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

HUNTINGTON DIVISION

GENBIOPRO, INC.,

Plaintiff,

v. CIVIL ACTION NO. 3:23-0058

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.

MEMORANDUM OPINION AND ORDER

Pending before the Court are Defendant Mark A. Sorsaia and Defendant Patrick Morrisey's Motions to Dismiss. ECF Nos. 17 & 19. For the following reasons, the Motions to Dismiss are **GRANTED**, in part, and **DENIED**, in part.

I. BACKGROUND

Plaintiff GenBioPro, Inc. ("GenBioPro") is the only United States manufacturer of generic mifepristone. Pl.'s Opp'n to Def. Morrisey's Mot. to Dismiss at 1, ECF No. 35. Mifepristone is a Food and Drug Administration ("FDA") approved and regulated medication which is commonly prescribed as step one in a two-step medication abortion regimen. Compl. ¶ 2, ECF No. 1. Mifepristone and misoprostol—the other medication abortion drug—are Plaintiff's "sole source of revenue." *Id*. ¶ 23. Mifepristone has been approved for nationwide use and sale by the FDA, and GenBioPro sells the drug throughout a national market. *Id*. ¶ 77.

On June 24, 2022, the Supreme Court decided *Dobbs v. Jackson Women's Health Organization*, reversing *Roe v. Wade*[1] and "return[ing] the issue of abortion to the people and their elected representatives." 142 S. Ct. 2228, 2279 (2022). Following this grant of authority, West Virginia passed the Unborn Child Protection Act ("UCPA") in September 2022. W. Va. Code § 16-2R-1 *et seq*. The act of performing, inducing, or attempting to perform or induce an abortion is now illegal in the State, subject to a limited series of exceptions.[2] W. Va. Code § 16-2R-3. The UCPA expressly includes abortions performed or induced via "medicine" or "drug." W. Va. Code § 16-2R-2. The Act defines the prohibited "attempt to perform or induce an abortion" as "an act or the omission of an act that, under the circumstances as the person so acting or omitting to act believes them to be, constitutes a substantial step in a course of conduct intended to culminate in an abortion." *Id*. If a licensed medical professional "knowingly and willfully performs, induces, or attempts to perform or induce an abortion" with the intent to violate the UCPA, "the licensing board shall revoke medical professional's license." W. Va. Code § 16-2R-7. If a formerly licensed medical professional or any other person "knowingly and willfully performs, induces, or attempts to perform or induce an abortion," they are guilty of a felony and subject to imprisonment for "not less than three nor more than 10 years." W. Va. Code § 61-2-8(a), (b).

[1] 410 U.S. 113 (1973).

[2] Under the UCPA, "[a]n abortion may not be performed or induced or be attempted to be performed or induced unless in the reasonable medical judgment of a licensed medical professional: (1) The embryo or fetus is nonviable; (2) The pregnancy is ectopic; or (3) A medical emergency exists." W. Va. Code § 16-2R-3(a). This prohibition does not apply "to an adult within the first 8 weeks of pregnancy if the pregnancy is the result of sexual assault . . . or incest" and the patient has taken steps to report the assault or incest to law enforcement. W. Va. Code § 16-2R-3(b). Likewise, the prohibition does not apply to "a minor or an incompetent or incapacitated adult within the first 14 weeks of pregnancy if the pregnancy is the result of sexual assault … or incest" and either the patient has taken steps to report the assault or incest to law enforcement or has received medical treatment for the same. W. Va. Code § 16-2R-3(c).

Prior to the decision in *Dobbs* and the passage of the UCPA, West Virginia had provisions in place which Plaintiff asserts greatly limited the prescription and sale of mifepristone. Compl. ¶¶ 87-88. These restrictions required a waiting period and counseling before obtaining an abortion. W. Va. Code § 16-2I-2. The UCPA provides that this restriction has no effect while the UCPA is in force but would "become immediately effective" again should the UCPA "be judicially determined to be unconstitutional." W. Va. Code § 16-2R-9. Further pre-UCPA provisions continue to prohibit providers from prescribing medication abortion drugs via telemedicine. W. Va. Code §§ 30-3-13a(g)(5); 30-1-26(b)(9).

