NO. 23-2194

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 (Huntington)
Case No. 3:23-cv-00058, Hon. Robert C. Chambers

BRIEF OF APPELLEES

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UNITED STATES COURT OF APPEALS FOR THE FOURTH CIRCUIT

DISCLOSURE STATEMENT

- In civil, agency, bankruptcy, and mandamus cases, a disclosure statement must be filed by **all** parties, with the following exceptions: (1) the United States is not required to file a disclosure statement; (2) an indigent party is not required to file a disclosure statement; and (3) a state or local government is not required to file a disclosure statement in pro se cases. (All parties to the action in the district court are considered parties to a mandamus case.)
- In criminal and post-conviction cases, a corporate defendant must file a disclosure statement.
- In criminal cases, the United States must file a disclosure statement if there was an organizational victim of the alleged criminal activity. (See question 7.)
- Any corporate amicus curiae must file a disclosure statement.
- Counsel has a continuing duty to update the disclosure statement.

No. 23-2194 Caption: GenBioPro, Inc. v. Kristina Raynes & Patrick Morrisey

Pursuant to FRAP 26.1 and Local Rule 26.1,

Patrick Morrisey, in his official capacity as Attorney General of West Virginia
(name of party/amicus)

who is Defendant/Appellee, makes the following disclosure:
(appellant/appellee/petitioner/respondent/amicus/intervenor)

1. Is party/amicus a publicly held corporation or other publicly held entity? ☐ YES ☑ NO

2. Does party/amicus have any parent corporations? ☐ YES ☑ NO
If yes, identify all parent corporations, including all generations of parent corporations:

3. Is 10% or more of the stock of a party/amicus owned by a publicly held corporation or other publicly held entity? ☐ YES ☑ NO
If yes, identify all such owners:

4. Is there any other publicly held corporation or other publicly held entity that has a direct financial interest in the outcome of the litigation? ☐YES ☑NO
If yes, identify entity and nature of interest:

5. Is party a trade association? (amici curiae do not complete this question) ☐YES ☑NO
If yes, identify any publicly held member whose stock or equity value could be affected substantially by the outcome of the proceeding or whose claims the trade association is pursuing in a representative capacity, or state that there is no such member:

6. Does this case arise out of a bankruptcy proceeding? ☐YES ☑NO
If yes, the debtor, the trustee, or the appellant (if neither the debtor nor the trustee is a party) must list (1) the members of any creditors' committee, (2) each debtor (if not in the caption), and (3) if a debtor is a corporation, the parent corporation and any publicly held corporation that owns 10% or more of the stock of the debtor.

7. Is this a criminal case in which there was an organizational victim? ☐YES ☑NO
If yes, the United States, absent good cause shown, must list (1) each organizational victim of the criminal activity and (2) if an organizational victim is a corporation, the parent corporation and any publicly held corporation that owns 10% or more of the stock of victim, to the extent that information can be obtained through due diligence.

Signature: /s/ Curtis R. A. Capehart Date: 11/29/2023

Counsel for: Patrick Morrisey, WV Atty General

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UNITED STATES COURT OF APPEALS FOR THE FOURTH CIRCUIT

DISCLOSURE STATEMENT

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- Counsel has a continuing duty to update the disclosure statement.

No. 23-2194 Caption: Genbiopro, Inc. v. Kristina Raynes, et al.

Pursuant to FRAP 26.1 and Local Rule 26.1,

Kristina Raynes, in her official capacity as Prosecuting Attorney of Putnam County
(name of party/amicus)

who is Appellee, makes the following disclosure:
(appellant/appellee/petitioner/respondent/amicus/intervenor)

1. Is party/amicus a publicly held corporation or other publicly held entity? ☐YES ☑NO

2. Does party/amicus have any parent corporations? ☐YES ☑NO
If yes, identify all parent corporations, including all generations of parent corporations:

3. Is 10% or more of the stock of a party/amicus owned by a publicly held corporation or other publicly held entity? ☐YES ☑NO
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Signature: Jennifer Lynn K Date: 1/5/2024

Counsel for: Kristina Raynes, Appellee

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INTRODUCTION

States have long possessed sovereign authority to protect the health and welfare of their citizens. Yet GenBioPro claims that the Food and Drug Administration's approval and regulation of the abortion drug mifepristone means that states are powerless to protect their citizens' safety. That defies ordinary preemption principles. It also runs contrary to the Supreme Court's admonition that "the issue of abortion [belongs] to the people's elected representatives." *Dobbs v. Jackson Women's Health Org.*, 597 U.S. 215, 232 (2022).

According to GenBioPro, because FDA determined that mifepristone is a uniquely harmful drug needing a Risk Evaluation and Mitigation Strategy (REMS) and elements to assure safe use, states cannot enact health- and safety-focused laws that may have an effect on access to such drugs. Thus, GenBioPro says, West Virginia's democratically enacted Unborn Child Protection Act (UCPA), which "protect[s] unborn lives" by limiting abortion to certain circumstances, is invalid. W. Va. Code § 16-2R-1.

But Congress never granted to any agency the authority to *require* nationwide access to abortion or other especially harmful drugs. The reach of the Food, Drug, and Cosmetic Act (FDCA) is much more modest. In contrast to the federal ceiling GenBioPro imagines, the FDCA merely empowers FDA to set a federal floor, ensuring that the drugs it approves are safe and effective. *Wyeth v. Levine*, 555 U.S. 555,

573–74 (2009). Consequently, the FDCA has long operated as a supplement to the states' traditional authority to protect health and safety, including the regulation of the practice of medicine.

The district court correctly rejected GenBioPro's claims, and the outcome here should be no different. To start, GenBioPro lacks standing to sue. It does not allege it sells its products in West Virginia, it is not subject to any sanction per the UCPA, and the actions it proposes would not violate the revised criminal statute. And while the pharmacies and prescribers that provide GenBioPro's products might be subject to the UCPA, GenBioPro lacks third-party standing to sue on their behalf. Moreover, GenBioPro lacks a private right of action to enforce the Supremacy Clause in any event.

GenBioPro fares no better on the merits. When Congress legislates in a field traditionally occupied by states, federal law does not preempt state law "unless that was the clear and manifest purpose of Congress." *Rice v. Sante Fe Elevator Corp.*, 331 U.S. 218, 230 (1947). But nothing in the FDCA's text indicates Congress meant to supersede state laws on health and safety, let alone laws on the major question of abortion. Indeed, the FDCA's saving clause points in the opposite direction. *See* Drug Amendments of 1962, Pub. L. No. 87-781, § 202, 76 Stat. 780, 793.

GenBioPro's argument that the REMS provisions allow FDA to impose a nationwide abortion-drug access mandate is wrong. To

conclude that the REMS provisions silently abrogated states' traditional authority to guard health and safety would lead to an absurd end: the riskier a drug, the less power states have to protect their citizens from that drug's risks. If GenBioPro were right, states could regulate antibiotics but not opioids. That result stands the FDCA and ordinary preemption principles on their head. This Court should affirm the grounds for dismissal below.

JURISDICTIONAL STATEMENT

This Court has appellate jurisdiction over GenBioPro's timely appeal under 28 U.S.C. § 1291. But the Court lacks jurisdiction to decide the merits of this appeal because the district court lacked subject-matter jurisdiction. *See Steel Co. v. Citizens for a Better Env't*, 523 U.S. 83, 95 (1998). For the reasons set forth in Point I of the Argument below, this matter does not present an Article III case or controversy. *Lujan v. Defs. of Wildlife*, 504 U.S. 555, 560 (1992). So the Court should remand with instructions to dismiss for lack of jurisdiction.

STATEMENT OF THE ISSUES

1. Whether GenBioPro has standing to challenge West Virginia's laws where GenBioPro does not allege it has ever sold mifepristone in the State.

2. Whether a private cause of action exists to challenge the enforcement of state law that purportedly conflicts with the FDCA.

3. Whether the FDCA and FDA's adoption of additional restrictions on high-risk drugs like mifepristone preempt state laws that protect health and safety, including West Virginia's laws on abortion.

STATEMENT OF THE CASE

I. West Virginia protects unborn life and maternal health.

Less than two years ago, the Supreme Court "return[ed] the issue of abortion to the people's elected representatives." *Dobbs v. Jackson Women's Health Org.*, 597 U.S. 215, 232 (2022). The Court held that "[s]tates may regulate abortion for legitimate reasons," including the "preservation of prenatal life" and the "protection of maternal health and safety." *Id.* at 300–01. West Virginia quickly enacted the Unborn Child Protection Act to do just that. W. Va. Code § 16-2R. The UCPA replaced the State's prior law governing informed consent for abortion. W. Va. Code § 16-2I-2.

A. The Unborn Child Protection Act.

The UCPA "protect[s] unborn lives" by limiting abortion except in certain circumstances. W. Va. Code § 16-2R-1. The Act defines "abortion" to mean "the use of any instrument, medicine, drug, or any other substance or device with intent to terminate the pregnancy of a patient known to be pregnant and with intent to cause the death and expulsion or removal of an embryo or a fetus." W. Va. Code § 16-2R-2. The UCPA excludes from this definition miscarriages, in vitro fertilization, contraception, and medical treatment that unintentionally injures an unborn child. W. Va. Code § 16-2R-4. The Act does not identify any drug by name.

