UNITED STATES DISTRICT COURT
MIDDLE DISTRICT OF NORTH CAROLINA
DURHAM DIVISION

AMY BRYANT, MD,

Plaintiff,

v.

JOSHUA H. STEIN, in his official capacity as Attorney General for the State of North Carolina; JEFF NIEMAN, in his official capacity as District Attorney for North Carolina 18th Prosecutorial District; KODY H. KINSLEY, in his official capacity as the North Carolina Secretary of Health and Human Services; MICHAUX R. KILPATRICK, MD, PhD, in her official capacity as President of the North Carolina Medical Board; and CHRISTINE M. KHANDELWAL, DO; DEVDUTTA G. SANGVAI, MD, MBA; JOHN W. RUSHER, MD, JD; WILLIAM M. BRAWLEY; W. HOWARD HALL, MD; SHARONA Y. JOHNSON, PhD, FNP-BC; JOSHUA D. MALCOLM, JD; MIGUEL A. PINEIRO, PA-C, MHPE; MELINDA H. PRIVETTE, MD, JD; ANURADHA RAO-PATEL, MD; and ROBERT RICH, JR., MD, in their official capacities as Board Members of the North Carolina Medical Board; PHILIP E. BERGER, President *Pro Tempore* of the North Carolina Senate, and TIMOTHY K. MOORE, Speaker of the North Carolina House of Representatives.

Defendants.

Case No. 1:23-cv-77

MEMORANDUM IN SUPPORT OF DEFENDANTS BERGER AND MOORE MOTION TO DISMISS UNDER FED. R. CIV. P. 12(b)(6)

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INTRODUCTION

North Carolina has the authority to enact laws for the general welfare that respect unborn life, promote maternal health, and uphold the integrity of the medical profession. While always true, the Supreme Court reaffirmed the proper allocation of regulatory power last summer in *Dobbs v. Jackson Women's Health Organization.* 142 S. Ct. 2228 (2022) (holding that "the authority to regulate abortion is returned to the people and their elected representatives"). Plaintiff, a North Carolina physician who performs abortions, seeks to eradicate important state-law protections for unborn children and their mothers' health and welfare. She makes the novel claim that the Food and Drug Administration's ("FDA") approval of chemical-abortion drugs for certain uses preempts North Carolina's police power and, as a result, the FDA's regulations bind and limit the state's laws on abortion.

Supreme Court precedent requires that an agency must identify clear congressional authorization to justify the agency's attempt to control actions related to a significant political issue under the major questions doctrine. *W. Va. v. EPA*, 142 S. Ct. 2587, 2609 (2022). Plaintiff's claim requires

a finding that when Congress passed the Federal Food, Drug, and Cosmetic Act ("FDCA") in 2007, it gave the FDA sole power to regulate chemical abortions in all fifty states.

Yet, the FDCA merely required the FDA to implement safety measures over the use of dangerous drugs, including the chemical-abortion drug Mifeprex. Nothing in the text of the FDCA suggests that Congress authorized the FDA to exercise exclusive, preemptive power over one of the most divisive and consequential social and political issues of our day and the past fifty years. The Supreme Court's decision in *Dobbs* directly controls the matter. States can pass these laws.

The FDA sets a floor to declare whether drugs are safe enough to market. FDA approval under the FDCA does not preempt state regulation of the use or prescription of drugs by state-licensed physicians to patients in the state. Nor does it trump compelling state interests in protecting unborn life, promoting maternal welfare, and regulating the medical profession. This Court should grant this motion and dismiss this lawsuit against all Defendants.[1]

[1] In granting these Defendants' Motion, the Court should dismiss the entire case against all parties because Plaintiff cannot continue without the President *Pro Tempore* and

STATEMENT OF FACTS

A. The FDCA.

In 1906, Congress passed the Federal Food and Drugs Act to "supplement[]" the protection for consumers already

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Speaker. They are necessary parties pursuant to North Carolina law:

> Whenever the validity or constitutionality of an act of the General Assembly or a provision of the Constitution of North Carolina is the subject of an action in any State or federal court, the Speaker of the House of Representatives and the President Pro Tempore of the Senate, as agents of the State through the General Assembly, shall be necessary parties and shall be deemed to be a client of the Attorney General for purposes of that action as a matter of law and pursuant to Section 7(2) of Article III of the North Carolina Constitution. In such cases, the General Assembly shall be deemed to be the State of North Carolina to the extent provided in G.S. 1-72.2(a) unless waived pursuant to this subsection. Additionally, in such cases, the General Assembly through the Speaker of the House of Representatives and President Pro Tempore of the Senate jointly shall possess final decision-making authority with respect to the defense of the challenged act of the General Assembly or provision of the North Carolina Constitution.

