Nos. 24-1576, 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

RESPONSE/REPLY BRIEF OF APPELLANTS

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INTRODUCTION

As the Attorney General concedes, "States ordinarily have wide latitude to protect the health and safety of their citizens in different ways, including with respect to the regulation of FDA-approved drugs." Brief of Amicus Curiae the State of North Carolina in Support of Plaintiff-Appellant at 2, *GenBioPro, Inc. v. Raynes*, No. 23-2194 (4th Cir. filed Feb. 14, 2024). Given that "Congress did not intend FDA oversight to be the exclusive means of ensuring drug safety and effectiveness," *Wyeth v. Levine*, 555 U.S. 555, 575 (2009), Plaintiff must persuade this Court that the FDAAA radically altered the federal-state balance long struck by Congress. It did not. Indeed, the case for preemption is particularly weak here because Congress is well aware of state drug regulation in this historical area of state concern and yet declined to expressly preempt state law.

Plaintiff distances herself from the decision below and says that obstacle preemption applies only to state requirements that the FDA has adopted and then rejected. That is nonsensical. That the FDA once found a safety requirement necessary for the safe use of a drug is a point in favor of a state imposing the protection—not against it. More fundamentally, obstacle preemption is based upon congressional purpose. Plaintiff never argues that Congress intended to regulate the minutiae of medical practice by eliminating follow-up visits or state reporting requirements. Instead, Plaintiff's obstacle-preemption theory

boils down to her claim that the FDAAA mandates access. To prevail, Plaintiff must establish that Congress intended the FDA to set a federal ceiling for high-risk drugs. But she cannot.

Even were this Court to apply Plaintiff's novel initially-adopted-and-later-rejected test, the challenged provisions would pass. Several were never adopted by the FDA. Others were never rejected. Plaintiffs and the Attorney General thus invite this Court to displace state law based on "similar" restrictions, "effective withdrawals," and vague "notions" of agency intent. And while the Attorney General insists that States retain the power to protect their citizens from high-risk drugs like opioids, the FDA has rejected opioid dosage and duration limitations—protections enacted by many States. No FDAAA provision carves out abortion drugs for preemption.

Plaintiff next argues this case is controlled by *Geier v. American Honda Motor Co.*, 529 U.S. 861 (2000). But the Supreme Court unanimously rejected her overreading of this case in *Williamson v. Mazda Motor of America, Inc.*, 562 U.S. 323, 337 (2011). Preemption does *not* occur merely because a federal regulation "leaves the manufacturer with a choice" which state law "restrict[s]." *Id.* at 332.

Further, Plaintiff objects to longstanding protections for women seeking abortions like modest waiting periods and informed consent. But such protections existed long before Congress enacted the FDAAA in 2007. And in the nearly twenty years since its passage, no one (until

very recently) has suggested that REMS displace state laws that survived under *Roe* and *Casey*. This Court would be the first to so hold.

In short, North Carolina's statutes regulating abortion drugs complement and reinforce Congress's purpose: to protect consumers from dangerous drugs like mifepristone and opioids. While States may not reduce or eliminate REMS restrictions, they may supplement them. This Court should decline Plaintiff's invitation to stretch obstacle preemption beyond recognition.

ARGUMENT

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

This case concerns only implied obstacle preemption. Plaintiff's invocation of that doctrine illustrates its dangers—she requests that this Court "elevate abstract and unenacted legislative desires above state law." *Va. Uranium, Inc. v. Warren*, 587 U.S. 761, 778 (2019) (plurality op. by Gorsuch, J., joined by Thomas, J., and Kavanaugh, J.). She says (at 51), for example, that because obstacle preemption is implied she need not show textual evidence that Congress intended to displace state law. That's wrong. Even for implied preemption, "evidence of preemptive purpose," must "be sought in the text and structure of the statute at issue." *Va. Uranium*, 587 U.S. at 778 (cleaned up). To hold otherwise, would invite the very "freewheeling judicial inquiry" the Supreme Court has cautioned against. *Chamber of*

Com. of U.S. v. Whiting, 563 U.S. 582, 607 (2011) (cleaned up). And Plaintiff insists (at 52) that, instead of applying a presumption against preemption, courts must presume the "opposite"—that Congress *wants* to displace state law. Not so.

Since the states "are independent sovereigns in our federal system," courts do not presume that Congress "cavalierly pre-empt[s] state-law causes of action." *Medtronic, Inc. v. Lohr*, 518 U.S. 470, 485 (1996). Rather, "any 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) (cleaned up). 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). And 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. Accordingly, 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 (cleaned up). That threshold is not met here.

Under obstacle preemption, this Court asks whether state law "stands as an obstacle to the accomplishment and execution of the full purposes and objectives of Congress" in enacting the FDAAA. *Guthrie*,

79 F.4th at 337 (cleaned up). There is no dispute that the FDCA's primary objective is to ensure the safety of food and drugs. *Wyeth*, 555 U.S. at 574; Food and Drug Cosmetic Amendment Act, Pub. L. No. 110-8521, 121 Stat. 823 (2007). Nor could there be. Congress "enacted the FDCA to bolster consumer protection against harmful products." *Wyeth*, 555 U.S. at 574. And while Congress has "enlarged the FDA's powers to protect the public health and assure the safety, effectiveness, and reliability of drugs," it has always taken "care to preserve state law." *Id.* at 567. This includes the 2007 Amendments. See Opening Br. at 21–36.

A. Plaintiff's "expressly considered and rejected" theory of obstacle preemption has no basis in precedent or the FDAAA.

Plaintiff attempts (at 6) to narrow the district court's preemption ruling to only state protections that "FDA explicitly considered and rejected." That reinterpretation of the ruling fails. The lower court was clear that it was finding preemption based on its determination that 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." JA 632.

Plaintiff's considered-and-rejected theory also fails on the law because the relevant question for obstacle preemption is whether the challenged laws actually obstruct "the accomplishment and execution of the full purposes and objectives of Congress." *Guthrie*, 79 F.4th at 337 (cleaned up). Plaintiff does not (and could not) claim that regulating the minutiae of REMS drugs is a federal purpose. Instead, Plaintiff ultimately resorts, as did the district court, to arguing that one of Congress's purposes in the FDAAA was to mandate access through a careful balancing of risks and benefits.

Plaintiff thus insists (at 3) that "North Carolina's restrictions on mifepristone are preempted because they upset the careful regulatory scheme established by federal law." And (at 22) that "a state may not impose restrictions on a REMS drug that conflict with FDA's efforts to assure access to the drug." In the end, Plaintiff insists (at) that REMS are preemptive because Congress charged the FDA in the FDAAA with the "precise balancing of risks and benefits." That argument *broadens* the district court's ruling—under Plaintiff's theory any additional state restriction on a REMS drug could be seen as interfering with the FDA's "precise balancing."

Attorney General Stein similarly claims that "most" state laws will remain in place (at 32) because obstacle preemption applies only when the FDA has rescinded a REMS. One searches the statute in vain for any such directive from Congress. Wish as the Attorney General

might, there is no provision of law (nor any statutory interpretation principle) providing that state abortion laws–and only state abortion laws–are preempted by the FDAAA. The Attorney General's made-for-this-case-only view of the FDAAA along with both the district court's "comprehensive regulatory framework" and Plaintiff's "precise balancing" and access arguments produces a world in which the FDAAA establishes not only a federal floor but a federal ceiling for REMS drugs. That can't be right. However narrow Plaintiff and the Attorney General seek to paint their preemption theory, this wolf comes as a wolf.

