No. 23-2194

In the United States Court of Appeals
for the Fourth Circuit

GENBIOPRO, INC.,

Plaintiff-Appellant,

v.

KRISTINA D. RAYNES, in her official capacity as Prosecuting Attorney of Putnam County, and PATRICK MORRISEY, in his official capacity as Attorney General of West Virginia,

Defendants-Appellees.

On Appeal from the United States District Court
for the Southern District of West Virginia

BRIEF OF AMICUS CURIAE THE STATE OF NORTH CAROLINA IN SUPPORT OF PLAINTIFF-APPELLANT

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The State of North Carolina respectfully submits this amicus brief in support of Plaintiff-Appellant.[1]

INTRODUCTION

Like West Virginia, North Carolina has enacted a number of restrictions on patient access to mifepristone, a safe and effective drug that the FDA has long approved for use in the termination of early pregnancy. And like West Virginia's laws, some of North Carolina's laws have been recently challenged on preemption grounds. In the North Carolina case, the parties have fully briefed and argued cross-motions for summary judgment and are awaiting a decision from the district court. *Bryant v. Stein*, No. 23-cv-77 (M.D.N.C.) (Eagles, C.J.).

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 imposes numerous other requirements on receiving the medication, including some requirements that reestablish restrictions that are identical to ones that the FDA has imposed and rescinded.

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[1] No counsel for any party authored this brief in whole or in part, and no entity or person made any monetary contribution toward its preparation or submission. *See* Fed. R. App. P. 29(a)(4)(E).

Our dual-sovereign system often benefits from unique state approaches to important policy questions. *See New State Ice Co. v. Liebmann*, 285 U.S. 262, 311 (1932) (Brandeis, J., dissenting). 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. *Wyeth v. Levine*, 555 U.S. 555, 579 (2009). For example, States may seek to curb opioid abuse by imposing additional restrictions on opioid prescription practices that exceed federal controls.[2] Indeed, North Carolina is one of many States that has imposed additional, complementary restrictions of this kind. *See, e.g.*, N.C. Sess. Law 2017-74 (Strengthen Opioid Misuse Prevention Act of 2017).

But here, the text of the federal law at issue, 21 U.S.C. § 355-1, together with well-established obstacle-preemption principles, shows that States do not have free rein to restrict patient access to mifepristone. For example, state laws cannot impede access to mifepristone by imposing the same restrictions that the FDA—acting

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[2] U.S. Dep't of Health & Human Servs., *Addressing Prescription Drug Abuse in the United States: Current Activities and Future Opportunities*, at 28 (2013), bit.ly/3DRTtRZ.

under express statutory authority to balance drug safety with ensuring patient access and minimizing burdens on the healthcare system—has imposed and then rescinded.

The State of North Carolina submits this brief to explain why, under the Supreme Court's obstacle-preemption cases, States cannot use state law to undermine the FDA's expert judgment regarding the extent to which drugs like mifepristone should be restricted. In addition, North Carolina seeks to underscore the fact that the Court's application of obstacle-preemption principles in this appeal may have immediate wider-ranging effects—including in the ongoing preemption challenge to North Carolina's state laws. Thus, if this Court reaches GenBioPro's obstacle- or impossibility-preemption arguments, the State urges the Court to make clear that—at minimum—States may not impose restrictions on access to mifepristone that the FDA has previously imposed and rescinded.

STATEMENT OF INTEREST

Amicus is the State of North Carolina, through its Attorney General, the State's chief legal officer. *See Tice v. Dep't of Transp.*, 312 S.E.2d 241, 244 (N.C. Ct. App. 1984); N.C. Gen. Stat. § 114-1.1. Home

to more than 2 million women and girls aged 15-44,[3] the State has a strong interest in protecting women's access to safe medical care, including by preserving the proper balance between state and federal authority over FDA-approved drugs like mifepristone.

In addition, several state actors are defendants in an ongoing lawsuit initiated by a North Carolina physician challenging various provisions of state law that restrict access to mifepristone. *Bryant v. Stein*, No. 23-cv-77 (M.D.N.C.) (Eagles, C.J.). The physician has sued the Attorney General, certain District Attorneys, the Secretary of the North Carolina Department of Health and Human Services, and the members of the North Carolina Medical Board. *Bryant*, Doc. 73-2 at 1-2. The Speaker of the North Carolina House of Representatives and the North Carolina Senate President Pro Tempore subsequently intervened as defendants. *Bryant*, Doc. 50. The District Attorneys, the Secretary, and the members of the Medical Board have not taken a position on the physician's claims. The Legislative Defendants have defended each challenged provision. *Id.*, Doc. 83-84, 88, 100.