N.C. GEN. STAT. § 120-32.6. *See also*, "The Speaker of the House of Representatives and the President Pro Tempore of the Senate, as agents of the State through the General Assembly, must be joined as defendants in any civil action challenging the validity of a North Carolina statute or provision of the North Carolina Constitution under State or federal law." N.C. GEN. STAT. § 1A-1, Rule 19.

provided by "state regulation" of adulterated and misbranded drugs. *Wyeth v. Levine*, 555 U.S. 555, 566 (2009). In 1938, Congress enacted the FDCA which, as amended, requires a manufacturer to prove its drug is "safe for use under the conditions prescribed, recommended, or suggested in the proposed labeling before it [can] distribute the drug." *Id.* at 567. Through many iterations and amendments to the FDCA, "Congress took care to preserve" parallel state laws protecting public health. *Id.* The 1962 amendments, in particular, included an express saving clause, providing that "a provision of state law would *only* be invalidated upon a 'direct and positive conflict' with the FDCA." *Id.* (emphasis added).

In 2007, Congress amended the FDCA to subject medications that present "serious safety concerns"—such as Mifeprex—to additional restrictions. Pub. L. No. 110-85, 121 Stat. 823 (2007). That amendment directed the FDA to adopt a new "drug safety program," known as the "Risk Evaluation and Mitigation Strategy" ("REMS"), when necessary, to ensure a drug's benefits outweigh its risks. 21 U.S.C. § 355-1. For "drugs with known serious risks," that are "associated with a serious

adverse" experience, the REMS must include "elements to assure safe usage" ("ETASUs"). § 355-1(e)-(f). This amendment required the FDA to impose a REMS with ETASUs for Mifeprex because of serious safety concerns and documented adverse experiences.

B. Mifeprex approval and REMS.

In 2000, the FDA approved a drug application for the chemical-abortion drug, Mifeprex.[2] Mifeprex (also known as "mifepristone" or "RU-486") was approved for use in the termination of intrauterine pregnancy up to 49 days of gestation.[3] The FDA approved Mifeprex for use as part of a two-drug chemical abortion regimen: (1) Mifeprex first, which blocks progesterone and cuts the unborn baby off from nutrition, starving the baby in the mother's womb; and (2) then misoprostol, which induces cramping and contractions to expel the baby from the mother's womb.

The FDA approved this chemical-abortion drug regimen pursuant to an accelerated approval process, which authorizes

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[2] Letter from FDA to Population Council on NDA 20-687 MIFEPREX (mifepristone) Tablets, 200mg (Sept. 28, 2000), available at https://www.accessdata.fda.gov/drugsatfda_docs/appletter/2000/20687appltr.pdf.

[3] *Id.*

the FDA to fast-track approval for certain drugs used to treat "serious or life-threatening illnesses."[4] 57 C.F.R § 58958, Subpart H (Dec. 11, 1992). The FDA was required to implement safety restrictions on the use of Mifeprex because it concluded the drug could not safely be used without them. 21 C.F.R. § 314.520(a).

In its 2000 approval decision, the FDA required multiple safety restrictions to ensure safe use of the chemical abortion drug regimen. For example, the FDA specified that only qualified physicians were permitted to dispense the drugs, or a "health care provider, acting under the supervision of a qualified physician . . . *provided state law permits this*." (Exhibit 1, Memorandum from FDA Population Council re: NDA 20-687 Mifeprex (mifepristone), p. 4-5 (Sept. 28, 2000).) The FDA also required that a physician have the ability to use ultrasound or clinical examination to date the gestational age of a baby and diagnose an ectopic pregnancy, the ability to perform a surgical procedure necessary to stop

[4] A pending federal lawsuit challenges whether the FDA properly approved the chemical abortion drugs under Subpart H. *See Alliance for Hippocratic Med. v. FDA*, Case 2:22-cv-00223-Z (N.D. TX).

bleeding or to treat an incomplete abortion, and admitting privileges at medical facilities within an hour's distance to provide emergency health care services, including hospitalizations resulting from these drugs. *Id.*

In 2007, when Congress amended the FDCA, the FDA had to implement a REMS for Mifeprex. *See* 21 U.S.C. § 355-1. The FDA-approved REMS retained the original protections and included the following ETASUs:

- A health care provider must be specially certified and must complete a Prescriber's Agreement;
- Mifeprex must be dispensed in-person in certain health care settings—specifically clinics, medical offices, and hospitals; and
- A patient must provide informed consent by signing a Patient Agreement.

