No. 23-2194

UNITED STATES COURT OF APPEALS
FOR THE FOURTH CIRCUIT

GENBIOPRO, INC.,
Plaintiff-Appellant,

v.

KRISTINA RAYNES, in her official capacity as
Prosecuting Attorney of Putman County, and
PATRICK MORRISEY, in his official capacity as
Attorney General of West Virginia,
Defendants-Appellees,

and

MARK A. SORSAIA, in his official capacity as
Prosecuting Attorney of Putman County,
Defendant.

On Appeal from the United States District Court for the
Southern District of West Virginia,
No. 3:23-cv-00058 (Hon. Robert C. Chambers)

Amicus Brief of Arkansas and 22 other States in Support of Defendants-Appellees

TIM GRIFFIN
Arkansas Attorney General
NICHOLAS J. BRONNI
Arkansas Solicitor General
ASHER STEINBERG
Senior Assistant Solicitor General
OFFICE OF THE ARKANSAS
ATTORNEY GENERAL
323 Center Street, Suite 200
Little Rock, Arkansas 72201
(501) 682-6302
Nicholas.Bronni@arkansasag.gov

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Two years 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.*, 597 U.S. 215, 222 (2022). Many States, including West Virginia, responded with laws prohibiting, restricting, or otherwise regulating abortion. GenBioPro disagrees with *Dobbs* and West Virginia's decision, and it brought this case to override both. The amici States of Arkansas, Alabama, Alaska, Florida, Georgia, Idaho, Indiana, Iowa, Kansas, Kentucky, Louisiana, Mississippi, Missouri, Montana, Nebraska, North Dakota, Oklahoma, South Carolina, South Dakota, Tennessee, Texas, Utah, and Wyoming all prohibit, restrict, or otherwise regulate abortion. Each amicus State has a sovereign interest in protecting its citizens—born and unborn—and in ensuring their laws aren't preempted by an outlandish interpretation of the Food, Drug and Cosmetic Act (FDCA).

SUMMARY OF ARGUMENT

GenBioPro claims that West Virginia can't ban abortion because that would incidentally restrict access to a drug regulated by the FDA. In particular, GenBioPro claims that the FDA's modest mifepristone safety regulations preempts all state laws that affect mifepristone access—a view that would preempt a host of state laws regulating everything from state laws regulating the practice of pharmacy and medicine to state malpractice law. Alternatively, GenBioPro argues

West Virginia's abortion ban is preempted because it conflicts with the supposed federal objective of facilitating mifepristone access.

The district court correctly rejected those far-fetched claims. As to field preemption, federal law that regulates something for one purpose doesn't displace state laws that regulate the same thing for an entirely different purpose—as GenBioPro's own citations make clear. Here, the FDA has regulated mifepristone to lessen the risks for women taking it, while West Virginia only incidentally regulates that drug as part of a generally applicable abortion ban that protects the unborn. Moreover, federal law and West Virginia don't even regulate the same subject: the FDA's mifepristone regulation modestly restricts how mifepristone may be dispensed; West Virginia regulates the prior question of when an abortion may be performed. And even if that weren't true, the Food Drug and Cosmetic Act's preemption savings clause makes clear there's no preemption where—like here—there is no "direct and positive conflict" between state and federal law.

As for conflict preemption, GenBioPro paradoxically claims that the FDA's minimal safety restrictions on dispensing mifepristone are designed to promote access and that West Virginia's abortion ban is preempted because it frustrates that purpose. But that argument fails from the get-go because the FDCA's savings clause limits that Act's preemptive reach to state laws that require manufacturers to violate its terms and GenBioPro can't claim that's true here. And even if that

weren't the case, West Virginia's law still wouldn't be preempted because far from mandating access and thereby preempting state laws incidentally affecting it, the FDCA merely directs the FDA not to unduly burden access with *its* safety regulations.

West Virginia's generally applicable abortion ban doesn't conflict with the FDA's regulation of mifepristone, and the judgment below should be affirmed.

ARGUMENT

I. West Virginia's abortion ban isn't field preempted.

GenBioPro claims that the FDA's approval of mifepristone, subject to minimal "safe-use elements," occupies the entire field of state law that might impinge on mifepristone access—including a generally applicable abortion ban. Appellant's Br. 26-42, 52-59. That argument fails because FDA drug approvals don't preempt state laws unless it's impossible to comply with both the FDA's directives and state laws, and that's not true here. Indeed, it doesn't violate federal law not to sell mifepristone. Recognizing that, GenBioPro pivots and paradoxically argues that because mifepristone is *less* safe than other drugs and Congress conditioned its approval on certain safety requirements, States have less authority to regulate access to mifepristone than other drugs.

