IN THE UNITED STATES DISTRICT COURT
SOUTHERN DISTRICT OF WEST VIRGINIA
HUNTINGTON DIVISION

GENBIOPRO, INC., **PLAINTIFF,**

v. **Case No. 3:23-cv-00058**

MARK A. SORSAIA, *et al.*, **DEFENDANTS.**

MOTION OF ARKANSAS, ALABAMA, FLORIDA, GEORGIA, IDAHO, INDIANA, IOWA, KANSAS, KENTUCKY, LOUISIANA, MISSISSIPPI, MISSOURI, MONTANA, NEBRASKA, NORTH DAKOTA, OHIO, OKLAHOMA, SOUTH CAROLINA, SOUTH DAKOTA, TENNESSEE, AND TEXAS AS AMICI CURIAE IN SUPPORT OF DEFENDANTS

Proposed Amici are the States of Arkansas, Alabama, Florida, Georgia, Idaho, Indiana, Iowa, Kansas, Kentucky, Louisiana, Mississippi, Missouri, Montana, Nebraska, North Dakota, Ohio, Oklahoma, South Carolina, South Dakota, Tennessee, and Texas. Proposed Amici respectfully move for leave to file an amicus brief in support of the Defendants in this matter.

INTEREST OF PROPOSED AMICI CURIAE

Eight months ago, the Supreme Court overruled *Roe v. Wade* and returned the authority to regulate or prohibit abortion to "the citizens of each State." *Dobbs v. Jackson Women's Health Org.*, 142 S. Ct. 2228, 2284 (2022). In response, many States enacted laws prohibiting, restricting, or otherwise regulating abortion. West Virginia was one of them. GenBioPro disagrees with *Dobbs* and the citizens of West Virginia, and it has brought this case to override both. The Proposed Amici States all prohibit, restrict, or otherwise regulate abortion. Each of the Proposed Amici has a sovereign interest in protecting their citizens—born and unborn—and write to explain why those laws are not preempted under an outlandish interpretation of the Food, Drug and Cosmetic Act.

ARGUMENT

District courts have broad discretion to allow participation of amici curiae. While this Court does not have specific rules for the filing of amicus briefs, it has "discretion" to allow them. *Ohio Valley Envtl. Coal., Inc. v. McCarthy*, 313 F.R.D. 10, 32 (S.D. W.Va. 2015). "Courts typically grant amicus status where the parties 'contribute to the court's understanding of the matter in question' by proffering timely and useful information." *Ga. Aquarium, Inc. v. Pritzker*, 135 F. Supp. 3d 1280, 1288 (N.D. Ga. 2015).

Here, Proposed Amici offer timely and useful information. This brief is submitted with sufficient time for Plaintiffs to respond. *Cf.* Fed. R. App. P. 29 advisory committee note (1998) (explaining that an amicus brief filed shortly after the brief it supports gives the opposing party sufficient time to respond). Indeed, opposing counsel had notice of the brief: Proposed Amici informed them of our plans to file a brief on February 23. Proposed Amici's brief will also be useful to the Court. *United States ex rel. Gudur v. Deloitte Consulting LLP*, 512 F. Supp. 2d, 920, 927 (S.D. Tex. 2007). *Dobbs* explained that States retain authority to regulate or prohibit abortion; the brief confirms that the FDA has not supplanted the States' role by determining that mifepristone is effective at killing unborn children.

With these arguments, the Proposed Amici will fulfill the classic role of amici curiae: "assisting the court in cases of general public interest by making suggestions to the court, by providing supplementary assistance to existing counsel, and by insuring a complete and plenary presentation of difficult issues so that the court may reach a proper decision." *Newark Branch, NAACP v. Harrison*, 940 F.2d 792, 808 (3d Cir. 1991) (citation omitted).

CONCLUSION

For all these reasons, the Court should grant this motion and allow Proposed Amici to file the attached brief.

Dated: February 28, 2023

Respectfully submitted,

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CERTIFICATE OF SERVICE

I certify that on February 28, 2023, I electronically filed the foregoing with the Clerk of the Court using the CM/ECF system, which will send notification of such filing to all counsel of record.

