Nos. 24-1576(L), 24-1600, 24-1617

UNITED STATES COURT OF APPEALS
FOR THE FOURTH CIRCUIT

AMY BRYANT, M.D.,

Plaintiff-Appellee,

v.

TIMOTHY K. MOORE, ET AL.,

Intervenors/Defendants-Appellants

and

JOSHUA H. STEIN, IN HIS OFFICIAL CAPACITY AS ATTORNEY GENERAL FOR THE STATE OF NORTH CAROLINA, ET AL.,

Defendants-Appellees.

On Appeal from the United States District Court
for the Middle District of North Carolina
Case No. 1:23-cv-00077-CCE-LPA

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TABLE OF CONTENTS

TABLE OF AUTHORITIES

Cases

Federal Statutes

State Statutes

Regulations

Other Authorities

INTRODUCTION

North Carolina possesses the sovereign authority to protect the health and welfare of its citizens. Yet the district court issued a sweeping decision declaring that state "safety-related restrictions" on high-risk abortion drugs are impliedly preempted because they pose an obstacle to a "comprehensive regulatory system" set by the federal government. JA 633. That ruling squares with neither basic preemption principles nor the text of the Food, Drug, and Cosmetic Act (FDCA). And it puts in jeopardy not only North Carolina's commonsense safety requirements for abortion drugs but also *any* state law that imposes a "safety-related" protection on particularly high-risk drugs.

To start, the district court's decision violates the presumption against preemption. Federal courts begin "with the assumption that the historic police powers of the States [are] not to be superseded by the Federal Act unless that was the clear and manifest purpose of Congress." *Rice v. Santa Fe Elevator Corp.*, 331 U.S. 218, 230 (1947). Yet the FDCA does not express any intent—much less a "clear and manifest" one—to preempt complementary state law. And because the relevant federal drug laws are *silent* as to preemption, Plaintiff alleges only implied obstacle preemption. But she cannot meet the "high threshold" necessary to show that a state law is impliedly preempted.

According to Plaintiff, the 2007 Amendments to the FDCA, the Food and Drug Administration Amendments Act (FDAAA), radically

altered the federal-state balance long struck by Congress with respect to drug regulation. Instead of setting the traditional federal floor, she argues, the FDAAA sets a federal ceiling, too, at least for the highest-risk drugs. On this view, the FDA—and only the FDA—"is responsible for deciding what terms are required for safe access to" REMS drugs. JA 632.

But that gets Congress's purpose backwards. The FDAAA is part of a long line of statutory enactments providing for *more* drug regulation—not less. Nothing in the text, structure, or history of that amendment suggests that Congress meant to reverse course and disallow complementary state regulation—much less with the clarity necessary to surmount the strong presumption against preemption. Under the district court's counterintuitive logic, the riskier a drug, the less a State can do to protect its citizens. Indeed, if the district court is right, States may regulate antibiotics but not opioids. That absurd result is contrary to the text of the FDAAA and conflicts with basic preemption principles. It could have devastating effects on real people. This Court should reverse.

JURISDICTIONAL STATEMENT

Intervenor-Appellants appeal the final judgment of the U.S. District Court for the Middle District of North Carolina. The district court entered final judgment on June 3, 2024. JA 657–59. On June 20, 2024, Appellants filed a timely notice of appeal. JA 660–63. Plaintiff Dr.

Bryant and the Attorney General both filed cross-appeals, which were consolidated with this case. JA 664–69. The district court had subject-matter jurisdiction under 28 U.S.C. § 1331. This Court has jurisdiction under 28 U.S.C. § 1291.

STATEMENT OF THE ISSUES

This case presents three important questions of federal law:

1. Whether the Food, Drug, and Cosmetic Act preempts long-standing and commonsense state laws protecting the health and safety of women taking abortion-inducing drugs.

2. Whether the Supremacy Clause grants a private right of action to challenge the enforcement of state law that allegedly conflicts with the FDCA.

3. Whether a district court abuses its discretion by enjoining unidentified provisions of state law that were not challenged.

STATEMENT OF THE CASE

I. North Carolina protects maternal health.

In North Carolina, abortion is lawful for any reason during the first 12 weeks of pregnancy. N.C. Gen. Stat. § 90-21.81B. Past that point, abortion is prohibited, except in cases of rape or incest through the twentieth week of pregnancy, when a physician determines a life-limiting fetal anomaly exists through twenty-four weeks, or to protect the life of the mother anytime during her pregnancy. *Id.* North

Carolina's definition of abortion excludes the treatment of miscarriages and ectopic pregnancies. *Id.* § 90-21.81(4e).

Consistent with its long-standing authority to regulate for health and safety, North Carolina enacted several protections for women who use abortion-inducing drugs. First, North Carolina requires that an abortion provider obtain informed consent. A woman must be orally informed of specific information "[a]t least 72 hours prior to the medical abortion." *Id.* § 90-21.83A(b)(1). That information must include, among other things, "[t]he name of the physician who will prescribe, dispense, or otherwise provide the abortion-inducing drug," *id.* § 90-21.83A(b)(2)(a), and "[t]he probable gestational age of the unborn child as determined by both patient history and by ultrasound results," *id.* § 90-21.83A(b)(2)(b).

Second, North Carolina requires the physician "prescribing, administering, or dispensing an abortion-inducing drug" to "examine the woman in person … prior to providing an abortion-inducing drug." *Id.* § 90-21.83B(a). During that examination, the physician must "[d]etermine the woman's blood type," *id.* § 90-21.83B(a)(2), and "the probable gestational age" of her unborn child, *id.* § 90-21.83B(a)(7).[1]

[1] The statute also requires that the physician "[d]ocument in the woman's medical chart the probable … existence of an intrauterine pregnancy," *id.*, but that requirement has been enjoined in a separate case, *see Planned Parenthood S. Atl. v. Stein*, No. 1:23-cv-480, 2024 WL 3551906, at *14 (M.D.N.C. July 26, 2024).

These requirements are necessary because Rh-negative blood type can cause serious complications during pregnancy, JA 247, and the FDA has approved mifepristone for use only up to ten weeks gestation, JA 589.

Third, consistent with the FDA's original REMS requiring in-person dispensing, North Carolina requires an abortion provider to "be physically present in the same room as the woman when the first drug or chemical is administered." N.C. Gen. Stat. § 90-21.83A(b)(2)(a).