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[3] *Data for North Carolina*, March of Dimes PeriStats (last updated Jan. 2022), bit.ly/3ULWr3H.

The parties in that case have cross-moved for summary judgment and are awaiting the district court's ruling. As discussed below, the Attorney General has argued that federal law preempts various North Carolina laws to the extent that the state laws enforce regulations that the FDA has imposed and rescinded. *See infra* Part II.

Although this appeal involves a different State's laws—and therefore somewhat different preemption arguments—the State of North Carolina respectfully submits this brief to aid the Court in considering all of the potential ramifications of this particular case.

ARGUMENT

I. When State Laws Require Restrictions That the FDA Has, Under Its REMS Authority, Imposed and Rescinded, Those State Laws Must Yield.

Under well-established obstacle-preemption principles, States cannot require the same restrictions on mifepristone access that the FDA has, acting under its statutory authority to balance drug safety with patient access, imposed and rescinded.

This rule derives from the Supremacy Clause, U.S. const. art. VI, which prohibits state laws from "stand[ing] 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 decide whether a state law interferes with Congress's purposes and objectives, courts do not require "an express statement by Congress," for that would demand "an approach to pre-emption that renders" obstacle preemption "meaningless." *PLIVA, Inc. v. Mensing*, 564 U.S. 604, 621 (2011). Rather, courts ask two questions. First, courts seek to "ascertain the nature of the federal interest." *Hillman v. Maretta*, 569 U.S. 483, 491 (2013). And second, courts ask whether the state law "interferes with" or "frustrates" that federal interest. *Id.* at 494 (quoting *Wissner v. Wissner*, 338 U.S. 655, 659 (1950)).

A party asserting an obstacle-preemption claim carries a heavy burden in showing an impermissible conflict between state and federal law. Obstacle preemption "does not justify 'a freewheeling judicial inquiry into whether a state statute is in tension with federal objectives.'" *Chamber of Commerce v. Whiting*, 563 U.S. 582, 607 (2011) (plurality opinion) (quoting *Gade v. Nat'l Solid Wastes Mgmt. Ass'n*, 505 U.S. 88, 111 (1992) (Kennedy, J., concurring in part and concurring in the judgment)). To avoid this kind of "freewheeling judicial inquiry" in cases that, like this one, involve federal agency action, courts often look

to what actions the federal agency has taken with its congressionally delegated authority and whether those actions conflict with state law to help "determine the answer to the pre-emption question." *Merck Sharp & Dohme Corp. v. Albrecht*, 139 S. Ct. 1668, 1679 (2019).

A. The Supreme Court's decisions in *Geier* and *Wyeth* show how to apply obstacle preemption here.

Two Supreme Court cases—*Geier v. American Honda Motor Co.*, 529 U.S. 861 (2000), and *Wyeth v. Levine*, 555 U.S. 555 (2009)—show how to apply these obstacle-preemption principles in practice.

The Court's decision in *Geier* illustrates the type of narrow circumstances where state law may impermissibly frustrate federal objectives. In *Geier*, the Court held that federal law preempted a state tort lawsuit alleging that car manufacturers had been negligent for failing to install a driver-side airbag in all of their vehicles. 529 U.S. at 865.

The Court first sought to ascertain the nature of the federal interest. The Court explained that the Department of Transportation, acting under the agency's statutory authority, had issued a rule "allowing manufacturers to choose among different passive restraint mechanisms, such as airbags, automatic belts, or other passive

restraint technologies." *Id.* at 878. The agency had considered adopting a rule requiring car manufacturers to install airbags in all of their vehicles. But the agency expressly declined to do so. The agency explained that it "rejected" such an "'all airbag' standard because of safety concerns (perceived or real) associated with airbags." *Id.* at 879 (quoting 49 Fed. Reg. 28,990, 29,001 (1984)). The Court gleaned from this regulatory history that there was a federal interest in maintaining a "variety and mix of [passive-restraint] devices." *Id.* at 881.

