is impossible to comply with both state and federal law. *See* Doc. 85 at 32 n.8; Doc. 96 at 13.

preemption, they first examine "the clear and manifest purpose of Congress" in enacting the federal law. *Wyeth*, 555 U.S. at 565 (holding congressional purpose is "ultimate touchstone in every preemption case"). After courts identify Congress' purpose, they evaluate whether the state law or regulation will "prevent or frustrate the accomplishment of a federal objective." *Geier v. Am. Honda Motor Co.*, 529 U.S. 861, 873 (2000); *accord Guthrie*, 79 F.4th at 338. If it does, the conflicting state law is nullified by the Supremacy Clause. *Geier*, 529 U.S. at 873. And when a state adopts a law that imposes a requirement a federal agency deliberately rejected because it conflicts with Congress' goals, then it is preempted. *See id.* at 881 (finding conflict preemption where plaintiff sought to impose automobile safety requirement federal agency had deliberately rejected); *Bethlehem Steel Co. v. N.Y. State Lab. Rels. Bd.*, 330 U.S. 767, 774 (1947) (noting state regulation preempted where federal agency had determined that the regulation was not appropriate); *see also Wyeth*, 555 U.S. at 581 n.14 (declining to find preemption and distinguishing *Geier* because the FDA "did not consider and reject" additional warnings).

## IV. The Food and Drug Administration and its Governing Law

Congress passed the Federal Food and Drug Act in 1906 to prohibit "the manufacture or interstate shipment of adulterated or misbranded drugs." *Wyeth*, 555 U.S. at 566. The Act "supplemented the protection for consumers already provided by state regulation and common-law liability." *Id.* Some 30 years later, in 1938, Congress enacted the Food, Drug, and Cosmetic Act, creating the Food and Drug Administration. *See id.*; *Zogenix, Inc. v. Patrick*, No. 14-CV-11689, 2014 WL 1454696, at *2 (D. Mass.

Apr. 15, 2014). The FDCA required, among other things, that every drug manufacturer submit a new drug application ("NDA") to the FDA for pre-market approval of drugs and their labels. *Wyeth*, 555 U.S. at 566; 21 U.S.C. § 355(a). If the FDA did not act, the "application became effective 60 days after the filing." *Wyeth*, 555 U.S. at 566.

Congress amended the FDCA in 1962 to shift the burden to the manufacturer to show that a drug was safe and effective before the FDA could approve it. *Id.* at 567. With this change, a drug could not be sold until the FDA gave affirmative approval. *See id.* Congress included a savings clause as part of the amendments providing that "[n]othing in the amendments made by this Act" invalidates "any provision of State law which would be valid in the absence of such amendments unless there is a direct and positive conflict." *See* Drug Amendments of 1962, Pub. L. No. 87-781, § 202, 76 Stat. 780, 793.

Through regulation, the FDA established requirements for new drug applications submitted by manufacturers. *See* 21 C.F.R. § 314; *see generally Burroughs Wellcome Co. v. Schweiker*, 649 F.2d 221, 223 (4th Cir. 1981) (describing NDA process then in place under statute and regulation). NDAs must include relevant clinical data, the labeling proposed for the drug, and "a discussion of why the drug's benefits exceed the risks under the conditions stated in the labeling." *Mut. Pharm. Co. v. Bartlett*, 570 U.S. 472, 476 (2013) (cleaned up). The FDA may approve an NDA only if it finds that the drug in question is "safe for use" under "the conditions of use prescribed, recommended, or suggested in the proposed labeling thereof." *Id.* (quoting 21 U.S.C. § 355(d)). For the

FDA to find a drug safe, the drug's "probable therapeutic benefits must outweigh its risk of harm." *Id.* (cleaned up).

The FDA also began to evaluate some drugs with conditions of restricted use or distribution under a regulation known as Subpart H. *See* 21 C.F.R. §§ 314.500–314.560. When the FDA approved drugs under Subpart H, it could limit distribution "to certain facilities or physicians with special training or experience," or condition distribution "on the performance of specified medical procedures." § 314.520. Thus, the FDA could regulate the practice of medicine to a limited extent as it related to the prescribing of these drugs.

In 2007, Congress again amended the FDCA when it enacted the FDAAA. Pub. L. No. 110-85, 121 Stat. 823 (2007). Among other things, Congress gave the FDA[5] the authority to decide if a risk evaluation and mitigation strategy ("REMS") "is necessary to ensure that the benefits of [a] drug outweigh the risks of the drug." 21 U.S.C. § 355-1(a)(1). Congress authorized the FDA to require a REMS as part of an NDA and directed the FDA to consider certain factors when it decides whether a REMS program is necessary for a new drug. *See id.*[6] The FDA can also impose a REMS program for a

[5] Congress expressly delegates the authority to decide whether a REMS is necessary and what restrictions should be included in a REMS to the Secretary of Health and Human Services, "in consultation with the office responsible for reviewing the drug and the office responsible for post approval safety with respect to the drug." *See* § 355-1(a)(1) (cleaned up); § 355-1(c)(2). For simplicity and ease of reading, the Court refers to the FDA instead of individual agency members when discussing the authority to implement and manage REMS programs.

[6] For new drugs, Congress directed the FDA to consider the following in deciding whether a REMS is necessary to ensure that the benefits of the drug outweigh the risks of the drug:

(A) The estimated size of the population likely to use the drug involved.

(B) The seriousness of the disease or condition that is to be treated with the drug.

drug it has already approved if it "becomes aware of new safety information" that makes "such a strategy necessary." § 355-1(a)(2) (cleaned up).[7] If the FDA approves a drug subject to a REMS, then a person may not introduce or deliver the drug into interstate commerce if "the person fails to maintain compliance with the requirements of the approved strategy." § 355(p)(1)(B). Any holder of a drug application previously approved with Subpart H restrictions had to submit a proposed REMS so the drug could be considered by the FDA under the 2007 amendments. *See* Pub. L. No. 110-85, 121 Stat. 823, 950–51 (2007); *see also* discussion *supra* pp. 3–4.

As part of a REMS program, Congress authorized the FDA to require additional restrictions on use called "elements to assure safe use" ("ETASUs") for drugs that have "inherent toxicity or potential harmfulness." §§ 355-1(f)(1), (3). The FDA can require ETASUs for a drug when other elements authorized by statute are not sufficient "to mitigate a specific serious risk." §§ 355-1(f)(1)(A), (B). These drugs "can be approved only if, or would be withdrawn unless," they have ETASUs in place. § 355-1(f)(1)(A). Any ETASUs must be "commensurate with" and promote the goal of mitigating "a specific serious risk listed in the labeling of the drug." §§ 355-1(f)(2)(A), (3). Congress

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(C) The expected benefit of the drug with respect to such disease or condition.
(D) The expected or actual duration of treatment with the drug.
(E) The seriousness of any known or potential adverse events that may be related to the drug and the background incidence of such events in the population likely to use the drug.
(F) Whether the drug is a new molecular entity.

§ 355-1(a)(1).

[7] Because the FDA does not rely on a defined category of drugs or a specific risk factor to decide when a drug needs a REMS strategy, the Court will at times refer to drugs generally subject to REMS requirements as "higher-risk drugs."

also required that any ETASU must not be "unduly burdensome on patient access to the drug," and must be implemented "so as to minimize the burden on the health care delivery system." §§ 355-1(f)(2)(C), (D).

Congress authorized the FDA to require ETASUs that impose restrictions on physicians and pharmacies that dispense REMS drugs. *See, e.g.*, § 355-1(f)(3)(B). Among other things, Congress specifically said that the FDA could require that (A) health care providers who prescribe the drug have specific training, experience, or certification, (B) pharmacies that dispense the drug get special certification, (C) the drug be dispensed only in certain settings, and (D) patients receive documentation outlining safe-use conditions. *See* §§ 355-1(f)(3)(A)–(D). Thus, Congress authorized the FDA to regulate the practice of medicine in connection with REMS drugs, at least to a degree.