In contrast, the FDA has continually eased restrictions on access to mifepristone. The FDA is tasked with promulgating regulations concerning the approval of prescription medications for sale under the Food, Drug, and Cosmetic Act ("FDCA"). 21 U.S.C. § 393(b)(1). Under regulations known as "Subpart H," the FDA approves drugs which treat "serious or life-threatening illnesses and that provide meaningful therapeutic benefit to patients over existing treatments" subject to "restrictions to assure safe use." 21 C.F.R. §§ 314.500, 314.520; Compl. ¶ 36. According to the Complaint, in 2000, Danco Laboratories, LLC's Mifeprex—name-brand mifepristone—was approved under the Subpart H regulatory scheme, which imposed certain restrictions on prescription and administration of the drug to assure safe use. Compl. ¶¶ 38-39. In 2007, Congress enacted the Food and Drug Administration Amendments Act ("FDAAA"), requiring that drugs formerly approved under Subpart H be re-approved under a new regulatory scheme, entitled the Risk Evaluation and Mitigation Strategy ("REMS"). *See* 21 U.S.C. §§ 355-1(a), (g)(4)(B), (h); Compl. ¶ 41. If the FDA determines that a drug may cause an "adverse drug experience," then the agency must design and implement a REMS. § 355-1(a), (b)(1). However, any restrictions imposed under the regulatory scheme must "not be unduly

burdensome on patient access to the drug." § 355-1(f)(2)(C). The FDA must reassess a drug's REMS periodically. § 355-1(d).

Following the passage of the FDAAA and the implementation of the REMS schema, the manufacturer of Mifeprex proposed a REMS for its product to the FDA. Compl. ¶ 55. The FDA approved the proposed REMS in 2011. *Id*. The 2011 REMS[3] allowed Mifeprex to be prescribed by certified physicians up to 49 days of pregnancy, dispensed in certain healthcare facilities, and taken in the provider's clinic. *Id*. ¶ 56. In 2016, the FDA revised the Mifeprex REMS,[4] increasing the gestational age through which the drug is indicated, expanding those who could be certified to prescribe Mifeprex from "physicians" to "healthcare providers," and reducing the number of required patient visits to their healthcare providers. *Id*. ¶ 58. In April 2019, the FDA approved GenBioPro's generic version of mifepristone, subject to the same REMS as Mifeprex.[5] *Id*. ¶¶ 60-61. In response to the COVID-19 pandemic two years later, the FDA announced it would stop enforcing the in-person dispensation requirement of the mifepristone REMS. *Id*. ¶ 62. On January 3, 2023,[6] the FDA promulgated a new REMS[7] for mifepristone which no longer limits dispensation of the drug to healthcare settings, thereby allowing patients to receive the

[3] U.S. Food & Drug Admin., NDA 20-687 MIFEPREX (mifepristone) Tablets, 200 mg, Risk Evaluation and Mitigation Strategy (REMS) (June 2011), https://perma.cc/3S5M-WMQ6.
[4] U.S. Food & Drug Admin., NDA 020687 MIFEPREX (mifepristone) Tablets, 200 mg, Risk Evaluation and Mitigation Strategy (REMS) (Mar. 2016), https://perma.cc/KC6Z-NQUA.
[5] U.S. Food & Drug Admin., Mifepristone Tablets, 200 mg, Risk Evaluation and Mitigation Strategy (REMS) Single Shared System for Mifepristone 200mg (Apr. 2019), https://perma.cc/2XSU-3HYT.
[6] The Court notes that while the REMS was most recently updated in March 2023 "to add space to allow for additional contact information on the forms" and "correct a typographical error," the last significant modification was in January 2023. *See Update History*, Mifepristone, Shared System REMS, U.S. Food & Drug Admin., https://perma.cc/RE9X-NUJF (last accessed Aug. 9, 2023).
[7] U.S. Food & Drug Admin., Mifepristone Tablets, 200 mg, Risk Evaluation and Mitigation Strategy (REMS) Single Shared System for Mifepristone 200mg (Mar. 2023), https://perma.cc/224Y-KFLE [hereinafter 2023 REMS].