That makes no sense, and it's not what the statute says. But even if the FDA's post-approval regulation of less-safe drugs occupied some regulatory field,

that field would be far narrower than GenBioPro suggests. The FDA regulates mifepristone post-approval for the sole purpose of avoiding "serious adverse drug experience[s]" for the women who use it. 21 U.S.C. 355-1(f)(1)(A). That regulation doesn't displace generally applicable state laws that incidentally impacts access—a field that would include everything from the regulation of the practice of pharmacy and medicine to, as here, a generally applicable abortion ban.

A. West Virginia's abortion ban isn't field-preempted because it and the FDCA have different purposes.

"Field preemption occurs when federal law occupies a field of regulation so comprehensively that it has left no room for supplementary state legislation." *Murphy v. NCAA*, 584 U.S. 453, 479 (2018) (internal quotation marks omitted). Accordingly, to decide whether a state law is preempted, courts first must "identify the field in which" federal law regulates and assess whether state law is regulating in the same field. *Kansas v. Garcia*, 140 S. Ct. 791, 804 (2020). Then, they ask whether federal regulation in that field is so comprehensive that it displaces "even complementary state regulation." *Arizona v. United States*, 567 U.S. 387, 401 (2012). If state and federal law are regulating in different fields, there's no need to answer the second question. *See, e.g.*, *Garcia*, 140 S. Ct. at 804-05.

To define the field, courts look to the federal regulation's purpose and use it as a key metric for limiting preemption. For example, in *Ray v. Atlantic Richfield Co.*, one of the cases GenBioPro claims supports field preemption here, *see*

Appellant's Br. 34-36, the Supreme Court distinguished a series of cases upholding state laws regulating vessels for "other purposes" than federal law's "vessel safety regulations." 435 U.S. 151, 164 (1978). The Court did "not question in the slightest the prior cases holding that [federally licensed] vessels must conform to reasonable, nondiscriminatory . . . measures imposed by a State." *Id.* (alteration omitted) (internal quotation marks omitted). What field preemption precluded, the Court explained, were only scenarios where federal vessel regulation was "addressed to the object also sought to be achieved by the challenged state regulation." *Id.*

Later cases also underscore the point that regulatory purpose helps define the outer limit of field preemption. In *Oneok, Inc. v. Learjet, Inc.*, for example, natural gas producers claimed that FERC's regulation of wholesale natural gas prices preempted a state-law antitrust suit that alleged manipulation of both wholesale and retail natural gas prices. 575 U.S. 373, 376 (2015). Even though the suit concerned the manipulation of federally regulated prices, the Supreme Court held federal regulation didn't preempt the suit. The Court said its field-preemption precedents "emphasize the importance of considering the *target* at which the state law *aims* in determining whether that law is pre-empted." *Id.* at 385. It further explained that "a single physical action . . . could be the subject of many different laws," *id.* at 386, and that "no one could claim that FERC's regulation of this physical activity for purposes of wholesale rates forecloses every other form of state

regulation that affects those rates," *id.* at 386-87. Because the state's antitrust law was "not aimed at natural-gas companies in particular, but rather all businesses in the marketplace," *id.* at 387, the Court held the suit fell outside the preempted field.

That principle resolves GenBioPro's field-preemption claim. The FDA's risk evaluation and mitigation strategy for mifepristone regulates mifepristone for the sole purpose of "mitigat[ing] a specific serious risk" from taking mifepristone, 21 U.S.C. 355-1(f)(1)(A), namely "serious complications" suffered by women who take it.[1] That limited writ to subject its approval to "safe-use elements" doesn't include the power to decide whether killing an unborn child should be permitted.

By contrast, West Virginia's law is a generally applicable prohibition of abortion—irrespective of method, whether chemical or surgical—enacted to "protect[] unborn lives." W. VA. Code 16-2R-1. That is, West Virginia didn't enact that ban because it disagrees with FDA's assessment of mifepristone's risks to women, or FDA's judgment that mifepristone will kill an unborn child, but because West Virginia believes that doctors should not kill unborn children in the first place. So like in *Oneok*, where the state didn't enact its antitrust law to target federally regulated gas prices, West Virginia didn't enact its abortion ban to target

[1] *REMS Single Shared System for Mifepristone 200 mg* at 1, FDA (Mar. 2023) ("2023 Mifepristone REMS"), https://perma.cc/5CR7-8YUM.

federally regulated mifepristone; it enacted its abortion ban to prohibit abortions performed by any drug, device, or other means.

