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

UNITED STATES COURT OF APPEALS
FOR THE FOURTH CIRCUIT

AMY BRYANT, M.D.,

Plaintiff-Appellee,

v.

TIMOTHY K. MOORE, et al.,

Intervenors/Defendants-Appellants

and

JEFFREY NEALE JACKSON, 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

SUPPLEMENTAL BRIEF OF APPELLANTS

Alexander C. Dale
WARD AND SMITH, PA
P.O. Box 7068
Wilmington, NC 28406-7068
(910) 794-4800
acd@wardandsmith.com

Erin M. Hawley
Erik C. Baptist
Allison H. Pope
ALLIANCE DEFENDING FREEDOM
440 First Street NW, Suite 600
Washington, DC 20001
(202) 393-8690
ehawley@ADFlegal.org
ebaptist@ADFlegal.org
apope@ADFlegal.org

Counsel for Appellants

TABLE OF CONTENTS

TABLE OF AUTHORITIES

Cases

Statutes

INTRODUCTION

In *GenBioPro v. Raynes*, 144 F.4th 258 (4th Cir. 2025), this Court rejected the argument—made by Plaintiff Bryant here—that the Food and Drug Administration Amendments Act (FDAAA) radically altered the federal-state balance and preempted states' long-recognized police power to regulate the practice of medicine. *Id.* at 277. The Court explained that the FDAAA "falls well short of expressing a clear intention to displace the states' historic and sovereign right to protect the health and safety of their citizens." *Id.* at 267.

As a result, *GenBioPro* resolved the key dispute here. In rejecting GenBioPro's implied preemption claim—the only type of preemption alleged by Plaintiff here—the Court nixed the argument that the FDAAA was "intended to protect access to REMS drugs." *Id.* at 276 (emphasis omitted). In this Court's view, interpreting that statute to impose an access mandate "fundamentally misunderstands the FDA's mission," and would "radically redefine the FDA's historic role," authorizing "an unprecedented federal intrusion." *Id.* The Court also confirmed that Congress intended the FDAAA—like the Federal Food, Drug, and Cosmetic Act (FDCA)—to enhance drug safety by setting a regulatory floor, not a ceiling. *Id.* at 274, 276.

Those principles decide this case. The Court should follow *GenBioPro* and hold that North Carolina's abortion laws, like West Virginia's, are not preempted by the FDAAA.

ARGUMENT

I. In *GenBioPro*, this Court held that the FDAAA does not preempt West Virginia's abortion regulations.

In *GenBioPro*, this Court rejected an implied preemption claim nearly identical to the one Plaintiff Bryant and the Attorney General assert here.

There, mifepristone manufacturer GenBioPro sought to enjoin West Virginia officials from enforcing a state statute that limited abortion to certain circumstances at certain gestational ages. 144 F.4th at 268. GenBioPro argued that the FDAAA preempted West Virginia's law in three ways: First, by "establish[ing] a comprehensive scheme for regulating the narrow field of REMS drugs with safe-use elements that left no room for complementary state regulation" (field preemption). *Id.* Second, by "authoriz[ing] the sale of mifepristone while the state has banned its use" (impossibility preemption). *Id.* at 275. And third, by "frustrat[ing] the balance that the FDAAA struck between drug safety and patient access" (implied obstacle preemption). *Id.* at 268.

The district court disagreed. Although it held West Virginia's in-person-dispensing requirement for mifepristone invalid under "impossibility preemption"—a basis not asserted here, *see* Bryant Opening Br. at 22–25; AG Reply at 11—it granted West Virginia's motion to dismiss the claims against the remaining laws. *GenBioPro, Inc. v. Sorsaia*, No. 3:23-cv-0058, 2023 WL 5490179, at *10–11, *15

(S.D. W.Va. Aug. 24, 2023). GenBioPro later dropped its claim against the in-person-dispensing requirement and appealed. Motion to Amend Complaint and Joint Stipulation, *id.*, (S.D. W.Va. Oct. 18, 2023), Dkt. No. 73; *GenBioPro*, 144 F.4th at 269.