/s/ Jeffrey A. Kimble
Jeffrey A. Kimble

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AMICUS BRIEF OF ARKANSAS, ALABAMA, FLORIDA, GEORGIA, IDAHO, INDIANA, IOWA, KANSAS, KENTUCKY, LOUISIANA, MISSISSIPPI, MISSOURI, MONTANA, NEBRASKA, NORTH DAKOTA, OHIO, OKLAHOMA, SOUTH CAROLINA, SOUTH DAKOTA, TENNESSEE, AND TEXAS IN SUPPORT OF DEFENDANTS' MOTION TO DISMISS

Eight months ago, the Supreme Court overruled *Roe v. Wade* and returned the authority to regulate or prohibit abortion to "the citizens of each State." *Dobbs v. Jackson Women's Health Org.*, 142 S. Ct. 2228, 2284 (2022). In response, many States enacted laws prohibiting, restricting, or otherwise regulating abortion. West Virginia was one of them. GenBioPro disagrees with *Dobbs* and the citizens of West Virginia, and it has brought this case to override both. The amici States of Arkansas, Alabama, Florida, Georgia, Idaho, Indiana, Iowa, Kansas, Kentucky, Louisiana, Mississippi, Missouri, Montana, Nebraska, North Dakota, Ohio, Oklahoma, South Carolina, South Dakota, Tennessee, and Texas all prohibit, restrict, or otherwise regulate abortion. Each of the amici States has a sovereign interest in protecting their citizens—born and unborn—and has an interest in ensuring their laws are not preempted under an outlandish interpretation of the Food, Drug and Cosmetic Act (FDCA). This Court should dismiss the complaint.

GenBioPro claims that because mifepristone is mostly prescribed for abortion, West Virginia's ban of *abortion* "constitutes a determination on the part of [its] legislators that a manufacturer [of mifepristone] *cannot* sell its product in the State." Compl. ¶ 90. That supposed

determination, it says, creates "a direct conflict with federal law," which authorizes manufacturers to sell mifepristone. *Id.*

That argument fails for two primary reasons. First, West Virginia's general abortion ban doesn't override the "FDA's judgment" that manufactures may sell mifepristone. Compl. ¶ 83. Instead, West Virginia's law, like the laws of several of the amici States, is a generally applicable prohibition on killing an unborn child regardless of whether death is accomplished by chemical or other means. And where one of the various exceptions to the general prohibition contained in West Virginia law applies—as in cases of medical emergency, sexual assault, or incest—or where a doctor prescribes mifepristone for some non-abortion purpose, West Virginia permits doctors to prescribe mifepristone. Thus, West Virginia hasn't banned mifepristone; it's merely banned a kind of conduct, abortion, for which mifepristone is one means. That's not a preemption problem.

Second, even if West Virginia had banned mifepristone, there still wouldn't be a preemption problem. To the contrary, nothing in the FDCA forecloses a State from banning a drug that federal law otherwise permits. The only kind of state law the Supreme Court has held the FDCA preempts is state law that a manufacturer cannot comply with without violating the FDCA, and it doesn't violate the FDCA for GenBioPro to not sell its drug in West Virginia.

ARGUMENT

I. West Virginia hasn't banned mifepristone, but the killing of unborn children.

Eight months ago, the Supreme Court held that nothing in the Constitution "prohibit[s] the citizens of each State from regulating or prohibiting abortion." *Dobbs*, 142 S. Ct. at 2284. Yet GenBioPro claims that even if the Constitution doesn't prohibit the States from prohibiting abortion, the Food, Drug and Cosmetic Act does. Under that statute, it argues, the FDA approved mifepristone for sale. But when States prohibit their citizens from using mifepristone to

kill an unborn child, GenBioProm reasons, they prevent women from obtaining mifepristone for its intended purpose. And so, it says, state abortion bans like West Virginia's must step aside in favor of the FDA's approval of mifepristone. In other words, GenBioPro argues that federal approval of a product for *sale* preempts any state regulation of its *use*.

The consequences of that theory of preemption are staggering and nonsensical. It would mean that whenever a federal agency authorizes the sale of a product, that authorization becomes a shield that peddlers and users can hide behind to violate state law. It would mean, for example, that when the Environmental Protection Agency approves a pesticide for sale in the United States, *see* 7 U.S.C. 136a, a purchaser can use the pesticide to kill a state-protected animal or plant, reasoning that applying the state prohibition to him would restrict his use of a federally approved product. It would mean that when the FDA approves a drug that when administered in large doses can facilitate assisted suicide, a State cannot prohibit a doctor from assisting suicide with the FDA-approved drug. *But see Gonzales v. Oregon*, 546 U.S. 243 (2006) (holding that the federal government's authority over such drugs does not allow it to prohibit doctors from using those drugs to assist suicide). And as applied to the abortion ban at issue here, it would not only preempt applications of that ban to mifepristone, but also and equally preempt applications of that ban to FDA-regulated and FDA-approved abortion devices. *See* 21 C.F.R. 884.5050, 884.5070 (regulating those devices under the Medical Device Amendments of 1976). Indeed, as all abortions, absent malpractice, are performed with some FDA-regulated drug or device, GenBioPro's theory would mean that by regulating those products, the FDA has inadvertently preempted any state restriction on abortion at any stage.

