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

GENBIOPRO, INC.,

***Plaintiff*,**

v.

MARK A. SORSAIA*, 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)

PLAINTIFF'S OPPOSITION TO DEFENDANT PATRICK MORRISEY'S MOTION TO DISMISS

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INTRODUCTION AND BACKGROUND

West Virginia has unlawfully attempted to ban a drug that Congress required the U.S. Food and Drug Administration ("FDA") to regulate as part of a comprehensive scheme that assures access to the drug for its approved indication. States cannot deny patients access to mifepristone (Mifepristone Tablets, 200 mg), because Congress authorized only FDA to restrict patients' access to this drug.

GenBioPro is the only U.S. manufacturer of generic mifepristone, one drug in a two-drug regimen for medication abortion. FDA approved mifepristone in 2000 as a safe and effective method to terminate a pregnancy. At that time, FDA imposed postmarket restrictions on how mifepristone could be dispensed and administered (known as "elements to assure safe use"), including requiring qualified physicians to supervise its provision and limiting where patients could take it. Compl. ¶¶ 36-39. Medication abortion, which allows patients to terminate a pregnancy at home, has grown as a share of overall elective abortions in recent years.

In 2007, Congress enacted the Food and Drug Administration Amendments Act ("FDAAA"), Pub. L. No. 110-85, 121 Stat. 823, amending 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 FDAAA expanded FDA's authority to regulate certain drugs, following their approval, under a Risk Evaluation and Mitigation Strategy ("REMS"). *See* 21 U.S.C. § 355-1. In the FDAAA, Congress specifically "deemed" mifepristone and 15 other drugs FDA had approved with "elements to assure safe use" to "have in effect an approved [REMS]." § 909(b)(1), 121 Stat. at 950-51, *reprinted at* 21 U.S.C. § 331 note. For other drugs, FDA would consider whether to impose a REMS in the first instance.

Congress required FDA to ensure that any additional elements to assure safe use restricting access to a REMS drug provide "safe access for patients" while assuring its "safe use." 21 U.S.C. § 355-1(f). Restrictions may "not be unduly burdensome on patient access" and must "minimize the burden on the health care delivery system." *Id.* § 355-1(f)(2)(C)-(D). Since 2007, FDA has regulated mifepristone subject to this statute, updating mifepristone's REMS in 2023 to allow patients to receive the drug from certified pharmacies. Compl. ¶ 9.

West Virginia contravened Congress's mandate by enacting laws, on topics addressed by FDA, that bar patient access to the drug. The Unborn Child Protection Act, W. Va. Code § 16-2R-1 *et seq.*, and associated penalties, *id.* § 61-2-8, (collectively, the "Criminal Abortion Ban" or "Ban"), ban abortion in almost all circumstances for which mifepristone is indicated. The Ban imposes burdens on patients' access to the drug and on the healthcare delivery system, including criminal penalties, severely constricting the market for mifepristone in West Virginia. *See* Compl. ¶ 71; Opposition To Defendant Mark A. Sorsaia's Motion To Dismiss at 11 & n.3 (Mar. 7, 2023), ECF No. 31 ("Sorsaia Opp."). Even before it took effect, West Virginia restricted access to mifepristone, limiting GenBioPro's ability to market it in the State. *See* W. Va. Code §§ 16-2I-2 (requiring a waiting period and counseling before an abortion), 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 prescription of mifepristone via telemedicine) (collectively, the "Restrictions"). Because those provisions are preempted and run afoul of the dormant Commerce Clause, GenBioPro has stated legally sufficient claims.

STANDARD OF REVIEW

In ruling on a motion to dismiss, the Court "accept[s] as true all well-pleaded facts in [the] complaint and construe[s] them in the light most favorable to the plaintiff," *Wikimedia*

Found. v. NSA, 857 F.3d 193, 208 (4th Cir. 2017), and denies the motion if the complaint contains enough facts "to state a claim to relief that is plausible on its face." *Bell Atl. Corp. v. Twombly*, 550 U.S. 544, 570 (2007).

ARGUMENT

I. GENBIOPRO HAS STANDING BECAUSE WVAG CREDIBLY THREATENED TO ENFORCE THE BAN THAT CONSTRICTS ITS ABILITY TO MARKET MIFEPRISTONE IN WEST VIRGINIA

To establish standing, "a plaintiff must show (1) an 'injury in fact,' (2) a sufficient 'causal connection between the injury and the conduct complained of,' and (3) a 'likel[ihood]' that the injury 'will be redressed by a favorable decision.'" *Susan B. Anthony List v. Driehaus*, 573 U.S. 149, 157-58 (2014) (quoting *Lujan v. Defs. of Wildlife*, 504 U.S. 555, 560-61 (1992)). GenBioPro has standing to challenge the Ban and Restrictions, which constrict its pool of customers in the State.

A. GenBioPro's Injuries Include Economic Harm And Threatened Enforcement

West Virginia's Ban imposes "financial harm," the "classic and paradigmatic form of injury in fact," on GenBioPro. *Md. Shall Issue, Inc. v. Hogan*, 971 F.3d 199, 210 (4th Cir. 2020)). "[L]ost business opportunities" and "the operation of a challenged statute that results in the constriction of a vendor's buyers' market plainly inflict[] an injury in fact." *Id.* at 211 (alterations and internal quotation marks omitted) (citing *Craig v. Boren*, 429 U.S. 190, 194 (1976)). The Ban and Restrictions "severely constricted the market for mifepristone statewide," Compl. ¶¶ 11-12, "mak[ing] it impossible for GenBioPro to promote and market its product in West Virginia as it does in other states," *id.* ¶ 77, and "caus[ing] significant, ongoing economic injury to GenBioPro in the form of lost sales, customers, and revenue," *id.* ¶¶ 78-79. GenBioPro would be able to provide mifepristone to more patients in West Virginia if the Ban did not

prevent Walgreens and CVS, which stated they intend to sell it, and HoneyBee Health, which ships prescription drugs nationwide, from selling it there. *Id.*

GenBioPro is independently injured because it "alleges 'an intention to engage in a course of conduct arguably affected with a constitutional interest, but proscribed by a statute, and there exists a credible threat of prosecution thereunder.'" *Susan B. Anthony*, 573 U.S. at 159 (quoting *Babbitt v. United Farm Workers Nat'l Union*, 442 U.S. 289, 298 (1979)). The Ban violates the Supremacy Clause, *see infra* pp. 8-22; Compl. ¶¶ 94-99, so GenBioPro's intended sales raise "a constitutional interest." *Susan B. Anthony*, 573 U.S. at 159. The threat of prosecution is "credible." *Id.* Attorney General Patrick Morrisey ("WVAG"), as the State's chief legal officer, has authority to enforce the Ban. *See* W. Va. Code § 5-3-1.[1] He signed a public letter stating his intent to stand by state law restrictions on mifepristone. Compl. ¶ 25 & n.8. The pharmacies through which GenBioPro seeks to provide mifepristone in West Virginia take such threats of state enforcement seriously.[2]

WVAG concedes (at 12-13) that West Virginia restricts sales of mifepristone for its approved indication, but argues the drug may be used off-label and "in the few situations exempt from the [Ban's] general prohibition." *See also* Amicus Brief for State Att'ys Gen. at 4 (Mar. 6, 2023), ECF No. 30 ("Amicus Br.") (arguing GenBioPro can sell the drug "off-label"). Mifepristone is indicated for medication abortion up to 70 days' gestation, without restriction as

[1] Off. of Att'y Gen. of W. Va., *Mission of the Office of the Attorney General* (stating that WVAG is "entrusted with enforcing the laws of the State," including "prosecuting and defending legal actions on behalf of the state"), https://ago.wv.gov/about/Pages/default.aspx (last visited Mar. 17, 2023).