Fourth, North Carolina requires abortion providers to "schedule an in-person follow-up visit … approximately seven to 14 days after providing the abortion-inducing drug." *Id.* § 90-21.83A(b)(4)(l). This makes sense given that the FDA's own label for the drug notes that roughly 1 in 25 women end up in the emergency room. JA 596, 605. In fact, the FDA itself required a follow-up visit for the first 16 years of the drugs' use. To comply with the North Carolina requirement, an abortion provider must notify the patient that a follow-up visit will be scheduled, N.C. Gen. Stat. § 90-21.83A(b)(4)(l), and "make all reasonable efforts to ensure that [she] returns for the scheduled appointment," *id.* § 90-21.83B(b). The provider must also report to the State "[a] brief description of the efforts made" to ensure the patient attends her follow-up appointment and whether she "returned for [that] appointment." *Id.* § 90-21.93(b)(8)–(9).

Finally, the abortion provider must report certain information to North Carolina's Department of Health and Human Services. *Id.* § 90-

21.93(a). The reportable information includes, among other things, "[t]he probable gestational age of the unborn child," "the date of the ultrasound used to estimate gestational age," and "[a]ny specific complications the woman suffered from the abortion procedure." *Id.* § 90-21.93(b). The abortion provider must also report adverse events to the FDA. *Id.* § 90-21.93(c).

II. Congress supplements the States' longstanding authority to regulate the medical profession.

A. The Food and Drugs Act

In 1906, Congress enacted the Food and Drugs Act, the first law designed to protect public health by "supplement[ing] the protection for consumers already provided by state regulation and common-law liability." *Wyeth v. Levine*, 555 U.S. 555, 566 (2009). That law "prohibited the manufacture or interstate shipment of adulterated or misbranded drugs." *Id.*

B. The Food, Drug, and Cosmetic Act

Congress enacted the Food, Drug, and Cosmetic Act (FDCA) in 1938 to respond to "increasing[] concern[s] about unsafe drugs and fraudulent marketing." *Id.* This statute further supplemented state regulation, providing "for premarket approval of new drugs" by the FDA. *Id.* (citing Federal Food, Drug, and Cosmetic Act, 21 U.S.C. § 301 *et seq.*). The FDCA "require[s] every manufacturer to submit a new drug application ... to the FDA for review." *Id.*; 21 U.S.C. § 355(a). Under the

1938 statute, "[t]he FDA could reject an application if it determined that the drug was not safe for use as labeled." *Wyeth*, 555 U.S. at 566. But if the FDA "failed to act" on the application within "60 days after the filing," the application would become effective, and the manufacturer could begin distributing the drug. *Id.* That put the burden on the FDA to reject a drug.

C. The 1962 and 1976 Amendments

Congress amended the FDCA in 1962 to increase consumer drug protections in light of the thalidomide tragedy in Europe. Harvey Teff & Colin R. Munro, *Thalidomide: The Legal Aftermath* 1–10 (1976). That drug was marketed as a remedy for morning sickness—without adequate testing—and caused widespread and serious birth defects. *Id.* The 1962 amendments thus "shifted the burden of proof from the FDA to the manufacturer." *Wyeth*, 555 U.S. at 567. They "required the manufacturer to demonstrate that its drug was 'safe to use under the conditions prescribed, recommended, or suggested in the proposed labeling' *before* it could distribute the drug." *Id.* (quoting 21 U.S.C. § 355(d)) (emphasis added).

Yet even while Congress increased the FDA's authority to protect consumers, it "took care to preserve state law." *Wyeth*, 555 U.S. at 567. The 1962 amendments included a savings clause preserving state laws that also protect health: "Nothing in the amendments made by this Act

… shall be construed as invalidating any provision of State law … unless there is a direct and positive conflict." Drug Amendments of 1962, Pub. L. No. 87-781, § 202, 76 Stat. 780, 793. The 1962 amendments thus continued the long tradition of allowing complementary state drug safety laws.

In 1976, Congress amended the FDCA—yet again, "to provide for the safety and effectiveness of medical devices." Medical Device Amendments of 1976, Pub. L. No. 94-295, § 521, 90 Stat. 539, 539. This time, Congress changed course: Unlike prescription-drug regulations, the new medical-device regulations superseded state law. The 1976 amendments expressly preempted any state requirement "different from, or in addition to" the federal requirements for medical devices. *Id.* § 521, 90 Stat. at 574. But Congress "declined to enact such a provision for prescription drugs." *Wyeth*, 555 U.S. at 567.

D. The Food and Drug Administration Amendments Act

In 2007, Congress passed the Food and Drug Administration Amendments Act (FDAAA) to "enhance the postmarket authorities" of the FDA "with respect to the safety of drugs." Pub. L. No. 110-85, 121 Stat. 823, 823 (codified at 21 U.S.C. § 355-1). The FDAAA was Congress's response to the Vioxx controversy. Approved in 1999, the pain medication became one of America's bestselling drugs. Yet post-approval studies showed that Vioxx caused serious adverse events,

potentially doubling the risk of heart attacks and strokes. Jerry Avorn *et al.*, *The FDA Amendment Act of 2007—Assessing Its Effects a Decade Later*, 379 New Engl. J. Med. 1097, 1097 (2018). Enter the FDAAA. Recognizing that post-approval safety measures are essential to ensuring that the benefits of high-risk drugs outweigh their risks, Congress authorized additional safety restrictions. 21 U.S.C. § 355-1(a).

In particular, the FDAAA authorized the FDA to impose "risk evaluation and mitigation strategies," or REMS, when necessary to "ensure that the benefits of the drug outweigh the risks of the drug." *Id.* § 355-1(a)(1). Among other things, REMS may require the drug's sponsor to create a medication guide and patient insert to be dispensed with the drug. *Id.* § 355-1(a), (e)(2).

Congress also authorized the FDA to impose additional safety measures—called "elements to assure safe use" (ETASUs)—for drugs that pose a particularly "serious risk," such as death, hospitalization, or birth defects. *Id.* § 355-1(b)(4)–(5), (f)(1)–(2). ETASUs are appropriate only where drugs are "associated with a serious adverse drug experience" and where necessary "to mitigate ... serious risk." *Id.* ETASUs may include requirements that prescribers and pharmacies be specially certified, that the drug be dispensed only in certain healthcare settings or under certain safe-use conditions, or that users be registered or monitored. *Id.* § 355-1(f)(1), (3).

At the same time, Congress placed clear limits on the FDA's authority to impose federal safe-use elements. It directed the FDA to ensure that its ETASUs do not "unduly burden patient access" to the drug. *Id.* § 355-1(f)(2)(C). And it instructed the FDA to take certain steps to minimize the "burden on the health care delivery system" imposed by its ETASUs. *Id.* § 355-1(f)(2)(D).