A REMS must include a timetable for ongoing assessments by the FDA of these risk evaluation and mitigation strategies. *See* §§ 355-1(c), (d). Congress authorized the FDA to require additional assessments beyond those statutorily required. *See* § 355-1(g). When the FDA conducts a strategy assessment, it must review all REMS requirements, including any ETASUs, and assess whether the requirements continue to allow safe use without unduly burdening patient access or the health care system. §§ 355-1(f)(5)(B), (g)(2)(C); *see also* discussion *supra* p. 4. The FDA can eliminate the risk assessments after three years if it "determines that serious risks of the drug have been adequately identified and assessed and are being adequately managed." *See* § 355-1(d)(4)(C).

Once a drug is subject to a REMS, the holder of an approved application or the FDA can initiate modification of the REMS. *See* § 355-1(g)(4). A citizen can also ask

the FDA to modify a REMS program through a citizen petition. *See* 21 C.F.R. § 10.30; *see also* Doc. 82-16 (FDA response to 2019 citizen petition). Proposed modifications do not take effect unless and until they are approved by the FDA. *See* 21 U.S.C. §§ 355-1(h)(2)(A), (B).

In the 2007 amendments, Congress did not address preemption.

## V. Regulatory History of Mifepristone

In 2000, the FDA approved Mifeprex, the brand name of mifepristone, with distribution restrictions under Subpart H. Doc. 82-3 at 2. The original Subpart H restrictions required that Mifeprex could only be "provided by or under the supervision of a physician" who was qualified by the FDA and who had signed the Prescriber Agreement. *Id.* at 3; Doc. 82-6 (2000 Prescriber Agreement). Among other things, a certified physician had to (1) be able to accurately assess the duration of pregnancy and diagnose ectopic pregnancies, (2) provide surgical intervention or have plans to provide surgical intervention through others if needed, (3) give patients a Medication Guide and Patient Agreement and obtain a signed Patient Agreement, (4) fully explain the procedure, and (5) report any hospitalizations or serious adverse events. *See* Doc. 82-3 at 3. Patients had to take the medication in their provider's office and had to agree to return for a follow-up appointment. *See* Doc. 82-7 at 2 (2000 Patient Agreement).

Because the FDA approved Mifeprex with Subpart H restrictions, Mifeprex automatically had a REMS in place when the 2007 amendments became effective. *See* Pub. L. No. 110-85, 121 Stat. 823, 950–51 (2007). In September 2008, the manufacturer

of Mifeprex submitted a proposed REMS, as required by the 2007 amendments, which the FDA adopted in 2011. *See id.*; Doc. 82-9 at 2, 5.

Because of the drug's "inherent toxicity or potential harmfulness," 21 U.S.C. § 355-1(f)(1), the 2011 Mifeprex REMS program included as ETASUs the same distribution restrictions that Mifeprex had in place under Subpart H before the 2007 amendments. *Compare* Doc. 82-4 at 7 (2000 approval memorandum), *with* Doc. 82-8 at 2–3, 8, 10 (2011 REMS). Physicians prescribing Mifeprex had to (1) be able to accurately assess the duration of pregnancy and diagnose ectopic pregnancies, (2) provide surgical intervention or have plans to provide surgical intervention through others if needed, (3) give patients a Medication Guide and Patient Agreement and obtain a signed Patient Agreement, (4) fully explain the procedure, and (5) report any hospitalizations or serious adverse events. *See* Doc. 82-8 at 8 (2011 Prescriber Agreement). The FDA required patients to take Mifeprex in their provider's office and attend an in-person follow-up appointment 14 days after taking the drug. *Id.* at 10. The FDA also required that Mifeprex only be dispensed "in certain health care settings, specifically clinics, medical offices, and hospitals." *Id.* at 3.

In 2015, the manufacturer of Mifeprex proposed modifications to the REMS. *See* Doc. 82-11 at 3. The FDA assessed the REMS to "determine whether each Mifeprex REMS element remain[ed] necessary to ensure that the drug's benefits outweigh the risks" and found that the REMS should be modified, *id.*, which happened the next year.

In those 2016 changes, the FDA decided that the limitation that only physicians could prescribe Mifeprex was not necessary and began allowing other medical

professionals to prescribe the drug. *See* Doc. 82-12 at 7 (rationale for expanding prescribing to qualified health care providers); Doc. 82-14 at 6 (2016 Prescriber Agreement). The requirement that Mifeprex only be dispensed in-person "in certain health care settings, specifically clinics, medical offices, and hospitals" remained in place, Doc. 82-14 at 3 (cleaned up); in other words, the drug could not be picked up at a pharmacy. And providers still had to (1) be able to accurately assess the duration of pregnancy and diagnose ectopic pregnancies, (2) provide surgical intervention or have plans to provide surgical intervention through others if needed, (3) give patients a Medication Guide and Patient Agreement and obtain a signed Patient Agreement, and (4) fully explain the procedure. *Id.* at 2–3.

But the FDA removed the requirement that patients must take Mifeprex in their providers' offices and the requirement that patients must return for an in-person follow-up appointment 14 days later. *Compare* Doc. 82-8 at 10 (2011 Patient Agreement), *with* Doc. 82-14 at 8 (2016 Patient Agreement). Patients were still encouraged to follow-up with their providers seven to 14 days after taking the drug but were not required to come back to their provider's office. *See* Doc. 82-14 at 8. The FDA also removed the requirement that providers report any hospitalizations or serious adverse events; the only adverse events providers were required to report going forward were deaths. *Id.* at 3.

In 2019, the FDA approved a generic version of Mifeprex subject to the same REMS. Doc. 82-16 at 5. The shared REMS is often referred to as the mifepristone REMS program. *Id.*

Early in the COVID-19 pandemic, the American College of Obstetricians and Gynecologists ("ACOG") sued the FDA, seeking a preliminary injunction to prevent the FDA from enforcing the mifepristone in-person dispensing requirement. *See* Doc. 82-17 at 8. After initially resisting the injunction,[8] the FDA announced in April 2021 that it would not enforce the in-person dispensing requirement, given the COVID-19 pandemic, so long as the other mifepristone REMS elements were followed. *Id.* at 8–9.

A few weeks later, on May 7, 2021, the FDA said it would review the mifepristone REMS program. *Id.* at 9. After the FDA conducted an extensive review and the manufacturers of the drug submitted multiple proposed modifications, *see* Doc. 82-20 at 4, the FDA decided the mifepristone REMS program needed revisions. Doc. 82-18 at 2.

In December 2021, the FDA removed the in-person dispensing requirement, finding that it was not needed for safety and that removal would make the REMS "less burdensome to health care providers and patients." Doc. 82-16 at 2, 7 (cleaned up). The FDA also decided that a pharmacy certification requirement and Pharmacy Agreement form should be added to the REMS, because removal of the prescriber, in-person dispensing requirement meant pharmacies could now dispense the drug. *See* Doc. 82-18 at 2–3; Doc. 82-20 at 10. The FDA found these changes were necessary "to minimize the burden on the health care delivery system of complying with the REMS and to ensure

[8] In July 2020, a Maryland district court granted the preliminary injunction. Doc. 82-17 at 8; *ACOG v. FDA*, 472 F. Supp. 3d 183, 233 (D. Md. 2020). In January 2021, the Supreme Court granted a stay of the injunction "pending disposition of the appeal" in the Fourth Circuit. *FDA v. ACOG*, 141 S. Ct. 578, 578 (2021). On May 19, 2021, the Fourth Circuit dismissed the appeal as moot. *See sub nom. ACOG v. Indiana*, No. 20-CV-1320, 2021 WL 3276054, at *1 (4th Cir. May 19, 2021).

that the benefits of the drug outweigh the risks." Doc. 82-20 at 10; *see also id.* at 20–22 (FDA discussion of proposed modifications).

As of 2023, the mifepristone REMS allows a certified provider, who need not be a physician, to prescribe mifepristone to a patient. *See* Doc. 82-1 at 2–3 (January 2023 REMS referencing health care providers); Doc. 82-12 at 7 (reasoning for change from "physician" to "health care provider" in 2016). The provider must (1) be able to accurately assess the duration of pregnancy and diagnose ectopic pregnancies, (2) provide surgical intervention or have plans to provide surgical intervention if needed, (3) give patients a Patient Agreement and obtain a signed Patient Agreement, (4) fully explain the procedure, and (5) report any deaths. *See* Doc. 82-1 at 2–3. Patients can get the medicine either directly from a health care practitioner, someone working under the practitioner's supervision, or a certified pharmacy after being provided a prescription from a health care practitioner. *See id.* at 7–8, 11–12. The patient can then take the drug at a location of her choice, including her home. *See id.* at 11.

