UNITED STATES DISTRICT COURT
MIDDLE DISTRICT OF NORTH CAROLINA
DURHAM DIVISION

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

REPLY IN SUPPORT OF MOTION TO DISMISS

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ARGUMENT[1]

Plaintiff's arguments fail for two reasons: (1) Congress has not given the FDA authority to mandate the major question of abortion policy in all states, and (2) North Carolina's laws do not obstruct the FDA's Mifeprex REMS or Congress's objectives. This Court should dismiss Plaintiff's claims.

I. Mandating abortion in every state is a major question that Congress never delegated to the FDA.

Abortion is one of the most consequential and divisive social and political issues of the past fifty years. The Supreme Court has repeatedly found that abortion issues involve a "critical moral question," and there are "profound moral and spiritual implications of terminating a pregnancy, even in its earliest stage." *Dobbs v. Jackson Women's Health Org.*, 142 S. Ct. 2228, 2258 (2022); *Planned Parenthood of Se. Penn. V. Casey*, 505 U.S. 833, 850 (1992).

[1] Defendant Attorney General Stein joins Plaintiff in opposing the Motion to Dismiss. Defendant Secretary Kinsley filed a non-responsive brief unrelated to the legal issues before this Court. To the extent those briefs are duplicative of Plaintiff's arguments or irrelevant, the Legislative Leader Defendants do not address them. The remaining Defendants take no position on the Motion.

Yet, according to Plaintiff, Congress impliedly gave the FDA—when it approved a REMS for Mifeprex—the authority to regulate chemical abortion nationwide and strip safety protections from state law.[2] Plaintiff claims that it is *not* extraordinary for an agency to single-handedly invalidate every state pro-life law or to impose a federal ceiling on prescription drug regulation notwithstanding the states' traditional and long-standing role in regulating for health and safety. (DE# 68 at 15.) Plaintiff is wrong.

In fact, the FDA has never claimed authority to preempt state abortion regulations based on drug approval procedures. Such an assertion of agency power would be far "beyond what Congress could reasonably be understood to have granted." *West Virginia v. Env't Prot. Agency*, 142 S. Ct. 2587, 2609 (2022). It would encroach on the long-exercised and historic power of states to regulate health and safety. *Hillsborough Cnty. v. Automated Med. Labs.*, 471 U.S. 707, 719 (1985). For

[2] Chemical abortions using Mifeprex account for a majority of abortions in the United States. *See* Guttmacher Institute, *Medication Abortion Now Accounts for More Than Half of All US Abortions*, available at: https://www.guttmacher.org/article/2022/02/medication-abortion-now-accounts-more-half-all-us-abortions (Feb. 24, 2022).

these reasons, the FDA has acknowledged that states *may* impose additional restrictions beyond the Mifeprex REMS, like limiting dispensing authority to only physicians as North Carolina law requires.[3]

Within the past year, the Supreme Court held that a state law "regulating abortion, like other health and welfare laws, is entitled to a 'strong presumption of validity.' It must be sustained if there is a rational basis on which the legislature could have thought that it would serve legitimate state interests." *Dobbs*, 142 S. Ct. at 2284 (citation omitted). In so holding, the Supreme Court gave no indication that its decision was toothless because the FDA controlled state abortion laws and had already imposed a federal ceiling. *Id.* at 2279 ("[T]he authority to regulate abortion must be returned to the people and their elected representatives.").

[3] FDA, *Questions and Answers on Mifepristone for Medical Termination of Pregnancy Through Ten Weeks Gestation*, available at: https://www.fda.gov/drugs/postmarket-drug-safety-information-patients-and-providers/questions-and-answers-mifepristone-medical-termination-pregnancy-through-ten-weeks-gestation (January 4, 2023) ("Some states allow health care providers other than physicians to prescribe medications. Health care providers should check their individual state laws.").

