No. 23-2194

UNITED STATES COURT OF APPEALS FOR THE FOURTH CIRCUIT

GENBIOPRO,

Plaintiff-Appellant,

v.

KIRSTINA D. RAYNES, in her official capacity as Prosecuting Attorney of Putnam County, and PATRICK MORRISEY, in his official capacity as Attorney General of West Virginia,

Defendants-Appellants.

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

BRIEF OF DOCTORS FOR AMERICA AS *AMICUS CURIAE* IN SUPPORT OF APPELLANT AND REVERSAL

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Pursuant to FRAP 26.1 and Local Rule 26.1, *Amicus Curiae* Doctors for America makes the following disclosure:

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4. There is no other publicly held corporation or other publicly held entity that has a direct financial interest in the outcome of the litigation.

5. Doctors for America is not a trade association.

6. This case does not arise out of a bankruptcy proceeding.

7. This is not a criminal case in which there was an organizational victim.

/s/ Brian T. Burgess
Brian T. Burgess

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INTEREST OF *AMICUS CURIAE* [1]

Doctors for America ("DFA") is an organization of over 27,000 physician and medical-student advocates from all 50 States and the District of Columbia, representing all areas of specialization. DFA mobilizes its members to be leaders in improving the health of their patients, communities, and the Nation. DFA focuses solely on what is best for patients, not on the business side of medicine, and does not accept any funding from pharmaceutical or medical-device companies. This uniquely positions DFA as a medical organization that puts patients over politics and patients over profits.

DFA believes that access to reproductive healthcare is not just essential to adequate healthcare, but also a basic human right. DFA is one of two founding members of the Reproductive Health Coalition, a group comprising a range of medical-professional associations and allied organizations that collectively represent over 150 million members, which advocates for protecting access to reproductive healthcare. In addition, DFA's Health, Justice, and Equity Impact Area has published a number of guides to navigating the evolving patchwork of state laws restricting abortion.[2]

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[1] Plaintiff-Appellant and Defendants-Appellees consent to the filing of this brief. No counsel for any party authored this brief in whole or in part, and no party, counsel, or person other than *amicus* and its counsel contributed money to fund the preparation or submission of this brief.

[2] *See Reproductive Rights*, Doctors for America, http://tinyurl.com/yjy6v4h7.

DFA is also committed to ensuring the Food and Drug Administration ("FDA") has the authority and expertise to act in the interest of patients across the Nation. To that end, DFA has created an FDA Task Force, which brings together a multi-specialty group of clinicians to provide unbiased advice to the FDA and regulatory stakeholders. The FDA Task Force has engaged in a variety of actions in connection with the FDA regulatory process, including advocacy for expanding safe access to abortion medications like mifepristone.

The question presented in this appeal—whether West Virginia has the power to nullify the FDA's exhaustively considered judgment about the proper conditions for patient access to a critical medication—therefore goes to the heart of DFA's interests. For that reason, DFA, which prides itself on its independence from the pharmaceutical industry, has taken the unusual step of filing an *amicus* brief in support of a drug manufacturer, GenBioPro. DFA submits this brief to explain how the district court's preemption analysis is wrong as a matter of law and to provide the Court context to understand why, if the decision is allowed to stand, it will set a dangerous precedent—one that would give all 50 States free rein to create their own politicized drug-access regimes, with disastrous results for the medical profession and millions of patients across the Nation.

INTRODUCTION

West Virginia has banned abortion in all but a small set of exceptional circumstances. As a result, patients are generally forbidden from using a critical and sometimes life-saving medication, mifepristone, for its federally approved use. That result is directly contrary to the determinations of the FDA, which, over the course of nearly a quarter century, has crafted a uniquely exhaustive regulatory regime for the drug—one that combines a risk evaluation and mitigation strategy ("REMS") with elements to assure safe use ("ETASU"). This REMS/ETASU framework is the result of intensive, continual deliberation regarding the proper use of mifepristone for a particular indication (i.e., termination of intrauterine pregnancy through 70 days of gestation), and it regulates virtually every circumstance relating to the medication: not just its labeling, but also all the conditions for prescription and dispensing. Congress requires the FDA to re-evaluation this framework regularly, and in the course of fulfilling that responsibility, the FDA has consistently decided that that the facts support *expanding* conditions for access to mifepristone. As even the district court recognized, perhaps no other prescription drug in the Nation's history has been subject to such careful scrutiny at the federal level.