That mismatch between the FDA's and West Virginia's respective purposes for regulating mifepristone means West Virginia's law isn't preempted. As the district court aptly explained, JA273 & n.11, the Supreme Court's discussion of why federal regulation of livestock slaughter doesn't preempt state laws that ban horse slaughter neatly illustrates the point. 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 (2017). That regulation includes, in those States that allow it, the slaughter of horses for human consumption. *See id.* at 467. In striking down a California law that regulated the manner of slaughtering all livestock, the Supreme Court distinguished cases 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; instead, under those laws, "no horses will be ordered for purchase [by slaughterhouses] in the first instance." *Id.* Rather than taking a view on which methods were humane or safe, the States that enacted those laws believed horses should not be slaughtered for human consumption altogether.

West Virginia's abortion ban has the same relation to the FDA's regulation of mifepristone. 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.

B. The FDA's regulation of mifepristone and West Virginia's abortion ban regulate different activities.

West Virginia's abortion ban also falls outside any preempted field because the FDA 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." JA315. Although the FDA's risk evaluation mitigation strategy for mifepristone addresses, in part, prescribers, "the requirements apply only to drug manufacturers"; prescribers can't be sanctioned for noncompliance. 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 compliance responsibility to manufacturers). West Virginia's law, by contrast, regulates practitioners, prohibiting them from inducing abortion by any method, 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, West Virginia's abortion ban will reduce mifepristone sales, given that drug's narrow use. But a regulation's indirect effects on upstream federally regulated commercial activity doesn'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 didn't regulate. *Id.* at 1901, 1906. Even though the company challenging that law alleged it was intended to indirectly prohibit milling for safety reasons, the Supreme Court affirmed the dismissal of the 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 Virginia's purposes irrelevant given the federal statute's silence on mining. *Id.* at 1902-09 (Gorsuch, J.). A concurring opinion for three Justices suggested the state's purpose for regulating could matter, 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 mining ban's effects on uranium milling, West Virginia's abortion ban "makes it far less likely" 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 that 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 can't plausibly claim that West Virginia banned abortion to dry up the mifepristone market. Rather, everyone agrees West Virginia banned abortion to protect unborn life regardless of abortion method. 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.*

GenBioPro nevertheless claims that West Virginia and the FDA actually do regulate the same field because the FDA's risk evaluation and mitigation strategy places extremely modest requirements on mifepristone prescribers, Appellant's Br.

64, 69—even though only GenBioPro, and not the prescribers, can be sanctioned for non-compliance. But as the district court explained, those "logistical safety standards" on mifepristone's dispensation, JA273 n.12, are far afield from West Virginia's regulation of "*when* an abortion may be performed, without touching [on] *how*," JA273. The main requirement the FDA's REMS imposes on mifepristone prescribers is that they give their patients an informed consent form. *See* 2023 Mifepristone REMS, *supra* note 2, at 8, 10; Appellant's Br. 14. Contrary to what GenBioPro claims, it says nothing about "which patients may access [mifepristone," or "under what circumstances." Appellant's Br. 64. It only addresses "*how* medication abortion is to be performed." JA273.

C. The FDA's post-approval regulation of less-safe drugs doesn't give rise to field preemption.

West Virginia's generally applicable abortion ban is far outside the field of mifepristone-specific safety regulation addressed by the FDA. But even if West Virginia and the FDA did regulate the same field, the FDA's REMS still wouldn't preempt West Virginia's law because the Food Drug and Cosmetic Act (FDCA) only preempts state laws where manufacturers cannot comply with both FDA regulations and state law, which is not the case here.

The FDCA's text limits its preemptive reach to impossibility preemption. FDA approval as we know it today was born in the 1962 amendments to the FDCA. *See Wyeth v. Levine*, 555 U.S. 555, 567 (2009). Those amendments

"added a saving clause" to the Act. *Id.* It provides 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 (1962). Though that saving clause only refers to the 1962 amendments, the Supreme Court has held that clause to applies to the entire FDCA, saving state law absent "a 'direct and positive conflict' with the FDCA." *Wyeth*, 555 U.S. at 567.