The consequences of that theory alone are enough to reject it. But it also falls afoul of three basic rules of preemption and administrative law. First, federal law does not preempt state

law when the two regulate separate activities. Second, federal law does not preempt state law when federal and state government regulate even the same activity for distinct purposes. Third, for the FDA to have the preemptive power over state abortion law that GenBioPro would assign to it, Congress would need to assign that power clearly—and it has hardly done so here.

A. The FDA's regulation of mifepristone does not preempt West Virginia's abortion ban because the two regulate different activities.

The FDCA and West Virginia regulate different actors engaging in different conduct in different parts of the drug market. The FDA authorized GenBioPro "to manufacture and market generic mifepristone within the United States." Compl. ¶ 60. Though the FDA's risk evaluation mitigation strategy (REMS) for mifepristone addresses, in part, prescribers, "the requirements apply only to drug manufacturers"; prescribers can't be sanctioned for not complying. Patricia J. Zettler, *Pharmaceutical Federalism*, 92 Ind. L.J. 845, 874 (2017); *see* 21 U.S.C. 333(f)(4)(A), 355(p), 355-1(b)(7) (limiting responsibility for compliance to manufacturers). West Virginia's law, by contrast, applies to practitioners, prohibiting them from inducing abortion by any method, mifepristone or otherwise, subject to various exceptions. GenBioPro remains free to market its drug to wholesalers, wholesalers remain free to sell it to pharmacies, and even doctors remain free to prescribe and pharmacies to dispense it for lawful purposes, whether an abortion permitted under West Virginia's exceptions or other off-label uses.

To be sure, just as West Virginia's abortion ban will be bad for sales of apparatuses used to surgically kill unborn children, it will also be bad for mifepristone sales, given the narrow utility of that drug. But a regulation's indirect effects on a federally regulated activity upstream in the chain of commerce don't make that regulation preempted. That's the lesson of *Virginia Uranium, Inc. v. Warren*. There, federal law regulated uranium "milling"—the purification of mined uranium ore into pure uranium—and preempted state safety regulation of that activity. 139 S.

Ct. 1894, 1900-02 (2019). Fearing the radiation hazards of uranium milling, Virginia cut off the market for milling at the source by banning uranium *mining*, an activity federal law did not regulate. *Id.* at 1901, 1906. Even though the company challenging that law alleged its purpose was to indirectly prevent milling on safety grounds, the Fourth Circuit and Supreme Court affirmed the dismissal of its complaint, reasoning that whatever Virginia's purpose, federal law's silence on mining meant Virginia could regulate mining even to the point of drying up milling. A plurality opinion deemed both Virginia's and Congress's purposes irrelevant given the federal statute's silence on mining. *Id.* at 1902-09 (Gorsuch, J.). A concurring opinion for three Justices was more nuanced, but concluded that "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." *Id.* at 1914-15 (Ginsburg, J., concurring in the judgment). And the same rule applied, the concurring opinion said, "whether the state-regulated activity is upstream or downstream of the federally preempted field." *Id.* at 1915 n.4.

For the same reason, West Virginia's law is not preempted. Indeed, this is an easier case under that rule than *Virginia Uranium*. Like the Virginia uranium mining ban's effects on uranium milling, West Virginia's abortion ban "makes it far less likely, though not impossible," that GenBioPro will have a significant market for its product in West Virginia. *Id.* at 1914. But like Virginia's law, West Virginia does not regulate federally regulated activity; it only regulates abortion providers' prescriptions of mifepristone, an activity "downstream" of the manufacturer sales federal law regulates. *Id.* at 1915 n.4. And unlike *Virginia Uranium*, where the plaintiff alleged Virginia banned mining as a pretext for eliminating milling, GenBioPro doesn't even allege West Virginia banned abortion for the purpose of drying up the market for mifepristone. Rather, everyone agrees West Virginia banned abortion to protect unborn life, no matter the

method used to kill an unborn child. So even if GenBioPro were right that federal regulation of its mifepristone sales made those sales a "federally preempted field" that States can't touch, West Virginia's law would stand because it solely regulates far "downstream" of that field. *Id.*

B. West Virginia's abortion ban isn't preempted because state law and the FDCA have different purposes.

Not only does West Virginia solely regulate conduct downstream of GenBioPro's federally regulated sales, it regulates that conduct for entirely different purposes than the FDA's regulation of mifepristone. The FDA's sole purpose in regulating mifepristone is to ensure that mifepristone does not endanger the woman using it and that it has "the effect it purports . . . to have"—that is, it kills an unborn child. 21 U.S.C. 355(d). The FDA lacks any legal authority to determine whether killing an unborn child should be permitted. Indeed, whatever the FDA's view of the morality of killing unborn children, if a manufacturer seeks approval for an abortion drug that will effectively kill an unborn child, under the FDCA, it cannot disapprove it. *See id.*