(Exhibit 2, 2011 REMS for NDA 20-687 Mifeprex (mifepristone) Tablets, 200MG (June 8, 2011).)

In 2016, at the request of the drug manufacturer, the FDA eliminated several safeguards on chemical-abortion drugs:

- increased the gestational age limit from 49 days to 70 days,
- changed the dosage and route of administration of the drugs;
- reduced the number of required in-person office visits from three to one,

- allowed non-physicians to prescribe and administer the drugs, and

- eliminated the requirement for prescribers to report nonfatal adverse events.

(Exhibit 3, FDA, Center for Drug Evaluation and Research, Summary Review of Application Number: 020687Orig1s020 (Mar. 29, 2016).) Then, in 2023, the FDA eliminated the ETASU requirement that Mifeprex be dispensed in-person only in certain healthcare settings such as a hospital or clinic. This allowed Mifeprex to be dispensed in certified pharmacies or by mail. (Exhibit 4, FDA, Center for Drug Evaluation and Research, Summary Review of Application Number: 020687Orig1s020, p. 41 (Jan. 3, 2023).)

C. North Carolina's longstanding laws protect unborn life and promote maternal health and welfare.

Like most states, North Carolina passed laws protecting unborn life and prohibiting abortion in the 1800s, over 140 years ago.[5] N.C. GEN. STAT. §§ 14-44, 14-45. These laws specifically restricted the use of any "drug" or "medicine" to induce an abortion. Shortly before the Supreme Court decided *Roe v. Wade*, 410 U.S. 113 (1973), North Carolina only

[5] *See* AN ACT TO PUNISH THE CRIME OF PRODUCING ABORTION, N.C. Pub. L. ch. 351 (1881) (enacting N.C. GEN. STAT. §§ 14-44, 14-45).

permitted licensed physicians to perform abortions in certain circumstances, such as to save the life of the mother or if the pregnancy resulted from rape or incest.[6] North Carolina law provided almost total protection for unborn life for nearly a century until the Supreme Court's decision in *Roe*.

Post-*Roe*, North Carolina sought to bring its laws into compliance with *Roe* while still protecting life.[7] It amended its abortion laws to permit licensed physicians to perform abortions in a hospital or certified clinic. N.C. GEN. STAT. § 14-45.1. In the years that followed, the North Carolina General Assembly passed laws to protect unborn life and maternal health under the restrictions of *Roe* and the evolving Supreme Court jurisprudence du jour.

This included passing laws that:

- protect unborn children from discrimination on the basis of sex, N.C. GEN. STAT. § 90-21.121(a);
- require parental consent for a minor seeking an abortion, N.C. GEN. STAT. § 90-21.7(a);

[6] *See* AN ACT TO AMEND ARTICLE II, CHAPTER 14 OF THE GENERAL STATUTES RELATING TO ABORTION AND KINDRED OFFENSES, N.C. Sess. L. ch. 367 (1967) (enacting N.C. GEN. STAT. § 14-45.1).

[7] *See* AN ACT TO MAKE CHANGES IN THE ABORTION LAW IN ORDER TO COMPLY WITH RECENT UNITED STATES SUPREME COURT DECISIONS, N.C. Sess. L. ch. 711 (1973).

- require that a physician obtain informed consent from women and provide a 72-hour reflection period after giving information about risks and alternatives to abortion, N.C. GEN. STAT. § 90-21.82;

- require that a physician be physically present when performing an abortion, including administering the first chemical-abortion drug (Mifeprex), N.C. GEN. STAT. § 90-21.82 (1)(a); and

- prohibit the use of State funds for abortions, N.C. GEN. STAT. § 143C-6-5.5.

Additionally, North Carolina Department of Health and Human Services ("NCDHHS") regulations require abortion facilities to meet safety standards, maintain ultrasound equipment, and meet record-keeping and reporting requirements. 10A N.C. ADMIN CODE 14E (first effective in 1976, as amended or re-adopted since then).

D. Plaintiff's Lawsuit.

On January 25, 2023, Plaintiff filed a Complaint asking this Court to declare several North Carolina laws unconstitutional as applied to chemical abortions based on the claim that the FDA preempted them under the Supremacy Clause of the United States Constitution, including:

- Criminal prohibitions on non-licensed medical professionals providing abortions, N.C. GEN. STAT. §§ 14-44, 14-45;

- Requirement that only licensed physicians may perform abortions, N.C. GEN. STAT. §14-45.1;

- Two provisions ensuring informed consent and a 72-hour waiting period, N.C. GEN. STAT. § 90-21.82, 90-21.90; and

- The entire safety code chapter related to how an abortion facility must be built and operated, 10A N.C. ADMIN. CODE Subchapter 14E.

