No. 24-1576(L)

In the United States Court of Appeals
for the Fourth Circuit

AMY BRYANT, M.D.,
Plaintiff-Appellee, Cross-Appellant

v.

TIMOTHY K. MOORE, et al.,
Intervenor-Defendants-Appellants, Cross-Appellees

and

JOSHUA H. STEIN, in his official capacity as Attorney General for the State of North Carolina,
Defendant-Appellee, Cross-Appellant

and

JEFF NIEMAN, in his official capacity as District Attorney for North Carolina 18th Prosecutorial District, et al.,
Defendants-Appellees.

On Appeal from the United States District Court
for the Middle District of North Carolina

OPENING/RESPONSE BRIEF OF ATTORNEY GENERAL JOSHUA H. STEIN

JOSHUA H. STEIN
Attorney General

Sarah G. Boyce
Deputy Attorney General & General Counsel

Amar Majmundar
Senior Deputy Attorney General

Sripriya Narasimhan
Deputy General Counsel

Stephanie A. Brennan
Special Deputy Attorney General

N.C. Department of Justice
Post Office Box 629 Raleigh, NC 27602
(919) 716-6400

CORPORATE DISCLOSURE STATEMENT

I certify, pursuant to Federal Rule of Appellate Procedure 26.1 and Local Rule 26.1, that no appellant is in any part a publicly held corporation, a publicly held entity, or a trade association, and that no publicly held corporation or other publicly held entity has a direct financial interest in the outcome of this litigation.

Dated: October 10, 2024 /s/ Sripriya Narasimhan

TABLE OF CONTENTS

Page

TABLE OF AUTHORITIES

Page(s)

Cases

Statutes

Regulations

Other Authorities

JURISDICTIONAL STATEMENT

Plaintiff Dr. Amy Bryant seeks to enjoin defendant state officials from enforcing various state laws that she alleges violate the Supremacy Clause of the United States Constitution. JA 69-73. The district court had jurisdiction under 28 U.S.C. § 1331.

The district court entered a final judgment on June 3, 2024. JA 657-659. The Legislative Intervenors timely filed a notice of appeal on June 20. JA 660-663; Fed R. App. P. 4(a)(1)(A). Dr. Bryant and Attorney General Joshua H. Stein timely cross-appealed on June 28 and July 2, respectively. JA 664-669; Fed. R. App. P. 4(a)(3). This Court has jurisdiction under 28 U.S.C. § 1291.

ISSUE PRESENTED

Under the Food and Drug Administration Amendments Act, Congress empowered the FDA to impose additional safety requirements on certain high-risk drugs. 21 U.S.C. § 355-1. For the last 24 years, the FDA has exercised this authority to develop and revise a framework for regulating the prescription, dispensation, and administration of mifepristone, a drug used to terminate pregnancies in their early stages. The issue presented is:

I. Does the Supremacy Clause permit the North Carolina legislature to impose restrictions on mifepristone that the FDA initially imposed, but ultimately rescinded?

INTRODUCTION

For more than two decades, the Food and Drug Administration has approved and regulated mifepristone, a drug used for the medical termination of early pregnancy. Based on extensive evidence, the agency has determined that mifepristone is safe and that serious complications are extremely rare.

The FDA regulates mifepristone pursuant to express statutory authority, which empowers the agency to weigh the benefits of the drug against its risks and to impose conditions on its administration. 21 U.S.C. § 355-1(a)(1). These conditions—also known as a Risk Evaluation and Mitigation Strategy, or REMS—reflect the agency's expert judgment on the best way to ensure drug safety while also minimizing burdens on patient access and the healthcare system. *Id.* § 355-1(f).

Since approving mifepristone in 2000, the FDA has regularly modified the drug's REMS based on evidence compiled across two decades of use. More specifically, the FDA has rescinded certain conditions that, in the agency's expert scientific judgment, are no longer necessary to ensure the drug's safety.

North Carolina law nonetheless imposes some of the very same restrictions on mifepristone that the FDA has implemented and then subsequently withdrawn. Under settled preemption principles that the Supreme Court has applied for decades, the Supremacy Clause does not permit States to frustrate the considered judgment of a federal agency in that manner.

To be sure, States ordinarily have wide latitude to protect the health and safety of their citizens in different ways, and state laws generally "offer[ ] an additional, and important, layer of consumer protection that complements FDA regulation." *Wyeth v. Levine*, 555 U.S. 555, 579 (2009). But when state law imposes the same restrictions that a federal agency tasked with "achiev[ing] a somewhat delicate balance of statutory objectives" has deliberately rescinded, state law must yield. *Buckman Co. v. Plaintiffs' Legal Comm.*, 531 U.S. 341, 348 (2001); *see also Geier v. Am. Honda Motor Co.*, 529 U.S. 861, 874-86 (2000).

The district court appropriately applied these preemption principles to enjoin some of the challenged North Carolina laws—but the court should have enjoined them all. Each one countermands the

FDA's expert judgment on how to balance regulatory burdens against patient access to a safe and effective drug that has been in use for decades. For that reason, each of the challenged laws frustrates Congress's purposes and objectives and is, accordingly, preempted. This Court should affirm in part and reverse in part the district court's judgment.

STATEMENT OF THE CASE

A. Congress empowers the FDA to ensure that drugs are safe and effective.

In 1938, Congress passed the Food, Drug, and Cosmetic Act, which charges the FDA with overseeing the safety, marketing, and distribution of drugs. 21 U.S.C. § 301 *et seq*. The FDA must, among other responsibilities, "promote the public health" by ensuring that "drugs are safe and effective." *Id.* § 393(b)(1)-(2).

The FDA accomplishes this aim by approving new drugs before they enter the interstate market. *Id.* § 355. To secure this approval, drug manufacturers submit an application to the FDA. *Id.* § 355(b)(1)(A); 21 C.F.R. § 314.50. The FDA must then determine whether the drug "is safe for use under the conditions prescribed,

recommended, or suggested in the proposed labeling thereof." 21 U.S.C. § 355(d).

The FDA's regulatory authority does not stop at the approval of a new drug, however. After a drug has been approved and marketed, the manufacturer must investigate and report to the FDA any adverse events associated with the drug's use and must periodically submit any new information that may affect the FDA's previous conclusions about the drug's safety or efficacy. 21 C.F.R. §§ 314.80-.81.

In 2007, Congress passed the Food and Drug Administration Amendments Act of 2007, Pub. L. No. 110-85, 121 Stat. 823. The 2007 Amendments expanded the FDA's authority in significant ways. As relevant here, the 2007 Amendments gave the FDA the power to impose additional safety requirements—what the statute refers to as a "risk evaluation and mitigation strategy" or a "REMS"—on certain drugs. 21 U.S.C. § 355-1. When the FDA determines that a REMS is "necessary to ensure that the benefits of the drug outweigh the risks of the drug," the 2007 Amendments authorize the FDA to require that a drug manufacturer submit a proposed risk-mitigation strategy, which the FDA then reviews and may modify or approve. 21 U.S.C. § 355-1(a)(1),

(g), (h). These risk-mitigation measures may include, for example, a medication guide, letters to healthcare providers about drug risks, or various packaging requirements. *Id.* § 355-1(e). Congress gave the FDA full authority to determine which drugs are subject to a REMS and what obligations a REMS will impose. *See id.* § 355-1(a)(1).

For certain high-risk drugs that are "inherent[ly] toxic[ ]" or "potential[ly] harmful[ ]," Congress gave the FDA still more regulatory authority. *See id.* § 355-1(f)(1). Congress stated its intent to ensure "safe access for patients to drugs with known serious risks that would otherwise be unavailable." *Id.* § 355-1(f). For this class of drugs—drugs with "known serious risks" that have nonetheless been "shown to be effective"—the FDA may require a REMS to include "elements to assure safe use," or "ETASU." *Id.* § 355-1(f)(1). These elements of safe use may include requirements that:

- healthcare providers who prescribe the drug have "particular training or experience, or are specially certified";
- "pharmacies, practitioners, or health care settings that dispense the drug are specially certified";
- "the drug be dispensed to patients only in certain health care settings";

- "the drug be dispensed to patients with evidence or other documentation of safe-use conditions, such as laboratory test results";
- "each patient using the drug be subject to certain monitoring"; or
- "each patient using the drug be enrolled in a registry."