By contrast, those questions are the province of the States. It is the States, not the FDA, that may decide whether "respect for and preservation of prenatal life," "the preservation of the integrity of the medical profession," and the answers to other "profound moral question[s]" justify "prohibiting abortion." *Dobbs*, 142 S. Ct. at 2284. West Virginia exercised that judgment here and, subject to several exceptions, prohibited abortion by any method, not because it disagrees with FDA's judgment that mifepristone will kill an unborn child, but because it believes doctors should not kill unborn children in the first place.

That complete mismatch between the purposes for which the FDA regulates mifepristone and the purposes for which West Virginia does suffices to uphold West Virginia's law. Indeed, even if West Virginia's abortion ban directly regulated GenBioPro's sales of mifepristone, West

Virginia's law would still stand. A couple of analogies to laws upheld by the Supreme Court and lower courts illustrate why.

In *Oneok, Inc. v. Learjet, Inc.*, for example, a state-law antitrust suit alleged manipulation of both wholesale and retail natural gas prices. 575 U.S. 373, 376 (2015). The former, but not the latter, were regulated by FERC. *Id.* Even though the suit attacked, in part, the manipulation of federally regulated prices, the Supreme Court rejected the argument that federal regulation preempted the suit, even in part. In explaining why, the Court emphasized "the importance of considering the *target* at which the state law *aims* in determining whether that law is pre-empted." *Id.* at 385. The states under whose antitrust laws the plaintiffs sued did not pass those laws to regulate "natural-gas companies in particular, but rather all businesses in the market-place," and that "broad applicability of state antirust law support[ed] a finding of no pre-emption [t]here." *Id.* at 387. Likewise, West Virginia did not enact its abortion ban to target federally regulated mifepristone; it enacted its abortion ban to prohibit abortions performed by any drug, any device, or any other means.

The Court's decision in a case involving the Federal Meat and Inspection Act even better illustrates the point. Under that Act, the Department of Agriculture regulates the slaughter of livestock to promote "safe meat and humane slaughter." *Nat'l Meat Ass'n v. Harris*, 565 U.S. 452, 456 (2012). That regulation includes, in those States that allow it, the slaughter of horses for human consumption. *See id.* at 467. In striking a California law that regulated the manner of slaughtering all livestock, displacing the federal standard with different and conflicting rules, the Supreme Court distinguished court of appeals cases in several circuits upholding state bans on slaughtering horses for human consumption. *See id.* Those laws, it explained, were not enacted to regulate the "activities that the [federal law] most directly governs," slaughter methods; under

them, "no horses will be ordered for purchase [by slaughterhouses] in the first instance." *Id.* Rather than taking a view on which methods of slaughter were humane or safe, the States that enacted those laws believed horses should not be slaughtered for human consumption altogether. In *Virginia Uranium*, three Justices in the majority likened those laws to Virginia's uranium-mining ban and indicated they were valid. *Va. Uranium*, 139 S. Ct. at 1914 (Ginsburg, J., concurring in the judgment).

West Virginia's abortion ban has the same relation to the FDA's regulation of mifepristone as state horse-slaughter bans had to federal law's regulation of slaughter methods. Rather than attack any particular abortion method—or render a differing judgment on the safety and efficacy questions the FDA has addressed—West Virginia's law says, on entirely distinct moral grounds, that abortions may not be performed altogether.

II. West Virginia hasn't banned mifepristone, but even if it did, the FDCA would not preempt such a ban.

As we've explained, West Virginia's abortion ban does not "constitute[]" a ban of mifepristone, as GenBioPro claims. Compl. ¶ 91. So the Court need not decide whether the FDCA preempts bans of FDA-approved drugs. Yet even if West Virginia had banned mifepristone, the FDCA would not preempt such a ban.

A. The FDCA only preempts state law if manufacturers can't both comply with that state law and the FDCA.

The Supreme Court has repeatedly held that the FDCA only preempts state law if manufacturers cannot both comply with state law and the FDCA. The FDCA's text says as much. FDA approval as we know it today was born in the 1962 amendments to the FDCA, which for the first time required manufacturers to show that their drugs were both safe and effective. *See Wyeth v. Levine*, 555 U.S. 555, 567 (2009). Those amendments "added a saving clause" to the Act. *Id.* at 567. It provided that "[n]othing in the amendments . . . 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." Drug Amendments of 1962, Pub. L. No. 87-781, sec. 202, 76 Stat. 780, 793. Though that saving clause only refers to the 1962 amendments, given those amendments' importance the Supreme Court has read the clause to apply to the FDCA as a whole, saving state law absent "a 'direct and positive conflict' with the FDCA." *Wyeth*, 555 U.S. at 567.