Importantly, the FDCA does not contain a private right of action. It vests enforcement authority solely with the United States: any "proceedings for the enforcement, or to restrain violations," of the FDCA must "be by and in the name of the United States." *Id.* § 337(a). As a result, private litigants may not file suit for noncompliance. *Buckman Co. v. Plaintiffs' Legal Comm.*, 531 U.S. 341, 349 n.4, 352 (2001); *Medtronic, Inc. v. Lohr*, 518 U.S. 470, 487 (1996) (plurality opinion).

E. The Mifepristone REMS

In 2000, the FDA first approved Mifepristone (brand name Mifeprex) to induce abortion during the first seven weeks of pregnancy. JA 108. From its initial approval, FDA recognized the serious risks posed by the drug. The FDA-approved label includes a black box warning that "[s]erious and sometimes fatal infections and bleeding" may occur. JA 589. As a result, the FDA limited prescribing authority to doctors, required three in-person visits with the doctor, and required the drug to be administered in person. JA 97, 104. The FDA also required abortion

providers to "report incidents of hospitalizations, blood transfusions, or other serious adverse events to the drug sponsor (who, in turn, was required to report the events to the FDA)." JA 105.

The FDA originally restricted Mifeprex under its own Subpart H regulations. 21 C.F.R. § 314.520 (a). But when Congress enacted the FDAAA in 2007, it required the sponsors of drugs approved under Subpart H to submit a proposed REMS. The manufacturer of Mifeprex did so, and FDA adopted a REMS for Mifeprex in 2011. JA 171, 174. To mitigate the "serious risk" posed by mifepristone and minimize adverse events, 21 U.S.C. § 355-1(b)(4)–(5), (f)(1)–(2), the 2011 REMS included ETASUs imposing the same safeguards as the 2000 Subpart H approval, JA 160–61.

In 2016, the manufacturer of Mifeprex sought, and FDA approved, the removal of some of these protections. JA 176, 183. The modified REMS increased the indicated gestational age from seven to ten weeks, reduced the number of office visits from three to one, and allowed non-physicians to prescribe the drug. JA 186. It also changed the reporting requirements, requiring abortion providers to report only fatalities, not hospitalizations, blood transfusions, or other serious adverse events. JA 220.

In 2019, the drug manufacturer GenBioPro submitted an application for, and FDA approved, the generic version of mifepristone. JA 233. The generic drug is subject to the same REMS as Mifeprex. *Id.*

In April 2021, the FDA suspended the in-person administration requirement because of the COVID-19 pandemic. JA 277–78. And in December of that year, the FDA formally removed this requirement from the REMS. JA 322, 236. The current 2023 REMS allows certified providers to prescribe mifepristone without an in-office visit with the patient. JA 79–80.

III. Procedural History

Plaintiff is an abortion provider. JA 30–31. In January 2023, she filed suit alleging that several of North Carolina's laws governing the safe use of abortion drugs were preempted. JA 69–72. Senate President Pro Tempore Philip E. Berger and Speaker of the House Timothy K. Moore (collectively, "the Legislative Leaders") intervened and moved to dismiss. JA 19, 612. The district court converted the motion into cross-motions for summary judgment and granted summary judgment in part to Plaintiff and in part to the Legislative Leaders. JA 612–13, 655–56.

The district court started by recognizing that "health and safety matters, the practice of medicine, and the regulation of medical professionals are traditionally matters of state concern." JA 626. The court acknowledged the long federal-state cooperation on matters of drug safety and explained that "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." JA 627 (quoting *Wyeth*, 555 U.S. at 575). What's more, the court affirmed that *Wyeth* held that the FDCA establishes a federal floor for drug approvals. *See* JA 650.

The court nevertheless brushed aside that long history of federal-state cooperation and *Wyeth* because the FDAAA post-dated *Wyeth*'s inception. JA 627–28, 650–51. According to the court, Congress had a new purpose in the FDAAA: "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." JA 632. Thus state laws regulating these drugs based on their "health and safety risks stand[] as an obstacle to Congress' goal of creating a comprehensive regulatory framework." *Id.*

Applying this framework, the lower court analyzed the challenged state laws to determine whether they regulated mifepristone's "health and safety risks." JA 633–52. The court upheld certain provisions of North Carolina law, finding they were "directed to broader health concerns." JA 637. These included North Carolina's informed-consent requirement, 72-hour waiting period, ultrasound requirement, in-person examination requirement, blood-type determination requirement, and state health department reporting requirement. JA 640.

In contrast, the district court held that four provisions of North Carolina law were preempted. The court concluded these provisions

were "designed to reduce the risks associated with" mifepristone. *Id.* It thus enjoined the physician-only prescribing requirement, the in-person administration requirement, the requirement that physicians schedule a follow-up visit, and the requirement that physicians report non-fatal adverse events to the FDA. JA 652.

Over the Legislative Leaders' objection, the district court also enjoined "any other provisions of North Carolina law" "to the extent" those unidentified laws sought to accomplish the same purposes. JA 658. The undisclosed—but nevertheless enjoined—laws include any that "prohibit any healthcare provider other than a licensed physician from prescribing mifepristone," "require that mifepristone be provided in person," "require scheduling an in-person follow-up visit after providing mifepristone or efforts to ensure such a follow-up appointment," or "require the reporting of non-fatal adverse events related to mifepristone to the FDA." *Id.* This appeal follows.

SUMMARY OF THE ARGUMENT

The district court's far-reaching decision precludes States from enacting health and safety regulations for the most dangerous drugs approved by the FDA—and only the most dangerous drugs. That befuddling result runs contrary to basic preemption principles and has no basis in the text Congress wrote.

Ordinarily, preemption analysis starts with the assumption that state law is not preempted absent a "clear and manifest" congressional

purpose. That assumption applies with special force when Congress legislates in a field of traditional state concern. The Supreme Court has long recognized "the historic primacy of state regulation of matters of health and safety" regulated by the FDCA. *Medtronic*, 518 U.S. at 485.

To prevail, Plaintiff must establish a "clear and manifest" congressional purpose to set aside state health and safety laws. She cannot. Nothing in the text, structure, or history of the FDCA or the FDAAA suggests Congress intended to set aside state law and establish a federal ceiling. In particular, Plaintiff cannot meet the "high threshold" to show that a state law is impliedly preempted. Far from posing an "actual" conflict with federal law, North Carolina's safety protections complement the FDCA.