Id. § 355-1(f)(3).

In imposing additional safety measures of this kind, the FDA must "assur[e]" patient access and "minimiz[e]" burdens. *Id.* § 355-1(f)(2). Specifically, the FDA must ensure that the elements of safe use are "commensurate with the specific serious risk listed in the labeling of the drug," are not "unduly burdensome on patient access to the drug;" and, "to the extent practicable," "minimize the burden on the health care delivery system." *Id.* § 355-1(f)(2)(A), (C), (D).

Congress also required the FDA to regularly assess—and, if necessary, modify—any REMS that it imposes. *Id.* § 355-1(c)(1), (d). To that end, a drug manufacturer must provide the agency with routine assessments of the approved mitigation strategy. *Id.* § 355-1(g)(1)-(2). In addition, the FDA may, at any time, request or receive a proposal to modify the approved REMS. *Id.* § 355-1(g)(4). The FDA must also "periodically evaluate" and "modify" a drug's elements of safe use to

ensure that the existing elements are continuing to achieve their goals of safe use, patient access, and minimizing burdens on the healthcare system. *Id.* § 355-1(f)(5)(B), (C).

The FDA currently approves REMS for only 73 drugs. *See* FDA Risk Evaluation and Mitigation Strategy (REMS) Public Dashboard, https://shorturl.at/mYsns (last accessed Oct. 10, 2024). These drugs treat a range of conditions, from acne to mental health to cancer. *See id.*

B. The FDA develops and revises a framework for regulating patient access to mifepristone.

In 2000, the FDA approved mifepristone, subject to certain restrictions, for use in terminating early pregnancies. JA 108-110. The FDA has since twice modified the mifepristone REMS, including as recently as last year, as evidence of mifepristone's safety has continued to accumulate.

1. FDA's initial approval in 2000

On September 28, 2000, after reviewing more than 90 submissions on safety and efficacy across five years, the FDA approved Mifeprex, the trade name for mifepristone, for use in terminating early pregnancies. JA 108.

As part of its initial approval, the FDA imposed a number of restrictions on patient access to mifepristone, including:

- The drug could only be dispensed and administered under the supervision of a physician with the ability to provide or arrange for surgical intervention in the case of an incomplete abortion or severe bleeding. JA 109.

- The physician administering the drug had to be able to diagnose ectopic pregnancies. JA 109.

- The physician had to report any serious adverse events to the drug sponsor. JA 109.

- The patient had to take the drug in the physician's office. JA 104.

- After taking the initial dose of mifepristone, the patient had to return to the physician's office for a second drug, misoprostol. The patient had to return to the physician's office for a third time for a follow-up appointment. JA 104-105.

- The patient had to sign an agreement form detailing the risks and benefits of taking mifepristone and be provided with a medication guide. JA 98, JA 109.

The FDA considered and rejected other restrictions, however. For example, although the FDA "carefully considered" requiring an ultrasound, JA 116, the agency ultimately recommended ultrasound evaluation only "as needed," and left the decision of whether to conduct an ultrasound "to the medical judgment" of the provider. JA 116.

In addition, the FDA also declined to require physicians to perform blood-type testing. JA 96. The FDA explained that this decision had been made because patients with a blood type that puts them at risk for pregnancy complications did not need to receive treatment at the same location where they received mifepristone. JA 247.

Because mifepristone's initial approval predated the 2007 Amendments establishing the REMS framework, these restrictions were originally imposed under 21 C.F.R. § 314 Subpart H. 21 C.F.R. §§ 314.500-.560. Subpart H restrictions are the precursors to REMS.

2. FDA's REMS implementation in 2011

In 2007, when Congress enacted the REMS framework, it required drug manufacturers who had received approval under Subpart H to submit a proposed REMS for approval. Pub. L. No. 110-85, § 909(b) (21 U.S.C. § 331 note). In 2011, the FDA approved the proposed REMS for mifepristone. The 2011 REMS mirrored the restrictions that had been adopted as part of the Subpart H regulations. JA 160-174.

3. FDA's REMS modification in 2016

The FDA made its first major set of modifications to the mifepristone REMS in 2016. The agency made these changes after having "determined that the approved REMS for [mifepristone] should be modified to continue to ensure that the benefits of [mifepristone] outweigh its risks and to minimize the burden on the healthcare delivery system of complying with the REMS." JA 177. The FDA came to this conclusion after weighing "20 years of experience with [mifepristone], guidelines from professional organizations here and abroad, and clinical trials that have been published in peer-reviewed medical literature." *Application Number: 020687Orig1s020, Medical Review(s)* at 17, Food & Drug Admin., Ctr. Drug Evaluation & Rsrch. (Mar. 29, 2016), bit.ly/3D8Rwjv.

Nothing in the FDA's review prompted the agency to change its conclusion that mifepristone is safe and effective. To the contrary, the FDA concluded that some of the mifepristone restrictions were unnecessary and unduly burdensome and should therefore be eliminated. Specifically, the FDA modified the mifepristone REMS in four ways that are relevant here:

- First, the FDA expanded the class of medical professionals who may provide mifepristone from only specially certified "physician[s]" to specially certified healthcare providers, including physicians, nurse practitioners, certified midwives, and physician assistants. JA 196, JA 238.

- Second, while the FDA retained the requirement that mifepristone be *dispensed* in a healthcare provider's office, the FDA removed the requirement that the drug be *administered* there. *Compare* JA 220-21, *with* JA 168.

- Third, the FDA eliminated the requirement that prescribers report serious adverse events but retained the requirement that prescribers report deaths. JA 233, JA 249.

- Fourth, the FDA eliminated the requirement that the patient return to a doctor's office for follow-up visits. JA 232.

4. FDA's REMS modification in 2023

The FDA began another review of the mifepristone REMS in 2021. JA 278. As part of this review, the FDA conducted extensive analysis of published safety data and other scientific studies. JA 235, 280-306. Again, none of the evidence submitted changed the FDA's conclusion that mifepristone is safe and effective.

As in 2016, however, the FDA concluded that some of the mifepristone restrictions were unduly burdensome and no longer necessary to ensure the drug's safe use. JA 329-330. Accordingly, the FDA modified two significant elements of the REMS:

- First, the FDA enabled certified pharmacies to dispense mifepristone directly to patients. JA 350-52;

- Second, the FDA eliminated the requirement that mifepristone be dispensed at a healthcare provider's office. JA 348-52, 357-59.

C. Dr. Bryant sues to enjoin enforcement of North Carolina laws that impose additional barriers to mifepristone access.

Under current law, women in North Carolina may seek a medication abortion during the first twelve weeks of pregnancy. N.C. Gen. Stat. § 90-21.81B(2). But state law also imposes numerous other requirements on receiving the medication.

Plaintiff Dr. Amy Bryant is a board-certified and licensed physician in North Carolina who regularly prescribes mifepristone. JA 26. She sued Attorney General Josh Stein; Jeff Nieman, District Attorney for North Carolina's 18th Prosecutorial District; Kody H. Kinsley, North Carolina Secretary of Health and Human Services; and the members of the North Carolina Medical Board. JA 31-34. Dr. Bryant alleged that federal law preempts several North Carolina laws restricting access to mifepristone. JA 69-73. Specifically, she challenged the following state laws, *see* JA 63-67, JA 625:

- **The physician-only restriction.** State law requires that only a physician may prescribe, dispense, and administer mifepristone. *See, e.g.*, N.C. Gen. Stat. §§ 90-21.83A(b)(2)a, 90-21.83B, 90-21.93(b)(1).

- **The 72-hour consultation requirement.** State law requires that a "qualified physician or qualified professional" consult with a patient in person at least 72 hours before dispensing mifepristone. *Id.* § 90-21.83A(b)(1)-(2), (5); *id.* § 90-21.90(a).

- **In-person examination, administration, and dispensation requirements.** State law requires that a physician examine a patient and dispense mifepristone in person. *Id.* § 90-21.83B(a); *id.* § 14-44.1. Similarly, state law requires that the patient then take the medication in the presence of a physician. *Id.* § 90-21.83A(b)(2)a.

- **In-person, 14-day follow-up requirement.** State law requires that a physician must schedule an in-person follow-up appointment within fourteen days of administering mifepristone and must document her efforts to ensure that the patient keeps the appointment. *Id.* §§ 90-21.83A(b)(4)*l*, 90-21.83B, 90-21.93(b)(8)-(9).