By saying that the FDCA only preempted state law in cases of "direct and positive conflict," Congress indicated it "did not intend FDA approval decisions to preempt state bans on any theory other than impossibility" of complying with both the FDCA and state law. *Zettler*, 92 Ind. L.J. at 868. After all, if all the clause did is incorporate the ordinary rules of implied conflict preemption there would have been no point of enacting the clause. The requirement of a "*direct and positive* conflict" before courts can hold the FDCA preempts state law must mean something more.

And indeed, the Supreme Court has repeatedly held that unless it is impossible to comply with both the FDCA and state law, state law is not preempted. The Supreme Court has heard four cases about FDCA preemption, each involving a state tort suit challenging the sufficiency of a manufacturer's FDA-approved warning label. Those cases follow a consistent pattern. Unless the FDCA prohibits a manufacturer from modifying its FDA-approved label to comply with state tort law, state tort law isn't preempted. *Compare Mut. Pharm. Co. v. Bartlett*, 570 U.S. 472, 486-87 (2013) (finding preemption because modification would violate the FDCA); *PLIVA, Inc. v. Mensing*, 564 U.S. 604, 624 (2011) (same); *with Wyeth*, 555 U.S. at 571, 581 (not finding preemption because modification would not violate the FDCA); *see also Merck Sharp & Dohme*

Corp. v. Albrecht, 139 S. Ct. 1668, 1677-79 (2019) (requiring proof that modification would violate the FDCA).

Thus, in every FDCA case the Supreme Court has heard, the only form of preemption the Court has recognized is the "demanding" doctrine of "[i]mpossibility pre-emption." *Merck*, 139 S. Ct. at 1678 (quoting *Wyeth*, 555 U.S. at 573). Under that doctrine, it's not enough to allege that "the laws of one sovereign permit an activity that the laws of the other sovereign restrict or even prohibit." *Id.* Instead, manufacturers must show that it's "impossible . . . to comply with both state and federal requirements." *PLIVA*, 564 U.S. at 618.

GenBioPro cannot meet that standard here, and as a result, its claims fail as a matter of law. To start, the FDCA doesn't speak to—let alone mandate—abortion practitioners' prescribing FDA-approved drugs. Regulating that is in the States' domain. *See Dobbs*, 142 S. Ct. at 2284 (returning that question to "the citizens of each State . . . and their elected representatives"); 21 U.S.C. 396 (providing that nothing in the FDCA shall be construed to regulate providers' prescription choices). So GenBioPro can hardly argue that West Virginia's abortion ban forces those it regulates to violate federal law.

Yet even accepting GenBioPro's gross mischaracterization of West Virginia's abortion ban as somehow banning mifepristone, GenBioPro's impossibility preemption argument fares no better. Federal law may *allow* manufacturers to sell mifepristone for elective abortions, but it does not *mandate* GenBioPro to sell mifepristone. *See* William M. Janssen, *A "Duty to Continue Selling Medicines*, 40 Am. J.L. & Med. 330, 363 (2014) ("Existing law, however creatively repackaged, does not impose upon pharmaceutical manufacturers a 'duty' to keep selling their medicines"). So it is possible for GenBioPro to comply with both the FDCA and any West Virginia ban: it need only market—or not, as it chooses—mifepristone in States where it is legal, in

compliance with both federal and state law, and not market mifepristone in States where it is not, again in compliance with both federal and state law. No "direct and positive conflict" with the FDCA arises in that circumstance. This Court should therefore reject GenBioPro's claim and dismiss the complaint.

B. A ban of mifepristone would not be obstacle-preempted.

Yet suppose, contrary to the Supreme Court's decisions and the text of the statute, that other, less direct conflicts would suffice to preempt state law—specifically that the less demanding doctrine of obstacle preemption applies. Under that doctrine, state laws that "stand[] as an obstacle to the accomplishment and execution of the full purposes of Congress" may be preempted. *Hines v. Davidowitz*, 312 U.S. 52, 67 (1941). Even if the FDCA's saving clause permitted application of that doctrine, the FDCA still would not preempt a mifepristone ban. That's because states can add additional layers of regulations that complement—not contradict—the FDCA's safety goal. And the FDCA doesn't pass on the moral questions underlying West Virginia's abortion ban at all.