B. Congress enacted the FDAAA as a federal floor to protect consumers from high-risk drugs.

The FDAAA's text belies any access mandate. In it, Congress sought "to enhance the postmarket authorities of the [FDA] with respect to the safety of drugs[.]" 121 Stat. at 823. The FDAAA did not change Congress's long-running intent to "regard[] state laws as a complementary form of drug regulation." *Wyeth*, 555 U.S. at 578. *See* Opening Br. 20–26.

The FDA acknowledges as much. Addressing its opioid REMS, the FDA acknowledges that federal REMS are just one among several options to enhance drug safety, including state regulation. *See* Amicus Br. of North Carolina at 15, *GenBioPro*, No. 23-2194 (citing U.S. Food & Drug Admin., *Opioid Analgesic Risk Evaluation and Mitigation Strategy (REMS)*, https://perma.cc/8YED-DJKR). REMS are, in other

words, a federal floor. And in the most recent *mifepristone* REMS (as in every prior version), the FDA identifies its purpose. JA 77. The FDA explains: "The goal of the REMS for mifepristone is to mitigate the risk of serious complications associated with mifepristone." JA 77. The agency does so by: (1) "Requiring healthcare providers who prescribe mifepristone to be certified in the Mifepristone REMS Program;" (2) "Ensuring that mifepristone is only dispensed by or under the supervision of certified prescribers, or by certified pharmacies on prescriptions issued by certified prescribers"; and (3) "Informing patients about the risk of serious complications associated with mifepristone." JA 77. There is nary a word about mifepristone access.

Section 355-1(f), the only statutory access hook identified by Plaintiff—far from preempting state law—limits only the FDA. *See* Opening Br. 23–24. 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).

Plaintiff asks this Court to infer from the "mere existence" of a REMS that Congress "intends to bar States from imposing stricter standards." *Williamson*, 562 U.S. at 335. Yet it is impossible to "reconcile this consequence with a statutory saving clause that foresees the likelihood of a continued meaningful role for state tort law." *Id.* The

FDCA's savings clause broadly and expressly preserves state law absent a "direct and positive conflict." *Wyeth*, 555 U.S. at 567 (quoting 76 Stat. 793). That unusually comprehensive language sets forth Congress's directive that state law is preempted only when it is impossible to comply with both federal and state law, *i.e.*, when there is a direct and positive conflict. It precludes a judicial inquiry into whether state law undermines a federal purpose–precisely the murky inquiry that Plaintiff asks this Court to undertake.

Plaintiff insists (at 46) that obstacle preemption applies regardless of the FDCA's savings clause. But that argument is overbroad by half. Congressional intent is the touchstone of the preemption analysis. *Medtronic*, 518 U.S. at 485. At a minimum, a savings clause is relevant. *Williamson*, 562 U.S. at 335 (rejecting the argument that agency standards "were *maximum* standards" because a saving clause "fores[aw] the likelihood of a continued meaningful role for state tort law"). And here the text of the savings clause expresses Congress's desire that state law supplement federal law unless a "direct and positive" conflict exists.

Plaintiff also suggests (at 47) that the FDAAA's savings clause should be ignored because it applies only to the 1962 amendments. Yet as the Supreme Court held in *Wyeth*, this savings clause reaffirmed, consistent with decades of congressional intent, that the FDCA writ large "carefully preserve[s] state authority." 555 U.S. at 566. And

nothing about the savings clause suggests that Congress intended *other* FDCA amendments "to be the exclusive means of ensuring drug safety and effectiveness." *Id*. at 575.

"The case for 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." *Bonito Boats, Inc. v. Thunder Craft Boats, Inc.*, 489 U.S. 141, 166–67 (1989) (cleaned up). This is especially true given the presumption "that the historic police powers of the States" are not superseded "unless that was the clear and manifest purpose of Congress." *Wyeth*, 555 U.S. at 565 (quoting *Medtronic*, 518 U.S. at 485).

Plaintiff has no response to the fact that the FDAAA expressly preempts only a narrow category of state regulation—state registration requirements for certain clinical trials. § 801(d), 121 Stat. at 922. This targeted provision shows that Congress knows how to preempt state law when it wants to and yet "declined" to do so for REMS drugs. *Wyeth*, 555 U.S. at 567; *see also 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. For all the reasons listed in the

Legislative Intervenors' opening brief, the FDAAA does not mandate access.

C. Plaintiff's smorgasbord of arguments in favor of preemption fail.

1. *Geier* does not support obstacle preemption.

Plaintiff invites this Court to resurrect the overreading of *Geier* that a unanimous Supreme Court rejected in *Williamson*, 562 U.S. at 330. She claims (at 57) that state law is preempted whenever it "limit[s] the range of choices" left open by a federal agency. Not so. Preemption does *not* occur merely because a federal regulation "leaves the manufacturer with a choice" that state law "restrict[s]." *Williamson*, 562 U.S. at 332. Instead, "a conflict results *only* when [federal law] does not just set out options for compliance, but also provides that the regulated parties *must remain free* to choose among those options." *Id.* at 338 (Sotomayor, J., concurring) (emphasis added) (quotation omitted). Thus, where federal law provides "multiple options … a suit claiming that a manufacturer should have chosen one particular option" is not preempted unless the agency "determine[s] that the availability of options was necessary to promote safety." *Id.* at 332, 336.

In *Geier*, for example, the Department of Transportation desired a "mix" of passive restraint devises because the agency had safety concerns with and was worried about a public backlash against an all-airbag standard. *Id.* at 331–32. The Department thus concluded "that

safety would best be promoted if manufacturers installed *alternative* protection systems in their fleets rather than one particular system in every car.'" *Williamson*, 562 U.S. at 332 (quoting *Geier*, 529 U.S. at 881 (quoting United States Brief in *Geier* 25–26)). In this unusual circumstance, an airbags-only requirement was preempted. *Id.*

To the extent *Geier* is "pathmarking," Bryant Br. 4, the path it marks is seldom trod. The Supreme Court essentially limited *Geier* to its facts in *Williamson*—a case involving the very same agency and very same statute. *See* 562 U.S. at 330 (evaluating "the regulation, including its history, the promulgating agency's contemporaneous explanation of its objectives, and the agency's current views of the regulation's pre-emptive effect"). And that's for good reason. Federal law often leaves regulated parties with choice—and unless multiple options is itself a federal purpose—state law "may restrict" that choice because doing so "does not stand as an obstacle to the accomplishment of the full purposes and objectives of federal law." *Id.* at 336 (cleaned up).

As a fallback, Plaintiff repeatedly cites *Geier* for the untenably broad principle that state law is preempted whenever it "upset[s] the careful regulatory scheme established by federal law." *See, e.g.*, Bryant Br. 64 (citing *Geier*, 529 U.S. at 870). Many federal regulatory schemes are carefully established. Yet not all of them give rise to obstacle preemption. *Hillsborough Cnty. v. Automated Med. Lab'ys, Inc.,* 471 U.S. 707, 717 (1985). Indeed, "[f]ar 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." *N.Y. State Dep't of Soc. Servs. v. Dublino*, 413 U.S. 405, 417 (1973) (quoting *Schwartz v. Texas*, 344 U.S. 199, 202–03 (1952)).

