

In the United States Court of Appeals
for the Fourth Circuit

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

v.

TIMOTHY K. MOORE; PHILIP E. BERGER,
Intervenor-Defendants-Appellants, Cross-Appellees

and

JEFFREY NEALE JACKSON, in his official capacity as Attorney
General for the State of North Carolina,
Defendant-Appellee, Cross-Appellant

and

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

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

**SUPPLEMENTAL BRIEF OF
DEFENDANT ATTORNEY GENERAL JEFF JACKSON**

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TABLE OF CONTENTS

	Page
TABLE OF AUTHORITIES.....	ii
ISSUE PRESENTED	1
INTRODUCTION.....	1
ARGUMENT	3
I. <i>GenBioPro</i> Does Not Control This Case.....	3
II. <i>GenBioPro's</i> Reasoning Supports Finding Preemption Here.....	7
CONCLUSION.....	12
CERTIFICATE OF COMPLIANCE	
CERTIFICATE OF SERVICE	

TABLE OF AUTHORITIES

	Page(s)
Cases	
<i>Dobbs v. Jackson Women’s Health Org.</i> , 597 U.S. 215 (2022)	12
<i>GenBioPro, Inc. v. Raynes</i> , 144 F.4th 258 (4th Cir. 2025).....	passim
<i>GenBioPro, Inc. v. Sorsaia</i> , No. 23-cv-58, 2023 WL 5490179 (S.D. W. Va. Aug. 24, 2023)	3, 4, 5, 6, 8

ISSUE PRESENTED

On April 14, 2026, this Court granted Legislative Intervenors' motion for the parties to file supplemental briefs addressing this Court's decision in *GenBioPro, Inc. v. Raynes*, 144 F.4th 258 (4th Cir. 2025). Dkt. 86, 87.

INTRODUCTION

In *GenBioPro*, this Court held that the FDA's mifepristone regulations did not preempt West Virginia's near-total ban on medication abortion. 144 F.4th at 266-67. That opinion does not control this case. After all, *GenBioPro* does not address—and could not have addressed—the narrow question at issue here: whether a state may, unlike West Virginia, allow access to mifepristone while nonetheless imposing restrictions on the drug that the FDA has implemented but then since withdrawn. As for this separate question, *GenBioPro* is silent.

But *GenBioPro*'s reasoning supports, rather than undermines, the case for preemption on these unique facts. The Court's opinion establishes that states may decide the threshold question of whether mifepristone should be available in the first place. *Id.* at 273. Yet the

Court’s discussion of the FDA’s statutory authority over REMS drugs also confirms that the agency regulates how mifepristone should be prescribed, dispensed, and administered once the drug is otherwise available. *Id.* States may, *GenBioPro* holds, pass laws that operate “upstream” of these rules. *Id.*

Here, however, the challenged North Carolina laws neither operate upstream of, nor run alongside, the FDA’s mifepristone regulations. Rather, the challenged state laws directly conflict with those regulations by seeking to reimpose restrictions on the drug that the FDA has rescinded. The challenged state laws thus interfere with the FDA’s congressionally authorized decisions about “how mifepristone must be prescribed and dispensed *if and when* a medication abortion is performed.” *Id.* Preemption applies as a result.

Attorney General Jackson respectfully requests that this Court affirm in part and reverse in part the district court’s judgment for the reasons set out in this supplemental brief, as well as the Attorney General’s opening/response and reply briefs.¹

¹ Attorney General Jackson was automatically substituted as a defendant in this case for former Attorney General Josh Stein. Dkt. 75; Fed. R. App. P. 43(c)(2).

ARGUMENT

I. *GenBioPro* Does Not Control This Case.

GenBioPro resolved a preemption challenge to a West Virginia abortion ban that bears little resemblance to the challenged North Carolina laws here. This Court's holding that the FDA's mifepristone regulations did not preempt West Virginia's abortion ban thus does not resolve the preemptive effect of the FDA regulations in this case.

Start with the facts of *GenBioPro*. There, the manufacturer of generic mifepristone alleged that the FDA's mifepristone regulations preempted three different West Virginia abortion laws. *GenBioPro, Inc. v. Sorsaia*, No. 23-cv-58, 2023 WL 5490179, at *1 (S.D. W. Va. Aug. 24, 2023). First, West Virginia law banned abortion, including medication abortion, with certain limited exceptions. *Id.* (citing W. Va. Code §§ 16-2R-2, -3). Second, West Virginia law banned prescribing mifepristone by telemedicine. *Id.* at *2 (citing W. Va. Code §§ 30-3-13a(g)(5), 30-1-26(b)(9)). And third, West Virginia law required a waiting period and counseling session before taking mifepristone. *Id.* (citing W. Va. Code § 16-2I-2).

