

**IN THE UNITED STATES DISTRICT COURT
FOR THE SOUTHERN DISTRICT OF WEST VIRGINIA
HUNTINGTON DIVISION**

GENBIOPRO, INC.,

Plaintiff,

v.

**KRISTINA 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.**

**Civil Action No.: 3:23-cv-00058
(Hon. Robert C. Chambers)**

**MOTION TO AMEND COMPLAINT
AND JOINT STIPULATION**

Plaintiff GenBioPro, Inc., moves for leave to amend its complaint, Dkt. No. 1, under Federal Rule of Civil Procedure 15(a)(2) by filing Plaintiff's First Amended Complaint, attached as Exhibit A. Plaintiff's purpose in amending its complaint is to bring proceedings in this Court to a close and to facilitate an appeal of the remaining issues in this litigation.

Plaintiff GenBioPro, Inc., and Defendants Kristina Raynes, in her official capacity as Prosecuting Attorney for Putnam County, and Patrick Morrissey, in his official capacity as Attorney General of the State of West Virginia, stipulate and consent to the filing of Plaintiff's First Amended Complaint under Federal Rule of Civil Procedure 15(a)(2). The Amended Complaint, attached as Exhibit A, no longer brings a federal preemption challenge to West Virginia's laws prohibiting providers from prescribing mifepristone via telemedicine, W. Va. Code §§ 30-1-26(b)(9), 30-3-13a(g)(5). Other than this change, the Amended Complaint is substantively identical to the Original Complaint Plaintiff filed on January 25, 2023, Dkt. No. 1. A redline comparison showing differences between the Original Complaint and Amended Complaint is

attached for the Court's convenience as Exhibit B.

Plaintiff has met and conferred with Defendants, and all parties consent to this motion. Defendants agree to waive notice and service of the Amended Complaint.

The parties jointly stipulate and agree that Plaintiff will no longer challenge West Virginia Code sections 30-1-26(b)(9) and 30-3-13a(g)(5) — the statutes governing prescribing mifepristone by telemedicine — as federally preempted. Plaintiff dismisses its preemption challenge to sections 30-1-26(b)(9) and 30-3-13a(g)(5) with prejudice.

As to the remaining claims, the parties stipulate that the Amended Complaint presents no new bases for relief. The parties stipulate that the Court's memorandum opinions and orders on the motions to dismiss, Dkt. Nos. 54, 66, apply to the claims in the Amended Complaint. The parties preserve all objections and their rights to appeal.

WHEREFORE, the parties jointly stipulate that:

1. Plaintiff's First Amended Complaint shall be the operative complaint in this case;
2. Plaintiff dismisses with prejudice its federal preemption challenge to West Virginia Code sections 30-1-26(b)(9) and 30-3-13a(g)(5); and
3. Because the Amended Complaint presents no new bases for relief, the Court's memorandum opinions and orders on the motions to dismiss, Dkt. Nos. 54, 66, apply to the Amended Complaint.

Dated: October 18, 2023

Respectfully submitted,

PATRICK MORRISEY

West Virginia Attorney General

/s/ Curtis R. A. Capehart (by permission)

Douglas P. Buffington, II (WV Bar # 8157)

Chief Deputy Attorney General

Curtis R. A. Capehart (WV Bar # 9876)

Deputy Attorney General

OFFICE OF THE ATTORNEY GENERAL

State Capitol Complex

1900 Kanawha Boulevard E.

Building 1, Room E-26

Charleston, WV 25305-0220

Tel.: (304) 558-2021

Fax: (304) 558-0140

curtis.r.a.capehart@wvago.gov

*Counsel for Defendant Patrick Morrisey, in his
official capacity as Attorney General of the State
of West Virginia*

KRISTINA RAYNES

Putnam County Prosecuting Attorney

/s/ Jennifer Scragg Karr (by permission)

Jennifer Scragg Karr (WV Bar # 8051)

Assistant Prosecuting Attorney

OFFICE OF THE PROSECUTING ATTORNEY

Putnam County Judicial Building

12093 Winfield Rd.

Winfield, WV 25213

Tel.: (304) 586-0205

Fax: (304) 586-0269

jkarr@putnamwv.org

*Counsel for Defendant, Kristina Raynes, in her
official capacity as Prosecuting Attorney for
Putnam County*

GENBIOPRO, INC.

/s/ Anthony J. Majestro

Anthony J. Majestro (WV Bar # 5165)

Christina L. Smith (WV Bar # 7509)

POWELL & MAJESTRO P.L.L.C.
405 Capitol Street, Suite 807
Charleston, WV 25301
Tel.: (304) 346-2889
amajestro@powellmajestro.com
csmith@powellmajestro.com

Counsel for Plaintiff, GenBioPro, Inc.

**IN THE UNITED STATES DISTRICT COURT
FOR THE SOUTHERN DISTRICT OF WEST VIRGINIA
HUNTINGTON DIVISION**

GENBIOPRO, INC.,

Plaintiff,

v.

**KRISTINA 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.**

**Civil Action No.: 3:23-cv-00058
(Hon. Robert C. Chambers)**

CERTIFICATE OF SERVICE

I hereby certify that, on this 18th day of October, 2023, I electronically filed the foregoing stipulation with the Clerk of Court and all parties using the CM/ECF System.

/s/ Anthony J. Majestro

Anthony J. Majestro

Exhibit A

**IN THE UNITED STATES DISTRICT COURT
FOR THE SOUTHERN DISTRICT OF WEST VIRGINIA
HUNTINGTON DIVISION**

GENBIOPRO, INC.,

Plaintiff,

v.

**KRISTINA 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.

**Civil Action No.: 3:23-cv-00058
(Hon. Robert C. Chambers)**

FIRST AMENDED COMPLAINT

INTRODUCTION

1. This case is about a federally approved medication that Congress subjected to a substantial and detailed federal regulatory program with which West Virginia law interferes. That state law must give way to the comprehensive federal regime Congress enacted and the Food and Drug Administration (“FDA”) implemented.

2. Plaintiff GenBioPro, Inc. (“GenBioPro”) is a private company that spent almost a decade developing a generic version of the drug mifepristone to give patients a safe, effective, non-invasive medication option for terminating a pregnancy. Mifepristone is the first drug in a two-drug regimen FDA approved that facilitates a medication abortion: (1) mifepristone interrupts early pregnancy by blocking the effect of progesterone, a hormone necessary to maintain a pregnancy, and (2) misoprostol causes uterine contractions, leading to the contents of the uterus being expelled.

3. Since 2019, when it received approval from FDA to sell generic mifepristone, GenBioPro has marketed and sold approximately 850,000 units of generic mifepristone

throughout the United States. Between 2017 and 2020 (a year after GenBioPro began marketing its product), the number of medication abortions in the United States increased by 45 percent, even as the number of abortions overall has declined significantly since the 1990s.¹ Medication abortion now accounts for the majority of pregnancy terminations in the United States, despite the fact that people can use medication only to terminate early pregnancies.²

4. Medical termination of pregnancy offers patients significant advantages. Patients can take the medication at home, at a time of their choosing, and in complete privacy. Medication abortions do not require administration of anesthesia; many patients use over-the-counter analgesics like Advil to relieve the period-like cramps patients typically experience.³ Medical termination often costs less than a surgical termination, too.⁴

5. FDA approved branded mifepristone (“Mifeprex”) for sale in 2000 and, in doing so, imposed specific restrictions it determined were necessary to assure the drug’s safe use. For example, in that early period FDA required that mifepristone be prescribed by a qualified physician, and be dispensed to patients by their physician, rather than at a pharmacy. Mifepristone joined the ranks of just fifteen other drugs that FDA had determined to warrant special restrictions.

¹ Rachel K. Jones, Marielle Kirstein & Jesse Philbin, *Abortion Incidence and Service Availability in the United States, 2020*, 54 Persps. on Sexual & Reprod. Health 128, 136 (Dec. 2022).

² *Id.*

³ Univ. of Cal. S.F. Health (“UCSF”), *Aspiration Versus Medication Abortion*, <https://www.ucsfhealth.org/education/aspiration-versus-medication-abortion> (last visited Jan. 22, 2023); Am. College of Obstetricians & Gynecologists, *Medication Abortion Up to 70 Days of Gestation*, 136 Obstetrics & Gynecology e31, e37 (Oct. 2020, reaffirmed 2023), <https://www.acog.org/clinical/clinical-guidance/practice-bulletin/articles/2020/10/medication-abortion-up-to-70-days-of-gestation>.

⁴ Allison McCann, *What It Costs to Get an Abortion Now*, N.Y. Times (Sept. 28, 2022), <https://www.nytimes.com/interactive/2022/09/28/us/abortion-costs-funds.html>.

6. In 2007, Congress enacted the Food and Drug Administration Amendments Act of 2007 (“FDAAA”), Pub. L. No. 110-85, 121 Stat. 823, codifying many of FDA’s risk management regulations into law, and authorizing FDA to design and implement risk evaluation and mitigation strategies for drugs moving forward.

7. As part of the FDAAA, Congress specified that the 16 drugs FDA had already approved with “elements to assure safe use” — including mifepristone — would immediately be “deemed to have in effect an approved risk evaluation and mitigation strategy.”⁵ *Id.* § 909(b)(1), 121 Stat. 950-51, *reprinted at* 21 U.S.C. § 331 note. In other words, Congress approved of how FDA regulated medications that previously had been approved with “elements to assure safe use.”

8. The FDAAA requires FDA to ensure that any elements to assure safe use of drugs subject to a risk evaluation and mitigation strategy “[p]rovid[e] safe access for patients” while “assur[ing the drug’s] safe use.” *Id.* § 505-1(f), 121 Stat. 926, 930 (codified at 21 U.S.C. § 355-1(f)). Restrictions may “not be unduly burdensome on patient access to the drug” and must “minimize the burden on the health care delivery system.” *Id.* § 505-1(f)(2)(C)-(D), 121 Stat. 930 (codified at 21 U.S.C. § 355-1(f)(2)(C)-(D)).

9. Since Congress “deemed” mifepristone to have a risk evaluation and mitigation strategy in effect in 2007, FDA has regulated mifepristone under the FDAAA’s special congressional mandate. As required by statute, FDA regularly reevaluates whether mifepristone should remain subject to this strategy and updates the restrictions on the drug in light of its

⁵ FDA identified those 16 drugs by name in a list published in the Federal Register. Identification of Drug and Biological Products Deemed to Have Risk Evaluation and Mitigation Strategies for Purposes of the Food and Drug Administration Amendments Act of 2007, 73 Fed. Reg. 16313 (Mar. 27, 2008).

assessment of evolving scientific evidence. Most recently, on January 3, 2023, FDA updated the REMS elements on mifepristone to enable patients to receive it through certified pharmacies.

10. Despite that federal statutory and regulatory regime, which carefully balances patient access and safety, West Virginia officials banned mifepristone.

11. In September 2022, in the wake of the Supreme Court’s holding in *Dobbs v. Jackson Women’s Health Organization*, 142 S. Ct. 2228 (2022), West Virginia’s Legislature enacted the Unborn Child Protection Act (the “Criminal Abortion Ban” or the “Ban”). This law prohibits abortion in almost all cases, at any stage of pregnancy. W. Va. Code § 16-2R-1 *et seq.*; *id.* § 61-2-8. The Criminal Abortion Ban severely constricted the market for mifepristone statewide.

12. Even before the Ban took effect, West Virginia law restricted the provision of mifepristone. *See id.* §§ 16-2I-2 (requiring a waiting period and counseling before an abortion procedure); 30-3-13a(g)(5) (prohibiting providers from prescribing mifepristone via telemedicine); *see also id.* § 30-1-26(b)(9) (providing for a rule banning prescribing mifepristone via telemedicine) (collectively “Restrictions”).

13. The Ban declares that some of these Restrictions (such as the waiting period and counseling requirement) have “no effect” while the Ban is in force. But if a court rules the Ban statute is unconstitutional, the limitations on abortion the Ban paused will again “become immediately effective.” *Id.* § 16-2R-9 (articles 2F, 2I, 2M, 2O, 2P, and 2Q of chapter 16 and article 42 of chapter 33).⁶ Once back in effect, these Restrictions will obstruct West Virginia

⁶ Article 2F contains provisions requiring parental notification before a minor undergoes an abortion procedure. W. Va. Code § 16-2F-1 *et seq.* Article 2I contains counseling and waiting period requirements patients must fulfill before obtaining an abortion. *Id.* § 16-2I-1 *et seq.* Article 2M prohibited providers from performing abortions after 20 weeks of gestation. *Id.*

residents’ access to mifepristone and stifle GenBioPro’s ability to conduct business in West Virginia.

14. Other restrictions, such as West Virginia’s prohibitions on providers using telemedicine to prescribe mifepristone, are in force. *Id.* § 30-3-13a(g)(5); *see id.* § 30-1-26(b)(9).

15. Federal law preempts West Virginia’s Ban and waiting period and counseling requirements. These laws impermissibly restrict patients’ access to mifepristone and GenBioPro’s opportunity and ability to market, promote, and sell the medication in the State. In “deem[ing]” mifepristone to be one of the few drugs subject to heightened FDA regulation, Congress authorized FDA, and only FDA, to impose restrictions on access to mifepristone. Before FDA may impose any restrictions, Congress requires the agency to determine that they are necessary for patient safety and will not unduly burden patient access. The Ban and waiting period and counseling requirements frustrate and conflict with that congressional mandate. West Virginia cannot override FDA’s determinations about the appropriate restrictions on a medication that FDA approved for use and Congress subjected to this enhanced regulatory regime.

16. West Virginia’s Ban and Restrictions also burden the healthcare delivery system in violation of the Supremacy Clause of the U.S. Constitution. U.S. Const. art. VI, cl. 2. The Ban and Restrictions make it impossible for providers to prescribe and dispense — and in turn,

§ 16-2M-1 *et seq.* Article 2O prohibited abortions using the dilation and evacuation method. *Id.* § 16-2O-1. Article 2P contains steps providers had to follow if an attempted abortion procedure resulted in a live birth. *Id.* § 16-2P-1. Article 2Q banned abortions sought because of fetal disability. *Id.* § 16-2Q-1. Article 42 of chapter 33 prohibited “partial-birth” abortions, defined as “abortion[s] in which the person performing the abortion partially vaginally delivers a living fetus before killing the fetus and completing the delivery.” *Id.* § 33-42-3(3); *see id.* § 33-42-1 *et seq.*

make it nearly impossible for GenBioPro to market, promote, and sell — mifepristone for its indicated use.

17. West Virginia’s Ban and Restrictions also violate the Commerce Clause of the U.S. Constitution. U.S. Const. art. I, § 8, cl. 3. Congress determined that mifepristone, a drug subject to a REMS, should be subject to FDA’s determinations that balance risks against access. Individual state regulation of mifepristone destroys the national common market and conflicts with the strong national interest in ensuring access to a federally approved medication to end a pregnancy, resulting in the kind of economic fracturing the Framers intended the Clause to preclude. A State’s police power does not extend to functionally banning an article of interstate commerce — the Constitution leaves that to Congress.

18. This Court should declare West Virginia’s Ban and Restrictions invalid and enjoin their enforcement because they adversely affect the sale and use of mifepristone within the State.

JURISDICTION AND VENUE

19. This Court has subject matter jurisdiction over this action pursuant to 28 U.S.C. §§ 1331 and 1343(a)(3) because GenBioPro’s claims present federal questions that arise under the laws of the United States, including the Supremacy and Commerce Clauses of the U.S. Constitution, Article VI, Clause 2 and Article I, Section 8, Clause 3, 21 U.S.C. § 355-1, and 42 U.S.C. § 1983.