A licensed medical professional may perform an abortion under the UCPA if the unborn child is "nonviable" due to a lethal anomaly, the "pregnancy is ectopic," or a "medical emergency exists." W. Va. Code §§ 16-2R-2, 16-2R-3(a). The Act also allows abortion at an early stage if the pregnancy resulted from sexual assault or incest reported to law enforcement. W. Va. Code § 16-2R-3(b) (8 weeks for adults), § 16-2R-3(c) (14 weeks for minors).

If a licensed medical professional performs, induces, or attempts to perform or induce an abortion outside these circumstances, the appropriate licensing board "shall revoke" the professional's license. W. Va. Code § 16-2R-7. An unlicensed person who performs, induces, or attempts an abortion commits a felony. W. Va. Code § 61-2-8(a), (b).[1] This provision does not apply to or impose any penalty on the pregnant woman on whom the abortion is performed. W. Va. Code § 61-2-8(c).

B. The Informed-Consent Law.

Consistent with long-standing pre-*Dobbs* Supreme Court precedent, West Virginia sought to protect women who chose abortion in that era. The Women's Right to Know Act, for instance, required abortion providers to obtain informed consent from their patients. W. Va. Code § 16-2I. The Act required an abortion provider to inform the woman, at

[1] This section of code was revised contemporaneous with the enactment of the UCPA, replacing a then-extant pre-*Roe* criminal abortion statute.

least 24 hours before the abortion, of the medical risks of her abortion procedure, the probable gestational age of her child, and the medical risks of carrying her child to term. W. Va. Code § 16-2I-2(a)(1)–(3); *see also* W. Va. Code § 16-2I-2(b), (c) (listing additional information to be provided). If the provider intended to induce an abortion using the two-drug regimen of mifepristone and misoprostol, the provider had to inform the woman of the possibility of abortion-pill reversal. W. Va. Code § 16-2I-2(a)(4); *see* JA299. The informed-consent law is not in effect now because the UCPA expressly supersedes it so long as no UCPA provision is "judicially determined to be unconstitutional." W. Va. Code §§ 16-2I-9, 16-2R-9.

II. The FDCA protects consumers from dangerous drugs.

A. The Federal Food and Drugs Act.

Congress enacted the Federal Food and Drugs Act, its "first significant public health law," in 1906. Ch. 3915, Pub. L. No. 381, 34 Stat. 78; *Wyeth v. Levine*, 555 U.S. 555, 566 (2009). The Act "supplemented the protection for consumers already provided by state regulation and common-law liability," *Wyeth*, 555 U.S. at 566, by prohibiting "the manufacture, sale, or transportation of adulterated or misbranded ... drugs," 34 Stat. at 78.

B. The Federal Food, Drug, and Cosmetic Act.

Congress enhanced those protections in 1938 by passing the Federal Food, Drug, and Cosmetic Act (FDCA). Ch. 675, Pub. L. No. 717, 52 Stat. 1040 (codified as amended at 21 U.S.C. §§ 301–99). Through the FDCA, Congress sought to further supplement state regulation and "bolster consumer protection against harmful products." *Wyeth*, 555 U.S. at 566, 574. The FDCA requires drug sponsors to file an application with, and receive approval from, FDA before introducing any new drug to the market. 21 U.S.C. § 355. The sponsor must include investigative reports and tests in the application to show that the drug is both "safe" and "effective." § 355(b)(1)(A).

Critically, any "proceedings for the enforcement, or to restrain violations," of the FDCA must "be by and in the name of the United States." § 337(a). Only the federal government—not private litigants—may file suit for noncompliance. *Buckman Co. v. Plaintiffs' Legal Comm.*, 531 U.S. 341, 349 n.4, 352 (2001); *Medtronic, Inc. v. Lohr*, 518 U.S. 470, 487 (1996) (plurality opinion).

C. The Drug Amendments Act of 1962.

In 1962, Congress amended the FDCA to "protect the public health" and "assure the safety, effectiveness, and reliability of drugs." Drug Amendments Act of 1962, Pub. L. No. 87-781, 76 Stat. 780, 780. Under the original version of the FDCA, FDA had to prove harm to reject an application. *Wyeth*, 555 U.S. at 567. But the 1962 amendments

shifted this burden. *Id.* The sponsor now had to prove the new drug was safe and effective under the conditions described in its proposed labeling. 21 U.S.C. § 355(d).

When amending the FDCA, Congress "took care to preserve state law." *Wyeth*, 555 U.S. at 567. It included a saving clause to preserve state laws that also protect public health: "Nothing in the amendments made by this Act ... shall be construed as invalidating any provision of State law which would be valid in the absence of such amendments unless there is a direct and positive conflict between such amendments and such provision of State law." § 202, 76 Stat. at 793. "Consistent with that provision, state common-law suits continued unabated despite FDA regulation." *Wyeth*, 555 U.S. at 567 (cleaned up).

D. The Medical Device Amendments of 1976.

Congress amended the FDCA yet again in 1976, this time "to provide for the safety and effectiveness of medical devices." Medical Device Amendments of 1976, Pub. L. No. 94-295, 90 Stat. 539, 539. The 1976 amendments expressly preempted any state requirement "different from, or in addition to," federal requirements for medical devices. § 521, 90 Stat. at 574. Importantly, Congress "declined to enact such a provision for prescription drugs." *Wyeth*, 555 U.S. at 567.

E. The FDA Amendments Act of 2007.

In 2007, Congress passed the Food and Drug Administration Amendments Act (FDAAA) to "enhance the postmarket authorities" of FDA "with respect to the safety of drugs." Pub. L. No. 110-85, 121 Stat. 823, 823 (codified at 21 U.S.C. § 355-1). Recognizing that post-market safety measures could be essential to ensure that certain high-risk drugs' benefits outweighed their risks, the FDAAA authorized FDA to establish safety programs for such drugs. 21 U.S.C. § 355-1(a). As part of these "risk evaluation and mitigation strategies," or REMS, FDA may require the drug's sponsor to create a medication guide and patient package insert to be dispensed with the drug. § 355-1(a), (e)(2).

Congress also authorized FDA to impose additional safety measures—called "elements to assure safe use"—for drugs that pose a particularly "serious risk," such as death, hospitalization, or birth defects. § 355-1(b)(4)–(5), (f)(1)–(2). Due to the "inherent toxicity or potential harmfulness" of these drugs, FDA may require that prescribers and pharmacies be specially certified, that the drug be dispensed only in certain healthcare settings or under certain safe-use conditions, and that users be registered or monitored. § 355-1(f)(1), (3).

At the same time, Congress limited FDA's authority to impose federal safe-use elements. It directed that FDA's elements to assure safe use must not unduly burden patient access to the drug. § 355-1(f)(2)(C). And it instructed FDA to take certain steps to minimize the

elements' "burden on the health care delivery system." § 355-1(f)(2)(D) (directing FDA to conform safe-use elements with those "for other drugs with similar, serious risks" and to make them "compatible with established ... systems" for distributing and dispensing drugs).

III. FDA creates a mifepristone REMS with safe-use elements.

In 2000, FDA approved Mifeprex, Danco Laboratories' brand-name mifepristone, for the termination of pregnancy up to seven weeks' gestation. JA309–310. FDA has always recognized that the drug poses serious health risks. The FDA-approved label includes a black-box warning that "[s]erious and sometimes fatal infections and bleeding" may occur.[2] And the label shows that the drug sends roughly 1 in 25 users to the emergency room and that up to 7% of users will need surgery to stop bleeding or end the pregnancy.[3]

FDA initially restricted Mifeprex under its own Subpart H regulations. JA310; *see* 21 C.F.R. § 314.520(a). But when the FDAAA created the REMS regime in 2007, it implemented a temporary stopgap measure to facilitate the transition. Previously approved drugs with Subpart H restrictions were temporarily "deemed to have in effect an

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[2] Mifeprex (Mifepristone) Label at 1 FDA (Jan. 2023) ("2023 Mifepristone Label"), https://www.accessdata.fda.gov/drugsatfda_docs/label/2023/020687Orig1s025Lbl.pdf.

[3] *Id.* at 8 tbl. 2, 17.

approved [REMS]." § 909(b)(1), 121 Stat. at 950. Sponsors had to propose a new REMS for the drugs within 180 days. § 909(b)(3), 121 Stat. at 951. FDA later identified Mifeprex as one drug that was subject to Subpart H regulations. JA301.

Danco submitted a proposed REMS for Mifeprex, and FDA approved it in 2011. JA314. The 2011 REMS provided that the drug could be prescribed only by certified physicians and dispensed and taken only in certain healthcare settings.[4] JA314. In 2016, FDA revised the REMS to increase the indicated gestational age from seven to ten weeks, reduce the number of office visits from three to one, and allow non-physicians to prescribe the drug.[5] JA314.

FDA approved GenBioPro's generic version of mifepristone in 2019. JA315. The generic is subject to the same REMS as Mifeprex.[6] JA315.