[2] *See* Letter from Danielle Gray, Exec. Vice President, Walgreens, to Kris Kobach, Att'y Gen., Kansas (Feb. 17, 2023) (agreeing not to sell mifepristone in Kansas due to fear of prosecution), https://perma.cc/5C4Y-9XE2; Alice Miranda Ollstein, *Walgreens Won't Distribute Abortion Pills in States Where GOP AGs Object*, Politico (Mar. 2, 2023), https://www.politico.com/news/2023/03/02/walgreens-abortion-pills-00085325; *see also* Sorsaia Opp. 6-8.

to the cause of the patient's pregnancy. *See* Compl. ¶ 58. GenBioPro is therefore injured because, as WVAG does not contest, the State banned it for its FDA-approved indication.

WVAG incorrectly (at 7) casts GenBioPro's intent to provide mifepristone in West Virginia as "conjectural." GenBioPro alleges ongoing and immediate harm: limits on its ability to provide mifepristone for its approved use in West Virginia. GenBioPro *currently* provides the product throughout the United States and would do so in West Virginia if the Ban and Restrictions did not constrict its market. Compl. ¶¶ 3, 11, 74, 79, 110. Prescribers and pharmacies that stock the product in other states will not do so in West Virginia because of the Ban. *Id.* ¶ 78 & n.32; *see also* Sorsaia Opp. 5-6; *supra* p. 4 & n.2. GenBioPro is not required to demonstrate that it *previously* sold mifepristone in West Virginia, and WVAG cites no case supporting his contrary assertion.[3] *See* Mot. 7.

The cases WVAG cites (at 7) are distinguishable because the plaintiffs did not have definite plans to engage in the proscribed conduct and because their injuries were noneconomic. In *Lujan*, the individuals claiming injury had no plans to observe the endangered species in question and conceded that events unrelated to the defendant prevented them from doing so. 504 U.S. at 563-64. In contrast to *Doe v. Obama*, 631 F.3d 157, 162-63 (4th Cir. 2011), holding that parents who were "considering adopting" embryos lacked standing, but for the Ban, GenBioPro would be providing mifepristone in West Virginia, not simply "considering" that step.

B. GenBioPro's Injuries Are Redressable And Comstock Does Not Bar Relief

WVAG does not dispute that GenBioPro's injury is fairly traceable to the Ban, nor could he. "[W]hen a 'challenged provision[ ] . . . inhibits [a vendor's] ability to' conduct its business,

[3] If the Court believes (contrary to precedent) past sales, or any other facts are necessary, it should permit Plaintiff to amend the Complaint to allege them.

'the alleged injury is . . . traceable to the' provision at issue." *Md. Shall Issue*, 971 F.3d at 213 (quoting *Air Evac EMS, Inc. v. Cheatham*, 910 F.3d 751, 760 (4th Cir. 2018)). The Ban constrains GenBioPro from providing its product in West Virginia, limiting its potential customer base and causing it to lose "sales, customers, and revenue." *See* Compl. ¶¶ 77-79.

WVAG argues (at 8, 17, 20) that a favorable decision will not redress GenBioPro's injuries because shipping mifepristone into West Virginia violates the Comstock Act of 1873, which forbids shipping by common carrier "[e]very obscene, lewd, lascivious, indecent, filthy or vile article, matter, thing, device, or substance; and — Every article or thing designed, adapted, or intended for producing abortion, or for any indecent or immoral use." 18 U.S.C. § 1461; *see id.* § 1462. For a century, courts have held that the Comstock Act does not forbid shipping products "employed by conscientious and competent physicians," such as prescription medications. *United States v. One Package*, 86 F.2d 737, 739 (2d Cir. 1936); *see New York v. Sanger*, 118 N.E. 637, 637-38 (N.Y. 1918) (holding that physicians could not be prosecuted for shipping contraception). Rather, it criminalizes shipping black-market, unregulated materials. WVAG cites no authority for his contrary interpretation.

Moreover, the Comstock Act's prohibitions on mailing "obscene, lewd, lascivious, indecent, filthy or vile" devices and substances "intended for producing abortion" are a dead letter that "have never been applied to prosecute the recipients of abortion- and contraception-related materials."[4] Reading them to prohibit shipping mifepristone would be nonsensical after Congress and FDA ratified provision of mifepristone under a REMS. *See* FDAAA § 909(b)(1), 121 Stat. at 950-51 (mifepristone among drugs "deemed to have in effect an approved

[4] Application of the Comstock Act to the Mailing of Prescription Drugs That Can Be Used for Abortions, 46 Op. O.L.C. slip op. at 1-2 n.3 (Dec. 23, 2022), https://www.justice.gov/d9/opinions/attachments/2023/01/03/2022-12-23_-_comstock_act_1.pdf.

[REMS]"). Mifepristone's REMS allows pharmacies to dispense it by mail. U.S. Food & Drug Admin., *Risk Evaluation and Mitigation Strategy (REMS) Single Shared System for Mifepristone 200 mg* at 3 (Jan. 2023) ("2023 REMS Document"); *see Vt. Agency of Nat. Res. v. U.S. ex rel. Stevens*, 529 U.S. 765, 786 n.17 (2000) ("[I]t is well established that a court can, and should, interpret the text of one statute in the light of text of surrounding statutes, even those subsequently enacted.").

WVAG's remaining standing arguments (at 7-8) fail. He argues that redressability hinges on third parties' responses, but the pharmacies through which GenBioPro intends to provide mifepristone would dispense it absent the Ban. Compl. ¶ 78; *see supra* p. 4 & n.2. And WVAG cites no support for the contention that GenBioPro insufficiently alleged it would benefit if the Ban and Restrictions were lifted.

WVAG next argues (at 8) that GenBioPro cannot challenge the waiting period and counseling requirements, W. Va. Code § 16-2I-2, because they are not operative. But those provisions, which restricted GenBioPro's market in West Virginia, remain part of the Code and will go into effect if a court strikes down any part of the Ban. *Id.* § 16-2R-9. WVAG points to *California v. Texas*, but that case involved a toothless law: an Affordable Care Act provision that carried a penalty of $0 and had "no means of enforcement." 141 S. Ct. 2104, 2114 (2021); *see* Mot. 8. Here, GenBioPro's requested relief (enjoining the Ban) will make the waiting period and counseling restrictions operative and enforceable, thereby rendering jurisdiction proper. *See Associated Indem. Corp. v. Fairchild Indus., Inc.*, 961 F.2d 32, 35 (2d Cir. 1992) ("That the liability may be contingent does not necessarily defeat jurisdiction . . . .).

