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

GENBIOPRO, INC.,

Plaintiff,

v. **Civil Action No. 3:23-cv-00058**

MARK A. SORSAIA, in his official capacity, AND PATRICK MORRISEY, in his official capacity, **Hon. Robert C. Chambers**

Defendants.

MEMORANDUM IN SUPPORT OF MOTION TO DISMISS

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INTRODUCTION

Plaintiff GenBioPro, a pharmaceutical company that manufacturers the chemical abortion drug mifepristone,[1] makes the sweeping claim that the Food and Drug Administration's ("FDA") approval of the drug and its imposition of additional safety requirements somehow preempts any state law that results in some impact on the drug's use or sale, including every state law regulating abortion, and that any such law is invalid under the dormant Commerce Clause. GenBioPro's ("GBP") claims turn on the peculiar argument that Congress gave a federal agency the power to mandate nationwide abortion access vis-à-vis an administrative review process focused on patient safety and effectiveness as well as an obscure and rarely used provision in the Federal Food Drug and Cosmetic Act ("FDCA"). To be clear, nothing in the text of the FDCA suggests that Congress authorized FDA to exercise such extraordinary power to displace states in addressing matters of health care practice and prescriptive authority, let alone over the social and political issue that is abortion. Also, it more than strains belief to suggest that the U.S. Supreme Court in *Dobbs* failed to recognize the FDCA's alleged import when it held that the people of the states may enact laws protecting unborn life "at every stage of development." *Dobbs v. Jackson Women's Health Org.*, 142 S. Ct. 2228, 2284 (2022). In reality, FDA has long existed as gatekeeper setting a federal floor on which complementary state legislation may build. This Court should dismiss this lawsuit.

FACTS

A. The Federal Food, Drug, and Cosmetic Act

In 1906, Congress passed the Federal Food and Drugs Act to "supplement[]" "state regulation" of adulterated and misbranded drugs. *Wyeth v. Levine*, 555 U.S. 555, 566 (2009). In 1938, Congress enacted the FDCA which, as amended, requires a manufacturer to show its drug

[1] The Complaint states that GenBioPro also manufactures misoprostol, which is the second drug in a 2-drug series with mifepristone used to cause a chemical abortion.

is "safe for use under the conditions prescribed, recommended, or suggested in the proposed labeling before it [can] distribute the drug." *Id.* at 567 (cleaned up). Through many iterations and amendments to the FDCA, "Congress took care to preserve" parallel state laws protecting the public health. *Id.* The 1962 amendments, in particular, included an express saving clause, providing that "a provision of state law would only be invalidated upon a 'direct and positive conflict' with the FDCA." *Id.*

In 2007, Congress amended the FDCA to subject medications that present "serious safety concerns" to additional restrictions. Pub. L. No. 110-85, 121 Stat. 823 (2007). That amendment directed FDA to adopt a new "drug safety program," known as the "Risk Evaluation and Mitigation Strategy" (REMS), when necessary to ensure a drug's benefits outweigh its risks. 21 U.S.C. § 355-1. And for "drugs with known serious risks," that are "associated with a serious adverse" experience, the REMS must include "elements to assure safe usage" ("ETASUs"). *Id.* § 355-1(e)-(f). Because of serious safety concerns and documented adverse experiences, FDA established both REMS and ETASUs for mifepristone. Compl. ¶ 54, ECF No. 1 (only 97 of more than 20,000 FDA-approved prescription drugs were concerning enough for ETASUs).

In 2016, FDA revised the REMS for mifepristone to increase the gestational age limit, change the dosage and route of administration, reduce the number of required in-person office visits, allow non-physicians to prescribe and administer the drug, and eliminate the requirement for prescribers to report nonfatal adverse events. Then, in 2021, FDA revised the REMS again, allowing prescribers to dispense mifepristone by mail or mail-order pharmacy.[2]

[2] These various decisions relative to mifepristone are the subject of ongoing litigation elsewhere.

B. The West Virginia Legislature's efforts to protect unborn life

Like most states, West Virginia long had a statute protecting unborn life and prohibiting abortion, which here included an exception for abortions "done in good faith, with the intention of saving the life of such woman or child." W. VA. CODE § 61-2-8. This statute protected unborn life until the Supreme Court issued *Roe v. Wade* in 1973.

Thereafter, the West Virginia Legislature (the "Legislature") continued to do what it could to protect unborn life and maternal health, as well as related medical practice, over the coming decades, enacting numerous statutes in the 20th century.[3] Since 2000, the Legislature enacted yet more statutes,[4] including 2017's amendment to § 30-3-13a(g)(5) limiting telemedicine prescribing authority for drugs to cause an abortion, effectively requiring in-person examination to determine gestational age and detect ectopic pregnancies.