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[4] *NDA 20-687 MIFEPREX (mifepristone) Tablets, 200 mg Risk Evaluation and Mitigation Strategy (REMS)*, FDA (June 2011), https://www.fda.gov/media/164648/download?attachment.

[5] *NDA 020687 MIFEPREX® (mifepristone) Tablets, 200 mg Risk Evaluation and Mitigation Strategy (REMS)*, FDA (Mar. 2016), https://www.fda.gov/media/164649/download?attachment.

[6] *Risk Evaluation and Mitigation Strategy (REMS) Single Shared System for Mifepristone 200mg*, FDA (Apr. 2019), https://www.fda.gov/media/164650/download?attachment.

In 2021, FDA removed the in-person-dispensing safety requirement, allowing the drugs to be dispensed through the mail.[7] JA315. It revised the REMS in 2023 to allow certified pharmacies to dispense mifepristone. JA317. The current REMS requires participating prescribers, pharmacies, and patients to sign specific agreement forms.[8] JA317. And the REMS makes drug manufacturers like GenBioPro responsible for certifying healthcare providers to prescribe mifepristone and pharmacies to dispense it.[9] Those certified prescribers and pharmacies also must report all deaths associated with the drug to GenBioPro, which must report them to FDA.[10]

IV. GenBioPro does not sell mifepristone in West Virginia.

Despite FDA's approval of generic mifepristone five years ago, JA315, GenBioPro has taken no steps to distribute the drug in West Virginia. Indeed, GenBioPro's complaint does not allege its mifepristone

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[7] The Supreme Court is considering the lawfulness of this action and the 2016 REMS revisions. *See U.S. Food & Drug Admin. v. Alliance for Hippocratic Med.*, No. 23-235; *Danco Lab'ys, L.L.C. v. Alliance for Hippocratic Med.*, No. 23-236. Oral argument took place on March 26, 2024.

[8] *Risk Evaluation and Mitigation Strategy (REMS) Single Shared System for Mifepristone 200mg*, FDA (Mar. 2023) ("2023 Mifepristone REMS"), https://www.accessdata.fda.gov/drugsatfda_docs/rems/Mifepristone_2023_03_23_REMS_Full.pdf.

[9] *Id.* at 2, 4.

[10] *Id.* at 2, 3, 5.

has ever been sold in West Virginia. While a few national pharmacy chains have indicated that they intend to sell mifepristone in some locations, none currently sells the drug in West Virginia. JA322. And GenBioPro does not allege that it has certified any pharmacy locations in West Virginia. Indeed, GenBioPro does not allege it has certified *any* healthcare providers in West Virginia to prescribe mifepristone, and GenBioPro itself has not received a manufacturer's license from the West Virginia Board of Pharmacy.[11]

V. The district court dismisses GenBioPro's complaint.

After filing and then voluntarily dismissing a challenge to Mississippi's abortion laws,[12] GenBioPro brought this lawsuit against West Virginia's similar laws, despite having not sold mifepristone in the State. The complaint alleges that the UCPA and other laws regulating abortion violate the Supremacy and Commerce Clauses of the United States Constitution because they restrict GenBioPro's sale of, and patients' access to, mifepristone. JA22–23.

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[11] *Licensee Verification*, West Virginia Board of Pharmacy (last accessed Mar. 20, 2024), https://www.wvbop.com/public/verify/index.asp. The Court may take judicial notice of government records. *United States v. Cecil*, 836 F.2d 1431, 1452 (4th Cir. 1988); *Goldfarb v. Mayor of Balt.*, 791 F.3d 500, 508 (4th Cir. 2015).

[12] *GenBioPro, Inc. v. Dobbs*, 3:20-cv-00652, Dkt. 46 (S.D. Miss. Aug. 18, 2022).

The district court dismissed nearly all of GenBioPro's claims. JA289. The lower court determined that GenBioPro had standing but that neither conflict nor field preemption principles applied to the UCPA. JA116, JA269–270, JA277. Examining the FDAAA's text, the court determined the patient access and burden provisions "plainly" were "limitation[s] on the FDA's *own restrictions* on a drug, rather than a command that the FDA assure access for all patients." JA268. It could not "find any evidence of Congressional intent in the FDCA or FDAAA amendments to preempt state laws of the type challenged here." JA266. The court also found it implausible that Congress intended "the FDAAA access language to preempt state abortion restrictions which would have been unconstitutional at the time the FDAAA was passed." JA268–269 (citing *Planned Parenthood of Se. Penn. v. Casey*, 505 U.S. 833, 846 (1992)). The UCPA thus did "not pose an 'unacceptable obstacle to the accomplishment and execution of the full purposes and objectives of Congress.'" JA269 (quoting *Wyeth*, 555 U.S. at 563–64).

The district court also concluded that the UCPA did not make it impossible for GenBioPro or medical professionals to comply with federal law. JA270–273. The court explained GenBioPro was "not regulated by the UCPA *at all*," since it is not a "licensed medical professional" under West Virginia law. JA270–271. Although medical professionals would have to take several steps to prescribe mifepristone under both the REMS and the UCPA, the court found this "scheme

coheres with traditional conceptions of the practice of medicine and the scope of physicians' authority as state matters." JA272. Because the UCPA "limited *when* an abortion may be performed, without touching *how* medication abortion is to be performed," the court reasoned, it did not directly conflict with "the logistical REMS regulations." JA272–273 (citing *Virginia Uranium, Inc. v. Warren*, 139 S. Ct. 1894, 1901 (2019); *Nat'l Meat Ass'n v. Harris*, 565 U.S. 452, 467 (2012)).

The court also held that Congress had not occupied the field of drug regulation generally or GenBioPro's narrowed field of "drugs subject both to a REMS and to additional elements to assure safe use." JA274. The saving clause in the 1962 amendments "foreclosed any argument for complete field preemption." JA275. The REMS provision did not change the analysis, in part because the presumption against preemption was "strongest" when Congress acts in a field the states have traditionally occupied. JA275–276 (citing *Wyeth*, 555 U.S. at 565). And "the Supreme Court has repeatedly held that the FDCA does not preempt state action in the field of healthcare or medicine absent a direct conflict." JA275 (citing *Wyeth*, 555 U.S. at 581; *Mutual Pharm. Co. v. Bartlett*, 570 U.S. 472, 486–87 (2013)). The court distinguished *United States v. Locke*, 529 U.S. 89 (2000), because "regulating interstate navigation is historically an area of federal concern" and the limited saving clauses at issue there preserved state action in only a certain sub-field. JA276–277. In contrast, regulating the practice of

medicine is not a traditional federal concern, and the Supreme Court has found the FDCA's saving clause to "contain breadth." JA277 (citing *Wyeth*, 555 U.S. at 567).

Because West Virginia's informed-consent law is not currently operative, the court did not analyze whether it was preempted. JA278. While the court found West Virginia's in-person-dispensing requirement for mifepristone to be preempted, JA277–278 (citing W. Va. Code §§ 30-3-13a(g)(5), 30-1-26(b)(9)), GenBioPro later amended its complaint to remove this claim, JA293–294.

The court also held the UCPA did not violate the Commerce Clause. JA278–289.[13] It entered final judgment dismissing the case. JA337. GenBioPro appealed. JA338.

SUMMARY OF THE ARGUMENT

GenBioPro's claim that FDA's regulation of mifepristone somehow creates a national mandate to abortion access until ten weeks' gestation fails for three reasons: (1) it lacks standing; (2) it lacks a cause of action; and (3) its preemption theory fails on the merits.

First, GenBioPro lacks standing because it does not allege that it has sold mifepristone in West Virginia or taken any steps to do so. Plus,

[13] By failing to challenge this holding in its opening brief on appeal, GenBioPro has abandoned its Commerce Clause claim. *See Suarez-Valenzuela v. Holder*, 714 F.3d 241, 248–49 (4th Cir. 2013) ("[C]ontentions not raised in the argument section of the opening brief are abandoned.") (emphasis removed) (citation omitted).

West Virginia law would not even prohibit such sales. GenBioPro's "lost sales" theory relies on third-party standing based on harm to GenBioPro's putative customers, but GenBioPro has not alleged its own injury in fact. The Court should therefore direct a dismissal for lack of jurisdiction.

Second, GenBioPro lacks a cause of action to bring its Supremacy Clause claim, and this Court can affirm on that basis. Section 1983 provides a cause of action for the violation of federal rights, but the Supremacy Clause is not itself the source of any rights. The FDCA explicitly states that only the federal government may bring a claim for its enforcement. 21 U.S.C. § 337(a). The United States has not brought such a claim here.

Third, the FDCA does not preempt West Virginia's laws protecting life and health. GenBioPro's preemption claims must clear two demanding hurdles: the presumption against preemption for areas of historic state regulation, and the major questions doctrine. None of GenBioPro's preemption theories can surmount these two obstacles. There is no field preemption because the UCPA and FDCA regulate separate fields, and in any event, Congress has not preempted the field for drug safety, even for REMS drugs. Nor is there impossibility pre-emption because the FDCA does not mandate access to REMS drugs and the UCPA does not prevent compliance with federal law. There is

no obstacle preemption either because West Virginia's laws and the FDCA serve complementary purposes.