On appeal, this Court also rejected GenBioPro's preemption arguments. It held that GenBioPro had standing to sue and that West Virginia forfeited its argument that GenBioPro lacked a cause of action. *GenBioPro*, 144 F.4th at 269–70 & n.2.[1] But, emphasizing the important federalism principles at stake, this Court held that the FDAAA did not demonstrate the "clear intention" necessary to preempt West Virginia's abortion laws and that the FDAAA left "the question of [REMS drug] access to state governance." *Id.* at 270–78.

II. *GenBioPro* held that the FDAAA does not preempt state abortion laws that enhance safety.

In reaching its no-preemption holding, this Court in *GenBioPro* affirmed the Legislative Intervenors' interpretation of the FDAAA. It confirmed that the presumption against preemption applies to state abortion regulations. 144 F.4th at 271–72. And with that presumption

[1] This ruling does not prevent the Court from deciding that Plaintiff Bryant lacks a cause of action. Legislative Intervenors' Opening Br. at 34–36. The Court maintains discretion to reach even forfeited issues, *Stokes v. Stirling*, 64 F.4th 131, 136 n.3 (4th Cir. 2023), and Plaintiff Bryant commits a fundamental error by asserting a non-existent federal right under a non-existent cause of action, Legislative Intervenors' Reply at 38–39.

in mind, it held that the FDAAA does not reveal the clear intent necessary to preempt abortion laws that enhance safety. *Id.* at 278. Rather, the Court held that the FDAAA creates a safety floor, not a ceiling, for high-risk REMS drugs like mifepristone. *Id.* at 274. And it held that the FDAAA sets no "access mandate" for these high-risk drugs. *Id.* at 276. Based on the FDAAA's plain text and the long history of complementary state regulation, this Court held that West Virginia's abortion laws were not preempted. *Id.* at 272, 275, 278.

A. *GenBioPro* held that the presumption against preemption applies to state abortion regulations.

This Court began by emphasizing the "enduring wisdom of our republic's federalist design." *GenBioPro*, 144 F.4th at 270. It reaffirmed the "well-established" principle that "[i]n areas of traditional state regulation, [courts] assume that a federal statute has not supplanted state law unless Congress has made such an intention 'clear and manifest.'" *Id.* at 271 (quoting *Bates v. Dow Agrosciences LLC*, 544 U.S. 431, 449 (2005)). This "presumption against preemption" applies to "the regulation of matters related to health and safety"—including "state regulation of abortion." *Id.* at 271–72 (quoting *Hillsborough Cnty. v. Automated Med. Laby's, Inc.*, 471 U.S. 707, 715 (1985)). "Given the Supreme Court's emphasis on the historic ability of states to regulate the use of drugs or medicine to accomplish an abortion, it [was] clear that the presumption against preemption must apply." *Id.* at 272 (citing

Dobbs v. Jackson Women's Health Org., 597 U.S. 215, 250, 302–30 (2022)).

B. *GenBioPro* held that the FDAAA does not demonstrate clear Congressional intent to preempt state abortion laws that enhance safety.

With the presumption against preemption in mind, this Court searched the FDAAA for the necessary "clear intention" to displace states' historic right to enact abortion laws to protect health and safety. 144 F.4th at 267. It found no such intent. *Id.*

1. This Court held that the FDAAA sets a federal safety floor, not a ceiling.

The Court first examined the FDAAA's text and concluded that "Congress intended to create a regulatory floor, not a ceiling." *Id.* at 274. So while states are "not free to dilute congressional safety measures," they are "free to strengthen them." *Id.*

In doing so, this Court highlighted the FDCA's express-preemption provision for medical devices and the 1962 amendments' saving clause. *Id.* at 274–75 (citing Medical Device Amendments of 1976, Pub. L. No. 94-295, 90 Stat. 539, 574, 21 U.S.C. § 360k(a); Drug Amendments Act of 1962, Pub. L. No. 87-781, 76 Stat. 780, 793). The express-preemption provision shows that "Congress knows how to preempt state public health laws when it wants to," but "did not do so in the FDAAA." *Id.* And the saving clause, even though it does not

"directly control the preemptive effect of the later-enacted FDAAA," still provides "powerful evidence that Congress did not intend FDA oversight to be the exclusive means of ensuring drug safety and effectiveness." *Id.* at 275 (quoting *Wyeth v. Levine*, 555 U.S. 555, 575 (2009)).