That "1962 saving clause," as the district court held, "foreclose[s] any argument for complete field preemption." JA275. By providing for preemption only in cases of "direct and positive conflict," Congress made clear 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 the clause merely incorporated the ordinary rules of implied preemption—or even conflict preemption—it would serve no purpose. So the requirement of a "*direct and positive* conflict" must mean something more.

And indeed, as the district court explained, "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." JA275-76. 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 wouldn't violate the FDCA); *see also Merck Sharp & Dohme Corp. v. Albrecht*, 587 U.S. 299, 313-15 (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*, 587 U.S. at 314 (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 offers two responses. Neither is availing. First, relying on a single case interpreting a savings clause in a different and unrelated statute, *United States v. Locke*, 529 U.S. 89 (2000), it argues that savings clauses are somehow incapable of disclaiming field preemption, even if—as is the case of the FDCA's

savings clause—that's what they literally say. Appellant's Br. 57-59. But *Locke* says nothing of the kind. As the district court explained, the savings clause in *Locke* was a narrow one that only "le[ft] room for complementary state action in a specified area," JA276—namely, "imposing any additional liability or requirements with respect to . . . the discharge of oil," *Locke*, 529 U.S. at 104 (quoting 33 U.S.C. 2718(a)(1)(A)). *Locke* merely held the state law at issue there fell outside that narrow carve-out from an otherwise preempted field. The FDCA's savings clause, by contrast, isn't limited to any particular type of state regulation. Instead, it saves "*any* provision of State law which would be valid in the absence" of the FDCA absent "a direct and positive conflict."[2] 76 Stat. at 793.

Second, GenBioPro attempts to distinguish cases like *Wyeth* by arguing that the FDA's normal approval process is less comprehensive than its regulatory oversight over less-safe drugs like mifepristone, and that only the latter gives rise to field preemption. Appellant's Br. 55-57. It's true that the FDA has post-approval authorities over drugs like mifepristone that it doesn't have over ordinary drugs. But when it comes to cases like *Wyeth*, that's a distinction without a difference.

[2] GenBioPro also string-cites *Morales v. Trans World Airlines, Inc.* for the proposition that "Congress does not 'undermine' a 'carefully drawn statute through a general saving clause.'" Appellant's Br. 59 (quoting 504 U.S. 374, 385 (1992)). But *Morales* merely held that a "general 'remedies' saving clause cannot be allowed to supersede [a] specific substantive pre-emption provision." *Morales*, 504 U.S. at 385. There is no express preemption provision here.

For the tort claims at issue in those cases addressed drug labeling, a subject firmly within the FDA's ordinary regulatory authority. Yet the Supreme Court still held that the FDA's broad authority over labeling didn't occupy the field of drug-labeling regulation.

And the FDA's oversight over mifepristone prescribing and dispensation is hardly more comprehensive than its oversight over labeling. *Compare Wyeth*, 555 U.S. at 568 (discussing FDA's oversight over the exact language in drug labels) *with* 21 U.S.C. 355-1(f)(1). If the FDA's plenary control over drug labeling was insufficient to displace state tort claims that attacked drug labels, its oversight over mifepristone prescribing and dispensation is insufficient to displace any law that indirectly impinges on prescribing and dispensing mifepristone.

II. West Virginia's abortion ban isn't barred by conflict preemption.

West Virginia's abortion ban also isn't barred by conflict preemption. Conflict preemption normally exists either where it's impossible to comply with both state and federal law, or where state law is an obstacle to federal law's purposes. Here, however, both the FDCA's savings clause and the Supreme Court's FDCA preemption cases limit conflict preemption to impossibility preemption. And it's not impossible to comply with West Virginia's abortion ban and the FDA's mifepristone regulation, because that regulation doesn't mandate anyone to sell

mifepristone. Yet even if obstacle preemption could apply in this context, West Virginia's abortion ban isn't an obstacle to the purposes of FDA regulation.

In claiming otherwise, GenBioPro says one of the purposes of FDA regulation of less-safe drugs like mifepristone is to expand access to them. That defies common sense. The FDA's safety regulation of less-safe drugs reduces access; it doesn't increase it. And this Court should reject GenBioPro's bizarre attempt to twist a statutory instruction to the FDA to mitigate access burdens from its own regulation into a mandate to promote access generally. There is no conflict.

A. It isn't impossible to comply with both West Virginia law and the FDA's mifepristone REMS.

As discussed, the only form of preemption the FDCA provides is the "demanding" doctrine of "[i]mpossibility pre-emption." *Merck*, 587 U.S. at 314 (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." *PLIVA*, 564 U.S. at 618.

