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, No. 1:23-cv-00077-CCE-LPA

SUPPLEMENTAL BRIEF FOR AMY BRYANT, M.D.

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INTRODUCTION

GenBioPro, Inc. v. Raynes, 144 F.4th 258 (4th Cir. 2025), does not call into question the district court's holding that North Carolina is preempted from imposing restrictions on mifepristone that FDA specifically considered and rejected.

In *GenBioPro*, this Court held that FDA's regulation of mifepristone did not preempt West Virginia's near-total ban on abortion, which was passed "for the express purpose of 'protecting unborn lives'" and is unrelated to "how mifepristone must be prescribed and dispensed *if and when* a medication abortion is performed." *Id.* at 272–73 (quoting W. Va. Code. § 16-2R-1). In rejecting GenBioPro's argument that the ban was preempted, the Court emphasized the "sheer breadth of GenBioPro's position," under which "any state law restricting access to [REMS] drugs" would have been preempted. *Id.* at 276–77. The Court made clear, however, that its decision was "a narrow one" that should not be read to "suggest that the FDAAA lacks any preemptive effect." *Id.* at 278.

This case is fundamentally different. The district court correctly held that North Carolina, having chosen to allow medication abortion, cannot impose the very same restrictions on mifepristone that FDA has

"consider[ed] and reject[ed]." JA641 (quoting *Wyeth v. Levine*, 555 U.S. 555, 581 n.14 (2009)). For example, it cannot ban the use of telemedicine that FDA affirmatively sought to encourage and reimpose the same restrictions FDA decided were unwarranted and unduly burdensome. But the district court did not hold, and Dr. Bryant does not argue, "that all state regulations of REMS drugs are preempted." Bryant Br. 6.

The Supreme Court considered this very issue in *Geier v. American Honda Motor Co.*, 529 U.S. 861 (2000), a case not cited or discussed in *GenBioPro*. As the district court recognized, *Geier* establishes that state law is preempted where, pursuant to a "federal regulatory scheme," the responsible federal agency "specifically considered and rejected [the] requirements that state law would impose." JA632. *Geier* was not relevant in *GenBioPro* because FDA had not considered and rejected the type of blanket abortion ban imposed by West Virginia, which dealt with matters "upstream" of FDA's concerns about "medication safety." 144 F.4th at 273. But it is squarely on point here.

Preemption of North Carolina's restrictions is thus easy to square with *GenBioPro*. Confirming as much, the district court decision that *GenBioPro* affirmed held both that West Virginia's abortion ban was not

preempted and that its ban on prescribing mifepristone via telemedicine—a ban analogous to North Carolina's restrictions—was "unambiguously preempted." *GenBioPro, Inc. v. Sorsaia*, 2023 WL 5490179, at *10 (S.D. W. Va. Aug. 24, 2023). This Court should likewise hold North Carolina's restrictions preempted.

ARGUMENT

I. The challenged North Carolina restrictions are preempted under Supreme Court precedent, and *GenBioPro* does not change that result.

The West Virginia law in *GenBioPro* and the North Carolina laws at issue here operate in different spheres and give rise to different preemption considerations. West Virginia's law regulates abortion and has only incidental effects on a federally regulated drug. North Carolina's laws, on the other hand, are aimed squarely at overriding the choices FDA has made with respect to the precise issues that Congress entrusted to FDA. Correspondingly, the preemption theory adopted by the district court in this case is fundamentally different from the theory rejected in *GenBioPro* and relies on binding Supreme Court precedent that *GenBioPro* did not consider. And while this Court was troubled by the broad implications of the preemption theory advanced in *GenBioPro*, here

it is intervenors' arguments *against* preemption that would upend the federal-state balance in the area of drug regulation.

A. *GenBioPro* rejected only the sweeping argument that *any* state regulation that incidentally affects a REMS drug is preempted.

In *GenBioPro*, this Court emphasized "the sheer breadth of GenBioPro's position." 144 F.4th at 276. As described by the Court, GenBioPro was arguing "that Congress intended to *guarantee* nationwide access" to mifepristone and other REMS drugs, that it gave FDA "*exclusive* authority to regulate access to" those drugs, and that federal law "would preempt *any* state law restricting access to those drugs." *Id.* at 266–67, 276–77 (emphasis added). The Court viewed this argument as threatening "a radical change in the federal-state balance." *Id.* at 277; *see also id.* at 272–73 (stating that GenBioPro's argument would "supplant[] every state law tangentially touching the federal domain"); *id.* at 278 (rejecting the "sweeping" argument that state laws are preempted if they "touch upon [REMS] drugs in any way").