The lower court avoided this conclusion—and the requirement that an "actual" conflict exist—by discovering a novel purpose in the FDAAA. In the court's view, Congress intended the FDAAA to upend federal-state relations by imposing a "comprehensive regulatory system" and federal ceiling for high-risk drugs. But that is the language of field preemption, not obstacle preemption. And there is no indication that Congress intended the FDAAA to transform the FDA into the exclusive drug-safety czar for high-risk drugs (and only for high-risk drugs).

The FDAAA's text states its purpose: to "enhance" existing federal safeguards to better protect consumers. That amendment nowhere

indicates that Congress reversed its long-running intent to "regard[] state laws as a complementary form of drug regulation." *Wyeth*, 555 U.S. at 578. To the contrary, Congress's goal in the FDAAA was to ensure drugs in the marketplace were safer, not reduce protections for high-risk drugs.

That the FDAAA preempts state law in one narrow area of regulation—by prohibiting state licensing of clinical studies—shows that Congress chose not to broadly preempt other state laws. Indeed, the case for preemption is particularly weak here because Congress is well aware of state drug regulation and has concluded time and again that these additional regulations better protect consumers.

More fundamentally, the district court avoided the requirement that North Carolina law *actually* conflict with federal law by concluding that the "comprehensiveness" of the federal REMS scheme gave rise to implied obstacle preemption. But it is well settled that mere "comprehensiveness" does not justify implied obstacle preemption. An actual conflict is required. Were the rule otherwise, implied obstacle preemption would exist anytime a federal agency regulated comprehensively. The traditional federal-state balance is not so fragile.

North Carolina's statutes regulating abortion drugs do not stand as an obstacle to the accomplishment of Congress's health and safety purpose. Rather, these commonsense safety requirements complement and reinforce Congress's purpose: to protect consumers from dangerous

drugs like mifepristone and opioids. While the FDAAA allows the federal government to set certain restrictions on the use of such drugs, those restrictions establish a federal floor, not a ceiling. As the Supreme Court said in *Wyeth*, "Congress did not intend FDA oversight to be the exclusive means of ensuring drug safety and effectiveness." 555 U.S. at 575.

Plaintiff's claim fails for the additional reason that she lacks a cause of action to bring her Supremacy Clause challenge. There is no private right of action under the Supremacy Clause. And one does not exist in equity because the FDCA expressly vests exclusive enforcement authority with the federal government. The United States has brought no claim here.

Even if this Court holds that the FDAAA fundamentally altered the federal-state balance, and that Plaintiff has an equitable cause of action, it should still vacate the district court's injunction, which goes beyond the statutes challenged by Plaintiff. The district court abused its discretion by purporting to enjoin provisions of North Carolina law not before the court, including laws not yet enacted. In doing so, it extended relief beyond what was necessary to remedy Plaintiff's alleged injuries and put state officials in the untenable position of having to guess which actual or potential segments of North Carolina laws are enjoined.

For these reasons, this Court should reverse the district court's judgment and vacate its permanent injunction.

STANDARD OF REVIEW

This Court "review[s] the grant of a motion for summary judgment de novo." *Greater Balt. Ctr. for Pregnancy Concerns, Inc. v. Mayor & City Council of Balt.*, 879 F.3d 101, 107 (4th Cir. 2018). "Summary judgment is appropriate where there is no genuine dispute of material fact and the moving party is entitled to judgment as a matter of law." *Id.* (cleaned up).

While discretionary, the scope of injunctive relief is "not boundless." *Mayor of Baltimore v. Azar*, 973 F.3d 258, 293 (4th Cir. 2020). Any relief awarded must be "carefully addressed to the circumstances of the case" and "no more burdensome to the defendant than necessary to provide complete relief to the plaintiffs." *Id.* Injunctions "may go no further than necessary to provide … relief to the parties." *Labrador v. Poe by & through Poe*, 144 S. Ct. 921, 921 (2024) (Gorsuch, J., concurring). "A district court abuses its discretion if its injunctive order is guided by erroneous legal principles or rests upon a clearly erroneous factual finding, or it otherwise acts arbitrarily or irrationally in its ruling." *Id.* (citation omitted).

ARGUMENT

I. The FDCA does not preempt North Carolina's laws regulating abortion drugs.

Since the States "are independent sovereigns in our federal system," courts do not presume that Congress "cavalierly pre-empt[s]

state-law." *Medtronic*, 518 U.S. at 485. "[A]ny analysis of preemption begins with the basic assumption that Congress did not intend to displace state law." *Guthrie v. PHH Mortg. Corp.*, 79 F.4th 328, 336 (4th Cir. 2023). This is especially true "in areas of traditional state regulation," where courts must "assume that a federal statute has not supplanted state law unless Congress has made such an intention clear and manifest." *Bates v. Dow Agrosciences LLC*, 544 U.S. 431, 449 (2005) (cleaned up).

This case concerns only implied obstacle preemption. Plaintiff has disavowed any claim that the challenged laws are expressly preempted, field preempted, or preempted because of a direct conflict between state and federal law. JA 614 n.4. The Legislative Leaders dispute that implied obstacle preemption is a valid basis for federal preemption. It is unsupported by the Supremacy Clause and inconsistent with separation of powers principles because it permits the elevation of "abstract and unenacted legislative desires above state law." *Virginia Uranium, Inc. v. Arren*, 587 U.S. 761, 778 (2019) (plurality opinion written by Gorsuch, J., and joined by Thomas, J., and Kavanaugh, J.).

Still, Plaintiff's claim also fails under existing precedent. Obstacle preemption occurs only when the state law "stands as an obstacle to the accomplishment and execution of the full purposes and objectives of Congress." *Guthrie*, 79 F.4th at 337. Accordingly, a reviewing court must first "determine Congress's significant objectives in passing the

federal law." *Id.* at 338 (citation omitted). Then, the court must decide "whether the state law stands as an obstacle to the accomplishment of a significant federal regulatory objective." *Id.* The district court erred at each step. Because North Carolina's abortion laws do not conflict with the FDCA's health and safety purpose, they are not preempted.

A. Congress enacted the FDCA as a federal floor to protect consumers from dangerous drugs.

"[T]he purpose of Congress is the ultimate touchstone in every preemption case." *Wyeth*, 555 U.S. at 565. Thus, "[i]mplied preemption analysis does not justify freewheeling judicial inquiry into whether a statute is in tension with federal objectives." *Chamber of Com. v. Whiting*, 563 U.S. 582, 607 (2011). On the contrary, "evidence of pre-emptive purpose" must "be sought in the text and structure of the statute at issue." *Virginia Uranium*, 587 U.S. at 778 (cleaned up). Where, as here, "Congress has legislated in a field which the States have traditionally occupied," this inquiry starts "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." *Wyeth*, 555 U.S. at 565 (cleaned up). That presumption holds true for the FDCA and its subsequent amendments.