20. This Court has authority to grant declaratory and injunctive relief under 42 U.S.C. § 1983 and the Declaratory Judgment Act, 28 U.S.C. §§ 2201-2202.

21. This Court has jurisdiction and equitable power to enjoin actions by state officials that are preempted by federal law. *See Ex parte Young*, 209 U.S. 123, 150-51 (1908).

22. Venue is proper in this district under 28 U.S.C. § 1391(b) because all Defendants maintain an office and conduct official duties in this judicial district and because a substantial part of the events giving rise to the claims at issue occurred in this district.

PARTIES

23. Plaintiff GenBioPro, Inc. is a Nevada corporation headquartered at 651 Lindell Road, Suite D1041 (P.O. Box 32011), Las Vegas, Nevada 89103. GenBioPro holds an approved abbreviated new drug application for generic mifepristone, No. 091178, and sells the drug nationwide. GenBioPro sells only generic mifepristone and misoprostol. Both drugs are used in medication abortions, and their sales are the company's sole source of revenue.

24. Defendant Kristina Raynes is the Prosecuting Attorney for Putnam County, West Virginia, and maintains an office at 12093 Winfield Road, Winfield, West Virginia 25213. Defendant Raynes has authority to prosecute violations of the Criminal Abortion Ban and other criminal restrictions on abortion in Putnam County. *See* W. Va. Code § 7-4-1(a). In 2022, the Prosecuting Attorney for Putnam County was quoted as stating publicly that “[a]s prosecutors we have a clear obligation to enforce the laws of our state. I believe if abortion is illegal then no responsible medical provider will be doing them.”⁷ This Complaint is brought against Defendant Raynes in her official capacity.

25. Defendant Patrick Morrissey is the Attorney General and chief legal officer of West Virginia and maintains an office at 1900 Kanawha Boulevard E., Charleston, West Virginia 25305. As Attorney General and chief legal officer, Defendant Morrissey has responsibility for enforcing the laws of West Virginia. Attorney General Morrissey recently signed a public letter

⁷ Rachel Pellegrino, *West Virginia Lawmakers to Provide Clarity on Roe v. Wade*, WOWK (July 1, 2022), <https://www.wowktv.com/news/local/west-virginia-lawmakers-to-provide-clarity-on-roe-v-wade>.

calling FDA’s determinations with respect to mifepristone “illegal and dangerous” and evincing his intent to stand by state law imposing restrictions on mifepristone notwithstanding FDA’s determinations pursuant to its congressional mandate.⁸ The Attorney General has the authority to enforce restrictions on abortion at the request of the Governor. *See* W. Va. Code § 5-3-1. This Complaint is brought against Defendant Morrissey in his official capacity.

26. This Court has equitable authority to enjoin these Defendants from enforcing unconstitutional state laws. *See Ex parte Young*, 209 U.S. at 150-51.

FACTUAL ALLEGATIONS

A. Congress Authorized FDA To Approve Drugs Like Mifepristone For Distribution And Sale In The United States

27. Congress first authorized FDA to regulate food and drugs more than a century ago in the Pure Food and Drugs Act, Pub. L. No. 59-384, 34 Stat. 768 (1906) (repealed 1938).

28. In 1938, Congress created the modern framework for FDA’s regulation of prescription drugs in the Federal Food, Drug, and Cosmetic Act (“FDCA”), Pub. L. No. 75-717, 52 Stat. 1040 (1938) (codified at 21 U.S.C. § 301 *et seq.*). The FDCA authorized the agency to develop a comprehensive regulatory scheme governing medications sold in the United States and to promote the public health by reviewing clinical research promptly and taking appropriate action on applications for marketing those drugs. 21 U.S.C. § 393(b)(1). The FDCA prohibited a drug manufacturer from distributing a drug until it submitted a new drug application to FDA for review, and authorized FDA to reject an application if it determined the drug was unsafe. FDCA § 505(a), (d)-(e), 52 Stat. 1040, 1052 (codified at 21 U.S.C. § 355).

⁸ *See* Letter from Att’y Gen., to Robert Califf, Comm’r, U.S. Food & Drug Admin. (Jan. 13, 2023) (“Letter from Att’y Gen.”), https://www.alabamaag.gov/Documents/news/Letter_from_Ala_Atty_Gen_Steve_Marshall_et_al_to_FDA.pdf.

29. In 1951, Congress amended the FDCA to define a new category of drugs — drugs that must be prescribed by a healthcare provider (as opposed to drugs that patients could obtain over the counter). Act of Oct. 26, 1951, Pub. L. No. 82-215, 65 Stat. 648. These “prescription” drugs included medications that required medical supervision to ensure their safe use. *Id.*

30. In 1962, Congress amended the FDCA to further strengthen FDA’s mandate “[t]o protect the public health” and “assure the safety, effectiveness, and reliability of drugs.” Drug Amendments of 1962, Pub. L. No. 87-781, pmb., 76 Stat. 780, 780. Before 1962, Congress required FDA to demonstrate that a drug was harmful to deny an application and keep the drug from entering interstate commerce; after the amendment, Congress required *manufacturers* to prove to FDA that their products were safe and effective. Once FDA approved a manufacturer’s application, it authorized that manufacturer to sell and distribute its product nationwide.

31. The 1962 amendments included a provision stating: “Nothing in the amendments made by this Act . . . shall be construed as invalidating any provision of State law which would be valid in the absence of such amendments unless there is a direct and positive conflict between such amendments and such provision of State law.” *Id.* § 202, 76 Stat. 780, 793. When there is such a conflict, state law must yield.

32. In the half century since then, Congress has enacted additional statutes and amendments enhancing FDA’s mandate to ensure safe and effective drugs are available to patients in the United States. *E.g.*, Drug Price Competition and Patent Term Restoration Act of 1984, Pub. L. No. 98-417, §§ 101(j)(1), 202(e)(1), 98 Stat. 1585, 1603 (Sept. 24, 1984) (codified at 21 U.S.C. §§ 271(e)(1), 355(j)(1)) (establishing an expedited approval process for generic drugs along with incentives for generic manufacturers to make generic drugs available on the

market quickly)⁹; 21 U.S.C. § 393(b)(1), (2) (enacted in 1997) (requiring FDA to “promptly and efficiently review[] clinical research and tak[e] appropriate action on the marketing of regulated products in a timely manner”); *id.* § 360bbb(b), (c) (enacted in 1997) (authorizing FDA to “[e]xpand[] access to unapproved therapies and diagnostics,” by allowing access to “investigational drug[s]” under certain circumstances); Food and Drug Administration Modernization Act of 1997, Pub. L. No. 105-15, § 101(1), 111 Stat. 2296, 2298 (Nov. 21, 1997), *reprinted at* 21 U.S.C. § 379g note (stating that “prompt approval of safe and effective new drugs and other therapies is critical to the improvement of the public health so that patients may enjoy the benefits provided by these therapies to treat and prevent illness and disease”); 21 U.S.C. § 356c(g) (enacted in 2012) (requiring FDA to mitigate and prevent shortages of certain drugs), *id.* § 356c-1 (enacted in 2012) (requiring FDA to report annually to Congress its actions to prevent or mitigate drug shortages).

33. The FDCA also requires manufacturers to label drugs with adequate instructions for their safe use, prescribing information, and the treatment for which that drug is approved (the “indication”). 21 U.S.C. §§ 352(f), 355(a); *see also* 21 C.F.R. § 201.57(c).

1. For The Past Forty Years, FDA Has Developed And Implemented Strategies For Ensuring The Safety Of Certain Drugs

34. While Congress charges FDA with assessing drug safety, FDA’s determination that a drug is safe for use for an indication does not mean that the drug is completely risk free. All drugs, even over-the-counter drugs, carry some risk. Rather, FDA approves a drug if its benefits to patients outweigh those risks. Furthermore, FDA can impose special regulatory

⁹ *See also Andrx Pharms., Inc. v. Biovail Corp. Int’l*, 256 F.3d 799, 809 (D.C. Cir. 2001) (explaining that the purpose of the 1984 amendments was to “get generic drugs into the hands of patients at reasonable prices — fast” (citation omitted)).

programs to mitigate a drug's risks that facilitate regulatory approval of the drug and its availability to patients.

35. FDA began developing risk management programs to mitigate drug risks in the 1980s. One early example is FDA's risk management program for isotretinoin (then sold as "Accutane"), a drug that treats severe acne. After approving Accutane in 1982, FDA determined that, if taken by a pregnant person, Accutane could affect fetal development. To minimize the risk that a pregnant person might take Accutane, FDA created special package inserts and developed educational programs to warn providers and patients.

36. By the 1990s, FDA had promulgated regulations enabling it to approve drugs that treat "serious or life-threatening illnesses and that provide meaningful therapeutic benefit to patients over existing treatments" subject to certain "restrictions to assure safe use." *See* 21 C.F.R. §§ 314.500, 314.520. These regulations (known as "Subpart H") limited any restriction FDA could impose to those "commensurate with the specific safety concerns presented by the drug product." *Id.* § 314.520.

37. Under Subpart H, FDA implemented risk management programs with "elements to assure safe use" for only 16 drugs and biologics.¹⁰ One of those drugs was mifepristone.

2. *After Determining That It Was Safe And Effective, FDA Approved Branded Mifepristone Under Subpart H*

38. French pharmaceutical company Roussel Uclaf developed mifepristone in 1980. Since its development, more than eighty countries have approved mifepristone's use in

¹⁰ The 16 drugs and biologics included: abarelix, alosetron, ambrisentan, bosentan, clozapine, dofetilide, eculizumab, fentanyl PCA, fentanyl citrate, isotretinoin, lenalidomide, mifepristone, natalizumab, the smallpox vaccine, sodium oxybate, and thalidomide.

medication abortions.¹¹ The United States joined those ranks in 2000, when FDA approved a new drug application for Mifeprex — the brand name for mifepristone as distributed and marketed by Danco Laboratories, LLC (“Danco”) — for the medical termination of intrauterine pregnancy through 49 days’ gestation.

39. In approving Mifeprex for sale, FDA determined that it treats a serious or life-threatening condition (*i.e.*, unwanted or unintended pregnancies), and provides a “meaningful therapeutic benefit to some patients over surgical abortion.”¹² According to FDA, “unwanted pregnancy, like a number of illnesses or conditions, can be serious for certain populations or under certain circumstances.”¹³ FDA recognized that, despite being associated with some risks, mifepristone conferred important therapeutic benefits and therefore approved Mifeprex subject to certain restrictions under Subpart H.

3. In The FDAAA, Congress Authorized FDA To Create Risk Evaluation And Mitigation Strategies And Imposed A Strategy On Mifepristone

40. In 2007, Congress enacted the FDAAA to require FDA to ensure patient access to medications for which there is a potential risk of a serious adverse drug experience. 21 U.S.C. § 355-1. The FDAAA functionally codified FDA’s risk management regulations and instructed FDA to continue regulating access to particular drugs to ensure that they remain available, and that any restrictions do not unduly burden patient access or the healthcare delivery system.

¹¹ U.S. Food & Drug Admin., *Questions and Answers on Mifepristone for Medical Termination of Pregnancy Through Ten Weeks Gestation* (Jan. 4, 2023), <https://perma.cc/AB7X-64A5>.

¹² *Id.*

¹³ See Letter from Janet Woodcock, Dir., Ctr. for Drug Evaluation & Rsch., U.S. Food & Drug Admin., to Donna Harrison, Executive Dir., Am. Ass’n of Pro Life Obstetricians & Gynecologists, Gene Rudd, Sr. Vice Pres., Christian Med. & Dental Ass’ns, & Penny Young Nance, CEO & Pres., Concerned Women for Am. (Mar. 29, 2016) (“Woodcock Letter”).

41. To do so, Congress authorized FDA to implement a program called a Risk Evaluation and Mitigation Strategy (“REMS”). A REMS represents a determination by FDA that when a drug is prescribed or administered in a particular manner, that drug’s benefits outweigh the risk of a serious adverse drug experience. *See id.* § 355-1(a).

42. After amending the FDCA with the FDAAA, Congress directed that drugs FDA had previously approved with restrictions under Subpart H — including Mifeprex — would be “deemed to have in effect” an approved REMS. FDAAA § 909(b)(1), 121 Stat. 950-51. Congress thereby codified the restrictions FDA had imposed under Subpart H on this group of drugs, including Mifeprex. *See id.*

43. As part of the FDAAA, Congress required those 16 drugs’ sponsors to submit new REMS to FDA for the agency’s consideration. *Id.* The FDAAA authorized FDA to modify, or even remove, the REMS for those drugs. *E.g.*, 21 U.S.C. § 355-1(g)(4)(B), (h).

44. The FDAAA specifies how FDA must assess whether a REMS is appropriate. It requires FDA first to determine whether a REMS is necessary and evaluate “[t]he seriousness of any known or potential adverse events that may be related to the drug.” *Id.* § 355-1(a). If FDA concludes the drug poses a risk of an “adverse drug experience” and determines a REMS is necessary to ensure that the drug’s benefits outweigh its risks, FDA must design and implement a REMS. *Id.* An adverse drug experience includes “any adverse event associated with the use of a drug . . . whether or not” the adverse event is “considered drug related.” *Id.* § 355-1(b)(1).

45. In imposing a REMS, FDA can require drug companies to include medication guides or inserts for patients, implement communications plans (which may include sending letters to healthcare providers), or dispense the drug in special packaging to ensure patients use the drug safely. *Id.* § 355-1(e).

46. The statute authorizes FDA to impose additional REMS elements “necessary to assure safe use of the drug” (also referred as “ETASU”). These elements may be imposed only if FDA determines the drug is “associated with a serious adverse drug experience” and requires a REMS to mitigate that “specific serious risk.” *Id.* § 355-1(f)(1). A “serious risk” or “serious adverse drug experience” includes adverse drug experiences that could result in “inpatient hospitalization” or a “substantial disruption of the ability to conduct normal life functions.” *Id.* § 355-1(b)(4), (5).

47. The elements FDA imposes must be “commensurate with the specific serious risk listed” on the drug’s label. *Id.* § 355-1(f)(2)(A). For example, FDA may restrict dispensing of the drug to certain settings, like hospitals. *Id.* § 355-1(f)(1), (3).

48. If FDA determines that it can approve a drug only with a REMS that incorporates such additional elements to assure safe use, Congress directs FDA to ensure that these elements “[p]rovid[e] safe access for patients to [these] drugs.” *Id.* § 355-1(f).

49. In a provision entitled, “Assuring access and minimizing burden,” Congress mandates that these elements to assure safe use, considering the drug’s risk, “not be unduly burdensome on patient access to the drug,” taking into account three considerations: patients with serious or life-threatening conditions, patients with difficulty accessing healthcare (such as patients in “rural or medically underserved areas”), and patients with functional limitations. *Id.* § 355-1(f)(2)(A), (C)(i)-(iii). Congress requires any additional elements or restrictions to be compatible with the requirements for similar drugs and compatible with established drug distribution systems, “so as to minimize the burden on the health care delivery system.” *Id.* § 355-1(f)(2)(D).

50. In creating a REMS, FDA must seek input from patients and healthcare providers in evaluating the restrictions to ensure they are not “unduly burdensome on patient access to the drug,” *id.* § 355-1(f)(5), and minimize the “burden on the health care delivery system,” *id.* § 355-1(f)(2)(D). In other words, Congress mandated that FDA balance two competing values: the safety of the drug and patient access to the drug.

51. Any person can petition FDA to amend a drug’s REMS by submitting a citizen petition pursuant to 21 C.F.R. § 10.30.

52. Section 355-1 requires FDA to reassess a drug’s REMS periodically. 21 U.S.C. § 355-1(d). After each reassessment, FDA may eliminate a REMS — or a component of a REMS — if it determines that the REMS elements are no longer necessary to ensure a medication’s benefits outweigh its risks.

