No. 24-1576(L), 24-1600, 24-1617

UNITED STATES COURT OF APPEALS FOR THE FOURTH CIRCUIT

AMY BRYANT, M.D.,
Plaintiff-Appellee,
v.
TIMOTHY K. MOORE, ET AL.,
Intervenors/Defendants-Appellants,
and
JOSHUA H. STEIN, in his official capacity as Attorney General for the State of North Carolina, ET AL.,
Defendants-Appellees.

On Appeal from the United States District Court
for the Middle District of North Carolina (Greensboro, No. 23-cv-00077)
(Osteen, J.)

BRIEF OF DOCTORS FOR AMERICA AS *AMICUS CURIAE* IN SUPPORT OF PLAINTIFF-APPELLEE AMY BRYANT, M.D.

Christopher Morten
Nora M. Franco
SCIENCE, HEALTH & INFORMATION CLINIC
MORNINGSIDE HEIGHTS LEGAL SERVICES, INC.
Columbia Law School
435 West 116th Street
New York, NY 10027
Tel.: +1 212 854-4291

Brian T. Burgess
GOODWIN PROCTER LLP
1900 N Street, N.W.
Washington, D.C. 20036
Tel.: +1 202 346 4000

William E. Evans
Samantha L. Jandl
GOODWIN PROCTER LLP
100 Northern Ave.
Boston, MA 02210
Tel.: +1 617 570 1000

Counsel for Amicus Curiae
Doctors for America

October 17, 2024

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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 is 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

[1] The Intervenors, Dr. Bryant, and all Defendants-Appellees other than Jeff Nieman and Kody H. Kinsley consent to the filing of this *amicus* brief. Defendants-Appellees Jeff Nieman and Kody H. Kinsley take no position on the filing of this *amicus* brief. No party opposes filing of this *amicus* 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.

published a number of guides for clinicians to navigating the evolving patchwork of state laws restricting abortion.[2]

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 North Carolina has the power to displace the FDA's exhaustively considered regulations concerning the proper conditions for patient access to mifepristone, a critical medication—therefore goes to the heart of DFA's interests. Accordingly, DFA submits this brief to explain why Dr. Bryant's view of the preemption analysis is correct and the Intervenors' view is wrong, and to provide the Court context to understand why, if the Intervenors' arguments against preemption succeed, it would 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.

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

INTRODUCTION

North Carolina has passed an onerous set of restrictions on access to mifepristone, a medication approved by FDA for termination of pregnancies through 70 days of gestation. Under the North Carolina regime, only physicians may prescribe mifepristone, and patients can only access the drug in-person—and only *after* completing an in-person consultation at least 72 hours before use of the drug, and *then* undergoing an in-person examination in which a physician must, among many other things, perform an ultrasound, determine the patient's blood type, "[s]creen the woman for coercion[] [or] abuse," and "[i]nform [her] that she may see the remains of her unborn child in the process of completing the abortion." N.C. Gen. Stat. § 90-21.83B(a). The result is that patients in North Carolina cannot access this critical and sometimes life-saving drug without securing in-person appointments with a physician and jumping over a series of elaborate and uncomfortable procedural hurdles.

That result is directly contrary to the determinations of the FDA, which, over the course of nearly a quarter century, has developed a comprehensive regime covering the appropriate conditions for accessing mifepristone—a regime that combines a risk evaluation and mitigation strategy ("REMS") with elements to assure safe use ("ETASU"). Relevant here, FDA's REMS/ETASU framework for mifepristone originally included a number of the very same restrictions North

Carolina has newly imposed (including in-person-administration and physician-only restrictions on access). But after more than two decades of exhaustive study and experience with the drug, the agency removed these restrictions, and in the process made express determinations that these restrictions no longer strike the right balance between patient safety and patient access. And in fulfilling its statutory mandate to re-evaluate the REMS/ETASU framework regularly, the FDA has consistently decided that the facts support *expanding* conditions for accessing mifepristone.