## VI. The North Carolina Statutory Provisions at Issue

In North Carolina, subject to extensive regulatory, procedural, and medical requirements, it is lawful to procure or cause an abortion, including a "medical abortion"[9] using mifepristone, during the first 12 weeks of a person's pregnancy. N.C. Gen. Stat. § 90-21.81B(2); *see generally* §§ 90-21.80–21.99. Dr. Bryant contends that several of

[9] The plaintiff uses the term medication abortion, but the statute uses the phrase "medical abortion." § 90-21.81(4e). The Court will use the term "medical abortion" to be consistent with the language of the relevant state law.

the state requirements create an obstacle to Congress' purpose in delegating to the FDA the ability to establish, monitor, and update REMS programs through the FDAAA. *See* Doc. 99 at 10–15.

In summary, Dr. Bryant challenges the North Carolina requirements (1) that only physicians can prescribe mifepristone, (2) that physicians prescribing mifepristone must dispense and administer the drug in-person, (3) that the drug can only be prescribed after an in-person examination, determination of the patient's blood type and gestational age by ultrasound, and an in-person consultation, (4) that a provider must schedule a follow-up appointment with the patient and document all efforts to get the patient to attend the appointment, and (5) that providers must report all "adverse events" and "complications," both defined broadly, to the state and the FDA.

Medical professionals who violate these provisions, collectively called in the statute "Abortion Laws," § 90-21.80, can face professional, civil, and criminal penalties. Possible repercussions include discipline by the appropriate licensing agency or board, *see* § 90-21.88A, or a civil action for damages and attorneys' fees if the person seeking damages can show that the physician acted in "knowing or reckless violation of [the] Article." §§ 90-21.88(a), (c). Criminal penalties can include a fine of $5,000 per violation for "any individual within the State, including a physician" who violates the in-person requirements of § 90-21.83A(b)(2)a. *See* §§ 14-44.1(a)(1), (b).[10]

[10] There has been no challenge to Dr. Bryant's standing, and she has standing to contest the laws. Dr. Bryant personally faces civil and criminal penalties, §§ 90-21.88(a), (c); § 14-44.1, and the possibility of professional discipline, § 90-21.88A, if she provides a medical abortion to a patient in violation of these laws. The credible threat of these types of injuries can support a

North Carolina's Abortion Laws contain a severability clause. *See* § 90-21.92. If any portion of the law "is found to be unconstitutional," that portion will be declared severable from the law, and "the balance of [the] Article shall remain effective." *Id.*

**VII. Obstacle Preemption**

As discussed previously, health and safety matters, the practice of medicine, and the regulation of medical professionals are traditionally matters of state concern. *See supra* p. 6; note 3. States have an interest in promoting maternal health and safety and may regulate to that end, within constitutional bounds. *See Dobbs v. Jackson Women's Health Org.*, 597 U.S. 215, 300–01 (2022). As the Supreme Court said in *Dobbs*, "a law regulating abortion, like other health and welfare laws, is entitled to a strong presumption of validity" because there are legitimate state interests in "respect for and preservation of prenatal life," "the protection of maternal health and safety," and "the preservation of the integrity of the medical profession." *Id.* at 301 (cleaned up).

At the same time, Congress has delegated to the FDA the authority to regulate higher-risk drugs through a REMS program. *See* 21 U.S.C. § 355-1. For drugs with "inherent toxicity or potential harmfulness," § 355-1(f)(1), Congress has directed the FDA to implement ETASUs that impact matters of health and safety, the regulation of medical professionals, and the practice of medicine. *See* § 355-1(f)(3) (authorizing the

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plaintiff's standing. *See, e.g.*, *Am. Inst. of Certified Pub. Accts. v. IRS*, 746 F. App'x 1, 6 (D.C. Cir. 2018) (discussing injury sufficient to create standing based on potential professional discipline, including "suspension, disbarment, disqualification or monetary penalties"). And, as a doctor who provides obstetric and gynecological services, Dr. Bryant can assert third-party standing. *See June Med. Servs. L.L.C. v. Russo*, 591 U.S. 299, 318 (2020) (collecting cases), *abrogated on other grounds by Dobbs v. Jackson Women's Health Org.*, 597 U.S. 215 (2022).

FDA to, among other things, require health care providers prescribing a REMS drug to have specific training, experience, or certification and to limit the settings where a REMS drug can be dispensed); *see also* discussion *supra* p. 12.

Given Congress' explicit permission and requirement that the FDA regulate aspects of the practice of medicine as to REMS drugs, the mere fact that a state law regulates the practice of medicine as to that drug does not give the law an automatic free pass to avoid a preemption challenge. *See* Patricia J. Zettler, *Pharmaceutical Federalism*, 92 IND. L.J. 845, 862, 870–73 (2017). On the other hand, there is an obvious tension and overlap between state and federal regulation of prescription drugs and the providers who prescribe and distribute them. *See id.* at 852 (noting "the boundary between medical practice and medical products – which is thought to serve as a dividing line between federal and state jurisdiction today – has long been blurry"). As the Supreme Court noted in a case refusing to find obstacle preemption under a previous version of the FDCA, "federal preemption is particularly weak where Congress has indicated its awareness of the operation of state law in a field of federal interest and has nonetheless decided to stand by both concepts and to tolerate whatever tension there is between them." *Wyeth*, 555 U.S. at 575 (quoting *Bonito Boats, Inc. v. Thunder Craft Boats, Inc.*, 489 U.S. 141, 166–67 (1989)) (cleaned up).

*Wyeth*, however, dealt with a state tort lawsuit for inadequate labeling of a prescription drug, which this case does not concern, and it arose before the enactment of the 2007 amendments. *See id.* at 567. Those amendments, discussed *supra* pp. 10–13, significantly increased the FDA's regulatory role and responsibilities for certain

prescription drugs like mifepristone. *Wyeth* also did not involve a state's imposition of requirements that a federal agency had affirmatively and clearly rejected as unnecessary or inappropriate, which the Supreme Court has held can constitute obstacle preemption. *See Geier*, 529 U.S. at 881. Thus, as the Supreme Court did in *Wyeth* and in *Geier*, it is necessary to examine "Congress' significant objectives" in passing the 2007 amendments and then to decide whether the North Carolina statutes at issue "stand as an obstacle to the accomplishment of a significant federal regulatory objective." *Va. Uranium, Inc. v. Warren*, 848 F.3d 590, 599 (4th Cir. 2017) (cleaned up), *aff'd*, 139 S. Ct. 1894 (2019); *accord Guthrie*, 79 F.4th at 338.

### A. Congress' Significant Objectives

To determine Congress' objectives and the nature of the federal interest, courts must "examine the federal statute as a whole and identify its purpose and intended effects." *Crosby*, 530 U.S. at 373 (cleaned up). The FDAAA is a detailed and complicated statute which made significant changes to many aspects of existing law. *See* Michelle L. Richards, *12 Angry Men v. The Agency: Why Preemption Should Resolve this Conflict in Drug Labeling Litigation*, 100 MARQ. L. REV. 1309, 1319 (2017) (calling the FDAAA "the most extensive revision of the FDCA since 1962"); Lindsey K. Peterson, *Evading Preemption: The State's Search for Recovery for the Masses*, 9 CHARLESTON L. REV. 403, 410 (2015) (referring to the FDAAA as an "overhaul of the FDCA").

As is most relevant here, Congress gave the FDA many more duties and responsibilities over the regulation of higher-risk drugs through the enactment of the

REMS statute. *See generally* 21 U.S.C. § 355-1. But there were many other big changes as well. For example, the amendments:

- increased public access to clinical trial results for FDA-approved products, *Seife v. U.S. Dep't of Health and Hum. Servs.*, 440 F. Supp. 3d 254, 264–65 (S.D.N.Y. 2020),
- limited the circumstances under which the FDA can delay an abbreviated new drug application because of a citizen petition, *see Apotex, Inc. v. Acorda Therapeutics, Inc.*, No. 11-CV-8803, 2013 WL 12617608, at *3 (S.D.N.Y. Feb. 7, 2013), *aff'd*, 823 F.3d 51 (2d Cir. 2016),
- enacted specific legislation pertaining to television advertising of drug products, *see Merck & Co., Inc. v. U.S. Dep't of Health and Hum. Servs.*, 385 F. Supp. 3d 81, 95 (D.D.C. 2019), *aff'd*, 962 F.3d 531 (D.C. Cir. 2020),
- gave the FDA "the authority to require post-approval studies and clinical trials and increase[d] the FDA's authority to require labeling changes to be made over a shorter time period in response to new safety information," Sara Lykken, *We Really Need to Talk: Adapting FDA Processes to Rapid Change*, 68 FOOD & DRUG L.J. 357, 368–69 (2013), and
- imposed "stricter conflict of interest rules on FDA advisory committees." *Id.* at 369.