53. Congress provided that, although either a drug’s manufacturer or FDA can propose a modification to a REMS, any such modification requires prior FDA approval. Without that approval, the existing REMS remains in effect. *Id.* § 355-1(g)(1), (h)(1), (h)(2)(A)-(B).

54. Of the more than 20,000 prescription drugs FDA has approved for marketing in the United States, the agency has subjected only 301 to a REMS.¹⁴ FDA has subjected 97 of those drugs to additional elements to assure safe use.¹⁵

¹⁴ U.S. Food & Drug Admin., *FDA Risk Evaluation and Mitigation Strategy (REMS) Public Dashboard* (Jan. 17, 2023), <https://fis.fda.gov/sense/app/ca606d81-3f9b-4480-9e47-8a8649da6470/sheet/994e7e67-d815-4204-8758-095c2abe2eda/state/analysis>.

¹⁵ *Id.*

B. FDA Determined That Mifepristone Requires A REMS With Additional Elements To Assure Safe Use

1. The Early Mifeprex REMS

55. After Congress mandated that Mifeprex be “deemed to have in effect” an approved REMS in the FCAAA, in September 2008, Danco submitted a supplemental new drug application proposing a REMS for Mifeprex. FDA approved the proposed REMS in June 2011.

56. As approved, the 2011 REMS required that only certified physicians prescribe Mifeprex; specified that Mifeprex be dispensed only in certain healthcare settings such as clinics (known as the “in-person dispensing requirement”) and taken in a provider’s clinic; and required Danco to ensure that every doctor prescribing Mifeprex was specially certified.

57. In approving these REMS, FDA “determined that a REMS [wa]s necessary” for Mifeprex “to ensure the benefits of the drug outweigh[ed] the risks of serious complications by requiring prescribers to certify that they [were] qualified to prescribe” the drug, and could “assure patient access to appropriate medical facilities to manage any complications.”¹⁶

58. In 2015, Danco submitted a supplemental new drug application to FDA to revise Mifeprex’s label and REMS. FDA approved almost all of Danco’s proposed modifications to the label and REMS, including: increasing the gestational age through which Mifeprex is indicated from 49 days to 70 days; reducing the number of patient visits to a clinic; and expanding those who could be certified to prescribe Mifeprex to include “healthcare providers,” rather than just “physicians.”

¹⁶ Letter from Ctr. for Drug Evaluation & Rsch., U.S. Food & Drug Admin., to Danco Labs., LLC 1 (June 8, 2011), https://www.accessdata.fda.gov/drugsatfda_docs/appletter/2011/020687s014ltr.pdf.

59. FDA determined that the remaining REMS requirements, such as the in-person dispensing requirement, “remain[ed] necessary to ensure that the drug’s benefits outweigh its risks”¹⁷ and to assure Mifeprex’s safe use.¹⁸

2. FDA Approved GenBioPro’s Generic Mifepristone

60. GenBioPro spent almost a decade bringing a generic version of mifepristone to market. On April 11, 2019, FDA approved GenBioPro’s application to manufacture and market generic mifepristone within the United States. As required by section 355, GenBioPro’s generic mifepristone and Danco’s Mifeprex have substantively identical labels. *See* 21 U.S.C. § 355(j)(2)(A)(v), (j)(4)(G).

61. FDA subjected GenBioPro’s generic mifepristone to a REMS pursuant to 21 U.S.C. § 355-1(i). FDA determined that the branded and generic mifepristone should share a single REMS, to be called the “Mifepristone REMS Program.”

3. FDA Halted Enforcement Of, And Reevaluated Part Of, The Mifepristone REMS

62. In April 2021, FDA announced it would stop enforcing the in-person dispensing requirement of the Mifepristone REMS Program. The agency determined that requiring a patient to visit a clinic during the COVID-19 public health emergency could pose serious risks to patients and healthcare personnel and that new clinical data demonstrated that the in-person dispensing requirement was not necessary to ensure mifepristone remained safe for patients.

¹⁷ Letter from Ctr. for Drug Evaluation & Rsch., U.S. Food & Drug Admin., to Danco Labs., LLC 2 (Mar. 29, 2016), https://www.accessdata.fda.gov/drugsatfda_docs/appletter/2016/020687Orig1s020ltr.pdf.

¹⁸ *See* U.S. Gov’t Accountability Off., GAO-18-292, Food and Drug Administration: Information on Mifeprex Labeling Changes and Ongoing Monitoring Efforts 12 (2018).

63. FDA continued its review of the Mifepristone REMS Program during the COVID-19 pandemic. In addition to analyzing newly published scientific literature, FDA evaluated safety information submitted to the agency during the COVID-19 public health emergency, reports of adverse events related to the drug, the first REMS assessment report for the Mifepristone REMS Program, and other information provided by the public. In December 2021, FDA announced its determination that certain elements of the Mifepristone REMS Program remained necessary to assure the drug's safe use, while other elements would need to be modified "to reduce burden on patient access and the health care delivery system and to ensure the benefits of [mifepristone] outweigh [its] risks."¹⁹

64. After completing that review, FDA instructed Danco and GenBioPro to modify the Mifepristone REMS Program by removing the requirement that mifepristone be dispensed only in certain healthcare settings and adding a requirement that pharmacies dispensing mifepristone be specially certified.

65. In December 2021, FDA responded to a Citizen's Petition from American Association of Pro Life Obstetricians and Gynecologists, the Christian Medical Association, and Concerned Women for America, rejecting their requests to impose additional burdens on access to mifepristone, including (1) limiting mifepristone's indication to 49 days' gestation; (2) requiring physicians, and not other providers, to prescribe mifepristone; (3) requiring patients to make three different office visits to their physicians as part of the REMS; and (4) requiring that mifepristone be dispensed only in certain healthcare settings.²⁰

¹⁹ U.S. Food & Drug Admin., *Questions and Answers on Mifepristone for Medical Termination of Pregnancy Through Ten Weeks Gestation* (Dec. 16, 2021), <https://perma.cc/V7RX-ZUAX>.

²⁰ See Woodcock Letter, *supra* note 13, at 5, 9, 13-15, 18-19, 25.

4. FDA Updated The Mifepristone REMS Program, Expanding Methods By Which Patients May Access Mifepristone

66. On January 3, 2023, FDA published a new, shared system REMS for mifepristone (the “2023 REMS”) covering both Mifeprex and generic mifepristone.²¹ Consistent with FDA’s December 2021 statements, the 2023 REMS no longer limits mifepristone dispensing to certain healthcare settings; patients may receive mifepristone by mail or from a specially certified pharmacy.

67. The 2023 REMS requires patients to sign a Patient Agreement Form before receiving a prescription for mifepristone.²² This form includes a section in which patients acknowledge having “decided to take “mifepristone and misoprostol to end [their] pregnancy” and agreeing to “follow [their] healthcare provider’s advice about when to take each drug and what to do in an emergency.”²³ The form requires patients to assert that they “understand” that they “will take mifepristone” and then “the misoprostol tablets 24 to 48 hours after” taking mifepristone.²⁴ FDA determined that these new REMS “continue to ensure the benefits of mifepristone for medical abortion outweigh the risks while minimizing the burden imposed by the REMS on healthcare providers and patients.”²⁵

²¹ U.S. Food & Drug Admin., *Risk Evaluation and Mitigation Strategy (REMS) Single Shared System for Mifepristone 200mg* (Jan. 2023), https://www.accessdata.fda.gov/drugsatfda_docs/remis/Mifepristone_2023_01_03_REMS_Full.pdf.

²² U.S. Food & Drug Admin., *Patient Agreement Form* (Jan. 2023), https://www.accessdata.fda.gov/drugsatfda_docs/remis/Mifepristone_2023_01_03_REMS_Full.pdf.

²³ *Id.*

²⁴ *Id.*

²⁵ *Id.*

C. West Virginia Law Restricts Patients' Access To Mifepristone And Regulates How The Healthcare Delivery System Provides Mifepristone

68. On September 13, 2022, the West Virginia governor signed the “Unborn Child Protection Act,” banning abortion at all stages of pregnancy except in limited circumstances. *See* W. Va. Code § 16-2R-1 *et seq.*; *id.* § 61-2-8. The law also declared that several provisions of the West Virginia Code related to abortion, including the counseling and waiting period requirements, would have “no force or effect unless any provision of the . . . Act is judicially determined to be unconstitutional.” 2022 W. Va. H.B. 302. The legislature amended the Act’s severability provision in March 2023, revising it to state that if a court invalidates the Act in its entirety, those restrictions are reactivated. W. Va. Code § 16-2I-9.

69. The Ban states that “[a]n abortion may not be performed or induced or be attempted to be performed or induced unless in the reasonable medical judgment of a licensed medical professional: (1) The embryo or fetus is nonviable; (2) The pregnancy is ectopic; or (3) A medical emergency exists.” *Id.* § 16-2R-3(a).²⁶ As a result, West Virginians no longer have a meaningful choice about whether to carry a pregnancy to term or to terminate using medication abortion. *Id.* §§ 16-2R-3, 16-2R-7.

70. The Ban amends mifepristone’s indication by changing the time for which mifepristone is indicated from a period spanning 70 days’ gestation, to no time at all for most patients.

71. While the Ban does not punish patients who terminate their pregnancies, it subjects certain healthcare providers who perform abortions to loss of their professional license,

²⁶ The Ban also includes limited exceptions for a pregnancy that is within eight weeks’ gestation (or, if a minor or incompetent or incapacitated adult, 14 weeks) and is the result of sexual assault or incest that the patient has reported to law enforcement. W. Va. Code § 16-2R-3(b), (c).

id. § 16-2R-7, and makes it a felony punishable by imprisonment for any other “person” to induce an abortion, *id.* § 61-2-8(a). The Ban imposes criminal penalties on some healthcare providers eligible to prescribe mifepristone under the 2023 REMS if they prescribe mifepristone to induce an abortion. *Id.* (defining “licensed medical professional” to exclude certain REMS-authorized providers); *see id.* § 16-2R-2.

72. In imposing the Ban, West Virginia officials eliminated access to mifepristone in the State in almost all circumstances. Even before the Ban, however, West Virginia regulated access to mifepristone in a manner restricting GenBioPro’s ability to distribute its FDA-approved product to West Virginians who qualified for access to it in compliance with FDA requirements.

73. As part of these Restrictions, West Virginia:

- (a) required providers to obtain “informed consent” from patients at least 24 hours before having a medication abortion, delaying care when, medically, it should be provided as soon as possible to ensure safety and effectiveness and avoid forcing patients out of the 70-day window in which mifepristone is indicated for use. *Id.* § 16-2I-2(a). The law enacting the Ban provides that this waiting-period requirement “is of no force or effect unless” a court rules any provision of the Ban (§ 16-2R-1 *et seq.*) unconstitutional. *Id.* § 16-2I-9.
- (b) required providers to communicate specific information to patients that is not part of the Mifepristone REMS Program, including that: “[s]ome suggest that it may be possible to counteract the intended effects of a mifepristone chemical abortion by taking progesterone if the female changes her mind, before taking the second drug,” *id.* § 16-2I-2(a)(4)(A); and “the

father, if his identity can be determined, is liable to assist in the support of her child,” *id.* § 16-2I-2(b)(2). The law enacting the Ban provides that this counseling requirement “is of no force or effect unless” a court rules any provision of the Ban (§ 16-2R-1 *et seq.*) is unconstitutional. *Id.* § 16-2I-9.

- (c) bans providers from using telemedicine to prescribe mifepristone, which means patients must visit a provider in person to obtain a prescription. *Id.* § 30-3-13a(g)(5) (stating that a “physician or health care provider may not prescribe any drug with the intent of causing an abortion” via telemedicine); *see id.* § 30-1-26(b)(9).

74. These Restrictions, which are in force or would become operative again if the Ban is judicially determined to be unconstitutional, constrict GenBioPro’s ability to market its FDA-approved product to West Virginians who need it. The Ban makes such commercial opportunities virtually impossible.

75. On January 13, 2023, shortly after FDA issued the 2023 REMS, Defendant Morrissey, the Attorney General of West Virginia, joined a letter in which a number of state attorneys general proclaimed to FDA that they “will not yield” to FDA’s federally based authority to approve drugs and to strike the optimal regulatory balance between risk mitigation and ensuring patient access because, in their view, the 2023 REMS fail “to protect women’s health and safety.” Defendant Morrissey and his co-signers wrote that “[t]o be crystal clear,” FDA “ha[s] not negated any of our laws that forbid the remote prescription, administration, and use of abortion-inducing drugs” and “[n]othing in the FDA’s recent changes affects” how they will enforce those laws.²⁷

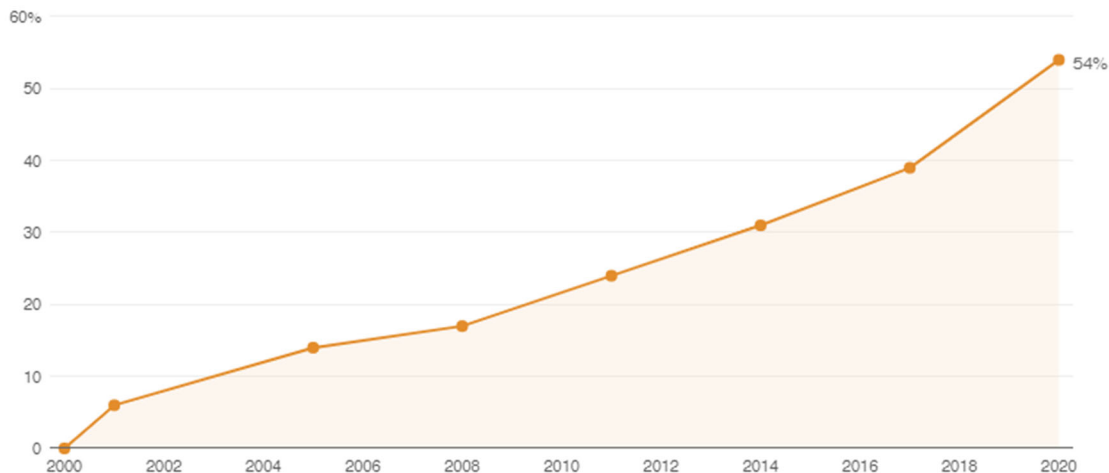
²⁷ Letter from Att’y Gen., *supra* note 8, at 3.

D. West Virginia’s Abortion Ban And Restrictions Harm GenBioPro And Prevent Patients From Accessing A Federally Approved Medication

76. More than eighty countries have approved mifepristone’s use in medication abortions, and many patients in the United States use mifepristone.²⁸ In 2020, approximately 492,210 medication abortions occurred in the United States, up from approximately 339,650 just three years earlier.²⁹ The market for mifepristone is strong and sales have grown over time, even as the number of total U.S. abortions (including surgical) has declined.³⁰ Medication abortions account for more than half of U.S. abortions, despite the fact that FDA approves of mifepristone’s use only up to 70 days’ gestation.³¹

More than half of U.S. abortions are medication abortions

Since the FDA approved mifepristone in 2000, use of the drug for abortions (vs. surgical procedure) has increased steadily.



Source: *Guttmacher Institute* (2020 numbers are estimates)

Credit: Alyson Hurt and Laurel Wamsley/NPR

²⁸ U.S. Food & Drug Admin., *Questions and Answers on Mifepristone for Medical Termination of Pregnancy Through Ten Weeks Gestation* (Jan. 4, 2023), <https://perma.cc/AB7X-64A5>.

²⁹ Rachel K. Jones et al., *supra* note 1, at 135.

³⁰ *Id.*

³¹ *Id.*; Laurel Wamsley, *How Medication Abortion Works and What the End of Roe v. Wade Could Mean for It*, NPR (May 13, 2022), <https://www.npr.org/2022/05/13/1098000879/abortion-pills-medication-abortion-ro-v-wade>.