The Court then asked whether state law frustrated this federal interest in maintaining a mix of safety devices. The Court held that imposing an all-airbag requirement under state law "would have presented an obstacle" to the federal interest by *requiring* an all-airbag rule—a rule that the Department of Transportation had specifically declined to impose. *Id.* As a result, the state tort suit was preempted. *Id.* at 886.

By contrast, the Court in *Wyeth* held that federal law did not preempt a state tort lawsuit. The state tort lawsuit in *Wyeth* alleged that a drug manufacturer had been negligent because its drug label failed to adequately warn of certain health risks. 555 U.S. at 558. The

manufacturer argued that the lawsuit was preempted because the suit would have required safety warnings beyond those required in the drug's FDA-approved label. *Id.* at 573. Those additional requirements, the manufacturer reasoned, would stand as an obstacle to the FDA's considered judgment as to the type of warnings that the label should include. *Id.*

The Court disagreed. First, it held that the FDA's statutory authority to approve a manufacturer's label did not mean that the agency had "primary responsibility for . . . drug labeling at all times." *Id.* at 579. Rather, when the Court examined the federal drug-labeling statutes, it found that drug "manufacturers, not the FDA," retained primary responsibility for drug labeling. *Id.* Because the FDA had only "limited resources to monitor the 11,000 drugs on the market," the onus was on manufacturers to revise their labels whenever they became aware of new evidence regarding their drugs' safety risks. *Id.* at 578-79. The Court thus held that Congress had not identified a federal interest in the FDA's controlling the type of warnings that drug labels should include. *See id.* at 579.

Second, even if the FDA had this exclusive authority, the Court saw no "contemporaneous record" to "reveal[ ] the factors the agency had weighed and the balance it had struck" when approving this particular drug's label. *Id.* at 580; *see also id.* at 575 (rejecting the argument that the FDA had "performed a precise balancing of risks and benefits"). As a result, any state failure-to-warn requirements could only complement, rather than conflict, with a federal interest in ensuring proper labeling. *Id.* at 578.

In reaching this conclusion, the Court expressly distinguished its earlier decision in *Geier*. Unlike the Department of Transportation in *Geier*, which had considered and rejected the all-airbag standard that state law sought to impose, the FDA in *Wyeth* had never "consider[ed] and reject[ed] a stronger warning" on the drug's label. *Id.* at 581 n.14. Indeed, the record showed that the FDA "had paid no more than passing attention to the question." *Id.* at 563. This absence of regulation made the record in *Wyeth* "quite different" from the agency action that the Court considered in *Geier*. *Id.* at 580.[4]

[4] Other obstacle-preemption cases have similarly looked to the authority given to federal agencies in this way. *See Buckman Co. v.*

B. Under *Geier* and *Wyeth*, States cannot require mifepristone restrictions that the FDA has imposed and rescinded.

Applying *Geier* and *Wyeth* here, States cannot seek to restrict access to mifepristone in ways that the FDA has expressly rejected.

As discussed, preemption analysis begins by identifying the nature of the federal interest. Here, the relevant statute shows a strong federal interest in giving the FDA the primary responsibility to balance the safety of certain drugs, including mifepristone, against the need to ensure patient access to those drugs. In 2007, Congress amended the Federal Food, Drug, and Cosmetic Act to give the FDA authority to impose a "risk evaluation and mitigation strategy," or REMS, for certain drugs. 21 U.S.C. § 355-1. As part of this authority, the FDA may impose additional restrictions, known as safe-use elements, to provide "safe access for patients to drugs with known serious risks that would otherwise be unavailable." *Id.* § 355-1(f). Considering the

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Plaintiffs' Legal Comm., 531 U.S. 341, 348 (2001) (when a "federal statutory scheme amply empowers the FDA . . . to achieve a somewhat delicate balance of statutory objectives," state laws that could "skew[ ]" that balance are impliedly preempted); *Int'l Paper Co. v. Ouellette*, 479 U.S. 481, 494 (1987) (when a federal agency strikes "the balance of public and private interests so carefully addressed by" a federal statutory regime, state law may not "upset[ ]" that balance).

relevant safety risks, the agency may establish various conditions on the drug's administration—for example, that healthcare providers who prescribe a drug have particular training or experience. *Id.* § 355-1(f)(3)(A). *See generally id.* § 355-1(f)(3)(A)-(F).