These undisputed facts should make the preemption question here straightforward. As the district court correctly concluded, because the North Carolina provisions seek to re-impose the same restrictions FDA removed from the REMS/ETASU framework, those restrictions are preempted as an obstacle to federal law. But the district court erred in declining to find obstacle preemption with respect to North Carolina's in-person consultation and examination requirements, as well as a requirement that all adverse events related to use of mifepristone be reported to the State. Although the court framed those restrictions as measures to ensure general patient safety, their practical effect is to veto the FDA's thoroughly considered determination that mifepristone should be made available to patients remotely by a range of qualified medical professionals, and that reporting non-fatal adverse events is unnecessary.

More generally, accepting Intervenors' arguments for avoiding obstacle preemption would substantially compromise the FDA's authority, 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 right conditions for accessing other drugs that have been subject to REMS or ETASU schemes, including critical drugs such as revolutionary HIV prevention medicines and important pain-management opioids. Such a displacement of the FDA would roll back a century of law and policy favoring a uniform framework of drug laws set at the federal level.

Ultimately, as DFA's own physician members can attest, 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, in rural areas, and across state borders has become commonplace and is sometimes the only means for underserved patients to access healthcare. A patchwork of state drug restrictions will make it increasingly difficult to maintain these uniform standards of practice. And as the example of abortion makes clear, politicized limits on access to 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. North Carolina's restrictions on mifepristone pose an obstacle to FDA's decisions concerning access to this critical medication.

"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 Dr. Bryant's brief ably explains, it does so here, because North Carolina's restrictions on access to mifepristone interfere with FDA's comprehensive judgment regarding the proper conditions for safe access to that drug.

Well-established principles of obstacle preemption resolve this appeal. "Obstacle preemption applies where state law stands as an obstacle to accomplishment and execution of the full purposes and objectives of Congress." *Equal Rts. Ctr. v. Niles Bolton Assocs.*, 602 F.3d 597, 601 (4th Cir. 2010) (quotation marks omitted) (quoting *Freightliner Corp. v. Myrick*, 514 U.S. 280, 287 (1995)). "A state law may pose an obstacle to federal purposes by interfering with the accomplishment of Congress's actual objectives, or by interfering with the *methods* that Congress selected for meeting those legislative goals." *PPL EnergyPlus, LLC v. Nazarian*, 753 F.3d 467, 478 (4th Cir. 2014) (citation omitted), *aff'd, Hughes*, 578 U.S. 150.

North Carolina's mifepristone restrictions run afoul of these preemption principles. To use the district court's words, these additional state-law requirements upset the careful regulatory "balance" Congress has entrusted the FDA to strike between "safety, efficacy, patient access, and burdens on the health care system." JA 631. And they wreck that balance by trenching directly on the FDA's decisions "around who, where, and how [this] REMS drug can be prescribed, dispensed, and administered" JA 642 (citing 21 U.S.C. §§ 355-1(f)(3)(A)–(C)).

1. Start with the North Carolina mifepristone restrictions the district court properly held to be preempted by the FDA's REMS regime: the requirements (1) that only physicians prescribe the drug, N.C. Gen. Stat. § 90-21.83B(a); (2) that the physician prescribing mifepristone be "physically present in the same room as the woman" when she takes the drug, *id.* § 90-21.83A(b)(2)(a); (3) that there must be a follow-up appointment between physician and patient after mifepristone is taken, *id.* § 90-21.83B(b); and (4) that physicians must report any adverse effects from use of mifepristone to FDA, *id.* § 90-21.93(c).

As the district court recognized, the preemption analysis for these restrictions is straightforward. That is because Congress has expressly given FDA the power to identify the kinds of "health care providers who [may] prescribe" REMS drugs like mifepristone, and to choose which "health care settings" are appropriate for dispensing of such drugs. 21 U.S.C. §§ 355-1(f)(3)(A)–(C).

