No. 24-1576

UNITED STATES COURT OF APPEALS
FOR THE FOURTH CIRCUIT

AMY BRYANT, MD,
Plaintiff-Appellee,

v.

JOSHUA H. STEIN, ET AL.,
Defendants-Appellees,

and

PHILIP E. BERGER, ET AL.,
Intervenors-Defendants-Appellants.

On Appeal from the United States District Court for the
Middle District of North Carolina,
No. 3:23-cv-00077 (Hon. Catherine C. Eagles)

Amicus Brief of Iowa, Arkansas, South Carolina, and 15 other States in Support of Appellants

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TABLE OF CONTENTS

TABLE OF AUTHORITIES

Page(s)

Cases

Statutes

Rules

Other Authorities

INTEREST OF AMICI CURIAE

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 North Carolina, responded with laws prohibiting, restricting, or otherwise regulating abortion. North Carolina maintains authority under its traditional police powers to enact laws for the general welfare that respect unborn life, protect mothers' healthcare, and uphold the medical profession's integrity. Dr. Amy Bryant disagrees with *Dobbs* and North Carolina's decision to impose common-sense regulations on abortion and brought this case to override both.

The amici States of Iowa, Arkansas, South Carolina, Alabama, Florida, Georgia, Indiana, Kentucky, Louisiana, Mississippi, Montana, Nebraska, North Dakota, Oklahoma, South Dakota, Tennessee, Utah, and Wyoming all prohibit, restrict, or otherwise regulate abortion. Each amicus State has a sovereign interest in protecting its citizens and in ensuring its laws are not preempted by an aggressive and expansive interpretation of the Food, Drug and Cosmetic Act (FDCA).

SUMMARY OF ARGUMENT

Bryant contends that North Carolina cannot incidentally restrict access to an abortion drug regulated by the FDA. Bryant believes that the FDA's modest mifepristone safety regulations preempt state laws that affect mifepristone access—a

view that would preempt many state laws regulating everything from the practice of pharmacy and medicine to malpractice. Alternatively, Bryant argues North Carolina's abortion laws are preempted because they conflict with the supposed federal objective of facilitating mifepristone access.

The district court entered a permanent injunction against enforcing multiple sections of North Carolina law. They include laws that (1) prohibit "any healthcare provider other than a licensed physician from providing mifepristone," N.C. Gen. Stat. §§ 90-21.83A, 90-21.83B, 90-21.93; (2) laws that "require mifepristone be provided in person," including N.C. Gen. Stat. §§ 14-44.1, 90-21.83A, 90-21.83B; (3) laws that "require scheduling an in-person follow-up visit after providing mifepristone," including N.C. Gen. Stat. §§ 90-21.83A, 90-21.83B, 90-21.93; and even (4) reporting requirements for "non-fatal adverse events related to mifepristone to the FDA," including N.C. Gen. Stat. § 90-21.93. Dkt. 105.

In entering that broad injunction, the district court abused its discretion. The FDS's Risk Evaluation and Mitigation Strategy (REMS) for mifepristone is no basis for preemption. Here, the FDA has regulated mifepristone to lessen the risks for women taking it, which North Carolina bolsters through its additional safety protections. And even if there is disagreement on that point, the FDCA's preemption saving clause makes clear there is no preemption where—as here—there is no "direct and positive conflict" between state and federal law.

As for conflict preemption, Bryant paradoxically claims that the FDA's minimal safety restrictions on dispensing mifepristone are designed to promote access and that North Carolina's laws are preempted because they frustrate that purpose. But that argument fails because the FDCA's saving clause limits that Act's preemptive reach to state laws that require manufacturers to violate its terms and Bryant cannot claim that here. And even if that were not the case, North Carolina's laws still would not be preempted because the FDCA merely directs the FDA not to unduly burden access with its safety regulations.

North Carolina's common-sense laws protecting unborn life, maternal healthcare, and the integrity of the medical profession do not conflict with the FDA's regulation of mifepristone, and the judgment below should be vacated.

ARGUMENT

I. North Carolina's abortion laws are not field preempted.

The district court explained that, in its reading, all parties agreed that neither field preemption nor impossibility preemption apply here. Dkt. 103 at 7 n.4. But given the briefing below, it may help this Court for a fuller explanation about why field preemption does not apply here. The FDA does not occupy the entire field of state law that might affect mifepristone access. Dkt. 99 at 1. That argument fails because the FDA drug approvals preempt state laws only if it is impossible to comply with both the FDA's directives and state laws. Here, North Carolina law imposes a

safety floor above that required by the FDA. There is no field or impossibility preemption.