Wyeth demonstrates why. There, the Court entertained an argument that obstacle preemption displaced state tort law that required manufacturers to add warnings to their FDA-approved labels—and discourage FDA-approved uses of their drugs. Specifically, the tort suit in *Wyeth* claimed that the manufacturer should have instructed doctors not to administer a drug by a certain type of intravenous injection, 555 U.S. at 560, while the FDA-approved label said such injections could be performed with "extreme care" and detailed how to perform them, *id.* at 560 n.1.

Much like GenBioPro here, Wyeth claimed that "the FDCA establishes both a floor and a ceiling for drug regulation," *Wyeth*, 555 U.S. at 573, and that the FDA's label approval represented "a precise balancing of risks and benefits . . . that leaves no room for different state-law

judgments," *id.* at 575. The Court disagreed. Far from interfering with an FDA judgment that the disputed type of intravenous injection was safe and beneficial, the Court viewed state law as "a complementary form of drug regulation," *id.* at 578, that "offers an additional, and important, layer of consumer protection," *id.* at 579, by "uncover[ing] unknown drug hazards," *id.* Though the dissent contended that state-law regulation of drug labeling threatened to deny patients "potentially lifesaving benefits" by making manufacturers warn against uses the FDA deemed beneficial on balance, *id.* at 626 (Alito, J., dissenting), the majority said the FDCA had one primary purpose—safety, not a "precise balancing of risks and benefits," *id.* at 575 (maj. op.). Because "an additional . . . layer" of safety regulation only furthered Congress's safety objectives, *id.* at 579, even state tort law that contradicted FDA's safety determinations, as the suit in *Wyeth* did, was no obstacle to achieving those aims.

Likewise, a mifepristone ban, were a State to enact one, would not pose an obstacle to the accomplishment of the FDCA's purposes. Such a law would only be different in degree from the claim allowed in *Wyeth*, where state tort law effectively prohibited one of a drug's FDA-approved uses. Whether state law prohibits a drug as unsafe in whole or part, it is still serving the FDCA's overriding safety objective, not frustrating it.[1]

For though GenBioPro may claim otherwise, where the FDCA is concerned there is no drug-access objective on the other side of the balance. The FDCA, as Justice Thomas has observed, does "not give drug manufacturers an unconditional right to market their federally

[1] For example, a state ban of particularly harmful opioids, which the FDA has been slow to regulate, would only advance the FDCA's purposes. And while one district court has held the FDCA likely preempts state bans of opioids, implausibly claiming the purpose of the FDCA's restrictive drug-approval regime is "to make drugs available," *Zogenix, Inc. v. Patrick*, 2014 WL 1454696, at *2 (D. Mass. Apr. 15, 2014) (granting preliminary injunction), the bulk of authority holds the FDCA does not preempt state regulation of opioids. *See* Catherine M. Sharkey, *The Opioid Litigation: The FDA is MIA*, 124 Dick. L. Rev. 669, 680-86 (2020).

approved drug at all times"; it merely says they "may not market a drug without federal approval." *Wyeth*, 555 U.S. at 592 (Thomas, J., concurring). Nor does it impose a duty on manufacturers to sell their drugs; in none of the many suits alleging such a duty "did any court unearth such an obligation." Janssens, 40 Am. J.L. & Med. at 364. Much less does it require manufacturers to sell their drugs "at an affordable price, or in a manner that ensures easy access." Lars Noah, *State Affronts to Federal Primacy in the Licensure of Pharmaceutical Products*, 2016 Mich. St. L. Rev. 1, 11-12. Rather, the FDCA is "a fairly stringent barrier to entry," *id.* at 11, "designed to restrict rather than promote ready patient access," *id.* at 9.

Nor, even, is the FDCA particularly geared toward securing drugs' benefits in the abstract. With rare exceptions, as when the FDA reviews an application for expedited approval of a drug that treats life-threatening diseases, *see* 21 U.S.C. 356, the FDCA doesn't require the FDA to find a drug is beneficial. All the FDA must find in the way of benefit is that a drug "will have the effect it purports or is represented to have" by its manufacturer. 21 U.S.C. 355(d). Whether that effect is beneficial is not the FDA's call. The FDA does not pass on whether killing an unborn child is moral, any more than it passes on whether artificially reducing frown lines with Botox is a good idea. Those are questions of medical practice and are left to the States, whose "historic police powers," *Wyeth*, 555 U.S. at 565, have always included "the regulation of health and the practice of medicine," *Lambert v. Yellowley*, 272 U.S. 581, 593 (1926), and which *Dobbs* held includes the power to regulate abortion. West Virginia, like the Amici States, exercised that power. And were the FDA to attempt to override that judgment, *it*, not the States, would be acting outside its authority. For "the FDCA expressly disclaims any intent to directly regulate the practice of medicine." *Buckman Co. v. Plaintiffs' Legal Comm.*, 531 U.S. 341, 350-51 (2001) (citing 21 U.S.C. 396).