Further, in *Geier*, "the agency's own view … ma[de] a difference." 529 U.S. at 883; *Williamson*, 562 U.S. at 335 (same). Instead of endorsing Plaintiff's federal maximalist view of the REMS, the FDA has time and again acknowledged that state law may go above and beyond them. In particular, the FDA advises mifepristone prescribers that they must comply not only with the REMS certification requirements but also state law. To determine their prescribing eligibility, "health care providers should check their individual state laws." FDA, Questions & Answers on Mifepristone, JA 470. The FDA is similarly clear that it "does not regulate the practice of medicine" or the "availability" of a drug.[1] And as the Attorney General recently told this Court, the FDA "explicitly envisions that States will enact complementary laws that reinforce, rather than frustrate, the REMS" for opioids. Amicus Br. of North Carolina at 15, *GenBioPro*, No. 23-2194. According to the FDA, those REMS are only "one strategy among multiple national *and state* efforts to reduce the risk of abuse, misuse, addiction, overdose, and

[1] U.S. Food & Drug Admin., *About FDA: Patient Q&A*, (Nov. 2024), https://perma.cc/6Y3E-7GWP.

deaths due to prescription opioid analgesics."[2] These agency admissions establish that not even the FDA views REMS as setting a federal maximum.

2. *Wyeth* rejected Plaintiff's theory of drug regulation.

In a surprising move, Plaintiff (but not the Attorney General) asserts that *Wyeth* supports her preemption position. Bryant Br. 28–30. It does not. In *Wyeth*, the Supreme Court rejected the claim Plaintiff makes here: that "the FDCA establishes both a floor and a ceiling for drug regulation." 555 U.S. 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. *Wyeth* held that "Congress did *not* intend FDA oversight to be the exclusive means of ensuring drug safety and effectiveness." *Id.* at 575 (emphasis added).

Plaintiff nevertheless relies on a footnote in *Wyeth* to claim that obstacle preemption obtains whenever the FDA has rejected a safeguard. Bryant Br. 30. That argument confuses obstacle preemption with impossibility preemption and misses the fundamental distinction between failure-to-warn labeling cases—like *Wyeth*—and this one.

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[2] U.S. Food & Drug Admin., *Opioid Analgesic Risk Evaluation and Mitigation Strategy (REMS)*, (Oct. 31, 2024), https://perma.cc/8YED-DJKR (emphasis added).

In a failure-to-warn case, the relevant inquiry is binary: could the manufacturer have included the warning required by state law consistent with federal law? The answer to this question is often yes because non-generic manufacturers have a duty to update a drug's label to warn consumers of risks and can do so without prior FDA approval. *Wyeth*, 555 U.S. at 571. Thus, in *Wyeth*, the Court held that such a manufacturer could not "show that there is an actual conflict between state and federal law such that it was impossible to comply with both." *Merck Sharp & Dohme Corp. v. Albrecht*, 587 U.S. 299, 314–15 (2019) (citing *Wyeth*, 555 U.S. at 571–73). But where a manufacturer *cannot* change the label—either because it manufactures generics or because the FDA has already rejected the warning—complying with the state warning requirement would render the drug misbranded under federal law, raising classic impossibility preemption. *Wyeth*, 555 U.S. at 573. In *Merck*, for example, the manufacturer claimed that it was unable to include the warning allegedly required by state law because the FDA would not have approved it. 587 U.S. at 308–09. So abiding by state law would have rendered its product misbranded under federal law, rendering compliance with both impossible. *Id.*

"[T]he regulatory scheme in this case ... is quite different." *Wyeth*, 555 U.S. at 580. As Plaintiff acknowledges (at 30–32), the contents of mifepristone's label are not at issue and compliance with both federal and state law is not impossible. That complying with North Carolina's

requirements does not render mifepristone misbranded in violation of federal law dooms Plaintiff's impossibility preemption analogy.

Plaintiff pivots to claim (at 31) that the distinction between different theories of preemption should not matter because the FDA's judgment is undermined more by a state regulation than by a labeling change. The Supreme Court's cases say differently. Impossibility preemption does not exist "where the laws of one sovereign permit an activity that the laws of the other sovereign restrict or even prohibit." *Merck*, 587 U.S. at 314 (citing cases). Rather, where federal law sets a federal floor—especially in an area of historical state concern—it is well settled that states may provide more protection. *See Wyeth*, 555 U.S. at 565, 574, 579.

Plaintiff worries that state law might present a patchwork of different safety measures. But that is a feature of federal drug regulation, not a bug. As the Attorney General recently told this Court in a related case, "[o]ur dual-sovereign system often benefits from unique state approaches to important policy questions." Amicus Br. of North Carolina at 15, *GenBioPro*, No. 23-2194 (citing *New State Ice Co. v. Liebmann*, 285 U.S. 262, 311 (1932) (Brandeis, J., dissenting)). Thus, Congress has long sought to preserve state law: "As it enlarged the FDA's powers to 'protect the public health' and 'assure the safety, effectiveness, and reliability of drugs,' ... Congress took care to preserve state law." *Wyeth*, 555 U.S. at 567 (citation omitted). And for good

reason. The FDCA nowhere provides a remedy "for consumers harmed by unsafe or ineffective drugs." *Id.* at 574–75. Instead, Congress "determined that widely available state rights of action provided appropriate relief for injured consumers." *Id.* at 574.

Plaintiff's assertion that the FDAAA silently displaced this "important[] layer of consumer protection," leaving injured consumers without recourse, is nonsensical. *Id.* at 579. There is no statutory basis to infer that Congress meant to get rid of the only consumer remedy available for high-risk drugs. Indeed, the lack of a federal remedy prompted the *Wyeth* Court to conclude that "Congress did not intend FDA oversight to be the exclusive means of ensuring drug safety and effectiveness." *Id.* at 575.

Nor can Plaintiff argue that state tort law is different from the statutes she challenges here. There is no way to "draw[] a distinction between common-law exposure to liability and a statutory legal mandate." *Mutual Pharm. Co., Inc. v. Bartlett*, 570 U.S. 472, 491 (2013) (cleaned up). Both impose legal duties. *Id.* at 482 n.1. Thus, as the Supreme Court has recognized, any "distinction between common law and statutory law is irrelevant" to preemption. *Id.* at 491.

3. Section 355-1 does not override the FDCA's prohibition on FDA regulation of the practice of medicine.

The Attorney General claims (at 33) that the FDA "enjoys sweeping authority to inject itself into nearly every facet of the prescription-drug process" for REMS drugs. He says (at 46) that the FDA "can even regulate the practice of medicine" by "requiring health care providers" to do certain things. Plaintiff, too, makes the bold claim (at 31) that Section 355-1 "gives the FDA broad authority to regulate many aspects of medical practice ordinarily left to the States." This argument fundamentally misunderstands the role Congress has long provided for the FDA.