In June 2022, the Supreme Court overturned *Roe v. Wade* and held that abortion is an issue the Constitution entrusts to "the people and their elected representatives." *Dobbs*, 142 S. Ct. at 2284. As a result, the Court returned the issue to "the citizens of each State," holding that States may protect their "legitimate interests" in protecting unborn life, maternal health, and protecting the integrity of the medical profession. *Id.*

In a special session in September 2022, the Legislature largely replaced its previous abortion regulations with the Unborn Child Protection Act. W. VA. CODE §§ 16-2R-1–9 (the

[3] *See, e.g.*, W. VA. CODE § 16-2F-3–8 (parental notification and reporting requirements adopted in 1984); § 9-2-11 (enacted in 1993, prohibited state funds from paying for abortions); § 33-42-8 (enacted in 1998, subjected the doctors who performed partial-birth abortions to criminal penalties).

[4] *See, e.g.*, W. VA. CODE §§ 16-2I-1–8 (enacted in 2003, required informed-consent); § 61-2-30 (enacted in 2005, the Unborn Victims of Violence Act, making "a pregnant woman" and her child "separate and distinct victims" of crimes); § 16-2M-2–6 (a pain-capable law enacted in 2015); §16-2O-1 (enacted in 2016, prohibited dismemberment abortions); § 16-2P-1 (enacted in 2020, required medical care for a baby born-alive via abortion); §16-2Q-1 (prohibited abortions based on disability discrimination, enacted in 2022).

"UCPA" or the "Act").[5] That statute made abortions unlawful except (1) when, "in the reasonable medical judgment of a licensed medical professional," the child is not viable, the pregnancy is ectopic, or there is a medical emergency; or (2) in cases of rape or incest before 8 weeks, or 14 weeks for a minor. *Id.* § 16-2R-3(a)–(c). The Act defines "abortion" to exclude miscarriages, stillbirths, and in vitro fertilization. *Id.* Any "licensed medical professional" as defined in the Act[6] who violates §16-2R-3 shall have their license revoked. *Id.* § 16-2R-7.

In the same bill, West Virginia amended its pre-*Roe* criminal statute to clarify that non-licensed medical professionals are prohibited from performing abortions. *Id.* § 61-2-8. That bill also required health care boards to adopt implementing rules regarding "[a] prohibition of prescribing or dispensing an abortifacient" relative to telemedicine. *Id.* § 30-1-26(b)(9).[7]

On January 25, 2023, GBP filed this Complaint, asking the Court to declare the UCPA unconstitutional, along with: (1) the criminal prohibition on non-licensed medical professionals providing abortions, *id.* § 61-2-8; (2) the telemedicine prescribing authority limitations regarding abortifacients and related directive regarding health care board rules, *id.* §§ 30-1-26(b)(9), 30-3-13a(g)(5); and (3) two of the dormant provisions requiring informed consent and patient counseling, *id.* §§ 16-2I-2, 16-2I-9, under the Supremacy and Commerce Clauses of the United States Constitution.

[5] The Unborn Child Protection Act provides that most prior abortion regulations are "of no force or effect" unless any part of the Act was declared unconstitutional. 2022 W. Va. H.B. 302 (making inoperative § 16-2F-1–9) (parental notification and reporting requirements), e.g., § 16-2I-1–9 (informed consent).

[6] Those licensed under Chapter 30, Articles 3 (Medical Practice Act) and 14 (Osteopathic Physicians and Surgeons).

[7] The Legislature had previously limited telehealth prescribing authority in this area in 2019, adding language directing that "A physician or health care provider may not prescribe any drug with the intent of causing an abortion." W. VA. CODE §30-3-13a(g)(5).

LEGAL STANDARD

Under Fed. R. Civ. P. 12(b)(1), a complaint must be dismissed when the court lacks subject-matter jurisdiction, *Steel Co. v. Citizens for a Better Env't*, 523 U.S. 83, 94 (1998), as when the facts are undisputed and "the moving party is entitled to prevail as a matter of law," *Napper v. United States*, 374 F. Supp. 3d 583, 587 (S.D. W. Va. 2019). Proving jurisdiction is GBP's burden. *Richmond, Fredericksburg & Potomac R.R. Co. v. United States*, 945 F.2d 765, 768 (4th Cir. 1991).

Under Fed. R. Civ. P. 12(b)(6), a complaint states a claim if it contains "sufficient factual matter, accepted as true, to state a claim to relief that is plausible on its face." *Ashcroft v. Iqbal*, 556 U.S. 662, 678 (2009) (cleaned up). The factual allegations must "raise a right to relief above the speculative level." *Bell Atl. Corp. v. Twombly*, 550 U.S. 544, 545 (2007). The Court need not "accept as true a legal conclusion couched as a factual allegation." *Id.* at 555.