In short, GenBioPro cannot show the existence of an actionable controversy, a cause of action, or a meritorious claim. The Court should direct the dismissal of its case for lack of jurisdiction or affirm the district court's dismissal with prejudice.

STANDARD OF REVIEW

This Court reviews a district court's grant of a motion to dismiss for failure to state a claim de novo. *Weidman v. Exxon Mobil Corp.*, 776 F.3d 214, 219 (4th Cir. 2015). A district court's standing determinations are also reviewed de novo. *Maryland Shall Issue, Inc. v. Hogan*, 971 F.3d 199, 209 (4th Cir. 2020).

To survive a motion to dismiss, a complaint must allege "enough facts to state a claim to relief that is plausible on its face." *Bell Atl. Corp. v. Twombly*, 550 U.S. 544, 570 (2007). Although the Court must accept the complaint's factual allegations as true, it need not accept legal conclusions couched as factual allegations. *Ashcroft v. Iqbal*, 556 U.S. 662, 678 (2009). And the Court may take judicial notice of "matters of public record" and other adjudicative facts under Federal Rule of Evidence 201. *Goldfarb v. Mayor of Balt.*, 791 F.3d 500, 508–09 (4th Cir. 2015).

ARGUMENT

I. GenBioPro lacks standing.

Article III of the Constitution limits the judicial power to "Cases" and "Controversies." Courts enforce this jurisdictional limit by ensuring litigants have standing to sue. *Spokeo, Inc. v. Robbins*, 578 U.S. 300, 338 (2016). To establish standing, a plaintiff must show it has suffered an "injury in fact" that is "concrete and particularized" and "actual or imminent, not conjectural or hypothetical," and that is "fairly traceable" to the defendant's actions and subject to redress by the court. *Lujan v. Defenders of Wildlife*, 504 U.S. 555, 560–61 (1992) (cleaned up). Since GenBioPro filed suit before any enforcement occurred, it must allege "an intention to engage in a course of conduct arguably affected with a constitutional interest, but proscribed by a statute, and there exists a credible threat of prosecution thereunder." *Susan B. Anthony List v. Driehaus*, 573 U.S. 149, 159 (2014).

GenBioPro lacks standing because it does not allege that it has sold or intends to sell mifepristone in West Virginia. It implied to the district court that it had done so, JA127, but did not provide any proof or attempt to amend its complaint to so allege.

GenBioPro does not allege that it has taken the most basic steps that would be required to sell mifepristone in West Virginia. Though the REMS requires sponsors like GenBioPro to "[e]nsure" prescribers

and pharmacies are specially certified,[14] GenBioPro doesn't allege it has done so for any providers in West Virginia. JA322. Nor is GenBioPro licensed to sell its product in the State.[15] Because West Virginia's laws do not apply to extraterritorial conduct, GenBioPro must at least allege *some* action within the State's borders. It hasn't alleged anything.

What's more, GenBioPro cannot establish that its conduct is prohibited by the UCPA. *See SBA List*, 573 U.S. at 159. Nothing in that statute prohibits the sale of mifepristone. Rather, the UCPA regulates performing an unlawful abortion. W. Va. Code § 61-2-8(a). And the UCPA contains several exceptions that allow abortion (and mifepristone use) in certain situations, including lethal fetal anomalies and medical emergencies, W. Va. Code § 16-2R-3(a), as well as sexual assault and incest, § 16-2R-3(b), (c). Plus, the UCPA does not prevent mifepristone from being used for purposes other than abortion, such as miscarriage management or Cushing's syndrome treatment.

GenBioPro gestures towards West Virginia's criminal statutes and the "attempt" provisions of the UCPA. GenBioPro Br. 44 (citing W. Va. Code §§ 61-2-8(a), (b); 16-2R-2). But those statutes do not apply to GenBioPro. The UCPA does not restrict the sale of mifepristone in West Virginia at all. It merely limits the performance of abortions in the

[14] 2023 Mifepristone REMS, *supra* note 8, at 2, 4, 5.

[15] *Licensee Verification, supra* note 11.

State to licensed medical professionals, W. Va. Code § 16-2R-3(g), which is reflected in the revised criminal statute, § 61-2-8(a). And even if GenBioPro sold its product with the intent that it be stocked by pharmacies or physicians in the State, it would have no knowledge of whether the drug was going to be used in one of several lawful ways or for an unlawful abortion. It is thus difficult to foresee a factual scenario where GenBioPro would violate these various provisions. GenBioPro's complaint does not allege any situation in which it would know an individual patient's circumstances.

GenBioPro suggests alternatively that it has standing because it has lost sales since West Virginia's laws allegedly "make it impossible ... to promote and market its product" in the State. JA322, JA320. But again, GenBioPro has *never* sold the drug in the State or taken appropriate steps to do so, before or after the UCPA. *Cf. SBA List*, 573 U.S. at 159–61 (describing plaintiffs who had engaged in prohibited activity in the past). So any lost sales are purely "hypothetical." *Lujan*, 504 U.S. at 560. There is no injury GenBioPro can claim as its own.

Neither can GenBioPro rely on third-party standing by alleging derivative harm to pharmacies and doctors who might sell or prescribe mifepristone in West Virginia. JA322. That doctors and pharmacies might be subject to penalties for violating the UCPA does not give GenBioPro standing, since a plaintiff "generally must assert his own legal rights and interests, and cannot rest his claim to relief on the legal

rights or interests of third parties." *Warth v. Seldin*, 422 U.S. 490, 499 (1975). To invoke third-party standing, GenBioPro must show not only that the law "injures the rights of others," *Maryland Shall Issue, Inc. v. Hogan*, 971 F.3d 199, 214 (4th Cir. 2020), but also that GenBioPro is threatened by the application of the law and suffers its *own* injury, *Craig v. Boren*, 429 U.S. 190, 194 (1976). And to have standing to challenge a state law before it has been enforced, a plaintiff must demonstrate a credible threat that the law will be enforced against *the plaintiff*. *Younger v. Harris*, 401 U.S. 37, 42 (1973); *SBA List*, 573 U.S. at 158–59. GenBioPro has not alleged (and cannot allege) that here, so it lacks standing. This Court should dismiss.

II. GenBioPro lacks a cause of action.

GenBioPro also lacks a cause of action for its preemption claims. GenBioPro looks to Section 1983, which provides a cause of action to protect "any rights, privileges, or immunities secured by the Constitution and laws." JA328 (citing 42 U.S.C. § 1983). But Section 1983 is unavailable because the Supremacy Clause does not create any judicially enforceable "federal rights." *Armstrong v. Exceptional Child Ctr., Inc.*, 575 U.S. 320, 324 (2015) (citation omitted). It simply "creates a rule of decision ... instruct[ing] courts what to do when state and federal law clash." *Id.* at 324–25. It does not confer a cause of action or say "who may enforce federal laws in court." *Id.* at 325. Accordingly,

neither the Supremacy Clause nor Section 1983 give GenBioPro a "right to enforce federal laws against the States." *Id.*

Equity does not recognize any basis for GenBioPro to sue under the Supremacy Clause to enforce the FDCA either. As the Supreme Court explained in *Armstrong*, "the power of federal courts of equity to enjoin unlawful executive action is subject to express and implied statutory limitations," and courts cannot "disregard statutory and constitutional requirements and provisions." *Id.* at 327 (citations omitted). Thus, in *Armstrong*, the Court rejected an equitable action to enforce the Supremacy Clause where two statutory features of the Medicaid Act "implicitly preclude[d] private enforcement" and showed "Congress's intent to foreclose equitable relief." *Id.* at 328 (cleaned up).

That result is even more appropriate here because Congress has *explicitly* prohibited private enforcement of the FDCA: "[A]ll such proceedings for the enforcement, or to restrain violations, of this chapter shall be by and in the name of the United States." 21 U.S.C. § 337(a). Thus, as the Supreme Court has recognized, "[p]rivate parties may not bring enforcement suits" under the FDCA. *POM Wonderful LLC v. Coca-Cola Co.*, 573 U.S. 102, 109 (2014). Regulated parties, including pharmaceutical companies, have no private right of action to enforce the FDCA. *See Mylan Laby's, Inc. v. Matkari*, 7 F.3d 1130, 1139 (4th Cir. 1993); *Sandoz Pharms. Corp., v. Richardson-Vicks, Inc.*, 902 F.2d 222, 231 (3d Cir. 1990); *PhotoMedex, Inc. v. Irwin*, 601 F.3d 919,

924 (9th Cir. 2010); *Amarin Pharma, Inc. v. Int'l Trade Comm'n*, 923 F.3d 959, 966 (Fed. Cir. 2019).

Because "[t]he FDCA leaves no doubt that it is the Federal Government rather than private litigants who are authorized to file suit" to enforce its provisions, *Buckman Co. v. Plaintiffs' Legal Comm.*, 531 U.S. 341, 349 n.4 (2001), any attempt to enforce the Supremacy Clause in equity is barred just like the state-law fraud-on-the-FDA claims in *Buckman*, *id.* at 350. The United States has declined to sue here, and GenBioPro has no statutory or equitable right to do so in the United States' absence.