Section 396 of the FDCA "expressly disclaims any intent to directly regulate the practice of medicine." *Buckman Co. v. Plaintiffs' Legal Comm.*, 531 U.S. 341, 350–51 (2001) (citing 21 U.S.C. § 396 (1994 ed., Supp. V)). Indeed, it is the "FDA's mission to regulate in this area *without* directly interfering with the practice of medicine." *Sigma-Tau Pharms., Inc. v. Schwetz*, 288 F.3d 141, 148 (4th Cir. 2002) (emphasis added) (quoting *Buckman Co.,* 531 U.S. at 350); *Shuker v. Smith & Nephew, PLC*, 885 F.3d 760, 766 (3d Cir. 2018) (same); *United States v. Caronia*, 703 F.3d 149, 153 (2d Cir. 2012) ("[T]he FDA generally does not regulate how physicians use approved drugs."). The FDA agrees that Section 396 makes clear that Congress "did not purport to regulate the practice of medicine." Legal Status of Approved Labeling for

Prescription Drugs, 37 Fed. Reg. 16503 (Aug. 15, 1972); *see also* James M. Beck & Elizabeth D. Azari, *FDA, Off-Label Use, and Informed Consent: Debunking Myths and Misconceptions*, 53 Food & Drug L.J. 71, 76–77 (1998) (noting that the "FDA never has had authority to regulate the practice of medicine").

Section 355-1 does not override this longstanding prohibition. Indeed, the Attorney General is wrong (at 33) that Section 355-1 regulates *health care providers* at all. It does no such thing. Rather, precisely because the FDA is prohibited from regulating the practice of medicine, the REMS operate only on drug manufacturers. Under the REMS, manufacturers certify healthcare providers, who in turn agree to certain conditions, but the FDA does not oversee healthcare providers. JA 77–81. This two-steps-removed regime is necessary precisely because the FDCA forbids the FDA from regulating the practice of medicine. 21 U.S.C. § 396. This prohibition reinforces the conclusion that the REMS do not preempt state laws regulating medical practice.

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

Plaintiff and the Attorney General are wrong that the FDAAA can be interpreted to preempt only state abortion law. If this Court identifies access as a core congressional purpose in the FDAAA, then almost any additional state regulation on a REMS drug could be

accused of impeding access. That theory would run riot through state health and safety codes. Plaintiffs' view would take this Court through the looking glass to a world where the FDAAA preempts state laws regulating everything from opioids, to acne medication, to mifepristone.

At the outset, even limiting preemption to mifepristone would blue pencil dozens of different state laws. Opening Br. 32–33 (listing state laws). Stretching preemption to the provisions the district court upheld would rewrite dozens more. Thirty-four States have informed consent laws[3] and twenty-five have a modest waiting period.[4]

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[3] Ala. Code § 26-23A-4; Alaska Stat. Ann. § 18.16.060; Ariz. Rev. Stat. Ann. § 36-2153(A); Ark. Code Ann. § 18.16.060; Conn. Agencies Regs. § 19a-116-1; Fla. Stat. Ann. § 390.0111(3); Ga. Code Ann. § 31-9A-3; Idaho Code Ann. § 18-609; Ind. Code Ann. § 16-34-2-1.1; Iowa Code Ann. § 146A.1; Kan. Stat. Ann. § 311.725; Ky. Rev. Stat. Ann. § 311.725; La. Stat. Ann. § 1061.17(B); Me. Stat. tit. 22 § 1599-A(2); Mass. Gen. Laws ch. 112 §12R; Mich. Comp. Laws Ann. § 333.17015(1); Miss. Code Ann. § 41-41-33; Mo. Ann. Stat. § 188.039(2); Mont. Code Ann. § 50-20-106; Neb. Rev. Stat. Ann. § 28-327; Nev. Rev. Stat. Ann. § 442.253; N.C. Gen. Stat. Ann. § 90-21.82; N.D. Cent. Code Ann. § 14-02.1.-03; Ohio Rev. Code. Ann. § 2317.56(B); Okla. Stat. tit. 63 § 1-738.2; 18 Pa. Cons. Stat. § 3205; 23 R.I. Gen. Laws Ann. §4.7-1 et seq.; S.C. Code Ann. § 44-41-30; S.D. Codified Laws § 34-23A-10.1; Tenn. Code Ann. § 39-15-202; Tex. Health & Safety Code Ann. § 171.012; Utah Code Ann. § 76-7-305; Va. Code Ann. § 18.2-76; Wis. Stat. Ann. § 253.10(3).

[4] Ala. Code § 26-23A-4(a) (48 hours); Ariz. Rev. Stat. Ann. § 36-2153(A)(1) (24 hours); Fla. Stat. Ann. § 390.0111(3)(a)(1) (24 hours); Ga. Code Ann. § 31-9A-3(1) (24 hours); Idaho Code Ann. § 18-609(4) (24 hours); Ind. Code Ann. § 16-34-2-1.1(a)(1) (18 hours); Iowa Code Ann. § 146A.1(1) (24 hours); Kan. Stat. Ann. § 65-6716(c)(1) (24 hours); Ky. Rev. Stat. Ann. § 311.7735(1) (24 hours); La. Rev. Stat. Ann. §

The Attorney General is wrong that opioid regulation would survive a win for Plaintiff's here. Viewing the FDAAA as either a comprehensive balancing scheme or one that mandates access would preempt state opioid laws. JA 609. As for Plaintiff's rejection theory of preemption, the FDA has rejected opioid restrictions, too. The agency, for example, has come out against setting maximum daily doses or duration-of-use limitations for prescription opioids. The FDA was clear: when denying a citizen petition, the FDA refused "to specify or recommend a maximum daily dose or duration of use for any opioid."[5] Rejecting concerns over the long-term use of opioids, the FDA refused to adopt a 90-day prescription limit and instead stated its view that "the initial course of opioid treatment" could last from "several weeks to

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40:1061.17(B)(3)(a) (72 hours); Mich. Comp. Laws Ann. § 333.17015(3) (24 hours); Miss. Code Ann. § 41-41-33(1)(a) (24 hours); Mo. Ann. Stat. § 188.027(1) (72 hours); N.C. Gen. Stat. Ann. § 90-21.83A(b)(1) (72 hours); Neb. Rev. Stat. Ann. § 28-327(1) (24 hours); N.D. Cent. Code Ann. § 14-02.1-02 (24 hours); Ohio Rev. Code Ann. § 2317.56(B)(1) (24 hours); 18 Pa. Cons. Stat. § 3205(a)(1) (24 hours); S.C. Code. Ann. § 44-41-330(C) (24 hours); S.D. Codified Laws § 34-23A-56 (72 hours); Tenn. Code Ann. § 39-15-202(d)(1) (48 hours); Tex. Health & Safety Code Ann. § 171.012(a)(4) (24 hours); Utah Code Ann. § 76-7-305(2) (72 hours); W. Va. Code Ann. § 16-2I-2(a) (24 hours); Wis. Stat. Ann. § 253.10(3)(c)(1) (24 hours).