FDA has exercised that power with respect to mifepristone. For a time, FDA had regulations on the books requiring that prescription and dispensing of the drug be in-person and physician-only, and also mandating follow-up appointments and reporting of all adverse events to the agency—in other words, regulations materially identical to a number of these new restrictions imposed under North Carolina law. *See Information about Mifepristone for Medical Termination of Pregnancy Through Ten Weeks Gestation*, FDA (Mar. 23, 2023), http://tinyurl.com/5n8jdukk. But in the course of fulfilling its statutory obligation to regularly revisit and refine the REMS regime, the agency ultimately concluded that all of these requirements were no longer necessary for safe and efficient access to mifepristone. *Questions and Answers on Mifepristone for Medical Termination of Pregnancy Through Ten Weeks Gestation*, FDA (Sept. 1, 2023), http://tinyurl.com/54dannd5 (*Questions and Answers*).

The district court therefore correctly concluded that this is a classic obstacle-preemption scenario, where the federal agency given power to regulate has expressly considered and rejected imposing certain requirements, and a state then seeks to countermand that reasoned decision by imposing the rejected restrictions. *Cf. Geier v. Am. Honda Motor Co.*, 529 U.S. 861, 881 (2000) (state tort theory that would effectively impose a requirement that was considered and rejected by federal regulators was preempted).

2. The district court went astray, however, when it decided that obstacle preemption does not invalidate three other North Carolina mifepristone provisions, which require (1) that the patient have an in-person consultation, N.C. Gen. Stat. § 90-21.83A, (2) that a physician examine the patient in-person before administering mifepristone, *id.* § 90-21.83B(a), and (3) that all mifepristone-related adverse events be reported to the State, *id.* § 90-21.93.

These requirements are elaborate. For example, the in-person consultation must occur "[a]t least 72 hours prior to the medical abortion," and it requires the patient be "orally informed" of and sign an exhaustive consent form. N.C. Gen. Stat. § 90-21.83A(b). And the in-person examination must be conducted by "[a] physician," who must, among other things, perform an ultrasound, determine the patient's blood type, and "[s]creen the woman for coercion[] [or] abuse." *Id.* § 90-21.83B(a). The result is that North Carolina patients cannot take mifepristone without first jumping through significant procedural hoops that impose practical burdens (*e.g.*, performing the consultation at least 72 hours prior to use of the drug) and emotional challenges (*e.g.*, undergoing probing questions about potential abuse).

Again, the structure and history of FDA's mifepristone regulations straightforwardly compel the conclusion that these restrictions are preempted as well. As already explained, FDA has express authority to decide the who, what, where, when, and how of prescribing, administering, and dispensing REMS drugs

like mifepristone. 21 U.S.C. §§ 355-1(f)(3)(A)–(C). Exercising that authority, FDA has expressly considered and rejected arguments that patients taking mifepristone should be required to undergo either a consultation or an examination in-person. JA241. In doing so, the agency has determined that "[c]ertified prescribers do not have to be physically present with the patient" to perform any medically necessary evaluation, and that "physical proximity" is not required for securing patient consent. JA241. The agency has also concluded, after studying its "15 years of adverse event reports" and extensive experience with "the well-characterized safety profile of" mifepristone, that mandatory reporting of all adverse events is not necessary for this drug. JA249.

Stepping back, the record reveals an important general pattern: as it has continually revised and refined its REMS/ETASU framework for mifepristone, FDA has consistently decided that the best choice, as a matter of science and policy, is to modify the framework to *expand* rather than restrict access to the drug. Repeatedly, after exhaustive and rigorous review, the agency has "determined, based on the available data and information," that access-enlarging measures are the right way to "reduce burden on the health care delivery system and to ensure the benefits of [mifepristone] outweigh the risks." *Questions and Answers, supra*.

Accordingly, just like the other provisions the district court held to be preempted, these three North Carolina measures (the in-person consultation, in-

person examination, and adverse-event-reporting requirements) would impose restrictions FDA has considered and repudiated, running directly counter to the agency's access-expanding decisions. Because they plainly "limit the availability of an option that [a] federal agency consider[s] essential to ensure its ultimate objectives," these restrictions are also preempted. *Geier*, 529 U.S. at 882.