GenBioPro cannot meet that standard. The FDA's mifepristone REMS does not require anyone to manufacture, sell, prescribe, or dispense mifepristone; it only says that if they do, they must sell it under a certain label and sign certain forms. *See* Appellant's Br. 14 (summarizing the REMS's requirements); 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's possible for GenBioPro and those who buy mifepristone from it to comply with both West Virginia's abortion ban and the REMS. In the bulk of cases where abortion is illegal, prescribers may not prescribe mifepristone to cause an abortion, and in the cases where one of the exceptions to the ban permits abortion, prescribers that choose to use mifepristone to cause an abortion must follow the REMS's protocols. In either scenario, GenBioPro and prescribers have complied with both the REMS and West Virginia law.

GenBioPro doesn't claim that it's impossible to comply with both. Instead, GenBioPro claims that the only way for it to do so is to largely stop selling in West Virginia. Appellant's Br. 43. That may be true, but it doesn't mean that West Virginia's law is preempted. In arguing that it does, GenBioPro solely relies on the Supreme Court's decision in *Bartlett.* There, the Supreme Court held a tort claim that required a manufacturer to modify its label in a way that violated the FDCA was preempted. In reaching that conclusion, it rejected the argument that compliance with the FDCA and state tort law was possible because the manufacturer could simply stop selling its drug in the relevant state. *See Bartlett*, 570 U.S. at 488. GenBioPro claims that means that if the only way to avoid a conflict between

state and federal law's commands is to stop selling a product, federal law preempts state law. Appellant's Br. 43.

That 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 mandate market participants 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 so long as federal law regulates a product, States can't ban it. For example, in the case where impossibility preemption began, the Supreme Court explained that if federal law banned avocados with more than 7% oil content, California law couldn't require a minimum of 8%, because it would be impossible to comply with both requirements. *Fla. Lime & Avocado Growers, Inc. v. Paul*, 373 U.S. 132, 143 (1963). That's true even though an importer could "comply" by not importing avocados into California. But even though California couldn't 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 avocado ban. 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*, 587 U.S. at 314.

So too, the FDCA, like any federal statute, preempts state laws mandating regulated actors 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 manufacturer to stop selling its drug, the FDCA doesn't preempt state law, because the FDCA doesn't require manufacturers to sell their drugs in the first place.

B. West Virginia's abortion ban is not obstacle-preempted.

Even if the FDCA allowed for obstacle preemption, West Virginia's law still wouldn't be preempted. Under obstacle preemption, 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). West Virginia's law doesn't pose an obstacle to the FDCA's purposes. That's because the FDCA's overriding aim is safety, not access to drugs. And the FDCA doesn't pass on the moral questions underlying West Virginia's abortion ban.

Wyeth demonstrates why there's no obstacle preemption here. 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. 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, an abortion ban poses no obstacle to the accomplishment of the FDCA's purposes. As applied to mifepristone, such a law merely differs in degree

from the claim allowed in *Wyeth*. There, state tort law effectively prohibited one of a drug's FDA-approved uses; here, state law prohibits, with exceptions, mifepristone's sole FDA-approved use, abortion. Whether state law effectively prohibits a drug's use in whole or part, it doesn't frustrate the FDCA's objectives.

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 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.

C. GenBioPro's counterarguments fail.

Despite all this, GenBioPro claims that mifepristone is uniquely immune from state regulation because it's 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 "a balance between access and burden," Appellant's Br. 47, and concludes that States may not "impos[e] restrictions FDA determined were unnecessary to assure safety," *id.* at 48.

That claim has little, if any, textual support. Indeed, the claim is so unsupported that GenBioPro falsely attributes the purpose of expanding access to the preamble of the bill that created FDA's REMS authority, claiming it states the purpose "to expand access to life-saving drugs that would not be available to patents but for FDA's 'enhance[d]' 'postmarket authorit[y].'" Appellant's Br. 45 (quoting 121 Stat. 823, 823 (2007)). But the preamble actually says the bill's objective was "to enhance the postmarket authorities of the Food and Drug Administration with respect to the safety of drugs"; access isn't mentioned. 121 Stat. at 823.

Beyond that, as the district court explained, GenBioPro's argument confuses "a limitation on the FDA's *own restrictions* on a drug" with a grant of preemptive authority. JA268. 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). Claiming that prohibition preempts state regulation that reduces access for other reasons is like arguing that whenever Congress instructs an agency that regulates a product's safety not to impose unnecessary costs, 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 for all purposes. 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.