Currently, twenty-seven states have laws protecting unborn life that would—according to Plaintiff's position—be preempted by the FDA's Mifeprex REMS.[4] Plaintiff attempts to upend *Dobbs* and require every state to allow chemical abortion by mail without any physician oversight. The Supreme Court rejected that argument when it returned the power to legislate abortion policy to the states.

And Congress never gave to the FDA the power to overturn North Carolina's duly enacted laws regulating abortion. Plaintiff claims to discover such a "newfound power" hidden "in the vague language of an ancillary provision" of the FDCA, even though the "Congress ha[s] conspicuously and repeatedly declined to enact" such a regulation itself. *West Virginia*, 142 S. Ct. at 2610; *see* Women's Health Protection Act of 2021, H.R.3755, 117th Cong. (2021) (failed to pass). Courts presume that "Congress intends to make major policy decisions itself,

[4] *See* NBC News, *Map: Where medication abortion is and isn't legal*, available at: https://www.nbcnews.com/health/womens-health/map-pills-medication-abortions-are-legal-rcna70490 (April 25, 2023); The New York Times, Tracking the States Where Abortion Is Now Banned, https://www.nytimes.com/interactive/2022/us/ abortion-laws-roe-v-wade.html#:~:text=Abortion%20is%20banned%20after%2020,from%20laws%20in%20other%20states. (updated on May 24, 2023).

not leave those decisions to agencies." *West Virginia*, 142 S. Ct. at 2609 (citation omitted). "Extraordinary grants of regulatory authority are rarely accomplished through "subtle device[s]." *Id.*

In fact, in *West Virginia* the Supreme Court rejected such an attempt by the Environmental Protection Agency ("EPA") to expand authority to set emission limits on power plants into an unheralded power that would substantially restructure the entire American energy market. *Id.* at 2610. There, as here, no "clear congressional authorization" for the alleged agency power existed. *Id.* at 2609. Just as the EPA could not bootstrap its delegated authority to regulate some aspects of pollution control into a newly discovered, implied, and vast power to regulate the energy markets in all 50 states, the FDA cannot force every state to permit chemical abortion in direct contravention to their duly enacted health and welfare laws.

Forcing a state to bless chemical abortion implicates the major question of who has authority to set national chemical abortion policy. Plaintiff can point to no congressional authorization–express, implied, or in between–

for the FDA to make that important decision, because it does not exist.

Thus, Plaintiff's attempt to use the FDA's Mifeprex REMS as a sword to undo these challenged North Carolina laws fails. The FDA does not possess the authority to deal with that major question. The Court should, respectfully, dismiss Plaintiff's claims against all parties.

II. The challenged North Carolina laws do not obstruct compliance with the FDA's Mifeprex REMS.[5]

Obstacle preemption exists only when state law stands as an obstacle to the purposes Congress delegated to the agency. *Arizona v. United States*, 567 U.S. 387, 399 (2012). "Implied preemption analysis does not justify a 'freewheeling judicial inquiry into whether a state statute is in tension with federal objectives,'" and "[Supreme Court] precedents 'establish that a high threshold must be met if a state law is to be preempted for conflicting with the purposes of a federal Act.'" *Chamber of Com. of U.S. v. Whiting*, 563 U.S. 582, 607 (2011) (citations omitted).

[5] Plaintiff concedes that neither field nor impossibility preemption applies here, relying only on an argument that North Carolina's laws pose an obstacle to FDA's Mifeprex REMS. Pl. Opp'n 17.

Here, Congress unambiguously dictated the FDA's purpose: to "protect the public health by ensuring that ... drugs are safe and effective." 21 U.S.C. § 393(b)(2)(B). The challenged North Carolina laws complement rather than pose an obstacle to Congress's stated purpose.

Further, the 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." *Arizona*, 567 U.S. at 387 (cleaned up). This is especially true where, as here, Congress legislates "in a field which the States have traditionally occupied." *Wyeth v. Levine*, 555 U.S. 555, 565 (2009). This presumption requires Plaintiff to show that Congress clearly intended to preempt state law. She cannot.

