23-2194

IN THE UNITED STATES COURT OF APPEALS
FOR THE FOURTH CIRCUIT

GenBioPro, Inc.,
Plaintiff-Appellant,
v.
Kristina Raynes, et al.,
Defendants-Appellees.

On Appeal from the United States District Court
for the Southern District of West Virginia, No. 3:23-0058,
The Honorable Robert C. Chambers, Judge

BRIEF OF CITY OF BALTIMORE AND BALTIMORE COUNTY, MARYLAND IN SUPPORT OF APPELLANT AND REVERSAL

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TABLE OF CONTENTS

TABLE OF AUTHORITIES

CASES

STATUTES

OTHER AUTHORITIES

STATEMENT OF INTEREST

Amici are the City of Baltimore and Baltimore County, Maryland.[1] We file this brief in furtherance of our interest in preserving access to essential reproductive healthcare and addressing health disparities—inequities between groups with respect to health (e.g., disease incidence), health care (e.g., access to physicians and other providers), and health outcomes (e.g., mortality). *Amici* and others in Maryland strive to provide regional leadership, services, and support when our peer governments fall short, as the state of West Virginia has done in its handling of reproductive healthcare.

West Virginia effectively deauthorizing mifepristone has overburdened *amici*'s health systems and funds. Pregnant people who are unable to access mifepristone in West Virginia are now traveling to Maryland for abortion care, and often later in their pregnancies due to the challenges of having to leave their home state–leading to more

[1] No counsel for a party authored this brief in whole or in part, and no party or counsel for a party made a monetary contribution intended to fund its preparation or submission. No person other than amicus or amicus' counsel made a monetary contribution to the preparation or submission of this brief. All parties consented to the filing of this brief, so no motion for leave to file this brief is required.

complications and poorer health outcomes. *Amici*'s providers, clinics, and support networks have taken extraordinary measures to serve and protect these West Virginians and will continue to do so–working overtime and providing hundreds of thousands of dollars in funds to West Virginians who need financial support to travel to Maryland to get the care they need. But this surge of West Virginians into our jurisdictions is straining even *amici*'s health care system capacity, and our providers struggle to meet this influx while also providing necessary healthcare to our own residents. If the decision below is affirmed, there will be significant consequences for *amici*.

SUMMARY OF ARGUMENT

The District Court's decision granting, in part, the motion to dismiss should be reversed, because West Virginia's ban on mifepristone is clearly preempted by federal law. Congress occupied the field for a limited set of drugs, which includes mifepristone, due to the need to finely calibrate among authorization, access, and safe usage. In reversing the decision below, this Court should understand that West Virginia's decisions have impacts across state lines. In particular, providers and clinics in Maryland have seen a significant surge in patient demand from

West Virginia residents, burdening health care delivery systems in our state and impairing our ability to meet the new demand as well as the needs of our own residents.

ARGUMENT

I. CONGRESS OCCUPIED THE REGULATORY FIELD—AND PREEMPTED THE STATES' ROLE—FOR A SUBSET OF DRUGS, INCLUDING MIFEPRISTONE, BY DEMANDING COMPLEX BALANCING OF INTERESTS AND DATA.

Among the tens of thousands of drugs that the Food and Drug Administration (the FDA) has approved, a tiny subset raises particularly challenging questions of access and safety. Congress recognized this particular niche of pharmaceutical regulation in the Food and Drug Agency Amendments Act of 2007 (FDAAA). That statute instructed the FDA to impose restrictions on the distribution, prescription, and dispensation of certain drugs that require a closer look. 21 U.S.C. §§ 355-1(a), (f). Mifepristone has been one of the drugs subject to such a Risk Evaluation and Mitigation Strategy (REMS) from the beginning. The detailed and precise balancing of safety concerns and the burdens on patient access to these drugs reflects congressional intent for the FDA to occupy the regulatory field, and simply could not be replicated at the state or local level. Accordingly, although we are loath to undermine

states' general role in regulating medical activities, the REMS regulatory regime for mifepristone (and other REMS drugs) must be uniform and federal.

Courts rightly impose a number of presumptions against preemption of state regulatory power, although Congress can overcome each of them. *See Mut. Pharm. Co. v. Bartlett*, 570 U.S. 472, 503 (2013) (Sotomayor, J., dissenting) (bemoaning the Court's willingness to find that the FDA preempted state law and invoking the presumption against preemption).[2] Congress displays such an intent to occupy a field when it establishes (or directs an agency to establish) a "scheme of federal regulation . . . so pervasive as to make reasonable the inference that Congress left no room for the States to supplement it." *Ray v. Atl. Richfield Co.*, 435 U.S. 151, 157 (1978). Preemption is particularly justified where this scheme requires an agency to "balance a number of [competing] considerations." *Id.* at 177.