The district court reached the opposite conclusion because these three provisions were framed as being "directed to broader health concerns," leading the court to believe they were "regulation[s] of the practice of medicine" permitted under the State's traditional police powers. JA 627-638. The preemption analysis, however, is keyed to the state law's "practical impact" on the relevant federal scheme, 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 about the ultimate effect of these North Carolina mifepristone restrictions. Patients who cannot afford multiple in-person appointments with a physician, or who are unable to find a physician nearby with the equipment needed to perform an ultrasound or blood tests, will be unable to take mifepristone. And many patients who could theoretically secure the in-person

appointments will undoubtedly be discouraged from doing so for reasons both practical and emotional. Some patients will be unable to take the time off from work necessary to make multiple in-person appointments within the timeframe imposed by the laws. Others will be discouraged from going through the process because they may not feel safe being asked about abuse. The upshot is that access to mifepristone will inevitably be significantly restricted.

This is exactly why, when faced with state-law restrictions on a REMS-regulated drug that would "undeniably make[] [the drug] less available," another federal district court readily concluded there was "a constitutional problem." *Zogenix, Inc. v. Patrick*, 2014 WL 3339610, at *3-4 (D. Mass. July 8, 2014) (granting preliminary injunction against Massachusetts regulation of REMS-regulated opioid, Zohydro, that would have required physicians to attempt to use other medications before turning to Zohydro), *injunction vacated in part after modification to challenged regulations*, 2014 WL 4273251 (D. Mass. Aug. 28, 2014). As that court reasoned, although a state's "police powers permit it to regulate the administration of drugs by the health professions," a state "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." *Id*. The same logic applies here.

II. The North Carolina restrictions pose 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.

This case illustrates the principle. Allowing North Carolina's mifepristone restrictions to stand would risk serious downstream effects on the national healthcare system. Among other consequences, doing so could encourage states to impose their own onerous barriers to accessing other prescription drugs and medical devices that are politically controversial. 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.

A. North Carolina's mifepristone restrictions, if upheld, will encourage states to frustrate access to other essential drugs approved by the FDA.

As discussed, North Carolina's mifepristone restrictions seek to second-guess the FDA's exhaustively considered determinations about the who, what, where, when, and how of access to mifepristone. While the district court correctly

recognized that some of the restrictions pose an obstacle to FDA's REMS/ETASU regime and are preempted, it declined to find other restrictions preempted when they were framed as regulating broader health issues.

The endpoint of that logic is troubling: States will be encouraged to find creative ways to frustrate access to politically controversial REMS medications by enacting onerous restrictions couched in the rhetoric of general health-and-safety regulation. The resulting patchwork of regulatory schemes 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), https://tinyurl.com/44usy7yc. 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. At first (and much like with mifepristone), when PrEP was initially approved in 2012, FDA's REMS framework for the drug required patients to undertake frequent in-person visits with their doctor and answer detailed questions about their sexuality. *See, e.g.*, *Truvada® Checklist for Prescribers*, https://tinyurl.com/3ed42wwk. After a number of years of experience with the drug

and extensive deliberation, the agency decided that these requirements were unnecessary and removed the REMS regulations for PrEP. *See FDA in Brief*, FDA (July 1, 2019), http://tinyurl.com/35h6pvbk/. That decision has significantly increased access to PrEP, particularly for patients in underserved communities. Stephen Bonett et al., *Telehealth Models for PrEP Delivery*, 28 Aids and Behavior 2875, 2875-76 (June 10, 2024) (*PrEP Delivery*), https://tinyurl.com/2b8rbww9 (explaining that "[t]elehealth delivery models for PrEP ... can enhance PrEP access and adherence by providing flexible care remotely" and bypassing "significant barriers" to access in underserved communities).

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.[3] The governors of a number of states have also blocked funding for PrEP and HIV-related care, or have threatened to do so.[4]

The North Carolina restrictions offer states a playbook for how to engage in further obstruction of FDA's judgment regarding access to PrEP. For example, a state could pass a measure requiring patients seeking access to PrEP to disclose details of their sexual history, undergo screening for drug use, or read literature purporting to describe the risks of homosexual sex. The state passing such consultation and examination restrictions might, like North Carolina has done here, insist that these measures are "not directed solely to reducing or managing the safety risks of" PrEP, "but instead are directed to broader health concerns," JA 637, such as discouraging prostitution, sexual promiscuity, and intravenous drug use. Under the district court's reasoning, that could be a permissible exercise of the state's police powers over health and medical practice.