In setting out these requirements, Congress specifically prohibited the agency from implementing regulations that are "unduly burdensome on patient access" and directed the agency to minimize "the burden on the health care delivery system." *Id.* § 355-1(f)(2)(C), (D). The agency must also periodically assess whether the requirements it has imposed are "unduly burdensome on patient access" and "the health care delivery system" in light of all available evidence. *Id.* § 355-1(f)(5)(A).

And considering this evidence, the agency has an obligation to "modify" a drug's safe-use elements "as appropriate." *Id.* § 355-1(f)(5)(C)(ii). Since the FDA first approved mifepristone in 2000, the agency has regularly exercised its statutory responsibility to modify the drug's safe-use elements in a way that eases burdens on patient access. To take just one example, although the FDA once required that prescribers dispense mifepristone to patients in person at a clinic or

hospital, the FDA has subsequently removed this requirement.[5] Under its statutory authority to balance drug safety, patient access, and burdens on the healthcare system, the agency has removed or eased numerous other mifepristone restrictions as well. *See infra* Part II.

By imbuing the FDA with the specific authority to balance safe use of REMS drugs *and* patient access, Congress established a strong federal interest in allowing the FDA to calibrate the conditions for the availability, prescription, dispensation, and administration of these drugs. This federal interest closely resembles the federal interest at issue in *Geier*, where Congress delegated authority to the Department of Transportation to promulgate rules for passive-restraint devices in cars. *See* 529 U.S. at 881. And it stands in sharp contrast to the FDA's labeling authority in *Wyeth*, where private manufacturers, rather than the agency itself, had the "primary responsibility" over safety warnings. 555 U.S. at 579.

Having identified the nature of the federal interest, the next question is whether state law impermissibly frustrates or impedes this

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[5] *See* U.S. Food & Drug Admin., *Questions and Answers on Mifepristone for Medical Termination of Pregnancy Through Ten Weeks Gestation* (Sept. 1, 2023), bit.ly/48gj7fg.

interest. Here, state laws seeking to impose mifepristone regulations that the FDA has deliberately rescinded stand as an obstacle to achieving the federal interest set forth in the REMS statute.

When States pass laws that the FDA has imposed and rescinded, those state laws necessarily frustrate the strong federal interest, reflected in the text of 21 U.S.C. § 355-1, in empowering the FDA to balance drug safety with patient access. *See Geier*, 529 U.S. at 879 (state law frustrated federal law when it imposed a standard that the federal agency had "rejected"); *Wyeth*, 555 U.S. at 581 n.14 (state law did not frustrate federal law because the record showed no evidence that the agency had "consider[ed] and reject[ed]" the rule that state law sought to impose).

To be sure, neither *Geier* nor *Wyeth* negates a State's vital role in protecting public health and safety, as these are "primarily, and historically, a matter of local concern." *Hillsborough Cnty. v. Automated Med. Labs, Inc.*, 471 U.S. 707, 719 (1985). Obstacle preemption applies only to a small subset of cases in which state laws frustrate an important federal interest, often a carefully calibrated regulatory scheme. Indeed, in most cases, state laws are likely to be

compatible with, not contradictory to, such a federal scheme. *See, e.g.*, *Wyeth*, 555 U.S. at 578. As a result, state laws can generally "offer[ ] an additional, and important, layer of consumer protection that complements" federal regulation. *Id.* at 579. Where state laws and regulations enact additional complementary safeguards, there is no reason why those laws would be preempted.

Take, for example, opioids-regulating state laws. The FDA itself has noted that although it has "determined that a REMS is necessary for all opioid analgesics intended for outpatient use," the REMS are "one strategy among multiple national and state efforts to reduce the risk of abuse, misuse, addiction, overdose, and deaths due to prescription opioid analgesics."[6] Indeed, the FDA explicitly envisions that States will enact complementary laws that reinforce, rather than frustrate, the REMS. *See supra* n.6.

North Carolina, moreover, has done just that. In 2017, the State enacted the Strengthen Opioid Misuse Prevention (STOP) Act, which aims to reduce the supply of unused, misused, and diverted opioids

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[6] U.S. Food & Drug Admin., *Opioid Analgesic Risk Evaluation and Mitigation Strategy (REMS)*, bit.ly/3SAS4p7 (content current as of Nov. 14, 2023; last accessed Feb. 8, 2024).

circulating in the State. N.C. Sess. Law 2017-74. One provision requires that, with some limited exceptions, prescribers must electronically prescribe all targeted controlled substances. N.C. Gen. Stat. § 90-106(a1). Because the FDA's opioids REMS do not contain limitations on the format of opioid prescriptions, the North Carolina statute provides what the FDA explicitly invites: complementary regulation. State laws like these are therefore not preempted.