This Court rejected the notion that the FDAAA drastically altered the federal-state balance by granting "an exclusive federal power that preempts the ability of the states to protect the well-being of their very own citizens." *Id.* at 275. "The very presence of the saving clause," this Court explained, "indicates that Congress has chosen to tread carefully and incrementally in the field of drug regulation." *Id.* And the "long history" of complementary state laws supports a "tradition of shared authority between the federal government and the states." *Id.* (citation omitted).

2. This Court held that Congress did *not* intend in the FDAAA to guarantee nationwide access to mifepristone.

This Court then addressed—and rejected out of hand—GenBioPro's argument that West Virginia's law conflicts with the FDAAA. GenBioPro argued that it could not "comply with both federal and state law because the FDA has authorized the sale of mifepristone while the state has banned its use." *Id.* at 275. It also argued that West Virginia's law "pose[d] an obstacle to the FDAAA's goal of ensuring drug access"

by disrupting the "careful balance" that Congress struck "between drug safety and access." *Id.*

This Court rebuffed both of GenBioPro's conflict-preemption theories and the "flawed premise" on which they relied—namely, "that Congress intended to guarantee nationwide access to mifepristone when it enacted the FDAAA." *Id.* at 276. In fact, this Court found "no indication," in the statutory text or otherwise, that Congress enacted any sort of "access mandate." *Id.*

GenBioPro's contrary claim—that the FDAAA "struck a balance that authorized additional safety measures while also guaranteeing access"—"fundamentally misunderst[ood] the FDA's mission." *Id.* at 276. The agency's task has always been to "ensure[ ] that drugs on the market are safe and effective." *Id.* (citation omitted). And in enacting the FDAAA, Congress "authorized the FDA to establish minimum safety rules for administering drugs like mifepristone." *Id.*

This Court concluded that a "much clearer" statement was necessary to "radically redefine the FDA's historic role" and "authorize an unprecedented federal intrusion into" the states' longstanding authority to regulate the practice of medicine. *Id.* at 276–77 (citing *Gonzales v. Oregon*, 546 U.S. 243, 275 (2006)). The Court warned, moreover, that finding preemption would render states "powerless" to "limit prescriptions of addictive opioids" or "enforce their bans on

physician-assisted suicide against doctors seeking to prescribe lethal [REMS] drugs." *Id.* at 277.

In short, this Court held that the FDAAA "means exactly what it says." *Id.* "[T]he FDA can impose safe-use restrictions on high-risk drugs, and *those restrictions* cannot unduly burden access to the drug." *Id.* But nothing in the FDAAA limits the states from regulating abortion to enhance safety. *Id.* at 277–78.

III. *GenBioPro* confirms the validity of North Carolina's abortion laws.

GenBioPro controls this case. Like West Virginia's law, North Carolina's laws are duly enacted state-abortion regulations intended to enhance safety. Legislative Intervenors' Opening Br. at 3–6, 29–30; *accord* Bryant Opening Br. at 6. And like GenBioPro, Plaintiff Bryant and the Attorney General argue that those laws "are preempted because they upset the careful regulatory scheme established by" the FDAAA. Bryant Opening Br. at 3 (citation omitted); AG Opening Br. at 30–31. They attempt to narrow their theory to safeguards that the FDA considered and rejected, but even that standard would cause a "radical change in the federal-state balance" that *GenBioPro* warned against. *GenBioPro*, 144 F.4th at 277. For the same reasons West Virginia's laws are not preempted, neither are North Carolina's.

A. *GenBioPro* forecloses the conclusion that the FDAAA preempts state abortion laws that enhance safety.

GenBioPro conclusively rejects many of the arguments that Plaintiff Bryant and the Attorney General assert, and that the district court accepted, here.