QUESTION PRESENTED

Whether FDA regulations preempt North Carolina's chemical-abortion laws when the FDCA is silent on the topic?

LEGAL STANDARD

A complaint fails to state a claim if it does not contain "sufficient factual matter, accepted as true, to state a claim to relief that is plausible on its face." *Ashcroft v. Iqbal*, 556 U.S. 662, 678 (2009). This requirement "protects against meritless litigation by requiring sufficient factual allegations 'to raise a right to relief above the speculative level' so as to 'nudge[ ] the[ ] claims across the line from conceivable to plausible.'" *Shore v. Charlotte-Mecklenburg Hosp. Auth.*, 412 F. Supp. 3d 568, 572 (M.D.N.C. 2019) (quoting *Bell Atl. Corp. v. Twombly*, 550 U.S. 544, 545 (2007)). A claim is plausible on its face if "the plaintiff pleads factual content that allows the court to draw the reasonable inference

that the defendant is liable" and demonstrates "more than a sheer possibility that a defendant has acted unlawfully." *Atkinson v. Credit Acceptance Corp. Primeritus Fin. Servs. Inc.*, No. 1:22-CV-369, 2023 WL 2429527, at *2 (M.D.N.C. Mar. 9, 2023) (quoting *Twombly*, 550 U.S. at 556–57). A court need not "accept legal conclusions as true, and '[t]hreadbare recitals of the elements of a cause of action, supported by mere conclusory statements, do not suffice.'" *Id.* (quoting *Iqbal*, 556 U.S. at 678.)

ARGUMENT

North Carolina has always retained the ability to pass and enforce reasonable health and safety regulations, including those for doctors and their patients. Safety reasons abound for the challenged laws.[8] Plaintiff argues that North Carolina's laws are unconstitutional because they impose greater safety protocols than the current FDA-approved abortion-drug regimen. Plaintiff misses the mark twice in her

[8] One in five women suffers complications from chemical abortions. *See* Niinimäki M, et al., National Library of Medicine, Immediate complications after medical compared with surgical termination of pregnancy (Oct. 2009), https://pubmed.ncbi.nlm.nih.gov/19888037/.

effort to undercut state law and expand federal agency regulatory authority.

First, it violates the fundamental principle of separation of powers. A federal agency is merely a creature of Congress. A federal agency possesses only the powers vested in it by Congress. The major questions doctrine protects this principle: Congress must give an agency "clear congressional authorization" "if it wishes to assign to an agency decisions of vast . . . political significance." *W. Va.*, 142 S. Ct. at 2609, 2605 (quoting *Util. Air Regul. Grp. v. EPA*, 573 U.S. 302, 324 (2014)). Plaintiff cannot show that Congress expressly or silently authorized the FDA to establish nationwide chemical abortion policy when it amended the FDCA to require a REMS for dangerous drugs. Plaintiff's preemption claim fails outright because Congress has not given to the FDA, or any federal agency, the authority to regulate chemical abortion in all fifty states.

Second, the courts have long considered FDA approval as a federal floor on which states may impose additional safety measures, not a ceiling prohibiting further state regulation. *Wyeth, 555 U.S. at 578.* The Supreme Court has stressed that

"the regulation of health and safety matters is primarily, and historically, a matter of local concern." *Hillsborough Cnty. v. Automated Med. Labs.*, 471 U.S. 707, 719 (1985). These historic state police powers include the authority to regulate abortion. *Dobbs*, 142 S. Ct. at 2284.

North Carolina laws that promote health and safety by implementing protections around chemical-abortion procedures fall squarely within the state's purview. They do not infringe upon the FDA's limited purpose under the FDCA to ensure drugs clear a minimum safety-and-efficacy hurdle before the drugs can be sold in the United States. 21 U.S.C. § 393(b)(2)(B).

Plaintiff's preemption argument fails because she cannot establish that North Carolina laws conflict with any federal law or frustrate any federal objectives. Plaintiff's claim that these laws protecting life and health might limit her ability "to provide medical abortion care to a larger number of patients at lower cost" (Compl. ¶ 10) cannot recast otherwise constitutional state laws into a Supremacy Clause preemption battle.