Bryant pivots to argue 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. *See id.* at 1–2. 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 is far narrower than Bryant suggests. The FDA regulates mifepristone post-approval solely to avoid "serious adverse drug experience[s]" for the women who use it. 21 U.S.C. 355-1(f)(1)(A). That regulation does not displace generally applicable state laws that raise the floor for safe use in a way that does not conflict with the FDA's REMS.

A. North Carolina's laws are not preempted because they 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). So 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 cited as supporting field preemption here, *see* Dkt. 64 at 16, 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 added 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 any 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. *See REMS Single Shared System for Mifepristone 200 mg* at 1, FDA (Mar. 2023), https://perma.cc/5CR7-8YUM. That limited writ to subject its approval to "safe-use elements" does not prevent States from establishing even higher safety standards to protect their citizens.

By contrast, North Carolina's laws establish a framework for dealing with various situations that could impact maternal health or unborn life. That is, North Carolina built on the FDA's assessment of mifepristone's risks to women and the

FDA's judgment that mifepristone will kill an unborn child to impose more safety restrictions. As in *Oneok*, where the State did not enact its antitrust law to target federally regulated gas prices, North Carolina enacted its abortion laws to increase safety requirements on dispensing and using mifepristone.

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

North Carolina's laws are also not preempted by the FDA's REMS because the 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. The 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. Though that saving clause only refers to the 1962 amendments, the Supreme Court has held that clause 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 forecloses any argument for complete field preemption. 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. Patricia J. Zettler, *Pharmaceutical Federalism*, 92 Ind. L.J. 845, 868 (2017). 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.

Bryant's arguments that *Wyeth* does not apply here are unavailing. *Cf.* Dkt. 99 at 5. Indeed, 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. 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 is not 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 pre-emption 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.

Bryant attempts to distinguish cases like *Wyeth* by arguing that it only applies to preemption under the 1962 amendments—not later REMSes like those affecting mifepristone. Dkt. 99 at 4–5. But when it comes to cases like *Wyeth*, that's a distinction without a difference. As discussed above, cases post-*Wyeth* considered and rejected a field preemption that would preclude laws like North Carolina's from going into effect.

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 the 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. The district court's permanent injunction should be vacated.

II. North Carolina's abortion laws are not barred by conflict preemption.

North Carolina's laws protecting unborn life, maternal healthcare, and the integrity of the medical profession are not barred by conflict preemption. Conflict preemption normally exists either where it is 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 saving clause and the Supreme Court's FDCA preemption cases limit conflict preemption to impossibility preemption. And it is not impossible to comply with North Carolina law and the FDA's mifepristone regulation. Yet even if obstacle preemption could apply in this context, North Carolina's laws are not an obstacle to the purposes of FDA regulation.

In claiming otherwise, Bryant says one of the purposes of FDA regulation of less-safe drugs like mifepristone is to expand access. That defies common sense. The FDA's safety regulation of less-safe drugs reduces access. And this Court should reject Bryant's 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 here and the injunction should be vacated.

A. North Carolina's laws and the FDA's mifepristone REMS are complementary.

As discussed, the only form of pre-emption 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.

Bryant cannot meet that standard—and indeed, the district court acknowledged that impossibility preemption is not available here. Dkt. 103 at 7. Instead, the district court explained that the "challenged state laws present an obstacle" to the FDA's objectives. *Id.* But the FDA's mifepristone REMS requires no one 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 id.* at 13–17 (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 is possible for Bryant and those who prescribe mifepristone to comply with both North Carolina law and the REMS. And Bryant does not claim that it is impossible to comply with both. Instead, Bryant claims that North Carolina law

represents an effort by the State to "directly override" the FDA's policy choices. Dkt. 68 at 13.

According to Bryant, once the FDA sets a floor of safety requirements to prescribe a medication, a State may impose no more requirements on that medication without creating an obstacle. *See id.* But that is an error. Bryant primarily relies on *Geier v. American Honda Motor Co.*, 529 U.S. 861, 874–75 (2000), to contend that a State law requiring auto manufacturers to equip cars with side air bags when the federal agency did not was obstacle preempted. *Id.* (citing *Geier*, 529 U.S. at 874–75, 881–82). But as Bryant acknowledges, there the agency had explicitly rejected a proposed "all airbag" standard as inconsistent with its goal. *Id.* And that case is distinguishable from the present one in that North Carolina's laws regulate uses of a drug rather than its manufacture.[1] Bryant tries to stretch *Geier* to the context here, in which the FDA's changing REMS imposes some but not all safety requirements on mifepristone. That extends *Geier* beyond its potential application. Under that approach, any drug approval would render additional State safety standards likely unavailable.