The state moved to dismiss, and the district court granted the motion in part. The district court dismissed the manufacturer's preemption challenge to West Virginia's abortion ban. *Id.* at *5-*10. The court reasoned that the ban was "a restriction on the incidence of abortion, rather than a state directive in direct conflict with the logistical REMS regulations." *Id.* at *8. The ban "limited *when* an abortion may be performed." *Id.* By contrast, the FDA's regulations concerned "*how* medication abortion is performed." *Id.* In view of these differences, the district court held that there was no conflict between the FDA regulations and the West Virginia law. *Id.*

The court reached a different conclusion on West Virginia's telemedicine ban, however. The court held that this law was "unambiguously preempted." *Id.* at *10. The court explained that the telemedicine ban impermissibly conflicted with FDA regulations expressly permitting mifepristone to be prescribed in that way. *Id.* The court reasoned that the telemedicine ban "dictates the manner in which mifepristone may be prescribed," a decision "which Congress has allocated to the FDA" and that the state could not override. *Id.* at *11.

The court finally stated that West Virginia’s waiting period and counseling session requirements “might be likewise preempted,” because they too were in “direct conflict” with the FDA’s regulations, “as they similarly dictate the way mifepristone may be prescribed.” *Id.* But because West Virginia law provided that these requirements did not take effect unless a court struck down the state’s underlying abortion ban, the district court held that it had no reason to rule on laws that were not operative. *Id.*

After the court’s decision, the manufacturer amended its complaint to facilitate the entry of final judgment. The amended complaint abandoned the manufacturer’s challenge to the telemedicine ban. *GenBioPro, Inc. v. Sorsaia*, No. 23-cv-58, Dkt. 75. Consistent with its prior order, the district court dismissed the manufacturer’s remaining claims, and an appeal followed. *Id.* Dkt. 77, 78.

This Court affirmed. The Court expressly limited its analysis to West Virginia’s abortion ban. *GenBioPro*, 144 F.4th at 268 n.1. West Virginia’s telemedicine ban, by contrast, was “not at issue in [the] appeal.” *Id.* The Court therefore left undisturbed the district court’s holding that the telemedicine ban was “unambiguously preempted” by

the FDA’s mifepristone regulations. *GenBioPro*, 2023 WL 5490179, at *10. Nor did the Court purport to address the manufacturer’s challenge to West Virginia’s waiting period and counseling requirements. After all, under state law, those provisions did not go into effect so long as the state’s abortion ban remained in place. *Id.* at *11. This Court therefore also left undisturbed the district court’s forecast that these requirements “might be likewise preempted.” *Id.*

On the one question before the Court—whether West Virginia’s near-total abortion ban was preempted—this Court held that federal law did not preempt state law. *GenBioPro*, 144 F.4th at 278. The Court explained that West Virginia’s abortion ban “determines whether an abortion may be performed at all, prohibiting the procedure in all but a few specific circumstances.” *Id.* at 273. The FDA’s mifepristone regulations, by contrast, “regulate how mifepristone must be prescribed and dispensed *if and when* a medication abortion is performed.” *Id.* As a result, there was no conflict between state and federal law.

Here, unlike West Virginia, North Carolina allows patients to access medication abortion. Instead of banning the drug, the challenged North Carolina laws regulate how the drug is prescribed, dispensed,

and administered. AG Opening/Response Br. 15-16. Whether laws of that kind are preempted is not a question that *GenBioPro* addressed. Indeed, the challenged North Carolina laws in this appeal are like the West Virginia laws that this Court did *not* consider—the state’s telemedicine ban, waiting period, and counseling requirement. Thus, at a minimum, this Court’s decision in *GenBioPro* does not control the outcome of this appeal.

II. *GenBioPro*’s Reasoning Supports Finding Preemption Here.

GenBioPro’s reasoning supports, rather than undermines, the case for preemption on these unique facts.

First, the contrast between the West Virginia abortion ban in *GenBioPro* and the challenged North Carolina laws in this case helps demonstrate why the North Carolina laws are preempted. The West Virginia abortion ban did not interfere with the FDA’s mifepristone regulations in any way. To the contrary, the ban operated “upstream” of the federal regulations. *GenBioPro*, 144 F.4th at 273. It concerned a threshold question about whether mifepristone would be available at all, not the subsequent question of how the drug would be regulated or administered once it was on the market. By contrast, the challenged

North Carolina laws purport to dictate “how mifepristone must be prescribed and dispensed *if and when* a medication abortion is performed”—the same issue that this Court in *GenBioPro* held that the FDA has statutory authority to decide. *See id.*

The challenged North Carolina laws thus do not operate upstream of any federal regulations—they are *midstream* rules, and they directly interfere with the balance that the FDA has struck in following Congress’s directive to regulate REMS drugs by reimposing rules that the FDA has withdrawn. In this way, the challenged North Carolina laws are preempted for the same reason that the district court in *GenBioPro* struck down West Virginia’s telemedicine ban: “Rather than indicating what [abortion] procedures are allowed,” laws of this kind “dictate[] the manner in which mifepristone may be prescribed,” “a determination which Congress has allocated to the FDA” and that states cannot countermand. *GenBioPro*, 2023 WL 5490179, at *11.