There is no dispute that the FDCA's primary objective is to ensure the safety of food and drugs. *Id.* at 574; Federal Food, Drug, and Cosmetic Act, Pub. L. No. 75-717, 52 Stat. 1040, 1040. As the Supreme

Court has recognized, Congress "enacted the FDCA to bolster consumer protection against harmful products." *Wyeth*, 555 U.S. at 574. To be sure, Congress has over the years "enlarged the FDA's powers to protect the public health and assure the safety, effectiveness, and reliability of drugs," but it has always taken "care to preserve state law." *Id.* at 567 (citation omitted).

Indeed, in *Wyeth*, the Supreme Court rejected the claim Plaintiff makes here—that "the FDCA establishes both a floor and a ceiling for drug regulation." *Id.* at 573–74. "The most glaring problem with th[at] argument," the Court wrote, "is that all evidence of Congress' purposes is to the contrary." *Id.* at 574. In fact, "Congress did not provide a federal remedy for consumers harmed by unsafe or ineffective drugs" at all. *Id.* Instead, it "determined that widely available state rights of action provided appropriate relief for injured consumers." *Id.* at 574–75. And consistent with Congress' directive that the FDCA is a federal floor, the FDA itself has "long maintained that state law offers an additional, and important, layer of consumer protection that complements FDA regulation." *Id.* at 578–79.

The *Wyeth* Court held that two amendments to the FDCA demonstrate that "Congress did not intend FDA oversight to be the exclusive means of ensuring drug safety and effectiveness." *Id.* at 575. First, Congress amended the Act in 1962 to "protect the public health" and "assure the safety, effectiveness, and reliability of drugs." § 202, 76

Stat. at 780; *Wyeth*, 555 U.S. at 567. Those amendments continued Congress's long-standing policy to supplement, rather than supersede, state law by including an express savings clause preserving state law absent a "direct and positive conflict." § 202, 76 Stat. at 793.

Second, Congress amended the FDCA to include an express preemption provision for medical devices, Medical Device Amendments of 1976, § 521, 90 Stat. at 574, but "declined" to enact a similar preemption provision for prescription drugs, *Wyeth*, 555 U.S. at 567. Congress's "silence on the issue[] ... is powerful evidence that Congress did not intend FDA oversight to be the exclusive means of ensuring drug safety and effectiveness." *Id.* at 575. In short, *Wyeth* held that "Congress did not intend FDA oversight to be the exclusive means of ensuring drug safety and effectiveness." *Id.* at 575.

Plaintiff says that the savings clause in the 1962 amendments should be ignored because it applied only to those amendments. But that ignores the text and history of the FDCA writ large. The savings clause reaffirmed that, consistent with decades of congressional intent, the 1962 amendments were meant to "supplement" state health and safety laws. *Id.* at 566. Nothing about those amendments, which carefully preserved state authority, suggests that Congress intended *other* FDCA amendments "to be the exclusive means of ensuring drug safety and effectiveness." *Id.* at 575.

B. Nothing in the FDAAA's text or history suggests Congress intended to alter the federal-state balance and supersede state law.

Plaintiff argues, and the district court held, that the FDAAA silently affected a sea change in federal-state relations for the highest-risk drugs, booting States from their traditional consumer-protection role. JA 628–33. The court ignored *Wyeth*'s holding that the FDCA establishes a federal floor and discovered instead the opposite purpose in the 2007 amendments. JA 650–51. In its view, the FDAAA fundamentally altered drug regulation by imposing a federal ceiling. *Id.* This change was apparent, it said, given the FDAAA's "clear and manifest purpose of providing a comprehensive regulatory framework" for REMS drugs. JA 640. Not so.

The FDAAA's purpose is found in its text: Congress sought "to enhance the postmarket authorities for [FDA] with respect to the safety of drugs[.]" 121 Stat. at 823. That amendment did not change Congress's long-running intent to "regard[] state law[s] as a complementary form of drug regulation." *Wyeth*, 555 U.S. at 578. Rather, the FDAAA was enacted to *increase* drug regulation, not do away with complementary state health and safety requirements.

The FDAAA comes nowhere close to preempting complementary state law—much less with the clarity needed to overcome the strong presumption against preemption. Indeed, the only regulatory limits identified by Plaintiff are those placed on the *federal* agency. The

FDAAA instructs the FDA to ensure that its elements to assure safe use "not be unduly burdensome on patient access to the drug." 21 U.S.C. § 355-1(f)(1)(2). Likewise, the FDA must "to the extent practicable" make the elements conform with those of similar drugs and with established systems "to minimize the burden on the health care delivery system." *Id*. In other words, while the FDAAA "requires the FDA to consider patient access and burden[,] ... this requirement is plainly a limitation on the FDA's *own restrictions* on a drug." *GenBioPro, Inc. v. Sorsaia*, No. CV 3:23-0058, 2023 WL 5490179, at *6 (S.D.W. Va. Aug. 24, 2023) (emphasis in original).

There is "no merit" in the argument that Congress entrusted the FDA and only the FDA to balance safety with competing interests like access. *Id.* at *6. "[T]his argument," the Supreme Court said in *Wyeth*, "relies on an untenable interpretation of congressional intent and an overbroad view of an agency's power to pre-empt state law." 555 U.S. at 573. So too here. Congress's purpose in the FDAAA was to "ensure that the elements themselves would not be unduly burdensome upon patient access"; the purpose was not to preempt state law. *GenBioPro,* 2023 WL 5490179, at *6.

The FDAAA's structure and context confirm that Congress did not intend to broadly preempt state law. In fact, Congress preempted only a narrow category of state regulation—state registration requirements for certain clinical trials. 121 Stat. at 922 ("[N]o State or political

subdivision of a State may establish or continue in effect any requirement for the registration of clinical trials or for the inclusion of information relating to the results of clinical trials in a database."). This targeted provision shows that Congress knows how to preempt state law when it wants to and chose *not* to do so for REMS drugs broadly. *See Riegel v. Medtronic, Inc.*, 552 U.S. 312, 333, 342 (2008) (Ginsburg, J., dissenting). Congress's "silence on the issue[] ... 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 575.