77. Although Congress and FDA granted GenBioPro authority to sell mifepristone nationwide, West Virginia's severe abortion Restrictions and Criminal Abortion Ban make it impossible for GenBioPro to promote and market its product in West Virginia as it does in other states. The State has long had only a single clinic providing abortions.

78. Major national pharmacy chains, including Walgreens and CVS, which operate stores in Hurricane and Winfield, have indicated publicly that they intend to sell mifepristone now that the REMS permits them to do so.³² Providing mifepristone through such pharmacies would enable GenBioPro to serve more patients with its product. West Virginia's Ban and Restrictions, however, block GenBioPro from providing mifepristone through these integral healthcare distribution mechanisms in West Virginia. HoneyBee Health, which ships prescription drugs nationwide, is also prevented by West Virginia's Ban and Restrictions from providing mifepristone to patients in West Virginia.³³

79. West Virginia's Criminal Abortion Ban and Restrictions have caused significant, ongoing economic injury to GenBioPro in the form of lost sales, customers, and revenue. Defendants' enforcement of the Ban and Restrictions severely constricts GenBioPro's pool of potential customers — including healthcare providers that purchase from GenBioPro and certified pharmacies — and impermissibly constrains GenBioPro's ability to market its product in West Virginia.

³² Spencer Kimball & Bertha Coombs, *CVS and Walgreens Plan to Sell Abortion Pill Mifepristone at Pharmacies After FDA Rule Change*, CNBC (Jan. 5, 2023), <https://www.cnbc.com/2023/01/05/abortion-cvs-and-walgreens-will-sell-mifepristone-in-pharmacies.html>.

³³ Celine Castronuovo, *Abortion Pill Access to Ease with First FDA-Certified Pharmacy*, Bloomberg News (Jan. 3, 2023), <https://news.bloomberglaw.com/health-law-and-business/abortion-pill-access-to-ease-with-first-fda-certified-pharmacy>.

80. GenBioPro further alleges that, based on the foregoing, healthcare providers in West Virginia would prescribe mifepristone to their patients and purchase that mifepristone from GenBioPro, and that pharmacies in West Virginia would dispense GenBioPro's mifepristone to their customers, but do not because of the Ban and the Restrictions.

E. West Virginia's Abortion Ban And Other Restrictions Conflict With Federal Law And Regulate Access To Mifepristone, A Function Congress Delegated Exclusively To FDA

81. West Virginia's Ban and abortion Restrictions frustrate and conflict with Congress's determination that FDA must exercise regulatory authority through REMS and elements to assure safe use under 21 U.S.C. § 355-1(f) that States are not free to second-guess or override. Developing such a REMS requires FDA to first determine that restrictions are necessary to ensure that the drug's benefits outweigh its risks, and then to impose restrictions that address the drug's risks while minimizing the burden on patients' access to the drug and on the healthcare delivery system. *See* 21 U.S.C. § 355-1(f)(2).

82. Section 355-1(f)(2) requires FDA to balance competing obligations, to maximize safety while minimizing burden, and to regulate patients' access to, and the healthcare delivery system's distribution of, mifepristone. The statute delegates to FDA exclusive authority to conduct that balancing, deploying its unique expertise in determining whether scientific evidence demonstrates that a serious adverse experience is associated with a drug, and how best to mitigate that risk while ensuring that its efforts do not unduly burden patient access to the drug. FDA's REMS therefore necessarily establishes both a "floor" and "ceiling" on permissible regulation of mifepristone. The elements FDA determined are necessary to ensure mifepristone's safety are the *only* restrictions that may be imposed on a patient's access to, and the healthcare delivery system's distribution of, mifepristone. Just as a state may not pass a law purporting to remove one of the REMS requirements (such as waiving the requirement of a

Patient Agreement Form), it also may not impose any other elements restricting access. Doing so would disturb the balancing that Congress required FDA to conduct in regulating access to mifepristone via the Mifepristone REMS Program.

83. West Virginia's Ban prevents almost all patients from accessing mifepristone, including those who otherwise would be eligible to receive the drug under the 2023 REMS. In so doing, it functionally displaces FDA's judgment in approving mifepristone and imposing a REMS. West Virginia's Ban also prevents the healthcare delivery system from distributing mifepristone to patients for whom providers would otherwise prescribe the drug. It burdens both the patient's access to mifepristone and the healthcare delivery system by imposing criminal and professional penalties on the prescription and distribution of mifepristone. *See* W. Va. Code § 16-2R-1 *et seq.*; *id.* § 61-2-8.

84. The State's laws interfere with and seek to contradict Congress's directive to FDA to determine what elements will assure safe use of a REMS drug without being "unduly burdensome on patient access" and "minimiz[ing] the burden on the health care delivery system." 21 U.S.C. § 355-1(f)(2)(C), (D).

85. The Ban and Restrictions conflict with FDA's determinations pursuant to section 355-1(f)(2). The Ban and Restrictions make it impossible for GenBioPro to market and distribute mifepristone in West Virginia in accordance with FDA's requirements and determinations as to the balance Congress mandated between safety-based restrictions and patient access to the drug.

86. Even if the Ban is invalidated or repealed, the telemedicine ban will be in force and the counseling and waiting period requirements would again come into force. Each of these Restrictions conflicts with the 2023 REMS and regulates in an arena that Congress left to FDA.

87. West Virginia’s waiting period and counseling requirements, W. Va. Code § 16-2I-2, require providers to obtain “informed consent” from patients at least 24 hours before prescribing mifepristone and require providers to communicate specific information to patients that is not part of the counseling required by the Mifepristone REMS Program. The prescriber agreement in the REMS requires only that a physician review the Patient Agreement Form, “fully explain[]” the “risks of the mifepristone treatment regimen,” answer any “questions the patient may have,” and ensure the patient receives and signs the Patient Agreement Form.³⁴

88. West Virginia’s telemedicine restrictions, *id.* § 30-3-13a(g)(5); *see id.* § 30-1-26(b)(9), purport to bar healthcare providers from prescribing any abortion drug via telemedicine. The Mifepristone REMS Program does not prohibit providers from using telemedicine to prescribe mifepristone. In 2019, several advocacy groups asked FDA to add a requirement to the REMS that a provider prescribe mifepristone in person, rather than by telemedicine or over the Internet. FDA specifically considered and rejected the proposed requirement as unnecessary to ensure mifepristone’s safety. West Virginia’s Restriction conflicts with this FDA determination.

89. West Virginia’s Ban and Restrictions conflict with mifepristone’s label and indication. FDA determined that mifepristone is indicated for use up to 70 days’ gestation, but West Virginia law conflicts with that determination by banning use of mifepristone by nearly all patients at any stage of pregnancy and limiting mifepristone to emergency use.

90. By enacting the FDCA and its amendments, Congress authorized FDA to approve drugs in the United States and determine whether a manufacturer can sell its product in interstate

³⁴ U.S. Food & Drug Admin., *Patient Agreement Form* (Jan. 2023), https://www.accessdata.fda.gov/drugsatfda_docs/remis/Mifepristone_2023_01_03_REMS_Full.pdf.

commerce. *See, e.g.*, Act of Oct. 10, 1962, Pub. L. No. 87-781, § 104, 76 Stat. 780, 784; 21 U.S.C. § 393(b)(1). A state ban like West Virginia’s constitutes a determination on the part of state legislators that a manufacturer *cannot* sell its product in the State, creating a direct conflict with federal law. *See* Act of Oct. 10, 1962, Pub. L. No. 87-781, § 102, 76 Stat. 780, 781.

91. A favorable decision from this Court declaring the Ban and waiting period and counseling restrictions invalid as applied to the sale and distribution of mifepristone and enjoining their enforcement by state officials due to their constitutional infirmities will remedy these conflicts and redress GenBioPro’s economic injury by enabling West Virginians to access its product.

92. Settled preemption and Commerce Clause principles govern states’ efforts to restrict access to an FDA-approved medication. The Supreme Court’s decision in *Dobbs* did not displace Congress’s and FDA’s roles in protecting the public health by deciding whether drugs are safe and effective, determining which precautions — if any — are necessary to ensure a drug’s safe use, and ensuring safe and effective drugs are available to the public. *Dobbs* addressed only the underlying personal constitutional privacy right as it pertains to abortion; it did not speak to federal law regulating a drug maker’s sale and distribution of, or a patient’s access to, medication that is FDA-approved for distribution nationwide.

CLAIMS FOR RELIEF

COUNT I

Declaratory and Injunctive Relief — 42 U.S.C. § 1983 — Federal Law Preempts West Virginia’s Ban and Waiting Period and Counseling Requirements

93. GenBioPro re-alleges and incorporates by reference each of the preceding paragraphs.

94. The U.S. Constitution’s Supremacy Clause makes federal laws enacted under the authority of the United States the “supreme Law of the Land.” U.S. Const. art. VI, cl. 2. Under the Clause, federal law preempts any state regulation to the contrary. *See Gade v. Nat’l Solid Wastes Mgmt. Ass’n*, 505 U.S. 88, 108 (1992).

95. West Virginia’s Ban, W. Va. Code §§ 16-2R-1 *et seq.*, 61-2-8, and waiting period and counseling requirements, *id.* §§ 16-2I-2, 16-2I-9, are preempted by the FDCA as amended, 21 U.S.C. § 355-1. States may not restrict access to FDA-approved drugs in ways that countermand the agency’s specific safety considerations or restrictions.

96. West Virginia’s Ban and waiting period and counseling requirements conflict with that mandate, including by imposing the burden of criminal penalties on REMS-eligible providers’ prescription of mifepristone. The Ban and waiting period and counseling requirements frustrate FDA’s determinations about how mifepristone should be regulated and invade an area Congress determined only FDA may occupy. *See, e.g., Mut. Pharm. Co. v. Bartlett*, 570 U.S. 472, 479-80 (2013); *Arizona v. United States*, 567 U.S. 387, 403 (2012); *Geier v. Am. Honda Motor Co.*, 529 U.S. 861, 873 (2000). The Ban and waiting period and counseling requirements further stand as an obstacle to FDA’s determination that GenBioPro’s mifepristone is safe and effective, and GenBioPro may distribute it to patients pursuant to the REMS.

97. Federal law therefore preempts Article 2R, Chapter 16 of the West Virginia Code and Section 61-2-8, insofar as these statutes ban patients from using mifepristone in almost all instances.

98. Federal law preempts West Virginia Code §§ 16-2I-2, 16-2I-9 insofar as it requires patients seeking mifepristone to fulfill waiting period and counseling requirements.

99. Section 1983 of Title 42 of the United States Code provides that “Every person who, under color of any statute, ordinance, regulation, custom, or usage, of any State . . . , subjects, or causes to be subjected, any citizen of the United States or other person within the jurisdiction thereof to the deprivation of any rights, privileges, or immunities secured by the Constitution and laws, shall be liable to the party injured in an action at law, suit in equity, or other proper proceeding for redress”

100. West Virginia’s Ban and waiting period and counseling requirements conflict with the rights, privileges, or immunities secured by FDA approval of mifepristone under Title 21 of the United States Code and the REMS to market and distribute its FDA-approved product in West Virginia subject only to those regulations and restrictions FDA imposed pursuant to its mandate under the FDCA as amended, 21 U.S.C. § 355-1.

COUNT II

Declaratory and Injunctive Relief — 42 U.S.C. § 1983 — West Virginia’s Ban and Restrictions Violate the Commerce Clause

101. GenBioPro re-alleges and incorporates by reference each of the preceding paragraphs.

102. The Commerce Clause grants Congress alone the power to “regulate Commerce . . . among the several States.” U.S. Const. art. I, § 8, cl. 3. It prevents a state from taking any action that may impede the free flow of trade in the national common market or create an undue burden on access to an article of commerce that requires uniform national regulation.

103. The Commerce Clause renders invalid state laws that impose “undue burdens” on interstate commerce, including by regulating articles of commerce Congress determined require a uniform system of regulation at the national level. *South Dakota v. Wayfair, Inc.*, 138 S. Ct. 2080, 2091 (2018). The Clause likewise invalidates state laws, such as West Virginia’s Ban and

Restrictions, that preclude the use of a drug manufactured out of state for use in the State to terminate a pregnancy, *see Healy v. Beer Inst.*, 491 U.S. 324, 336 (1989) (laws that, if imposed by several states, would have the “practical effect” of regulating commerce outside the state violate the Commerce Clause), or of banning an article of commerce, *see Schollenberger v. Pennsylvania*, 171 U.S. 1, 13 (1898).

104. Section 1983 of Title 42 of the United States Code provides a remedy for any person who suffers deprivation of rights, privileges, and immunities secured by the U.S. Constitution, including the Commerce Clause.

105. West Virginia’s Ban, W. Va. Code § 16-2R-1 *et seq.*; *id.* § 61-2-8, and Restrictions, *id.* §§ 16-2I-2, 16-2I-9, 30-1-26(b)(9), 30-3-13a(g)(5), interfere with the uniform regulation of mifepristone, a drug subject to extensive federal regulation at the national level, thereby destroying the common market for mifepristone.

106. Article 2R, Chapter 16 of the West Virginia Code and § 61-2-8 violate the Commerce Clause by, in effect, banning an article of commerce and preventing GenBioPro from developing a market for its product, mifepristone, in West Virginia.

107. West Virginia Code § 16-2I-2 violates the Commerce Clause by forcing patients to fulfill waiting period and counseling requirements before accessing mifepristone. This State law disrupts FDA’s federal regulatory scheme and undermines the need for national uniformity in the regulation of REMS drugs such as mifepristone.

108. West Virginia Code § 30-3-13a(g)(5) violates the Commerce Clause by preventing providers from prescribing mifepristone via telemedicine, meaning that patients are required to visit a healthcare professional in person to obtain a prescription. *See id.* § 30-1-

26(b)(9). This State law disrupts FDA's federal regulatory scheme and undermines the need for national uniformity in the regulation of mifepristone, as subject to the FDA's REMS.

109. Each of these Restrictions and West Virginia's Ban constrict the market for GenBioPro's product, excessively burden interstate commerce, and vitiate the national common market the Framers envisioned.

110. West Virginia's Ban and Restrictions conflict with the rights, privileges, or immunities secured by FDA approval of mifepristone under Title 21 of the United States Code and the REMS to market and distribute the drug under applicable federal rules. As such, 42 U.S.C. § 1983 provides a cause of action and remedy for such violations.

PRAYER FOR RELIEF

WHEREFORE, Plaintiff respectfully requests that this Court enter an order and judgment as follows:

- A. A declaratory judgment, pursuant to 28 U.S.C. § 2201, that West Virginia Code §§ 16-2R-1 *et seq.*, 16-2I-2, 16-2I-9, and 61-2-8 are invalid and unenforceable because they violate both the Supremacy Clause and the Commerce Clause of the U.S. Constitution;
- B. A declaratory judgment, pursuant to 28 U.S.C. § 2201, that West Virginia Code §§ 30-1-26(b)(9) and 30-3-13a(g)(5) are invalid and unenforceable because they violate the Commerce Clause of the U.S. Constitution;
- C. Such further relief as permitted under 28 U.S.C. § 2202, including a permanent injunction enjoining Defendants from enforcing the challenged provisions;
- D. Injunctive relief under this Court's equitable power to enjoin enforcement of unconstitutional state laws;

- E. An order awarding GenBioPro its costs and attorneys' fees pursuant to 42 U.S.C. § 1988; and
- F. Such other and further relief as the Court deems just and proper.