These undisputed facts should make the preemption question here straightforward. Congress and the FDA's uniquely comprehensive REMS/ETASU framework for the drug leaves no room for state regulation, so field preemption

applies. And because the West Virginia ban effectively vetoes the FDA's painstaking determination about when and how patients should be able to access mifepristone, conflict preemption applies, too. The district court decided otherwise, based on an overgeneralization regarding the regulatory field at stake (the police power over health issues rather than the unprecedented detail of the REMS/ETASU framework) and a mistaken belief that the stated purpose of the law (to express disapproval of abortion rather than a judgment regarding the safety and efficacy of mifepristone) trumps the law's actual effect on the federal scheme. Because that reasoning was erroneous, the decision should be reversed.

If the district court's decision is affirmed, the FDA's authority would be compromised, with consequences likely to ripple far beyond access to mifepristone. States would be given the green light to interfere with the FDA's determinations regarding the proper access to other drugs that have been subject to elaborate REMS or ETASU schemes (but which have sometimes been the subject of political controversy), including critical drugs such as revolutionary HIV medicines and important pain-management opioids. That would roll back a century of law and policy favoring a uniform framework of drug laws set at the federal level—a framework that has been essential to the smooth functioning and innovation of our healthcare system.

Ultimately, the biggest losers will be the medical profession and millions of patients across the Nation. The medical community depends on uniform national standards to guide care throughout the Nation, particularly now, when the practice of providing treatment remotely and across state borders has become commonplace and is sometimes the only means for underserved patients to access healthcare. A patchwork of state drug bans will make it difficult, if not impossible, to maintain these uniform standards of practice, throwing medical education and cross-border practice into disarray. And as the example of abortion makes clear, politicized bans of life-saving medications inflict the greatest harms on underprivileged Americans who are already most at risk. These are exactly the scenarios a century-long history of federal oversight of drug regulation and access was supposed to avoid.

ARGUMENT

I. The FDA's comprehensive regulation of access to mifepristone preempts West Virginia's abortion ban.

"The Supremacy Clause makes the laws of the United States 'the supreme Law of the Land; ... any Thing in the Constitution or Laws of any State to the Contrary notwithstanding.'" *Hughes v. Talen Energy Mktg., LLC*, 578 U.S. 150, 162 (2016) (quoting U.S. Const., Art. VI, cl. 2). "Put simply, federal law preempts contrary state law." *Id.* As GenBioPro's brief ably explains, it does so here: under principles of both field and conflict preemption, the West Virginia ban must give

way to the FDA's comprehensive judgment regarding access to mifepristone. The district court's conclusion to the contrary violated basic principles of preemption.

1. Field preemption "applies when Congress has legislated comprehensively to occupy an entire field of regulation, leaving no room for the States to supplement federal law." *PPL EnergyPlus, LLC v. Nazarian*, 753 F.3d 467, 474 (4th Cir. 2014) (citation and quotation marks omitted), *aff'd*, 578 U.S. 150. "Actual conflict between a challenged state enactment and relevant federal law is unnecessary to a finding of field preemption; instead, it is the mere fact of intrusion that offends the Supremacy Clause." *Id*. "If Congress evidences an intent to occupy a given field, any state law falling within that field is pre-empted." *Id.* That is the case here with respect to prescription drugs subject to the FDA's comprehensive REMS/ETASU framework. Drugs subject to this framework have not only been approved by the FDA as safe and effective for their intended use, *see* 21 U.S.C. § 355(b), (j), but are also governed by exhaustive post-approval requirements to ensure their benefits to patients outweigh the potential risks.

a. The field-preemption question here is narrow. It concerns a specific and extraordinary form of regulation: the FDA's history of controlling the availability of mifepristone, which has culminated in the exhaustive REMS/ETASU framework for the drug.

This history goes back more than twenty years. It began in 2000, when the FDA approved use of mifepristone subject to specific risk-management procedures and "restrictions to assure safe use," which the FDA determined were "commensurate with the specific safety concerns presented by the drug product." 21 C.F.R. § 314.520. As a result, mifepristone became one of only 16 prescription drugs and biologics subjected to this heightened form of access regulation. JA309 (¶ 37). That was just the beginning of the FDA's regulation of mifepristone. As part of the 2007 Food and Drug Administration Amendments Act ("FDAAA"), Pub. L. No. 110-85, 121 Stat. 823, these earlier regulations were deemed to constitute an approved REMS for mifepristone, with the additional requirement that the FDA establish a new REMS/ETASU framework for the drug. *See* FDAAA § 909(b)(1), 121 Stat. 950-51.