Accordingly, though States continue to have general authority over ensuring the health and safety of their populations, States cannot require restrictions that the FDA, through REMS, has imposed and rescinded.

II. North Carolina's Restrictions on Mifepristone Are Preempted Under This Framework.

Despite these well-established preemption principles, some States have nonetheless sought to reimpose restrictions on mifepristone that the FDA has deliberately rescinded. These state laws have—not surprisingly—been the subject of recent preemption challenges. And the Attorney General of North Carolina has taken the position that, under the Supremacy Clause, these kinds of state laws cannot stand.

North Carolina's laws provide a helpful illustration. In *Bryant v. Stein*, a provider challenged seven requirements related to the prescription, administration, and dispensation of the drug. *Bryant v. Stein*, No. 23-cv-77, Doc. 99 at 10-15 (M.D.N.C.). Each of those restrictions, the provider argued at summary judgment, are preempted because they impose a set of controls on mifepristone that the FDA has considered and rejected. *Id.* at 10.

Applying longstanding preemption principles, *see supra* Part I, the Attorney General argued that each of the challenged provisions was preempted by the mifepristone REMS. Indeed, the FDA—under its express statutory obligation to reevaluate REMS restrictions on an ongoing basis—had affirmatively implemented and then deliberately rescinded some of the very same challenged state requirements. 21 U.S.C. § 355-1(f)(5), (g)(4). Therefore, the Attorney General argued, by reimposing the same requirements that the FDA had expressly rejected, the North Carolina legislature had frustrated the carefully calibrated REMS designed by the FDA, in violation of the Supremacy Clause.

For example, North Carolina law requires that a qualified physician examine a patient and dispense mifepristone *in person*. N.C.

Gen. Stat. § 90-21.83A(b)(2)a. Similarly, state law requires that the patient then take the medication in the presence of a physician. *Id.* § 90-21.83B(a). When the FDA first approved mifepristone, it required a physician to examine the patient and dispense the medication in person. *Bryant*, Doc. 82-8 (2011 REMS).[7] In addition, the patient was required to take the medication in the presence of a physician. *Id.* Now, however, the FDA has expressly removed the requirement that a patient be examined in person prior to taking mifepristone, and mifepristone can be dispensed by certified pharmacies. *Id.*, Doc. 82-14 (2016 REMS), 82-20 (2023 REMS Modification Review). In addition, the FDA has also rescinded the restriction that a physician must be present when the patient takes the drug. *Id.* Therefore, North

[7] Congress first enacted the REMS statute in 2007, which postdates mifepristone's FDA approval in 2000. Food and Drug Administration Amendments Act of 2007, Pub. L. No. 110-85, § 901, 121 Stat. 823, 926 (enacting 21 U.S.C. § 355-1). Mifepristone was first approved under a separate statutory provision that operated as the precursor to the 2007 REMS statute. When the REMS statute was first enacted, Congress expressly deemed those drugs that had approved risk mitigation plans under the statute's precursor as having REMS. *See* FDAAA § 909(b), 121 Stat. at 950-51. So when the FDA approved the first REMS for mifepristone in 2011, it essentially adopted all the same risk mitigation plans as it had when it first approved the drug in 2000. *Bryant*, Doc. 82-16 (2021 Citizen Petition Denial Letter).

Carolina law seeks to reimpose in-person requirements that the FDA, acting under its statutory authority, has expressly rescinded.

North Carolina law also requires that a qualified physician consult with a patient in-person at least 72 hours before dispensing mifepristone. N.C. Gen. Stat. § 90-21.83A(b)(1), (5); *id.* § 90-21.90(a). When the FDA first approved mifepristone, it required a physician to inform the patient of the risks and benefits of mifepristone in person. *Bryant*, Doc. 82-8 (2011 REMS). Now, however, the FDA has determined that a healthcare professional can "fully explain the risks of the mifepristone treatment regimen, and answer any questions, as in any consent process, without physical proximity." *Id.*, Doc. 82-16 (2021 Citizen Petition Denial Letter). Therefore, North Carolina law seeks to reimpose in-person counseling requirements that the FDA, in its expert judgment, has expressly rescinded.