[2] Likewise, in 1962, Congress enacted a savings clause expressly preserving consistent state remedies as not preempted by the FDA's pre-market regulatory regime. Drug Amendments of 1962, Pub. L. No. 87-781, § 202, 76 Stat. 780, 793 (codified at 21 U.S.C. § 301).

The FDA's REMS regime for mifepristone exemplifies the pervasive nature of the agency's regulatory scheme and the careful balancing of safety and access that the REMS process requires. Congress delegated to the FDA the balancing of risk mitigation, patient access, and burden on the healthcare delivery system. *See* 21 U.S.C. § 355-1 (f)(2). This includes particular attention to access for certain groups of patients: "(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).

As the District Court acknowledged, the FDA engaged in rigorous agency and pharmaceutical industry review processes. *See* JA258 (citation omitted). "Mifepristone has been subject to more regulatory and congressional scrutiny than perhaps any other prescription drug." *Id.* (citation omitted). In contrast, the West Virginia Legislature effectively undid the FDA's work and disapproved the drug for use in the state without any consideration for the congressional objectives, let alone an internal team of experts conducting medical, pharmacological, or statistical reviews of all available data on mifepristone.

The state legislature's lack of understanding is reflected in one of the requirements that threatens to take effect if the UCPA is struck down. The legislature requires patients taking mifepristone to certify that they have been informed that "[s]ome suggest that it may be possible to counteract the intended effects of a mifepristone chemical abortion, but this process has not been approved by FDA." W. Va. Code § 16-2I-2(a)(4)(A), (C).[3] Not a single credibly designed scientific study supports "abortion pill reversal," and it is rejected by the American College of Obstetricians and Gynecologists as failing to meet clinical standards and compromising patient care and safety.[4] West Virginia's failure to detect

[3] The district court did not address this requirement because it incorrectly allowed the UCPA to stand. Should this Court correct the district court's error, it would be necessary to likewise hold that this statute is preempted.

[4] *See* Sara K. Redd et al., *Medication Abortion "Reversal" Laws: How Unsound Science Paved the Way to Dangerous Abortion Policy*, 113 Am. J. Pub. Health 202, 202 (2023); American College of Obstetricians and Gynecologists, *Facts Are Important: Medication Abortion "Reversal" Is Not Supported by Science*, https://www.acog.org/advocacy/facts-are-important/medication-abortion-reversal-is-not-supported-by-science; American College of Obstetricians and Gynecologists, *Medication abortion up to 70 days of gestation* (Oct. 2020), https://www.acog.org/clinical/clinical-guidance/practicebulletin/articles/2020/10/medication-abortion-up-to-70-days-of-gestation; Daniel Grossman & Kari White, Abortion "Reversal" – Legislating Without Evidence, 379 New Eng. J. Med. 1491, 1492 (2018); Ruth Graham, *The Dubious Research on Abortion-Pill*

the unreliability of studies supporting so-called "abortion pill reversal" while promoting it in legislation demonstrates why FDA is the appropriate, sole, national regulator of REMS drugs like mifepristone. The West Virginia legislature is simply insufficiently resourced to study and appropriately legislate around the specific challenging questions of access and safety of REMS drugs like mifepristone. Only the FDA has the resources and mandate to do it.

Meanwhile, the West Virginia legislature ignored a real risk of restricting access to mifepristone that the FDA has considered: the risk of self-managed abortion. A self-managed abortion is one that occurs outside the traditional healthcare setting and includes methods such as medication, herbs and botanicals, and self-harm. Self-managed abortions induced using medications such as mifepristone or misoprostol are associated with low levels of complications, but those who lack access or live in states that criminalize self-managed abortion or impair access to medication abortion may turn to more dangerous methods. Those who use unsafe methods of self-management have higher chances of mortality

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"Reversal", Slate (July 19, 2018), https://slate.com/human-interest/2018/07/why-an-abortion-pill-reversal-study-has-been-temporarily-withdrawn-by-the-pro-life-journal-that-published-it.html.

and may need life-saving care for sepsis, hemorrhage, pelvic-organ injury, or toxic exposures.