I. Congress did not delegate major question authority to the FDA to set nationwide chemical abortion policy.

Congress passed the FDCA to give the FDA the responsibility of determining if a particular drug is safe enough to be sold and prescribed in the United States. This sets a floor from which the FDA, as specifically authorized by Congress, can preclude the sale of certain drugs. Congress did not grant any specific authority to the FDA to prohibit the various states from further regulating how a physician, licensed by those states, prescribes any particular drug to her patients in those states. The FDA has no role in the individual, state-specific practice of medicine after the FDA performs its initial gatekeeper function under the FDCA.

Congress did not establish a ceiling with the FDCA. The FDA has authority to regulate what can be sold. That is just the floor. So, the states are free to regulate above the floor established by FDA regulation as authorized by the FDCA.

The floor acts to prevent a state from allowing the sale of a drug that the FDA determined lacked the requisite safety. However, if the FDA allows the sale of a drug, a state can regulate how a physician it licenses can prescribe that drug up to the ceiling established by whatever state regulation

the state may legally enact. The General Assembly duly enacted the challenged laws.

Plaintiff claims that the FDCA "granted the FDA exclusive authority to impose restrictions on the prescribing, dispensing, and administration of drugs that the Agency deems to pose particular risks." (Compl. ¶ 2.) Plaintiff claims Congress gave the FDA sole authority to "strik[e] a balance between access to treatments and protections from identified risks" and that states lack any authority to impose additional safety measures to protect their citizens from drugs with identified risks. (Compl. ¶¶ 1-2.) By Plaintiff's logic, the FDA's approval of *additional* restrictions on drugs it found posed a heightened health risk, means the states have *less* authority to regulate those drugs for other purposes.

Plaintiff advocates a broad and unsupported expansion of FDA power. The FDA, like any other federal agency, has only the power given it by Congress. Thus, before this Court need even address the substance of Plaintiff's preemption claim, it must first confront a more fundamental question of agency power. Did Congress confer to the FDA this power that

Plaintiff seeks to wield as a sword against North Carolina laws?

Nothing in the text of the FDCA suggests that Congress accorded the FDA any power, much less "exclusive" power, to set national abortion policy. Under the most basic principles of statutory interpretation, that contention fails. The text of the FDCA does not so much as mention abortion. Nor does it direct the FDA to consider the legitimate and important state interests in protecting unborn life, maternal health, and the integrity of the medical profession. The Supreme Court has long recognized that states may limit abortion both before and after *Roe*, and certainly now in the wake of *Dobbs*. *See, e.g.*, *Roe*, 410 U.S. at 154; *Dobbs*, 142 S. Ct. at 2284.

Separation of powers principles, which compel a court to find "clear congressional authorization" for expansive assertions of agency authority, reinforce this conclusion. *W. Va.*, 142 S. Ct. at 2609. Under the major questions doctrine, "courts expect Congress to speak clearly if it wishes to assign to an agency decisions of vast economic and political significance." *Util. Air Regul. Grp.*, 573 U.S. at 324; *see also W. Va.*, 142 S. Ct. at 2609 (courts must "presume that

Congress intends to make major policy decisions itself, not leave those decisions to agencies") (cleaned up). Terminating a pregnancy is an issue with "profound moral and spiritual implications … even [at] its earliest stage." *Planned Parenthood of Se. Penn. V. Casey*, 505 U.S. 833, 850 (1992).

Since abortion is, and has been for at least fifty years, one of the most debated and litigated social and political topics in the United States, whether the FDA can step in and bind all fifty states makes this is a major questions case. *See W. Va.*, 142 S. Ct. at 2610. Thus, Plaintiff must assert more than a merely "plausible textual basis" for her claim that Congress yielded nationwide abortion policy to the FDA. *Id.* at 2609. She must also proffer "clear congressional authorization" on the topic of that major question. *Id.* She can produce neither.

Plaintiff offers only the REMS provision, 21 U.S.C. § 355-1, as text from a statute supporting her claim that Congress told the FDA to dictate abortion policy to all of the states. (Compl. ¶ 2.) That provision merely requires the FDA to ensure that the *added* safety requirements that the FDA *itself* imposes on more dangerous drugs are not "unduly

burdensome on patient access to the drug." *Id.* § 355-1(f)(2)(C). That provision cannot and does not give the FDA "clear congressional authorization" to override important state laws concerning public health and safety. It says nothing at all about chemical-abortion drugs.