medication either by mail or from certified pharmacies and no longer requiring in-person visits to healthcare providers.[8] *Id*. ¶ 66.

The FDA made these changes to the REMS in response to overwhelming evidence of the safety and efficacy of mifepristone. *Id*. ¶ 38, 58-59, 62-64. Decades of usage of the drug—both in the United States and abroad—as well as a rigorous agency and pharmaceutical industry review process have demonstrated that the FDA may promulgate REMS allowing for increased access without risking patient safety. *See, e.g.*, U.S. Food & Drug Admin., *Questions & Answers on Mifepristone for Med. Termination of Pregnancy Through Ten Weeks Gestation* (Jan. 4, 2023) (discussing safety and access determinations made by the agency), https://perma.cc/6TDS-F9FL (last accessed Aug. 9, 2023). As summarized by Food and Drug Law and Health Law Scholar *amici*, "mifepristone has been subject to more regulatory and congressional scrutiny than perhaps any other prescription drug." ECF No. 40-1, at 5. Each time the REMS were altered, the FDA "used an internal team of experts . . . to conduct medical, chemistry, pharmacology, statistical, clinical pharmacology, and biopharmaceutrics reviews of all data" in accordance with the FDCA and agency practice. *Id*. at 10. The result of this heightened scrutiny and extensive review is a REMS which unambiguously assures the safety of the drug without any additional safeguards

[8] On the eve of entry of this Opinion, the Fifth Circuit issued its decision affirming a stay of the 2016 REMS and the FDA's 2021 non-enforcement decision, later codified in the 2023 REMS. *All. for Hippocratic Med. v. FDA*, — F.4th —, 2023 WL 5266026 (5th Cir. Aug. 16, 2023). The Court has reviewed the Fifth Circuit decision and does not find its primary determinations to be persuasive. Nevertheless, the Court notes the direct effect of that decision on this case, as mifepristone is currently subject to the "conditions for use that existed in 2016" pending the litigation of *Alliance for Hippocratic Medicine*. *Id*. at *1-2. However, the Fifth Circuit noted that its "holding is subject to the prior order of the Supreme Court, which stayed the district court's order pending resolution of this appeal and disposition of any petition for writ of certiorari." *Id*. at * 4. Regardless, 2023 REMS remains law, and the Court will consider Plaintiff's claims as to those restrictions.

from the States. Defendants have not disputed the safety of the mifepristone REMS, nor could they.

Confronted with West Virginia's additional barriers to prescribing its product, Plaintiff filed suit in this Court on January 25, 2023, alleging that the UCPA and prior restrictions violate the Supremacy and Commerce Clauses by limiting the sale of mifepristone in West Virginia. Prosecuting Attorney of Putnam County Mark Sorsaia and Attorney General of West Virginia Patrick Morrisey were named as defendants in their official capacities. Both Defendants have filed motions to dismiss. ECF Nos. 17 & 19. Each Defendant disputes GenBioPro's standing, as well as Plaintiff's interpretation of the Supremacy and Commerce Clauses. The Court heard oral argument on the issue of standing on April 24, 2023, and subsequently issued a Memorandum Opinion and Order finding that Plaintiff had standing on behalf of itself and on behalf of third-party vendees. ECF No. 54. On May 23, 2023, the Court heard oral argument on the remainder of the Motions to Dismiss. Accordingly, the matter is now ripe for adjudication.