- **Ultrasound requirement.** State law requires that physicians perform a (necessarily in-person) ultrasound on patients before prescribing mifepristone. *Id.* §§ 90-21.83A(b)(2)b, 90-21.93(b)(6); 10A N.C. Admin. Code § 14E.0305(d).

- **Blood-type determination requirement.** State law requires that, during an in-person examination, a physician must determine the patient's blood type before prescribing mifepristone. N.C. Gen. Stat. § 90-21.83B(a)(2).

- **Reporting requirements.** State law requires that physicians report not just fatal complications, but also a number of non-fatal complications to both the North Carolina Department of

Health and Human Services and the FDA. *Id.* § 90-21.93(b)(10), (c), (e).

Dr. Bryant sought a declaration that federal law preempts these state laws and an injunction against their enforcement. JA 73.

After reviewing and analyzing Dr. Bryant's legal claims, counsel for the Attorney General notified the Speaker of the North Carolina House of Representatives and the North Carolina Senate President Pro Tempore that the Department had "concluded that Plaintiff's preemption arguments [were] legally correct." *Bryant v. Stein*, No. 23-cv-77 (M.D.N.C.), ECF Doc. 30-1 at 1. The Speaker and President Pro Tem then intervened to defend the challenged provisions. JA 18-20. District Attorney Nieman, the Secretary, and the members of the Medical Board have not taken a position on Dr. Bryant's claims.

Legislative Intervenors moved to dismiss. JA 612. With the consent of the parties, the district court converted the motion to dismiss into cross-motions for summary judgment. JA 612-613.

D. The district court holds that federal law preempts some of the challenged state laws, but not others.

The district court held that federal law preempts some, but not all, of the challenged state laws.

The district court started with the legal framework for preemption. At the outset, the court recognized that Dr. Bryant advanced only one type of preemption argument here: that the challenged state laws "stand[ ] as an obstacle to the accomplishment of the full purposes and objectives of Congress"—so-called "obstacle preemption." JA 614 (quoting *Silkwood v. Kerr-McGee Corp.*, 464 U.S. 238, 248 (1984)). To decide whether a state law impermissibly frustrates Congress's purposes and objectives, the court asked two questions. First, the court examined the "clear and manifest purpose of Congress" in enacting the federal law. JA 615 (quoting *Wyeth v. Levine*, 555 U.S. 555, 565 (2009)). Second, the court evaluated whether the state law would "prevent or frustrate the accomplishment of a federal objective." JA 615 (quoting *Geier v. Am. Honda Motor Co.*, 529 U.S. 861, 873 (2000)).

To begin, the court recognized that the relevant federal law here is Congress's enactment of the 2007 Amendments to the Food, Drug, and Cosmetic Act. The FDCA, the court explained, was "traditionally known as a consumer protection statute designed in large part to protect consumers from unsafe drugs." JA 629. In enacting the 2007

Amendments, the court recognized that Congress "continued to promote consumer protection by expanding the FDA's ability to regulate the sale and distribution of prescription drugs that benefit the public and to promote the safe use of those drugs." JA 629-630. Specifically, the court noted that Congress made the "FDA responsible for deciding what restrictions need to be imposed on the distribution of drugs with serious risks of harm and on the providers who prescribe and distribute those drugs." JA 630.

The court observed that Congress gave the FDA wide latitude to implement drug-safety restrictions across a variety of healthcare contexts. For example, Congress gave the FDA authority to impose requirements that healthcare providers be specially certified; that pharmacies, practitioners, and healthcare settings that dispense a drug be specially certified; that limit the settings in which the drug can be dispensed; that mandate that "documentation of safe-use conditions" be included with the drug; and that patients using the drug be subject to certain monitoring. JA 631-632 (citing 21 U.S.C. § 355-1(f)). At the same time, however, Congress also prohibited the FDA from implementing safety requirements that would be broader than

necessary to address the relevant risks, unduly burdensome on patient access, or unduly burdensome on the healthcare system. JA 630.

Based on this statutory text and structure, the court held that Congress's purpose was "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. And for drugs with "inherent toxicity or potential harmfulness," Congress had the "additional clear and manifest objective" of requiring the FDA to regulate those drugs "without unnecessarily reducing patient access or burdening the health care system." JA 631.

Next, the court analyzed whether the challenged state laws frustrate this objective. The court explained that "Congress has made the FDA responsible for evaluating whether a restriction is necessary to address the safety risks of REMS drugs." JA 645. As a result, state laws that "second-guess" the FDA's judgment on how to "manage risks from and safely prescribe, dispense, and administer REMS drugs, including mifepristone," are preempted. JA 645. Here, the court focused in particular on those state laws that impose restrictions that

"have been explicitly rejected by the FDA as unnecessary for safe administration and as unnecessary burdens on the health care system and patient access." JA 646. Under this framework, the court held that the following state laws were preempted: (1) the physician-only restriction; (2) the in-person prescribing, dispensing, and administering requirements; (3) the in-person follow-up appointment requirement; and (4) the reporting requirements for non-fatal adverse events to the FDA. JA 641-649. These state laws, the court concluded, were all impermissible regulations "directed solely to risks associated with mifepristone and other abortion-inducing drugs." JA 645.

The court distinguished these safety-related regulations from provisions regulating "general patient health and welfare and informed consent" that are "unrelated to mifepristone." JA 633. Restrictions of this kind, the court concluded, are not preempted. Under this framework, the court held that the following state laws were not preempted: (1) the in-person advance-consultation requirement, (2) the ultrasound requirement, (3) the in-person examination requirement, (4) the blood-type determination requirement, and (5) the reporting

requirements for adverse events to the North Carolina Department of Health and Human Services. JA 633-638.[1]

The district court enjoined all defendants from enforcing the preempted provisions and dismissed Dr. Bryant's challenges to the remaining state laws. JA 658-659.

Legislative Intervenors timely appealed. JA 660-663. Dr. Bryant and the Attorney General timely cross-appealed. JA 664-669.

SUMMARY OF THE ARGUMENT

This Court should affirm in part and reverse in part the district court's judgment.

It is undisputed that when a state law "stands as an obstacle to the accomplishment and execution of the full purposes and objectives of Congress," the state law must yield. *Hines v. Davidowitz*, 312 U.S. 52, 67 (1941). Although this kind of obstacle preemption is rare, it carries particular force when state law interferes with Congress's efforts to strike a balance among competing objectives. *Buckman Co. v. Plaintiffs'*

---

[1] The court also rejected the Legislative Intervenors' alternative argument under the major-questions doctrine. JA 652-654. Legislative Intervenors seem to have abandoned that argument on appeal, mentioning the major questions doctrine only once in passing. *See* Br. 26.

Legal Comm., 531 U.S. 341, 348 (2001). State laws that upset this balance effectively overrule the policy choices of the federal government, contrary to the Supremacy Clause.

The district court below correctly applied these legal principles in holding that North Carolina law cannot regulate mifepristone "based solely on [the drug's] health and safety risks." JA 632. As the district court rightly explained, Congress charged the FDA with "creating a comprehensive regulatory framework" that balances those risks against other competing considerations, like patient access and burdens on the healthcare system. JA 632-633. The district court thus correctly held that North Carolina laws imposing regulations that the FDA has itself imposed and then withdrawn are obstacles to Congress's objectives and are preempted as a result.

The district court's only error was to create an exception to this rule for state laws that purport to regulate "medical care generally." JA 633. But the district court's distinction between laws regulating drug safety and laws regulating "medical care generally" is untenable in this unique context. After all, the federal law at issue here gives the FDA broad authority to regulate many aspects of medical practice ordinarily

left to the States. *See* 21 U.S.C. § 355-1(e), (f). When state laws impose rules of this kind that the FDA has affirmatively deemed unnecessary and unduly burdensome, the preemption analysis is the same, whether those laws purport to regulate drug safety or other aspects of medical care that Congress has charged the FDA with overseeing. Thus, the district court erred in declining to enjoin the challenged state laws that, in the court's view, regulate only medical practice.

For their part, Legislative Intervenors contend that federal law does not preempt *any* of North Carolina's mifepristone restrictions. Legislative Intervenors are mistaken.