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[3] The district court in this case ultimately sided with the plaintiffs on some of their claims. *See Braidwood Mgmt.*, ECF 113. That decision was affirmed in part and reversed in part by the Fifth Circuit. *Braidwood Mgmt., Inc. v. Becerra*, 104 F.4th 930 (5th Cir. 2024). The government has filed a petition for a writ of certiorari with the Supreme Court. *See Becerra v. Braidwood Mgmt., Inc.*, No. 24-316 (U.S. Sept. 19, 2024).

[4] *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.

As a consequence, HIV patients in some states would face onerous, embarrassing, and potentially dangerous hurdles to accessing a revolutionary medicine. Research suggests that "[u]ptake" for this crucial medication, meaning "the number of people seeking and using PrEP," "is shaped by awareness of, and confidence in, PrEP services as non-judgmental[] [and] confidential," among "other factors." Southern AIDS Coalition, *Towards PrEP Access for All* (March 2024), https://tinyurl.com/7e4rs2ya. The flip side of this is that among the most "significant barriers to achieving wide-spread uptake of PrEP" are obstacles like "limited appointment availability with PrEP providers, experiences of stigma and discrimination while seeking healthcare, and logistical barriers related to transportation and scheduling." *PrEP Delivery, supra*, at 2876. It is therefore unsurprising that even mild restrictions on access to PrEP substantially decrease patients' access to PrEP and thereby increase rates of HIV transmission. *See* Neal Carnes, et al., *Restricting Access: A Secondary Analysis of Scope of Practice 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 this Court agrees with Intervenors that North Carolina's mifepristone restrictions are not preempted, state legislatures may come to believe that they are empowered to directly disagree with the FDA's determinations and further restrict use of opioids in medical practice—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. 12, *supra*, at least one state (Massachusetts) has already attempted to take such measures with respect to an FDA-approved opioid, Zohydro, over concerns about addiction and misuse. A federal court, reasoning that "that [Massachusetts was] trying to make scarce or altogether unavailable a drug that the FDA, by approving it, has said should be available," enjoined that effort. *Zogenix*, 2014 WL 3339610, at *3-4. But if North Carolina's mifepristone regulations are allowed to stand, the next attempt to frustrate the availability of a REMS drug may be more successful.

To be clear, DFA does not agree with Intervenors' argument (at 33) that finding preemption in this case would require concluding that run-of-the-mill state-level regulation of opioids (such as additional licensing requirements for prescribers) are likewise preempted. States retain significant authority to regulate medical practice, including medical practice related to REMS drugs, and they may enact a range of extra safeguards concerning the use and prescription of opioids. But those safeguards must *complement* the federal regulatory regime. They cannot, as North Carolina's mifepristone restrictions do here, *directly undermine* the FDA's judgment concerning the proper conditions for prescribing, dispensing, and administering a REMS drug.

3. For these reasons, greenlighting North Carolina's efforts to second-guess the FDA's expert, careful judgment regarding the proper conditions for accessing mifepristone risks creating a patchwork system of drug regulations. The resulting crazy-quilt of access regimes, in which the practical availability of life-saving medications could differ dramatically state-by-state and depend on regional politics rather than science, goes contrary to 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), https://tinyurl.com/2fjfcj8p. 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). State-level restrictions like North Carolina's mifepristone laws undermine this promise, a lynchpin of the American healthcare system.

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

1. A patchwork of state-level restrictions on REMS medications like mifepristone 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. Relevant here, the American College of Obstetricians and Gynecologists ("ACOG") has promulgated guidance on "medication abortion." *Medication Abortion Up to 70*

Days of Gestation, ACOG (Oct. 2020), http://tinyurl.com/47zmtcum (*Medication Abortion*). 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.