GenBioPro doesn't dispute that Section 355-1's text only limits the burdens the FDA places on access. It only argues that "[i]t would not make sense to say the federal government must be careful not to burden access while allowing states to do so." Appellant's Br. 61. But that's exactly what Congress did; it expressly required the FDA not to unduly burden access in its own regulations, while not expressly preempting state laws that did the same—all against the backdrop of a longstanding savings clause that says the FDCA does not preempt state law absent a direct and positive conflict.

III. The major questions doctrine bars GenBioPro's expansive view of preemption.

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*, 597 U.S. 697, 723 (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 716 (quoting *Util. Air Reg. Grp.*, 573 U.S. at 324). GenBioPro's basic contention is that by authorizing the FDA to issue a REMS for mifepristone, Congress entrusted "FDA to determine the situations in which mifepristone is accessible," Appellant's Br. 48, and thereby authorized it to preempt state abortion bans.

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*, 597 U.S. at 223. GenBioPro would have this 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 not to unnecessarily burden drug access when it adopts any drug-risk mitigation strategy, *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. Section 355-1 clearly says nothing of the kind. But at minimum, there is no "clear congressional authorization," *West Virginia*, 597 U.S. at 723, 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). It doesn't grant FDA the power to decide the appropriate level of access to drugs in light of other considerations, such as the moral and ethical reasons

for banning abortion that underlie West Virginia's law. Or, at the very least, the statute can be read to deny the FDA that power, and because it can, under the major questions doctrine it must.

Indeed, the Supreme Court has already rejected a similar argument. 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 to prescribe controlled substances. 546 U.S. 243, 253-54 (2006). 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, *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 preempt state law is a limit on the *FDA's* authority to mitigate the risks of mifepristone.

The district court held that this is not a major questions case because it found that the FDA's mifepristone REMS did not "implicate th[e] major questions" surrounding abortion, JA261, which it agreed were "profound." JA264. But GenBioPro's strained reading of the statute would certainly implicate those questions, and that alone rules out that reading.

CONCLUSION

This Court should affirm the District Court's dismissal of GenBioPro's suit.

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Respectfully submitted,

TIM GRIFFIN
Arkansas Attorney General

Nicholas J. Bronni
Arkansas Solicitor General

Asher L. Steinberg
Senior Assistant Solicitor General
OFFICE OF THE ARKANSAS
ATTORNEY GENERAL
323 Center Street, Suite 200
Little Rock, Arkansas 72201
(501) 682-6302
Nicholas.Bronni@arkansasag.gov

Counsel for Amici States

ADDITIONAL COUNSEL

STEVE MARSHALL
Alabama Attorney General

TREG TAYLOR
Alaska Attorney General

ASHLEY MOODY
Florida Attorney General

CHRIS CARR
Georgia Attorney General

RAÚL R. LABRADOR
Idaho Attorney General

THEODORE E. ROKITA
Indiana Attorney General

BRENNA BIRD
Iowa Attorney General

KRIS W. KOBACH
Kansas Attorney General

RUSSELL COLEMAN
Kentucky Attorney General

LIZ MURRILL
Louisiana Attorney General

LYNN FITCH
Mississippi Attorney General

ANDREW BAILEY
Missouri Attorney General

AUSTIN KNUDSEN
Montana Attorney General

MICHAEL T. HILGERS
Nebraska Attorney General

DREW WRIGLEY
North Dakota Attorney General

ALAN WILSON
South Carolina Attorney General

MARTY JACKLEY
South Dakota Attorney General

JONATHAN SKRMETTI
Tennessee Attorney General & Reporter

KEN PAXTON
Texas Attorney General

SEAN REYES
Utah Attorney General

BRIDGET HILL
Wyoming Attorney General

CERTIFICATE OF COMPLIANCE

I certify that this brief complies with the type-volume limitation of Fed. R. App. P. 29(a)(5) and 32(a)(7)(B)(i) because it contains 6,328 words, excluding the parts exempted by Fed. R. App. P. 32(f).

I also certify that this brief complies with the requirements of Fed. R. App. P. 32(a)(5)-(6) because it has been prepared in 14-point Times New Roman, using Microsoft Word.

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/s/ Nicholas J. Bronni
Nicholas J. Bronni

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I certify that on April 15, 2024, I electronically filed the foregoing with the Clerk of Court using the CM/ECF system, which shall send notification of such filing to any CM/ECF participants.

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Nicholas J. Bronni