In the district court, GenBioPro might have been able to assert the Supremacy Clause as the rule of decision in connection with its separate claims that West Virginia's laws violate the dormant Commerce Clause. JA328–330. But the district court dismissed those claims with prejudice, and GenBioPro has voluntarily abandoned them on appeal, leaving only its preemption theory. JA289; *Valenzuela*, 714 F.3d at 248–49. And since GenBioPro's preemption theory lacks a cause of action, this Court should affirm dismissal on that basis, as it may "affirm on any ground appearing in the record, including theories not relied upon or rejected by the district court." *United States v. McHan*, 386 F.3d 620, 622–23 (4th Cir. 2004) (quoting *Scott v. United States*, 328 F.3d 132, 137 (4th Cir. 2003)); *see also Blum v. Bacon*, 457 U.S. 132, 138 (1982)

("[A]n appellee may rely upon any matter appearing in the record in support of the judgment below.").

III. The Unborn Child Protection Act is not preempted.

The district court rightly rejected GenBioPro's preemption theory on the merits. At the start, GenBioPro's claims face two interpretive canons that pose insuperable hurdles to its novel theory: (1) the presumption against preemption; and (2) the major questions doctrine.

The preemption analysis starts "with the assumption that the historic police powers of the States [are] not to be superseded by the Federal Act unless that was the clear and manifest purpose of Congress." *Rice v. Santa Fe Elevator Corp.*, 331 U.S. 218, 230 (1947); *Wyeth v. Levine*, 555 U.S. 555, 565 (2009). "That assumption applies with particular force when Congress has legislated in a field traditionally occupied by the States." *Altria Grp., Inc. v. Good*, 555 U.S. 70, 77 (2008). This presumption, based on the "historic presence of state law," is so strong that it applies even when the federal government has also regulated in an area "for more than a century." *Wyeth*, 555 U.S. at 565 n.3. Thus, in applying that presumption to a federal statute "susceptible of more than one plausible reading, courts ordinarily 'accept the reading that disfavors pre-emption.'" *Altria*, 555 U.S. at 77 (quoting *Bates v. Dow Agrosciences LLC*, 544 U.S. 431, 449 (2005)).

That presumption applies here. "The States traditionally have had great latitude under their police powers to legislate as 'to the protection

of the lives, limbs, comfort, and quiet of all persons.'" *Metropolitan Life Ins. Co. v. Massachusetts*, 471 U.S. 724, 756 (1985) (citation omitted). The Supreme Court has long recognized "'the historic primacy of state regulation of matters of health and safety'" regulated by the UCPA. *Medtronic, Inc. v. Lohr*, 518 U.S. 470, 485 (1996). And as to abortion specifically, "the vast majority of the States enacted statutes criminalizing abortion at all stages of pregnancy," presenting an "overwhelming consensus" that "endured until the day *Roe* was decided." *Dobbs v. Jackson Women's Health Org.*, 597 U.S. 215, 248–49 (2022). GenBioPro cannot rebut the strong presumption that West Virginia laws protecting the health and safety of its citizens are not preempted.

The major questions doctrine also counsels against a reading of the FDCA that would hang a major policy question—a federal abortion mandate—on the miniscule statutory hook of FDA's REMS authority.[16] Based on "both separation of powers principles and a practical understanding of legislative intent," the major questions doctrine reflects the presumption that "Congress intends to make major policy decisions itself." *West Virginia v. E.P.A.*, 597 U.S. 697, 723 (2022) (citation omitted). And if Congress instead chooses to delegate a major policy

[16] The district court held the major questions doctrine was inapplicable outside of the administrative-law context, JA261–262, but the doctrine may also be understood as an interpretive canon—as "a tool for discerning ... the text's most natural interpretation." *Biden v. Nebraska*, 143 S. Ct. 2355, 2376 (2023) (Barrett, J., concurring).

decision to a federal agency, Congress must speak clearly; it does not "hide elephants in mouseholes." *Whitman v. Am. Trucking Ass'ns*, 531 U.S. 457, 468 (2001).

The major questions doctrine applies with particular force where, as here, there is a "lack of historical precedent" for the plaintiffs' theory of interpretation. *Nat'l Fed'n of Indep. Bus. v. Dep't of Lab., Occupational Safety & Health Admin.*, 595 U.S. 109, 119–20 (2022) (per curiam). Indeed, not even the federal government advances GenBioPro's exorbitant reading of the FDCA. The "sheer scope" of GenBioPro's theory of preemption warrants caution, *Ala. Ass'n of Realtors v. Dep't of Health & Hum. Servs.*, 141 S. Ct. 2485, 2489 (2021) (per curiam), particularly after the Supreme Court returned the question of abortion "to the people and their elected representatives." *Dobbs*, 597 U.S. at 259. So this Court should bring a strong "measure of skepticism" to a theory of an abortion mandate derived from a statute and regulations that say nothing about it. *Util. Air Regul. Grp. v. E.P.A.*, 573 U.S. 302, 324 (2014). "It strains credulity to believe" that the FDCA grants FDA "the sweeping authority" that GenBioPro asserts. *Ala. Ass'n of Realtors*, 141 S. Ct. at 2486.

None of GenBioPro's four preemption theories succeed against this backdrop. First, field preemption does not apply because the UCPA and the FDCA regulate completely different fields and because the FDCA provides only a regulatory floor, not a ceiling, for laws addressing

dangerous drugs. Second, it is not impossible to comply with both the UCPA and the FDCA, since the REMS do not purport to mandate access to mifepristone. Third, the UCPA does not present an obstacle to fulfilling the FDCA's purpose because the two statutes are complementary. And fourth, all of GenBioPro's preemption arguments against West Virginia's long-standing informed-consent law lack merit.

A. Field preemption does not apply.

GenBioPro first gerrymanders the preemption analysis by arguing that Congress occupied the "field" of "regulating access to REMS drugs subject to safe-use elements." GenBioPro Br. 26. This theory is doubly flawed. For one, the UCPA does not regulate drugs at all but rather the conduct of abortion. And for another, the FDCA does not purport to completely regulate the field of REMS drugs with safe-use elements, but rather leaves room for additional state-law regulation.

1. The FDCA and UCPA regulate separate fields.

Field preemption does not apply because the FDCA and UCPA operate in different fields. The statutes regulate different subjects and serve different functions.

To determine preemptive intent, courts look to a statute's text, structure, context, and purpose. *Virginia Uranium, Inc. v. Warren*, 139 S. Ct. 1894, 1901 (2019). None of those support field preemption here. As a matter of basic structure and purpose, the FDCA's REMS program

is directed to drug safety, while the UCPA regulates abortion. The UCPA prohibits the intentional performance of an abortion, subject to certain exceptions. W. Va. Code § 16-2R-2 (defining "Abortion"); § 16-2R-3 (describing circumstances). The statute does not mention mifepristone or regulate whether or how it should be prescribed or dispensed.

The UCPA's abortion regulations are also "fundamentally unrelated" to the mifepristone REMS regime because they serve an "entirely different function[ ]"—the protection of unborn life. *Kansas v. Garcia*, 140 S. Ct. 791, 804–05 (2020) (distinguishing submission of tax withholding forms and the federal employment verification system); *see also Wyeth*, 555 U.S. at 579 (explaining that state tort suits serve a "distinct compensatory function"). The distinct function of the UCPA forecloses GenBioPro's preemption theory.

That the UCPA may have an incidental effect on the number of drugs sold does not turn the FDAAA into some sort of super-preemption statute. As Justice Ginsburg explained, "A state law regulating an upstream activity within the State's authority is not preempted simply because a downstream activity falls within a federally occupied field." *Virginia Uranium*, 139 S. Ct. at 1914–15 (Ginsburg, J., concurring in the judgment). So even if the FDCA occupied the downstream field of drug safety (which, as explained below, it does not), that does not mean it preempts the UCPA's upstream regulation of abortion.

2. Congress did not occupy the field.

GenBioPro's preemption theory also fails because it cannot show that FDA has occupied the relevant field. Field preemption occurs in the "rare" situation where Congress has "legislated so comprehensively" in a certain field that it has "left no room for supplementary state regulation." *Kansas*, 140 S. Ct. at 804 (quoting *R. J. Reynolds Tobacco Co. v. Durham Cnty.*, 479 U.S. 130, 140 (1986)). Field preemption may also be found where a federal interest is "so dominant" that courts assume federal law "preclude[s] enforcement of state laws on the same subject." *Arizona v. United States*, 567 U.S. 387, 399 (2012).

But Congress's intent to supersede state laws in an entire field must be "clear and manifest." *English v. General Elect. Co.*, 496 U.S. 72, 79 (1990). A detailed federal regulatory scheme "does not by itself imply preemption." *Id.* at 87. Rather, because "every subject that merits congressional legislation is, by definition, of national concern," *Hillsborough Cnty. v. Automated Med. Laby's,* 471 U.S. 707, 719 (1985), the Court looks for "special features" that warrant field preemption, *id.* Here, there are none.