C. GenBioPro's counterarguments fail.

Despite all this, GenBioPro claims that mifepristone is uniquely immune from state regulation because it is subject to a risk evaluation and mitigation strategy, or REMS. A REMS is nothing more than a dispensation protocol that the FDA is required to adopt if it finds a drug would be *too* risky for use absent risk mitigation, *see* 21 U.S.C. 355-1(a), (e), as it did in the case of mifepristone. A set of safety guardrails for exceptionally risky drugs is an unlikely place to find preemption of further state regulation. Yet GenBioPro claims the REMS statute, unlike the FDCA generally, embodies the precise risk/access balancing the Supreme Court found lacking in the FDCA in *Wyeth*. Specifically, because the REMS statute instructs the FDA not to adopt a REMS that is "unduly burdensome on patient access to the drug," 21 U.S.C. 355-1(f)(2)(C), GenBioPro claims that the REMS statute pursues "two competing values: the safety of the drug and patient access," Compl. ¶ 50, and concludes that FDA's mifepristone REMS is a "'ceiling' on permissible regulation of mifepristone" that contains "the *only* restrictions that may be imposed on a patient's access to . . . mifepristone," *id.* ¶ 82.

That argument confuses a limit on the FDA's power with a grant of preemptive authority. The REMS statute merely prohibits the FDA from adopting a REMS that restricts access more than necessary to address a particular "serious risk" the FDA has identified. 21 U.S.C. 355-1(f)(1)(A), (f)(2)(A). Arguing that that prohibition preempts state regulation that reduces access on other grounds is like arguing that whenever Congress instructs an agency that regulates a product for *one* purpose not to impose unnecessary cost, it thereby preempts state regulation for any other purpose that might increase the same product's cost. The FDA isn't directed to calculate an optimal level of access for a drug, taking into account all possible grounds for regulating it. It's merely directed to mitigate particular kinds of grave risks in a manner "commensurate with the specific serious risk" it's trying to mitigate. 21 U.S.C. 355-1(f)(2)(A); *id.* 355-1(b)(4)-

(5) (defining "serious risk" as a "risk of a serious adverse drug experience" and narrowly defining "serious adverse drug experience"). That doesn't preempt a separate sovereign from determining that a different risk—or moral and ethical concerns—justifies restricting access. Indeed, *Wyeth* suggests it doesn't even preempt a separate sovereign from reaching a different conclusion about the same risk. After all, that's precisely what happened in *Wyeth*: the FDA thought a method of administration was safe and beneficial enough to allow, but a state court concluded the opposite.

Finally, GenBioPro may claim, like some of the academics who made similar arguments after *Dobbs*, that the Supreme Court's FDCA preemption cases already bar state bans of an FDA-approved drug. Those academics point to *Bartlett*, where the Supreme Court held a tort claim that required a manufacturer to modify its label in a way that violated the FDCA was preempted, rejecting the argument compliance with the FDCA and tort law was possible because the manufacturer could simply not sell its drug in the relevant state altogether. *See Bartlett*, 570 U.S. at 488. That implies, these academics say, that "states cannot ban FDA-approved drugs." David S. Cohen et al., *The New Abortion Battleground*, 123 Colum. L. Rev. 1, 62 (2022).

That claim badly overreads *Bartlett*. In *Bartlett*, the Court explained that a market participant's ability to "simply leav[e] the market" doesn't save state laws that direct market participants to break federal law. *Bartlett*, 570 U.S. at 489. If it did, "impossibility pre-emption would be all but meaningless." *Id.* at 488 (internal quotation marks omitted). But it hardly follows that whenever federal law regulates a product, States cannot ban it. For example, in the case that originated impossibility preemption, the Supreme Court explained that if federal law banned avocados with more than 7% oil content, California could not require a minimum of 8% avocado oil content—for it would be impossible for an avocado importer to comply with both. *Fla. Lime*

& Avocado Growers, Inc. v. Paul, 373 U.S. 132, 143 (1963). That is true even though an importer could "comply" by not importing avocados into California. But even though California could not invoke the ability to voluntarily exit its market as a defense, it doesn't follow that the federal maximum on avocado oil would preempt a total ban of avocados. That would flout the blackletter rule that there is no impossibility preemption "where the laws of one sovereign permit an activity"—in the hypothetical, importing avocados with oil below the federal limit—"that the laws of the other sovereign restrict or even prohibit." *Merck*, 139 S. Ct. at 1678.

So too, the FDCA, like any federal statute, preempts state law that compels regulated actors to violate the FDCA—even if the regulated actors could technically comply with both if they "simply ceased acting" in either direction. *Bartlett*, 570 U.S. at 488. But where state law directs a regulated actor to do just that—cease acting—the FDCA does not preempt state law, because the FDCA does not require manufacturers to sell their approved drugs in the first place.