II. LEGAL STANDARD

To survive a motion to dismiss, a complaint must contain "a short and plain statement of the claim showing [the plaintiff] is entitled to relief." Fed. R. Civ. P. 8(a)(2). While the facts alleged in the complaint need not be probable, the statement must contain "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). A claim has facial plausibility when "the plaintiff pleads factual content that allows the court to draw the reasonable inference that the defendant is liable for the misconduct alleged." *Ashcroft v. Iqbal*, 556 U.S. 662, 678 (2009) (citation omitted). In considering the plausibility of a plaintiff's claim, the Court accepts all well-pleaded factual allegations in the complaint as true.

Id. Still, "[t]hreadbare recitals of the elements of a cause of action, supported by mere conclusory statements, do not suffice." *Id*. (citation omitted).

Determining whether a complaint states a plausible claim is a "context-specific task that requires the reviewing court to draw on its judicial experience and common sense." *Id*. at 679. If the court finds from its analysis that "the well-pleaded facts do not permit the court to infer more than the mere possibility of misconduct, the complaint has alleged—but it has not 'show[n]'—'that the pleader is entitled to relief.'" *Id*. (quoting, in part, Fed. R. Civ. P. 8(a)(2)). Nonetheless, a plaintiff need not show that success is probable to withstand a motion to dismiss. *Twombly*, 550 U.S. at 556 ("[A] well-pleaded complaint may proceed even if it strikes a savvy judge that actual proof of those facts is improbable, and that a recovery is very remote and unlikely.").

III. DISCUSSION

A. Major Questions Doctrine

In his Motion to Dismiss, Defendant Morrisey argues that this is a major questions case. Def. Morrisey's Mem. of Law in Supp. of Mot. to Dismiss at 8-10, ECF No. 20. The Supreme Court inaugurated the so-called "major questions doctrine" in *West Virginia v. EPA*, 142 S. Ct. 2587 (2022). "Under that doctrine's terms, administrative agencies must be able to point to clear congressional authorization when they claim the power to make decisions of vast economic and political significance." *Id*. at 2616 (Gorsuch, J., concurring) (cleaned up); *see also Util. Air Regulatory Grp. v. EPA*, 573 U.S. 302, 324 (2014) ("When an agency claims to discover in a long-extant statute an unheralded power to regulate a significant portion of the American economy, we typically greet its announcement with a measure of skepticism." (internal quotation omitted)). Relying on a concatenation of caselaw in which agencies were found to lack the

authority to regulate broadly under ambiguous delegation provisions, *West Virginia* invalidated the Environmental Protection Agency's interpretation of a broad provision in the Clean Air Act as granting the agency comprehensive authority to regulate national energy systems. 142 S. Ct. at 2610-14; *see also Biden v. Nebraska*, 143 S. Ct. 2355, 2374 (2023) ("[W]hile the major questions 'label' may be relatively recent, it refers to 'an identifiable body of law that has developed over a series of significant cases' spanning decades." (quoting *West Virginia*, 142 S. Ct. at 2609)). In doing so, *West Virginia* held that courts must "presume that Congress intends to make major policy decisions itself, not leave those decisions to agencies." 142 S. Ct. at 2609 (internal quotation omitted). As abortion is one such major policy decision, Defendant Morrisey argues that this Court must conclude Congress did not intend to delegate the authority to the FDA to decide access issues for mifepristone. *See* Def. Morrisey's Mem. of Law in Supp. of Mot. to Dismiss at 9.