Dated: October 18, 2023

David C. Frederick*
Ariela M. Migdal*
Eliana Margo Pfeffer*
Mary Charlotte Y. Carroll*
KELLOGG, HANSEN, TODD,
FIGEL & FREDERICK, P.L.L.C.
1615 M Street, N.W., Suite 400
Washington, D.C. 20036
Tel: (202) 326-7900
dfrederick@kellogghansen.com
amigdal@kellogghansen.com
epfeffer@kellogghansen.com
mcarroll@kellogghansen.com

Skye L. Perryman*
Kristen Miller*
DEMOCRACY FORWARD
FOUNDATION
P.O. Box 34553
Washington, D.C. 20043
Tel: (202) 448-9090
sperryman@democracyforward.org
kmiller@democracyforward.org

Respectfully submitted,

/s/ Anthony J. Majestro

Anthony J. Majestro
W. Va. Bar No. 5165
Christina L. Smith
W. Va. Bar No. 7509
POWELL & MAJESTRO P.L.L.C.
405 Capitol Street
Suite P-1200
Charleston, WV 25301
Tel: (304) 346-2889
amajestro@powellmajestro.com
csmith@powellmajestro.com

John P. Elwood*
Daphne O'Connor*
Robert J. Katerberg*
ARNOLD & PORTER KAYE SCHOLER LLP
601 Massachusetts Avenue, N.W.
Washington, D.C. 20001
john.elwood@arnoldporter.com
daphne.oconnor@arnoldporter.com
robert.katerberg@arnoldporter.com

** Admitted pro hac vice*

Counsel for Plaintiff GenBioPro, Inc.

Exhibit B

**IN THE UNITED STATES DISTRICT COURT
FOR THE SOUTHERN DISTRICT OF WEST VIRGINIA
HUNTINGTON DIVISION**

GENBIOPRO, INC.,

Plaintiff,

v.

**MARK A. SORSA AKRISTINA RAYNES, in
his official capacity as Prosecuting Attorney of
Putnam County, AND PATRICK MORRISEY,
in his official capacity as Attorney General of
West Virginia,**

Defendants.

**Civil Action No.: 3:23-cv-00058
(Hon. Robert C. Chambers)**

FIRST AMENDED COMPLAINT

INTRODUCTION

1. This case is about a federally approved medication that Congress subjected to a substantial and detailed federal regulatory program with which West Virginia law interferes. That state law must give way to the comprehensive federal regime Congress enacted and the Food and Drug Administration (“FDA”) implemented.

2. Plaintiff GenBioPro, Inc. (“GenBioPro”) is a private company that spent almost a decade developing a generic version of the drug mifepristone to give patients a safe, effective, non-invasive medication option for terminating a pregnancy. Mifepristone is the first drug in a two-drug regimen FDA approved that facilitates a medication abortion: (1) mifepristone interrupts early pregnancy by blocking the effect of progesterone, a hormone necessary to maintain a pregnancy, and (2) misoprostol causes uterine contractions, leading to the contents of the uterus being expelled.

3. Since 2019, when it received approval from FDA to sell generic mifepristone, GenBioPro has marketed and sold approximately 850,000 units of generic mifepristone

throughout the United States. Between 2017 and 2020 (a year after GenBioPro began marketing its product), the number of medication abortions in the United States increased by 45 percent, even as the number of abortions overall has declined significantly since the 1990s.¹ Medication abortion now accounts for the majority of pregnancy terminations in the United States, despite the fact that people can use medication only to terminate early pregnancies.²

4. Medical termination of pregnancy offers patients significant advantages. Patients can take the medication at home, at a time of their choosing, and in complete privacy.

Medication abortions do not require administration of anesthesia; many patients use over-the-counter analgesics like Advil to relieve the period-like cramps patients typically experience.³

Medical termination often costs less than a surgical termination, too.⁴

5. FDA approved branded mifepristone (“Mifeprex”) for sale in 2000 and, in doing so, imposed specific restrictions it determined were necessary to assure the drug’s safe use. For example, in that early period FDA required that mifepristone be prescribed by a qualified physician, and be dispensed to patients by their physician, rather than at a pharmacy.

Mifepristone joined the ranks of just fifteen other drugs that FDA had determined to warrant special restrictions.

¹ Rachel K. Jones, Marielle Kirstein & Jesse Philbin, *Abortion Incidence and Service Availability in the United States, 2020*, 54 Persps. on Sexual & Reprod. Health 128, 136 (Dec. 2022).

² *Id.*

³ Univ. of Cal. S.F. Health (“UCSF”), *Aspiration Versus Medication Abortion*, <https://www.ucsfhealth.org/education/aspiration-versus-medication-abortion> (last visited Jan. 22, 2023); Am. College of Obstetricians & Gynecologists, *Medication Abortion Up to 70 Days of Gestation*, 136 Obstetrics & Gynecology e31, e37 (Oct. 2020, reaffirmed 2023), <https://www.acog.org/clinical/clinical-guidance/practice-bulletin/articles/2020/10/medication-abortion-up-to-70-days-of-gestation>.

⁴ Allison McCann, *What It Costs to Get an Abortion Now*, N.Y. Times (Sept. 28, 2022), <https://www.nytimes.com/interactive/2022/09/28/us/abortion-costs-funds.html>.

6. In 2007, Congress enacted the Food and Drug Administration Amendments Act of 2007 (“FDAAA”), Pub. L. No. 110-85, 121 Stat. 823, codifying many of FDA’s risk management regulations into law, and authorizing FDA to design and implement risk evaluation and mitigation strategies for drugs moving forward.

7. As part of the FDAAA, Congress specified that the 16 drugs FDA had already approved with “elements to assure safe use” — including mifepristone — would immediately be “deemed to have in effect an approved risk evaluation and mitigation strategy.”⁵ *Id.* § 909(b)(1), 121 Stat. 950-51, *reprinted at* 21 U.S.C. § 331 note. In other words, Congress approved of how FDA regulated medications that previously had been approved with “elements to assure safe use.”

8. The FDAAA requires FDA to ensure that any elements to assure safe use of drugs subject to a risk evaluation and mitigation strategy “[p]rovid[e] safe access for patients” while “assur[ing the drug’s] safe use.” *Id.* § 505-1(f), 121 Stat. 926, 930 (codified at 21 U.S.C. § 355-1(f)). Restrictions may “not be unduly burdensome on patient access to the drug” and must “minimize the burden on the health care delivery system.” *Id.* § 505-1(f)(2)(C)-(D), 121 Stat. 930 (codified at 21 U.S.C. § 355-1(f)(2)(C)-(D)).

9. Since Congress “deemed” mifepristone to have a risk evaluation and mitigation strategy in effect in 2007, FDA has regulated mifepristone under the FDAAA’s special congressional mandate. As required by statute, FDA regularly reevaluates whether mifepristone should remain subject to this strategy and updates the restrictions on the drug in light of its

⁵ FDA identified those 16 drugs by name in a list published in the Federal Register. Identification of Drug and Biological Products Deemed to Have Risk Evaluation and Mitigation Strategies for Purposes of the Food and Drug Administration Amendments Act of 2007, 73 Fed. Reg. 16313 (Mar. 27, 2008).

assessment of evolving scientific evidence. Most recently, on January 3, 2023, FDA updated the REMS elements on mifepristone to enable patients to receive it through certified pharmacies.

10. Despite that federal statutory and regulatory regime, which carefully balances patient access and safety, West Virginia officials banned mifepristone.

11. In September 2022, in the wake of the Supreme Court’s holding in *Dobbs v. Jackson Women’s Health Organization*, 142 S. Ct. 2228 (2022), West Virginia’s Legislature enacted the Unborn Child Protection Act (the “Criminal Abortion Ban” or the “Ban”). This law prohibits abortion in almost all cases, at any stage of pregnancy. W. Va. Code § 16-2R-1 *et seq.*; *id.* § 61-2-8. The Criminal Abortion Ban severely constricted the market for mifepristone statewide.

12. Even before the Ban took effect, West Virginia law restricted the provision of mifepristone. *See id.* §§ 16-2I-2 (requiring a waiting period and counseling before an abortion procedure); 30-3-13a(g)(5) (prohibiting providers from prescribing mifepristone via telemedicine); *see also id.* § 30-1-26(b)(9) (providing for a rule banning prescribing mifepristone via telemedicine) (collectively “Restrictions”).

13. The Ban declares that some of these Restrictions (such as the waiting period and counseling requirement) have “no effect” while the Ban is in force. But if a court rules ~~any part of~~ the Ban statute is unconstitutional, the limitations on abortion the Ban paused will again “become immediately effective.” *Id.* § 16-2R-9 (articles 2F, 2I, 2M, 2O, 2P, and 2Q of chapter 16 and article 42 of chapter 33).⁶ Once back in effect, these Restrictions will obstruct West

⁶ Article 2F contains provisions requiring parental notification before a minor undergoes an abortion procedure. W. Va. Code § 16-2F-1 *et seq.* Article 2I contains counseling and waiting period requirements patients must fulfill before obtaining an abortion. *Id.* § 16-2I-1 *et seq.* Article 2M prohibited providers from performing abortions after 20 weeks of gestation. *Id.*

Virginia residents’ access to mifepristone and stifle GenBioPro’s ability to conduct business in West Virginia.

14. Other restrictions, such as West Virginia’s prohibitions on providers using telemedicine to prescribe mifepristone, are in force. *Id.* § 30-3-13a(g)(5); *see id.* § 30-1-26(b)(9).

15. Federal law preempts West Virginia’s Ban and ~~Restrictions~~waiting period and counseling requirements. These laws impermissibly restrict patients’ access to mifepristone and GenBioPro’s opportunity and ability to market, promote, and sell the medication in the State. In “deem[ing]” mifepristone to be one of the few drugs subject to heightened FDA regulation, Congress authorized FDA, and only FDA, to impose restrictions on access to mifepristone. Before FDA may impose any restrictions, Congress requires the agency to determine that they are necessary for patient safety and will not unduly burden patient access. The Ban and ~~Restrictions~~waiting period and counseling requirements frustrate and conflict with that congressional mandate. West Virginia cannot override FDA’s determinations about the appropriate restrictions on a medication that FDA approved for use and Congress subjected to this enhanced regulatory regime.

16. West Virginia’s Ban and Restrictions also burden the healthcare delivery system in violation of the Supremacy Clause of the U.S. Constitution. U.S. Const. art. VI, cl. 2. The Ban and Restrictions make it impossible for providers to prescribe and dispense — and in turn,

§ 16-2M-1 *et seq.* Article 2O prohibited abortions using the dilation and evacuation method. *Id.* § 16-2O-1. Article 2P contains steps providers had to follow if an attempted abortion procedure resulted in a live birth. *Id.* § 16-2P-1. Article 2Q banned abortions sought because of fetal disability. *Id.* § 16-2Q-1. Article 42 of chapter 33 prohibited “partial-birth” abortions, defined as “abortion[s] in which the person performing the abortion partially vaginally delivers a living fetus before killing the fetus and completing the delivery.” *Id.* § 33-42-3(3); *see id.* § 33-42-1 *et seq.*

make it nearly impossible for GenBioPro to market, promote, and sell — mifepristone for its indicated use.

17. West Virginia’s Ban and Restrictions also violate the Commerce Clause of the U.S. Constitution. U.S. Const. art. I, § 8, cl. 3. Congress determined that mifepristone, a drug subject to a REMS, should be subject to FDA’s determinations that balance risks against access. Individual state regulation of mifepristone destroys the national common market and conflicts with the strong national interest in ensuring access to a federally approved medication to end a pregnancy, resulting in the kind of economic fracturing the Framers intended the Clause to preclude. A State’s police power does not extend to functionally banning an article of interstate commerce — the Constitution leaves that to Congress.

18. This Court should declare West Virginia’s Ban and Restrictions invalid and enjoin their enforcement because they adversely affect the sale and use of mifepristone within the State.

JURISDICTION AND VENUE

19. This Court has subject matter jurisdiction over this action pursuant to 28 U.S.C. §§ 1331 and 1343(a)(3) because GenBioPro’s claims present federal questions that arise under the laws of the United States, including the Supremacy and Commerce Clauses of the U.S. Constitution, Article VI, Clause 2 and Article I, Section 8, Clause 3, 21 U.S.C. § 355-1, and 42 U.S.C. § 1983.

20. This Court has authority to grant declaratory and injunctive relief under 42 U.S.C. § 1983 and the Declaratory Judgment Act, 28 U.S.C. §§ 2201-2202.

21. This Court has jurisdiction and equitable power to enjoin actions by state officials that are preempted by federal law. *See Ex parte Young*, 209 U.S. 123, 150-51 (1908).

22. Venue is proper in this district under 28 U.S.C. § 1391(b) because all Defendants maintain an office and conduct official duties in this judicial district and because a substantial part of the events giving rise to the claims at issue occurred in this district.

PARTIES

23. Plaintiff GenBioPro, Inc. is a Nevada corporation headquartered at 651 Lindell Road, Suite D1041 (P.O. Box 32011), Las Vegas, Nevada 89103. GenBioPro holds an approved abbreviated new drug application for generic mifepristone, No. 091178, and sells the drug nationwide. GenBioPro sells only generic mifepristone and misoprostol. Both drugs are used in medication abortions, and their sales are the company's sole source of revenue.

24. Defendant ~~Mark A. Sorsaia~~Kristina Raynes is the Prosecuting Attorney for Putnam County, West Virginia, and maintains an office at 12093 Winfield Road, Winfield, West Virginia 25213. Defendant ~~Sorsaia~~Raynes has authority to prosecute violations of the Criminal Abortion Ban and other criminal restrictions on abortion in Putnam County. *See* W. Va. Code § 7-4-1(a). ~~Defendant Sorsaia has been~~In 2022, the Prosecuting Attorney for Putnam County was quoted as stating publicly that “[a]s prosecutors we have a clear obligation to enforce the laws of our state. I believe if abortion is illegal then no responsible medical provider will be doing them.”⁷ This Complaint is brought against Defendant ~~Sorsaia~~Raynes in his~~her~~ official capacity.

25. Defendant Patrick Morrissey is the Attorney General and chief legal officer of West Virginia and maintains an office at 1900 Kanawha Boulevard E., Charleston, West Virginia 25305. As Attorney General and chief legal officer, Defendant Morrissey has responsibility for

⁷ Rachel Pellegrino, *West Virginia Lawmakers to Provide Clarity on Roe v. Wade*, WOWK (July 1, 2022), <https://www.wowktv.com/news/local/west-virginia-lawmakers-to-provide-clarity-on-ro-e-v-wade>.

enforcing the laws of West Virginia. Attorney General Morrissey recently signed a public letter calling FDA's determinations with respect to mifepristone "illegal and dangerous" and evincing his intent to stand by state law imposing restrictions on mifepristone notwithstanding FDA's determinations pursuant to its congressional mandate.⁸ The Attorney General has the authority to enforce restrictions on abortion at the request of the Governor. *See* W. Va. Code § 5-3-1. This Complaint is brought against Defendant Morrissey in his official capacity.

26. This Court has equitable authority to enjoin these Defendants from enforcing unconstitutional state laws. *See Ex parte Young*, 209 U.S. at 150-51.

FACTUAL ALLEGATIONS

A. Congress Authorized FDA To Approve Drugs Like Mifepristone For Distribution And Sale In The United States

27. Congress first authorized FDA to regulate food and drugs more than a century ago in the Pure Food and Drugs Act, Pub. L. No. 59-384, 34 Stat. 768 (1906) (repealed 1938).