ARGUMENT

GBP requests that this Court declare unconstitutional multiple acts of the Legislature on proper matters of state regulation because, in essence, these laws get in the way of GBP marketing and selling as many chemical abortion drugs as possible everywhere. GBP clothes such financially motivated claims in theories of preemption and the "Dormant" Commerce Clause. But both of those theories would require this Court to determine that Congress delegated authority—not just as to judgments of medication safety and efficacy—but to set national policy on the regulation of medical practice and abortion as a coincidence of safety and efficacy determinations That claim fails the straight-face test.

First, GBP fails to meet the most basic Article III requirement of injury in fact. It does not even allege that it has *ever* sold its chemical abortion drug in West Virginia. That admission is fatal to Article III jurisdiction and forecloses all of GBP's claims.

Second, under separation of powers principles, the major questions doctrine, and, indeed, ordinary statutory interpretation principles, GBP must point to clear congressional authorization empowering the FDA to mandate matters of medical practice, including nationwide abortion. But it cannot. Congress did not silently cede this vast area of historically state regulation to the FDA. *Hillsborough Cnty. v. Automated Med. Laboratories*, 471 U.S. 707, 719 (1985) (regulating "health and safety matters is primarily, and historically, a matter of local concern"). *Dobbs* unequivocally reaffirms this in the abortion context.

GBP's preemption claims doubly fail because Plaintiff has failed to establish any federal policy supporting its claimed right to "promote and market" abortion drugs nationwide. GBP argues that the FDA created national abortion access and removed states' ability to regulate abortion simply by approving one drug. That is a specious interpretation of the FDCA, which itself. is notably silent on the issue of abortion, and GBP fails to show that the FDCA has *ever* been interpreted to require nationwide access to any drug.[8] Congress defines the FDA's purpose much more narrowly "ensuring that … drugs are safe and effective." 21 U.S.C. § 393(b)(2)(B). GBP cannot show any conflict with federal law or policy; its preemption claims must fail.

Third, GBP's Commerce Clause claims fail because a minor decrease in a pharmaceutical company's bottom line in West Virginia does not outweigh the State's legitimate interests in protecting its most vulnerable lives. This Court should dismiss the Complaint.

I. GBP lacks standing.

To ensure an Article III case or controversy, a plaintiff must show the "irreducible constitutional minimum of standing," which "contains three elements": (1) "an injury in fact, (2) that is fairly traceable to the challenged conduct of the defendant, and (3) that is likely to be

[8] Indeed, other federal laws prohibit the mailing of abortion drugs.

redressed by a favorable judicial decision." *Spokeo, Inc. v. Robins*, 578 U.S. 330, 338 n.7 (2016). "[S]tanding cannot be inferred argumentatively from averments in the pleadings"; a plaintiff must allege facts "essential to show jurisdiction." *FW/PBS, Inc. v. Dallas*, 493 U.S. 215, 231 (1990).

GBP fails to allege an injury in fact. An injury in fact must be "concrete and particularized" and "actual or imminent, not conjectural or hypothetical." *Spokeo*, 578 U.S. at 339 (cleaned up). Most of GBP's alleged harms—those regarding patient access, Compl. ¶¶ 15, 73(a)–(c), 83, and provider options, *id.* ¶ 16—are not particularized because they do not affect Plaintiff "in a personal and individual way." *Spokeo*, 578 U.S. at 339; *Kowalski v. Tesmer*, 543 U.S. 125, 129 (2004) (party must assert its own rights and interests).

GBP's other allegations are conjectural and hypothetical. Nowhere does GBP allege that it has ever sold chemical abortion drugs in West Virginia, nor does it allege any specific plan to do so. Rather, it claims the challenged laws have hurt its "*opportunity* and *ability* to market, promote, and sell" its drugs, Compl. ¶ 15; *accord* ¶¶ 77, 85, which, in turn, restricts its "pool of *potential* customers," thus costing it "lost sales, customers, and revenue," *id.* ¶ 79 (emphasis added). But Plaintiff's "'some day' intentions—without any description of concrete plans, or indeed even any specification of *when* the some day will be—do not support a finding of the 'actual or imminent' injury that our cases require." *Lujan v. Defs. of Wildlife*, 504 U.S. 555, 564 (1992). *See also Doe v. Obama*, 631 F.3d 157, 162 (2011) (parents "actively considering adopting" human embryos did not satisfy *Lujan*'s requirement that injuries "proceed with a high degree of immediacy").

GBP also fails to show redressability. First, it is much "more difficult to show standing" when one's "asserted injury arises from … allegedly unlawful regulation of someone else" because redressability then hinges on that third party's response. *Lujan*, 504 U.S. at 562. In such a case, the plaintiff must "adduce facts showing that those choices have been or will be made in such

manner as to … permit redressability of injury." *Id.* Here, the challenged laws address licensed medical professionals, not drug manufacturers like GBP. And GBP has not sufficiently alleged that, even if the challenged laws were overturned, its product would necessarily benefit.