Second, this Court’s analysis of the Food and Drug Administration Amendments Act of 2007 further underscores why the challenged North Carolina laws are preempted. The 2007 Amendments repeatedly direct the FDA to ensure “access” to REMS drugs. *GenBioPro*, 144 F.4th at

276 (citing 21 U.S.C. § 355-1(f), (f)(2), (f)(5)). The Court explained that this access mandate requires the FDA “to ensure that *its own* restrictions do not unduly burden access.” *Id.* at 277. The Court therefore interpreted the FDA’s authority over REMS drugs to “align[] with its traditional function of ensuring the safety of drugs on the market while leaving the question of access to state governance.” *Id.* at 276.

Here, instead of regulating the threshold question of drug access, the challenged state laws interfere with the balance that the FDA has struck in ensuring that its own regulations account for drug safety while maintaining patient access in markets where the drug is otherwise available. The challenged laws do so by seeking to reimpose some of the very restrictions on mifepristone that the FDA has rescinded. Under *GenBioPro*, a state may decide to ban mifepristone. But once the drug is on the market, a state is not free to reverse the FDA’s congressionally mandated judgment about how the medication must be prescribed, dispensed, and administered. The safety of otherwise available drugs, *GenBioPro* confirms, is the FDA’s traditional function. And the 2007 Amendments, in specifically requiring the FDA

to balance safety against patient access and burdens on the healthcare system, do not permit states to frustrate how the agency exercises that traditional function, as the challenged state laws do here.

Third, the preemption arguments that the Attorney General has advanced in this appeal are far narrower than those that the manufacturer pressed, and that this Court rejected, in *GenBioPro*. There, the manufacturer asked this Court to disregard the presumption against preemption, claiming that federal law guarantees “nationwide access to mifepristone.” *GenBioPro*, 144 F.4th at 276. Taking that argument to its logical conclusion, the Court stressed, would effect a “radical change in the federal-state balance” that would leave states “powerless” to regulate REMS drugs. *Id.* at 277.

But that argument is not the Attorney General’s. The Attorney General has always agreed that the presumption against preemption applies in this context. *Compare* AG Opening/Response Br. 25-26; AG Reply Br. 19-20, *with GenBioPro*, 144 F.4th at 272-73 (rejecting manufacturer’s arguments against the presumption). And the Attorney General has never argued that the FDA’s regulations cover the waterfront when it comes to REMS drugs. *Compare* AG

Opening/Response Br. 50-52; AG Reply Br. 22-27, *with GenBioPro*, 144 F.4th at 273-75 (rejecting manufacturer’s arguments that the FDA occupies the field of REMS drugs regulations).

Indeed, the Attorney General’s argument has always been that the FDA does *not* have exclusive authority in this area. Only when a state attempts to impose a restriction on a REMS drug that the FDA has rescinded is that restriction preempted. AG Opening/Response Br. 50-52; AG Reply Br. 22-27. Whether that is the case depends on the specific state law at issue and the history of each drug’s REMS. It in no way threatens to “cut the states out of the picture” on issues of drug regulation. *GenBioPro*, 144 F.4th at 277. To the contrary, by allowing preemption under only these limited circumstances, the rule that the Attorney General has proposed here fully aligns with this Court’s holding in *GenBioPro* that federal law envisions “a complementary exercise of federal and state power when it comes to the safe utilization of high risk drugs, not a one-sided ouster of state efforts in this area.” *Id.* at 275.

Fourth, this Court expressed concern that preempting West Virginia’s abortion ban would “defy,” *id.* at 266, the Supreme Court’s

decision in *Dobbs v. Jackson Women’s Health Organization*, 597 U.S. 215 (2022). The Court in *Dobbs* held that the Constitution does not protect a substantive due process right to an abortion. 597 U.S. at 231. But the Court did not purport to displace ordinary preemption principles in any case that touches on the issue of abortion. To the contrary, the Court emphasized that courts should not “engineer exceptions to longstanding background rules” when abortion is at issue. *Id.* at 287. Here, for decades, the Supreme Court has held that federal law may, in narrow circumstances, preempt state laws that impermissibly conflict with the purposes and objectives of Congress. AG Opening/Response Br. 25-31. Applying those ordinary rules in this case would therefore follow, rather than defy, *Dobbs*.

CONCLUSION

Seeking to respect the states’ historic police powers on matters of health and safety, this Court in *GenBioPro* held that federal law did not preempt a state’s ban on a REMS drug. The Court further confirmed that states may pass laws that complement existing federal regulations when REMS drugs are otherwise available. The different issue here is whether a state may seek to reverse the FDA’s congressionally

authorized regulations on how REMS drugs are prescribed and administered by reimposing rules that the FDA has since withdrawn. On that narrow question, *GenBioPro* does not control, and its reasoning supports finding preemption on these unique facts.

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

Respectfully submitted,

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April 27, 2026

CERTIFICATE OF COMPLIANCE

I certify that this brief complies with this Court's April 14, 2026 order because it contains fewer than 15 pages. 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 27th day of April 2026.

/s/ Nicholas S. Brod
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CERTIFICATE OF SERVICE

I certify that on April 27, 2026, I filed the foregoing with the Clerk of the Court for the United States Court of Appeals for the Fourth Circuit by using the appellate CM/ECF system. Participants in the case are registered CM/ECF users and service will be accomplished by the appellate CM/ECF system.

Respectfully submitted, this the 27th day of April 2026.

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