C. GenBioPro Has Third-Party Standing

Alternatively, GenBioPro has third-party standing to challenge the Ban on behalf of the pharmacies and healthcare providers that would prescribe and dispense mifepristone in West

Virginia and are prevented from doing so because they are subject to enforcement. "[A] vendor has a sufficiently close relationship with its customers when a challenged statute prevents that entity from transacting business with them." *Md. Shall Issue*, 971 F.3d. at 216. GenBioPro meets this test for the reasons explained in the Sorsaia Opp. (at 12-14).

II. THE FDAAA PREEMPTS WEST VIRGINIA'S BAN AND RESTRICTIONS

The Supremacy Clause makes the laws of the United States "the supreme Law of the Land." U.S. Const. art. VI, cl. 2. "Federal preemption of state law is the result of that basic structural guarantee." *Air Evac*, 910 F.3d at 761. Field preemption occurs when Congress "mandate[s] federal rules on the subjects or matters there specified, demanding uniformity" and "leaves no room for the States to impose different or stricter . . . requirements." *United States v. Locke*, 529 U.S. 89, 110 (2000). In addition, "it has long been settled that state laws that conflict with federal law are 'without effect,'" *Mut. Pharm. Co. v. Bartlett*, 570 U.S. 472, 479-80 (2013), including when a federal agency "has promulgated its own requirement on the subject or has decided that no such requirement should be imposed at all." *Locke*, 529 U.S. at 110. Finally, federal law preempts state law that "stands as an obstacle to the accomplishment and execution of the full purposes and objectives of Congress." *Geier v. Am. Honda Motor Co.*, 529 U.S. 861, 873 (2000) (internal quotation marks omitted).

Each of these doctrines applies here. First, where FDA determines a REMS is necessary, Congress authorized only FDA to impose restrictions on a patient's access to that drug, and required FDA to balance any restrictions with patients' access to the drug. West Virginia's attempts to impose its own access restrictions encroaches on this field. Second, because FDA imposed certain elements to assure safe use on mifepristone (and declined to impose others), West Virginia's conflicting elements that alter the balance FDA struck are preempted. Finally,

Congress determined that mifepristone should have a REMS, and thus intended patients to have access to it; the Ban and Restrictions obstruct that purpose.

A. Congress Occupied The Field Of Restrictions On Drugs Subject To A REMS

Congress preempted state laws banning or restricting access to drugs regulated by a REMS. Once FDA determines a drug requires a REMS, state attempts to impose additional restrictions on access to the drug encroach impermissibly on the preempted field. Field preemption occurs where Congress has created a "framework of regulation so pervasive that Congress left no room for the States to supplement it." *Arizona v. United States*, 567 U.S. 387, 399 (2012) (alterations and internal quotation marks omitted). Where Congress mandates federal regulation "demanding uniformity," it "leaves no room for the States to impose different" regulations on the same matter. *Locke*, 529 U.S. at 110 (quoting *Ray v. Atl. Richfield Co.*, 435 U.S. 151, 168 (1978)).

The FDAAA created a pervasive framework governing the subset of drugs subject to a REMS, leaving no room for states to supplement. Historically, FDA evaluated only a drug's safety and efficacy before approving it. *See Wyeth v. Levine*, 555 U.S. 555, 574 (2009) ("Congress enacted the FDCA to bolster consumer protection against harmful products."). But Congress enacted the FDAAA to "enhance the postmarket authorities of [FDA] with respect to the safety of drugs." FDAAA pmbl., 121 Stat. at 823. Congress granted FDA "[e]nhanced [a]uthorit[y]" to implement a comprehensive scheme regulating the prescribing, dispensing, packaging, and even disposal of a subset of drugs: those requiring a REMS. *Id.*, tit. IX, 121 Stat. at 922. Only the Secretary of Health and Human Services (or specified "division directors") may determine whether a REMS "is necessary to ensure that the benefits of the drug outweigh the risks of the drug." 21 U.S.C. § 355-1(a)(1), (2), (4). Under the FDAAA, FDA "shall" consider an enumerated list of factors in making that determination. *Id.* § 355-1(a). If

FDA concludes a REMS is necessary, the Secretary "shall" consult with "the office responsible for reviewing the drug and the office responsible for postapproval safety with respect to the drug" in determining whether any "additional elements" are necessary to ensure safe access to the medication. *Id.* § 355-1(c)(2). Any such elements "shall . . . not be unduly burdensome on patient access to the drug, considering in particular [ ] patients with serious or life-threatening . . . conditions." *Id.* § 355-1(f)(2)(C).[5]

Congress thereby authorized FDA to do even more than evaluate safety and efficacy. If FDA determines that a drug requires a REMS, FDA "shall" review and act on a proposed REMS. *Id.* § 355-1(a), (h)(2). The statute authorizes FDA to take additional steps it deems necessary to maintain safety while assuring patient access to the medication, and it requires FDA avoid any requirements that would be "unduly burdensome" to "patient access."[6] Unlike drug approval and label regulation, a REMS governs a drug's approval, prescribing, distribution, dispensing, packaging, accessibility to certain patient groups, and even disposal. *See generally id.* § 355-1.

The comprehensiveness of the REMS regime evinces Congress's intent for FDA alone to control how drugs with REMS move through the market from manufacturer to patient. In 2007,

[5] FDA determined that "[p]regnancy can be a serious medical condition." Letter from Janet Woodcock, Dir., Ctr. for Drug Evaluation & Rsch., U.S. Food & Drug Amin., 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. at 4 (Mar. 29, 2016), https://downloads.regulations.gov/FDA-2002-P-0364-0002/attachment_1.pdf; *see also* Compl. ¶ 39.

[6] Those measures include regulating how manufacturers distribute the drugs, *see* 21 U.S.C. § 355-1(f)(4); who can prescribe them, *id.* § 355-1(f)(3)(A), and to whom, *id.* § 355-1(f)(3)(D); who can dispense them, *id.* § 355-1(f)(3)(B); how the drugs can be packaged and dispensed, *id.* § 355-1(e)(4), (f)(3)(C); what information prescribers must know before dispensing, *id.* § 355-1(e)(3); what information prescribers must convey to patients using the drugs, *see id.* § 355-1(e)(2); and even how patients dispose of the drugs, *see id.* § 355-1(e)(4).

Congress subjected mifepristone to this end-to-end regulation.[7] West Virginia's attempt to regulate mifepristone differently — by banning it, limiting which patients may receive it, and restricting how they access it — encroach on that comprehensive structure. *See Locke*, 529 U.S. at 111 (where statute covered "design, construction, alteration, repair, maintenance, operation, equipping, personnel qualification, and manning of tanker vessels . . . Congress has left no room for state regulation of these matters") (internal quotation marks omitted); *see also Sperry v. Fla. ex rel. Fla. Bar*, 373 U.S. 379, 385 (1963) (state may not "impose upon the performance of activity sanctioned by federal license additional conditions not contemplated by Congress").