The statute makes the FDA's task clear: for drugs that require the REMS/ETASU framework, the FDA must "[p]rovid[e] safe access for patients to [these] drugs." 21 U.S.C. § 355-1(f). What that means is that, to "[a]ssur[e] access and minimize[e] burden" on patients, the REMS/ETASU framework must "not be unduly burdensome on patient access to the drug[s], considering in particular" the following factors: "(i) patients with serious or life-threatening diseases or conditions; (ii) patients who have difficulty accessing health care (such as patients in rural or medically underserved areas); and (iii) patients with functional limitations." *Id.*

§ 355-1(f)(2)(C). In fulfilling this mandate, the FDA is required to "seek input from patients, physicians, pharmacists, and other health care providers about how elements to assure safe use under this subsection for 1 or more drugs may be standardized so as not to be": "(i) unduly burdensome on patient access to the drug; and (ii) to the extent practicable, minimize the burden on the health care delivery system." *Id.* § 355-1(f)(5)(A).

Accordingly, since 2007, the FDA has regulated mifepristone under an elaborate REMS/ETASU regime. That regime governs the drug in ways that go far beyond standard FDA issues of approval and labeling. It reaches deep into the relationship between patients and prescribers and regulates issues normally left to the discretion of the medical community. Among other things, the mifepristone REMS/ETASU framework puts extensive controls over who is certified to prescribe the drug; the requirements of certification; the conditions under which prescription may occur; and the information prescribers are required to give patients in connection with a prescription. *See Information about Mifepristone for Medical Termination of Pregnancy Through Ten Weeks Gestation*, FDA (Mar. 23, 2023), http://tinyurl.com/5n8jdukk; GenBioPro ("GBP") Br. at 13-14.

The upshot is that mifepristone has been heavily regulated by federal law for more than two decades, and at a level of intensity and detail far greater than the average drug. Today, it is regulated by the FDA at every stage, from approval to

prescription to dispensing. It would be hard to imagine a specific regulatory field the federal government has occupied more comprehensively.

b. The district court acknowledged this extraordinary regulatory context. It recognized that the "FDA is acting narrowly pursuant to an explicit grant of authority as to a single prescription medication." JA262. It conceded that these comprehensive regulations were developed from "overwhelming evidence" and "rigorous agency and pharmaceutical industry review." JA258. And it credited expert *amicus* submissions showing that "mifepristone has been subject to more regulatory and congressional scrutiny than perhaps any other prescription drug." JA258 (quoting ECF No. 40-1, at 5).[3] But the court nonetheless refused to hold that field preemption applied. Its reasons for doing so were wrong.

The court believed that, because the West Virginia law concerns "health, medicine, and medical licensure," which "are traditional areas of state authority," "the presumption against preemption" was at its "strongest" and was not overcome. JA275. That misunderstands the inquiry. No party disputes that States retain substantial authority to legislate in the broad realm of "health, medicine, and medical licensure." The field at issue here is far more specific: the select category of drugs that have been subject to exhaustive REMS or ETASU regulations by the FDA.

[3] Unless otherwise indicated, "ECF" citations are to the district court's docket in this case.

There is no tradition of giving the States power over those drugs or over the minute drug-access issues governed by the REMS/ETASU framework.

Even if the presumption against preemption did apply, the district court would still be wrong on field preemption. That is because the REMS/ETASU framework for mifepristone expressly goes beyond traditional federal realms of drug regulation (approval and labeling) and regulates issues normally left to the States' police powers: the doctor-patient relationship. For *this* specific regulatory regime, then, "the clear and manifest purpose of Congress" was that the federal government should have comprehensive control, and so the presumption against preemption must give way. *Arizona v. United States*, 567 U.S. 387, 400 (2012) (citation omitted).

2. The West Virginia law also must give way under principles of conflict preemption. "[W]here [a] state law limit[s] the availability of an option that [a] federal agency consider[s] essential to ensure its ultimate objectives," conflict preemption applies. *Geier v. Am. Honda Motor Co.*, 529 U.S. 861, 882 (2000) (citing *Fidelity Fed. Sav. & Loan Ass'n v. de la Cuesta*, 458 U.S. 141, 156 (1982)). West Virginia's law runs afoul of this preemption rule as well.