First, Legislative Intervenors repeatedly emphasize that neither the FDCA nor the 2007 Amendments contains an express statement of Congress's intent to preempt state law. Br. 26. But the only preemption theory in this case is obstacle preemption, for which no express statement of preemption is required. *Geier*, 529 U.S. at 869.

Second, Legislative Intervenors contend that finding preemption here would jeopardize many other state efforts to protect consumers with respect to REMS drugs. Not so. The Attorney General's preemption theory is narrow: Obstacle preemption applies only when

state laws seek to impose a restriction on a REMS drug that the FDA has *affirmatively rescinded*. Under that theory, the vast majority of state laws regulating high-risk drugs or the practice of medicine more generally will remain in place.

Third, Legislative Intervenors contend that Congress's purpose in passing the FDCA was to ensure drug safety. But that ignores the critical statute here—the 2007 Amendments. And it is incompatible with the text of those Amendments, where Congress sought to protect patient safety while *also* minimizing burdens on patient access and the healthcare system. 21 U.S.C. § 355-1(f).

Finally, Legislative Intervenors have no answer for the Supreme Court's decision in *Geier*, which directly rejects their arguments that state law may override a balance of competing objectives that a federal agency has struck. 529 U.S. at 874-86.

Because the state laws at issue here seek to countermand the FDA's expert judgment about how to weigh mifepristone's safety, patient access, and burdens on the healthcare system, all of the challenged laws are preempted.

This Court should affirm in part and reverse in part.

ARGUMENT

Standard of Review

This Court reviews a district court's ruling on cross-motions for summary judgment de novo. *Bostic v. Schaefer*, 760 F.3d 352, 370 (4th Cir. 2014).

Discussion

I. The Challenged State Laws Are Preempted Because They Frustrate the Careful Balance the FDA Struck in Providing Patient Access to Mifepristone.

A. Longstanding preemption principles forbid States from enforcing laws and regulations that frustrate a federal framework.

Because the "States are independent sovereigns in our federal system," courts have "long presumed" that state laws are not preempted by federal statutes. *Medtronic, Inc. v. Lohr*, 518 U.S. 470, 485 (1996). The presumption that "Congress did not intend to preempt state law is especially strong when it has legislated in a field which the States have traditionally occupied," such as "protecting the health and safety of their citizens." *Anderson v. Sara Lee Corp.*, 508 F.3d 181, 192 (4th Cir. 2007) (quotation marks omitted); *see also Metropolitan Life Ins. Co. v. Massachusetts*, 471 U.S. 724, 756 (1985). As a result, courts do not

lightly infer congressional intent to preempt state health-and-safety laws, which "can normally coexist with federal regulations." *Hillsborough Cnty. v. Automated Med. Labs. Inc.*, 471 U.S. 707, 718 (1985).

Although a "court should not find preemption too readily in the absence of clear evidence of a conflict," in rare circumstances, federal and state law may be so incompatible that both cannot coexist. *Geier v. Am. Honda Motor Co.*, 529 U.S. 861, 885 (2000). Such a conflict can occur when a state law "stands as an obstacle to the accomplishment and execution of the full purposes and objectives of Congress." *Hines v. Davidowitz*, 312 U.S. 52, 67 (1941). To ascertain whether a given state law poses that kind of obstacle, courts will begin by "examining the federal statute as a whole and identifying its purpose and intended effects." *Crosby v. Nat'l Foreign Trade Council*, 530 U.S. 363, 373 (2000). When state law frustrates the statute's purposes or intended effects, the state law is preempted. *Hillman v. Maretta*, 569 U.S. 483, 494 (2013).

A state law may frustrate federal objectives in this way when it upsets a balance that Congress has charged a federal agency with

striking. When that happens, the Supreme Court has not hesitated to strike down state laws that undermine the agency's expert judgment. *Buckman Co. v. Plaintiffs' Legal Comm.*, 531 U.S. 341, 348 (2001); *Geier*, 529 U.S. at 874-86. In particular, the Supreme Court has repeatedly held that preemption principles bar States from imposing restrictions that a federal agency has indisputably considered and rejected in crafting a comprehensive regulatory scheme. This has been true even in cases where the state and federal laws share the same goal—including promoting public health and safety. *See Geier*, 529 U.S. at 878-89; *Int'l Paper Co. v. Ouellette*, 479 U.S. 481, 494 (1987). After all, a "[c]onflict in technique can be fully as disruptive to the system Congress erected as [a] conflict in overt policy." *Motor Coach Emps. of Am. v. Lockridge*, 403 U.S. 274, 287 (1971); *see also PPL EnergyPlus, LLC v. Nazarian*, 753 F.3d 467, 478 (4th Cir. 2014).

The Supreme Court's decision in *Geier* is particularly instructive in illustrating these principles. There, the plaintiffs invoked state tort law to sue a car manufacturer for failing to install driver-side airbags. 529 U.S. at 865. But the car manufacturer's airbags decision had not occurred in a vacuum. Under the federal motor-vehicle-safety

regulatory scheme in place at the time, the Department of Transportation had deliberately balanced public safety, public acceptance, technological advances, and cost. *Id.* at 878-79. And in doing so, DOT had specifically declined to require mandatory airbags in every car, in favor of a more varied mix of passive-restraint systems. *Id.* at 879. Allowing state tort lawsuits for failure to install airbags would therefore have frustrated federal interests by imposing a requirement that DOT had specifically considered and rejected. *Id.* at 880-81. As a result, the Supreme Court held that the state tort lawsuit was preempted. *Id.* at 881-82.

The Court reached this conclusion even though both state tort law and DOT's regulations were directed at the same objective—passenger safety. DOT had settled on its chosen strategy to "encourage manufacturers to equip *at least some* of their cars with airbags" after concluding that more airbag installations would improve safety outcomes. *Id.* at 880 (quotation marks omitted). State tort law could theoretically have been used to compel even *more* airbag installations, presumably leading to even further improved safety outcomes. Nevertheless, the Supreme Court held that the state tort lawsuit was

preempted. *Id.* at 881-82. Allowing the state tort lawsuit to move forward, the Court reasoned, would have subverted an expert agency's careful calibration of competing interests. *Id.* And that result would have run counter to both congressional intent and the Supremacy Clause. *Id.*

The Supreme Court's decision in *Wyeth v. Levine*, 555 U.S. 555 (2009), provides a helpful contrast. In that case, a plaintiff filed a state tort lawsuit against a pharmaceutical company for designing a label that failed to adequately warn of the drug's risks. *Id.* at 559. In response, the pharmaceutical company argued that the lawsuit was preempted because it interfered with Congress's "purpose to entrust an expert agency to make drug labeling decisions that strike a balance between competing objectives." *Id.* at 573 (quoting Brief for Petitioner at 46, *Wyeth*, 555 U.S. 555).

The Supreme Court disagreed. "[T]hrough many amendments to the FDCA and to FDA regulations," the Court said, "it has remained a central premise of federal drug regulation that the *manufacturer*"—not the FDA—"bears responsibility for the content of its label at all times." *Id.* at 570-71 (emphasis added). Indeed, under the relevant federal

regulations, as soon as a manufacturer becomes aware of new risks inherent in a particular drug, it has a "duty to provide a warning," even before the FDA's approval. *Id.* at 571. Given that context, the Court found it impossible to conclude that Congress had meant for the FDA to have sole authority to balance the competing considerations involved in drug labeling. *Id.* at 574-81.

The Court also expressly distinguished its earlier decision in *Geier*. Unlike DOT, which in *Geier* had expressly considered and rejected an all-airbag standard, in *Wyeth*, the FDA had never "consider[ed] and reject[ed] a stronger warning" on the drug's label. *Id.* at 581 n.14. This different history mattered to the Court. Because the *Wyeth* record did not demonstrate that the FDA had concluded that a stricter warning would upset the "balance it had struck" with respect to the drug's label, a state-tort claim for failing to impose a stricter warning was not preempted. *Id.* at 580-81.