As noted, the presumption against preemption applies in full force here because health and safety regulations are areas of historical state concern. *Rice*, 331 U.S. at 230. Just two years ago, the Supreme Court recognized that the regulation of abortion is an area of longstanding state concern. *Dobbs*, 597 U.S. at 248–49. And health and safety are

areas of historical state regulation that the federal government has only more recently entered. *Lohr*, 518 U.S. at 475. The Supreme Court thus has consistently found the FDCA to *co*-regulate matters of health and safety *with* the states, rather than dominate them. *E.g.*, *Wyeth*, 555 U.S. at 573–75; *Lohr*, 518 U.S. at 485, 487. And because the FDCA does not preempt state failure-to-warn claims, *Wyeth*, 555 U.S. at 581, it certainly does not occupy the entire field of safety regulation pertaining to drugs.

Recognizing this problem, GenBioPro tries to artificially narrow the field to "restrictions on access to drugs subject to a REMS with safe-use elements." GenBioPro Br. 22. It claims regulation of *these* dangerous drugs is an area of "historical" federal concern. GenBioPro Br. 58. But REMS drugs with elements to assure safe use are hardly an area of historical federal concern—the REMS regime has existed for only 17 years. GenBioPro points to no statutory evidence that clearly shows Congress intended to preempt traditional state laws regulating the practice of medicine and related health and safety, even if such regulation touches on high-risk drugs. Frankly, allowing a party to conspicuously tailor what constitutes the relevant field, as GenBioPro seeks to do here, would ensure field preemption in *any* case and would make that doctrine all but meaningless.

The FDCA's saving clause defeats field preemption as well. A saving clause is "fundamentally incompatible with" field preemption. *In*

re NOS Commc'ns, MDL No. 1357, 495 F.3d 1052, 1058 (9th Cir. 2007). This is because such a "clause demonstrates that congressional intent to completely preempt this area of law is neither clear nor manifest." *Johnson v. Am. Towers, LLC*, 781 F.3d 693, 703 (4th Cir. 2015). *Accord*, *e.g.*, *Farina v. Nokia, Inc.*, 625 F.3d 97, 121 (3d Cir. 2010); *Aldridge v. Mississippi Dep't of Corr.*, 990 F.3d 868, 874–75 (5th Cir. 2021).

The detailed nature of Section 355-1 does not change this reality. True, FDA must consider a number of factors when determining whether to require a REMS. § 355-1(a)(1)(A)–(F). And it must consider whether *its own safety measures* will unduly burden patient access or the healthcare delivery system. § 355-1(f)(1)–(2). But "merely because the federal provisions were sufficiently comprehensive to meet the need identified by Congress" does not mean states are "barred from identifying additional needs or imposing further requirements in the field." *Hillsborough Cnty.*, 471 U.S. at 717. This is particularly true here, where the FDCA has long contemplated—and expressly provided for—the coexistence of federal and state protections.

Finally, GenBioPro's theory of field preemption is ambitious to a fault. It would preempt any state law that touches drugs with REMS and safe-use elements, even when that contact is only tangential and historically grounded. FDA currently has a REMS in place for 68 drugs,

and 64 of those have elements to assure safe use.[17] By definition, these are the most high-risk drugs on the market, including opioids.[18] States have a legitimate and important interest in ensuring these drugs are prescribed and distributed safely. But if the FDCA "occupied" this field, states could do virtually nothing at the prescriber level to combat the opioid crisis. The FDCA would preempt state laws limiting prescribing authority, *see* Ky. Rev. Stat. § 218A.205(3)(b); limiting dosages, *see* 12-5 Vt. Code R. § 53; and requiring prescribers to obtain a controlled substances certificate, *see* Ala. Code § 20-2-51. There is no basis to infer this vast displacement of state law on traditional matters of state concern without even a word from Congress.

B. GenBioPro can comply with the FDCA and the UCPA.

GenBioPro's impossibility preemption theory also fails. GenBioPro must show that it is "impossible for it to comply with both federal and state requirements." *Wyeth*, 555 U.S. at 573; *Drager v. PLIVA USA*, 741 F.3d 470, 475 (4th Cir. 2014). Impossibility occurs "when federal law forbids an action that state law requires," *Bartlett*, 570 U.S. at 486, or

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[17] *Approved Risk Evaluation and Mitigation Strategies (REMS)*, FDA (last accessed Mar. 24, 2024), https://www.accessdata.fda.gov/scripts/cder/rems/index.cfm.

[18] *Approved Risk Evaluation and Mitigation Strategies (REMS), Opioid Analgesic REMS*, FDA (last accessed Mar. 24, 2024), https://www.accessdata.fda.gov/scripts/cder/rems/index.cfm?event=RemsDetails.page&REMS=17.

when "state law penalizes what federal law requires," *Geier v. Am. Honda Motor Co.*, 529 U.S. 861, 873 (2000); *see, e.g., Florida Lime & Avocado Growers, Inc. v. Paul*, 373 U.S. 132, 143 (1963) (describing hypothetical federal law that forbade avocadoes with more than 7% oil and state law that required avocadoes with more than 8% oil).

It is not impossible for GenBioPro to comply with both the mifepristone REMS and the UCPA. To begin, the UCPA does not purport to regulate out-of-state actions of manufacturers like GenBioPro. In addition, nothing in the FDCA mandates access to mifepristone. Nor is it true that complying with both the FDCA and the UCPA prevents GenBioPro from selling the drug in West Virginia. The Court should reject GenBioPro's impossibility theory.

1. The UCPA does not regulate GenBioPro.

Impossibility preemption does not apply because, as the district court concluded, the UCPA does not regulate GenBioPro's conduct in selling mifepristone "*at all*." JA271. Simply put, the UCPA regulates the practice of abortion in West Virginia; it does not regulate the sale or marketing of any instrumentality or drug used for abortions, like mifepristone. The UCPA does not apply extraterritorially or to the commercial distribution of mifepristone in West Virginia.

While GenBioPro asserts (for the first time) that it could face criminal penalties, GenBioPro Br. 44, that newly asserted theory does not hold up. To start, since GenBioPro did not argue that the related

criminal statute, W. Va. Code § 61-2-8(a), applies to it before the district court, it waived the argument.

Beyond that, W. Va. Code § 61-2-8(a) existed before *Dobbs* and now speaks to *who* may perform abortions in West Virginia. It prohibits anyone other than a licensed medical professional from "knowingly and willfully perform[ing], induc[ing], or attempt[ing] to perform or induce an abortion." *Id.* GenBioPro does not allege that it performs or induces abortions. Meanwhile, the UCPA defines "[a]ttempt to perform an abortion" as "an act or omission … that, *under the circumstances as the person so acting or omitting to act believes them to be*, constitutes a substantial step in a course of conduct intended to culminate in an abortion." W. Va. Code § 16-2R-2 (emphasis added). This would demand a great deal from the manufacturer of a legal product to establish criminal liability. GenBioPro is far removed from the doctor's conversation with a particular patient and determination whether an abortion would be legal in her circumstances. GenBioPro does not allege it would be involved in that process or know whether the circumstances of a given use of its product make it illegal under the UCPA. GenBioPro thus does not allege that it has taken or will take any action that will subject it to punishment under the related criminal statute.

2. The FDCA does not mandate drug access.

GenBioPro identifies no provision in the FDAAA or REMS that requires something the UCPA prohibits or prohibits something the

UCPA requires. Instead, its impossibility argument hinges on the false premise that the FDAAA and REMS *mandate* access to mifepristone. But they do no such thing. The FDAAA does not require drug manufacturers to sell their approved drugs to all eligible patients. Though the mifepristone REMS imposes a variety of obligations on GenBioPro and others in the chain of distribution,[19] it does not require any provider to prescribe mifepristone, any pharmacy to dispense it, or any manufacturer or distributor to sell it (much less at an affordable price). Without such a duty, there can be no impossibility conflict.

3. *Bartlett* does not save GenBioPro's claims.

GenBioPro unpersuasively attempts to compare its position to that of the generic manufacturer asked to "stop selling" its product in *Bartlett*. GenBioPro Br. 42–44. That case involved a state tort-law challenge to the formulation and labeling of an FDA-approved drug, where federal law prohibited any changes to the drug's design or label without FDA approval. *Bartlett*, 570 U.S. at 475. It was a paradigmatic case of impossibility preemption: by deeming the product defective in its design, "[s]tate law imposed a duty ... *not* to comply with federal law." *Id.* The Court rejected the notion that the manufacturer could avoid the conflict if it "stop[ped] selling" its product: "our pre-emption cases presume that a manufacturer's ability to stop selling does not turn

[19] *See* 2023 Mifepristone REMS, *supra* note 8, at 1–5.

impossibility into possibility," since holding otherwise would render impossibility pre-emption "all but meaningless." *Id.* at 487 n.3.

This reasoning does not apply here for two reasons. *First*, and most simply, the "stop selling" rationale does not apply where a manufacturer has not even *started* selling its product in-state.