The FDCA was traditionally known as a consumer protection statute designed in large part to protect consumers from unsafe drugs. *See Wyeth*, 555 U.S. at 566. In passing the 2007 amendments, Congress continued to promote consumer protection by

expanding the FDA's ability to regulate the sale and distribution of prescription drugs that benefit the public and to promote the safe use of those drugs. *See* Pub. L. No. 110-85, 121 Stat. 823, 823 (2007). As codified in the REMS statute, Congress had the clear and manifest purpose of making the FDA responsible for deciding what restrictions need to be imposed on the distribution of drugs with serious risks of harm and on the providers who prescribe and distribute those drugs. *See* 21 U.S.C. § 355-1.

Congress directed the FDA to decide when a REMS program is necessary, § 355-1(a), and delegated to the FDA the authority to decide the structure of a REMS program, § 355-1(c), a decision that can be made only by a subset of people within the FDA. *See* § 355-1(a)(4) (requiring that "individuals at or above the level of individuals empowered to approve a drug" shall make REMS decisions). Congress also required the FDA to continuously monitor REMS drugs and their restrictions for at least three years. *See* § 355-1(d). The FDA must decide what if any additional, appropriate elements of strategy are needed to reduce the risks of harm from a drug and must modify or remove restrictions that are unnecessary to assure safe use of drugs, all without over-restricting patient access or unduly burdening the health care system. *See* §§ 355-1(e), (f), (g)(4).

For drugs with an "inherent toxicity or potential harmfulness," like mifepristone, the statute directs the FDA to impose "elements to assure safe use" or ETASUs. *See* §§ 355-1(f)(1), (3); discussion *supra* pp. 11–12. Congress required that any ETASU imposed by the FDA be no broader than necessary to address risk. *See* § 355-1(f)(2)(A) (elements must "be commensurate with the specific serious risk" of the drug). And Congress expressly mandated that the FDA, "considering such risk," impose restrictions

that are not "unduly burdensome on patient access to the drug." § 355-1(f)(2)(C). Congress instructed the FDA to consider "patients who have difficulty accessing health care," § 355-1(f)(2)(C)(ii), and, "to the extent practicable," to impose restrictions that "minimize the burden on the health care delivery system." § 355-1(f)(2)(D). Congress thus had the additional clear and manifest objective of directing the FDA to regulate the safe use of drugs with inherent toxicity or potential harmfulness without unnecessarily reducing patient access or burdening the health care system.

The headings Congress used further clarify this purpose. The provision now codified at § 355-1(f), which covers drugs with inherent toxicity or potential harmfulness, is entitled "Providing Safe Access for Patients to Drugs with Known Serious Risks that Would Otherwise Be Unavailable." *See* Pub. L. No. 110-85, 121 Stat. 823, 930 (2007). The provision now codified at subsection (f)(1) is entitled "Allowing Safe Access to Drugs with Known Serious Risks," and subsection (f)(2) is entitled "Assuring Access and Minimizing Burden." *Id.* For these inherently toxic drugs, Congress' purpose was to make the FDA responsible for deciding upon and implementing safety restrictions to balance safety, efficacy, patient access, and burdens on the health care system.

Congress explicitly authorized and required the FDA to regulate who could prescribe these inherently toxic or potentially harmful drugs by empowering the FDA to require health care providers to "have particular training or experience or [be] specially certified." § 355-1(f)(3)(A). The FDA can also impose special certification requirements on "pharmacies, practitioners, or health care settings that dispense the drug" and limit the settings in which the drug can be dispensed. §§ 355-1(f)(3)(B), (C). And the FDA can

mandate that "documentation of safe-use conditions" be included with the drug and that patients using the drug be subject to certain monitoring or enrolled in a registry. *See* §§ 355-1(f)(3)(D)–(F).

Congress' clear and manifest purpose was thus to create a comprehensive federal strategy under which the FDA is responsible for deciding what safety restrictions on higher-risk drugs are necessary to make the use of those drugs less risky. *See* § 355-1; *see also Wyeth*, 555 U.S. at 565 (directing courts to identify congressional purpose). For drugs with inherent toxicity or potential harmfulness, Congress had the additional manifest purpose of requiring the FDA to regulate within the medical profession for the health and safety of patients and to regulate without unduly impeding patient access or burdening the health care system. *See* §§ 355-1(f)(2), (3). A state law that stands as an obstacle to this clear and manifest purpose of Congress is preempted. *See Guthrie*, 79 F.4th at 338; *see also Geier*, 529 U.S. at 881 (finding state tort lawsuit preempted where agency deliberately established federal regulatory scheme and specifically considered and rejected requirements that state law would impose); *Hillman v. Maretta*, 569 U.S. 483, 494 (2013) (holding state statute that interfered with congressional scheme and "frustrate[d] the deliberate purpose of Congress" was preempted).

A state law regulating the use and administration of an inherently toxic or potentially harmful drug like mifepristone based solely on its health and safety risks stands as an obstacle to Congress' goal of creating a comprehensive regulatory framework under which the FDA is responsible for deciding what terms are required for safe access to and use of these drugs while considering patient access and burdens on the

health care system. State laws which disagree or interfere with the FDA's judgments are preempted.

But nothing in the REMS statute or the FDAAA suggests that Congress intended to preempt all state informed consent laws concerning health conditions treated by prescription medicines or to restrict state rules that otherwise are directed to regulating medical care generally. A state health and welfare law focused on the protection of prenatal life, general patient health and safety, or broad regulation of the medical profession is thus not preempted by the REMS regulations.

**B. Preemption Analysis**

Some of the North Carolina statutory provisions at issue here concern general patient health and welfare and informed consent unrelated to mifepristone rather than the health and safety risks of the drug. Congress did not intend to preempt state regulation of medical care provided for a particular health condition merely because a REMS drug treats or is directed to that condition, and thus these state statutory provisions are not preempted. But other statutory provisions impose safety-related restrictions on the distribution of abortion-inducing drugs and stand as an obstacle to the congressional objective of providing a comprehensive regulatory system for the use and distribution of higher-risk drugs under the direction and supervision of the FDA. Those provisions are preempted. *See Warren*, 848 F.3d at 599; *Guthrie*, 79 F.4th at 338.

**1. North Carolina Statutory Provisions that are Not Preempted**

Neither the FDAAA nor the mifepristone REMS address broader health issues associated with pregnancy or with ensuring informed consent to the termination of a

pregnancy, about which the states remain free to regulate. Some of the state statutory requirements challenged here do just that.

**a. In-person Advance Consultation, Use of an Ultrasound, In-person Examination, and Blood Type Determination**

State law requires physicians or qualified professionals to complete an in-person consultation with the patient at least 72 hours in advance of prescribing mifepristone. N.C. Gen. Stat. § 90-21.83A(b)(1). The same requirement exists for surgical abortions. *See* § 90-21.82(b)(1). As part of this consultation, the provider and the patient must review the information in the consent form. *See* § 90-21.83A(b)(1); § 90.82(b)(1).[11] For medical abortions, the consent form contains "[i]nformation about Rh incompatibility," including treatment options for patients with Rh-negative blood type, § 90-21.83A(b)(2)g, and "[t]he probable gestational age" of the fetus determined through the patient's medical history and an ultrasound. § 90-21.83A(b)(2)b.