WVAG does not seriously contest this issue, stating only (at 11) — without citation or argument — that GenBioPro "cannot show field preemption." WVAG thereby waived any argument that field preemption precludes enforcement of West Virginia's Ban and Restrictions. *See Moseley v. Branker*, 550 F.3d 312, 325 n.7 (4th Cir. 2008) ("As a general rule, arguments not specifically raised and addressed in opening brief . . . are deemed waived.").

B. West Virginia's Ban Conflicts With The Restrictions FDA Imposed

West Virginia's Ban and Restrictions also conflict with the specific restrictions FDA imposed under the FDAAA. Conflict preemption occurs where state law "limit[s] the availability of an option the [federal agency] considered essential to" ensure its objectives. *Fid. Fed. Sav. & Loan Ass'n v. de la Cuesta*, 458 U.S. 141, 156 (1982). In such circumstances,

[7] In the FDAAA, Congress determined that any "drug that was approved before the effective date of this Act" where FDA had imposed "elements to assure safe use" would be "deemed to have in effect an approved" REMS. FDAAA § 909(b)(1), 121 Stat. at 950-51; 21 U.S.C. § 355-1. When FDA approved branded mifepristone in 2000, it did so with several elements to assure safe use. Compl. ¶¶ 36-39. FDA had approved only 15 other drugs with elements to assure safe use by 2007. *Id.* ¶ 37 & n.10; *see also* 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) (identifying the 16 drugs that FDA noted that Congress determined would have a REMS).

"States are not permitted to use their police power to enact such a regulation." *Locke*, 529 U.S. at 110. Moreover, "[w]hen federal law forbids an action that state law requires, the state law is 'without effect.'" *Bartlett*, 570 U.S. at 486 (quoting *Maryland v. Louisiana*, 451 U.S. 725, 746 (1981)).

Where FDA determines a REMS is necessary, Congress authorized only the Secretary to require additional elements to assure safe use, specifying the factors FDA may consider. 21 U.S.C. § 355-1(f). Elements may not be "unduly burdensome on patient access," particularly considering patients with serious conditions, including pregnancy, *supra* pp. 9-10 & n.5, and must "minimize the burden on the health care delivery system." 21 U.S.C. §§ 355-1(f)(2), (5). FDA "shall" consult with "patients, physicians, pharmacists, and other health care providers" to ensure these factors are met. *Id.* § 355-1(f)(5). Mifepristone's REMS specifies how patients may receive the drug: through certified pharmacies and prescribers. *See generally* 2023 REMS Document. FDA did not limit mifepristone's dispensing or prescribing to certain patients (beyond those for whom the drug is contraindicated, as specified on its label) or require patients to prove their pregnancy was the result of sexual assault or incest.[8] *Cf.* 21 U.S.C. § 355-1(f)(3)(D) (permitting FDA to restrict dispensing to certain patients).

[8] FDA has included similar requirements in other REMS. For example, FDA prohibits pregnant people from taking isotretinoin, a medication that treats severe acne. U.S. Food & Drug Admin., *Risk Evaluation and Mitigation Strategy (REMS) Isotretinoin (iPLEDGE®) Shared System REMS Program* at 1-2 (Oct. 2022) ("Isotretinoin REMS Document"), https://www.accessdata.fda.gov/drugsatfda_docs/rems/Isotretinoin_2022_10_6_REMS_Full.pdf; Compl. ¶ 35. Before a patient who can get pregnant may take the drug, FDA requires that a healthcare provider "order[ ] and confirm[ ]" a "negative pregnancy test result," and "[d]ocument and submit the result to the REMS program." Isotretinoin REMS Document at 1. Prior to obtaining a prescription for a single month's supply, such a patient must correctly answer several "comprehension questions" about the drug and pledge to use two kinds of birth control while taking it for the next month. *See id.* at 2-3, 26, 69-82 (detailing possible questions).

The challenged statutes unlawfully alter the balance FDA struck and conflict with FDA's elements to assure safe use. West Virginia prohibits "perform[ing]," induc[ing]" or "attempt[ing]" to perform or induce an abortion, unless the pregnancy is within eight weeks' gestation and results from sexual assault or incest that was reported to law enforcement at least 48 hours before the procedure. W. Va. Code § 16-2R-3(b). It imposes a waiting period and mandatory counseling session, requiring healthcare providers to tell patients information that is different from (and in some cases, contradicts) the information in the Patient Agreement Form incorporated into the REMS, *see id.* § 16-2I-2; Compl. ¶ 87.[9] And it prohibits providers from prescribing mifepristone via telemedicine, W. Va. Code §§ 30-3-13a(g)(5), 30-1-26(b)(9), which FDA explicitly declined to include in the REMS. Compl. ¶ 88.

The Ban and Restrictions thus restrict patients' access to mifepristone and burden the healthcare delivery system, conflicting with Congress's determination in section 355-1 that only FDA may do so for REMS drugs. Where FDA determined that a restriction should govern how patients access a REMS drug with elements to assure safe use, it precludes contrary state restrictions. *Cf. Locke*, 529 U.S. at 110 (Congress in Title II of the Ports and Waterways Safety Act of 1972 "mandated federal rules on the subjects or matters there specified, demanding uniformity," leaving "no room for the States to impose different or stricter design requirements than those which Congress has enacted."). States' restrictions on access to REMS drugs "frustrate the congressional desire of achieving uniform" standards regulating access to these drugs. *Ray*, 435 U.S. at 168.

[9] The Patient Agreement Form in the REMS specifies that patients understand they will take both "mifepristone and misoprostol to end [their] pregnancy." Compl. ¶ 67; 2023 REMS Document at 10. In contrast, West Virginia requires healthcare providers to inform patients that "it may be possible to counteract the intended effects of . . . mifepristone . . . before taking" misoprostol." W. Va. Code § 16-2I-2(a)(4)(A).

C. The Ban And Restrictions Interfere With Congress's Purpose

When Congress enacted the FDAAA, it determined that 16 drugs FDA had approved with elements to assure safe use should continue to be available under 21 U.S.C. § 355-1. *See supra* p. 10 & n.7. Only FDA may restrict access to those drugs. It can impose only elements to assure safe use that do not unduly burden patient access. State bans or restrictions must give way where they present an "unacceptable obstacle to the accomplishment and execution of the full purposes and objectives of Congress," *Wyeth*, 555 U.S. at 563-64 (internal quotation marks omitted), by "upset[ting] the careful balance struck by Congress" when it enacted a scheme of federal regulation. *Edgar v. MITE Corp.*, 457 U.S. 624, 634 (1982). Banning access to a drug Congress earmarked for "access" frustrates Congress's purpose in doing so.