Second, even if GenBioPro were to start selling mifepristone in West Virginia, the UCPA would not demand that it stop because the statute regulates abortion, not the sale of a drug. W. Va. Code § 16-2R-3. GenBioPro is free to sell mifepristone in West Virginia. To the extent the UCPA restricts mifepristone use, it does so only where the drug would be used for illegal abortions—not for cases where abortion is lawful or for any other purpose for which a doctor might prescribe it, such as management and treatment of Cushing's syndrome and uterine leiomyomas. West Virginia's regulation of abortion does not demand anyone stop selling mifepristone any more than Virginia's prohibition of the death penalty demands anyone stop selling drugs that may be used for lethal injection. *See* Va. S.B. 1165 (Mar. 24, 2021).

GenBioPro's claim that the UCPA makes it "practically impossible" to sell its product, GenBioPro Br. 23, is off-base. The fact that the law limits the availability of abortion to finite circumstances, having a downstream reduction in market demand, does not create an impossibility conflict. That is a consequence of permissible regulation, not a basis for preemption. *Bartlett*, 570 U.S. at 489 n.5. Also,

commercially supplying a legal product used in abortions, like mifepristone, to healthcare providers violates no law, except in the unalleged scenario where the supplier possesses unusual and specific knowledge and intent to further an illegal abortion.

If the FDCA granted GenBioPro a "right" to sell mifepristone, perhaps GenBioPro would have a claim. *See Wyeth*, 555 U.S. at 590 (Thomas, J., concurring). But the FDCA does no such thing, and the district court correctly held that impossibility preemption does not apply.

C. The UCPA is not an obstacle to the REMS program.

GenBioPro also argues that the UCPA obstructs Congress's objectives because it "interfere[s] with the balance Congress and FDA struck." GenBioPro Br. 44. State laws that "stand[ ] as an obstacle to the accomplishment and execution of the full purposes and objectives of Congress" are impliedly preempted. *Hines v. Davidowitz*, 312 U.S. 52, 67 (1941).[20] But Supreme Court precedent establishes a "high threshold" to show a state law is "preempted for conflicting with the purposes of a federal Act." *Chamber of Com. v. Whiting*, 563 U.S. 582, 607 (2011) (citation omitted). This is especially true where the

[20] Appellees dispute that "purposes and objectives preemption" is a constitutionally valid basis for finding federal preemption of state law. *See Wyeth*, 555 U.S. at 583–88, 594–604 (Thomas, J., concurring). Appellees reserve the right to challenge this doctrine if this case is appealed to the United States Supreme Court.

presumption against preemption and major questions canons require clarity from Congress. And here, the objectives of the UCPA and the FDCA are in harmony, not in conflict.

Purposes-and-objectives preemption follows a two-part test: It first identifies "Congress's 'significant objectives' in passing the federal law." *Guthrie v. PHH Mortg. Corp.*, 79 F.4th 328, 338 (4th Cir. 2023), *petition for cert. filed* (Aug. 18, 2023). It next determines whether the state law is an obstacle to those objectives. *Id.*

1. The FDCA sets a federal safety floor, not a ceiling.

The FDCA has long been understood to set a federal safety floor and to *allow* complementary state regulation, which is the opposite of an obstacle. Indeed, in *Wyeth*, which involved a purported conflict between FDA's approved labeling allowing a specific method of drug administration and a state tort claim that would hold that method unsafe, the Supreme Court rejected the argument that "the FDCA establishes both a floor and a ceiling for drug regulation." 555 U.S. at 573–74. Rather, the Court determined that "all evidence of Congress' purposes is to the contrary." *Id.* at 574.

As the Court explained, "Congress enacted the FDCA to bolster consumer protection against harmful products," and state laws may further this consumer-protection objective with additional regulations. *Id.* In fact, FDA itself has "long maintained that state law offers an

additional, and important, layer of consumer protection that complements FDA regulation." *Id.* at 578–79.

The *Wyeth* Court identified two provisions of the FDCA that reenforce this historical understanding. 555 U.S. at 567, 574–75. First, the Drug Amendments Act of 1962 included a saving clause preserving state law unless it posed a "direct and positive conflict" with the amendments. § 202, 76 Stat. at 793. And second, Congress amended the FDCA to include an express preemption provision with respect to medical devices, Medical Device Amendments of 1976, § 521, 90 Stat. at 574, but "declined" to enact a similar preemption provision for prescription drugs, *Wyeth*, 555 U.S. at 567. Congress, of course, knows how to preempt state law and chose not to do so for REMS or any other drugs. *See Riegel v. Medtronic, Inc.*, 552 U.S. 312, 333, 342 (2008) (Ginsburg, J., dissenting).

2. The FDAAA regulates drug safety, not access.

Given that the FDCA has long allowed complementary state regulation, GenBioPro turns to the REMS provisions, arguing they reveal an intent to ensure drug access. GenBioPro Br. 45–52. Not so.

The FDCA's primary objective is to ensure the safety of the products it regulates. *See Wyeth*, 555 U.S. at 574; 52 Stat. at 1040. Congress amended the Act in 1962 to "protect the public health" and "assure the safety, effectiveness, and reliability of drugs." 76 Stat. at 780; *Wyeth*, 555 U.S. at 567. And it amended it again in 2007 "to

enhance the postmarket authorities for [FDA] *with respect to the safety of drugs*[.]" 21 Stat. at 823 (emphasis added); *cf.* GenBioPro Br. 45 ("The FDAAA's preamble states its objective."). Uniform nationwide drug access was not an objective—let alone a "significant" objective—when Congress passed these laws. *Guthrie*, 79 F.4th at 338.

The text of the REMS provisions comes nowhere close to authorizing a drug access mandate—much less with the clarity needed to overcome the presumption against preemption and major questions canons. The statute merely directs FDA to evaluate *how its own* safe-use elements will affect access. § 355-1(f)(1)(2). Indeed, the statute plainly applies its access specification *only* to these elements: It provides that "*[s]uch elements to assure safe use* under paragraph (1) shall … considering [the safety] risk, not be unduly burdensome on patient access to the drug" and "to the extent practicable" conform with the safe-use elements for other drugs with similar risks and distribution systems "so as to minimize the burden on the health care delivery system." § 355-1(f)(1)(2) (emphasis added). Thus, the district court correctly concluded that this provision "is plainly a limitation on the FDA's *own restrictions* on a drug, rather than a command that the FDA assure access for all patients." JA268.

GenBioPro's contrary reading of the REMS provision finds no support in the statutory context, either. If that provision mandated drug "access" as GenBioPro maintains, one would expect to see

conditions that go hand in hand with an "access" mandate—such as a requirement that drug manufacturers actually sell approved drugs. Or a requirement that manufacturers sell those drugs at an accessible price. The statute contains no such duties.

More statutory clues show Congress's overarching purpose. The relevant title in the FDAAA is named "Enhanced Authorities Regarding Postmarket *Safety* of Drugs." 121 Stat. at 922 (emphasis added). That title contains two subtitles: "A—Postmarket Studies and Surveillance" and "B—Other Provisions to Ensure Drug Safety and Surveillance." 121 Stat. at 922, 951. The overarching "goal" of REMS is to "mitigate" the risks of high-risk drugs, not guarantee access to them.[21]

Section 355-1's safety purpose is confirmed by the provisions addressing when FDA may require a REMS. FDA may institute a REMS if it determines one "is necessary to ensure that the benefits of the drug outweigh the risks of the drug" (*i.e.*, to enhance the drug's safety). 21 U.S.C. § 355-1(a)(1). In making this determination, FDA may consider patient population size, seriousness of the disease, expected drug benefit, treatment duration, seriousness of adverse events, and whether the drug is a new molecular entity. *Id.* FDA may also require a REMS if it learns of "new safety information" after a drug's initial approval. § 355-1(a)(2)(A); *see* § 355-1(b)(3). All these statutory factors

[21] 2023 Mifepristone REMS, *supra* note 8, at 1.

concern safety; none relate to access. Similarly, Congress incorporated safe-use elements to mitigate a "serious specific risk" from a drug's "inherent toxicity or potential harmfulness," not to ensure access. § 355-1(f)(1).

The only references to "access" in the REMS framework are addressed *to FDA*. "Congress's purpose" for these provisions was "to ensure that the elements *themselves* would not be unduly burdensome upon patient access." JA268. They do not purport to preempt the state's historical authority over health and safety—much less abortion regulation. Because those provisions are a limitation only on FDA, the lower court properly concluded that the UCPA did "not pose an 'unacceptable obstacle to the accomplishment and execution of the full purposes and objectives of Congress.'" JA269 (quoting *Wyeth*, 555 U.S. at 563–64).

3. The UCPA complements the FDCA.

The UCPA's objectives complement those of the FDCA. The "preservation of prenatal life" and the "protection of maternal health and safety" are "legitimate" state objectives. *Dobbs*, 597 U.S. at 301. The UCPA's limits on abortion do not obstruct the accomplishment and execution of the FDCA's health and drug-safety objectives. The UCPA does not eliminate any of FDA's mifepristone safety requirements. It instead protects maternal health by including exceptions for ectopic pregnancies and medical emergencies. W. Va. Code § 16-2R-3(a)(2)–(3).