The Court was especially troubled that this sweeping argument would preempt West Virginia's abortion ban even though that ban was not directed at the safe and effective use of mifepristone. "West Virginia's

law," the Court explained, "regulate[d] the incidence of abortion" and "determine[d] whether an abortion may be performed at all." *Id.* at 273. "In contrast," FDA regulates "how mifepristone must be prescribed and dispensed *if and when* a medication abortion is performed." *Id.* The law's effect on mifepristone was merely "incidental to the law's regulation of abortion." *Id.* at 272. In other words, West Virginia's focus on the legality of abortion was "upstream" of FDA's focus on identifying the right mix of regulatory controls to ensure drug safety without unnecessarily impeding access. *Id.* at 273; *see Pharm. Rsch. & Mfrs. of Am. v. McCuskey* (*PhRMA*), 171 F.4th 675, 692 (4th Cir. 2026) (explaining that *GenBioPro* found "state law not preempted when it regulated statewide availability of a medical procedure, leading only to an incidental, downstream effect on access to a type of federally regulated drug").

This distinction is important because, as the Court observed, states are allowed a freer hand when they regulate upstream of federal concerns. For example, the Supreme Court held that a state ban on uranium *mining* did not conflict with a federal law regulating how uranium is handled "*after* … it is removed from the earth." *Va. Uranium, Inc. v. Warren*, 587 U.S. 761, 779 (2019). And a state "ban on butchering

horses for human consumption" does not conflict with federal law regulating the operation of slaughterhouses. *Nat'l Meat Ass'n v. Harris*, 565 U.S. 452, 467 (2012). *GenBioPro* cited those precedents in explaining that West Virginia's regulation of the "upstream activity" of "abortion" did not conflict with FDA's regulation of the "downstream activity" of "medication safety." 144 F.4th at 273.

B. Dr. Bryant's preemption argument is fundamentally different from GenBioPro's and concerns specific restrictions that FDA has considered and rejected.

Dr. Bryant's argument is different, and much narrower, than the sweeping argument this Court rejected in *GenBioPro*. She has not claimed that FDA's regulatory authority over REMS drugs is exclusive or that any state law restricting access to those drugs is preempted. She has not, therefore, sought to "cut the states out of the picture." 144 F.4th at 277. She contends only that states may not regulate mifepristone in ways FDA has considered and rejected as unnecessary, unduly burdensome, and contrary to the goals of the federal regulatory scheme. *See* Bryant Br. 26–35.

Dr. Bryant is making a different argument than GenBioPro in part because the North Carolina restrictions are nothing like the West

Virginia abortion ban. Unlike West Virginia, North Carolina has chosen to allow abortion, including medication abortion—but it seeks to regulate use of and patient access to mifepristone in ways that FDA has deliberately rejected and that interfere with the federal regulatory scheme. If West Virginia was operating "upstream" of FDA, *GenBioPro*, 144 F.4th at 273, then North Carolina is building a dam right in FDA's pond. *See PhRMA*, 171 F.4th at 689 (state law is preempted when it "*targets* a federal domain" (quoting *GenBioPro*, 144 F.4th at 272)).

Dr. Bryant's brief describes the resulting conflicts. For example, FDA has concluded that mifepristone is safe when prescribed via telemedicine and has sought to facilitate telemedicine access by lifting in-person requirements and allowing qualified pharmacies to become federally certified to dispense mifepristone. Yet North Carolina blocks telemedicine by requiring multiple in-person visits and by prohibiting pharmacies that are federally certified to dispense mifepristone from doing so. Bryant Br. 38–41, 60–65. FDA has also determined that qualified nonphysicians can safely prescribe mifepristone, lifted restrictions on their ability to do so, and allowed them to become federally certified mifepristone prescribers. Yet North Carolina reimposes the

same restrictions FDA rejected and prohibits these practitioners from prescribing mifepristone in accordance with their federal certifications. Bryant Br. 36–38.

Intervenors' attempt to defend these restrictions only underscores that they are aimed directly at second-guessing FDA's judgments regarding "how mifepristone must be prescribed and dispensed *if and when* a medication abortion is performed." *GenBioPro*, 144 F.4th at 273. Intervenors insist that the restrictions are "safety measures" aimed at "protect[ing] … consumers from dangerous drugs" and ensuring that those drugs "are prescribed and distributed safely." Bryant Br. 67 (quoting Dkt. 100 at 1, 11). But determining the specific mix of regulatory controls that is sufficient to ensure a REMS drug's safety without unduly burdening access is incontrovertibly FDA's responsibility. *See* 21 U.S.C. § 355-1. And FDA has carefully considered and deliberately rejected the very same restrictions North Carolina is seeking to impose.