North Carolina law also requires that only a "qualified physician" may prescribe, dispense, and administer mifepristone. *See, e.g.*, N.C. Gen. Stat. §§ 90-21.83A(b)(1), 90-21.83A(b)(2)a, 90-21.93(b)(1). When the FDA first approved mifepristone, it required a physician to prescribe, dispense, and administer the medication. *Bryant*, Doc. 82-8

(2011 REMS). Now, however, the FDA has expressly allowed a range of "health care providers," including nurse practitioners, certified midwives, and physician assistants, to prescribe the medication. *Id.*, Doc. 82-16 (2021 Citizen Petition Denial Letter). Moreover, as noted above, now, mifepristone may be dispensed by pharmacies and may be administered anywhere—including in the privacy of the patient's home. *See supra* pp. 17-18. Therefore, North Carolina law seeks to reimpose requirements that only "qualified physician[s]" may be able to prescribe, dispense, and administer mifepristone—requirements that the FDA, in its expert judgment, has expressly rescinded.

The same reasoning applies to the other provisions challenged in *Bryant*:

- North Carolina law requires that a qualified physician must schedule an in-person follow-up appointment within fourteen days of administering mifepristone. N.C. Gen. Stat. §§ 90-21.83A(b)(4)*l*, 90-21.93(b)(8)-(9). When the FDA first approved mifepristone, it required patients to return for an in-person follow-up appointment. *Bryant*, Doc. 82-8 (2011 REMS). Now, however, the FDA has expressly removed those requirements. *Id.*, Doc. 82-16 (2021 Citizen Petition Denial Letter).

- North Carolina law requires that physicians report not just fatal complications, but also a slew of non-fatal complications to state and federal agencies. N.C. Gen. Stat. § 90-21.93(b)(1), (c). When the FDA first approved

mifepristone, it required physicians to report both fatal and nonfatal complications. *Bryant*, Doc. 82-8 (2011 REMS). Now, however, physicians need only report fatal complications. *Id.*, Doc. 82-14 (2016 REMS).

- North Carolina law requires that physicians perform a (necessarily in-person) ultrasound on patients before prescribing mifepristone. N.C. Gen. Stat. §§ 90-21.83A(b)(2)b, 90-21.93(b)(6); 10A Admin. Code § 14E.0305(d). The FDA, however, has expressly rejected an ultrasound requirement and, as noted above, no longer requires the patient to be examined in person at all. *Bryant*, Doc. 82-16 (2021 Citizen Petition Denial Letter).

- North Carolina 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). Like the ultrasound requirement, the FDA has never required a blood test and, again, does not require the patient to be examined in person at all. *Bryant*, Doc. 82-16 (2021 Citizen Petition Denial Letter).

In *Bryant*, the Attorney General argued at summary judgment that each of these North Carolina laws directly contradicts the careful balance that the FDA—at Congress's direction—has reached with respect to mifepristone access. The laws impose restrictions that the FDA initially included as part of mifepristone's REMS, but ultimately rescinded, based on the agency's considered judgment. Because well-settled preemption principles prohibit States from attempting to override the FDA's reasoned decisions about how to balance patient

safety against patient access in this unique context, the state laws at issue in *Bryant* must yield. *See Buckman Co.*, 531 U.S. at 348; *see also Geier*, 529 U.S. at 878-82.

CONCLUSION

If this Court reaches GenBioPro's obstacle- or impossibility-preemption arguments, the State urges the Court to make clear that—at minimum—States may not impose restrictions on access to mifepristone that the FDA has imposed and rescinded.

Respectfully submitted, this the 14th day of February 2024.

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CERTIFICATE OF COMPLIANCE

I certify that this brief complies with the type-volume limitations of Fed. R. App. P. 29(a)(5) and 32(a)(7)(B) because it contains 4,167 words, excluding the parts of the brief 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 14th day of February 2024.

/s/ Sarah G. Boyce
Sarah G. Boyce

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Respectfully submitted, this the 14th day of February 2024.

/s/ Sarah G. Boyce
Sarah G. Boyce

UNITED STATES COURT OF APPEALS FOR THE FOURTH CIRCUIT

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