Providers must make patients aware of the probable gestational age of the fetus as part of the informed consent process for both surgical and medical abortions. *See* § 90-21.82(b)(1a)c; § 90-21.83A(b)(2)b. They must also report probable gestational age to the North Carolina Department of Health and Human Services. *See* §§ 90-21.93(a), (b)(6) (listing gestational age confirmed by ultrasound as reporting requirement for both procedures); *see also* § 90-21.82(b)(1a)c (requiring probable gestational age be provided to patients seeking surgical abortion, but not specifying use of ultrasound). The state

[11] This case does not concern mifepristone's labeling or allege any conflicts between state and federal law over what risks and safety concerns must be disclosed.

requires the use of an ultrasound to determine gestational age before both medical and surgical abortions. *See* §§ 90-21.93(a), (b)(6).[12]

A physician must also conduct an in-person examination of a patient seeking a medical abortion. *See* § 90-21.83B(a). As part of the in-person exam, the physician must "determine the woman's blood type" and "verify the probable gestational age" of the fetus. §§ 90-21.83B(a)(2), (6).

The state's in-person advance consultation, ultrasound, in-person exam, and blood type determination requirements implicate general patient health and safety, informed consent to the termination of a pregnancy, and regulation of the medical profession, all beyond regulating the safe use of mifepristone. The in-person advance consultation and ultrasound requirements impose standards of care for obtaining a patient's informed consent to the procedure. An ultrasound ensures that a person contemplating the termination of a pregnancy has access to required gestational age information obtained through a reliable method before she makes a decision. *See* § 90-21.83A (informed consent to medical abortion); § 90-21.82 (informed consent to surgical abortion).

And the in-person advance consultation requirement is not solely, or even primarily, directed to the risks of mifepristone. An in-person consultation lets patients talk with a health care provider in real time and without the distance created by telephone or video calls before deciding to terminate a pregnancy. The state statute itself offers reasons for the in-person exam requirement unconnected to safe use of the drug: it

[12] There is no explicit requirement that a physician conduct the ultrasound.

allows a physician to "verify that the pregnancy exists," "provide medically indicated diagnostic tests," and "screen the woman for coercion or abuse." §§ 90-2183B(a)(1), (3), (4) (cleaned up). And the blood type determination requirement exists so that a physician can "offer necessary medical services, treatment, and advice, based on the physician's reasonable medical judgment of any medical risks associated with the woman's blood type." § 90-21.83B(a)(2). It is undisputed that Rh-negative blood type can give rise to serious complications during pregnancy. *See* Doc. 82-16 at 19 (responding to a citizen petition, the FDA discusses Rh-negative patients and states that "Rh-testing is [the] standard of care in the United States").

Congress does not direct the FDA through the REMS statute to control the scope and extent of informed consent laws that address matters beyond the specific risks and benefits associated with a REMS drug. And the FDCA does not preempt state regulation designed to give a patient the information the state deems helpful to informed consent to a procedure and to a patient's long-term health. Nothing about these state laws that require medical providers to examine patients in person and address broader health and safety matters that can arise during pregnancy interferes with the purposes of the REMS statute. *See Dobbs*, 597 U.S. at 301 (identifying "protection of maternal health and safety" as legitimate state interest). And Congress did not intend by enacting the REMS statute to preempt all medical examinations or tests that might be beneficial for a patient seeking medical care related to a condition addressed by a REMS drug.

The presumption against preemption is especially strong as to these state law provisions because they broadly address pregnancy-related health matters. *See Dobbs*,

597 U.S. at 301. The health and safety of a state's citizens is traditionally a matter of state concern. *See supra* p. 6; note 3. And informed consent laws have long been the primary responsibility of the state, including in connection with the termination of pregnancy. *See Planned Parenthood of Se. Pa. v. Casey*, 505 U.S. 833, 881–87 (1992) (recognizing state interest in providing truthful information about probable gestational age as part of informed consent procedure), *overruled on other grounds by Dobbs*, 597 U.S. 215.

The state's in-person advance consultation, use of an ultrasound, in-person examination, and blood type determination requirements do not stand as obstacles to Congress' purpose of creating a comprehensive regulatory framework for higher-risk drugs set forth in the FDCA. These requirements are not directed solely to reducing or managing the safety risks of mifepristone, which the FDA is responsible for evaluating and deciding, but instead are directed to broader health concerns and informed consent to the termination of a pregnancy. They are not preempted.

**b. Reports to the North Carolina Department of Health and Human Services**

The state law also requires a treating physician or provider to send a report to the North Carolina Department of Health and Human Services if a patient experiences any adverse events or complications, as defined in statute, after taking mifepristone. *See* § 90-21.93(c) (duty to report adverse events from abortion-inducing drugs); *see also* § 90-21.93(d) (duty to report adverse events and complications from abortion procedures). This report must include the adverse event or complication, "[t]he date the

woman presented for treatment of the adverse event or complication," and "the diagnosis or treatment that was provided." §§ 90-21.93(d), (e). There is nothing to indicate that Congress intended for the REMS statute or the FDCA to preempt states from collecting health and safety data acquired by medical professionals. This is a regulation of the practice of medicine and is not preempted.

**c. The Plaintiff's Contentions**

The plaintiff contends that because the FDA considered or had the authority to implement some of the practices that the state now requires, the mifepristone REMS requirements preempt these state laws. *See* Doc. 99 at 10–15. For example, in the first mifepristone REMS program, the FDA included a medication guide as a REMS element that directed patients to take mifepristone in their provider's office "[a]fter getting a physical exam." Doc. 82-8 at 6. In 2016, the FDA removed the medication guide from the REMS, effectively removing any in-person examination requirement.[13] *See* Doc. 82-13 at 3–4 (FDA recommendation to remove medication guide as a REMS element); *compare* Doc. 82-8 at 2 (2011 REMS with medication guide), *with* Doc. 82-14 at 2 (2016 REMS without medication guide as REMS element). And in setting restrictions on the use and distribution of mifepristone, the FDA has decided that the risks of mifepristone do not need to be covered in advance or in-person. *See, e.g.*, Doc. 82-1 at 11 (2023 Patient Agreement allowing electronic signature). The FDA also considered but did not

[13] The current REMS does not include a medication guide and does not state that a physical examination is required before a patient can receive the drug. *See* Doc. 82-1 at 2. A medication guide is still included in the drug's label, *see* Doc. 100-11 at 17–20, but it does not mention the need for an in-person examination before receiving the drug.

require an ultrasound when it initially approved mifepristone. *See* Doc. 82-4 at 6; Doc. 82-5 at 19 (stating "it was inappropriate for [the FDA] to mandate how providers clinically assess women for duration of pregnancy and for ectopic pregnancy"). Instead, the FDA left the decision of whether to perform an ultrasound up to the "medical judgment" of providers. Doc. 82-4 at 6. And the FDA has the authority to impose blood testing, *see* 21 U.S.C. § 355-1(f)(3)(D), but declined to do so when it decided the regulations necessary for safe use of the drug.

The Court appreciates that the defendant-intervenors have relied in part on safety-related reasons in support of the in-person exam and ultrasound requirements. *See, e.g.*, Doc. 84 at 17; Doc. 100 at 21. If the only reasons for the in-person exam or the ultrasound were to reduce or manage safety issues related to mifepristone, the plaintiff's argument would have more force. *See* discussion *infra* pp. 34–40. But they are not the only reasons, as the state statute itself reflects and as discussed *supra*. The fact that the FDA removed a practice or deemed it unnecessary as a REMS element related to the safe use of a REMS drug does not mean that the states are prohibited from imposing the practice to address broader health and safety concerns, such as care for a person with the medical condition treated by the REMS drug or informed consent to the chosen method of treatment. The FDA's REMS choices were focused on the regulation of mifepristone, not on broader health issues related to medical care for pregnant persons or the information patients should have before deciding to terminate a pregnancy. State laws regulating these broader issues are not preempted.

The plaintiff also contends that the state requirements will interfere with access to mifepristone. *See* Doc. 99 at 6–8; 10. Congress does require the FDA to consider access and possible impacts on access when it implements and evaluates REMS elements for a drug. *See* 21 U.S.C. § 355-1(f)(2)(C). But nothing in the 2007 amendments makes the FDA responsible for generally ensuring access to all REMS drugs. State laws that might affect ease of access to mifepristone are not preempted merely because of that potential effect, especially when Congress did not intend to prevent the state from requiring standards of medical practice to address other health concerns or informed consent procedures designed to better inform the patient's decision-making process.