Second, a favorable decision by this Court will not redress GBP's injuries because their business model to ship drugs into West Virginia is illegal under federal law. *See* 18 U.S.C. §§ 1461, 1462 (criminalizing using the mail and common carriers to move abortion drugs across state lines).

Third, GBP cannot possibly show redressability for W. VA. CODE §§ 16-2I-2 and 16-2I-9. As GBP notes, those provisions are not operative now and become operative only if part of the UCPA is held unconstitutional. Compl. ¶ 68. But GBP's UCPA claims fail, *see infra* Sections II and III, leaving Plaintiff no standing to challenge §§ 16-2I-2 and 16-2I-9. *California v. Texas*, 141 S. Ct. 2104, 2116 (2021) (unenforceable statutory provision is incapable of meeting the redressability requirement).

II. Congress did not delegate the ability to set nationwide abortion policy or displace state laws regulating medical practice.

A. FDA does not have the authority to set national abortion policy.

GBP claims that the FDCA "delegates to FDA exclusive authority" to balance the competing interests on abortion—one of the most consequential social and moral issues of our day—and mandate *nationwide* abortion access. Compl. ¶ 82. GBP believes Congress gave FDA the authority to unilaterally decide that chemical abortion should be legal in all 50 States and that FDA has exercised that authority by approving mifepristone.

That is a breathtaking assertion of federal agency power. It is blackletter law that FDA—like any other federal agency—has only the power given it by Congress. Thus, before this Court need even address GBP's preemption claim, it must first confront a more fundamental question of

agency power: "whether Congress in fact meant to confer the power the agency has asserted." *West Virginia v. Env't Prot. Agency*, 142 S. Ct. 2587, 2607–08 (2022). Nothing in the text of the FDCA suggests that Congress accorded FDA the unilateral—and indeed, "exclusive" power, to use GBP's word—to set national abortion policy. Under ordinary principles of statutory interpretation, that contention fails; the FDCA's text does not so much as mention abortion. Nor does it direct FDA to consider the legitimate and important state interests in protecting unborn life, maternal health, and the integrity of the medical profession—interests that the Supreme Court in *Dobbs* returned to elected representatives. This conclusion is reinforced by separation-of-powers principles, which compel reviewing courts to find "clear congressional authorization" for expansive assertions of agency authority, such as here. *Id.*

Under the major questions doctrine, "courts expect Congress to speak clearly if it wishes to assign to an agency decisions of vast economic and political significance." *Util. Air Regul. Grp. v. Env't Prot. Agency*, 573 U.S. 302, 324 (2014) (cleaned up); *see also West Virginia*, 142 S. Ct. at 2609 (courts must "presume that Congress intends to make major policy decisions itself, not leave those decisions to agencies") (cleaned up). Terminating a pregnancy is an issue with "profound moral and spiritual implications … even [at] its earliest stage." *Planned Parenthood of Se. Penn. v. Casey*, 505 U.S. 833, 850 (1992). "[T]his is a major questions case." *West Virginia*, 142 S. Ct. at 2610. Accordingly, GBP must more than a "plausible textual basis" for its claim that Congress yielded nationwide abortion policy to the FDA. *Id.* at 2609. It must (but cannot) proffer "clear congressional authorization." *Id.*

The only statutory support GBP offers is the REMS provision, 21 U.S.C. § 355-1. But that provision merely requires FDA to ensure that the *additional* safety requirements that FDA *itself* imposes on drugs with known serious risks associated with adverse reactions are not "unduly

burdensome on patient access to the drug." *Id.* § 355-1(f)(2)(C). In no way does that provision give FDA "clear congressional authorization" to overrule the policy judgment of states on a different question: whether they will allow abortions and, if so, when and how. It would be strange indeed for such an "extraordinary grant[] of regulatory authority" to be accomplished through such a "subtle device" like the REMS requirement. *See West Virginia*, 142 S. Ct. at 2609 (cleaned up).

Further, the FDCA has long been understood to set a federal *floor* on the approval of drugs, allowing complementary state regulations. *See Wyeth*, 555 U.S. at 555. Plaintiffs therefore "claim[] to discover in a long-extant statute an unheralded power" representing a "transformative expansion in [FDA's] regulatory authority." *UARG*, 573 U. S. at 324. This "newfound power" to regulate abortion hidden "in the vague language of an ancillary provision" of the FDCA, would allow FDA "to adopt a regulatory program that Congress ha[s] conspicuously and repeatedly declined to enact itself," *West Virginia*, 142 S. Ct. at 2610; *see* Women's Health Protection Act of 2021, H.R.3755, 117th Cong. (2021) (failed to pass). As the Supreme Court said in another FDA case, "Congress could not have intended to delegate" such a sweeping and consequential authority "in so cryptic a fashion." *Food & Drug Admin. v. Brown & Williamson Tobacco Corp.*, 529 U.S. 120, 160 (2000). Such is the case here, and GBP's claims fail as a matter of law.