The FDAAA's history also shows that Congress understood the amendments to continue the Act's long-standing policy of non-preemption of state law. Despite pressure from the pharmaceutical industry, Congress declined to enact a generally applicable preemption provision. Family Research Council & Concerned Women for America Amicus Br. Part I.B (Aug. 19, 2024). Indeed, Senator Ted Kennedy, the FDAAA's chief Senate sponsor, confirmed that nothing in the FDAAA should be construed as "comprehensive enough to preempt the field or every aspect of state law." 153 Cong. Rec. S25038 (Sept. 20, 2007) (statement of Sen. Kennedy). Citing a "creeping trend" toward implied preemption, Senator Durbin—another supporter of the bill—agreed, stating that "Congress does not intend to preempt state requirements" with the FDAAA but to "recognize[] that state liability laws ... play an

essential role in ensuring that drug products remain safe and effective for all Americans." *Id.* at S25042.

The FDA itself has never claimed the authority to preempt state laws regulating mifepristone. *See* JA 470 ("Health care providers should check their individual state laws."). And for good reason—doing so would violate not only the presumption against preemption but also the major questions doctrine. That doctrine "requires clear congressional authorization for agency action in extraordinary cases when the history and breadth and economic and political significance of the action at issue gives us reason to hesitate before concluding that Congress meant to confer such authority to act on the agency." *North Carolina Coastal Fisheries Reform Grp. v. Capt. Gaston LLC*, 76 F.4th 291, 296 (4th Cir. 2023) (cleaned up). Here, there is no doubt that the regulation of REMS drugs like mifepristone and opioids are questions of significant economic and political significance. Yet Plaintiff resorts to implied obstacle preemption, which necessarily means she lacks any "clear congressional authorization." *Id.* at 296.

The text, context, and history of the FDAAA all show that Congress was aware of the operation of state law and decided to preserve—not preempt—it. Plaintiff has not identified the clear statement of preemptive intent necessary to satisfy either implied obstacle preemption or the major questions doctrine.

C. The district court erred in concluding that comprehensive regulation justifies implied obstacle preemption.

The district court's conclusion that obstacle preemption may be implied based on a "comprehensive regulatory framework" is contrary to established precedent. JA 609. The lower court invalidated four provisions of North Carolina law that "regulat[e] ... mifepristone based solely on its health and safety risks" because, it said, they "stand[] 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." JA 632 (emphasis added). But Plaintiff has disclaimed any reliance on field preemption, JA 614 n.4, and it is blackletter law that "the existence of comprehensive federal regulations" is insufficient to show conflict preemption, *Guthrie*, 79 F.4th at 340.[2]

At the outset, "comprehensive" federal regulation that leaves no room for "complementary state regulation" is a hallmark of *field* preemption. *Arizona v. United States*, 567 U.S. 387, 401 (2012). And even in that context, the Supreme Court has rejected the "contention that pre-emption is to be inferred merely from the comprehensive

[2] In addition to being waived, field preemption is inapplicable here because Congress has long taken care to "preserve state law." *Wyeth*, 555 U.S. at 567. Plus, "the 1962 saving clause has foreclosed any argument for complete field preemption." *GenBioPro*, 2023 WL 5490179, at *9.

character" of federal law. *New York State Dep't of Soc. Servs. v. Dublino*, 413 U.S. 405, 415 (1973). To the contrary, "[t]he subjects of modern social and regulatory legislation often by their very nature require intricate and complex responses from the Congress, but without Congress necessarily intending its enactment as the exclusive means of meeting the problem." *Id.* at 415. Thus, "far more" than comprehensiveness is required "to show the 'clear manifestation of (congressional) intention' which must exist before a federal statute is held 'to supersede the exercise' of state action." *Id.* at 417 (quoting *Schwartz v. Texas*, 344 U.S. 199, 202–03 (1952)).

More to the point, this Court has explained that an actual conflict—not comprehensiveness—is required to find that Congress impliedly preempted state law. The "existence of comprehensive federal regulations that fail to occupy the regulatory field do not, by their mere existence, preempt non-conflicting state law." *College Loan Corp. v. SLM Corp.,* 396 F.3d 588, 598 (4th Cir. 2005). To find otherwise would be "[t]o infer pre-emption whenever [Congress] deals with a problem comprehensively." *Hillsborough Cnty. v. Automated Med. Lab'ys, Inc.,* 471 U.S. 707, 717 (1985). And that would be "tantamount to saying that whenever" Congress "decides to step into a field, its regulations will be exclusive." *Id.* at 717.

But "not all state-level[] differences frustrate the Constitution's uniformity principle." *Guthrie*, 79 F.4th at 340. Rather, implied obstacle

preemption "depends on an *actual* conflict" with federal law. *Id.* (emphasis added); *English v. General Elec. Co.,* 496 U.S. 72, 90 (1990) ("Pre-emption is ordinarily not to be implied absent an 'actual conflict.'"). Plaintiff has identified no actual conflict here. Nor could she, as North Carolina's laws further Congress's safety goals.

D. North Carolina's laws governing mifepristone complement Congress's health and safety objective.

The Supreme Court has "establish[ed] that a high threshold must be met if a state law is to be preempted for conflicting with the purposes of a federal Act." *Whiting*, 563 U.S. at 607. As explained above, implied obstacle "preemption depends on an actual conflict" with federal law. *Guthrie*, 79 F.4th at 340. Plaintiff has not met this high threshold.

The relevant question for obstacle preemption is whether the challenged laws actually "obstruct any other significant federal objective." *Id.* at 341. Here, North Carolina law complements federal objectives. Congress's purpose in enacting the FDAAA was to "enhance" the FDA's authority to protect consumers from high-risk drugs by requiring post-marketing studies and safeguards. This is consistent with Congress's long-running purpose to supplement state-law safety protections.

The enjoined provisions do not "obstruct" the FDAAA's health and safety purpose. Much the reverse. It is undisputed that each of the provisions enjoined by the district court—that physicians prescribe

mifepristone, dispense it in person, schedule a 14-day follow-up visit, and report non-fatal adverse events to the FDA—protect "safety." JA 640–41. Indeed, that is *why* the district court enjoined them. *Id.* (holding that the provisions preempted because they decrease mifepristone's risks). These requirements ensure, for instance, that a physician follows up with abortion patients and that the FDA has access to accurate data on the rate of adverse events. North Carolina's additional safeguards are perfectly consistent with the long understanding that the FDCA and its amendments set a federal floor, not a ceiling.