Geier and *Wyeth* are broadly consistent with other preemption cases recognizing that when a "federal statutory scheme amply empowers" an agency "to achieve a somewhat delicate balance of statutory objectives," state laws that "skew[ ]" that balance are

impliedly preempted—particularly when the state laws effectively seek to supersede the agency's expert judgment. *Buckman Co. v. Plaintiffs' Legal Comm.*, 531 U.S. 341, 348 (2001).[2] Together, these cases confirm a commonsense point—that "[i]t would be extraordinary for Congress, after devising an elaborate . . . system that sets clear standards, to tolerate [state action] that ha[s] the potential to undermine this regulatory structure." *Ouellette*, 479 U.S. at 497.

B. The challenged state laws regulating the use of mifepristone frustrate the FDA's regulatory regime and are therefore preempted.

Applying this legal framework here, the challenged North Carolina laws impose an impermissible obstacle to Congress's objective in authorizing the FDA to devise the mifepristone REMS. Specifically,

---

[2] *See Chicago & N.W. Transp. Co. v. Kalo Brick & Tile Co.*, 450 U.S. 311, 321 (1981) (holding that evidence of Congress's intention to preempt came from a federal agency's obligation to "*balance the interests* of" different regulated parties (emphasis added) (quotation marks omitted)); *cf. Arizona v. United States*, 567 U.S. 387, 406 (2012) (striking down state law that would "interfere with the *careful balance* struck by Congress with respect to unauthorized employment of aliens" (emphasis added)); *Guthrie v. PHH Mortg. Corp.*, 79 F.4th 328, 339 (4th Cir. 2023) (finding no obstacle preemption when the federal scheme was "scant at best," but recognizing that "comprehensive federal statutory or regulatory schemes may signal a balance of interests that preempts state law claims providing additional relief").

the state laws impose the same mifepristone restrictions that the FDA, pursuant to its statutory authority, has decided are no longer necessary to ensure the drug's safe use. Because the challenged laws functionally overrule the FDA's congressionally authorized policy choices about how to achieve the goals of ensuring safety while minimizing burdens on patient access and the healthcare system, they are preempted under the Supremacy Clause.

1. State laws that disrupt the balance the FDA has struck in devising a REMS framework are preempted.

In the Food, Drug, and Cosmetic Act, Congress anointed the FDA the gatekeeper for prescription drugs. 21 U.S.C. § 355(a) (barring manufacturers from "introduc[ing] or deliver[ing] for introduction into interstate commerce any new drug" without the FDA's approval). That statute charges the FDA with "promot[ing]" and "protect[ing] the public health" by ensuring that any drugs on the market "are safe and effective." *Id.* § 393(b)(1)-(2).

The 2007 Amendments to the Food, Drug, and Cosmetic Act vest the FDA with even more responsibility regarding high-risk drugs. For those kinds of drugs, the FDA must decide whether a REMS "is

necessary to ensure that the benefits of the drug outweigh the risks of the drug." *Id.* § 355-1(a)(1). If a REMS is necessary, a manufacturer cannot market the high-risk drug unless it complies with all restrictions set forth in the FDA's REMS, including any elements "necessary to assure safe use" that are part of the plan. *Id.* § 355(p)(1)(B); *id.* § 355-1(f).

The FDA, moreover, enjoys sweeping authority to inject itself into nearly every facet of the prescription-drug process when it decides to subject a drug to REMS restrictions and impose elements to assure safe use. The agency can dictate what a drug's medication guide must say. *Id.* § 355-1(e)(2). It can control a drug's packaging and disposal requirements. *Id.* § 355-1(e)(4). And it can even regulate the practice of medicine—requiring health care providers who will interact with the drug to offer it only in certain settings, get special training or certifications, share certain information with their patients, or conduct specific tests or examinations prior to the drug's dispensation or administration. *Id.* § 355-1(f)(3).

Congress was not mysterious about its objective in passing the 2007 Amendments and affording the FDA this expansive authority to

regulate drugs with "known serious risks." *Id.* Thus, contrary to what Legislative Intervenors suggest, no "freewheeling judicial inquiry" is necessary here. Br. 20 (quoting *Chamber of Comm. v. Whiting*, 563 U.S. 582, 607 (2011)). In the plain text of the statute, Congress explained that a purpose was to "allow[ ] safe access to drugs with known serious risks," while at the same time "minimizing [the] burden" on patient access and the "health care delivery system." *Id.* § 355-1(f)(1)-(2).

It is this purpose that is dispositive in evaluating the preemptive force of the FDA's REMS for mifepristone. *See Wyeth*, 555 U.S. at 565 (congressional objectives are the "ultimate touchstone in every preemption case"). As the FDA has modified mifepristone's REMS over time, it has continually recalibrated the appropriate balance between safe access and burden minimization. In several instances, having gathered more evidence about the safety of mifepristone, the FDA has eliminated restrictions that it determined improperly skewed that balance. *See supra* pp. 9-14. For instance, though the FDA initially believed that permitting doctors alone to prescribe and administer mifepristone was the optimal way to balance safe access against burden minimization, further evidence persuaded the agency otherwise. *See*

supra pp. 12-13. Consistent with *Geier* and *Wyeth*, it is these restrictions—the ones the FDA, in compliance with Congress's directive in section 355-1(f)— has expressly rejected that the Supremacy Clause plainly forbids States from imposing through state law. *Geier*, 529 U.S. at 879; *Wyeth*, 555 U.S. at 581 n.14. Any other outcome would allow States to countermand the FDA's deliberate, and congressionally authorized, decisions about how higher-risk drugs should be regulated and which restrictions are necessary.

2. The district court was correct to enjoin the North Carolina laws that it did.

The challenged North Carolina laws are exactly the kind of restrictions that are preempted by the mifepristone REMS. Each one seeks to impose a restriction that, over the course of the last 24 years, the FDA decided was unduly burdensome and interfered with patient access to an important drug. They therefore stand as an obstacle to Congress's goal of creating a comprehensive regulatory framework for high-risk drugs that appropriately balances safety, patient access, and burden on the healthcare system. As a result, the district court correctly held that all four requirements—the (1) physician-only; (2) in-person prescribing, dispensing, and administering; (3) in-person follow-

up appointments; and (4) FDA reporting requirements—are preempted. JA 640-649; *see also Geier*, 529 U.S. at 878-79; *Wyeth*, 555 U.S. at 581 n.14; *Arizona*, 568 U.S. at 406-07.

Physician-only requirement. North Carolina law requires that physicians alone prescribe, dispense, and administer mifepristone. N.C. Gen. Stat. §§ 90-21.83A(b)(2)a, 90-21.83B, 90-21.93(b)(1). These statutes impose precisely the same restrictions that the FDA initially imposed and then withdrew when calibrating the mifepristone REMS. They are therefore preempted.

Starting in 2000, as part of its authority to regulate who may prescribe, dispense, or administer mifepristone, 21 U.S.C. § 355-1(f)(3), the FDA required that mifepristone be prescribed, dispensed, and administered under the supervision of a physician. JA 115-117, JA 158. Since then, however, after reevaluation of the relevant scientific and medical evidence, the FDA has determined that mifepristone is "safe and effective when prescribed by midlevel providers." JA 238. The FDA further concluded that allowing a broader range of healthcare providers to prescribe, dispense, and administer the drug better aligned with the agency's mission to reduce burdens on patient access to the

drug and on the healthcare system. JA 177, 197. As a result, beginning in 2016, the FDA rescinded its prior restriction and began allowing nurse practitioners, midwives, and physicians' assistants to prescribe and dispense mifepristone. JA 196, JA 238. The FDA also lifted the requirement that the drug be administered at the healthcare provider's office. *Compare* JA 220-221, *with* JA 168.

More recently in 2023, to further "minimize[] the burden on the health care delivery system of complying with the REMS," the FDA stopped requiring healthcare providers to dispense mifepristone and began allowing patients to get the drug directly from a pharmacy and take it at home. JA 347-348. Thus, there is no longer any federal requirement that a physician alone may prescribe, dispense, and administer mifepristone. Any North Carolina laws to the contrary are preempted.

In-person prescribing, dispensing, and administering requirements. North Carolina law requires that physicians "prescribing, dispensing, or otherwise providing" mifepristone be "physically present in the same room" as patients when they take the drug. N.C. Gen. Stat. § 90-21.83A(b)(2)a; *see also id.* §§ 14-44.1, 90-

21.83B(a). These statutes also impose restrictions that the FDA has rescinded when calibrating the mifepristone REMS. Therefore, these laws, too, are preempted.