a. As noted, the FDA has continually revised and refined the detailed REMS/ETASU framework for mifepristone, so that the regulations now govern mifepristone at all stages and in all circumstances, from approval and labeling to prescription and dispensing. *See* pp. 7-8, *supra*. Importantly, the FDA has

consistently decided that the best choice, as a matter of science and policy, is to modify the REMS/ETASU framework to *expand* access to mifepristone. For example, the agency has enlarged the population of qualified prescribers from certified "physicians" to certified "healthcare providers" such as nurse practitioners. Similarly, the FDA has broadened mifepristone's labeling and now indicates use of mifepristone for terminating a pregnancy through its first 70 days, rather than just the first 49 days as was indicated in mifepristone's initial approval. The agency has also removed the in-person dispensing requirement for the drug. *See* JA314-315 (¶¶ 58, 62); GBP Br. at 12. The agency has "determined, based on the available data and information," that these "modifications" are necessary to "reduce burden on the health care delivery system and to ensure the benefits of [mifepristone] outweigh the risks." *Questions and Answers on Mifepristone for Medical Termination of Pregnancy Through Ten Weeks Gestation*, FDA (Sept. 1, 2023), http://tinyurl.com/54dannd5.

The record shows that the FDA made these decisions to expand access to mifepristone after extraordinarily thorough deliberation. Again, as the district court put it, the agency based its conclusion on "overwhelming evidence" and "rigorous agency and pharmaceutical industry review" after a process of "regulatory and congressional scrutiny [higher] than perhaps any other prescription drug." JA258. In the course of that process, the FDA has had many opportunities to consider

requests to change the framework. Stakeholders have the ability to object to the regulations and to request modification. 21 C.F.R. § 10.30. And some parties have done so, requesting that restrictions on mifepristone the FDA has discarded be revived. The FDA has carefully evaluated those requests and declined them. *See* ECF 44 at 11-12.

The West Virginia ban does not just interfere with the agency's considered decisions expanding access to the drug. It takes a bulldozer to them, making mifepristone effectively unavailable except in the most extreme circumstances, such as fetal nonviability, medical emergency, and certain instances of sexual assault. *See* W. Va. Code §§ 16-2R-2, 16-2R-3. So the state law here does not just "limi[t] the availability of an option that [the FDA] consider[s] essential to ensure its ultimate objectives," *Geier*, 529 U.S. at 882—it essentially abolishes it altogether.

b. Again, the district court admitted all of this: that the FDA has, after painstaking deliberation, consistently expanded access to mifepristone, and that the West Virginia law largely bans it. JA256. But as with field preemption, the court declined to apply conflict preemption, primarily on the basis that the ban was a "restriction on … abortion, rather than a state directive in direct conflict with the logistical REMS regulations." JA272. Here too, the district court misunderstood the preemption analysis. The inquiry turns on the law's "practical impact," not the "description or characterization given it by the [state] legislature." *Hughes v.*

Oklahoma, 441 U.S. 322, 336 (1979); *see also, e.g., Gade v. Nat'l Solid Wastes Mgmt. Ass'n*, 505 U.S. 88, 107 (1992) ("Whatever the purpose or purposes of the state law, pre-emption analysis cannot ignore the effect of the challenged state action on the pre-empted field.").

There is little doubt of the practical impact of the state law at issue here. By passing an across-the-board ban on abortion that includes the conditions of use for mifepristone, West Virginia has, within its jurisdictional boundaries, destroyed what the FDA has constructed over decades: a regulatory regime for mifepristone that strikes a thoughtful balance between assuring patient safety and ensuring ready access. In doing so, one State has substituted its own views for the federal agency's (and the national medical community's) expert judgment regarding whether, when, and how patients should use a life-saving medication.

Characterizing this usurpation of the FDA's role as incidental to the law's broader thrust or focusing on the announced purpose of the ban (to express disapproval of abortion rather than a scientific view of the safety and efficacy of the drug) does nothing to change the fundamental opposition between the federal and state regimes. Indeed, this is exactly why, when faced with a similar attempt by a State to ban a REMS-regulated drug, another district court concluded that the "FDA has the authority to approve for sale to the public a range of safe and effective prescription drugs," and "[i]f [a State] were able to countermand the FDA's

determinations and substitute its own requirements, it would undermine the FDA's ability to make drugs available to promote and protect the public health" and would "stand[] in the way of 'the accomplishment and execution of' an important federal objective." *Zogenix, Inc. v. Patrick*, 2014 WL 1454696, at *2 (D. Mass. Apr. 15, 2014) (quoting *Hines v. Davidowitz*, 312 U.S. 52, 67 (1941)) (preliminarily enjoining Massachusetts's emergency ban of a REMS-regulated opioid, Zohydro).[4] The district court should have done the same here.

II. The district court's decision poses a broader threat to the stability and uniformity of medical care across the Nation.