And it allows the use of FDA-approved drugs and devices for purposes other than illegal abortions. § 16-2R-4(a)(4), (b). GenBioPro does not even try to claim that the UCPA endangers patient health or drug safety.

The UCPA's measures do not disturb what GenBioPro calls FDA's "balance between access and burden." GenBioPro Br. 47. The only balancing FDA must conduct is to ensure that *its own* REMS requirements do not unduly burden access to the drug. *See* 21 U.S.C. § 355-1(f). The UCPA does not touch this balance. That's why the lower court concluded that it could not "find any evidence of Congressional intent in the FDCA or FDAAA amendments to preempt state laws of the type challenged here." JA266.

When a state, in the exercise of its historic authority, prohibits conduct before a federal regulatory regime even kicks in, the state's law does not disrupt the "balance" sought by the federal regime. In *Virginia Uranium, Inc. v. Warren*, the Supreme Court upheld Virginia's ban on uranium mining despite the fact that federal law regulated uranium milling, transfer, use, and disposal. 139 S. Ct. at 1900–01. This was so even though Virginia's ban on uranium mining "ma[de] it far less likely, though not impossible," that the federally supervised milling or tailings storage activities would take place. *Id.* at 1914 (Ginsburg, J., concurring in the judgment). And in *National Meat Association v. Harris*, the Court noted that a state ban on butchering horses for consumption would not

be preempted by a federal scheme that regulates how horses may be slaughtered. 565 U.S. 452, 467 (2012).

Here, the UCPA similarly regulates activity "upstream" of the federal REMS safeguards. *Virginia Uranium*, 139 S. Ct. at 1915 (Ginsburg, J., concurring in the judgment). Indeed, this is an easier case than *Virginia Uranium* because GenBioPro may freely sell mifepristone for legal uses, including for legal abortions, miscarriage management, and Cushing's syndrome treatment. As the lower court held, because the UCPA "limit[s] when an abortion may be performed, without touching how medication abortion is to be performed," it does not directly conflict with "the logistical REMS regulations." JA272–273.

In contrast, the cases GenBioPro cites for its "balancing" argument mostly involve "uniquely federal areas of interest." *Chamber of Com.*, 563 U.S. at 604; *e.g.*, *Buckman*, 531 U.S. at 352 (fraud on federal agency); *OpenRisk, LLC, v. Microstrategy Servs. Corp.*, 876 F.3d 518, 523 (4th Cir. 2017) (copyright); *Int'l Paper Co. v. Ouellette*, 479 U.S. 481, 487–88 (1987) (interstate water); *Amgen Inc. v. Sandoz*, 877 F.3d 1315, 1327 (Fed. Cir. 2017) (patent law); *Locke*, 529 U.S. at 97, 99 (maritime vessels). Regulating abortion "has never been considered … an area of dominant federal concern," and these cases "concern state actions that directly interfered with the operation of the federal program." *Chamber of Com.*, 563 U.S. at 604. Plus, as explained above, GenBioPro's reliance on *Buckman* simply confirms that it lacks the

authority to privately enforce provisions of the FDCA that Congress has committed exclusively to the federal government. The UCPA does not interfere with FDA's mifepristone REMS safety requirements.

Under GenBioPro's theory, Congress preempted complementary state regulation *only* for the most dangerous drugs like mifepristone and opioids. That makes no sense. Even if the UCPA indirectly regulates specific uses of mifepristone by regulating a procedure for which the drug is used, it is a permissible supplementary safety regulation. It does not prohibit GenBioPro, or any provider or pharmacy, from complying with the REMS requirements. Rather, it adds a step to the process, requiring the provider to assess the patient's circumstances and determine whether the drug may be prescribed to her under state law. *See* W. Va. Code §§ 16-2R-2, 16-2R-3. In cases where the UCPA allows abortion, it is simply the case that providers may prescribe mifepristone manufactured by GenBioPro and comply with the federal REMS.

D. The informed-consent law is not preempted.

Finally, GenBioPro argues that if the UCPA is preempted, then so is West Virginia's informed-consent law that would take effect if the UCPA were overturned. W. Va. Code § 16-2I. The Court need not (and must not) reach this issue because the informed-consent law is not in effect. *See* W. Va. Code §§ 16-2I-9, 16-2R-9. Plaintiffs cannot challenge a

law that is not in effect because they are not harmed by it and so cannot satisfy Article III standing requirements. *Cf. California v. Texas*, 593 U.S. 659, 669–71 (2021).

Regardless, the informed-consent law is not preempted for many of the same reasons set forth above. Congress has not "occupied the field." *Supra*, pp. 31–34. Nor does GenBioPro argue it is impossible to comply with both the informed-consent law and the mifepristone REMS. GenBioPro Br. 42–44 (arguing only that it cannot comply with both the REMS and the UCPA). *See Valenzuela*, 714 F.3d at 248–49 ("[C]ontentions not raised in the argument section of the opening brief are abandoned.").

This leaves obstacle preemption. West Virginia's informed-consent law does not obstruct the FDCA's drug-safety objective. *See supra* pp. 39–44. It neither removes nor interferes with any of the mifepristone REMS requirements; it simply complements them. Like the REMS, the informed-consent law requires healthcare providers to inform patients of mifepristone's serious risks. *Compare* W. Va. Code § 16-2I-2(a)(1) *with* 2023 Mifepristone REMS, *supra* note 8, at 1, 4. And the informed-consent law requires providers to tell patients the probable gestational age of their child, something certified providers must be able to do under the REMS. *Compare* W. Va. Code § 16-2I-2(a)(2) *with* 2023 Mifepristone REMS, *supra* note 8, at 1. Providers may prescribe mifepri-

stone consistently with both the REMS and West Virginia's informed-consent law.

Before *Dobbs*, the Supreme Court held that a truthful and non-misleading informed-consent requirement with a 24-hour waiting period did not unduly burden a woman's access to abortion. *Casey*, 505 U.S. at 833, 881–87, *overruled on other grounds by Dobbs*, 597 U.S. at 231. So West Virginia's informed-consent law cannot upset FDA's "balance" of safety and undue burden. Twenty-five states require modest waiting periods such as this one.[22] No one has ever suggested that the FDCA preempted them. Yet GenBioPro's theory would dispense with them all.

[22] Ala. Code § 26-23A-4(a) (48 hours); Ariz. Rev. Stat. Ann. § 36-2153(A)(1) (24 hours); Fla. Stat. § 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 § 16-34-2-1.1(a)(1) (18 hours); Iowa Code § 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. § 40:1061.17(B)(3)(a) (72 hours); Mich. Comp. Laws § 333.17015(3) (24 hours); Miss. Code Ann. § 41-41-33(1)(a) (24 hours); Mo. Rev. Stat. § 188.027(1) (72 hours); N.C. Gen. Stat. Ann. § 90-21.83A(b)(1) (72 hours); Neb. Rev. Stat. § 28-327(1) (24 hours); N.D. Cent. Code § 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 § 16-2I-2(a) (24 hours); Wis. Stat. § 253.10(3)(c)(1) (24 hours).

West Virginia's provision requiring disclosure of the possibility of abortion-pill reversal also does not conflict with the mifepristone REMS. *See* W. Va. Code § 16-2I-2(a)(4). FDA protocols contemplate that a woman who intends "to end [her] pregnancy" will take both mifepristone and misoprostol to complete the chemical abortion process.[23] But federal law does not *require* a woman to take the second abortion drug or allow a provider to force a woman to complete an abortion. The woman may change her mind. West Virginia's disclosure requirement informs her that abortion-pill reversal may be possible in case she does.

To be sure, the informed-consent law contains requirements not included in the mifepristone REMS. But states are not "barred from identifying additional needs or imposing further requirements" in a field merely because Congress has enacted federal provisions that are "sufficiently comprehensive" to meet its own need. *Hillsborough Cnty.*, 471 U.S. at 717.

Even under *Casey*, states could ensure women understood the consequences of their decisions and were provided with information empowering them to choose life. *Casey*, 505 U.S. at 882–86. Congress directed FDA to ensure drug safety while considering the patient-access and healthcare-system burdens imposed by its safe-use elements. West

[23] Patient Agreement Form (Jan. 2023), 2023 Mifepristone REMS, *supra* note 8.

Virginia decided to promote the protection of unborn life and ensure that women taking abortion drugs fully understood their options. Nothing in federal law prohibits the State from requiring that women be informed of the ability to make life-saving choices.

CONCLUSION

The Court should remand with instructions to dismiss for lack of jurisdiction or affirm the district court's dismissal with prejudice.

REQUEST FOR ORAL ARGUMENT

Due to the novelty and far-reaching effects of GenBioPro's preemption argument, Appellees request oral argument.

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CERTIFICATE OF COMPLIANCE

This brief complies with the type-volume limitation of Fed. R. App. P. 32(a)(7)(B) because this brief contains 11,388 words, excluding the parts of the brief exempted by Fed. R. App. P. 32(f), as determined by the word counting feature of Microsoft Office 365.

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