**d. Conclusion**

The REMS provisions of the 2007 amendments and the mifepristone REMS program enacted by the FDA under those amendments do not preempt a state from regulating or addressing potential health issues arising out of pregnancy. The North Carolina provisions that require an in-person 72-hour advance consultation, use of an ultrasound, an in-person examination, blood type determination, and reporting non-fatal adverse events to the state are not preempted.

**2. North Carolina Statutory Provisions that are Preempted**

Other statutory requirements of the state's Abortion Laws stand as obstacles to Congress' clear and manifest purpose of providing a comprehensive regulatory framework for safe use and distribution of higher-risk drugs run by the FDA. When a state imposes a restriction on the sale or distribution of an FDA-approved drug that is designed to reduce the risks associated with the drug even though the FDA explicitly

considered and rejected that restriction as unnecessary for safe use under the statutory regime imposed and required by Congress, then that state law is preempted. *See Geier*, 529 U.S. at 881 (finding state tort suit preempted as it stood as obstacle to federal objective and would create requirements federal agency deliberately rejected); *Bethlehem Steel*, 330 U.S. at 774; *see also Wyeth*, 555 U.S. at 581 n.14 (declining to find preemption and acknowledging holding different from *Geier* because FDA "did not consider and reject" drug label changes). This is especially true when the state's restrictions will also interfere with Congress' goal that any drug-related restrictions should take into account burdens on the health care system and on patient access.

**a. Physician Only, In-Person Prescribing, Dispensing, and Administering**

State law requires that only physicians prescribe mifepristone. *See* N.C. Gen. Stat. § 90-21.83B(a) (stating "[a] physician" will prescribe the drug); § 90-21.83A(b)(2)a (referencing "name of the physician" who will provide drug, and similar references). The "physician prescribing, dispensing, or otherwise providing" the drug must also be "physically present in the same room as the woman" when she takes the drug. § 90-21.83A(b)(2)a. And implicit in that requirement is that the physician must dispense the drug, rather than a pharmacy. These restrictions, which the defendant-intervenors say are necessary to reduce risks from the drug,[14] are an obstacle to meeting congressional objectives.

[14] The defendant-intervenors have not offered any other reason for these requirements beyond reducing the risks associated with mifepristone, nor have they pointed to any evidence in the record showing another reason.

Congress has directed the FDA to consider and implement as part of a REMS program restrictions around who, where, and how a REMS drug can be prescribed, dispensed, and administered. *See* 21 U.S.C. §§ 355-1(f)(3)(A)–(C). In these elements to assure safe use ("ETASUs"), the FDA can require "health care providers who prescribe" REMS drugs to "have particular training or experience" or be "specially certified." § 355-1(f)(3)(A). The FDA can also require special certifications for "pharmacies, practitioners, or health care settings that dispense the drug," § 355-1(f)(3)(B), and it can limit dispensing to "certain health care settings, such as hospitals." § 355-1(f)(3)(C).

Thus, the FDA has explicit statutory authorization to require that a REMS drug be administered in-person and prescribed and dispensed only by physicians. And the FDA did include such requirements when it first created the drug's REMS program. *See* Doc. 82-8 at 8 (2011 Prescriber Agreement requiring drug to be provided "by or under the supervision of a physician" who meets REMS qualifications); *see id.* at 3, 10 (2011 REMS limiting dispensing to certain health care settings and requiring patients to take drug in provider's office). But the FDA has decided these requirements are no longer necessary for safe use of mifepristone, and it no longer limits the use and distribution of the drug in these ways.

In 2016, the FDA updated the REMS elements to remove the requirements that the drug be prescribed by a physician and be taken in the presence of a physician. *See* Doc. 82-11 at 3 (adopting change from "licensed physician" to "licensed health care providers who prescribe" (cleaned up)); Doc. 82-14 at 8 (2016 Patient Agreement without requirement that mifepristone be taken in provider's office). In 2021, the FDA removed

the in-person dispensing requirement because it no longer promoted the goals of Congress. *See* Doc. 82-16 at 7 (the FDA's statement that an "in-person dispensing requirement is no longer necessary" for safe use and removal is less burdensome for health care providers and patients); Doc. 82-18 at 2 (2021 notification of REMS modifications stating removal of in-person dispensing "minimizes the burden on the health care delivery system of complying with the REMS" (cleaned up)). Because removal of in-person dispensing meant patients could now get the drug directly from a pharmacy, the FDA added a pharmacy certification requirement and Pharmacy Agreement form. *See* Doc. 82-18 at 2–3; Doc. 82-20 at 10. The FDA concluded that pharmacy certification was needed to "ensure[] that mifepristone is only dispensed pursuant to prescriptions that are written by certified prescribers." Doc. 82-20 at 14 (2023 REMS review).

Representatives of the American Association of Pro-Life Obstetricians and Gynecologists ("AAPLOG") and the American College of Pediatricians ("ACPeds") have directly asked the FDA to reimpose these exact requirements, *see* Doc. 82-16 at 2–3, but the FDA has declined to do so. When the representatives asked about the physician-only prescribing limitation, the FDA stated that it would not reinstate this requirement because mifepristone is "safe and effective when prescribed by midlevel providers." *See id.* at 10. In response to the request for in-person dispensing, the FDA said that "[c]ertified prescribers do not have to be physically present with the patient" when the drug is dispensed, *id.* at 13, and "mifepristone will remain safe and efficacy will be maintained" without in-person dispensing. *Id.* at 29. And in response to the request for in-person

administration, the FDA cited clinical data that shows the drug regimen is safe and effective when "self-administered at home" and said that removal of in-person administration maximizes the possibility that patients will be in a safe place when they start to experience the effects of the drug. *See id.* at 17. As of 2023, the FDA does not require any in-person appointments to prescribe, dispense, or administer the drug.[15]

Congress directed the FDA to impose a REMS element only if it mitigates a drug's risks, *see* 21 U.S.C. § 355-1(f)(1), and to reevaluate these requirements periodically. *See* §§ 355-1(d), (g). Through its reevaluation of the mifepristone REMS program, the FDA found that non-physician providers can safely prescribe the drug and that allowing non-physician providers to prescribe the drug better aligned the mifepristone elements with the REMS elements defined by Congress in statute. *See* Doc. 82-16 at 10; Doc. 82-11 at 3 (stating that allowing non-physician health care providers to prescribe better aligned with REMS statutory language). The FDA decided that in-person administration was not necessary to assure safe access to the drug, *see, e.g.*, Doc. 82-13 at 3, 7 (approving removal of language from Patient Agreement that stated location where drug should be taken and concluding change was necessary to ensure benefits outweigh risks), and that in-person dispensing imposed burdens on the health care system unnecessary for drug safety. *See, e.g.*, Doc. 82-18 at 2 (finding in-person dispensing was "no longer

[15] *Compare* Doc. 82-7 at 2 (2000 Patient Agreement requiring in-person counseling and administration), *and* Doc. 82-8 at 6, 10 (2011 REMS stating drug should be taken in provider's office), *with* Doc. 82-1 at 11 (2023 Patient Agreement containing no specification of in-person requirements and allowing electronic signature), *and* Doc. 82-20 at 10 (2023 review memo stating removal of in-person dispensing was needed).

necessary" to ensure benefits of drug outweigh risks and removal would minimize burden on health care system). As Congress directed it to do under the REMS statute, the FDA has assessed the risks associated with mifepristone, imposed REMS elements that adequately address those risks without unduly burdening the health care system or patient access, and removed those elements once they no longer served their congressional purpose.

North Carolina's requirements that only physicians can prescribe, dispense, and administer the drug, *see, e.g.*, N.C. Gen. Stat. § 90-21.83B(a), and that the physician "shall be physically present in the same room as the woman when the first drug . . . is administered" are directed solely to risks associated with mifepristone and other abortion-inducing drugs. § 90-21.83A(b)(2)a. Indeed, drug safety is the only basis of the defendant-intervenors' arguments that the state can impose these restrictions. *See* Doc. 100 at 15, 21 (referring to the state laws as "additional safeguards" and stating there is "no question that the challenged [state] provisions make abortion drugs safer"). Although a state can set standards of conduct or certification requirements for health care providers who prescribe drugs generally, Congress has made the FDA responsible for evaluating whether a restriction is necessary to address the safety risks of REMS drugs. As part of that, Congress has authorized the FDA to limit who can prescribe these drugs if necessary for safety, taking into account burdens on the health care system and patient access. North Carolina cannot second-guess the FDA's explicit judgment on how to manage risks from and safely prescribe, dispense, and administer REMS drugs, including mifepristone.