D. WVAG Fails To Show GenBioPro Has Not Stated A Preemption Claim

WVAG (at 10-11, 17) argues that States' historic police powers are not superseded absent the clear intent of Congress. But "an 'assumption' of nonpre-emption is not triggered when the State regulates in an area where there has been a history of significant federal presence." *Locke*, 529 U.S. at 108. Congress has long regulated drugs under a national system of approval and labeling, preserving only state regulation that did not pose a "direct and positive conflict" with the federal regime. *Wyeth*, 555 U.S. at 567-68 (explaining history of federal drug regulation); *see also Sorrell v. IMS Health Inc.*, 564 U.S. 552, 586 (2011) (Breyer, J., dissenting) ("The pharmaceutical drug industry has been heavily regulated" by federal statute "at least since 1906," resulting in "a traditional, comprehensive regulatory regime.").

1. WVAG Miscasts The Case As One About Regulating Abortion

West Virginia cannot cloak its impermissible regulation of a REMS drug by calling it a ban on abortion. Preemption is concerned with a law's "practical impact," not the "description or characterization given it by the [State] legislature." *Hughes v. Oklahoma*, 441 U.S. 322, 336

(1979) (internal quotation marks omitted). Otherwise, "state legislatures" could "nullify nearly all unwanted federal legislation by simply publishing a legislative committee report articulating some state interest or policy — other than frustration of the federal objective — that would be tangentially furthered by the proposed state law." *Perez v. Campbell*, 402 U.S. 637, 652 (1971).

It is irrelevant whether, as Amici claim (at 6-7), West Virginia's Ban has a different "purpose" in restricting access to mifepristone from Congress's purpose in making mifepristone available to patients under the REMS. "Whatever the purpose or purposes of the state law, pre-emption analysis cannot ignore the effect of the challenged state action on the pre-empted field." *Gade v. Nat'l Solid Wastes Mgmt. Ass'n*, 505 U.S. 88, 107 (1992); *see also Bartlett*, 570 U.S. at 480 ("[A]ny state law, however clearly within a State's acknowledged powers, which interferes with or is contrary to federal law, must yield."). Amici cite *Oneok, Inc. v. Learjet, Inc.*, 575 U.S. 383 (2015) (at 7), but that case does not support a conflict preemption argument. It concerned field preemption, and the Court contrasted conflict preemption cases in its analysis. 575 U.S. at 388-89. Moreover, *Oneok* concerned the field preempted by the Natural Gas Act, where the Court observed there was no "clear division between areas of state and federal authority." *Id.* at 388. By contrast, the Ban directly conflicts with, and encroaches on the field of, Congress's determination about how mifepristone must be regulated and FDA's regulation of the drug.

WVAG cannot save the Ban by noting that mifepristone can still be used off-label. Mot. 12-13; Amicus Br. 4. West Virginia bans mifepristone for its indicated use — medication abortion — in nearly all circumstances. *See supra* p. 4. WVAG's theory invites the very Supremacy Clause clash the Framers resolved in favor of federal law. Congress gave states no role in determining whether a drug requires a REMS — that is FDA's job. States may object to a REMS, *see* 21 C.F.R. § 10.30, but may not ban a REMS drug for its approved indication. Once a

REMS is in effect, a state may not add to or subtract from the requirements FDA imposed. GenBioPro's drug is approved only for medication abortion, and is subject to a REMS. Korlym, to which WVAG refers (at 18), is a different drug not subject to a REMS.[10]

Amici's discussion (at 4-6) of *Virginia Uranium, Inc. v. Warren*, 139 S. Ct. 1894 (2019), is inapt. There, federal law did not regulate uranium mining, only milling. Here, by contrast, the FDAAA establishes a regime regulating mifepristone at all stages — prescribing, distribution, and provision of the drug to patients by prescribers and pharmacies. *See supra* p. 10 & n.7. These are the very activities with which West Virginia's Ban interferes, limiting when mifepristone may be prescribed, how it may be dispensed, and whether it may be received via a certified pharmacy. *See supra* pp. 12-13. There is nothing "downstream" about the prescribing of mifepristone — that is precisely what Congress has reserved to FDA. *See supra* p. 10 & n.7 (listing statutory provisions governing prescribing and dispensing of mifepristone).

2. WVAG Misapprehends The Relevant Congressional Purpose

WVAG misses the point in arguing (at 5, 12-13) that West Virginia's Ban does not conflict with FDA's determinations about "safety" and "efficacy." Unlike the FDCA's approval provisions (on which WVAG erroneously relies (at 13)), the FDAAA expressly includes "patient access" among FDA's concerns. *See* 21 U.S.C. § 355-1(f)(2) (entitled "Assuring access and minimizing burden"). Congress reiterated this priority throughout the statute. *See id.* §§ 355-1(f) ("Providing safe access for patients to drugs . . . ."), 355-1(f)(1) ("Allowing safe access to

[10] *See* U.S. Dep't of Health & Hum. Servs., Approved Drug Products with Therapeutic Equivalence Evaluations § 1.2, at vii (43d ed. 2023) (defining "[p]harmaceutical equivalents" as drugs "in identical dosage forms . . . that contain identical amounts of the identical active drug ingredient), https://www.fda.gov/media/71474/download; Letter from Mary H. Parks, Dir., Div. of Metabolism & Endocrinology Prods., to Luana Staiger, Regulatory Affairs, Corcept Therapeutics at 4 (Feb. 17, 2012) ("Korlym Approval Letter") (approving Korlym and determining that "a REMS is not necessary" for the drug), https://www.accessdata.fda.gov/drugsatfda_docs/appletter/2012/202107s000ltr.pdf.

drugs"), 355-1(f)(2)(C) (requiring restrictions to "not be unduly burdensome on patient access to the drug"). States cannot interfere with the congressional judgment to provide access to healthcare.

WVAG and Amici rely on inapposite hypotheticals. They do not (and cannot) point to any drug FDA approved for "euthanasia," much less with a REMS subject to the strictures of section 355-1. Mot. 13; Amicus Br. 17-18. FDA does not approve drugs with an indication for "assisted suicide" or lethal injection. *See* Whether the Food and Drug Administration Has Jurisdiction over Articles Intended for Use in Lawful Executions, 43 Op. O.L.C. slip op. at 1-2 (May 3, 2019) (FDA does not regulate drugs used in executions), https://www.justice.gov/d9/opinions/attachments/2019/05/14/2019-05-03-fda-juris-exec_2.pdf. Any analogy would have to begin with a drug as to which Congress mandated access and that is subject to a REMS with elements to assure safe use. WVAG has cited none.

3. WVAG Misapplies The Supreme Court's Preemption Case Law

WVAG's reliance on cases recognizing Congress's preservation of state law remedies is misplaced. *See also* Amicus Br. 11-14 (arguing the REMS provides a "floor" on which States may layer additional restrictions). In *Wyeth*, the Supreme Court held that the FDCA preserved state tort remedies, in which the breach of the state law duty paralleled federal misbranding standards. 555 U.S. at 572-73. A state *ban* is entirely different in this context because FDA imposed a REMS precisely to ensure safe *access* to the medication.[11] Postmarket regulation of

[11] Although "state tort and contract law long have supplied the *remedy* for anyone injured by food or medical products . . . the *prevention* of injury through safety, efficacy, and marketing regulations has a substantial history of federal power." Elizabeth Y. McCuskey, *Body of Preemption: Health Law Traditions and the Presumption Against Preemption*, 89 Temp. L. Rev. 95, 131 (2016); *id.* at 135 (noting that "[r]egulation of medical products is thus heavily and historically federal, with an enormous, specially-devoted federal agency").