[5] Letter from Janet Woodcock, MD., Dir., Ctr. for Drug Evaluation and Rsch., U.S. Food and Drug Admin., to Andrew Kolodny, President, Physicians for Responsible Opioid Prescribing at 11 (Sept. 10, 2013), https://perma.cc/RK2J-HTAH.

several months."[6] The FDA also rejected claims that high-dose opioid therapy is associated with an increased overdose risk and "denie[d]" a "request that opioid labeling specify a maximum daily dose."[7] The FDA doubled down on this view in 2019, stating that "no particular dose of any opioid has been determined to be a cutoff point between safe-for-use or unsafe-for-use."[8]

Many States, including North Carolina, have chosen to be more protective of patients who are prescribed opioids. North Carolina law, for example, "sets a 5-day limit for an initial prescription for acute pain (7 days for pain following surgery) to reduce the number of people who become addicted to pain medications and reduce the number of unused pills sitting in medicine cabinets."[9] Such laws are nearly ubiquitous among states seeking to do what they can to remedy an opioid epidemic ravaging their communities. For example, six limit the dosage of opioids that a healthcare provider can prescribe,[10] eleven have limitations on

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[6] *Id.* at 15.

[7] *Id.* at 12.

[8] U.S. Food & Drug Admin., Mem. from Ning Hu, Med. Officer, Ctr. for Drug Evaluation and Rsch. (May 13, 2019), https://perma.cc/6HE3-ECAA.

[9] Att'y Gen. Josh Stein, *Opioid Crisis*, https://perma.cc/HM84-KYY4 (last visited Nov. 27, 2024).

[10] Ariz. Rev. Stat. Ann. § 32-3248.01(A) (90 morphine milligram equivalent daily limit); Ark. Code R. 002(4)(A) (including "the prescribing of excessive amounts" of opioids in the definition of

prescribing opioids to minors,[11] and twenty-nine limit the number of days' supply of opioids that can be prescribed for acute pain.[12] Finding them to be preempted could cause real harm to real people.

"malpractice" and defining "excessive" dosage as exceeding 50 morphine milligram equivalents per day); Me. Stat. tit. 32 § 3300-F(1)(A) (100 morphine milligram equivalent daily limit); Nev. Rev. Stat. Ann. § 639.2391(2)(a) (90 morphine milligram equivalent daily limit); 216 R.I. Gen. Laws Ann. § 20-20-4.4(C)(2) (30 morphine milligram equivalent daily limit); Tenn. Code. Ann. § 63-1-164(a)(9)(b) (180 morphine milligram equivalent total dosage limitation).

[11] Alaska Stat. Ann. § 08.64.363(a)(2) (seven-day prescription limitation); 24 Del. Admin Code § 9.5.2 (same); La. Stat. Ann. § 40:978(G)(1)(b) (same); Mass. Gen. Laws ch. 94C § 19D(a) (same); Neb. Rev. Stat. Ann. § 38-1,145(3) (same); Conn. Gen. Stat. § 20-14o(c) (five-day limitation); Minn. Stat. § 152.11(4)(a) (same); Ohio Admin. Code § 4731-11-13(A)(3)(a)(ii) (same); 216 R.I. Gen. Laws Ann. § 20-20-4.4(C)(5) (20 dose prescribing limit and documentation requirement for greater than 30 daily morphine milligram equivalents); S.C. Code Ann. § 44-53-363(E) (seventy-two hour limit with signed consent from guardian); W. Va. Code Ann. § 16-54-4(c) (three-day outpatient limit and requiring discussion of risks with guardian).

[12] Fla. Stat. Ann. § 456.44(5)(a) (three- or seven-day prescribing limit for acute pain); Ky. Rev. Stat. Ann. § 218A.205(3)(b) (three-day prescribing limit); Tenn. Code. Ann. § 63-1-164(a)(9)(b) (same); W. Va. Code Ann. § 16-54-4(a) (four-day outpatient prescribing limit); Ariz. Rev. Stat. Ann. § 32-3248(A) (five-day prescribing limit); N.J. Stat. Ann. § 24:21-15.2(a) (same); N.C. Gen. Stat. Ann. § 90-106(a3) (five- or seven-day prescribing limit); Alaska Stat. Ann. § 08.64.363(a)(1) (seven-day prescribing limit); Colo. Rev. Stat. § 12-30-109(1)(a) (same); Conn. Gen. Stat. § 20-14o(b) (same); 24 Del. Admin Code § 9.5.1 (same); Ind. Code Ann. § 25-1-9.7-2(a) (same); La. Stat. Ann. § 40:978(G)(1)(a) (same); Mass. Gen. Laws. Ch. 94C § 19D(a) (same); Mich. Comp. Laws Ann. § 333.733b(1) (same); Minn. Stat. § 152.11(4)(a) (same); Mo. Ann. Stat. § 195.080(2) (same); Mont. Code Ann. § 37-2-108(1) (same); Ohio Admin.

There are additional quirks to Plaintiff's view of FDAAA preemption. Under her adopted-then-rejected theory of obstacle preemption, if a subsequent administration views a protection differently and reinstates a safeguard, then States would once again be able protect their citizens. And as noted above, Plaintiff's view of the REMS as the agency's "precise balancing of risks and benefits," Bryant Br. 45–46, would mean that state tort law falls, too. This would leave injured consumers with no recourse for the highest-risk drugs and cannot be squared with Congress's purpose in the FDAAA.

E. North Carolina's protections for women taking mifepristone do not pose an obstacle to federal law.

Plaintiff does not (and cannot) point to any congressional objective to eliminate follow-up visits, minimize informed consent, or mandate who may prescribe certain drugs. Instead, Plaintiff's preemption theory boils down to her claim that the FDAAA somehow mandates access to REMS drugs. As explained above, "the most glaring problem with th[at]

Code § 4731-11-13(A)(3)(a)(i) (same); Okla. Stat. tit. 63 § 2-309I(A) (same); S.C. Code Ann. § 44-53-360(j)(1) (same); Utah Code Ann. § 58-37-6(F)(ii)(A) (same); Wyo. Stat. Ann. § 35-7-1030(e) (same); Wash. Rev. Code Ann. § 246-919-885(3) (requiring clinical documentation for prescriptions that exceed a seven-day supply); Tex. Health & Safety Code Ann. § 481.07636(b)(1) (ten-day prescribing limit); Nev. Rev. Stat. Ann. § 639.2391(2)(a) (fourteen-day initial prescribing limit); Haw. Rev. Stat. § 329-38(a)(2) (thirty-day prescribing limit); 720 Ill. Comp. Stat. 570/312(a) (same); Me. Stat. tit. 32 § 3300-F(1)(C)–(D) (seven-day acute pain prescribing limit; thirty-day chronic pain prescribing limit).

argument is that all evidence of Congress' purposes is to the contrary." *Wyeth*, 555 U.S. at 574. Each and every one of Plaintiff's challenges fail for the simple reason that North Carolina law does not pose an obstacle to the FDAAA.

The lower court erred by holding that four provisions of North Carolina law were preempted. 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." JA 635. In the court's view, four provisions—physician-only prescribing, 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—were "designed to reduce the risks associated with" mifepristone. JA 633. So it enjoined them.

In contrast, the lower 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 notation requirement, and state health department reporting. JA 637.