Preemption doctrine exists for a reason: to safeguard the Supremacy Clause's guarantee that, when the federal government decides to regulate an issue subject to its authority, that is the final word on the matter. Otherwise, the Constitution's careful division of power between federal and state governments would devolve into a zero-sum battle between sovereigns, making uniform government action on issues of national importance impossible.

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[4] *See also Zogenix, Inc. v. Patrick*, 2014 WL 3339610, at *3-4 (D. Mass. July 8, 2014) (similarly enjoining two related Massachusetts regulations that amounted to a "*de facto* ban" on Zohydro, and reasoning that "[s]ure enough, [a State's] police powers permit it to regulate the administration of drugs by the health professions," "[b]ut it may not exercise those powers in a way that is inconsistent with federal law," such as by "trying to make scarce or altogether unavailable a drug that the FDA, by approving it, has said should be available"), *injunction vacated in part after modification to challenged regulations*, 2014 WL 4273251 (D. Mass. Aug. 28, 2014).

This case illustrates the principle. The district court's decision, if affirmed, could have massive downstream effects on the national healthcare system. Among other consequences, it could encourage States to impose their own bans on other controversial prescription drugs and medical devices based on partisan political trends, not science. The result would replace the single, authoritative drug-access framework established by the FDA with a patchwork of more than 50 different regimes, leading to widespread negative consequences for doctors and patients alike—precisely the opposite of what decades of federal law and regulation have striven to achieve.

A. Under the district court's logic, States may ban other essential drugs approved by the FDA.

As discussed, the district court held that a State may effectively prohibit patients from accessing a drug subject to an exhaustive REMS/ETASU regime, at least so long as the ban is framed as an exercise of traditional police power over medical practice (as opposed to an express veto of the FDA's safety and efficacy determination). The endpoint of this logic is troubling: States will be encouraged to enact more bans targeted at politically controversial medications that have been subject to similarly comprehensive federal access schemes. The resulting patchwork of regulatory schemes—in which uses of a drug deemed safe and effective at the federal level may be criminalized at the state level—would be directly contrary to the century-long history and purpose of the federal drug laws.

1. Consider HIV pre-exposure prophylaxis, or "PrEP." This medication can reduce the risk of HIV transmission by up to 99%. *PrEP Effectiveness*, Ctrs. for Disease Control and Prevention (June 6, 2022), http://tinyurl.com/2tbcmamu. Indeed, one leading PrEP drug is so effective that it has been classified as an essential medicine by the World Health Organization. *WHO Classes HIV Drug as an Essential Medicine*, NewScientist (June 14, 2017), http://tinyurl.com/2bmhn29c. Because PrEP has valuable benefits but also risks, it has a long history of REMS regulation by the FDA. The agency only recently removed the REMS for PrEP in 2019, having concluded after extensive deliberation that the it was no longer necessary. *See FDA in Brief*, FDA (July 1, 2019), http://tinyurl.com/35h6pvbk/.

But PrEP remains controversial, and some critics and politicians believe that HIV medicines create a "moral hazard" that encourages non-traditional sexuality. Unsurprisingly, then, there have been attempts to frustrate access to the drug. For example, in 2020, a lawsuit was filed challenging a federal law requiring health insurers to cover PrEP. *See Braidwood Mgmt. Inc. v. Becerra*, No. 4:20-cv-00283-O (N.D. Tex. July 20, 2020), ECF 14 ("PrEP Complaint"). The complaint alleged the law "forces religious employers to provide coverage for drugs that facilitate and encourage homosexual behavior, prostitution, sexual promiscuity, and intravenous drug use," and so "imposes a substantial burden on the religious freedom of those who oppose homosexual behavior on religious grounds." PrEP Complaint ¶¶ 108-

109.[5] The governors of a number of States have also blocked funding for PrEP and HIV-related care, or threatened to do so.[6]

The district court's decision would encourage far more aggressive state-level efforts to interfere with access to PrEP. Indeed, a State could copy directly from West Virginia's playbook in this case: pass a broader ban aimed at medical services that purportedly "encourage … prostitution, sexual promiscuity, and intravenous drug use." Under the district court's reasoning, that would be a permissible exercise of the State's police power over "health, medicine, and medical licensure," placing a "restriction on" medical treatment of disfavored conduct, "rather than a state directive in direct conflict with the logistical [PrEP] regulations." JA272, 275. As a consequence, HIV patients in some States would be left without access to a revolutionary medicine, solely on the basis of partisan political trends. Research has shown that even mild restrictions on access to PrEP—such as limiting nurse practitioners' and physician assistants' freedom to prescribe PrEP—substantially decrease patients' access to PrEP and so increase rates of HIV transmission. *See* Neal Carnes, et al., *Restricting Access: A Secondary Analysis of Scope of Practice*

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[5] The district court in this case ultimately sided with the plaintiffs on some of their claims. *See Braidwood Mgmt.*, ECF 113. That decision is currently on appeal to the Fifth Circuit. *See* No. 23-10326.