The state here is imposing restrictions on who can prescribe a REMS drug and how that drug can be prescribed, dispensed, and administered. Those exact restrictions have been explicitly rejected by the FDA as unnecessary for safe administration and as unnecessary burdens on the health care system and patient access. They conflict with the clearly stated congressional goals of (1) having the FDA in charge of managing risks associated with REMS drugs, (2) limiting restrictions on REMS drugs to those necessary for safety purposes, and (3) avoiding restrictions that impose unnecessary burdens on the health care system and patient access. The state requirements that limit prescribing of mifepristone to only physicians and that require in-person prescribing, dispensing, and administering are obstacles to these goals and are preempted. *See Warren*, 848 F.3d at 599; *Guthrie*, 79 F.4th at 338; *see also Geier*, 529 U.S. at 881.

**b. In-person Follow-up Appointments**

State law requires physicians who provide abortion-inducing drugs, or their agents, to schedule a follow-up visit with patients and to "make all reasonable efforts to ensure" that patients attend these appointments. N.C. Gen. Stat. § 90-21.83B(b). During these appointments, physicians should "confirm that the pregnancy is completely terminated" and "assess the degree of bleeding" the patient experienced. *Id.*

Under the REMS statute, the FDA can require as an ETASU that patients who use a REMS drug "be subject to certain monitoring." 21 U.S.C. § 355-1(f)(3)(E). When the FDA first implemented the mifepristone REMS program, it required patients to return for a follow-up appointment after taking the drug. *See* Doc. 82-8 at 10 (2011 Patient Agreement stating "I must return to my provider's office in about 2 weeks . . . to be sure

that my pregnancy has ended and that I am well"). In 2016, the FDA removed the requirement that patients return in-person to their providers' offices but kept the direction that patients should follow-up with their providers to confirm the pregnancy has ended and the patient is well. *See* Doc. 82-14 at 8. When asked to reinstate the in-person follow-up appointment, the FDA declined and said that "[t]he safe use of mifepristone . . . is not contingent on a specific number of office visits." Doc. 82-16 at 14.

The stated purpose of North Carolina's in-person follow-up requirement is directly focused on drug safety and efficacy; it exists so that providers can "confirm that the pregnancy is completely terminated and [] assess the degree of bleeding." *See* N.C. Gen. Stat. § 90-21.83B(b). The defendant-intervenors contend that the requirement is reasonable given that mifepristone is a "high-risk drug" and suggest no other purpose. *See* Doc. 100 at 21–22. But Congress has placed the FDA in charge of imposing safety restrictions on the use and distribution of mifepristone, and the FDA has found that an in-person follow-up appointment is unnecessary for the safe use of the drug. *See* Doc. 82-16 at 14. North Carolina's effort to reimpose this unnecessary safety restriction creates an obstacle to Congress' purpose. *See* discussion *supra* pp. 38–39. The required scheduling and encouragement of an in-person follow-up appointment is preempted.

**c. Reporting to the FDA**

Lastly, state law requires physicians to report any adverse events from the use of mifepristone to the FDA. *See* N.C. Gen. Stat. § 90-21.93(c). No one disputes that the FDA has the authority to require similar adverse event reporting, and it initially did so.

*See* Doc. 82-6 at 3 (2000 Prescriber Agreement requiring prescribers to report "any hospitalization, transfusion or other serious event" to drug manufacturer).

But in 2016, after years of experience with mifepristone, the FDA removed this requirement in favor of a narrower rule. *See* Doc. 82-14 at 3. Providers are only obligated to report deaths to the drug manufacturers,[16] and the manufacturers must report deaths to the FDA. *Id.* at 3, 5; Doc. 82-1 at 3, 6. The FDA removed the non-fatal adverse event reporting because it was no longer needed to ensure safe use of the drug. *See* Doc. 82-16 at 21 (justifying removal of non-fatal adverse event reporting based on a safety profile of mifepristone developed over 15 years that was "well-characterized" and "essentially unchanged").

The 2007 Amendments made significant changes to the FDCA, including to the FDA's responsibilities to re-evaluate drug safety. Allowing a state to override the FDA's decision that the FDA does not need providers of mifepristone to report information about all adverse events is an obstacle to the congressional purpose placing such decisions in the FDA's hands. The state is preempted from imposing an FDA reporting requirement when the FDA itself rejects that requirement. *See Geier*, 529 U.S. at 881; *see also Hillman*, 569 U.S. at 494 (finding state law that displaced clear congressional scheme was preempted); *Arizona v. United States*, 567 U.S. 387, 406 (2012) (finding

[16] The current mifepristone REMS refer to the "Mifepristone Sponsor." *See, e.g.*, Doc. 82-1 at 3. Here, the sponsors are the drug's manufacturers and for simplicity and clarity, the Court will use the term manufacturers.

preemption when Congress engaged in reasoned decision-making and did not impose certain penalties the state sought to enact). This provision is preempted.

**d. The Defendant-Intervenors' Contentions**

The defendant-intervenors contend that these state laws are not preempted because Congress did not intend to give the FDA power to "set national abortion policy" through the FDCA. *See* Doc. 84 at 22. The Court agrees; indeed, it has upheld some provisions in the Abortion Laws because they are more directed to "abortion policy" and pregnancy-related concerns than to the risks and distribution of mifepristone. *See* discussion *supra* pp. 27–31.

But the REMS statute governs many drugs, not just mifepristone, and nothing in the 2007 amendments indicates that Congress gave the FDA less authority to regulate the use and distribution of mifepristone compared to any other REMS drug. It is the FDA's job to evaluate the risks and safety of mifepristone and other REMS drugs and to impose – or remove – restrictions according to its evaluation under the statutory guidelines. The defendant-intervenors justify North Carolina's additional restrictions on safety grounds, *see, e.g.*, Doc. 84 at 19; Doc. 100 at 8, 15, but states are preempted from overriding the FDA's judgment about whether specific restrictions are necessary for safe use.

The defendant-intervenors also cite the 1962 amendments to the FDCA, Doc. 100 at 12, which included an express savings clause providing that state laws remained valid unless there was a direct and positive conflict between the federal and state law. Drug Amendments of 1962, Pub. L. No. 87-781, § 202, 76 Stat. 780, 793. But that savings

clause applied by its terms only to the 1962 amendments, and the defendant-intervenors have not pointed to any such savings clause in the 2007 amendments. *See id.* (stating "[n]othing in the amendments made by *this Act*" invalidates "any provision of State law which would be valid in the absence of such amendments unless there is a direct and positive conflict" (emphasis added)); *see also* discussion *supra* p. 9.

Even if the 1962 provision did apply here, "the existence of a separate preemption provision does not bar the ordinary working of conflict preemption principles." *Hillman*, 569 U.S. at 498 (cleaned up); *see also Buckman Co. v. Plaintiffs' Legal Comm.*, 531 U.S. 341, 352 (2001) (holding "neither an express preemption provision nor a savings clause bars the ordinary working of conflict preemption principles" (cleaned up)). The 2007 amendments worked a substantial change in the FDCA and, as previously discussed, the congressional intent is clear. The conflict between the 2007 amendments as implemented by the FDA and these provisions of state law is direct and positive.

Finally, the defendant-intervenors rely on the Supreme Court's decision in *Wyeth*, in which the Court held that a state tort action based on a drug label's failure to warn was not preempted by obstacle preemption. *See, e.g.*, Doc. 84 at 18, 25–26; Doc. 100 at 15. They contend that the FDA's regulations set a floor from which states can further regulate. *See* Doc. 84 at 18; Doc. 100 at 15. There may be ways in which that can be true, but not here.