28. In 1938, Congress created the modern framework for FDA's regulation of prescription drugs in the Federal Food, Drug, and Cosmetic Act ("FDCA"), Pub. L. No. 75-717, 52 Stat. 1040 (1938) (codified at 21 U.S.C. § 301 *et seq.*). The FDCA authorized the agency to develop a comprehensive regulatory scheme governing medications sold in the United States and to promote the public health by reviewing clinical research promptly and taking appropriate action on applications for marketing those drugs. 21 U.S.C. § 393(b)(1). The FDCA prohibited a drug manufacturer from distributing a drug until it submitted a new drug application to FDA

⁸ *See* Letter from Att'y Gen., to Robert Califf, Comm'r, U.S. Food & Drug Admin. (Jan. 13, 2023) ("Letter from Att'y Gen."), https://www.alabamaag.gov/Documents/news/Letter_from_Ala_Atty_Gen_Steve_Marshall_et_al_to_FDA.pdf.

for review, and authorized FDA to reject an application if it determined the drug was unsafe. FDCA § 505(a), (d)-(e), 52 Stat. 1040, 1052 (codified at 21 U.S.C. § 355).

29. In 1951, Congress amended the FDCA to define a new category of drugs — drugs that must be prescribed by a healthcare provider (as opposed to drugs that patients could obtain over the counter). Act of Oct. 26, 1951, Pub. L. No. 82-215, 65 Stat. 648. These “prescription” drugs included medications that required medical supervision to ensure their safe use. *Id.*

30. In 1962, Congress amended the FDCA to further strengthen FDA’s mandate “[t]o protect the public health” and “assure the safety, effectiveness, and reliability of drugs.” Drug Amendments of 1962, Pub. L. No. 87-781, pmb., 76 Stat. 780, 780. Before 1962, Congress required FDA to demonstrate that a drug was harmful to deny an application and keep the drug from entering interstate commerce; after the amendment, Congress required *manufacturers* to prove to FDA that their products were safe and effective. Once FDA approved a manufacturer’s application, it authorized that manufacturer to sell and distribute its product nationwide.

31. The 1962 amendments included a provision stating: “Nothing in the amendments made by this Act . . . shall be construed as invalidating any provision of State law which would be valid in the absence of such amendments unless there is a direct and positive conflict between such amendments and such provision of State law.” *Id.* § 202, 76 Stat. 780, 793. When there is such a conflict, state law must yield.

32. In the half century since then, Congress has enacted additional statutes and amendments enhancing FDA’s mandate to ensure safe and effective drugs are available to patients in the United States. *E.g.*, Drug Price Competition and Patent Term Restoration Act of 1984, Pub. L. No. 98-417, §§ 101(j)(1), 202(e)(1), 98 Stat. 1585, 1603 (Sept. 24, 1984) (codified at 21 U.S.C. §§ 271(e)(1), 355(j)(1)) (establishing an expedited approval process for generic

drugs along with incentives for generic manufacturers to make generic drugs available on the market quickly)⁹; 21 U.S.C. § 393(b)(1), (2) (enacted in 1997) (requiring FDA to “promptly and efficiently review[] clinical research and tak[e] appropriate action on the marketing of regulated products in a timely manner”); *id.* § 360bbb(b), (c) (enacted in 1997) (authorizing FDA to “[e]xpand[] access to unapproved therapies and diagnostics,” by allowing access to “investigational drug[s]” under certain circumstances); Food and Drug Administration Modernization Act of 1997, Pub. L. No. 105-15, § 101(1), 111 Stat. 2296, 2298 (Nov. 21, 1997), *reprinted at* 21 U.S.C. § 379g note (stating that “prompt approval of safe and effective new drugs and other therapies is critical to the improvement of the public health so that patients may enjoy the benefits provided by these therapies to treat and prevent illness and disease”); 21 U.S.C. § 356c(g) (enacted in 2012) (requiring FDA to mitigate and prevent shortages of certain drugs), *id.* § 356c-1 (enacted in 2012) (requiring FDA to report annually to Congress its actions to prevent or mitigate drug shortages).

33. The FDCA also requires manufacturers to label drugs with adequate instructions for their safe use, prescribing information, and the treatment for which that drug is approved (the “indication”). 21 U.S.C. §§ 352(f), 355(a); *see also* 21 C.F.R. § 201.57(c).

1. For The Past Forty Years, FDA Has Developed And Implemented Strategies For Ensuring The Safety Of Certain Drugs

34. While Congress charges FDA with assessing drug safety, FDA’s determination that a drug is safe for use for an indication does not mean that the drug is completely risk free. All drugs, even over-the-counter drugs, carry some risk. Rather, FDA approves a drug if its

⁹ *See also Andrx Pharms., Inc. v. Biovail Corp. Int’l*, 256 F.3d 799, 809 (D.C. Cir. 2001) (explaining that the purpose of the 1984 amendments was to “get generic drugs into the hands of patients at reasonable prices — fast” (citation omitted)).

benefits to patients outweigh those risks. Furthermore, FDA can impose special regulatory programs to mitigate a drug's risks that facilitate regulatory approval of the drug and its availability to patients.

35. FDA began developing risk management programs to mitigate drug risks in the 1980s. One early example is FDA's risk management program for isotretinoin (then sold as "Accutane"), a drug that treats severe acne. After approving Accutane in 1982, FDA determined that, if taken by a pregnant person, Accutane could affect fetal development. To minimize the risk that a pregnant person might take Accutane, FDA created special package inserts and developed educational programs to warn providers and patients.

36. By the 1990s, FDA had promulgated regulations enabling it to approve drugs that treat "serious or life-threatening illnesses and that provide meaningful therapeutic benefit to patients over existing treatments" subject to certain "restrictions to assure safe use." *See* 21 C.F.R. §§ 314.500, 314.520. These regulations (known as "Subpart H") limited any restriction FDA could impose to those "commensurate with the specific safety concerns presented by the drug product." *Id.* § 314.520.

37. Under Subpart H, FDA implemented risk management programs with "elements to assure safe use" for only 16 drugs and biologics.¹⁰ One of those drugs was mifepristone.

2. *After Determining That It Was Safe And Effective, FDA Approved Branded Mifepristone Under Subpart H*

38. French pharmaceutical company Roussel Uclaf developed mifepristone in 1980. Since its development, more than eighty countries have approved mifepristone's use in

¹⁰ The 16 drugs and biologics included: abarelix, alosetron, ambrisentan, bosentan, clozapine, dofetilide, eculizumab, fentanyl PCA, fentanyl citrate, isotretinoin, lenalidomide, mifepristone, natalizumab, the smallpox vaccine, sodium oxybate, and thalidomide.

medication abortions.¹¹ The United States joined those ranks in 2000, when FDA approved a new drug application for Mifeprex — the brand name for mifepristone as distributed and marketed by Danco Laboratories, LLC (“Danco”) — for the medical termination of intrauterine pregnancy through 49 days’ gestation.

39. In approving Mifeprex for sale, FDA determined that it treats a serious or life-threatening condition (*i.e.*, unwanted or unintended pregnancies), and provides a “meaningful therapeutic benefit to some patients over surgical abortion.”¹² According to FDA, “unwanted pregnancy, like a number of illnesses or conditions, can be serious for certain populations or under certain circumstances.”¹³ FDA recognized that, despite being associated with some risks, mifepristone conferred important therapeutic benefits and therefore approved Mifeprex subject to certain restrictions under Subpart H.

3. In The FDAAA, Congress Authorized FDA To Create Risk Evaluation And Mitigation Strategies And Imposed A Strategy On Mifepristone

40. In 2007, Congress enacted the FDAAA to require FDA to ensure patient access to medications for which there is a potential risk of a serious adverse drug experience. 21 U.S.C. § 355-1. The FDAAA functionally codified FDA’s risk management regulations and instructed FDA to continue regulating access to particular drugs to ensure that they remain available, and that any restrictions do not unduly burden patient access or the healthcare delivery system.

¹¹ U.S. Food & Drug Admin., *Questions and Answers on Mifepristone for Medical Termination of Pregnancy Through Ten Weeks Gestation* (Jan. 4, 2023), <https://perma.cc/AB7X-64A5>.

¹² *Id.*

¹³ See Letter from Janet Woodcock, Dir., Ctr. for Drug Evaluation & Rsch., U.S. Food & Drug Admin., to Donna Harrison, Executive Dir., Am. Ass’n of Pro Life Obstetricians & Gynecologists, Gene Rudd, Sr. Vice Pres., Christian Med. & Dental Ass’ns, & Penny Young Nance, CEO & Pres., Concerned Women for Am. (Mar. 29, 2016) (“Woodcock Letter”).

41. To do so, Congress authorized FDA to implement a program called a Risk Evaluation and Mitigation Strategy (“REMS”). A REMS represents a determination by FDA that when a drug is prescribed or administered in a particular manner, that drug’s benefits outweigh the risk of a serious adverse drug experience. *See id.* § 355-1(a).

42. After amending the FDCA with the FDAAA, Congress directed that drugs FDA had previously approved with restrictions under Subpart H — including Mifeprex — would be “deemed to have in effect” an approved REMS. FDAAA § 909(b)(1), 121 Stat. 950-51. Congress thereby codified the restrictions FDA had imposed under Subpart H on this group of drugs, including Mifeprex. *See id.*

43. As part of the FDAAA, Congress required those 16 drugs’ sponsors to submit new REMS to FDA for the agency’s consideration. *Id.* The FDAAA authorized FDA to modify, or even remove, the REMS for those drugs. *E.g.*, 21 U.S.C. § 355-1(g)(4)(B), (h).

44. The FDAAA specifies how FDA must assess whether a REMS is appropriate. It requires FDA first to determine whether a REMS is necessary and evaluate “[t]he seriousness of any known or potential adverse events that may be related to the drug.” *Id.* § 355-1(a). If FDA concludes the drug poses a risk of an “adverse drug experience” and determines a REMS is necessary to ensure that the drug’s benefits outweigh its risks, FDA must design and implement a REMS. *Id.* An adverse drug experience includes “any adverse event associated with the use of a drug . . . whether or not” the adverse event is “considered drug related.” *Id.* § 355-1(b)(1).

45. In imposing a REMS, FDA can require drug companies to include medication guides or inserts for patients, implement communications plans (which may include sending letters to healthcare providers), or dispense the drug in special packaging to ensure patients use the drug safely. *Id.* § 355-1(e).

46. The statute authorizes FDA to impose additional REMS elements “necessary to assure safe use of the drug” (also referred as “ETASU”). These elements may be imposed only if FDA determines the drug is “associated with a serious adverse drug experience” and requires a REMS to mitigate that “specific serious risk.” *Id.* § 355-1(f)(1). A “serious risk” or “serious adverse drug experience” includes adverse drug experiences that could result in “inpatient hospitalization” or a “substantial disruption of the ability to conduct normal life functions.” *Id.* § 355-1(b)(4), (5).

47. The elements FDA imposes must be “commensurate with the specific serious risk listed” on the drug’s label. *Id.* § 355-1(f)(2)(A). For example, FDA may restrict dispensing of the drug to certain settings, like hospitals. *Id.* § 355-1(f)(1), (3).

48. If FDA determines that it can approve a drug only with a REMS that incorporates such additional elements to assure safe use, Congress directs FDA to ensure that these elements “[p]rovid[e] safe access for patients to [these] drugs.” *Id.* § 355-1(f).

49. In a provision entitled, “Assuring access and minimizing burden,” Congress mandates that these elements to assure safe use, considering the drug’s risk, “not be unduly burdensome on patient access to the drug,” taking into account three considerations: patients with serious or life-threatening conditions, patients with difficulty accessing healthcare (such as patients in “rural or medically underserved areas”), and patients with functional limitations. *Id.* § 355-1(f)(2)(A), (C)(i)-(iii). Congress requires any additional elements or restrictions to be compatible with the requirements for similar drugs and compatible with established drug distribution systems, “so as to minimize the burden on the health care delivery system.” *Id.* § 355-1(f)(2)(D).

50. In creating a REMS, FDA must seek input from patients and healthcare providers in evaluating the restrictions to ensure they are not “unduly burdensome on patient access to the drug,” *id.* § 355-1(f)(5), and minimize the “burden on the health care delivery system,” *id.* § 355-1(f)(2)(D). In other words, Congress mandated that FDA balance two competing values: the safety of the drug and patient access to the drug.

51. Any person can petition FDA to amend a drug’s REMS by submitting a citizen petition pursuant to 21 C.F.R. § 10.30.

52. Section 355-1 requires FDA to reassess a drug’s REMS periodically. 21 U.S.C. § 355-1(d). After each reassessment, FDA may eliminate a REMS — or a component of a REMS — if it determines that the REMS elements are no longer necessary to ensure a medication’s benefits outweigh its risks.

53. Congress provided that, although either a drug’s manufacturer or FDA can propose a modification to a REMS, any such modification requires prior FDA approval. Without that approval, the existing REMS remains in effect. *Id.* § 355-1(g)(1), (h)(1), (h)(2)(A)-(B).

54. Of the more than 20,000 prescription drugs FDA has approved for marketing in the United States, the agency has subjected only 301 to a REMS.¹⁴ FDA has subjected 97 of those drugs to additional elements to assure safe use.¹⁵

¹⁴ U.S. Food & Drug Admin., *FDA Risk Evaluation and Mitigation Strategy (REMS) Public Dashboard* (Jan. 17, 2023), <https://fis.fda.gov/sense/app/ca606d81-3f9b-4480-9e47-8a8649da6470/sheet/994e7e67-d815-4204-8758-095c2abe2eda/state/analysis>.

¹⁵ *Id.*

B. FDA Determined That Mifepristone Requires A REMS With Additional Elements To Assure Safe Use

1. The Early Mifeprex REMS

55. After Congress mandated that Mifeprex be “deemed to have in effect” an approved REMS in the FCAAA, in September 2008, Danco submitted a supplemental new drug application proposing a REMS for Mifeprex. FDA approved the proposed REMS in June 2011.

56. As approved, the 2011 REMS required that only certified physicians prescribe Mifeprex; specified that Mifeprex be dispensed only in certain healthcare settings such as clinics (known as the “in-person dispensing requirement”) and taken in a provider’s clinic; and required Danco to ensure that every doctor prescribing Mifeprex was specially certified.

57. In approving these REMS, FDA “determined that a REMS [wa]s necessary” for Mifeprex “to ensure the benefits of the drug outweigh[ed] the risks of serious complications by requiring prescribers to certify that they [were] qualified to prescribe” the drug, and could “assure patient access to appropriate medical facilities to manage any complications.”¹⁶

58. In 2015, Danco submitted a supplemental new drug application to FDA to revise Mifeprex’s label and REMS. FDA approved almost all of Danco’s proposed modifications to the label and REMS, including: increasing the gestational age through which Mifeprex is indicated from 49 days to 70 days; reducing the number of patient visits to a clinic; and expanding those who could be certified to prescribe Mifeprex to include “healthcare providers,” rather than just “physicians.”

¹⁶ Letter from Ctr. for Drug Evaluation & Rsch., U.S. Food & Drug Admin., to Danco Labs., LLC 1 (June 8, 2011), https://www.accessdata.fda.gov/drugsatfda_docs/appletter/2011/020687s014ltr.pdf.

59. FDA determined that the remaining REMS requirements, such as the in-person dispensing requirement, “remain[ed] necessary to ensure that the drug’s benefits outweigh its risks”¹⁷ and to assure Mifeprex’s safe use.¹⁸

2. FDA Approved GenBioPro’s Generic Mifepristone

60. GenBioPro spent almost a decade bringing a generic version of mifepristone to market. On April 11, 2019, FDA approved GenBioPro’s application to manufacture and market generic mifepristone within the United States. As required by section 355, GenBioPro’s generic mifepristone and Danco’s Mifeprex have substantively identical labels. *See* 21 U.S.C. § 355(j)(2)(A)(v), (j)(4)(G).

61. FDA subjected GenBioPro’s generic mifepristone to a REMS pursuant to 21 U.S.C. § 355-1(i). FDA determined that the branded and generic mifepristone should share a single REMS, to be called the “Mifepristone REMS Program.”