First, *GenBioPro* forecloses the conclusion that the FDAAA drastically altered the federal-state balance struck by Congress, transforming the FDA from a drug-approving agency to a medical-practice regulator that supplants states' traditional authority. *GenBioPro*, 144 F.4th at 276–77; *contra* JA650–51. *GenBioPro* confirms that "clear" Congressional direction would be necessary to make such a "significant alteration to our system of dual sovereignty." *GenBioPro*, 144 F.4th at 272, 277–78; *contra* Bryant Opening Br. at 52–54; AG Opening Br. at 49. And the FDAAA's text contains no such clear intent. *GenBioPro*, 144 F.4th at 278.

Second, *GenBioPro* affirms the purpose of the FDAAA: to enhance drug safety. *GenBioPro*, 144 F.4th at 276; *contra* AG Opening Br. at 53–55; AG Reply at 16. And it forecloses any argument that the FDAAA guarantees access to abortion drugs. GenBioPro, Plaintiff Bryant, and the Attorney General all claim that the respective state laws "burden patient access to mifepristone in ways that conflict with the carefully balanced regulatory structure FDA imposed in the Mifepristone REMS" and "interfere with FDA's efforts to facilitate patient access to

mifepristone."[2] Bryant Opening Br. at 24; *accord* AG Opening Br. at 34–36; *GenBioPro*, 144 F.4th at 275. But their "theories rely on the same flawed premise: that Congress intended to guarantee nationwide access to mifepristone when it enacted the FDAAA." *GenBioPro*, 144 F.4th at 276. This Court found "no indication" that Congress made any such guarantee. *Id.* Rather, states *may* "restrict[] access to mifepristone," Bryant Opening Br. at 70 (citing JA633), under their "historic ability ... to regulate the use of drugs or medicine to accomplish an abortion," *GenBioPro*, 144 F.4th at 272.

GenBioPro also clarifies that the FDAAA "create[s] a regulatory floor, not a ceiling," for REMS drugs. *Id.* at 274; *accord* Legislative Intervenors' Opening Br. at 20; *contra* JA650–51; AG Reply at 10. Thus "states are not free to dilute congressional safety measures, but they are free to strengthen them." *GenBioPro*, 144 F.4th at 274. None of the challenged North Carolina laws "dilute" the FDA's federal safety standards. *Id.* Rather, these laws enhance safety. Legislative Intervenors' Opening Br. at 29–30. According to the Attorney General, it "matters little" whether the "challenged state laws would increase

[2] Legislative Intervenors maintain that implied obstacle preemption is not a valid basis for federal preemption. Legislative Intervenors' Opening Br. at 19. But *GenBioPro* forecloses Plaintiff Bryant and the Attorney General's conflict-preemption claims even under existing precedent.

patient safety." AG Opening Br. at 57. According to this Court, it matters much.

In short, Congress did *not* intend to create a comprehensive strategy under which only the FDA could set restrictions on high-risk drugs and leave states powerless to protect their own citizens. *GenBioPro*, 144 F.4th at 275–277. State laws like North Carolina's that enhance drug safety complement, rather than obstruct, the safety purpose of the FDAAA. Legislative Intervenors' Opening Br. at 29–32.

B. *GenBioPro* forecloses Plaintiff's considered-and-rejected theory that would radically alter the federal-state balance.

Plaintiff Bryant and the Attorney General attempt to narrow their preemption theory by arguing that a state "may not impose restrictions on a REMS drug that FDA considered and rejected as unnecessary for safety and unduly burdensome on patient access." Bryant Opening Br. at 26; AG Reply at 11. But this theory, too, relies on the "same flawed premise" that GenBioPro's did: "that Congress intended to guarantee nationwide access to mifepristone when it enacted the FDAAA." *GenBioPro*, 144 F.4th at 276; *see* Bryant Opening Br. at 32–33 ("Congress clearly charged FDA with protecting and promoting patients' access to REMS drugs."). Congress did no such thing. *GenBioPro*, 144 F.4th at 276–77. Rather, "states ... are free" to "regulate the use of

drugs or medicine to accomplish abortion" and to "strengthen" federal safety measures for those drugs. *GenBioPro*, 144 F.4th at 272, 274.