Notably, the district court decision that *GenBioPro* affirmed agreed with this reasoning. It held that although West Virginia's abortion ban was not preempted, its separate ban on prescribing mifepristone via telemedicine was "unambiguously preempted" because it conflicted with

FDA's determination "that when mifepristone is prescribed, it may be prescribed via telemedicine." 2023 WL 5490179, at *10. The court explained that unlike the abortion ban, "[t]he telemedicine restriction is not 'upstream' from the REMS." *Id.* at *11. "Rather than indicating what procedures are allowed in West Virginia, the telemedicine restriction dictates the manner in which mifepristone may be prescribed"—a "determination which Congress has allocated to the FDA." *Id.* The court also observed that other restrictions that purported to "dictate the way mifepristone may be prescribed," rather than regulating the incidence of abortion, "might be likewise preempted by direct conflict with the REMS." *Id.*; *see PhRMA*, 171 F.4th at 691 (state law can "*operationally* clash with federal law … by creating inconsistencies").

The appeal in *GenBioPro* concerned only the abortion ban and did not require this Court to address the validity of the telemedicine ban and similar restrictions. 144 F.4th at 268 n.1. But the *GenBioPro* district court decision confirms that Dr. Bryant's argument is consistent with the reasoning that led this Court to uphold West Virginia's abortion ban.

C. Preemption here is compelled by Supreme Court precedent that was not discussed in *GenBioPro*.

The district court's preemption holding here is also firmly grounded in Supreme Court precedent that *GenBioPro* had no occasion to address.

The district court relied on the Supreme Court's decision in *Geier*, which establishes that state law is "preempted where [a federal] agency deliberately established [a] federal regulatory scheme and specifically considered and rejected [the] requirements that state law would impose." JA632; *see* Bryant Br. 27–28, 56–57; Bryant Reply Br. 6–9. The district court also recognized that in *Wyeth*, the Supreme Court confirmed that *Geier* applies in the context of federally regulated drugs and indicated that the validity of a state warning requirement depended on the fact that FDA "had not considered and rejected the exact requirements the state [sought] to impose." JA651 (citing *Wyeth*, 555 U.S. at 580–81 & n.14); Bryant Br. 28–31; Bryant Reply Br. 20–21. Those cases strongly support the district court's conclusion that North Carolina's restrictions on mifepristone are preempted.[1]

[1] In addition, North Carolina's requirement that physicians file reports with FDA that FDA does not need or want is preempted under Supreme Court precedent, recently applied by this Court, holding that states may not inject themselves into "the relationship between a federal

GenBioPro does not suggest otherwise. The Court there did not mention *Geier* at all—which was unsurprising, as GenBioPro did not rely on that case and did not contend that West Virginia was imposing restrictions FDA had considered and rejected. And the Court cited *Wyeth* only for the proposition that "Congress did not intend FDA oversight to be the exclusive means of ensuring drug safety and effectiveness." 144 F.4th at 275 (quoting *Wyeth*, 555 U.S. at 575). Dr. Bryant does not contend that FDA oversight is exclusive or that states are prohibited from enacting "complementary" regulations of REMS drugs, *id.*, that do not conflict with or second-guess FDA's judgments. *GenBioPro*, however, did not discuss *Wyeth*'s recognition that states can still be preempted from imposing restrictions that FDA has considered and rejected.

Intervenors may try to wrest isolated language from the *GenBioPro* decision out of context. For example, they may seize on the statements that "Congress intended to create a regulatory floor, not a ceiling" and that the FDAAA "limits the FDA but not the states from restricting access to REMS drugs." 144 F.4th at 274, 277. Those statements are true

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agency and the entit[ies] it regulates." *PhRMA*, 171 F.4th at 689 (quoting *Buckman Co. v. Plaintiffs' Legal Comm.*, 531 U.S. 341, 347 (2001)); *see* Bryant Br. 41–43.

as far as they go: States can impose restrictions above the federal baseline, but that does not mean states are free to contradict specific federal determinations. *GenBioPro* rejected the sweeping argument that the FDAAA "preempt[s] *any* state law restricting access to [REMS] drugs," *id.* at 276–77 (emphasis added), but it did not address the narrower question of whether states can impose specific restrictions that FDA has considered and rejected. In that respect *GenBioPro* is similar to *Wyeth*, which held that federal law does not establish "a ceiling for drug regulation" while still recognizing that a state could be preempted from imposing requirements FDA had "consider[ed] and reject[ed]." 555 U.S. at 573–74, 581 n.14.