The FDA was tasked to consider the needs of various people who seek essential mifepristone, and it struck a balance to provide safe, lifesaving, necessary healthcare access. The FDA occupies the regulatory field for REMS drugs because it can engage in careful policy analysis that West Virginia did not, and perhaps could not, do.

II. WEST VIRGINIA'S DEAUTHORIZATION OF MIFEPRISTONE UNDULY BURDENS PATIENTS AND THE HEALTH CARE DELIVERY SYSTEM, STRAINING WEST VIRGINIANS AND MARYLANDERS ALIKE.

Congress mandated that restrictions on REMS drugs "not be unduly burdensome on patient access to the drug, considering in particular . . . patients who have difficulty accessing health care (such as patients in rural or medically underserved areas)." 21 U.S.C. § 355-1(f)(2)(C)-(D). Congress also required that restrictions "minimize the burden on the health care delivery system." *Id.* West Virginia's deauthorization of mifepristone burdens underserved patients and regional health care delivery systems.

Meaningful health care access for medically underserved populations is vitally important to West Virginia, Baltimore City and

County, and Maryland. Nearly all of West Virginia's counties contain a federally designated medically underserved area or population, while more than 75% of Baltimore residents (and over a million Marylanders statewide) similarly reside in medically underserved areas.[5] While Baltimore has a large number of medical providers, not enough of them provide care to low-income people, and the available providers are not equally distributed throughout the city.[6] While some neighborhoods have no primary care provider at all, others have one for tens of thousands of people.[7] Wait times for even general medical care are several weeks for large portions of Baltimore City, even without the increased demand from out-of-staters seeking appointments and care.[8]

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[5] *See* U.S. Department of Health and Human Services, *Medically Underserved Area and Medically Underserved Population Designations Throughout the United States*, https://data.hrsa.gov/tools/shortage-area/mua-find; Maryland Department of Health, 2021 Primary Care Needs Assessment (Sept. 20, 2021), https://health.maryland.gov/pophealth/Documents/Primary%20care/Final%20Needs%20Assessment%20090221.pdf.

[6] Milbank Memorial Fund, *Assessing the Effectiveness of Policies to Improve Access to Primary Care for Underserved Populations: A Case Study Analysis of Baltimore City, Maryland* (Aug. 12, 2022), https://www.milbank.org/publications/assessing-the-effectiveness-of-policies-to-improve-access-to-primary-care-for-underserved-populations-a-case-study-analysis-of-baltimore-city-maryland/.

[7] *Id.*

[8] *See id.*

Lack of access to mifepristone in West Virginia has forced West Virginians to travel to Maryland, among other places, for abortion care. In just the first quarter of 2023, an estimated 3,980 people traveled to Maryland from out of state for abortion care.[9] Medical providers and staff, clinics, and hospitals in *amici*'s communities have made heroic efforts to meet the influx of West Virginians and other out-of-staters seeking medication abortion and other abortion care in Maryland that is unavailable in their home states.[10]

Many of these patients from West Virginia and elsewhere are arriving for care in Maryland at later stages in their pregnancies, requiring more invasive procedural abortions. *Id.* And some have had to delay care for so long due to the challenges of leaving West Virginia and traveling to Maryland that they will experience more complications and worse health outcomes. Many of these people would have opted for earlier, less invasive care with lower risk of complications in West Virginia if medication abortion were available there within the formal

[9] Guttmacher Institute, *Monthly Abortion Provision Study*, https://www.guttmacher.org/monthly-abortion-provision-study.
[10] Christina Cauterucci, *Maryland is Becoming the Patron State of Abortions*, Slate.com (July 17, 2023), https://slate.com/news-and-politics/2023/07/maryland-abortion-access-wes-moore.html.

health care system. Instead, they were forced to delay: saving funds and making arrangements to travel out of state.

Providing care for West Virginians traveling to Maryland strains provider availability for *amici*'s residents and exacts enormous costs on our providers, residents, and support networks. Clinic staff in Maryland have seen a surge of out-of-state patients and have had to work overtime to provide care.[11] Our providers, clinics, and support networks are also striving to meet other growing needs–handling hugely increased call volumes, and far more financial requests for travel, child care, and other logistical supports.[12] For example, Baltimore's City Council and Mayor have infused additional support to organizations providing abortion care.[13] This increase in grant funding has helped to increase abortion

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[11] Amy Zimmardi, *Maryland Becomes Haven for Out-of-State Abortion Seekers, Providers*, Capital News Service (Sept. 15, 2022), https://cnsmaryland.org/2022/09/15/maryland-becomes-haven-for-out-of-state-abortion-seekers-providers/.