3. FDA Halted Enforcement Of, And Reevaluated Part Of, The Mifepristone REMS

62. In April 2021, FDA announced it would stop enforcing the in-person dispensing requirement of the Mifepristone REMS Program. The agency determined that requiring a patient to visit a clinic during the COVID-19 public health emergency could pose serious risks to patients and healthcare personnel and that new clinical data demonstrated that the in-person dispensing requirement was not necessary to ensure mifepristone remained safe for patients.

¹⁷ Letter from Ctr. for Drug Evaluation & Rsch., U.S. Food & Drug Admin., to Danco Labs., LLC 2 (Mar. 29, 2016), https://www.accessdata.fda.gov/drugsatfda_docs/appletter/2016/020687Orig1s020ltr.pdf.

¹⁸ *See* U.S. Gov’t Accountability Off., GAO-18-292, Food and Drug Administration: Information on Mifeprex Labeling Changes and Ongoing Monitoring Efforts 12 (2018).

63. FDA continued its review of the Mifepristone REMS Program during the COVID-19 pandemic. In addition to analyzing newly published scientific literature, FDA evaluated safety information submitted to the agency during the COVID-19 public health emergency, reports of adverse events related to the drug, the first REMS assessment report for the Mifepristone REMS Program, and other information provided by the public. In December 2021, FDA announced its determination that certain elements of the Mifepristone REMS Program remained necessary to assure the drug's safe use, while other elements would need to be modified "to reduce burden on patient access and the health care delivery system and to ensure the benefits of [mifepristone] outweigh [its] risks."¹⁹

64. After completing that review, FDA instructed Danco and GenBioPro to modify the Mifepristone REMS Program by removing the requirement that mifepristone be dispensed only in certain healthcare settings and adding a requirement that pharmacies dispensing mifepristone be specially certified.

65. In December 2021, FDA responded to a Citizen's Petition from American Association of Pro Life Obstetricians and Gynecologists, the Christian Medical Association, and Concerned Women for America, rejecting their requests to impose additional burdens on access to mifepristone, including (1) limiting mifepristone's indication to 49 days' gestation; (2) requiring physicians, and not other providers, to prescribe mifepristone; (3) requiring patients to make three different office visits to their physicians as part of the REMS; and (4) requiring that mifepristone be dispensed only in certain healthcare settings.²⁰

¹⁹ U.S. Food & Drug Admin., *Questions and Answers on Mifepristone for Medical Termination of Pregnancy Through Ten Weeks Gestation* (Dec. 16, 2021), <https://perma.cc/V7RX-ZUAX>.

²⁰ See Woodcock Letter, *supra* note 13, at 5, 9, 13-15, 18-19, 25.

4. FDA Updated The Mifepristone REMS Program, Expanding Methods By Which Patients May Access Mifepristone

66. On January 3, 2023, FDA published a new, shared system REMS for mifepristone (the “2023 REMS”) covering both Mifeprex and generic mifepristone.²¹ Consistent with FDA’s December 2021 statements, the 2023 REMS no longer limits mifepristone dispensing to certain healthcare settings; patients may receive mifepristone by mail or from a specially certified pharmacy.

67. The 2023 REMS requires patients to sign a Patient Agreement Form before receiving a prescription for mifepristone.²² This form includes a section in which patients acknowledge having “decided to take “mifepristone and misoprostol to end [their] pregnancy” and agreeing to “follow [their] healthcare provider’s advice about when to take each drug and what to do in an emergency.”²³ The form requires patients to assert that they “understand” that they “will take mifepristone” and then “the misoprostol tablets 24 to 48 hours after” taking mifepristone.²⁴ FDA determined that these new REMS “continue to ensure the benefits of mifepristone for medical abortion outweigh the risks while minimizing the burden imposed by the REMS on healthcare providers and patients.”²⁵

²¹ U.S. Food & Drug Admin., *Risk Evaluation and Mitigation Strategy (REMS) Single Shared System for Mifepristone 200mg* (Jan. 2023), https://www.accessdata.fda.gov/drugsatfda_docs/remis/Mifepristone_2023_01_03_REMS_Full.pdf.

²² U.S. Food & Drug Admin., *Patient Agreement Form* (Jan. 2023), https://www.accessdata.fda.gov/drugsatfda_docs/remis/Mifepristone_2023_01_03_REMS_Full.pdf.

²³ *Id.*

²⁴ *Id.*

²⁵ *Id.*

C. West Virginia Law Restricts Patients' Access To Mifepristone And Regulates How The Healthcare Delivery System Provides Mifepristone

68. On September 13, 2022, the West Virginia governor signed the “Unborn Child Protection Act,” banning abortion at all stages of pregnancy except in limited circumstances. *See* W. Va. Code § 16-2R-1 *et seq.*; *id.* § 61-2-8. The law also declared that several provisions of the West Virginia Code related to abortion, including the counseling and waiting period requirements, would have “no force or effect unless any provision of the . . . Act is judicially determined to be unconstitutional.” 2022 W. Va. H.B. 302; ~~*see id.* § 16-2I-9. If. The legislature amended the Act’s severability provision in March 2023, revising it to state that if~~ a court invalidates ~~any part of the law~~ Act in its entirety, those restrictions are reactivated. W. Va. Code § 16-2I-9.

69. The Ban states that “[a]n abortion may not be performed or induced or be attempted to be performed or induced unless in the reasonable medical judgment of a licensed medical professional: (1) The embryo or fetus is nonviable; (2) The pregnancy is ectopic; or (3) A medical emergency exists.” *Id.* § 16-2R-3(a).²⁶ As a result, West Virginians no longer have a meaningful choice about whether to carry a pregnancy to term or to terminate using medication abortion. *Id.* §§ 16-2R-3, 16-2R-7.

70. The Ban amends mifepristone’s indication by changing the time for which mifepristone is indicated from a period spanning 70 days’ gestation, to no time at all for most patients.

²⁶ The Ban also includes limited exceptions for a pregnancy that is within eight weeks’ gestation (or, if a minor or incompetent or incapacitated adult, 14 weeks) and is the result of sexual assault or incest that the patient has reported to law enforcement. W. Va. Code § 16-2R-3(b), (c).

71. While the Ban does not punish patients who terminate their pregnancies, it subjects certain healthcare providers who perform abortions to loss of their professional license, *id.* § 16-2R-7, and makes it a felony punishable by imprisonment for any other “person” to induce an abortion, *id.* § 61-2-8(a). The Ban imposes criminal penalties on some healthcare providers eligible to prescribe mifepristone under the 2023 REMS if they prescribe mifepristone to induce an abortion. *Id.* (defining “licensed medical professional” to exclude certain REMS-authorized providers); *see id.* § 16-2R-2.

72. In imposing the Ban, West Virginia officials eliminated access to mifepristone in the State in almost all circumstances. Even before the Ban, however, West Virginia regulated access to mifepristone in a manner restricting GenBioPro’s ability to distribute its FDA-approved product to West Virginians who qualified for access to it in compliance with FDA requirements.

73. As part of these Restrictions, West Virginia:

- (a) required providers to obtain “informed consent” from patients at least 24 hours before having a medication abortion, delaying care when, medically, it should be provided as soon as possible to ensure safety and effectiveness and avoid forcing patients out of the 70-day window in which mifepristone is indicated for use. *Id.* § 16-2I-2(a). The law enacting the Ban provides that this waiting-period requirement “is of no force or effect unless” a court rules any provision of the Ban (§ 16-2R-1 *et seq.*) unconstitutional. *Id.* § 16-2I-9.
- (b) required providers to communicate specific information to patients that is not part of the Mifepristone REMS Program, including that: “[s]ome suggest that it may be possible to counteract the intended effects of a

mifepristone chemical abortion by taking progesterone if the female changes her mind, before taking the second drug,” *id.* § 16-2I-2(a)(4)(A); and “the father, if his identity can be determined, is liable to assist in the support of her child,” *id.* § 16-2I-2(b)(2). The law enacting the Ban provides that this counseling requirement “is of no force or effect unless” a court rules any provision of the Ban (§ 16-2R-1 *et seq.*) is unconstitutional. *Id.* § 16-2I-9.

- (c) bans providers from using telemedicine to prescribe mifepristone, which means patients must visit a provider in person to obtain a prescription. *Id.* § 30-3-13a(g)(5) (stating that a “physician or health care provider may not prescribe any drug with the intent of causing an abortion” via telemedicine); *see id.* § 30-1-26(b)(9).

74. These Restrictions, which are in force or would become operative again if ~~any portion of~~ the Ban is judicially determined to be unconstitutional, constrict GenBioPro’s ability to market its FDA-approved product to West Virginians who need it. The Ban makes such commercial opportunities virtually impossible.

75. On January 13, 2023, shortly after FDA issued the 2023 REMS, Defendant Morrissey, the Attorney General of West Virginia, joined a letter in which a number of state attorneys general proclaimed to FDA that they “will not yield” to FDA’s federally based authority to approve drugs and to strike the optimal regulatory balance between risk mitigation and ensuring patient access because, in their view, the 2023 REMS fail “to protect women’s health and safety.” Defendant Morrissey and his co-signers wrote that “[t]o be crystal clear,” FDA “ha[s] not negated any of our laws that forbid the remote prescription, administration, and

use of abortion-inducing drugs” and “[n]othing in the FDA’s recent changes affects” how they will enforce those laws.²⁷

D. West Virginia’s Abortion Ban And Restrictions Harm GenBioPro And Prevent Patients From Accessing A Federally Approved Medication

76. More than eighty countries have approved mifepristone’s use in medication abortions, and many patients in the United States use mifepristone.²⁸ In 2020, approximately 492,210 medication abortions occurred in the United States, up from approximately 339,650 just three years earlier.²⁹ The market for mifepristone is strong and sales have grown over time, even as the number of total U.S. abortions (including surgical) has declined.³⁰ Medication abortions account for more than half of U.S. abortions, despite the fact that FDA approves of mifepristone’s use only up to 70 days’ gestation.³¹

²⁷ Letter from Att’y Gen., *supra* note 8, at 3.

²⁸ U.S. Food & Drug Admin., *Questions and Answers on Mifepristone for Medical Termination of Pregnancy Through Ten Weeks Gestation* (Jan. 4, 2023), <https://perma.cc/AB7X-64A5>.

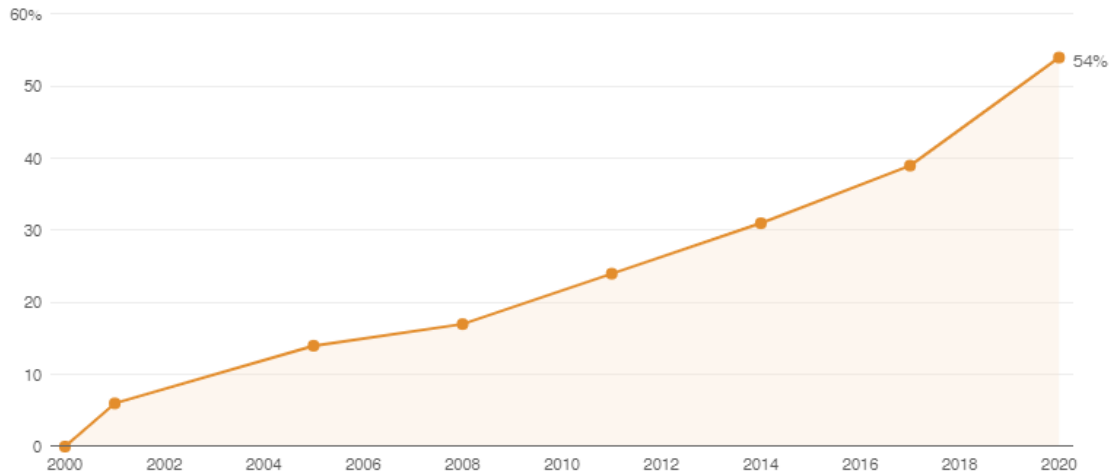
²⁹ Rachel K. Jones et al., *supra* note 1, at 135.

³⁰ *Id.*

³¹ *Id.*; Laurel Wamsley, *How Medication Abortion Works and What the End of Roe v. Wade Could Mean for It*, NPR (May 13, 2022), <https://www.npr.org/2022/05/13/1098000879/abortion-pills-medication-abortion-ro-v-wade>.

More than half of U.S. abortions are medication abortions

Since the FDA approved mifepristone in 2000, use of the drug for abortions (vs. surgical procedure) has increased steadily.



Source: Guttmacher Institute (2020 numbers are estimates)

Credit: Alyson Hurt and Laurel Wamsley/NPR

77. Although Congress and FDA granted GenBioPro authority to sell mifepristone nationwide, West Virginia's severe abortion Restrictions and Criminal Abortion Ban make it impossible for GenBioPro to promote and market its product in West Virginia as it does in other states. The State has long had only a single clinic providing abortions.

78. Major national pharmacy chains, including Walgreens and CVS, which operate stores in Hurricane and Winfield, have indicated publicly that they intend to sell mifepristone now that the REMS permits them to do so.³² Providing mifepristone through such pharmacies would enable GenBioPro to serve more patients with its product. West Virginia's Ban and Restrictions, however, block GenBioPro from providing mifepristone through these integral healthcare distribution mechanisms in West Virginia. HoneyBee Health, which ships

³² Spencer Kimball & Bertha Coombs, *CVS and Walgreens Plan to Sell Abortion Pill Mifepristone at Pharmacies After FDA Rule Change*, CNBC (Jan. 5, 2023), <https://www.cnbc.com/2023/01/05/abortion-cvs-and-walgreens-will-sell-mifepristone-in-pharmacies.html>.

prescription drugs nationwide, is also prevented by West Virginia's Ban and Restrictions from providing mifepristone to patients in West Virginia.³³

79. West Virginia's Criminal Abortion Ban and Restrictions have caused significant, ongoing economic injury to GenBioPro in the form of lost sales, customers, and revenue. Defendants' enforcement of the Ban and Restrictions severely constricts GenBioPro's pool of potential customers — including healthcare providers that purchase from GenBioPro and certified pharmacies — and impermissibly constrains GenBioPro's ability to market its product in West Virginia.

80. GenBioPro further alleges that, based on the foregoing, healthcare providers in West Virginia would prescribe mifepristone to their patients and purchase that mifepristone from GenBioPro, and that pharmacies in West Virginia would dispense GenBioPro's mifepristone to their customers, but do not because of the Ban and the Restrictions.

E. West Virginia's Abortion Ban And Other Restrictions Conflict With Federal Law And Regulate Access To Mifepristone, A Function Congress Delegated Exclusively To FDA

81. West Virginia's Ban and abortion Restrictions frustrate and conflict with Congress's determination that FDA must exercise regulatory authority through REMS and elements to assure safe use under 21 U.S.C. § 355-1(f) that States are not free to second-guess or override. Developing such a REMS requires FDA to first determine that restrictions are necessary to ensure that the drug's benefits outweigh its risks, and then to impose restrictions that address the drug's risks while minimizing the burden on patients' access to the drug and on the healthcare delivery system. *See* 21 U.S.C. § 355-1(f)(2).

³³ Celine Castronuovo, *Abortion Pill Access to Ease with First FDA-Certified Pharmacy*, Bloomberg News (Jan. 3, 2023), <https://news.bloomberglaw.com/health-law-and-business/abortion-pill-access-to-ease-with-first-fda-certified-pharmacy>.