[1] Considering *Geier*, North Carolina's laws are more analogous to speed limit laws on a highway than to laws regulating the manufacture of a vehicle. And as with state regulation of speed limits, North Carolina's abortion laws are well within the police powers of the state.

B. North Carolina's abortion laws are not obstacle-preempted.

Even if the FDCA allowed for obstacle preemption, North Carolina's laws still would not 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). North Carlina's laws do not 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 does not pass on the moral questions underlying North Carolina's laws.

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. The tort suit in *Wyeth* claimed that the manufacturer should have instructed doctors not to administer a drug by one 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 Bryant 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 found 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 the FDA's safety determinations, as the suit in *Wyeth* did, was no obstacle to achieving those aims.

Likewise, a law that regulates abortion 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 regulates the prescription and dispensing of mifepristone for its sole FDA-approved use, abortion. Even if state law effectively prohibits a drug's use in whole or part, it doesn't frustrate the FDCA's objectives.

For though Bryant 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." Janssen, 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*, Mich. St. L. Rev. 1, 11–12 (2016). 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. Laws regulating abortion are not uniquely situated under the FDCA.

Despite all this, Bryant contends that mifepristone is uniquely immune from State regulation because it is subject to a REMS. But a REMS is just 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 Bryant contends the REMS statute, unlike the FDCA generally, embodies the precise risk/access balancing the Supreme Court found lacking in the FDCA in *Wyeth*. 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), Bryant claims that the REMS statute pursues "regulatory balance," Dkt. 68 at 12, and concludes that States may not impose "unnecessary and burdensome restrictions," *id.* at 9.

The FDA is not directed to calculate an optimal level of access for a drug for all purposes. It's merely directed to mitigate some 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 does not preempt a separate sovereign from determining that the risks justify more restrictive processes for access. Indeed, *Wyeth* suggests it does not 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.

Bryant does not dispute that Section 355-1's text only limits the burdens the FDA places on access. She only argues that the "FDA has identified the specific mix of regulatory controls that, in the agency's view, protects patient safety without unduly burdening patient access or the healthcare system." Dkt. 68 at 11–12. But while Congress expressly required the FDA not to unduly burden access in its own regulations, it did not expressly preempt state laws that did the same. And all of this must be read against the backdrop of a longstanding saving clause that says the FDCA does not preempt state law absent a direct and positive conflict.

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

There is yet another reason the FDA's regulation of mifepristone cannot preempt North Carolina's laws: 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*, 573 U.S. at 324). Bryant's basic contention is that by authorizing the FDA to issue a REMS for mifepristone, Congress entrusted the FDA to determine the situations in which mifepristone is accessible, and thereby allowed it to preempt state abortion restrictions.

Despite Bryant's protestations to the contrary, that reading of the REMS statute assigns a question of vast political significance to the FDA. *Cf.* Dkt. 68 at 15.

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. And to affirm the permanent injunction would require this Court to 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 and 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, Bryant cannot succeed. Bryant'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 set up a regime in which more stringent State laws would conflict with the FDA's exclusive authority to decide how much mifepristone access could be restricted.

But Section 355-1 states nothing of the kind. At minimum, there is no "clear congressional authorization," *West Virginia*, 597 U.S. at 723, for Bryant's reading. The only power Section 355-1 expressly delegates to 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 does not grant the FDA the power to decide the appropriate level of access to drugs in light of other considerations, such as deeper health and welfare concerns that underlie

North Carolina's laws. 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 U.S. Attorney General, who enforced the Controlled Substances Act (CSA), 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 be prescribed only for "a legitimate medical purpose," *id.* at 257, and reasoned that assisted suicide was not one, *id.* at 254.

Though 49 States prohibited assisted suicide, *id.* at 272, the Court held the CSA did not delegate to the Attorney General the authority to decide whether assisted suicide was a legitimate medical purpose at all. 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 similar claim of regulatory authority, but with a much weaker statutory hook. Like the Attorney General's regulation, Bryant'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 in *Gonzales* at least had statutory authority to say whether a prescription was for a legitimate medical purpose, the only source of authority Bryant can point to for the 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 improperly entered a permanent injunction enjoining enforcement of North Carolina's laws. In so doing, the district court endorsed an impermissibly broad reading of FDA preemption that would render unenforceable many valid State laws. This Court should vacate that injunction.

CONCLUSION

This Court should vacate the District Court's injunction.

[Signatures on following page]

Dated: August 19, 2024

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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 4,654 words, excluding the parts exempted by Fed. R. App. P. 32(f).

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

I further certify that this PDF file was scanned for viruses, and no viruses were found on the file.

s/ Joseph D. Spate
Joseph D. Spate

CERTIFICATE OF SERVICE

I certify that on August 19, 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.

s/ Joseph D. Spate
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