North Carolina has long sought to protect women by requiring these safeguards—safeguards which promote FDA's safety raison d'être. In this case, the question presented is: can North Carolina law require that only a doctor dispense Mifeprex in an adequately-safe facility with appropriate informed consent?

Plaintiff says that the FDA considered and rejected, or rescinded, the safety measures that the challenged North Carolina laws require. But that is not the test for obstacle preemption. Rather, the question is whether state law stands as an obstacle to and frustrates the purpose of federal law. *Arizona*, 567 U.S. at 399.

"To determine whether a state law conflicts with Congress' purposes and objectives, [courts] must first ascertain the nature of the federal interest." *Hillman v. Maretta*, 569 U.S. 483, 491 (2013). Plaintiff claims the federal interest at issue is preserving a comprehensive federal regulatory scheme. Pl. Opp'n 14. But that broad, general purpose exists for nearly *every* federal law. Such a ubiquitous interest, standing alone, is never sufficient for preemption. *Wyeth*, 555 U.S. at 565.

"In order to identify the 'purpose of Congress,' it is appropriate to briefly review the history of federal regulation of drugs and drug labeling." *Wyeth*, 555 U.S. at 566–67. Congress has long sought to preserve complementary state law in the FDCA. *Id.* The first significant public health law, the Federal Food and Drugs Act, regulated adulterated or

misbranded drugs and "supplemented the protection for consumers already provided by state regulation and common-law liability." *Id.* In the 1930s, and again in the 1960s, Congress expanded the FDA's purview, requiring manufacturers to prove their drugs were both safe and effective. *Id.*

Yet as Congress "enlarged the FDA's powers to 'protect the public health' and 'assure the safety, effectiveness, and reliability of drugs,' [it] *took care to preserve state law*." *Id.* (emphasis added). In the 1962 amendments, for example, Congress included a savings clause "indicating that a provision of state law would only be invalidated upon a 'direct and positive conflict' with the FDCA." *Id.*[6] Thus, despite FDA regulation of pharmaceuticals, "state common-law suits 'continued unabated.'" *Id.* (quoting *Riegel v. Medtronic, Inc.*, 552 U.S. 310, 340 (2008) (Ginsburg, J., dissenting)).

Further, as the Supreme Court explained in *Wyeth*, if Congress had thought state law "posed an obstacle to its

[6] Plaintiff suggests that this clause applies only to the 1962 Amendments, but in *Wyeth*, the Supreme Court treated the savings clause as part and parcel of Congress's longstanding recognition of complementary state regulation. *Wyeth*, 555 U.S. at 566–67.

objectives, it surely would have enacted an express pre-emption provision at some point during the FDCA's 70-year history." *Id.* Congress did, in fact, enact a preemption provision for medical devices in 1976. "But despite [that] express pre-emption provision for medical devices, Congress has not enacted such a provision for prescription drugs." *Id.* at 574*; Riegel*, 552 U.S., at 327 ("Congress could have applied the pre-emption clause to the entire FDCA. It did not do so, but instead wrote a pre-emption clause that applies only to medical devices.").

Congress's "silence on the issue, coupled with its certain awareness of the prevalence of state tort litigation, is powerful evidence that Congress did not intend FDA oversight to be the exclusive means of ensuring drug safety and effectiveness." *Wyeth*, 555 U.S. at 574. Indeed, "[t]he case for federal pre-emption 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." *Bonito Boats, Inc. v. Thunder Craft Boats, Inc.*, 489 U.S. 141, 166–167 (1989) (cleaned up).

The challenged North Carolina laws do not frustrate the congressional purpose here. The FDA did not say that states may not, for example, require in-person visits. Instead, the FDA simply stated that, as a federal minimum, the recently enacted Mifeprex REMS did not require in-person visits. Again, the FDA acknowledges that states can layer additional requirements based upon state law, for example, by providing that only doctors may dispense chemical abortion drugs. *Supra* n.3.