B. FDA's approval of mifepristone plus a REMS does not preempt state law.

Even if Congress had given FDA the authority to mandate abortion nationwide (it did not), GBP's preemption claim fails as a matter of law. GBP argues that FDA's approval of mifepristone coupled with the imposition of additional REMS restrictions placed on drugs with elevated risks somehow preempts the ability of the people in every state, including West Virginia, to address abortion anew as permitted under *Dobbs*.

The Supremacy Clause makes federal law "the supreme Law of the Land." U.S. CONST. art. VI, cl. 2. Yet a preemption analysis starts with the assumption that "the historic police powers

of the States are not [to be] superseded unless that was the clear and manifest purpose of Congress." *Arizona v. United States*, 567 U.S. 387, 400 (2012) (cleaned up). This is especially true when Congress legislates "in a field which the States have traditionally occupied," such as public health and safety regulations. *Wyeth*, 555 U.S. at 565.

GBP does not pretend that any law expressly grants FDA preemption authority over West Virginia's ability to protect life or health or regulate the practice of medicine, so it is left only with disfavored "implied preemption." *See Kansas v. Garcia*, 140 S. Ct. 791, 807–08 (2020) (Thomas, J., concurring). There are three kinds of implied preemption: (1) field preemption, inferred from a "pervasive" framework of regulation; (2) impossibility preemption where "compliance with both federal and state regulations is a physical impossibility"; and (3) obstacle preemption where "the challenged state law stands as an obstacle to the accomplishment and execution of the full purposes and objectives of Congress." *Arizona*, 567 U.S. at 399 (cleaned up). GBP cannot show field preemption, gesturing instead towards impossibility and obstacle preemption. Both theories fail.

1. Compliance with both federal and state law is not impossible.

Under impossibility preemption, federal law preempts state law only when state law "directly conflict[s]" with federal law. *AT&T Co. v. Cent. Off. Tel., Inc.*, 524 U.S. 214, 227 (1998). Or, put differently, when the "state law penalizes what federal law requires." *Geier v. Am. Honda Motor Co.*, 120 S. Ct. 1913, 1921 (2000). This "is a demanding" standard to meet. *Wyeth*, 555 U.S. at 573. The "*possibility* of impossibility [is] not enough." *PLIVA, Inc. v. Mensing*, 564 U.S. 604, 625, n. 8 (2011) (emphasis added) (cleaned up). Rather, the Court must see "clear evidence" of impossibility, *Merck Sharp & Dohme Corp. v. Albrecht*, 139 S. Ct. 1668, 1678 (2019), and will not find "impossibility where the laws of one sovereign permit an activity that the laws of the other sovereign restrict or even prohibit." *Id.*

GBP argues that it cannot comply with both West Virginia's challenged laws and the mifepristone REMS.[9] Compl. ¶ 85. This is untrue. For a finding of impossibility preemption, state law must command something that federal law forbids or forbid something that federal law commands. *Mensing*, 564 U.S. at 620. Nothing in West Virginia law prevents GBP from complying with mifepristone's REMS requirements. In fact, West Virginia law does not require GBP to do anything or prevent it from marketing or selling mifepristone. This reveals GBP's real complaint: it believes West Virginia law negatively impacts its "opportunity and ability to market, promote, and sell the [chemical abortion drug] in the State," Compl. ¶ 15, and that is an impossibility-preemption nonstarter. While GBP may desire to sell lots of mifepristone in West Virginia, the company is under no *federal requirement* to do so—or to sell any— and its claim of impossibility preemption fails as a matter of law.[10]

2. The Unborn Child Protection Act does not conflict with federal law.

GBP next contends that the UCPA's provisions "frustrate and conflict" with federal law, namely its purported "authority to sell mifepristone nationwide." Compl. ¶ 15. Yet Congress has clearly stated FDA's purpose: to "protect the public health by ensuring that … drugs are safe and effective." 21 U.S.C. § 393(b)(2)(B).

The UCPA does not second-guess FDA's determinations as to the safety or efficacy of mifepristone. Rather, the FDCA does something else entirely: it protects unborn human life. The Legislature's determination that unborn human life is worthy of protection has nothing to do with the safety or efficacy of any drug, including mifepristone. The UCPA is no more about mifepristone than it is about scalpels. Indeed, mifepristone may still be used in West Virginia to

[10] To the extent GBP focuses on specific restrictions under West Virginia law, *i.e*, the telehealth and dormant counseling and informed consent provisions, those laws do not directly conflict with any REMS, either.

treat Cushing syndrome or cancer and to complete a miscarriage. That the law does not prevent mifepristone from being used as an abortifacient in the few situations exempt from the general prohibition on abortions conclusively demonstrates that the Legislature was concerned with saving unborn lives, not assessing the safety of any drug.