The Supreme Court has long understood the FDCA to set a federal *floor* on the approval of drugs, allowing complementary state regulations. *See Wyeth*, 555 U.S. at 575. The FDA has properly recognized this role, opening the door for states to regulate chemical-abortion drugs beyond the FDA's own restrictions. (*See* Exhibit 1, p. 4-5.) Regardless, the REMS provision makes no mention of abortion directly or indirectly. So, it cannot possibly support the required delegation of congressional authority to allow the FDA to superimpose its regulation as the ceiling preempting any further state regulation on this major question.

Because Congress did not delegate the power to set national abortion policy to the FDA, the generic FDA regulations do not preempt North Carolina's, or any other state's, laws on the topic of abortion. Thus, Plaintiff's

claims fail as a matter of law, and this Court should dismiss the case against all parties.

II. The FDA's approval of Mifeprex and a REMS does not preempt state law.

A. A REMS is not an agency regulation capable of preempting any state law.

First, 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," *Wyeth*, 555 U.S. at 576. The FDA does not adopt a REMS formally pursuant to the Administrative Procedures Act. *See Anderson v. Eby*, 998 F.2d 858, 863 (10th Cir. 1993) ("to have the force of law, at a minimum "a regulation must be "adopted according to the procedures embodied in the Administrative Procedures Act"). Thus, Plaintiff's claim fails as a matter of law because a REMS can never be a formal FDA regulation that might preempt parallel protections under state law.

B. The FDA's approval and a REMS for Mifeprex does not preempt North Carolina laws further regulating its use.

The Supremacy Clause makes federal law "the supreme Law of the Land." U.S. Const. art. VI, cl. 2. Yet preemption analysis starts with the assumption that "the historic police powers of the States are not superseded unless that was the

clear and manifest purpose of Congress." *Ariz. v. U.S.*, 567 U.S. 387, 400 (2012). Especially when Congress legislates "in a field which the States have traditionally occupied," such as public-health and safety regulations. *Wyeth*, 555 U.S. at 565. North Carolina, and every other state, can layer additional laws and regulation on top of an FDA approval of the sale of a drug to protect that state's citizens, mothers and children, and regulate the safe practice of medicine in the state.

The FDCA cannot, and does not attempt to, undermine that historic police power each state possessed since joining the union. Plaintiff argues that the FDA's imposition of a REMS for Mifeprex preempts the people in every state from protecting unborn children and their mothers. She also contends that, when imposing a REMS for Mifeprex, the FDA deliberately chose to stop imposing restrictions on Mifeprex similar to the restrictions North Carolina imposed. (Compl. ¶ 81.)

Plaintiff does not point to any law expressly granting the FDA preemption authority over North Carolina's ability to protect life or health. So, she argues that the disfavored

type of "implied preemption" applies. *See Wyeth*, 555 U.S. at 583 (Thomas, J., concurring). There are three kinds of implied preemption: (1) field preemption, inferred from a "pervasive" framework of regulation; (2) impossibility preemption where "compliance with both federal and state regulations is a physical impossibility"; and (3) obstacle preemption where "the challenged state law stands as an obstacle to the accomplishment and execution of the full purposes and objectives of Congress." *Ariz.*, 567 U.S. at 399. No field preemption exists here: Congress said nothing about the FDA regulating abortion in the fifty states. Plaintiff points instead to impossibility or obstacle preemption. Both fail.

i. Plaintiff can comply with both federal and state law.

Under impossibility preemption, a federal law preempts a state law only when the state law directly conflicts with the federal law. Or, put differently, when "compliance with both federal and state regulations is a physical impossibility." *Id.* This "is a demanding" standard to meet. *Wyeth*, 555 U.S. at 573. The "*possibility* of impossibility [is] not enough." *PLIVA, Inc. v. Mensing*, 564 U.S. 604, 624, n. 8 (2011) (emphasis added) (cleaned up). Rather, a court must see "clear

evidence" of impossibility, *Merck Sharp & Dohme Corp. v. Albrecht*, 139 S. Ct. 1668, 1678 (2019), and will not find "impossibility where the laws of one sovereign permit an activity that the laws of the other sovereign restrict or even prohibit." *Id.*

Plaintiff erroneously argues North Carolina's chemical abortion regulations conflict with federal law and upset the regulatory balance struck by the FDA. (Compl. ¶¶ 1, 6, 12, 76, 84, 86.) The Supreme Court has repeatedly held that state law is not preempted unless it is impossible to comply with both the FDCA and state law. *See e.g.*, *Mut. Pharm. Co. v. Bartlett*, 570 U.S. 472, 486-87 (2013); *PLIVA, Inc.*, 564 U.S. at 624; *Wyeth*, 555 U.S. at 571, 581; *Merck Sharp & Dohme Corp.*, 139 S. Ct. at 1677-79. Here, Plaintiff can, and has for years, complied both with the REMS requirements for Mifeprex and state laws that require her to perform abortions in person in a suitable facility after obtaining informed consent and providing a period of reflection. By complying with both for years, Plaintiff shows compliance is possible.