Plaintiff's suggestion that the district court found preemption only where a requirement was first adopted and then rejected by the FDA does not square with the court's opinion. And North Carolina's abortion laws would not be preempted even under such a theory. Many of them have never been adopted by FDA. And others have never been rejected. Recognizing this, Plaintiff resorts to saying the FDA has rejected "similar" requirements," Bryant Br. 40, that a requirement is "encompassed in" the agency's rejection of another protection, *id.* at 62, or that a state protection runs contrary to the "notion" of federal law, *id.*

The Attorney General, for his part, focuses on requirements that have been "effectively withdrawn" and would preempt any state law that (in his view) the FDA either "deemed unnecessary or unduly burdensome." AG Br. 41–42. But if the requirement is not included in a REMS, then, by definition, the FDA decided it was unnecessary. *See* 21 U.S.C. § 355-1(a)(1), (f)(1). This theory of preemption would encompass *every* additional state law that the FDA has declined to require for *every* REMS drug. To take the Attorney General's logic a step further, if FDA determines a REMS is not required, one could argue that decision preempts a state-law determination that any protection is necessary. *Wyeth* forecloses such an outcome.

1. *Physician-only prescribing.* The district court erred in finding physician-only prescribing preempted. Plaintiff concedes (at 38 note 3) that the FDA itself acknowledges that states may limit prescribing

authority for mifepristone under state law. In explaining the necessary qualifications for healthcare providers to prescribe mifepristone, the FDA acknowledges that states may come alongside and add safeguards to REMS drugs. The FDA notes that "[s]ome states allow health care providers other than physicians to prescribe medications." JA 470. As a result, before prescribing mifepristone, "[h]ealth care providers should check their individual state laws." JA 470. This explicit FDA directive to check state laws defeats Plaintiff's argument that the FDAAA preempts North Carolina's law regulating who may prescribe mifepristone.

Plaintiff asserts (at 38 note 3) that "a state may not single out a REMS drug and prohibit practitioners *who have prescribing privileges under state law* from prescribing" mifepristone. But in North Carolina, only physicians have prescribing privileges for mifepristone *under state law*, and the FDA relies on those state qualification requirements. Plaintiff responds (at 38 note 3) that the FDA "does not regulate general prescribing privileges under state law." In her view, North Carolina's law must give way because it "single[s] out" mifepristone. But she cites no case to support that targeted laws are more likely to be preempted. *See also Va. Uranium*, 587 U.S. at 778 (upholding state law targeting uranium mining against preemption challenge). On the contrary, "it is a black-letter principle of preemption law that generally applicable state laws may conflict with and frustrate the purposes of a

federal scheme just as much as a targeted state law." *Saleh v. Titan Corp.*, 580 F.3d 1, 12 n.8 (D.C. Cir. 2009). And indeed, a blanket state physicians-only prescribing law would "conflict with FDA's judgment about the qualifications necessary to prescribe" mifepristone just as much as North Carolina's law. Bryant Br. 38 n.3. Plaintiff's attempt to distance herself from that result is understandable–the FDA after all has rejected it–but unavailing.

2. *In-person dispensing.* Plaintiff complains (at 39) that North Carolina's requirement for the in-person dispensing of mifepristone "conflicts with FDA's expert judgment that mifepristone can be safely provided by pharmacies" and "undermines the agency's efforts to promote patient access and reduce burdens on the healthcare system." But Plaintiff has not shown an access mandate in the FDAAA. And because the FDAAA does not preclude healthcare providers from dispensing mifepristone in person, there is no conflict with federal law.

3. *In-person follow-up visit scheduling.* Plaintiff's insistence that the scheduling of a follow-up appointment is preempted demonstrates the sweep of her preemption theory. North Carolina law is minimally burdensome. It simply requires an abortion provider to *schedule* an in-person follow-up with her patients and to make reasonable efforts to ensure that women return for those appointments. N.C. Gen. Stat. Ann. § 90-21.83B(b). This is hardly unreasonable given that the FDA's label demonstrates that roughly 1 in 25 women go to the emergency room

after taking mifepristone and that up to 7% need surgical intervention either to control bleeding or complete the abortion. JA 596, JA 605.

Further, the FDA has never rejected the requirement that a provider *schedule* a follow-up appointment. The FDA merely explained that mifepristone does not "always require[] in-person follow-up." JA 242–244. North Carolina's requirement that a physician schedule a follow-up visit—which the patient may freely cancel and which the FDA acknowledges is *sometimes* required—does not frustrate federal law. To hold otherwise would place access over safety, in contravention of the FDAAA. Plaintiff insists (at 40) that the FDA has rejected a "similar" determination. But by looking to similar determinations, Plaintiff invites impermissible judicial forays into the unexpressed intent of Congress under the guise of obstacle preemption.

Plaintiff next says that North Carolina law conflicts with the REMS because it bars telemedicine follow-up appointments. That is false. North Carolina law does not prohibit a provider from using telemedicine. It merely requires a provider to *schedule* an in-person follow-up and to make reasonable efforts to ensure that women return for them. If a patient is unable to return in-person, a telemedicine visit complies with state law.

Even if the FDAAA mandated access (it does not), the scheduling provision does not interfere with patient access.[13] It applies *after* a patient has taken a drug. And any alleged burden on the healthcare system is minimal, especially in light of the serious adverse events—death, hemorrhaging, sepsis, retained products of conception, and infection—that the FDA warns may occur. JA 590, JA 600–01.

4. *Adverse event reporting to the FDA.* Plaintiff's claim that North Carolina's FDA-reporting requirement is preempted fails even her expansive preemption test. At the outset, the reporting requirement applies *after* a patient has taken a drug and so does not impede access to mifepristone. It also does not conflict with any congressional purpose in the FDAAA.

Nor is it true that the FDA doesn't want to hear about adverse events. As Plaintiff admits (at 43 note 5), mifepristone manufacturers must report all adverse events annually. 21 C.F.R. § 314.80(c)(1)–(2). The manufacturer learns of these adverse events from abortion providers. *See* Brief for Danco Laboratories, LLC at 44, *U.S. Food & Drug Admin. v. All. For Hippocratic Med.*, 602 U.S. 367 (2024) (Nos. 23-

[13] The Attorney General is wrong to say that North Carolina law requires scheduling the appointment before prescribing mifepristone. *See* N.C. Gen. Stat. § 90-21.83B(b).

235, 23-236). The requirement that providers report these events to the FDA as well creates no conflict.

Plaintiff next relies on *Buckman Co. v. Plaintiffs' Legal Committee*, 531 U.S. 341 (2001), but that case is inapposite. *Buckman* addressed a state-law fraud-on-the-FDA claim. *Id.* at 350. The Court held those claims were preempted because the FDA "has at its disposal a variety of enforcement options that allow it to make a measured response to suspected fraud upon the Administration." *Id.* at 349. Here, North Carolina has neither brought nor created a fraud-on-the-FDA claim, which would "exist solely by virtue of the FDCA disclosure requirements." *Id.* at 353. Instead, it requires reporting of certain adverse events to the FDA. The reporting requirement is "parallel" to "federal safety requirements" and is not preempted. *Id.*

5. *In-person examination.* The district court correctly concluded that North Carolina's in-person-examination requirement is not preempted. At the outset, an in-person examination indisputably promotes patient safety. It allows a physician to accurately assess gestational age and diagnose an ectopic pregnancy—both of which directly relate to safe use of the abortion drug. JA 576 (ACOG noting that an ultrasound is the most accurate way to diagnose an ectopic pregnancy); Mayo Clinic Staff, *Ectopic Pregnancy*, Mayo Clinic (Mar. 12, 2022), https://perma.cc/WBY3-D7TW (same). Mifepristone risks, for instance, increase with each passing gestational week. JA 601. So the

FDA has approved the drug only through 10 weeks. Ectopic pregnancies are *contraindicated* for the abortion drug. JA 594. The FDA thus directs providers to "exclude" an ectopic pregnancy before prescribing mifepristone because abortion-drug symptoms can mask the rupture of an ectopic pregnancy, a life-threatening emergency. JA 589.