In 2000, as part of its authority to regulate where mifepristone may be prescribed, dispensed, or administered, 21 U.S.C. § 355-1(f)(3), the FDA required that mifepristone be dispensed and administered only in a clinic, medical office, or hospital. JA 104. In 2016, however, the FDA removed the requirement that the drug be administered in a healthcare provider's office. *Compare* JA 220-221, *with* JA 168. And in 2023, relying on further scientific study, the FDA concluded both that the "in-person dispensing requirement [was] no longer necessary," and that removing the in-person dispensing requirement would be "less burdensome for healthcare providers and patients." JA 235. Together, these modifications eliminated all of the restrictions in the REMS that had required mifepristone to be prescribed, dispensed, or administered in person. JA 168, JA 220-221, JA 348-352, JA 357-359.

North Carolina law effectively overrides the FDA's congressionally authorized decision to expand mifepristone access by removing any in-person prescription, dispensation, and administration requirements.

These state laws therefore frustrate Congress's objectives, as implemented by the FDA, and are preempted.

In-person follow-up appointment requirement. North Carolina law requires that, before physicians prescribe or administer mifepristone, they schedule a follow-up visit with their patients and make "all reasonable efforts" to ensure that the patients keep these appointments. N.C. Gen. Stat. § 90-21.83B(b); *see also id.* §§ 90-21.83A(b)(4)*l*, 90-21.93(b)(8)-(9). These state laws also impose a requirement that the FDA previously imposed and then withdrew. Hence, they are similarly preempted.

In 2000, as part of its authority to require patients using a drug to be "subject to certain monitoring," 21 U.S.C. § 355-1(f)(3), the FDA required patients to return for an in-person follow-up appointment approximately two weeks after taking mifepristone. JA 104-105. But since then, the FDA has continued evaluating the medical evidence and concluded that "[t]he safe use of mifepristone . . . is not contingent on a specific number of office visits." JA 242. As a result, in 2016, the FDA eliminated the requirement that patients return for follow-up visits. JA 232.

The North Carolina legislature cannot reimpose the follow-up appointment requirement through state law. If the FDA has deemed in-person follow-up appointments unduly burdensome, the Supremacy Clause does not permit the North Carolina General Assembly to say otherwise. The district court thus appropriately enjoined these state laws.

FDA reporting requirements. North Carolina law requires that physicians report *any* adverse events from the use of mifepristone to the FDA. N.C. Gen. Stat. § 90-21.93(c). Once again, this requirement imposes a restriction that the FDA has rescinded. It similarly must yield under preemption principles.

In 2000, the FDA also required that physicians report any adverse events from the use of mifepristone to the drug sponsor (which then reported them to the FDA). JA 109, JA 156, JA 249. But since then, the FDA's continued reevaluation concluded that mifepristone's safety profile has been sufficiently developed after more than 15 years of accumulated evidence. JA 249. As a result, beginning in 2016, the FDA started requiring healthcare providers to report only *deaths* to the drug

manufacturers, and for the manufacturers to then report those fatalities to the FDA. JA 222, JA 249.

Because the FDA has deemed it unduly burdensome to require healthcare providers to report *all* adverse events, North Carolina state law cannot impose such a burden. This state-law requirement, too, is preempted.

3. The district court erred by failing to enjoin the other challenged state laws.

Though the district court correctly enjoined the aforementioned laws, it should not have stopped there. The state laws that the district court declined to enjoin similarly impose restrictions on the use of mifepristone that the FDA has, in its expert judgment, deemed unnecessary or unduly burdensome. They, too, are preempted. Accordingly, this Court should reverse the district court's judgment with respect to the following laws and enjoin their enforcement: (1) the in-person advance consultation requirement, (2) the ultrasound requirement, (3) the in-person examination requirement, (4) the blood-type testing requirement, and (5) the NCDHHS reporting requirements. JA 633-638.

In-person advance consultation and examination requirements. North Carolina law requires that physicians or qualified professionals complete an in-person consultation with patients at least 72 hours in advance of prescribing mifepristone. N.C. Gen. Stat. § 90-21.83A(b)(1)-(2). It also requires that physicians "must examine the woman in person . . . prior to providing" mifepristone. N.C. Gen. Stat. § 90-21.83B(a). These requirements—like the others that the district court enjoined—impose requirements that the FDA has effectively withdrawn. As explained above, the FDA initially required an in-person consultation and examination with a physician before mifepristone could be prescribed. JA 109; *see also* JA 164 (instructing the patient to, "[a]fter getting a physical exam, swallow 3 tablets of Mifeprex"). In the decades since, however, the FDA has eliminated all of its prior in-person requirements and has specifically allowed prescription through telemedicine, dispensation through the mail, and administration independently in the patient's home. JA 264-265.

North Carolina law cannot impose restrictions that the FDA has deemed unduly burdensome and withdrawn, without running afoul of *Geier* and black-letter preemption principles. The North Carolina

General Assembly's in-person consultation and examination requirements should therefore have been enjoined.

Ultrasound requirement. North Carolina law requires that physicians perform an ultrasound before prescribing mifepristone. N.C. Gen. Stat. § 90-21.93(b)(6). This requirement also imposes a restriction that conflicts with a regulation the FDA has deliberately withdrawn as unduly burdensome. It is therefore preempted.

As previously explained, in recent years, the FDA has specifically rescinded any requirement that patients see a healthcare provider in person prior to taking mifepristone. In-person requirements, the FDA has concluded, restrict patient access unnecessarily and are unduly burdensome to the healthcare system. JA 220-221, JA 232, JA 264-265, JA 348-352, JA 357-359. The North Carolina General Assembly's ultrasound requirement contravenes this conclusion. After all, one cannot receive an ultrasound without appearing in person to see a healthcare provider. The Supremacy Clause forbids the North Carolina legislature from overriding the FDA's expert judgment in this way.

What is more, there is also evidence in the record showing that the FDA specifically considered imposing an ultrasound requirement

when initially granting approval of mifepristone. JA 116, 138. However, since "dating pregnancies [can also] occur[ ] through using other clinical methods," the FDA ultimately recommended ultrasound evaluation only "as needed," and left the decision of whether to conduct an ultrasound "to the medical judgment" of the provider. JA 116. This record evidence further underscores that the FDA affirmatively rejected the notion of an ultrasound requirement. The district court was wrong to approve the General Assembly's contravention of that decision.

Blood-type determination requirement. North Carolina law further requires that, during the in-person consultation, the physician "determine the woman's blood type." N.C. Gen. Stat. § 90-21.83B(a)(2). This requirement, too, is irreconcilable with the FDA's judgment that requiring patients to appear in person to access mifepristone is unnecessary and unduly burdensome. For the same reason as the ultrasound requirement, then, the blood-type requirement should have been deemed preempted.

Reporting to the North Carolina Department of Health and Human Services. Finally, North Carolina law requires that healthcare providers report any adverse events or complications from taking

mifepristone to state Department of Health and Human Services. N.C. Gen. Stat. § 90-21.93(d), (e). But the FDA specifically lifted any reporting requirements that do not involve fatalities. *See supra* p. 13. As a result, the challenged law puts back in place reporting requirements that the FDA specifically removed. The law is therefore preempted.

* * *

The district court reached a contrary conclusion with respect to these challenged state laws. The court held that any restrictions imposed by the State regarding the distribution of mifepristone would be subject to preemption if the FDA had "implemented and then later affirmatively rejected and removed" those restrictions. JA 609. By contrast, the court reasoned that these particular regulations "focus[ed] more on the practice of medicine and a patient's informed consent," not the safety of a particular drug. JA 609. The Court thus found that they were not preempted.

This analysis misses the mark. A state legislature's reasons for passing a particular state law are immaterial in determining whether the state law is preempted. Rather, the inquiry focuses on the intent of

Congress in passing the federal laws that theoretically have preemptive force. It is therefore irrelevant whether the challenged state laws here were intended to address the "general welfare" or the "health and safety risk" of mifepristone—either kind of law could interfere with Congress's "clear and manifest objective" in "directing the FDA to regulate the safe use of drugs," depending on the circumstances. *See* JA 631.