There is zero evidence that any of the enjoined provisions increase patient health and safety risks. Nor could there be. For decades, the FDA found these very safety requirements necessary for the safe use of the drug. That should end the matter. Because none of the challenged laws make mifepristone *less* safe, they do not pose an "actual conflict" with the FDAAA and are not preempted.

Nor is it relevant that "the FDA explicitly considered and rejected" some of the challenged requirements. JA 640–41. The touchstone of preemption analysis is congressional intent. *Wyeth*, 555 U.S. at 565. Yet nothing about the *executive agency's* rejection of some of those requirements suggests that *Congress* meant to reverse regulatory tactics and establish a federal ceiling for high-risk drugs. *See supra* Part I.A. And in removing the relevant safeguards, the FDA did not find them

harmful, but merely that mifepristone's risk to women was tolerable without them. The upshot of this argument is that if a subsequent administration reinstates a safeguard, state law would spring back to life. But that's a strange view of a doctrine like preemption that turns on congressional intent.

The district court suggested that *Geier v. American Honda Motor Co., Inc.*, 529 U.S. 861, 864–65 (2000), supports preemption because the agency previously rejected the state-law claim at issue there. JA 641. But that case is inapposite. There, the Court held that a safety standard promulgated by the Department of Transportation preempted a state tort action for failure to equip an automobile with airbags. *Geier*, 529 U.S. at 864–65. The Department of Transportation had "deliberately provided the manufacturer with a range of choices among different passive restraint devices" in order to "bring about a mix of different devices introduced gradually over time." *Id.* at 875. Therefore, the Court held, "a rule of state tort law imposing" a "duty to install an airbag" would "present[] an obstacle to the variety and mix of devices that the federal regulation sought." *Id.* at 881.

"[T]he regulatory scheme in this case ... is quite different." *Wyeth*, 555 U.S. at 580. Congress did not intend to provide a "range of choices" regarding high-risk REMS drugs. *Id.* It intended to provide a floor of safety requirements for those dangerous drugs, and the challenged

state laws fit comfortably within that purpose. Indeed, "the longstanding coexistence of state and federal law, and the FDA's traditional recognition of state-law remedies"—along with the fact that "Congress has repeatedly declined to pre-empt state law" when amending and expanding the FDCA—demonstrate that Congress had no intention to preempt state law here. *Wyeth*, 555 U.S. at 580–81.

E. Plaintiff's broad argument upsets the federal-state balance and threatens patient safety.

The theory that the FDAAA transformed federal food and drug laws into a federal ceiling would run riot through state health and safety codes, invalidating not only laws like North Carolina's for abortion-inducing drugs, but also safeguards for other REMS drugs. This puts *any* state law that touches a REMS drug at risk. And many States have laws like those enjoined by the district court. Seventeen other States prevent non-physicians from prescribing mifepristone.[3] Six

[3] Ariz. Rev. Stat. Ann. § 36-2160(A); Ark. Code. Ann. § 20-16-1504(a); Fla. Stat. § 390.0111(2); Idaho Code Ann. § 18-608A; Ind. Code § 16-34-2-1(a)(1)(B); Iowa Code § 707.7(3)–(4); Ky. Rev. Stat. Ann. § 311.7733; Miss. Code Ann. § 41-41-107(1); Mo. Rev. Stat. § 188.020; Neb. Rev. Stat. § 28-335(1); Nev. Rev. Stat. § 442.250(1)(a); N.D. Cent. Code § 14-02.1-03.5(2); Ohio Rev. Code Ann. § 2919.123(A); 18 Pa. Cons. Stat. § 3204(a); (a)(1); Utah Code Ann. § 76-7-332(2); Tex. Health & Safety Code Ann. § 171.063; Wis. Stat. § 253.105(2).

require mifepristone to be dispensed in person.[4] Nine require a follow-up visit after a drug-induced abortion.[5] And seven require adverse events to be reported to the FDA.[6]

Looking beyond mifepristone and abortion, the FDA currently has a REMS in place for 68 drugs, and 64 of those have elements to assure safe use. JA 500–01. REMS drugs include the highest-risk drugs on the market, including opioids. Thus, as the district court acknowledged, JA 609, Plaintiff's theory of the FDAAA preempts state laws limiting opioid prescribing authority, *see* Ky. Rev. Stat. Ann. § 218A.205(3)(b); regulating opioid dosages, *see* 12-5 Vt. Code R. § 53; and requiring prescribers to obtain a controlled substances certificate before prescribing opioids, *see* Ala. Code § 20-2-51. But it makes no sense that state laws imposing additional safeguards on opioid prescription and use are invalid. The FDAAA was enacted in response to a public health

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[4] Ariz. Rev. Stat. Ann. § 36-3604; Ind. Code § 16-34-2-1; La. Rev. Stat. Ann. § 87.9(C)(5)(a); Neb. Rev. Stat. § 28-335(2); S.C. Code Ann. § 40-47-37(C)(7)(c); Wis. Stat. § 253.105(2)(b).

[5] Ariz. Rev. Stat. Ann. § 36-449.03(H)(1); Ark. Code Ann. § 20-16-1504 (f); Ky. Rev. Stat. Ann. § 311.7734(3)(a); Miss. Code Ann. § 41-41-107(6); Mont. Code Ann. § 50-20-705(3); Okla. Stat. Ann. tit. 63, § 1-756.4(C); S.D. Codified Laws § 36-4-47; Tenn. Code Ann. § 63-6-1104(c); Tex. Health & Safety Code Ann. § 171.063(e).

[6] Ky. Rev. Stat. Ann. § 311.7736(2); La. Rev. Stat. Ann. § 40:1061.11(D); Miss. Code Ann. § 41-41-109(1)(b); Mont. Code Ann. § 50-20-709(4); N.D. Cent. Code § 14-02.1-07(2)(b); Okla. Stat. Ann. tit. 63, § 1-757.9(D); Tex. Health & Safety Code Ann. § 171.063(g).

crisis and meant to "enhance" consumer safety. Pub. L. No. 110-85, 121 Stat. 823, 823 (codified at 21 U.S.C. § 355-1).

State tort law—long a complementary feature of drug regulation—is another casualty of Plaintiff's expansive view of preemption, at least where the highest-risk drugs are at issue. And the FDAAA does not provide federal remedies to take the place of tort relief. As the Supreme Court observed in *Wyeth*, instead of providing "a federal remedy for consumers harmed by unsafe or ineffective drugs," Congress "determined that widely available state rights of action provided appropriate relief for injured consumers." 555 U.S. at 574–75. There is no basis to infer such a vast displacement of state law on traditional matters of state concern without even a word from Congress.