Among other things, this guidance provides detailed advice to practitioners regarding "[w]ho is qualified to provide medication abortion, and in what settings ... medication abortion [can] be provided." *Medication Abortion*, *supra*. It advises that, "[i]n addition to physicians, advanced practice clinicians, such as nurse-midwives, physicians assistants, and nurse practitioners, possess the clinical and counseling skills necessary to provide first-trimester medication abortion"; indeed, the guidance cites "trial[]" results showing "that patients randomized to receive medication abortion under the care of a nurse or nurse-midwife had a statistically equivalent risk of complete abortion compared with those under the care of a physician, without increased risk of adverse events." *Id*. The guidance also explains that "[p]atients can safely and effectively use mifepristone at home for medication abortion," and that "[m]edication abortion can be provided safely and effectively by

telemedicine with a high level of patient satisfaction." *Id*.[5] This guidance comes with a caveat, however: "Despite th[e] evidence" driving ACOG's standard-practice recommendations, "some states have passed legislation" forbidding that mifepristone be prescribed via telemedicine or by a non-physician. *Id*.

As these state-level variations from the national standard proliferate, attempts to provide guidance for physicians across the country will become increasingly difficult, if not impossible. 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.

This is not just a theoretical concern—as a number of DFA's members can attest, because of state-law restrictions like North Carolina's mifepristone laws, medical professionals are already being put to this impossible choice. In a testimonial provided to DFA in connection with the preparation of its brief, one of DFA's physician members, Dr. Darshan Patel, explained that he and his colleagues see "no rationality or upside" to North Carolina's in-person consultation requirements for accessing mifepristone. As Dr. Patel puts it, these state-level

[5] The guidelines were promulgated in 2020, and they therefore describe the then-current FDA requirement for in-person dispensing of mifepristone. *Medication Abortion*, *supra*. The ACOG has since noted that FDA has repealed the in-person dispensing requirement, meaning that ACOG's standard-practice guidance and federal regulations are fully aligned on the issue. *ACOG Guidance for Medication Abortion: Evaluation, Dosing and Follow-Up*, ACOG, https://tinyurl.com/44vhupxt.

restrictions undercut the "nonpartisan expert guidance of the Food and Drug Administration" that he and his colleagues look to.

Another DFA physician member, Dr. Aliye Runyan, agrees that these additional restrictions on access to mifepristone "are in place for political reasons, not medical ones," and frustrate the ability of "physicians and the medical community to look to the FDA and other governing bodies, not the variations among state laws, for uniform guidelines and evidence based practice." The result, she believes, is that the "practice of medicine is being unethically limited by restrictive laws." As described by a third physician member, Dr. Kelley Butler, doctors around the country "cannot imagine having to only provide this care in person or subject patients to lab work and imaging when the barriers are already high to access this care in most states and none of these restrictions are evidence-based."

b. A patchwork of state drug laws would also complicate 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 balkanize the regulatory regimes for important medications like

mifepristone, 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.

c. This increasing divergence between national-practice standards and state-law regimes 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).

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. To quote again from the testimonial of Dr. Patel, one of DFA's physician members, medical professionals have "moved to embrace telemedicine" because it allows them to prescribe mifepristone to patients "without the added burden of an in-person visit."

But in the aftermath of new abortion restrictions like the North Carolina laws at issue here, "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 more state-level restrictions proliferate, and it may impede the expansion of telemedicine—another outcome directly at odds with federal policy.

2. Patients across the country will be harmed by this patchwork effect as well.

a. The North Carolina mifepristone restrictions show why. Around "21.0 percent of counties" in North Carolina "are defined as maternity care deserts," meaning that there are "zero" "[h]ospital birth centers offering obstetric care" and "zero" "[o]bstetric providers" in the area per 10,000 births; there are also dramatic disparities in access to maternity care across the State. *See Maternity Care in North Carolina*, March of Dimes (2023), https://tinyurl.com/4d3s9c63. With this in mind,

recall that mifepristone is only approved for safe use within 70 days of gestation. Then combine these data points with research showing that one in three women learn they are pregnant *after* the 6-week gestation mark.[6] From this, it quickly becomes apparent that North Carolina's mifepristone restrictions are much more serious than a bureaucratic nuisance. Instead, these restrictions will almost certainly make access to mifepristone difficult to impossible for the many North Carolinian patients who do not have ready access to maternal care and only discover their pregnancy shortly before the 70-day cutoff for taking mifepristone.