Besides, in passing the 2007 Amendments to the FDCA, Congress *has* authorized the FDA to regulate the practice of medicine and other areas related to "general welfare." The REMS statutory framework gives the FDA ample authority to, for example, require that providers perform certain lab tests before dispensing a drug or monitor patients using certain drugs. 21 U.S.C. § 355-1(f). These are quintessential areas in the general practice of medicine and are no more immune from obstacle preemption than other REMS requirements.

In any event, even accepting the district court's distinction, the challenged state laws would still be preempted because they are not, in fact, laws regulating pregnancy or health and safety generally. Rather, they are laws targeted specifically at patients seeking a medication abortion, which almost always occurs through use of mifepristone. All

of the challenged state laws are codified in Part I of the same state law entitled "Abortion Law Revisions."[3] N.C. Sess. Law 2023-14, Part I. The General Assembly has never pretended that these requirements are intended to apply to pregnancy (when termination is not being considered) or health and safety generally. Thus, even under the district court's own test, the challenged laws are preempted because they ultimately concern drug safety rather than the practice of medicine more generally.

C. Legislative Intervenors' arguments to the contrary fail.

Legislative Intervenors urge this Court to ignore longstanding preemption principles and allow States to impose mifepristone restrictions that the FDA has rescinded under its REMS authority. These arguments fail.

---

[3] *See* N.C. Gen. Stat. §§ 90-21.83A(b)(1) (in-person consultation requirement) (under "Informed consent to medical abortion"); *id.* § 90-21.83B(a) (in-person examination and blood-type requirements) (under "Distribution of abortion-inducing drugs and duties of physician"); *id.* § 90-21.93 (ultrasound and reporting to DHHS requirements) (requiring reporting of an ultrasound "[a]fter a surgical or medical abortion is performed" to DHHS within 15 days after the date of the follow-up appointment following a medical abortion).

1. Legislative Intervenors misunderstand the legal framework for obstacle preemption.

To start, Legislative Intervenors spend a significant portion of their brief focused on the fact that neither the FDCA nor the 2007 Amendments communicates Congress's express intent to preempt state law. Br. 23-26. They criticize Dr. Bryant for failing to "identif[y] the clear statement of preemptive intent necessary" to establish obstacle preemption. Br. 26. This argument confuses distinct preemption doctrines and should be rejected.[4]

Congress can preempt state law under three separate theories: express preemption, field preemption, and conflict preemption. *Pinney v. Nokia, Inc.*, 402 F.3d 430, 453 (4th Cir. 2005). "[U]nder express preemption, Congress expressly declares its intent to preempt state law." *Id.* For conflict preemption, by contrast, no express statement of congressional intent to preempt state law is required. *See id.* (acknowledging that conflict preemption is "implied[ ]"). Instead, courts

---

[4] That Legislative Intervenors effectively seek to convert obstacle preemption into express preemption is hardly surprising. After all, they "dispute that implied obstacle preemption is a valid basis for federal preemption." Br. 19. Supreme Court precedent says otherwise. *See Hillman*, 569 U.S. at 490; *Geier*, 529 U.S. at 873-74; *Buckman Co.*, 531 U.S. at 352-53.

ask whether—notwithstanding the absence of any express preemption clause—state law conflicts with Congress's purposes and objectives so significantly that state law must yield. *Id.*; *see also Geier*, 529 U.S. at 873.

Neither Dr. Bryant nor the Attorney General has argued for express preemption in this case. It therefore matters little whether, in passing the FDCA or the 2007 Amendments, Congress articulated a "clear statement of preemptive intent." Br. 26. No such clear statement is required.

Because none of the parties have advanced an express-preemption argument, much of Legislative Intervenors' discussion of statutes that *do* have express-preemption clauses is irrelevant. *See* Br. 22, 24-25. Nevertheless, it is worth clarifying the record. Legislative Intervenors emphasize that Congress amended the FDCA to "include an express preemption provision for medical devices, but 'declined' to enact a similar provision for prescription drugs." Br. 22 (citation omitted) (quoting *Wyeth*, 555 U.S. at 567). But they gloss over the fact that the amendment they reference was part of a 1976 statute focused exclusively on medical devices. Medical Device Amendments of 1976,

Pub. L. No. 94-295, 90 Stat. 539. In passing that statute, Congress would have had absolutely no reason to say anything about prescription drugs.

Moreover, as the district court observed, JA 649-650, the savings clause in the 1962 amendments to the FDCA applied—by its own terms—only to those amendments, which predated the 2007 Amendments by decades. Drug Amendments of 1962, Pub. L. No. 87-781, § 202, 76 Stat. 780, 793. Legislative Intervenors cite no savings provision in the 2007 Amendments establishing the REMS framework. And again, at any rate, "neither an express preemption provision nor a savings clause bars the ordinary working of conflict preemption principles." *Buckman Co.*, 531 U.S. at 352.

2. Legislative Intervenors misunderstand the Attorney General's position.

Legislative Intervenors also seem to misunderstand the scope of the Attorney General's obstacle preemption argument. At times, they seem to be attempting to refute a field-preemption argument: They resist the idea that the 2007 Amendments "boot[ed] States from their traditional consumer-protection role," Br. 23, and "le[ft] no room for

'complementary state regulation.'" Br. 27 (quoting *Arizona*, 567 U.S. at 401).

But this is not—and has never been—the Attorney General's position. The Attorney General has never argued that the FDA has *exclusive* authority over high-risk drugs subject to REMS restrictions, such that any state efforts to regulate those high-risk drugs are preempted. Rather, the Attorney General's position is significantly narrower: When a State attempts to impose a restriction on a REMS drug that the FDA has *affirmatively rescinded*, that state restriction is preempted. All other state efforts to regulate access to REMS drugs can stand.

Because the Attorney General's position is vastly narrower than Legislative Intervenors claim, their fears about invalidating dozens of other state laws are unfounded. *See* Br. 32-33 (expounding upon those fears). The Attorney General's position would leave untouched state laws regulating opioids and other dangerous drugs—as well as any state laws that regulate mifepristone in ways that do not directly contradict the FDA's expert judgment.

The same is true for state tort law. *But see* Br. 34 (claiming that Dr. Bryant's position—and, presumably, the Attorney General's—would threaten state tort law). Unless a state tort law somehow fell within the scope of the Attorney General's theory—and it is difficult to imagine how one would—traditional tort remedies should remain available.

To be crystal clear, no party in this litigation is suggesting that state law has no role to play in regulating REMS drugs. In the vast majority of circumstances, state law and REMS restrictions can continue to coexist. Where, as here, however, state laws impose restrictions that the FDA has expressly found to be unnecessary and unduly burdensome, obstacle preemption applies.

3. Legislative Intervenors misunderstand Congress's objective in establishing the REMS framework.

Legislative Intervenors also misunderstand Congress's purpose—the "ultimate touchstone in every preemption case." *Wyeth*, 555 U.S. at 565. They insist that the "primary objective" of the FDCA is "to ensure the safety of food and drugs." Br. 20. As a result, they claim, anything a State does that furthers that interest cannot be preempted. This argument also fails. First, the critical statute is the 2007 Amendments,

not the FDCA more broadly. And second, in the 2007 Amendments, Congress mandated a balanced approach to drug regulation that considers safety, access, *and* burden—not safety to the exclusion of all else.

To start, it is true that when Congress enacted the FDCA, the FDA's main purpose was to ensure the safety of food and drugs. *Wyeth*, 555 U.S. at 574. But since that time, Congress has repeatedly revised the FDCA, including when it passed the 2007 Amendments, the statute most relevant in this case. Pub. L. No. 110-85, 121 Stat. 823; *see also Wyeth*, 555 U.S. at 567. These revisions to the FDCA have significantly expanded the FDA's authority and granted the agency wide-ranging powers, particularly with respect to high-risk drugs. *See supra* pp. 5-9. To say that the FDCA's only purpose is to ensure the safety of food and drugs is to read the amendments out of the history of the FDCA.

What is more, the provisions in the 2007 Amendments that focus on REMS drugs make clear that Congress did *not* have a one-dimensional safety objective. Section 355-1 *explicitly* directs the FDA to implement restrictions that are "commensurate with the specific serious risk," while at the same time avoiding regulations that would be

"unduly burdensome on patient access to the drug" or "the health care delivery system." 21 U.S.C. § 355-1(f)(2)(A), (C), (D). Legislative Intervenors ask this Court to simply ignore the fact that Congress expressly directed the FDA not to focus exclusively on safety.