II. Plaintiff lacks a cause of action.

Even if Plaintiff could show her claim is meritorious (she cannot), she lacks a cause of action for her implied obstacle preemption claim. The Supremacy Clause "is not the source of any federal rights," nor does it "create a cause of action." *Armstrong v. Exceptional Child Ctr., Inc.*, 575 U.S. 320, 324–25 (2015) (citation omitted). The Supremacy Clause merely "creates a rule of decision ... instruct[ing] courts what to do when state and federal law clash." *Id.* It is "silent" on "who may enforce federal laws in court, and in what circumstances they may do so." *Id.* at

325. Thus Plaintiff may not rely on the Supremacy Clause to "enforce federal laws against the States." *Id.*

The typical case seeking to enjoin state law based on an alleged violation of federal law arises in equity. *Id.* at 326–27. This equitable cause of action is "judge-made" and "reflects a long history of judicial review of illegal executive action." *Id.* at 327. But equitable causes of action have limits. As the Supreme Court explained in *Armstrong*, "the power of federal courts of equity to enjoin unlawful executive action is subject to express and implied statutory limitations." *Id.* at 327 (citations omitted). "Courts of equity can no more disregard statutory and constitutional requirements and provisions than can courts of law." *Id.* at 327–28 (quoting *I.N.S. v. Pangilinan*, 486 U.S. 875, 883 (1988)).

In *Armstrong*, the Court rejected an equitable action to enforce the Supremacy Clause. The Court found two features of the Medicaid Act "implicitly preclude[d] private enforcement" and showed "Congress's intent to foreclose equitable relief." *Id.* at 328 (cleaned up). First, Congress had provided an administrative remedy. *Id.* And second, the "sheer complexity" of the statutory provision indicated that the Medicaid Act "precludes private enforcement." *Id.* at 329.

That result applies a fortiori here because Congress *explicitly* prohibited private enforcement of the FDCA: "[A]ll ... proceedings for the enforcement, or to restrain violations, of this chapter shall be by and in the name of the United States." 21 U.S.C. § 337(a). Thus, as the

Supreme Court has recognized, "[p]rivate parties may not bring enforcement suits" under the FDCA. *POM Wonderful LLC v. Coca-Cola Co.*, 573 U.S. 102, 109 (2014). Even regulated parties—which do not include physicians like Plaintiff, *see Buckman Co.*, 531 U.S. at 350–51 ("[T]he FDCA expressly disclaims any intent to directly regulate the practice of medicine.")—have no private right of action to enforce the FDCA. *See Mylan Laby's, Inc. v. Matkari*, 7 F.3d 1130, 1139 (4th Cir. 1993) (holding that drug company was "not empowered to enforce independently the FDCA"); *PhotoMedex, Inc. v. Irwin*, 601 F.3d 919, 924 (9th Cir. 2010) (holding that "the FDCA bars private enforcement of the statute"). Because the FDCA precludes private enforcement, Plaintiff has no basis to sue in equity to enforce it.

In sum, the FDCA "leaves no doubt that it is the Federal Government rather than private litigants who are authorized to file suit" to enforce its provisions. *Buckman Co.*, 531 U.S. at 349 n.4. Plaintiff's attempt to enforce the Supremacy Clause in equity is barred just like the fraud-on-the-FDA claims in *Buckman*. *Id.* at 350. And despite the ubiquity of state laws regulating REMS drugs, the United States has not opted to sue here or elsewhere. Plaintiff has no statutory or equitable right to do so in the United States' absence.

III. The district court abused its discretion by enjoining "other provisions of North Carolina law" not challenged in the complaint.

Under Rule 65, every injunction must "describe in reasonable detail—and not by referring to the complaint or other document—the act or acts restrained or required." Fed. R. Civ. P. 65 (d)(1)(C). This Court "will vacate an injunction if it is broader in scope than that necessary to provide complete relief to the plaintiff or if an injunction does not carefully address only the circumstances of the case." *PBM Prods., LLC v. Mead Johnson & Co.*, 639 F.3d 111, 128 (4th Cir. 2011) (cleaned up). An injunction is overbroad if it "go[es] beyond the extent of the established violation" to other laws or policies not challenged. *Hayes v. North State L. Enf't Officers Ass'n*, 10 F.3d 207, 217 (4th Cir. 1993).

Here, the district court abused its discretion by enjoining unspecified "other provisions of North Carolina law" that "prohibit any healthcare provider other than a licensed physician from providing mifepristone," "require that mifepristone be provided in person," "require scheduling an in-person follow-up visit after providing mifepristone," or "require the reporting of non-fatal adverse events related to mifepristone to the FDA." JA 658. It is unclear from the injunction which North Carolina laws, or segments of law, this language covers. Nor did Plaintiff's complaint mention any statutes—aside from those explicitly challenged—that impose such requirements.

State officials are therefore left to guess at which North Carolina laws they are prohibited from enforcing or passing under the injunction. This lack of clarity violates Rule 65. More fundamentally, the injunction purports to extend to additional North Carolina statutes that no court has found to "violate federal law." *Labrador*, 144 S. Ct. at 923. For these reasons, this Court should vacate at least those portions of the injunction that extend to "other provisions of North Carolina law."

CONCLUSION

For the foregoing reasons, this Court should reverse the judgment of the district court and hold that North Carolina's laws governing medical abortion are not preempted by federal law.

REQUEST FOR ORAL ARGUMENT

Due to the novelty and far-reaching effects of Plaintiff's preemption argument, the Legislative Leaders request oral argument.

Dated: August 12, 2024

Respectfully submitted,

s/Erin M. Hawley

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CERTIFICATE OF COMPLIANCE

This brief complies with the word limit of Fed. R. App. P. 32(a)(7)(B) because this brief contains 8,635 words, excluding parts of the brief exempted by Fed. R. App. P. 32(f).

This brief complies with the typeface requirements of Fed. R. App. P. 32(a)(5) and the type-style requirements of Fed. R. App. P. 32(a)(6) because this brief has been prepared in Word 365 using a proportionally spaced typeface, 14-point Century Schoolbook.

Dated: August 12, 2024

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CERTIFICATE OF SERVICE

I hereby certify that on August 12, 2024, I electronically filed the foregoing brief with the Clerk of the Court for the United States Court of Appeals for the Fourth Circuit using the appellate CM/ECF system. I certify that all participants in the case are registered CM/ECF users, and that service will be accomplished by the CM/ECF system.

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