GBP's claim that FDA approval requires nationwide drug access would work a fundamental change in the FDCA. That statute has never been interpreted to require national access. Thus, FDA has never required pharmaceutical companies to sell approved drugs or placed price caps on approved products to ensure access. Indeed, were GBP correct that the mere approval of a drug forces states to allow the use of the drug despite a state's authority to prohibit criminal conduct, FDA approval of a euthanasia drug would preempt state laws forbidding the practice. *But see Washington v. Glucksberg*, 521 U.S. 702, 719–26 (1997) (upholding ban on assisted suicide).[11]

Perhaps recognizing that FDA's mere approval of a drug has never been understood to mandate nationwide access, GBP next suggests there is something special about REMS. According to Plaintiff, FDA's additional imposition of REMS safety requirements "establishes both a 'floor' and 'ceiling' on permissible regulation of mifepristone" and thus preempts West Virginia law. *See ibid*. at ¶ 82, ¶¶ 87–90. GBP thus makes the counterintuitive argument that the graver the danger from a drug (reflected in greater protective requirements from FDA), the more certain it is that states have no place to take any action that could impact that drug. That argument fails for several reasons.

[11] *Zogenix, Inc. v. Patrick*, 2014 WL 1454696 (D. Mass. Apr. 15, 2014) is not to the contrary. In completely banning Zohydro ER, Massachusetts was not concerned with the underlying conduct – pain management – but with FDA's safety determination, banning the drug due to concerns it would "lead to opioid addiction and overdose fatalities." 2014 WL 1454696, at *1. And, again, West Virginia law does nothing to ban mifepristone.

First, it defies belief to suggest that the FDA's imposition of *additional* safeguards on objectively more dangerous drugs would somehow displace the states' traditional authority to regulate for health and safety, regulate the state-licensed practice of medicine, and implement criminal law.

Second, such an interpretation runs headlong into the "touchstone" of preemption analysis: "the purpose of Congress." *Wyeth*, 555 U.S. at 565. GBP's reading cannot be drawn from historical context or statutory language, and the statute itself is silent on abortion. And through many FDCA amendments, "Congress took care to preserve" parallel state laws protecting the public health, expressly providing that "a provision of state law would *only* be invalidated upon a 'direct and positive conflict' with the FDCA." *Wyeth*, 555 U.S. at 567 (emphasis added). Such direct and positive conflict is simply absent here.

Third, GBP rests its novel interpretation of FDA's "determinations as to the balance Congress mandated between safety-based restrictions and patient access to the drug." Compl. ¶ 85. But that statutory directive is plainly tasking FDA with ensuring that its own restrictions do not unduly limit access to inherently dangerous drugs; the text does not suggest these dangerous drugs must be uniformly accessible for all purposes or that states may not impose regulation based on interests the FDA did not consider. In fact, the *Wyeth* Court rejected a similar argument—that the "precise balancing of risks and benefits" required by the FDCA left "no room for different state-law judgments." 555 U.S. at 575. That argument, according to the Court, "relie[d] on an untenable interpretation of congressional intent and an overbroad view of an agency's power to pre-empt state law." *Id.* at 573.

The same is manifest here in GBP's Complaint. Its arguments about balancing drives home the point that Congress did *not* delegate the authority to regulate abortion to the FDA. Were

Congress in fact to delegate to an agency the authority to decide nationwide abortion policy or otherwise displace traditional state issues, it would have at a minimum included the relevant factors. Yet none of the REMS factors say anything about considering interests in protecting unborn life – an undeniable part of any abortion decision. *See Casey*, 505 U.S. at 866–67. Nor do the REMS factors say anything about other important interests like "the elimination of particularly gruesome or barbaric medical procedures; the preservation of the integrity of the medical profession; the mitigation of fetal pain; and the prevention of discrimination on the basis of race, sex, or disability." *Dobbs*, 142 S. Ct. at 2284.

At the end of the day, GBP can identify no federal law or policy mandating nationwide abortion access up to ten weeks gestational age (or any other time frame) that is frustrated by West Virginia law. Not a page of the voluminous briefing in *Dobbs* nor any one of the Court's many separate opinions flagged that there might be a national 10-week protection for chemical abortions either. In fact, Congress specifically declined to enact such a law following the Supreme Court's decision in *Dobbs*. H.R.3755, 117th Cong. (2021). And federal law points the opposite direction, by limiting access to abortion drugs, not promoting it. *See* 18 U.S.C. §§ 1461, 1462 (shipping abortifacients is illegal).