[12] Eden Stiffman, *Abortion Funds Face Slowdown in Giving a Year after Supreme Court Ruling*, The Chronicle of Philanthropy, June 12, 2023, https://www.philanthropy.com/article/abortion-funds-face-slowdown-in-giving-a-year-after-supreme-court-ruling.

[13] Baltimore City Press Release, *Mayor Scott Announces Additional Funding for Baltimore Organizations Providing Abortion Care* (July 25, 2023), https://mayor.baltimorecity.gov/news/press-releases/2023-07-25-mayor-scott-announces-additional-funding-baltimore-

access for Maryland residents and out-of-staters by allowing service providers to hire more staff, increase in–person and telehealth visits for medication abortion, and cover patients' travel and treatment costs.[14] The Baltimore Abortion Fund tripled its distributions to meet the enormous and growing need for the direct and indirect costs for those seeking abortion care.[15] And, from January 2022 to June 2023, another fund disbursed more than $150,000 to eight hundred mostly West Virginians to travel out of state for care.[16] Maryland clinics have also brought on more staff and expanded their schedules to accommodate higher patient demands from West Virginia and elsewhere.[17]

Baltimore City and Baltimore County do not foresee our providers, clinics, and support networks seeing a reduced need to provide care and

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organizations#:~:text=Early%20in%20June%202022%2C%20the,for%20people%20seeking%20to%20terminate.

[14] *Id.*

[15] Guttmacher Institute, *Monthly Abortion Provision Study*, https://www.guttmacher.org/monthly-abortion-provision-study.

[16] Leah Willingham, *New Maryland Provider Opening in Post-Roe Abortion Desert*, A.P. (Mar. 27, 2023), https://apnews.com/article/maryland-abortion-clinic-west-virginia-647cbd9eccfaaa740e523a5c39208b19.

[17] Christina Cauterucci, *Maryland is Becoming the Patron State of Abortions*, Slate.com (July 17, 2023), https://slate.com/news-and-politics/2023/07/maryland-abortion-access-wes-moore.html.

support to West Virginians until that state unblocks access to mifepristone. Without access to this necessary early-abortion medication, the impacts on West Virginians needing abortion care and on those in our jurisdictions extending themselves to provide it will remain steady or grow. We believe that access to safe and reliable healthcare should not depend on where people live, their race, ethnicity, or income level. And so, *amici*'s communities will strive to continue providing a baseline and uniform standard of access to safe and effective mifepristone and other abortion care to our residents and West Virginians alike, despite our strained capacity and resources. We hope that West Virginia will change course to ease the tremendous burdens it has placed on patients, providers, and health care delivery systems regionally, or that this Court will order it to do so.

Congress delegated to FDA the responsibility to balance risks, benefits, safety, and access to medications. FDA's balancing is particularly intricate for the tiny percentage of drugs subject to REMS. We are aware of no precedent for a state ban that effectively disapproves and makes practically unavailable another FDA-approved drug–no less a drug subject to the REMS regime. While mifepristone's intended use

may be offensive to some, Congress has assigned the question of its legality to the FDA. West Virginia's deauthorization of mifepristone threatens necessary healthcare, further burdens underserved patients, aggravates existing racial and economic disparities, undermines FDA's careful balancing of risks, benefits, and burdens, and strains Maryland providers, clinics, support networks, and residents. It should be checked.

CONCLUSION

For all of the foregoing reasons, the District Court's opinion granting Defendants' motions to dismiss should be reversed.

February 14, 2024

Respectfully submitted,

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CERTIFICATE OF COMPLIANCE

The undersigned counsel hereby certifies that this brief complies with type-volume limits and typeface requirements of Federal Rule of Appellate Procedure 32 and corresponding local rules. Excluding the parts of the document exempted by Fed. R. App. R. 32(f), this brief contains 2,494 words, determined using the word count function in Microsoft Word.

/s/ Joshua A. Rosenthal
Joshua A. Rosenthal

Dated: February 14, 2024

CERTIFICATE OF SERVICE

I hereby certify that a copy of the foregoing document was filed electronically with the Court's CM/ECF system on February 14, 2024. Service will be effectuated by the Court's electronic notification system upon all parties and counsel of record.

/s/ Joshua A. Rosenthal
Joshua A. Rosenthal

Dated: February 14, 2024