Contrast this regulatory framework with a case where the Supreme Court noted that a manufacturer could not follow both the state and federal rule at the same time. *Geier v. Am. Honda Motor Co., Inc.*, 529 U.S. 861, 884 (2000). Plaintiff can comply with both, and presumably has been for years leading up to the recent FDA Mifeprex REMS. Further, the Supreme Court has rejected the application of *Geier* in the context of FDA regulation because its "'complex and extensive' regulatory history and background . . . reveal the longstanding coexistence of state and federal law." *Wyeth*, 555 U.S. at 580. *Geier* does not support Plaintiff.

Arizona v. United States is also distinguishable. In *Arizona*, the Supreme Court relied on the federal government's "broad, undoubted power over the subject of immigration and the status of aliens" under the Constitution to hold that Congress had "enacted . . . a comprehensive framework for 'combating the employment of illegal aliens.'" 567 U.S. at 394, 404. Congress has no similar broad, constitutionally based power over the medical field or abortion regulations. *See Hillsborough*, 471 U.S. at 719; *Dobbs*, 142 S. Ct. at 2283–84. Congress expressly created the FDA to "protect the public health" and "assure the safety, effectiveness, and reliability of drugs," *Wyeth*, 555 U.S. at 567, not to impliedly regulate abortion.

Plaintiff nonetheless contends that *Geier* and *Arizona* control here, and that the Legislative Leader Defendants misconstrue *Wyeth*. In *Wyeth*, the drug manufacturer argued that the FDCA established both a floor and a ceiling for drug regulation, just like Plaintiff argues here. The *Wyeth* plaintiff contended that requiring it to comply with a state-law duty to provide a stronger warning on its drug label would interfere with Congress's purpose of entrusting an expert

agency with drug labeling decisions that strike a balance between competing objectives. *Id.* at 573.

The Supreme Court rejected this as reliant on "an untenable interpretation of congressional intent and an overbroad view of an agency's power to pre-empt state law." *Id.* Instead, it found that "all evidence of Congress' purposes is to the contrary," and "Congress enacted the FDCA to bolster consumer protection against harmful products" while preserving state protections. *Id.* at 574. The Supreme Court's rationale applies equally here.

This Court should reject Plaintiff's contention that the FDA's authority to balance interests in determining Mifeprex REMS authorizes it to go far beyond the well-established congressional intent of the FDCA and pre-empt state laws in a majority of states. In the FDCA, Congress "cast federal labeling standards as a floor upon which States could build." *Id.* at 577. The challenged North Carolina laws build on that floor; they do not conflict with the federal REMS. Nor do those laws stand as an obstacle to accomplishment and execution of the full purposes and objectives of the FDCA.

Congress's purpose in the FDCA is to ensure the safety of drugs distributed in interstate commerce by *supplementing* state regulation. *See Wyeth*, 555 U.S. at 566–67. North Carolina's challenged laws pose no obstacle to that purpose. Thus, the FDA Mifeprex REMS does not preempt the challenged North Carolina laws because they do not obstruct compliance with that REMS.

CONCLUSION

For the foregoing reasons, the Legislative Leader Defendants ask this Court to grant the Motion and dismiss the entirety of the case against all parties.

RESPECTFULLY SUBMITTED THIS 26th day of May, 2023.

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* This email address must be used in order to effectuate service under Rule 5 of the North Carolina Rules of Civil Procedure.

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

*** Special appearance granted.

CERTIFICATE OF SERVICE

I hereby certify that on May 26, 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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Attorney for Defendants Moore and Berger

CERTIFICATE OF COMPLIANCE

I hereby certify that the foregoing document complies with L.R. 7.3(d) and contains 2,654 words. I also certify that this document uses 13-point Courier New Font and has a top margin of 1.25" on each page in compliance with L.R. 7.1(a).

s/ W. Ellis Boyle
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