FDA-approved medication has long been federal, *see id.* at 567-68, not a matter of "historically local concern." Mot. 15.

With a single exception, no state has tried to ban a drug subject to a REMS, and that attempt was rejected. *See Zogenix, Inc. v. Patrick*, 2014 WL 1454696 (D. Mass. Apr. 15, 2014). WVAG's attempt to distinguish *Zogenix* (at 13 n.11) fails. He argues that West Virginia does not ban mifepristone, but does not dispute that the State bans mifepristone for its indicated use in almost all circumstances, which is functionally the same thing. WVAG cites no court upholding a state ban of an FDA-approved drug under any provision in the modern era of drug regulation.

WVAG (at 16) "place[s] more weight on the [FDCA's] savings clause than those provisions can bear, either from a textual standpoint or from a consideration of the whole federal regulatory scheme." *Locke*, 529 U.S. at 105. As in *Locke*, the statute preserves states' historic "important role" in providing parallel state law remedies to protect consumers, but does not "upset the settled division of authority by allowing States to impose additional" bans or restrictions on drugs Congress and FDA have included under section 355-1. *Id.* at 106; *see also Wyeth*, 555 U.S. at 567 (FDCA saving clause permits "state common-law suits").

Congress's limitations on the restrictions *FDA* can impose under section 355-1(f) does not help WVAG's position. Congress nowhere indicated its intent to allow 50 different state "ceilings." Instead, it asserted a federal interest in establishing the balance between safety and access for drugs subject to a REMS. Where Congress intended to allow states to ban a product notwithstanding a federal regulatory regime, it made this ability explicit. *See*, *e.g.*, *Bates v. Dow Agrosciences LLC*, 544 U.S. 431, 439, 446 (2005) (the Federal Insecticide, Fungicide, and Rodenticide Act permitted states to "ban the sale of a pesticide" as a result of language allowing states to "regulate the sale or use of any federally registered pesticide or device in the State").

The REMS' incorporation of state law for some purposes, *see* Mot. 16-17, demonstrates FDA's deliberate rejection of the kinds of restrictions advanced by West Virginia and, in any event, does not address whether Congress intended states to be able to impose directly their own restrictions on drugs regulated under section 355-1. The statutory text answers that question against state interference. *See supra* pp. 9-10.

Finally, it is no answer to say (at 11) that GenBioPro is not required to sell mifepristone. A "stop-selling rationale" is "incompatible" with the Supreme Court's FDA "pre-emption jurisprudence." *Bartlett*, 570 U.S. at 488.

E. *Dobbs* Does Not Alter The Preemption Analysis

WVAG (at 9-10) and Amici (at 6-7) erroneously rely on *Dobbs v. Jackson Women's Health Organization*, 142 S. Ct. 2228 (2022). There, the Court overruled *Roe v. Wade*, 410 U.S. 113 (1973), and *Planned Parenthood of Southeastern Pennsylvania v. Casey*, 505 U.S. 833 (1992), and "return[ed] the issue of abortion to the people's elected representatives," which include Congress. *Dobbs*, 142 S. Ct. at 2243. The Court did not address whether Congress and FDA's regulation of mifepristone under a REMS with elements to assure safe use preempts state bans on patients' access to the drug, as WVAG admits (at 15). Instead, it held that matters relating to abortion are subject to the normal political processes, *see Dobbs*, 142 S. Ct. at 2243, and to established legal rules, *see id.* at 2276 (overruling *Roe* and *Casey* because, *inter alia*, their holdings "require[d] courts to engineer exceptions to longstanding background rules" such as res judicata and First Amendment doctrines). Among those processes is Congress's decision to regulate access to certain drugs at the national level.

F. The Major Questions Doctrine Is Inapplicable

WVAG argues (at 8-9) that Congress did not grant FDA authority to "set national abortion policy." GenBioPro's Complaint does not concern "abortion policy," but Congress's

decision to establish uniform national regulation of federally approved medications, including mifepristone, for their indicated uses. In the case of mifepristone, the indicated use is medication abortion up to 70 days' gestation. Compl. ¶¶ 76, 89. Congress mandated that only FDA may determine whether to continue to subject mifepristone to a REMS and to impose elements to assure patients' safe use and access to the drug. 21 U.S.C. § 355-1(f).

1. The FDAAA Subjects Medication Abortion To The REMS Regime

WVAG's assertion (at 9) that the FDCA does not "mention abortion" — a predicate for his "major questions" argument — fails because Congress specifically addressed mifepristone in the FDAAA. Congress deemed that the 16 drugs with elements to assure safe use would have a REMS, mifepristone among them. FDAAA § 909(b)(1), 121 Stat. at 950-51. Mifepristone is indicated *only* for abortion.[12] By including mifepristone in the group of drugs it deemed to have a REMS, Congress addressed medication abortion.

The history of Congress's consideration of mifepristone bears out this conclusion. Before FDA approved mifepristone, Congress debated and rejected amendments to appropriations bills in 1998, 1999, and 2000 prohibiting FDA from using funds to test or approve any drug for medication abortion.[13] After FDA approved mifepristone, Congress continued to

[12] In fact, when Congress passed the FDAAA, the only FDA-approved mifepristone-based drug was branded mifepristone. FDA did not approve Korlym — the drug Amici incorrectly claim is also mifepristone — until 2012. *See* Korlym Approval Letter at 4.

[13] The proposed amendments provided that "[n]one of the funds made available in this Act may be used by the Food and Drug Administration for the testing, development, or approval (including approval of production, manufacturing, or distribution) of any drug for the chemical inducement of abortion." 144 Cong. Rec. H5089-100 (daily ed. June 24, 1998); 145 Cong. Rec. H3798-812 (daily ed. June 8, 1999); 146 Cong. Rec. H5693-709 (daily ed. July 10, 2000). Their sponsor, Senator Tom Coburn, urged: "[t]here is something terribly wrong when we ask the taxpayers of this country to spend money in a way which is designed to give the Food and Drug Administration the ability to research and approve drugs that are designed to kill unborn children." 145 Cong. Rec. at H3798 (statement of Sen. Coburn). Congress did not enact these provisions, and it ultimately included mifepristone in the FDAAA.

debate the issue before enacting the FDAAA. *See*, *e.g.*, 153 Cong. Rec. S5469-70 (daily ed. May 2, 2007) (statement of Sen. Jim DeMint) (urging greater restrictions on mifepristone).

Congress declared that the drugs in question would be deemed to have in effect a REMS with elements to assure safe use. FDAAA § 909(b)(1), 121 Stat. at 950-51. It did not delegate this determination to the agency in the first instance, but required FDA to evaluate and review the REMS going forward to ensure it did not unduly burden patient access or the healthcare system. *See* 21 U.S.C. § 355-1(f). Where Congress considered the issue and reached a statutory resolution from which it has not deviated, the major questions doctrine is not implicated.