A considered-and-rejected standard is also dangerously broad. If a state cannot impose any safety requirement that the FDA "considered and rejected," then it cannot impose any safety requirement at all. That's because a prerequisite for the FDA's approval of a drug is that the FDA has determined it is safe and effective under the conditions described in the proposed label. 21 U.S.C. § 355(d). If the labeling is insufficient to ensure safety, the FDA may impose further conditions in a REMS "to ensure that the benefits of the drug outweigh the risks." 21 U.S.C. § 355-1(a)(1), (f). Thus, with *every* drug approval, the FDA determines which conditions it deems necessary for safe use and necessarily rejects others. When the FDA approves a drug without a REMS, it determines that no REMS elements—such as prescriber certification, laboratory tests, or patient monitoring, 21 U.S.C. § 355-1(f)(3)—are needed. And when it approves a drug with a REMS, it necessarily rejects some of those elements as unnecessary to ensure a drug's safety. Thus, a considered-and-rejected theory would preempt safety measures not only for REMS drugs but for all FDA-approved drugs.

Plaintiff Bryant's and the Attorney General's own claims illustrate the breathtaking sweep of their theory. They object not just to laws requiring in-person dispensing for mifepristone but also to laws that

merely require *reporting* adverse events to the *state*. Bryant Opening Br. at 35–43, 59–65; AG Opening Br. at 35–45. And as *GenBioPro* warned, an access-mandate theory of the FDAAA would gut states' ability to "limit prescriptions of addictive opioids" and "enforce their bans on physician-assisted suicide." *GenBioPro*, 144 F.4th at 276–77; *accord* Legislative Intervenors' Opening Br. at 32–34; Legislative Intervenors' Reply at 19–23.

The Attorney General, at times, seeks to further narrow his theory to cover only protections "that the FDA has *affirmatively rescinded*." AG Opening Br. at 51. There is no meaningful difference between a requirement that the FDA decided not to impose in the first place and one it later rescinded. In either scenario, the FDA determined the requirement was not necessary to assure safe use. But *GenBioPro* teaches that "[t]he text" of the FDAAA "limits the FDA but not the states from restricting access to REMS drugs." *GenBioPro*, 144 F.4th at 277.

* * *

The FDA ensures that "drugs on the market are safe and effective." *Id.* at 276 (citation omitted). But even under the FDAAA, the states retain their longstanding traditional authority "to regulate the use of drugs or medicine to accomplish an abortion." *Id.* at 272, 276. That statute "limits the FDA but not the states from restricting access to REMS drugs." *Id.* at 277. It "falls well short of expressing a clear

intention to displace the states' historic and sovereign right to protect the health and safety of their citizens." *Id.* at 267.

CONCLUSION

For these reasons and those provided in the Legislative Intervenors' principal briefs, this Court should affirm in part, reverse in part, and hold that federal law preempts none of the North Carolina laws challenged here.

Dated: April 27, 2026

Respectfully submitted,

s/Erin M. Hawley

Alexander C. Dale
WARD AND SMITH, PA
P.O. Box 7068
Wilmington, NC 28406-7068
(910) 794-4800
acd@wardandsmith.com

Erin M. Hawley
Erik C. Baptist
Allison H. Pope
ALLIANCE DEFENDING FREEDOM
440 First Street NW, Suite 600
Washington, DC 20001
(202) 393-8690
ehawley@ADFlegal.org
ebaptist@ADFlegal.org
apope@ADFlegal.org

Counsel for Appellants

CERTIFICATE OF COMPLIANCE

This brief complies with the page limit requested in Appellants' unopposed motion for leave to file supplemental briefing because this brief consists of 14 pages, excluding parts of the brief exempted by Federal Rule of Appellate Procedure 32(f).

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

Dated: April 27, 2026

s/Erin M. Hawley
Erin M. Hawley
Counsel for Appellants

CERTIFICATE OF SERVICE

I hereby certify that on April 27, 2026, 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.

s/Erin M. Hawley
Erin M. Hawley
Counsel for Appellants