Despite these safety benefits, Plaintiff asserts that North Carolina's in-person-examination requirement presents an obstacle to the FDAAA. The best Plaintiff can do, though, is to cite the FDA's finding that prescribing mifepristone "does not necessarily require direct physical contact with the certified prescriber." Bryant Br. 61 (quoting JA 240–241). There is no conflict. North Carolina's determination that an in-person examination facilitates patient safety because it is the most accurate way to assess gestational age and diagnose ectopic pregnancy does not conflict with any federal purpose.

Nor has an in-person examination ever been required by the FDA—something Plaintiff (at times) says is necessary for preemption to attach. Acknowledging this hiccup, the Attorney General argues (at 42) that this Court should find preemption because the FDA has "effectively withdrawn" the requirement. Such an open-ended inquiry would impermissibly expand obstacle preemption.

6. *Ultrasound.* The district court correctly concluded that North Carolina's ultrasound requirement is not preempted. For one, the FDA has never required an ultrasound. The Attorney General (at 43)

attempts to skirt this fact by reasoning that the FDA has nevertheless "withdrawn" the requirement because "one cannot receive an ultrasound without appearing in person to see a healthcare provider." Under this logic, any medical practice that would be easier to perform in person would be considered "withdrawn." This sort of roving inquiry is wholly unmoored from congressional intent.

7. *Blood type notation.* The district court correctly concluded that North Carolina's requirement that a patient's blood type be noted in her chart is not preempted. Such a notation ensures Rh-negative women can be treated with Rhogam to help prevent complications in later pregnancies. If a woman does not receive treatment, this can lead to life-threatening anemia in her future children.[14] Plaintiff concedes (at 62) that the "FDA has not explicitly addressed blood testing." That concession dooms Plaintiff's challenge to the blood-type-notation requirement as well as her claim that her preemption theory is limited.

Echoing the Attorney General, Plaintiff claims that the FDA's "rejection" of the blood-type requirement "is encompassed in its determination that mifepristone can be prescribed safely without an in-person examination." Bryant Br. 62. But some women know their blood type and an in-person visit is not always required. More crucially, to find that state law is preempted under obstacle preemption any time it

[14] Mayo Clinic Staff, *Rh factor blood test*, Mayo Clinic (July 29, 2022), https://perma.cc/GX47-FDGS.

is "encompassed in" an agency determination would radically upset the federal-state balance in an area of traditional state concern.

8. *Informed consent.* The district court was correct to uphold North Carolina's informed-consent requirement. Plaintiff says (at 62) that the FDA has rejected "the notion" that informed consent should be in person. This tortured logic would require reviewing courts to determine whether state law poses an obstacle to "the notion" of federal law. Once again, such an approach would sanction the sort of free-wheeling judicial inquiry this Court has rejected time and again.

Plaintiff then says that the informed-consent requirement (and presumably all other in-person requirements) are "squarely preempted under *Geier*" because the "FDA 'deliberately provided … a range of choices' about how mifepristone can be prescribed (in person or via telemedicine)." Bryant Br. at 64 (quoting 529 U.S. at 875). But that view of *Geier* is untenable post-*Williamson*. Preemption does *not* obtain merely because a federal regulation "leaves the manufacturer with a choice" which state law "restrict[s]." 562 U.S. at 332. Rather as Justice Sotomayor emphasized, "a conflict results only when [federal law] does not just set out options for compliance, but also provides that the regulated parties *must remain free* to choose among those options." *Id.* at 338 (Sotomayor, J., concurring).

9. *Waiting period.* The district court was correct to uphold North Carolina's modest waiting period. Plaintiff says that the 72-hour

waiting period conflicts with mifepristone's 70-day gestational age limit and might restrict "patient access." Bryant Br. at 65. This argument highlights the novelty of Plaintiff's preemption theory. Waiting periods and informed-consent requirements have long been ubiquitous in state law—even in States that broadly allow abortion. The Supreme Court—and federal courts around the country—have repeatedly upheld waiting periods and informed-consent provisions against constitutional and other challenges. *A Woman's Choice-East Side Women's Clinic v. Newman*, 305 F.3d 684, 685–86, 693 (7th Cir. 2002) (Easterbrook, J.); *e.g., Planned Parenthood of Se. Pa. v. Casey*, 505 U.S. 833, 881–87 (1992); *Tex. Med. Providers Performing Abortion Servs. v. Lakey*, 667 F.3d 570, 580 (5th Cir. 2012); *EMW Women's Surgical Ctr., P.S.C. v. Beshear*, 920 F.3d 421, 424 (6th Cir. 2019). It beggars belief to think that these provisions were unlawful under the FDAAA all along.

Plus, under Plaintiff's preemption theory, *any* state regulation that leads to *any* delay would conflict with the mifepristone REMS. *See* Bryant Br. 65 (citing JA 232). The purpose of the FDAAA is not to get high-risk drugs to women as quickly as possible.

10. *Reporting to the Department of Health and Human Services.* The district court correctly upheld the state-reporting requirement. Consistent with its longstanding authority to regulate the practice of medicine, North Carolina requires that abortion providers report adverse events to the North Carolina Department of Health and Human

Services. For starters, the FDA has never rejected the requirement that providers report adverse events to state health departments. That's because a federal rule preventing a state from regulating medical providers would violate Section 396 of the FDCA and intrude into the traditional authority of the state to regulate medical providers. *See Buckman*, 531 U.S. at 350–51.

Further, North Carolina's reporting requirement applies to all abortions. N.C. Gen. Stat. Ann. § 90-21.93. It would be passing strange for federal law to preempt state law requiring reporting to a state agency of adverse events from chemical—but not surgical—abortions.

II. Plaintiff lacks a cause of action.

This Court should exercise its discretion to address Legislative Leaders' argument that Plaintiff lacks a cause of action.

The Supremacy Clause "does not create a cause of action." *Armstrong v. Exceptional Child Ctr., Inc.*, 575 U.S. 320, 325 (2015). Instead, it creates a "rule of decision" that "instructs courts what to do when state and federal law clash." *Id.* at 324–25. Plaintiff argues that she nevertheless "has an equitable cause of action under *Ex parte Young*, 209 U.S. 123 (1908), that allows her to 'petition a federal court to enjoin State officials ... from engaging in future conduct that would violate the Constitution.'" Bryant Br. 73–74 (quoting *Antrican v. Odom*, 290 F.3d 178, 184 (4th Cir. 2002)). While Plaintiff is correct that "in a

proper case, relief may be given in a court of equity," the "power of federal courts of equity to enjoin unlawful executive action is subject to express and implied statutory limitations." *Armstrong*, 575 U.S. at 327 (cleaned up).