82. Section 355-1(f)(2) requires FDA to balance competing obligations, to maximize safety while minimizing burden, and to regulate patients' access to, and the healthcare delivery system's distribution of, mifepristone. The statute delegates to FDA exclusive authority to conduct that balancing, deploying its unique expertise in determining whether scientific evidence demonstrates that a serious adverse experience is associated with a drug, and how best to mitigate that risk while ensuring that its efforts do not unduly burden patient access to the drug. FDA's REMS therefore necessarily establishes both a "floor" and "ceiling" on permissible regulation of mifepristone. The elements FDA determined are necessary to ensure mifepristone's safety are the *only* restrictions that may be imposed on a patient's access to, and the healthcare delivery system's distribution of, mifepristone. Just as a state may not pass a law purporting to remove one of the REMS requirements (such as waiving the requirement of a Patient Agreement Form), it also may not impose any other elements restricting access. Doing so would disturb the balancing that Congress required FDA to conduct in regulating access to mifepristone via the Mifepristone REMS Program.

83. West Virginia's Ban prevents almost all patients from accessing mifepristone, including those who otherwise would be eligible to receive the drug under the 2023 REMS. In so doing, it functionally displaces FDA's judgment in approving mifepristone and imposing a REMS. West Virginia's Ban also prevents the healthcare delivery system from distributing mifepristone to patients for whom providers would otherwise prescribe the drug. It burdens both the patient's access to mifepristone and the healthcare delivery system by imposing criminal and professional penalties on the prescription and distribution of mifepristone. *See* W. Va. Code § 16-2R-1 *et seq.*; *id.* § 61-2-8.

84. The State’s laws interfere with and seek to contradict Congress’s directive to FDA to determine what elements will assure safe use of a REMS drug without being “unduly burdensome on patient access” and “minimiz[ing] the burden on the health care delivery system.” 21 U.S.C. § 355-1(f)(2)(C), (D).

85. The Ban and Restrictions conflict with FDA’s determinations pursuant to section 355-1(f)(2). The Ban and Restrictions make it impossible for GenBioPro to market and distribute mifepristone in West Virginia in accordance with FDA’s requirements and determinations as to the balance Congress mandated between safety-based restrictions and patient access to the drug.

86. Even if the Ban is invalidated or repealed, the telemedicine ban will be in force and the counseling and waiting period requirements would again come into force. Each of these Restrictions conflicts with the 2023 REMS and regulates in an arena that Congress left to FDA.

87. West Virginia’s waiting period and counseling requirements, W. Va. Code § 16-2I-2, require providers to obtain “informed consent” from patients at least 24 hours before prescribing mifepristone and require providers to communicate specific information to patients that is not part of the counseling required by the Mifepristone REMS Program. The prescriber agreement in the REMS requires only that a physician review the Patient Agreement Form, “fully explain[]” the “risks of the mifepristone treatment regimen,” answer any “questions the patient may have,” and ensure the patient receives and signs the Patient Agreement Form.³⁴

88. West Virginia’s telemedicine restrictions, *id.* § 30-3-13a(g)(5); *see id.* § 30-1-26(b)(9), purport to bar healthcare providers from prescribing any abortion drug via

³⁴ U.S. Food & Drug Admin., *Patient Agreement Form* (Jan. 2023), https://www.accessdata.fda.gov/drugsatfda_docs/remis/Mifepristone_2023_01_03_REMS_Full.pdf.

telemedicine. The Mifepristone REMS Program does not prohibit providers from using telemedicine to prescribe mifepristone. In 2019, several advocacy groups asked FDA to add a requirement to the REMS that a provider prescribe mifepristone in person, rather than by telemedicine or over the Internet. FDA specifically considered and rejected the proposed requirement as unnecessary to ensure mifepristone's safety. West Virginia's Restriction conflicts with this FDA determination.

89. West Virginia's Ban and Restrictions conflict with mifepristone's label and indication. FDA determined that mifepristone is indicated for use up to 70 days' gestation, but West Virginia law conflicts with that determination by banning use of mifepristone by nearly all patients at any stage of pregnancy and limiting mifepristone to emergency use.

90. By enacting the FDCA and its amendments, Congress authorized FDA to approve drugs in the United States and determine whether a manufacturer can sell its product in interstate commerce. *See, e.g.*, Act of Oct. 10, 1962, Pub. L. No. 87-781, § 104, 76 Stat. 780, 784; 21 U.S.C. § 393(b)(1). A state ban like West Virginia's constitutes a determination on the part of state legislators that a manufacturer *cannot* sell its product in the State, creating a direct conflict with federal law. *See* Act of Oct. 10, 1962, Pub. L. No. 87-781, § 102, 76 Stat. 780, 781.

91. A favorable decision from this Court declaring the ~~laws at issue~~Ban and waiting period and counseling restrictions invalid as applied to the sale and distribution of mifepristone and enjoining their enforcement by state officials due to their constitutional infirmities will remedy these conflicts and redress GenBioPro's economic injury by enabling West Virginians to access its product. ~~And if this Court rules any part of the Ban statute unconstitutional as applied to mifepristone, the entire Ban is invalidated. W. Va. Code § 16-2R-9.~~

92. Settled preemption and Commerce Clause principles govern states' efforts to restrict access to an FDA-approved medication. The Supreme Court's decision in *Dobbs* did not displace Congress's and FDA's roles in protecting the public health by deciding whether drugs are safe and effective, determining which precautions — if any — are necessary to ensure a drug's safe use, and ensuring safe and effective drugs are available to the public. *Dobbs* addressed only the underlying personal constitutional privacy right as it pertains to abortion; it did not speak to federal law regulating a drug maker's sale and distribution of, or a patient's access to, medication that is FDA-approved for distribution nationwide.

CLAIMS FOR RELIEF

COUNT I

Declaratory and Injunctive Relief — 42 U.S.C. § 1983 — Federal Law Preempts West Virginia's Ban and ~~Restrictions~~Waiting Period and Counseling Requirements

93. GenBioPro re-alleges and incorporates by reference each of the preceding paragraphs.

94. The U.S. Constitution's Supremacy Clause makes federal laws enacted under the authority of the United States the "supreme Law of the Land." U.S. Const. art. VI, cl. 2. Under the Clause, federal law preempts any state regulation to the contrary. *See Gade v. Nat'l Solid Wastes Mgmt. Ass'n*, 505 U.S. 88, 108 (1992).

95. West Virginia's Ban, W. Va. Code §§ 16-2R-1 *et seq.*, 61-2-8, and ~~Restrictions~~waiting period and counseling requirements, *id.* §§ 16-2I-2, 16-2I-9, ~~30-1-26(b)(9); 30-3-13a(g)(5)~~, are preempted by the FDCA as amended, 21 U.S.C. § 355-1. States may not restrict access to FDA-approved drugs in ways that countermand the agency's specific safety considerations or restrictions.

96. West Virginia's Ban and ~~Restrictions~~waiting period and counseling requirements conflict with that mandate, including by imposing the burden of criminal penalties on REMS-eligible providers' prescription of mifepristone. The Ban and ~~Restrictions~~waiting period and counseling requirements frustrate FDA's determinations about how mifepristone should be regulated and invade an area Congress determined only FDA may occupy. *See, e.g., Mut. Pharm. Co. v. Bartlett*, 570 U.S. 472, 479-80 (2013); *Arizona v. United States*, 567 U.S. 387, 403 (2012); *Geier v. Am. Honda Motor Co.*, 529 U.S. 861, 873 (2000). The Ban and ~~Restrictions~~waiting period and counseling requirements further stand as an obstacle to FDA's determination that GenBioPro's mifepristone is safe and effective, and GenBioPro may distribute it to patients pursuant to the REMS.

97. Federal law therefore preempts Article 2R, Chapter 16 of the West Virginia Code and Section 61-2-8, insofar as these statutes ban patients from using mifepristone in almost all instances.

98. Federal law preempts West Virginia Code §§ 16-2I-2, 16-2I-9 insofar as it requires patients seeking mifepristone to fulfill waiting period and counseling requirements.

~~99. —Federal law preempts West Virginia Code § 30-3-13a(g)(5) insofar as it bans prescribing mifepristone via telemedicine and West Virginia Code § 30-1-26(b)(9) insofar as it provides for a rule banning prescribing mifepristone via telemedicine.~~

~~100.~~99. Section 1983 of Title 42 of the United States Code provides that "Every person who, under color of any statute, ordinance, regulation, custom, or usage, of any State . . . , subjects, or causes to be subjected, any citizen of the United States or other person within the jurisdiction thereof to the deprivation of any rights, privileges, or immunities secured by the

Constitution and laws, shall be liable to the party injured in an action at law, suit in equity, or other proper proceeding for redress”

~~101.100.~~ West Virginia’s Ban and ~~Restrictions~~waiting period and counseling requirements conflict with the rights, privileges, or immunities secured by FDA approval of mifepristone under Title 21 of the United States Code and the REMS to market and distribute its FDA-approved product in West Virginia subject only to those regulations and restrictions FDA imposed pursuant to its mandate under the FDCA as amended, 21 U.S.C. § 355-1.

COUNT II

Declaratory and Injunctive Relief — 42 U.S.C. § 1983 — West Virginia’s Ban and Restrictions Violate the Commerce Clause

~~102.101.~~ GenBioPro re-alleges and incorporates by reference each of the preceding paragraphs.

~~103.102.~~ The Commerce Clause grants Congress alone the power to “regulate Commerce . . . among the several States.” U.S. Const. art. I, § 8, cl. 3. It prevents a state from taking any action that may impede the free flow of trade in the national common market or create an undue burden on access to an article of commerce that requires uniform national regulation.

~~104.103.~~ The Commerce Clause renders invalid state laws that impose “undue burdens” on interstate commerce, including by regulating articles of commerce Congress determined require a uniform system of regulation at the national level. *South Dakota v. Wayfair, Inc.*, 138 S. Ct. 2080, 2091 (2018). The Clause likewise invalidates state laws, such as West Virginia’s Ban and Restrictions, that preclude the use of a drug manufactured out of state for use in the State to terminate a pregnancy, *see Healy v. Beer Inst.*, 491 U.S. 324, 336 (1989) (laws that, if imposed by several states, would have the “practical effect” of regulating commerce

outside the state violate the Commerce Clause), or of banning an article of commerce, *see Schollenberger v. Pennsylvania*, 171 U.S. 1, 13 (1898).

~~105.104.~~ Section 1983 of Title 42 of the United States Code provides a remedy for any person who suffers deprivation of rights, privileges, and immunities secured by the U.S. Constitution, including the Commerce Clause.

~~106.105.~~ West Virginia's Ban, W. Va. Code § 16-2R-1 *et seq.*; *id.* § 61-2-8, and Restrictions, *id.* §§ 16-2I-2, 16-2I-9, 30-1-26(b)(9), 30-3-13a(g)(5), interfere with the uniform regulation of mifepristone, a drug subject to extensive federal regulation at the national level, thereby destroying the common market for mifepristone.

~~107.106.~~ Article 2R, Chapter 16 of the West Virginia Code and § 61-2-8 violate the Commerce Clause by, in effect, banning an article of commerce and preventing GenBioPro from developing a market for its product, mifepristone, in West Virginia.

~~108.107.~~ West Virginia Code § 16-2I-2 violates the Commerce Clause by forcing patients to fulfill waiting period and counseling requirements before accessing mifepristone. This State law disrupts FDA's federal regulatory scheme and undermines the need for national uniformity in the regulation of REMS drugs such as mifepristone.

~~109.108.~~ West Virginia Code § 30-3-13a(g)(5) violates the Commerce Clause by preventing providers from prescribing mifepristone via telemedicine, meaning that patients are required to visit a healthcare professional in person to obtain a prescription. *See id.* § 30-1-26(b)(9). This State law disrupts FDA's federal regulatory scheme and undermines the need for national uniformity in the regulation of mifepristone, as subject to the FDA's REMS.

~~110.109.~~ Each of these Restrictions and West Virginia's Ban constrict the market for GenBioPro's product, excessively burden interstate commerce, and vitiate the national common market the Framers envisioned.

~~111.110.~~ West Virginia's Ban and Restrictions conflict with the rights, privileges, or immunities secured by FDA approval of mifepristone under Title 21 of the United States Code and the REMS to market and distribute the drug under applicable federal rules. As such, 42 U.S.C. § 1983 provides a cause of action and remedy for such violations.

PRAYER FOR RELIEF

WHEREFORE, Plaintiff respectfully requests that this Court enter an order and judgment as follows:

A. A declaratory judgment, pursuant to 28 U.S.C. § 2201, that West Virginia Code §§ 16-2R-1 *et seq.*, 16-2I-2, 16-2I-9, ~~30-1-26(b)(9), 30-3-13a(g)(5)~~, and 61-2-8 are invalid and unenforceable because they violate both the Supremacy Clause and the Commerce Clause of the U.S. Constitution;

~~B.~~ A declaratory judgment, pursuant to 28 U.S.C. § 2201, that West Virginia Code §§ 30-1-26(b)(9) and 30-3-13a(g)(5) are invalid and unenforceable because they violate the Commerce Clause of the U.S. Constitution;

~~B.C.~~ Such further relief as permitted under 28 U.S.C. § 2202, including a permanent injunction enjoining Defendants from enforcing the challenged provisions;

~~C.D.~~ Injunctive relief under this Court's equitable power to enjoin enforcement of unconstitutional state laws;

~~D.E.~~ An order awarding GenBioPro its costs and attorneys' fees pursuant to 42 U.S.C. § 1988; and

E.F. Such other and further relief as the Court deems just and proper.

Dated: ~~January 25~~October 18, 2023

David C. Frederick*
Ariela M. Migdal*
Eliana Margo Pfeffer*
Mary Charlotte Y. Carroll*
KELLOGG, HANSEN, TODD,
FIGEL & FREDERICK, P.L.L.C.
1615 M Street, N.W., Suite 400
Washington, D.C. 20036
Tel: (202) 326-7900
dfrederick@kellogghansen.com
amigdal@kellogghansen.com
epfeffer@kellogghansen.com
mcarroll@kellogghansen.com

Skye L. Perryman*
Kristen Miller*
DEMOCRACY FORWARD
FOUNDATION
P.O. Box 34553
Washington, D.C. 20043
Tel: (202) 448-9090
sperryman@democracyforward.org
kmiller@democracyforward.org

Respectfully submitted,

/s/ Anthony J. Majestro

Anthony J. Majestro
W. Va. Bar No. 5165
Christina L. Smith
W. Va. Bar No. 7509
POWELL & MAJESTRO P.L.L.C.
405 Capitol Street
Suite P-1200
Charleston, WV 25301
Tel: (304) 346-2889
amajestro@powellmajestro.com
csmith@powellmajestro.com

John P. Elwood*
Daphne O'Connor*
Robert J. Katerberg*
ARNOLD & PORTER KAYE SCHOLER LLP
601 Massachusetts Avenue, N.W.
Washington, D.C. 20001
john.elwood@arnoldporter.com
daphne.oconnor@arnoldporter.com
robert.katerberg@arnoldporter.com

* Admitted pro hac vice ~~forthcoming~~

Counsel for Plaintiff GenBioPro, Inc.

**IN THE UNITED STATES DISTRICT COURT
FOR THE SOUTHERN DISTRICT OF WEST VIRGINIA
HUNTINGTON DIVISION**

GENBIOPRO, INC.,

Plaintiff,

v.

**KRISTINA 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.***

**Civil Action No.: 3:23-cv-00058
(Hon. Robert C. Chambers)**

ORDER REGARDING MOTION TO AMEND COMPLAINT AND JOINT STIPULATION

The Court hereby **GRANTS** the Motion to Amend Complaint and Joint Stipulation filed by the parties on October 18, 2023, Dkt. No. ___, and deems Plaintiff's First Amended Complaint to be the operative complaint in this case.

The Clerk is directed to send copies of this Order to those counsel of record who have registered to receive an electronic NEF.

IT IS SO ORDERED this _____ day of October, 2023.

**Robert C. Chambers
United States District Judge**