Were there any doubt as to whether Congress might have delegated the authority to mandate nationwide access (and there is not), it would be foreclosed by the presumption against preemption. Where, as here, the area involves matters of historically local concern, the Court "start[s] with the assumption that the historic police powers of the States were not to be superseded by the Federal Act unless that was the clear and manifest purpose of Congress.'" *Jones v. Rath Packing Co.*, 430 U.S. 519, 525 (1977). It is impossible to find that it was the "clear and manifest purpose of Congress" in enacting the FDCA to "supersede[ ]" the States' "historic police power"

to protect the health and safety of its citizens, regulate the practice of medicine, and implement criminal law. *Wyeth*, 555 U.S. at 565. This Court should dismiss the preemption challenge to the UCPA.

3. West Virginia's other challenged laws do not conflict with federal law.

Plaintiff also seeks to invalidate as preempted West Virginia's determination that certain drugs should only be prescribed during in-person visits and not via telemedicine, W. VA. CODE §§ 30-1-26(b)(9), 30-3-13a(g)(5), as well as two dormant provisions of law requiring informed consent and patient counseling, *id.* §§ 16-2I-2, 16-2I-9.

The presumption against preemption applies with full force here, too. West Virginia retains the police power to regulate how drugs may be prescribed and dispensed by medical professionals. *See Gonzales v. Oregon*, 546 U.S. 243, 270–71 (2006). This presumption ensures that "the federal-state balance," will not "be disturbed unintentionally by Congress." *Jones*, 430 U.S. At 525. And as explained above, Congress has long recognized the complementary nature of additional state regulations, enacting a specific savings clause. It could have explicitly preempted state laws governing pharmaceuticals—as it did with medical devices—but "did not do so." *Riegel v. Medtronic, Inc.*, 552 U.S. 312, 327 (2008). Congress's refusal to do so, coupled with long-time state regulations, is powerful evidence that it did not intend FDA's oversight role to replace state legislation. *See Wyeth*, 555 U.S. at 574.

Indeed, FDA has never pretended the FDCA preempts state regulation of chemical abortion procedures. Just the opposite. Mifepristone's current REMS says certain healthcare providers may prescribe the drug, but that state law will govern whether non-physicians may do so: "Some states allow healthcare providers other than physicians to prescribe medications. Healthcare providers

should check their individual state laws." FDA, *Q&A on Mifeprex*, https://tinyurl.com/4jtfrjm8. This is an express acknowledgement that providers must comply with state law.[12]

In any event, the challenged laws complement rather than frustrate the purpose of the REMS. With respect to mifepristone, in-person appointments allow a physician to safely care for a pregnant mother by determining gestational age and for any other purpose, such as diagnosing an ectopic pregnancy. There is no conflict between the REMS and these modest regulations—regulations that are not even focused on mifepristone—or the patient counseling and informed consent provisions, certainly not one "strong enough to overcome the presumption that state and local regulation of health and safety matters can constitutionally coexist with federal regulation." *Hillsborough Cnty.*, 471 U.S. at 716.

Finally, as noted above, it is especially unlikely that a state prescription law preventing the prescription of abortifacients via telemedicine care violates any congressional objective given that Congress has prohibited the transmission of such drugs via the mails. *See* 18 U.S.C. §§ 1461, 1462. Given these laws, there is no basis for concluding that West Virginia's limitation on prescribing authority in such circumstances undermine any federal purpose.

III. GBP's Commerce Clause claim fails.

GBP argues that West Virginia's challenged laws violate the dormant aspect of the Commerce Clause. Compl. ¶ 17. Federal courts have "a two-tiered approach to" Dormant Commerce Clause challenges. *Brown-Forman Distillers Corp. v. N.Y. State Liquor Auth.*, 476 U.S. 573, 578 (1986). "First, state regulations may not discriminate against interstate commerce; and

[12] REMS are not even "agency regulation[s] with the force of law [that] can pre-empt conflicting state requirements," *Wyeth*, 555 U.S. at 576, because they are not adopted under the Administrative Procedures Act. *See Anderson v. Eby*, 998 F.2d 858, 863 (10th Cir. 1993) ("to have the force of law, at a minimum" a regulation must be "adopted according to the procedures embodied in the Administrative Procedures Act").

second, States may not impose undue burdens on interstate commerce." *South Dakota v. Wayfair, Inc.*, 138 S. Ct. 2080, 2091 (2018). There is no reasonable argument that West Virginia's abortion law discriminates against interstate commerce—either "facially, in its practical effect, or in its purpose." *McBurney v. Young*, 667 F.3d 454, 468 (4th Cir. 2012). Beyond that, GBP's claim that West Virginia's law unduly burdens interstate commerce, *see* Compl. ¶ 104, fails for two reasons.