III. The FDA's regulation of mifepristone does not preempt West Virginia's abortion ban under the major questions doctrine.

There is yet another reason that the FDA's regulation of mifepristone cannot preempt West Virginia's abortion ban: the major questions doctrine. Under that doctrine, Congress must give agencies "clear congressional authorization," *West Virginia v. EPA*, 142 S. Ct. 2587, 2609 (2022) (quoting *Util. Air Reg. Grp. v. EPA*, 573 U.S. 302, 324 (2014)), "if it wishes to assign to an agency decisions of vast . . . political significance," *id.* at 2605 (quoting *Util. Air*, 573 U.S. at 324). GenBioPro's basic contention is that by authorizing the FDA to issue a REMS for mifepristone, Congress "delegate[d] to FDA exclusive authority" to decide the "restrictions that may be imposed on a patient's access to . . . mifepristone," and thus to preempt, if FDA chooses, any State's ban of abortion. Compl. ¶ 82.

To say the least, that reading of the REMS statute assigns a question of vast political significance to the FDA. Whether States should allow or prohibit abortion, the Court acknowledged in the very first sentence of *Dobbs*, "presents a profound moral issue on which Americans hold sharply conflicting views." *Dobbs*, 142 S. Ct. at 2240. GenBioPro would have the Court hold that when Congress enacted Section 355-1 in 2007 by votes of 405-7 in the House and unanimous consent in the Senate, it tacitly decided that should *Roe* be overturned, the sole entity that would get to decide that profound moral question is the FDA. That claim strains credulity and triggers the major questions doctrine.

Under that doctrine, GenBioPro easily loses. GenBioPro's claim is that by instructing the FDA to not let any drug-risk mitigation strategy it chose to adopt for mifepristone unnecessarily burden drug access, *see* 21 U.S.C. 355-1(f)(2), Congress implicitly gave the FDA exclusive authority to decide how much mifepristone access could be restricted. The best view is that Section 355-1 clearly says nothing of the kind. But at minimum, there is no "clear congressional authorization," *West Virginia*, 142 S. Ct. at 2609, for GenBioPro's reading. The only power Section 355-1 expressly delegates the FDA is to mitigate serious risks, 21 U.S.C. 355-1(f)(1)(A), and to make sure that *its* mitigation efforts do not, "considering such risk," "unduly burden[]" access," *id.*, 355-1(f)(2)(C). The FDA has no power under Section 355-1 to regulate for other purposes, such as the moral grounds that underly West Virginia's abortion ban, and accordingly, no power to decide how much access may be restricted for other purposes. At the very least, the statute can be read in that way, and because it can, under the major questions doctrine it must.

Indeed, the Supreme Court has already rejected a similar argument under the major questions doctrine. In *Gonzales v. Oregon*, the Attorney General, who enforced the Controlled Substances Act, opined that it would violate the CSA for physicians to use federally controlled

substances to assist suicide, and that physicians who did so would therefore be denied registration under the CSA to prescribe controlled substances. 546 U.S. at 253-54. He relied, not implausibly, on provisions of the CSA that said drugs listed under it may only be prescribed for "a legitimate medical purpose," *id.* at 257, and reasoned that assisted suicide wasn't one, *id.* at 254. Though 49 States prohibited assisted suicide and "prominent medical organizations" deemed it unethical, *id.* at 272, the Court held the CSA did not delegate the Attorney General the authority to decide whether assisted suicide was a legitimate medical purpose in the first place. Given "[t]he importance of the issue of physician-assisted suicide," *id.* at 267, the Court held the claim that the CSA "effectively displace[d] the States' general regulation of medical practice," *id.* at 270, "through an implicit delegation in the CSA's registration provision [wa]s not sustainable," *id.* at 267. Instead, the Court narrowly read the "legitimate medical purpose" provision to only prohibit "illicit drug dealing and trafficking." *Id.* at 270.

This case presents a very similar claim of regulatory authority, but with a much weaker statutory hook. Like the Attorney General's regulation, GenBioPro's reading of the FDCA would authorize the FDA to preempt States' regulation of medical practice on the most sensitive of subjects. But where the Attorney General at least had statutory authority, which the Court had to strain to read narrowly, to say whether a prescription was for a legitimate medical purpose, the only source of authority GenBioPro can point to for FDA's supposed authority to decide abortion is a legitimate medical purpose is a limit on the *FDA's* authority to mitigate the risks of mifepristone.

CONCLUSION

The Court should grant Defendants' motion to dismiss.

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Respectfully submitted,

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