These obstacles to accessing mifepristone will be especially burdensome for the most vulnerable Americans. Abortion services are 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*

[6] *See One in three people learn they're pregnant past six weeks' gestation*, ANSIRH (Nov. 10, 2021), https://tinyurl.com/47faeuxw.

Maternal and Infant Health; Current Status and Efforts to Address Them, KFF (Nov. 1, 2022), http://tinyurl.com/yck4fs8p. Restrictions like North Carolina's, which require women to secure and pay for an in-person consultation and examination with a physician before they can use mifepristone, simply exacerbate these already-stark inequalities. *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

Additional bans of REMS/ETASU medications would compound these harms, and could ultimately 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 thrown up significant barriers to access. The example of abortion suggests that Americans who are already most at risk will be the ones most harmed.

And once again, the risk is not merely hypothetical—DFA's physician members are already dealing with the fallout from North Carolina's mifepristone regime. As Dr. Runyan notes, "clinics" in North Carolina "are often overburdened because there are fewer abortion clinics that are open in restricted states." As a result, even as far away as New York, where Dr. Runyan practices, she and her colleagues "routinely see patients from" states like North Carolina with restrictive regimes, which in turn "adds" to her own clinic's "workload" and its ability to keep

up with patient demand. Another DFA physician member, Dr. Maria Phillis, explains that North Carolina's "onerous non evidence based in person requirements for dispensing of mifepristone increases the demands on an already overwhelmed physician work-force," a burden that is only "magnified in settings where there are zero or limited providers of this care" and "for patients with less resources."

b. Widespread defection from federal law also undermines public trust in the authority of the FDA and the national medical community.

Confidence in federal healthcare policy is already fragile: the data show that 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), https://tinyurl.com/54pb4jcz. Direct conflict between the federal and state governments over drug access will only exacerbate the problem.

DFA's physician members are already seeing the evidence of this dangerous trend. Dr. Runyan observes that "laws limiting abortion access" like the North Carolina ones here "erode trust in the medical profession." Because of this, "patients who are already distrustful of the medical system, or are distrustful of physicians, are not likely to access care when complications occur." The results can be tragic. Take the already-notorious example of Candi Miller, a Black woman from Georgia

who, afraid of facing legal repercussions for seeing a medical professional about her pregnancy, "avoided doctors and navigated an abortion on her own," with fatal consequences. Kavitha Surana, *Afraid to Seek Care Amid Georgia's Abortion Ban, She Stayed at Home and Died* (Sept. 18, 2024), https://tinyurl.com/478wv8ft. Permitting states to second-guess FDA's reasoned judgment about the when, where, and how of accessing a critical medication will only drive a deeper wedge between Americans and the medical profession; from that loss of trust, the most vulnerable in our communities will suffer the most.

CONCLUSION

As set forth in Dr. Bryant's brief, the district court's decision should be affirmed in part and reversed in part.

Respectfully submitted,

/s/Brian T. Burgess

Brian T. Burgess
GOODWIN PROCTER LLP
1900 N Street, N.W.
Washington, D.C. 20036
Tel.: +1 202 346 4000

William E. Evans
Samantha L. Jandl
GOODWIN PROCTER LLP
100 Northern Ave.
Boston, MA 02210
Tel.: +1 617 570 1000

Counsel for Amicus Curiae *Doctors for America*

Christopher Morten
Nora M. Franco
SCIENCE, HEALTH & INFORMATION CLINIC
MORNINGSIDE HEIGHTS LEGAL SERVICES, INC.
Columbia Law School
435 West 116th Street
New York, NY 10027
Tel.: +1 212 854-4291

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CERTIFICATE OF SERVICE

I, Brian T. Burgess, hereby certify that on October 17, 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.

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Brian T. Burgess

CERTIFICATE OF COMPLIANCE

This brief complies with the type-volume limitation of Federal Rule of Appellate Procedure 29(a)(5). This brief contains 6429 words, excluding the parts of the brief exempted by Federal Rule of Appellate Procedure 32(f).

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/s/ Brian T. Burgess

Brian T. Burgess