First, the challenged laws survive because they do not unduly burden interstate commerce under *Pike v. Bruce Church, Inc.*, 397 U.S. 137, 142 (1970). "Where the statute regulates even-handedly to effectuate a legitimate local public interest, and its effects on interstate commerce are only incidental, it will be upheld unless the burden imposed on such commerce is clearly excessive in relation to the putative local benefits." *Id.*

Pike is a deferential test, with federal courts "recognizing [their] own institutional limitations" and "giving due deference to [the legislature] whose primary responsibility it is to judge the benefits and burdens" of state legislation. *Colon Health Centers of Am., LLC v. Hazel*, 813 F.3d 145, 156 (4th Cir. 2016). Federal courts are doubly cautious when considering healthcare legislation because that field "is infamously complicated, with patients, providers, insurers, government, and many others all attempting to come to terms over a particular service touching physical wellbeing and *sometimes even life itself*." *Id.* at 159–60 (emphasis added).

Legitimate interests. The court need not search far for legitimate state interests "because the Supreme Court has already done so." *Sandlands C & D LLC v. Cnty. of Horry*, 737 F.3d 45, 53 (4th Cir. 2013). West Virginia's important interests include: preserving unborn life and mitigating fetal pain, protecting a mother's health and safety, eliminating "gruesome or barbaric medical procedures," maintaining the medical profession's integrity, and preventing "discrimination on the basis of race, sex, or disability." *Dobbs*, 142 S. Ct. at 2284.

Incidental burden. GBP again claims that the challenged laws "preclude" the use of mifepristone and "ban[] an article of commerce." Compl. ¶ 104. Not so. West Virginia law regulates only primary conduct—that of aborting an unborn child—and leaves mifepristone untouched for other purposes, such as treating cancer or Cushing disease, as well as for any legal abortion within one of the Act's exceptions, including medical emergencies, rape, and incest. GBP is more honest where it describes the burden as "preventing GenBioPro from developing a market for its product." Compl. ¶ 107. However, the challenged laws do not "prevent" GBP from any commercial activity of GBP, including the marketing, sale, or distribution of its products; rather, these statutes target several aspects of regulating abortion as explained throughout this brief. But any incidental business development challenges in West Virginia resulting from these statutes do not impose a significant burden on interstate commerce. *Johnson v. Cnty. of Horry, S.C.*, 360 Fed.Appx 466, 472 n.7 (4th Cir. 2010) (shrinking the market for one or two highly specialized companies imposes no "significant practical burden upon interstate trade").

The burden does not clearly outweigh benefits. Given that West Virginia's laws advance legitimate state interests and impose only an incidental burden on interstate commerce, GBP bears the burden of proving that the burden imposed is "clearly excessive" relative to the benefits. *Hazel*, 813 F.3d at 155. This it cannot do. The incidental effect on interstate commerce does not remotely outweigh the many interests protected by West Virginia's challenged laws. Consider, for example, just one: the interest in preserving human life. It is within the Legislature's prerogative to determine that the most vulnerable human lives among us are incalculably important and worth protecting—and the preservation of life cannot be matched by other interests, be they public or private.

Second, "Dormant Commerce Clause restrictions apply only when Congress has not exercised its Commerce Clause power to regulate the matter at issue." *Tenn. Wine & Spirits Retailers Ass'n v. Thomas*, 139 S. Ct. 2449, 2465 (2019). Here, Congress *has* used that power to regulate the issue of abortifacients in interstate commerce, specifically making it illegal to send such materials in the mails. *See* 18 U.S.C. §§ 1461–1462. Thus, normal Dormant Commerce Clause restrictions are not apropos in the first place. To the contrary, because "Congress has proscribed [this] interstate commerce," a state law may "discriminate or burden that commerce" so long as it does not conflict with Congress's objectives. *Pic-A-State PA, Inc. v. Pennsylvania.*, 42 F.3d 175, 179 (3d Cir. 1994) (citing *California v. Zook*, 336 U.S. 725, 733 (1949)). West Virginia's challenged laws, though, neither discriminate nor truly burden commerce as explained above. Even if they did, such consequences would complement Congress's own handiwork and, thus, fail to violate the Commerce Clause. For this and the other reasons above, GenBioPro's Commerce Clause claims should be dismissed.

CONCLUSION

For the reasons set forth herein, Defendant Patrick Morrisey, in his official capacity as the Attorney General of the State of West Virginia, requests his Motion to Dismiss this matter be granted.

Respectfully submitted,

By counsel,

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

GENBIOPRO, INC.,

Plaintiff,

v. **Civil Action No. 3:23-cv-00058**

MARK A. SORSAIA, in his official capacity, AND PATRICK MORRISEY, in his official capacity, **Hon. Robert C. Chambers**

Defendants.

CERTIFICATE OF SERVICE

I hereby certify that, on this 21st day of February, I electronically filed the foregoing "Memorandum in Support of Motion to Dismiss" with the Clerk of Court and all parties using the CM/ECF System.

/s/ Curtis R. A. Capehart
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