Indeed, North Carolina laws and federal laws have historically overlapped in a complementary fashion on this

issue. North Carolina has long required that a licensed physician must perform an abortion. When the FDA approved Mifeprex in 2000, it incorporated the policies of states like North Carolina by requiring that a physician must provide chemical-abortion drugs in person and requiring three separate office visits. The FDA has long acknowledged that states may continue to require a physician to dispense these dangerous drugs. (Exhibit 1, p. 4-5; *see also* FDA, *Questions and Answers on Mifepristone for Medical Termination of Pregnancy Through Ten Weeks Gestation* (January 4, 2023), https://tinyurl.com/4jtfrjm8.)

Not until the 2011 REMS changes did the FDA loosen the physician-only restrictions to permit specially certified "health care providers" to dispense the drugs. (Exhibit 2, p. 1.) Even then, the drugs could only be dispensed in-person in certain health care settings, specifically clinics, medical offices, and hospitals. (*Id.* at p. 2.) These safeguards mirrored a similar requirement in North Carolina that abortions could only be performed in a "suitable facility" that complied with NCDHHS safety codes. North Carolina enacted that requirement for certified facilities in direct

response to *Roe*.[9] For fifty years, everyone understood that these measures complimented with or augmented -not circumvented- any FDA regulatory authority.

Moreover, North Carolina enacted its informed-consent laws requiring a woman's voluntary and informed consent and a brief waiting period a decade ago, two years after the FDA approved the Mifeprex REMS.[10] The notion that North Carolina's protections conflict with —rather than complement and build upon— the FDA's regulatory scheme is both novel and unfounded. Each time North Carolina enacted laws to protect life and promote maternal health, it did so to improve patient outcomes, consistent with and serving a complementary purpose to the floor set by the FDA.

Plaintiff cannot show that it is "impossible . . . to comply with both state and federal requirements." *See PLIVA*, 564 U.S. at 618. No conflict exists at all between the FDA's regulation of Mifeprex and North Carolina's laws on its use and prescription. Plaintiff may oppose the supposed "burdens"

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[9] AN ACT TO MAKE CHANGES IN THE ABORTION LAW IN ORDER TO COMPLY WITH RECENT UNITED STATES SUPREME COURT DECISIONS, N.C. Sess. L. ch. 711 (1973) (amending N.C. GEN. STAT. § 14-45.1).
[10] N.C. Sess. L. ch. 366 (2013) (amending N.C. GEN. STAT. § 90-21.82(1).

of the laws and "unnecessary costs" to her medical practice these safety precautions cause. But her profit motive does not create a constitutional crisis.

Plaintiff can, and has for years, apparently complied with the REMS and North Carolina's commonsense protections. Certainly, no conflict exists that suddenly, in the past few months, became "strong enough to overcome the presumption that state and local regulation of health and safety matters can constitutionally coexist with federal regulation." *Hillsborough Cnty.*, 471 U.S. at 716. Thus, Plaintiff's claim of impossibility preemption fails as a matter of law.

ii. North Carolina's challenged laws do not present obstacles.

The challenged laws promote the same goals as the FDA's regulations at issue. These laws present no barrier to the FDA fulfilling its mission as delegated by Congress.

Plaintiff contends that North Carolina law "frustrates Congress's objective of empowering the FDA to ensure safety while minimizing burdens on patient access and on the healthcare delivery system; upsets the deliberate and fine-tuned regulatory balance contemplated by federal law; and thus stands as an obstacle to the accomplishment and execution

of the full purposes and objectives of federal law." (Compl. ¶ 86.) According to Plaintiff, the FDA's imposition of a REMS sets both a floor and ceiling on permissible regulation of Mifeprex, thereby preempting any complimentary state law protections. Plaintiff makes the internally inconsistent argument that the deadlier a drug is, the less power a state has to protect its citizens from that deadly drug. Her argument fails for several reasons.

First, the FDA's imposition of *additional* safeguards on *more dangerous* drugs cannot displace the states' traditional authority to regulate for health and safety. Parallel, complementary state laws promoting safety and protection from a drug so dangerous that the FDA gives it a REMS *serve* the FDCA's overriding safety objective; they do not frustrate it.