[6] *See, e.g.*, Benjamin Ryan, *'Rick Scott had us on lockdown': how Florida said no to $70m for HIV crisis*, The Guardian (Sept. 11, 2019), http://tinyurl.com/5fafv8k3; Benjamin Ryan, *How Tennessee axed millions in HIV funds amid scrutiny from far-right provocateurs*, NBC News (Feb. 2, 2023), http://tinyurl.com/4pydppxb.

Laws and Pre-exposure Prophylaxis Prescribing in the United States, *2017*, 33 J. Ass'n Nurses in AIDS Care 89 (2022), http://tinyurl.com/2sem6eun.

2. Or consider an even higher-profile class of controversial drugs: opioids. Like mifepristone, these drugs serve a unique and essential clinical purpose: reducing severe pain. Yet opioids carry much greater risks for patients, communities, and public health. No one disputes there is a national crisis of addiction to opioids in both prescription and illicit forms. But the FDA has studied the issue, has maintained its view that opioids "are powerful pain-reducing medications," and has concluded that "a REMS is necessary … to ensure that the benefits of these drugs continue to outweigh the risks." *Opioid Analgesic Risk Evaluation and Mitigation Strategy (REMS)*, FDA (Nov. 14, 2023), http://tinyurl.com/mh7mhhvw.

If the district court's decision here is affirmed, state legislatures may come to believe that they are empowered to disagree with the FDA's determination and ban the use of opioids in medical practice altogether, even in the limited circumstances in which the FDA has authorized their use, and even when physicians believe they are the best medication for treatment of a patient's severe pain. As noted, *see* p. 14, *supra*, at least one State (Massachusetts) has already attempted to ban an FDA-approved opioid, Zohydro, over concerns about addiction and misuse. *Zogenix*, 2014 WL 1454696, at *2. When that ban was challenged, the district court

enjoined it, finding the ban likely preempted on the basis that, "[i]f [a State] were able to countermand the FDA's determinations and substitute its own requirements, it would undermine the FDA's ability to make drugs available to promote and protect the public health" and would "stand[] in the way of 'the accomplishment and execution of' an important federal objective." *Id.* (citation omitted).

In light of the district court's decision here, however, the next attempt may turn out differently. And States are clearly considering more opioid-related bans. Indeed, in an *amicus* brief filed with the district court in this case, 22 States expressed the opinion that such a ban "would only advance the [Food, Drug, and Cosmetic Act's ("FDCA")] purpose" of ensuring safe use of prescription drugs—regardless what the FDA, the agency charged with administering the FDCA, has actually said on the subject. ECF 30 at 12 n.1. That is wrong. An outright ban does not further the purpose of the FDCA or complement the FDA's regulations: it directly contradicts the statute's purpose and the agency's considered judgment. These opioids have been rigorously examined by the FDA, which has found that they are safe and effective for their intended use. And they are subject to REMS to ensure their safe use.

3. Permitting this kind of patchwork system, in which even the basic availability of life-saving medications could vary state-by-state and depend on

regional politics rather than science, would roll back a century's worth of law and policy.

Large-scale federal regulation of the pharmaceutical industry began in the early twentieth century precisely because both government and industry recognized that "inconsistencies in applicable state laws made operating on a national scale increasingly difficult." Ilyse D. Barkan, *Industry Invites Regulation: The Passage of the Pure Food and Drug Act of 1906*, 75 Am. J. Pub. Health 18, 20 (1985). The landmark statute that resulted—the Pure Food and Drug Act of 1906—aimed to "bring[] about … a uniformity of laws and regulations on the part of the States within their own several borders." H.R. Rep. No. 5056, 59th Cong., 1st Sess. 8-9 (1906). The national framework for drug regulation that developed from this legislation brought with it not just the general good of "uniformity," but also a more specific "promise" that has driven advances in American healthcare: "a national market for drugs that meet the demands of an onerous review process." David S. Cohen, Greer Donley, and Rachel Rebouché, *The New Abortion Battleground*, 123 Colum. L. Rev. 1, 63-64 (Jan. 2023). The district court's reasoning hollows out this promise, a linchpin of the American healthcare system, and may discourage the innovation that depends on it by potentially depriving manufacturers of a national market and subjecting them to balkanized state regimes instead.