Wyeth does not contradict this reading of the 2007 Amendments. Contrary to Legislative Intervenors' contention, *Wyeth* does not stand for the proposition that the only objective of the REMS statutory framework is safety. *Wyeth* involved a state tort lawsuit for inadequate *labeling* of a prescription drug—not a REMS framework. 555 U.S. at 567. And it pre-dates the 2007 Amendments entirely. *Id.* So when the Court held that the FDCA did not establish a "floor" and a "ceiling" for drug regulation, it was specifically referring to whether, once a label has been approved, "a state-law verdict may . . . deem the label inadequate" under a version of the FDCA that was operational before the 2007 Amendments were even enacted. *Id.* at 574.

Unlike Legislative Intervenors, the district court correctly focused on the 2007 Amendments and its provisions on REMS. JA 628-633. With respect to that particular statute, the district court rightly concluded that Congress's "clear and manifest objective" was "directing

the FDA to regulate the safe use of drugs with inherent toxicity or potential harmfulness *without unnecessarily reducing patient access or burdening the health care system*." JA 631 (emphasis added).

Section 355-1's tripartite focus on safety, access, *and* burden undermines Legislative Intervenors' arguments about complementarity. Br. 29-30. Legislative Intervenors claim that the challenged state laws cannot conflict with the mifepristone REMS because they both go to the same objective—"safety"—and are therefore complementary, not contradictory. Br. 29-30. But Congress did not direct the FDA to design REMS plans based solely on the restrictions that would make a particular drug the safest. Instead, the FDA is to evaluate each restriction to determine whether it appropriately balances safety against patient access and burden minimization. 21 U.S.C. § 355-1(f). This multidimensional focus means that the FDA is *statutorily required* to reject some regulations that might indisputably increase a drug's safety.

The Attorney General is doubtful that the challenged state laws actually render mifepristone safer to use. But even if they do, they may nevertheless run afoul of section 355-1(f) if they are unnecessary or

unduly burdensome. Where the FDA has affirmatively made that judgment, and withdrawn a restriction as a result, any state law that seeks to reimpose the restriction is preempted.

4. Legislative Intervenors have no persuasive answer to *Geier*.

The final nail in the coffin for Legislative Intervenors' position is *Geier*. Again, that case involved a Federal Motor Vehicle Safety Standard promulgated by DOT that required "auto manufacturers to equip some but not all of their 1987 vehicles with passive restraints." 529 U.S. at 864-65. The Supreme Court, relying on obstacle preemption, held that the Safety Standard preempted "a rule of state tort law" that would have imposed a duty on car manufacturers to install airbags in all 1987 vehicles. *Id.* at 881. Such a requirement, the Court said, "would have presented an obstacle to the variety and mix of devices that the federal regulation sought." *Id.* And it would have directly overridden the Department's affirmative decision *not* to impose an "'all airbag' standard." *Id.* at 879.

Legislative Intervenors insist *Geier* is "inapposite" to this case. Br. 31. That is incorrect.

First, *Geier* proves that a goal of promoting safety cannot insulate state laws from preemption. The Supreme Court was not persuaded by the fact that both the DOT's Safety Standard and the state tort law sought to increase auto-passenger safety. Because the Department had carefully and deliberately identified a specific strategy, and expressly rejected others, the Supremacy Clause barred state law from overriding that choice. *Id.* at 874-86; *see also Ouellette*, 479 U.S. at 494; *Motor Coach Employees*, 403 U.S. at 287.

So, too, here. It matters little whether Legislative Intervenors are correct that the challenged state laws would increase patient safety. Even if they do, that does not change Congress's decision to entrust the FDA with striking the optimal balance between safety, patient access, and healthcare burdens. The FDA, pursuant to that authority, has expressly concluded that the restrictions on mifepristone that the challenged state laws impose are unnecessary and unduly burdensome and, for that reason, has withdrawn them. The North Carolina legislature cannot overturn that decision.

Second, Legislative Intervenors suggest that the Attorney General's theory is wrong because it was an executive agency (the FDA)

that rejected the policies set forth in the challenged state laws, not Congress itself. Br. 30. This argument directly conflicts with *Geier*. There, too, it was an executive agency (DOT) that rejected a specific policy (an "all airbag" standard). 529 U.S. at 879. But that fact did not stop the Supreme Court from finding the state law to be preempted. *Id.* at 886.

Finally, Legislative Intervenors attempt to distinguish *Geier* by emphasizing that in that case, DOT had "deliberately provided the manufacturer with a range of choices among different passive restraint devices." Br. 31 (quoting *Geier*, 529 U.S. at 875). Since the agency chose a "range of choices," Legislative Intervenors say, it would have "present[ed] an obstacle" if state tort law had been allowed to instead mandate a single policy. Br. 31 (quoting *Geier*, 529 U.S. at 881).

Legislative Intervenors are wrong to suggest that the situation in *Geier* is different from the circumstances of this case. Here, the FDA has selected a REMS plan that authorizes numerous different avenues for accessing mifepristone—patients can choose to see a doctor in person, they can choose to see a different healthcare professional in person, or they can choose to see one of these kinds of healthcare

providers via telemedicine. In other words, they have "a range of choices." *Geier*, 529 U.S. at 875.

But the North Carolina legislature has sought to strip those choices away. They would limit access to mifepristone to one narrow path: patients can access the drug only by, among other things, having an ultrasound, waiting 72 hours, seeing a physician in person, and committing to an in-person follow-up appointment. This is the North Carolina legislature's version of imposing an "all airbags" standard using state law. And, like that state-law standard in *Geier*, these laws are preempted under the Supremacy Clause.[5]

[5] Legislative Intervenors argue in the alternative that Dr. Bryant lacks a cause of action. Br. 34-36. But Legislative Defendants did not raise this issue below, and the district court did not address it as a result. Because the existence of a "cause of action does not implicate subject-matter jurisdiction," *Steel Co. v. Citizens for a Better Env't*, 523 U.S. 83, 89 (1998), this Court should decline to reach this forfeited issue for the first time on appeal. Indeed, when "a party in a civil case fails to raise an argument in the lower court and instead raises it for the first time before [this Court], [the Court] may reverse only if the newly raised argument establishes 'fundamental error' or a denial of fundamental justice." *In re Under Seal*, 749 F.3d 276, 285 (4th Cir. 2014). In their opening brief, Legislative Defendants neither argue nor explain how this newly raised issue could meet that demanding standard.

CONCLUSION

For the foregoing reasons, Attorney General Stein respectfully requests that this Court affirm in part and reverse in part the district court's judgment.

October 10, 2024

Respectfully submitted,

JOSHUA H. STEIN
Attorney General

Sarah G. Boyce
Deputy Attorney General &
General Counsel

/s/ Sripriya Narasimhan
Sripriya Narasimhan
Deputy General Counsel

Amar Majmundar
Senior Deputy Attorney General

Stephanie A. Brennan
Special Deputy Attorney General

Counsel for Defendant Attorney General Joshua H. Stein

N.C. Department of Justice
Post Office Box 629
Raleigh, NC 27602
(919) 716-6400
sboyce@ncdoj.gov
snarasimhan@ncdoj.gov
amajmundar@ncdoj.gov
sbrennan@ncdoj.gov

CERTIFICATE OF COMPLIANCE

I certify that this brief complies with the type-volume limitations of Fed. R. App. P. 28.1(e)(2)(B)(i) because it contains 10,888 words, excluding the parts of the petition exempted by Fed. R. App. P. 32(f). This brief complies with the typeface and type-style requirements of Fed. R. App. P. 32(a)(5) & (6) because it has been prepared in a proportionally spaced typeface: 14-point Century Schoolbook font.

Respectfully submitted, this the 10th day of October 2024.

/s/ Sripriya Narasimhan
Sripriya Narasimhan

CERTIFICATE OF SERVICE

I certify that on October 10, 2024, I filed the foregoing with the Clerk of the Court for the United States Court of Appeals for the Fourth Circuit by using the appellate CM/ECF system. Participants in the case are registered CM/ECF users and service will be accomplished by the appellate CM/ECF system.

Respectfully submitted, this the 10th day of October 2024.

/s/ Sripriya Narasimhan
Sripriya Narasimhan