Whether Plaintiff "has asserted a cause of action ... depends ... on whether the class of litigants of which [Dr. Bryant] is a member may use the courts to enforce the right at issue." *Davis v. Passman*, 442 U.S. 228, 239 n.18 (1979). Plaintiff is a physician who wishes to provide abortion drugs without following North Carolina's patient protections. But the FDCA confers neither a federal right nor a cause of action upon physicians. Only the United States government may enforce the FDCA. 21 U.S.C. § 337(a).

Plaintiff responds (at 74) that she did not sue "to enforce or restrain a violation of the FDCA" but instead "to prevent state officials from enforcing state laws that violate the Supremacy Clause." But again "the Supremacy Clause is not the source of any federal rights." *Armstrong*, 575 U.S. at 324 (cleaned up). And a federal cause of action cannot exist absent a federal right. *See Safe Streets All. v. Hickenlooper*, 859 F.3d 865, 902 (10th Cir. 2017) ("'[T]o invoke the' Article III courts' equitable powers, a plaintiff asserting a cause of action to enforce a federal statute must have 'a federal right that [he or she] possesses against' the defendant.") (quoting *Va. Off. for Prot. & Advocacy v. Stewart*, 563 U.S. 247, 260 (2011)).

Plaintiff argues (at 75–76) that "Congress has not provided any alternative remedy to prevent the enforcement of state laws preempted by the FDCA." That's wrong. Plaintiff could raise preemption as a federal defense to a state enforcement action. *See Lontz v. Tharp*, 413 F.3d 435, 440 (4th Cir. 2005) ("Ordinary preemption has been categorized as a federal defense to the allegations.") (cleaned up). Indeed, that is precisely what happened in *Wyeth v. Levine*. 555 U.S. at 560 (raising federal preemption defense to state failure-to-warn claims). And while preemption claims are no doubt judicially administrable, "North Carolina's courts" are just as "capable of applying federal preemption law" as federal courts. *Burrell v. Bayer Corp.*, 918 F.3d 372, 388 (4th Cir. 2019).

Finally, Plaintiff argues (at 72) that the Legislative Intervenors "forfeited this argument by failing to raise it in the district court." But unlike a waived issue, "a court has discretion to reach a forfeited issue." *Stokes v. Stirling*, 64 F.4th 131, 136 n.3 (4th Cir. 2023). For instance, in *United States v. Simms*, this Court "opt[ed] to proceed to the merits" of a forfeited issue "in view of the exceptional importance and recurring nature of the question presented." 914 F.3d 229, 239 (4th Cir. 2019). And in *Stewart v. Hall*, this Court held that "the omission of the ordinary scheme of proof for an essential element of the cause of action is fundamental error undermining the integrity of the trial." 770 F.2d 1267, 1271 (4th Cir. 1985).

Here, Plaintiff lacks not only a federal cause of action but also any federal right upon which her alleged equitable cause of action is premised. No error could be more fundamental. Allowing Plaintiff to enforce a non-existent federal right to be free from state regulations would undermine the integrity of these proceedings. And the question of whether an equitable cause of action exists to allege the preemption of state laws by the FDCA is certainly one of exceptional importance.

Hicks v. Ferreyra is inapposite. There, the defendants did not argue that the lack of a cause of action was a fundamental error, but that it was jurisdictional. 965 F.3d 302, 310–11 (4th Cir. 2020). But an error may be fundamental without being jurisdictional. This Court should exercise its discretion to consider whether Plaintiff has alleged a proper cause of action.

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

As Plaintiff acknowledges (at 76) "injunctive relief should be no more burdensome to the defendant than necessary to provide complete relief to the plaintiffs." *PBM Prods., LLC v. Mead Johnson & Co.*, 639 F.3d 111, 128 (4th Cir. 2011) (cleaned up). In other words, an injunction "should not go beyond the extent of the established violation." *Hayes v. N. State L. Enf't Officers Ass'n*, 10 F.3d 207, 217 (4th Cir. 1993). This "narrow tailoring" requirement is "particularly important where ...

plaintiffs seek injunctive relief against a state or local government." *Bone v. Univ. of N.C. Health Care Sys.*, 678 F. Supp. 3d 660, 704 (M.D.N.C. 2023) (cleaned up); *see also Gunn v. Univ. Committee to End War in Viet Nam*, 399 U.S. 383, 389 (1970) (explaining that Fed. R. Civ. P. 65(d) "is absolutely vital in a case where a federal court is asked to nullify a law duly enacted by a sovereign state").

Consequently, a court may not enjoin laws or policies not challenged by the plaintiffs. For instance, in *Hayes*, the district court issued an order "enjoining all use of racially based criteria by the City of Charlotte in its employment decisions," even though the "only policy challenged ... was the police department's promotion policy with regard to sergeants." 10 F.3d at 217. This Court reversed, explaining that the injunction "clearly went further than was required to award full relief to the Plaintiffs in this case." *Id*. Similarly, in *Schmidt v. Lessard*, the Supreme Court held that an injunction against enforcement of "the present Wisconsin scheme" was not sufficiently definite to pass muster under Rule 65(d). 414 U.S. 473, 476 (1974) (per curiam).

Plaintiff relies (at 77) on two out-of-circuit cases issuing broad injunctions in the same-sex-marriage context to argue that such an injunction is appropriate here. But these out-of-circuit cases conflict with the Fourth Circuit's same-sex-marriage case, which affirmed a much narrower injunction of Virginia's marriage laws. *Bostic v. Schaefer*, 760 F.3d 352, 369 (4th Cir. 2014) (affirming *Bostic v. Rainey*,

970 F. Supp.2d 456, 484 (E.D. Va. 2014) (enjoining Virginia only "from enforcing Sections 20-45.2 and 20-45.3 of the Virginia Code and Article I, § 15-A of the Virginia Constitution, despite finding that "any other Virginia law that bars same-sex marriage" was also "unconstitutional")). And while the Western District of North Carolina issued a broad injunction against North Carolina's marriage laws in *General Synod of United Church of Christ v. Resinger*, 12 F. Supp. 3d 790, 792 (W.D.N.C. 2014), that injunction was not challenged on appeal.

Here, the district court had no grounds to enjoin North Carolina from enforcing "other provisions of North Carolina law" not challenged in the complaint. Plaintiff insists (at 76) that she "challenged certain categories of restrictions." But her complaint specifies the statutory requirements she challenged. JA 63–69. And the district court's preemption analysis was limited to those sections. JA 641–651.

Plaintiff argues (at 78) that "[a] prosecutor might claim that some other provision embodies the same preempted requirement." She identifies no such provision. Nor could the legislature "evade the injunction by recodifying the same preempted restrictions in different code sections." *Id.* at 78. Such a statute's constitutionality would be governed by prior precedent. This Court should limit the district court's injunction to the specific statutory sections identified in Plaintiff's complaint and analyzed in the district court's opinion.

CONCLUSION

For the foregoing reasons, this Court should reverse the judgment of the district court in part and hold that none of the challenged laws governing abortion drugs are preempted by federal law.

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Respectfully submitted,

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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 9,802 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.

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CERTIFICATE OF SERVICE

I hereby certify that on November 27, 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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