D. *GenBioPro*'s concern about radically altering the federal-state balance supports preemption here.

The *GenBioPro* Court's reluctance to accept "sweeping" arguments that would "upend the federal-state balance," 144 F.4th at 272–73, points in the opposite direction here. Not only is the district court's preemption holding narrow, but intervenors' arguments against preemption would have "astonishingly broad" consequences and "radically alter the federal-state balance." Bryant Br. 58–59; Bryant Reply Br. 23–29.

The district court's decision does not carry any of the broad implications that troubled the Court in *GenBioPro*. It would not, for example, render state governments "powerless" to "limit prescriptions of addictive opioids" or to "enforce their bans on physician-assisted suicide." 144 F.4th at 277. It would only prevent states from regulating opioids in ways FDA has deliberately rejected, and intervenors "fail to identify a single state law that imposes restrictions on opioids that FDA has considered and rejected." Bryant Reply Br. 25–27; *accord* AG Br. 50–52; District of Columbia Amicus Br. 21–22. States would also remain free to ban assisted suicide, as that issue is plainly "upstream" of FDA's concerns with the logistics of "medication safety." *GenBioPro*, 144 F.4th at 273. Indeed, the district court's decision was issued two years ago and has not led to any such dire consequences.

Nor does Dr. Bryant's position implicate the Supreme Court's decision in *Dobbs v. Jackson Women's Health Organization*, 597 U.S. 215 (2022). Because GenBioPro's argument would have overturned West Virginia's blanket abortion ban, this Court viewed that argument as "a fig leaf for an assault on the *Dobbs* decision" and thought accepting it would be "one small step short of defiance" of the Supreme Court's ruling.

144 F.4th at 266, 277–78. That is not true here. The decision below did not alter any state's right under *Dobbs* to restrict abortion; it simply held that North Carolina, a state that *permits* abortion, cannot impose restrictions on a REMS drug that FDA has considered and rejected.

Here it is intervenors' position, not Dr. Bryant's, that would have far-reaching consequences. If intervenors are right that states are free to impose restrictions on REMS drugs that FDA considered and rejected, that freedom will extend *a fortiori* to all drugs. The result would be an open invitation for states to second-guess FDA's judgments for tens of thousands of drugs. It is not hard to imagine where this could lead. As just one example, if FDA determined that a vaccine was safe and effective under certain conditions of use, a state could disagree with FDA's safety and efficacy judgments and impose restrictions on the vaccine's use that FDA had considered and rejected. Intervenors do not and cannot deny that their position would authorize such a state law and countless others like it.

Allowing states to contradict FDA's judgments in this way would be particularly incongruous given that a state cannot require a drug's manufacturer to alter a drug's labeling in ways FDA has rejected. *See*

Wyeth, 555 U.S. at 571; *Merck Sharp & Dohme Corp. v. Albrecht*, 587 U.S. 299, 310 (2019). So a state would be preempted from requiring manufacturers to *recommend* in mifepristone's labeling that prescribers observe the restrictions at issue here. *See* Bryant Br. 30–31; Bryant Reply Br. 22. Yet according to intervenors, the state can turn those preempted recommendations into *requirements* and impose them directly on physicians. *GenBioPro*'s limited holding does not compel that illogical result. Just because every state law with the ancillary effect of restricting access to a REMS drug is not automatically preempted does not mean states are free to restrict access in ways that directly contradict FDA's considered judgments.

II. *GenBioPro* confirms that intervenors forfeited their new argument that Dr. Bryant lacks a cause of action.

GenBioPro puts to rest the state's argument that Dr. Bryant lacks a cause of action for her preemption claim. The Court held that the same argument by West Virginia was "forfeited because it was not presented to the district court." 144 F.4th at 270 n.2. Intervenors similarly failed to present their argument to the district court, so it is likewise forfeited.

CONCLUSION

This Court should uphold Dr. Bryant's preemption claim.

Respectfully submitted,

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April 27, 2026

CERTIFICATE OF COMPLIANCE

This supplemental brief complies with the type-volume limitation set forth in the Court's May 14, 2026 Order.

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 it has been prepared in a proportionally spaced typeface (14-point Century Schoolbook) using Microsoft Word 365.

Date: April 27, 2026

s/Eva A. Temkin