In *Wyeth*, the Supreme Court was dealing with a state personal injury lawsuit over drug labeling, and the applicable law was the 1962 amendments, not the 2007 amendments; the Supreme Court only mentioned the 2007 amendments in passing. *See*

555 U.S. at 567–68. The 2007 amendments created a statute that is, as to REMS drugs like mifepristone, "substantially different" from the statute that was analyzed in *Wyeth*. *See Arizona*, 567 U.S. at 404–06 (finding state law preempted under current federal law which was "substantially different" from earlier federal law). The *Wyeth* Court did not assess any REMS restrictions, the congressional purpose of the 2007 amendments, or the preemptory effect of the REMS statutory provisions. *See* 555 U.S. at 567–68. And in *Wyeth*, the FDA had not considered and rejected the exact requirements the state now seeks to impose, a factor the Supreme Court deemed important enough to mention explicitly. *See id.* at 580, 581 n.14.

The defendant-intervenors' argument that the FDA sets a floor for drug regulation from which a state can impose any additional health and safety requirements would mean, if accepted, that a state could prohibit the prescription of a REMS drug within its borders absent additional clinical trials or absent a showing that side effects occurred less frequently than demonstrated in studies provided to the FDA. Such rules would almost certainly be preempted as inconsistent with the overall regulatory system for sale and distribution of prescription medicines on a nationwide basis. *See* Zettler, *supra* p. 20, at 872–75 (discussing Massachusetts Zohydro cases and the FDA's ability to regulate through REMS); *see also id.* at 885–87.

**e. Conclusion**

Without a doubt there are tensions between the federal system established by the 2007 amendments and the state's historical responsibility to regulate health and safety

matters. In the absence of express or field preemption, these tensions are tolerated when possible. *See Wyeth*, 555 U.S. at 575.

But when state laws undermine the national regulatory system established by Congress for evaluating and managing safe use and distribution of higher-risk drugs, they are obstacles to the purpose of Congress. Based on a disagreement with the FDA over what safety restrictions on the use of mifepristone are necessary, North Carolina has enacted laws requiring physician-only prescribing of mifepristone, in-person prescribing, dispensing, and administering of the drug, scheduling of an in-person follow-up appointment, and non-fatal adverse event reporting to the FDA; these parts of the Abortion Laws conflict with decisions made by the FDA explicitly finding such requirements to be unnecessary for safe use. Because these provisions are obstacles to congressional purpose, they are preempted. These state safety rules must yield to the safety decisions made by the federal agency in whose hands Congress placed decision-making authority about safety.

## VIII. The Major Questions Doctrine

As an alternative argument, the defendant-intervenors contend that the major questions doctrine precludes implied preemption. *See* Doc. 84 at 18. The major questions doctrine addresses "a particular and recurring problem: agencies asserting highly consequential power beyond what Congress could reasonably be understood to have granted." *West Virginia v. EPA*, 597 U.S. 697, 724 (2022).

Under this doctrine, courts "presume that Congress intends to make major policy decisions itself" and must not assume that Congress intends to leave such weighty

decisions to federal agencies in the absence of clear congressional instruction. *Id.* at 723 (cleaned up). "[W]hile the major questions label may be relatively recent, it refers to an identifiable body of law that has developed over a series of significant cases spanning decades." *Biden v. Nebraska*, 143 S. Ct. 2355, 2374 (2023) (internal quotation marks omitted). Each of those cases "involved novel agency interpretations of long-standing ambiguous regulatory provisions as major grants of authority to reconfigure large aspects of the economy." *GenBioPro, Inc. v. Sorsaia*, No. 23-CV-58, 2023 WL 5490179, at *4 (S.D.W. Va. Aug. 24, 2023) (citing *West Virginia*, 597 U.S. at 711–15; *Util. Air Regul. Grp. v. EPA*, 573 U.S. 302, 323–24 (2014); *Biden*, 143 S. Ct. 2373; *FDA v. Brown & Williamson Tobacco Corp.*, 529 U.S. 120, 160 (2000)), *appeal docketed sub nom.*, *GenBioPro, Inc. v. Raynes*, No. 23-2194 (4th Cir. Nov. 15, 2023).

The major questions doctrine does not apply here because the problem it seeks to solve, "agencies asserting highly consequential power" beyond what reasonably could be understood to have been granted by Congress, is absent. *West Virginia*, 597 U.S. at 724. There is no ambiguous regulatory provision at issue, and neither the FDA nor Dr. Bryant offer any novel interpretation of the FDCA or its 2007 amendments to broaden the agency's authority. No one disputes that in 2007, Congress granted the FDA the authority to adopt a REMS program for higher-risk drugs or that mifepristone was one of a number of prescription drugs requiring a REMS because the FDA approved it under Subpart H of the FDA's regulations. Nor does anyone dispute that the 2007 amendments authorize and indeed require the FDA to review, modify, and update a REMS program periodically. The defendant-intervenors do not point to any effort by the FDA to expand its authority

without congressional authorization. Here, the FDA acts in accordance with Congress' command: it has implemented a REMS for a variety of drugs, including mifepristone, imposing requirements to reduce risks to patients while declining to impose requirements which in the agency's judgment do not effectively reduce risks and ensure safe access. *See generally* 21 U.S.C. § 355-1.

The defendant-intervenors contend that "nothing in the text of the FDCA suggests that Congress accorded the FDA any power, much less exclusive power, to set national abortion policy." Doc. 84 at 22 (cleaned up). That is true, as discussed *supra* p. 42. But the statutory mandate authorizing the FDA to implement REMS programs applies to drugs without regard to their purpose; it does not impose different tests or rules for drugs that treat thyroid conditions or diabetes or any other conditions. The defendant-intervenors do not point to anything to indicate that the FDA is applying or interpreting the FDCA or its 2007 amendments to give the agency any greater authority over mifepristone than it has over any other REMS medications. Because no party says the FDA is applying the FDCA in a way that expands its authority beyond the congressional directive to implement REMS, the major questions doctrine is not relevant here.

## IX. Conclusion

North Carolina's police powers traditionally extend to areas of health, safety, and the medical profession, and, generally speaking, it can legislate in those fields. But when the FDA has created a REMS program for a higher-risk drug and expressly imposed and removed a REMS element, the state cannot reimpose that restriction based on drug safety concerns. Allowing it to do so would frustrate Congress' purpose.

The portions of North Carolina's Abortion Laws that require an in-person 72-hour advance consultation, use of an ultrasound, an in-person examination, blood testing, and reporting non-fatal adverse events to the state deal with informed consent and broader health and safety matters and are not preempted. But the provisions that require physician-only prescribing, in-person prescribing, dispensing, and administering, the scheduling of an in-person follow-up appointment, and non-fatal adverse event reporting to the FDA stand as obstacles to Congress' purpose in creating a comprehensive federal regulatory scheme for higher-risk drugs run by the FDA and are preempted.

In the complaint, the plaintiff asks for declaratory and injunctive relief. The parties shall meet and confer on the form of a proposed judgment and injunction, attempt to narrow areas of disagreement, and thereafter make appropriate submissions.

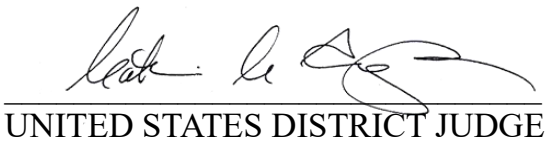
It is **ORDERED** that:

1. The defendant-intervenors' motion for summary judgment is **GRANTED in part**. The provisions of North Carolina's Abortion Laws that require an in-person 72-hour advance consultation, use of an ultrasound, an in-person examination, blood testing, and reporting non-fatal adverse events to the state deal with informed consent to the termination of pregnancy and broader health and safety matters and are not preempted. The defendant-intervenors' motion for summary judgment is otherwise **DENIED**.
2. The plaintiff's motion for summary judgment is **GRANTED in part**. The provisions of North Carolina's Abortion Laws requiring physician only prescribing, in-person prescribing, dispensing, and administering, scheduling

of an in-person follow-up appointment, and non-fatal adverse event reporting to the FDA violate the Supremacy Clause and are declared unconstitutional. The plaintiff's motion for summary judgment is otherwise **DENIED.**

3. The parties shall exchange proposed judgments and injunctions, meet and confer to narrow areas of disagreement, and thereafter file a joint submission with proposed judgments and injunctions attached no later than May 21, 2024. The joint submission is limited to identifying and briefly addressing points of disagreement as to form and may not exceed 3000 words. No additional briefing is otherwise authorized.

This the 30th day of April, 2024.



UNITED STATES DISTRICT JUDGE