B. Subverting the FDA's uniform regulatory scheme will inflict widespread harms on the medical profession and patients.

1. A patchwork of state drug bans will not just frustrate uniform regulation of the drug market and damage the innovative healthcare industry that depends on it. It will also pose a significant threat to the national standards governing the American medical profession.

a. Doctors rely on evidence-based, national clinical-practice guidelines to ensure that they are practicing according to generally accepted standards of care. To take an example relevant to the district court's decision, the American College of Obstetricians and Gynecologists ("ACOG") has promulgated guidance on "medication abortion," a practice ACOG indicates is "safe and effective" within the FDA-approved 70-day gestation period. *Medication Abortion Up to 70 Days of Gestation*, ACOG (Oct. 2020), http://tinyurl.com/47zmtcum. The guidelines lay down a detailed set of "clinical considerations and recommendations" regarding patient eligibility, counseling, pain management, and other best practices. *Id.* (capitalization omitted). The guidelines are developed through rigorous and continual review of the scientific literature and consultation with experts from the field, and "[t]here is increasing evidence" that the "standardization of care" enabled by these guidelines "improves patient outcomes." Douglas H. Kirkpatrick and Ronald T. Burkman, *Does Standardization of Care Through Clinical Guidelines*

Improve Outcomes and Reduce Medical Liability?, 116 Obstetrics & Gynecology 1022 (Nov. 2010), http://tinyurl.com/5n8vp7c7.

This guidance is now impossible to follow in West Virginia, setting up a conflict between the evidence-based national standard for care and the politicized vagaries of state law. And confusion over the proper standards for administering mifepristone will impact a wide range of practices and medical professionals: "Although obstetrician–gynecologists perform most abortions in the United States, family medicine physicians play an important role in the provision of these services," as do "[a]dvanced practice clinicians, including nurse practitioners, physician assistants, and certified nurse-midwives." *Abortion Training and Education*, ACOG (Nov. 2014), http://tinyurl.com/kc4w3urh. If States continue the trend and pass bans on additional controversial but essential medications, even more practices will be thrown into uncertainty. National standard-setting organizations will be unable to promulgate uniform guidelines for their fields, and doctors will find their legal obligations at odds with the generally accepted standard of care in their practice.

b. The scenario is especially concerning given the rapid growth in recent years of telemedicine—that is, the practice of prescribing and providing care remotely over the internet, often across state lines. *See, e.g.*, *Updated National Survey Trends in Telehealth Utilization and Modality (2021-2022)*, Off. of Health

Pol'y (Apr. 19, 2023), http://tinyurl.com/5972wuyb (noting significant increase in telehealth as a result of the COVID-19 pandemic, and explaining that, during the surveyed period, "[t]elehealth use was highest among those with Medicaid (28.3%) and Medicare (26.8%), Black respondents (26.1%), and those earning less than $25,000 (26.4%)"). This expansion has been strongly encouraged by the federal government. For example, the COVID-19 Telehealth Program has "provide[d] $200 million in funding, appropriated by Congress as part of the Coronavirus Aid, Relief, and Economic Security (CARES) Act, to help health care providers provide connected care services to patients at their homes or mobile locations in response to the COVID-19 pandemic." *COVID-19 Telehealth Program (Invoices & Reimbursements)*, Fed. Commc'ns Comm'n (April 13, 2023), http://tinyurl.com/yeyt6eas. As a result, the Federation of State Medical Boards reports that, by 2022, some 24% of physicians were licensed to practice in multiple States. *Physician Licensure in 2022*, Fed'n of State Med. Bds., http://tinyurl.com/2z2zx6ez.

But in the aftermath of new abortion restrictions like the West Virginia ban, "providers are finding themselves in a murky gray area legally, having to weigh how much risk they're willing to assume to care for their patients, or consider halting this aspect of care altogether." Farah Yousry, *Telemedicine abortions just got more complicated for health providers*, NPR (Sept. 26, 2022),

http://tinyurl.com/24cjtvk8. This situation will only become more complicated if similar bans follow, and it may impede the expansion of telemedicine—another outcome directly at odds with federal policy.

c. A patchwork of state drug laws would also fracture medical education. Medical schools prepare their students to practice throughout the United States, not just in the State where the school is located, and students enter these programs with the assumption that their education is portable throughout the country. In fact, nearly 50% of doctors-in-training plan to practice in a State other than the one in which their residency program is located. *Physician Retention in State of Residency Training, by State*, AAMC (2020), http://tinyurl.com/267shfd7.