2. Cases In Which Congress Rejected Agency Action Are Inapposite

The Supreme Court's decision in *West Virginia v. EPA*, 142 S. Ct. 2587 (2022), supports GenBioPro's position. There, the U.S. Environmental Protection Agency ("EPA") used its general Clean Air Act authority over pollution emissions to require coal-burning plants to reduce production of electricity and promote alternative forms of generation. The Court held that the agency's decision wrongly sought to derive authority from an ancillary provision of a statute designed to be a "gap filler" and was contrary to the statute's text, thereby constituting a "major question[]" that Congress had never left to EPA's discretion. *Id.* at 2610. The Court stressed that: EPA's novel interpretation was different from any authority it had exercised before; EPA claimed to find "newfound power" in a mere "ancillary provision" of the Clean Air Act, which had "rarely been used in the preceding decades," and never for that purpose; and EPA was exercising authority Congress had *refused* to grant it on at least four prior occasions. *Id.* at 2610-14 (Congress had "conspicuously and repeatedly declined to enact" similar plans). Congress also had not made that "major policy decision[] itself." *Id.* at 2609.

This case presents the opposite scenario. Congress gave FDA authority to weigh the benefits and burdens of imposing barriers to accessing particular medications. Since 2007, when

Congress included mifepristone among the drugs on which only FDA can impose restrictions, and *itself* deemed that group of drugs to have a REMS, FDA has continuously and conspicuously exercised this authority to regulate mifepristone. For the same reason, the case is unlike *Utility Air Regulatory Group v. EPA*, 573 U.S. 302, 324 (2014), where the agency sought expanded power without congressional authorization. Congress has not impeded FDA's determination of how to strike the balance, overruled it, or removed FDA's power to regulate access to medication abortion, and has regularly discussed and reviewed FDA's actions.[14]

FDA v. Brown & Williamson Tobacco Corp., 529 U.S. 120, 127 (2000), also is unlike this case. The Court there considered FDA's claim of authority to regulate cigarettes as "drug delivery devices." *See* Mot. 10. The Court stressed "Congress'[s] clear intent as expressed" in many other statutes to regulate, but not "remove [cigarettes] from the market." 529 U.S. at 143. It recounted the many times Congress refused to extend the FDCA to include regulation of tobacco products. *Id.* at 142-56. By contrast, since 2007 FDA has exercised authority Congress granted it to ensure patients' safe access to mifepristone. Congress repeatedly considered whether FDA should regulate a drug indicated only for medication abortion, but refused to remove that authority. *See supra* p. 20 n.13. Unlike in *Brown & Williamson*, where the agency used "vague language" of a "long-extant" statute that had "rarely been used" (*EPA*, 142 S. Ct. at 2610) to assert *new* authority in an area where it had previously denied regulatory competence, here FDA has consistently regulated access to mifepristone since Congress enacted the FDAAA.

[14] Members of Congress have proposed bills aimed at reversing FDA decisions about mifepristone by: adding additional consent provisions not adopted by FDA, H.R. 2010, 116th Cong. (2019); requiring patients be informed about possibility of reversing effects of mifepristone, H.R. 552, 117th Cong. (2021); banning mifepristone's provision through telehealth, H.R. 4935, 116th Cong. (2019), S. 3252, 116th Cong. (2020), H.R. 5136, 117th Cong. (2021), H.R. 626, 117th Cong. (2021); and exempting mifepristone from appropriations for telemedicine, H.R. 2112, 112th Cong. (2011) (amend. 463). None were enacted.

III. THE BAN AND RESTRICTIONS VIOLATE THE COMMERCE CLAUSE

The Commerce Clause grants Congress the power to regulate commerce "among the several States," U.S. Const. art. I, § 8, cl. 3, "limit[ing] the power of the States to erect barriers against interstate trade," *Dennis v. Higgins*, 498 U.S. 439, 446 (1991). The Framers sought "to prevent States from engaging in economic discrimination so they would not divide into isolated, separable units." *South Dakota v. Wayfair, Inc.*, 138 S. Ct. 2080, 2093-94 (2018). The Ban and Restrictions violate the Clause by imposing an undue burden on interstate commerce, by regulating extraterritorially, and by functionally banning an article of commerce. *See* Compl. ¶¶ 17, 104, 106-110. WVAG addresses only the first allegation (at 17-19), forfeiting any objections to GenBioPro's remaining arguments. *See Hannah v. Mullins Fam. Funeral Home, LLC*, 2022 WL 194413, at *6 (S.D.W. Va. Jan. 20, 2022) (arguments "not asserted in the defendant['s] opening memorandum" are "waived").

A. The Ban And Restrictions Unduly Burden Interstate Commerce

The Commerce Clause "confer[s] a 'right' to engage in interstate trade free from restrictive state regulation." *Dennis*, 498 U.S. at 448. West Virginia's Ban and Restrictions abridge that right by preventing GenBioPro from developing a market for its product in the State and depriving residents of access to a safe, FDA-approved medication available to other Americans. *See* Compl. ¶¶ 17, 107, 110. A state law violates the Commerce Clause when the "burden imposed on [interstate] commerce is clearly excessive in relation to the putative local benefits." *Pike v. Bruce Church, Inc.*, 397 U.S. 137, 142 (1970). When a statute serves a legitimate local interest, courts balance that interest against the interference with interstate commerce — including, but not limited to, the burden a statute creates by regulating "in an area where there is a

compelling need for national uniformity" in regulation. *Yamaha Motor Corp., U.S.A. v. Jim's Motorcycle, Inc.*, 401 F.3d 560, 572 (4th Cir. 2005).

A statute may violate the Clause under *Pike*'s balancing test when it "adversely affect[s] interstate commerce by subjecting activities to inconsistent regulations." *CTS Corp. v. Dynamics Corp.*, 481 U.S. 69, 88 (1987). The Supreme Court has "invalidated state laws under the dormant Commerce Clause . . . where such laws undermined a compelling need for national uniformity in regulation." *Gen. Motors Corp. v. Tracy*, 519 U.S. 278, 298 n.12 (1997); *see*, *e.g.*, *Bibb v. Navajo Freight Lines, Inc.*, 359 U.S. 520, 527-28 (1959) (despite state's significant interest in highway safety, state law governing mudflap length unduly burdened interstate commerce in area requiring national uniformity).

West Virginia's Ban and Restrictions regulate in an area requiring national uniformity and place an excessive burden on interstate commerce in relation to their local benefits.[15] Compl. ¶¶ 104-110. Congress authorized FDA alone to develop a uniform national system of regulation for medications it determined to require a REMS. *See supra* pp. 19-20. In implementing a REMS, FDA must balance safety and access concerns in a way that leaves no room for regulatory interference from states. *See* Compl. ¶ 17.