"Congress took care to preserve" parallel state laws protecting the public health in many FDCA amendments. *Wyeth*, 555 U.S. at 567. Congress expressly provided that "a provision of state law would *only* be invalidated upon a 'direct and positive conflict' with the FDCA." *Id.* (emphasis added). North Carolina may not permit the sale of a drug the FDA has determined is too dangerous to sell. This is the FDA's floor.

But, North Carolina's laws here stand on top of the FDA's regulatory shoulders. For Plaintiff's argument to prevail, North Carolina's laws must chip away at the FDA regulatory ceiling, not build upon its base.

Second, Plaintiff's novel interpretation hinges on the FDA's determinations about the balance Congress mandated between safety-based restrictions and patient access to the drug. (Compl. ¶ 86.) But, Congress's statutory directive purely tasked the FDA with ensuring that its own restrictions do not unduly limit access to inherently dangerous drugs. The text of the FDCA does not suggest these dangerous drugs must be uniformly accessible for all purposes in every state. Nor does the text say that a state may not impose additional restrictions based on its citizens' interests. The FDA does not need to consider everything that a state might consider when the state decides to layer on additional regulations for the safe use of a drug by the physicians that the state licenses.

Indeed, the Court rejected a similar argument in *Wyeth* — that the "precise balancing of risks and benefits" required by the FDCA left "no room for different state-law judgments."

555 U.S. at 575. That argument, according to the Court, "relie[d] on an untenable interpretation of congressional intent and an overbroad view of an agency's power to pre-empt state law." *Id.* at 573. The Supreme Court has already decided this precise issue, and Plaintiff's argument lost.

As the Supreme Court has directed "any '[e]vidence of pre-emptive purpose,' whether express or implied, must therefore be 'sought in the text and structure of the statute at issue.'" *Va. Uranium, Inc. v. Warren*, 139 S. Ct. 1894, 1907 (2019) (quoting *CSX Transp., Inc. v. Easterwood*, 507 U.S. 658, 664 (1993)). Plaintiff's arguments about balancing drives home the point that Congress did *not* delegate the authority to regulate abortion to the FDA vis-à-vis the FDCA. If Congress ever does, in fact, delegate the authority to decide nationwide abortion policy to any agency, Congress would have to include, at the very least, the relevant factors for that agency to consider. None of the REMS factors say anything about considering interests in protecting unborn life which is an undeniable part of any abortion decision. *See Casey*, 505 U.S. at 866–67.

Nor do the generally applicable REMS factors in the FDCA mention anything about other important interests like "the elimination of particularly gruesome or barbaric medical procedures; the preservation of the integrity of the medical profession; the mitigation of fetal pain; and the prevention of discrimination on the basis of race, sex, or disability." *Dobbs*, 142 S. Ct. at 2284. Simply put, and without rehashing major questions issues described above, congressional silence in the FDCA destroys any claim that Congress delegated this authority to the FDA.

Were there any doubt as to whether Congress might have delegated the authority to set nationwide abortion policy to the FDA, the presumption against preemption completely shuts the door. Where, as here, the area involves matters of historically local concern, the Court "start[s] with the assumption that the historic police powers of the States were not to be superseded by the Federal Act unless that was the clear and manifest purpose of Congress." *Jones v. Rath Packing Co.*, 430 U.S. 519, 525 (1977). No such "clear and manifest purpose of Congress" exists in the FDCA to "supersede[]" any state's "historic police power" to protect the health and

safety of its citizens and license physicians and regulate the practice of medicine. *Wyeth*, 555 U.S. at 565. Thus, Plaintiff's claim of obstacle preemption likewise fails.

CONCLUSION

For these reasons, Defendants Berger and Moore respectfully ask this Court to dismiss the case in full against all parties.

Respectfully submitted this 24th day of March, 2023.

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** Email address to be used for all communications other than service.

*** Special appearance granted.

CERTIFICATE OF SERVICE

I hereby certify that on March 24, 2023, I electronically filed the foregoing with the Clerk of Court by using the CM/ECF system which will send a notice of electronic filing to all counsel of record.

/s/ W. Ellis Boyle
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CERTIFICATE OF COMPLIANCE

I hereby certify that the foregoing document complies with L.R. 7.3(d) and contains 6,238 words. I also certify that this document uses 13-point Courier New Font and has a top margin of 1.25" on each page in compliance with L.R. 7.1(a).

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