If States are able to ban critical medications, medical schools in those States may not be able to educate their students to the national standard, and physicians earning their degrees from these schools may be unprepared to practice in other parts of the country. To return again to mifepristone: the Accreditation Council for Graduate Medical Education ("ACGME"), the organization that sets standards for U.S. graduate medical education programs and the institutions that sponsor them, requires residency programs in obstetrics and gynecology to provide abortion training, or else risk losing their accreditation. *Program Requirements for Graduate Medical Education in Obstetrics and Gynecology*, ACGME (Sept. 17, 2022), http://tinyurl.com/3swh7sh2. As a result, medical-training programs in States like

West Virginia now "fac[e] a treacherous choice": "continue to provide abortion training in [S]tates where the procedure is now outlawed" and face "prosecut[ion]," or else "risk losing their accreditation, which in turn would render their residents ineligible to receive specialty board certification and imperil recruitment of faculty and medical students." Jan Hoffman, *OB-GYN Residency Programs Face Tough Choice on Abortion Training*, N.Y. Times (Oct. 27, 2022), http://tinyurl.com/26e3hfh9. And this dilemma could not come at a worse time: there is already a "growing physician shortage … across multiple specialties, including maternity care," with "ramifications … [that] extend far beyond childbirth." Jamie Rosenberg, *Physician Shortage Likely to Impact OB/GYN Workforce in Coming Years*, AJMC (Sept. 21, 2019), http://tinyurl.com/5n6vj7bh.

2. Patients across the country will be harmed by this patchwork effect as well. The West Virginia ban shows why. Access to abortion services is especially critical for people living with low incomes: in 2014, 75% of abortion patients in the United States had family incomes of less than 200% of the federal poverty level. Jenna Jerman, Rachel K. Jones, and Tsuyoshi Onda, *Characteristics of U.S. Abortion Patients in 2014 and Changes Since 2008*, Guttmacher Institute (May 2016), http://tinyurl.com/mr3wpzc7. Further, more than half of all abortions are sought by women who identify as Black, Hispanic, Asian, or Pacific Islander, *id.*—women who are already two to three more times likely to die from pregnancy-related

causes than white women. Latoya Hill, Samantha Artiga, and Usha Ranji, *Racial Disparities in Maternal and Infant Health; Current Status and Efforts to Address Them*, KFF (Nov. 1, 2022), http://tinyurl.com/yck4fs8p. West Virginia's ban will therefore disproportionately harm some of our most vulnerable communities, stacking further economic and health risks on top of existing inequalities.[7]

Additional bans of REMS/ETASU medications would only exacerbate these harms, and they pose a real risk of creating a two-tier healthcare system—one for Americans in jurisdictions that follow the federal standard, and another for Americans in States that have banned critical medications. The example of abortion suggests that Americans who are already most at risk will be the ones most harmed.

Widespread defection from federal law also undermines public trust in the FDA's authority. Confidence in federal healthcare policy is already fragile: the data show that misplaced distrust of the federal government (and of the medical profession) has fueled vaccine hesitancy in connection with the COVID-19 pandemic. *See* Bipin Adhikari, Phaik Yeong Cheah, Lorenz von Seidlein, *Trust is the common denominator for COVID-19 vaccine acceptance: A literature review*, 12 Vaccine X 100213 (Sept. 2022). Direct conflict between the federal and state

[7] *See, e.g.*, Jennifer Ludden, *Women who are denied abortions risk falling deeper into poverty. So do their kids*, NPR (May 26, 2022), http://tinyurl.com/yc4vjv7a; Amanda Jean Stevenson, *The Pregnancy-Related Mortality Impact of a Total Abortion Ban in the United States: A Research Note on Increased Deaths Due to Remaining Pregnant*, 58 Demography 2019 (2021).

governments over which drugs patients should be able to access will only further undercut the authority of both the FDA and the national medical community, making the next national health crisis even more difficult to manage than this past one.

CONCLUSION

The district court's preemption decision should be reversed.[8]

Respectfully submitted,

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CERTIFICATE OF SERVICE

I, Brian T. Burgess, hereby certify that on February 14, 2024, I electronically transmitted the foregoing document to the Clerk's Office using the CM/ECF System. I certify that all participants in this case are registered CM/ECF users and that service will be accomplished by the CM/ECF system.

/s/ Brian T. Burgess

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CERTIFICATE OF COMPLIANCE

This brief complies with the type-volume limitation of Federal Rule of Appellate Procedure 29(a)(5). This brief contains 6,097 words, excluding the parts of the brief exempted by Federal Rule of Appellate Procedure 32(f).

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