WVAG (at 18) argues the Ban targets a litany of "legitimate state interests," without explaining how they apply to medication abortion. The only interest the statute

[15] WVAG argues (at 20) that the dormant Commerce Clause cannot apply here because Congress has already regulated abortion-inducing medications like mifepristone via the Comstock Act. But as discussed *supra* pp. 5-7, that argument fails because the Comstock Act does not apply to prescription medications like mifepristone.

identifies, "protecting unborn lives," W. Va. Code § 16-2R-1,[16] must be weighed against the burden on West Virginians' right to access lifesaving, safe, and necessary healthcare — access that Congress prioritized in section 355-1(f). "[S]imply . . . invoking [a] legitimate state interest" does not end the inquiry. *Am. Librs. Ass'n v. Pataki*, 969 F. Supp. 160, 178 (S.D.N.Y. 1997); *Hunt v. Wash. State Apple Advert. Comm'n*, 432 U.S. 333, 350 (1977) ("[A] finding that state legislation furthers matters of legitimate local concern, even in the health and consumer protection areas, does not end the inquiry.").

This interest, which results in forcing West Virginians to carry unwanted pregnancies until their lives are at risk, cannot overcome the burden on the national interest in access to effective medication and uniform pharmaceutical commerce. *See* Compl. ¶¶ 17, 108-110. Instead of all Americans benefiting from pharmaceutical ingenuity, West Virginia's approach forces companies to develop products based on which states they view as friendly markets. If manufacturers making drugs requiring a REMS face the prospect of 50 states overriding the federal rules governing access to their product, manufacturers will face increased regulatory costs and unresolvable complexity with deleterious effects throughout the national healthcare delivery system and the pharmaceutical market. *See id.* ¶ 17.

WVAG argues (at 18) that this Court must give "due deference" to the state legislature's analysis of the benefits and burdens of its legislation. But the Court cannot disregard the national interest in affording Americans access to safe and reliable drugs,

[16] *See Harper v. Pub. Serv. Comm'n*, 427 F. Supp. 2d 707, 713 (S.D.W. Va. 2006) (expressing skepticism about purported local benefits not "set forth in the statutory scheme"); *see also Chambers Med. Techs. of S.C., Inc. v. Bryant*, 52 F.3d 1252, 1259 (4th Cir. 1995) (courts should look to legislative statement of purpose in statutes to determine laws' local benefit).

no matter the State where they live, nor Congress's intent that FDA alone regulate, and impose restrictions on, REMS drugs. As WVAG acknowledges (at 18), "[t]he healthcare market is infamously complicated." *Colon Health Ctrs. of Am., LLC v. Hazel*, 813 F.3d 145, 159 (4th Cir. 2016). That is why drug regulation requires uniform federal regulation to be workable. *See* Compl. ¶¶ 106, 108-109. Congress did not impose national regulation on the hospital certificate of need laws at issue in *Colon Health*, but it did so for REMS drugs. West Virginia's Ban keeps patients from accessing FDA-approved, effective medication and burdens the national healthcare system,[17] creating the "economic Balkanization" that the Framers ratified the Commerce Clause to prevent. *Hughes*, 441 U.S. at 325-26; *see* Compl. ¶¶ 104, 110.

B. The Ban And Restrictions Violate The Clause's Prohibition On States Regulating Extraterritorially And Banning An Article Of Commerce

WVAG does not address GenBioPro's allegations that the Ban and Restrictions have the "practical effect" of regulating extraterritorially and that the laws functionally ban an article of commerce — something states cannot do.[18] Compl. ¶ 104; *see id.* ¶ 17. WVAG forfeited the argument that these allegations do not state Commerce Clause claims. A "critical inquiry" under the Commerce Clause is "whether the practical effect of the regulation is to control conduct beyond the boundaries of the State," which "must be evaluated . . . by considering . . . what effect would arise if not one, but many or every, State adopted similar legislation." *Healy v. Beer Inst., Inc.*, 491 U.S. 324, 336 (1989); *see* Compl. ¶ 104. If many states followed West

[17] Patients who wait until their lives are at risk to terminate a pregnancy are more likely to suffer complications that require hospital care. *See* Andrea MacDonald et al., *The Challenge of Emergency Abortion Care Following the* Dobbs *Ruling*, 328 JAMA 1691, 1691 (2022).

[18] While WVAG quotes (at 19) part of the Complaint's allegations about banning an article of commerce, he does so only in a paragraph arguing that West Virginia's statutes "do not impose a significant burden on interstate commerce" — a *Pike* undue burden argument.

Virginia, the interstate market for medications would be eviscerated by a patchwork of "inconsistent legislation." *Healy*, 491 U.S. at 337; *see* Compl. ¶ 106.

Under the Commerce Clause, "a lawful article of commerce cannot be wholly excluded from importation into a state from another state where it was manufactured or grown." *Schollenberger v. Pennsylvania*, 171 U.S. 1, 12 (1898). West Virginia's Ban does just that. Compl. ¶¶ 17, 104. Medication abortion is the *only* FDA-approved indication for GenBioPro's product. *See supra* pp. 4-5. While the Ban formally allows mifepristone to terminate a pregnancy in some situations, Compl. ¶ 69 & n.26, those situations are so rare as to be functionally nonexistent. Patients seeking to take mifepristone to terminate a pregnancy resulting from rape or incest must report their trauma to law enforcement and then wait two days before taking mifepristone (while still being within the 8-week window West Virginia purports to establish).[19] *Id.* WVAG cannot show at the pleading stage that the State's medical emergency exception will materially ameliorate the State's interference with interstate commerce. The Ban is, as Prosecuting Attorney Sorsaia acknowledges (at 4-6), a ban. Under the Commerce Clause, it is unconstitutional.

CONCLUSION

For these reasons, the Court should deny WVAG's Motion to Dismiss in its entirety. Alternatively, Plaintiff respectfully requests leave to amend should the Court find any deficiencies in the sufficiency of its Complaint.

[19] Most people do not know they are pregnant until around five and a half weeks, and one in three learn that they are pregnant after six weeks. Univ. of Cal. S.F., *One in Three People Learn They're Pregnant Past Six Weeks' Gestation* (Nov. 10, 2021), https://www.ansirh.org/research/research/one-three-people-learn-theyre-pregnant-past-six-weeks-gestation; Amy M. Branum & Katherine A. Ahrens, *Trends in Timing of Pregnancy Awareness Among US Women*, 21 Maternal Child Health J. 715, 715-26 (Apr. 2017), https://www.ncbi.nlm.nih.gov/pmc/articles/PMC5269518/pdf/nihms842105.pdf.

Dated: March 17, 2023

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

GENBIOPRO, INC.,

***Plaintiff*,**

v.

MARK A. SORSAIA*, 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)

CERTIFICATE OF SERVICE

I, the undersigned, counsel for Plaintiff, GenBioPro, Inc., do hereby certify that on March 17, 2023, I electronically filed and served the foregoing **PLAINTIFF'S OPPOSITION TO DEFENDANT PATRICK MORRISEY'S MOTION TO DISMISS** with the Clerk of the Court and all parties using the CM/ECF system.

Respectfully submitted,

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