The Court does not dispute the serious social, ethical, economic, and political issues implicated by abortion. There is no doubt that "terminating a pregnancy is an issue with 'profound moral and spiritual implications even at its earliest stage.'" Def. Morrisey's Mem. of Law in Supp. of Mot. to Dismiss at 9 (quoting *Planned Parenthood of Se. Penn. v. Casey*, 505 U.S. 833, 850 (1992)) (cleaned up). And yet, the Court disagrees that either the FDA's promulgation of the mifepristone REMS or GenBioPro's arguments concerning those REMS implicate those major questions. The seminal major questions cases all involved novel agency interpretations of long-standing ambiguous regulatory provisions as major grants of authority to reconfigure large aspects of the economy. *See West Virginia*, 142 S. Ct. at 2602-04; *Air Utility*, 573 U.S. at 323-24; *Biden v. Nebraska*, 143 S. Ct. at 2373 (involving attempted broad student loan forgiveness under a limited grant of emergency loan waiver authority); *FDA v. Brown &*

Williamson Tobacco Corp., 529 U.S. 120, 160 (2000) (involving attempted regulation of cigarettes as "drug delivery devices").

In contrast, here the FDA is acting narrowly pursuant to an explicit grant of authority as to a single prescription medication—the FDAAA's express command that the FDA promulgate a REMS for Subpart H-approved drugs (including mifepristone), subject to certain delineated principles, including ensuring accessibility. FDAAA, Section 909(b)(1); 21 U.S.C. § 355-1(f)(2)(C). That is all; the FDA is not making any novel claims to any broader authority hidden within the FDCA or the FDAAA amendments. In other words, the FDA's mifepristone REMS simply does not "effect a fundamental revision of the statute, changing it from one sort of scheme of regulation into an entirely different kind." *Biden v. Nebraska*, 143 S. Ct. at 2373 (quoting *West Virginia*, 142 S. Ct. at 2612) (cleaned up). Instead, the promulgation of the REMS was a routine regulatory action.

Nor is GenBioPro claiming that either the FDCA or the FDAAA amendments contain previously unstated broad abortion authority. GenBioPro's preemption argument can be characterized as: (1) the FDAAA commanded the FDA to consider access in promulgating a REMS for mifepristone; (2) pursuant to that authority, the REMS the FDA promulgated determined a standard of accessibility for the drug; and (3) West Virginia's abortion laws conflict with this standard. *See* Pl.'s Opp'n to Def. Morrisey's Mot. to Dismiss at 8-19. The Court will consider the cognizability of this preemption argument separately, below. But regardless of its validity, GenBioPro's argument does not allege an elephant hidden in a mousehole.

Defendant Morrisey argues that the FDCA "does not so much as mention abortion." Def. Morrisey's Mem. in Supp. of Mot. To Dismiss at 9. True—but nor does it mention any other

specific procedure, device, cosmetic, or medication it instructs the FDA to regulate. *See, e.g.*, 21 U.S.C. § 321(h)(1) (defining "medical devices" the FDA may regulate without specifying any particular device). Defendant misunderstands the purpose and scope of the statutory grants of agency authority by demanding that Congress have listed every possible medical condition and procedure when it instructed the FDA to regulate prescription medicine generally. For example—imagine if Congress were forced to list every endangered species for the Endangered Species Act ("ESA") to grant the Fish and Wildlife Service ("FWS") authority to protect any specific at-risk organism. *See* 16 U.S.C. § 1531 *et seq*. Calling this a "major questions case" and demanding the FDA refrain from treating abortion medications on par with other medications under the FDCA would make just as much sense as demanding the FWS refrain from listing the snail darter as an endangered species under the ESA. *See Tennessee Valley Auth. v. Hill*, 437 U.S. 153 (1978). If Defendant wishes to bring a delegation challenge, he will have to find standing to bring another suit.

But, significantly, Congress *did* specify that drugs previously approved under Subpart H would be deemed in effect to have a REMS in the 2007 FDAAA amendments.[9] FDAAA, Section 909(b)(1). Shortly thereafter, the FDA issued a notice indicating that mifepristone was one of these previously approved drugs. Dept. Health & Human Servs., *Identification of Drug & Biological Prods. Deemed to Have Risk Evaluation & Mitigation Strategies for Purposes of the Food & Drug Admin. Amendments Act of 2007*, 73 Fed. Reg. 16313-01, 16313 (Mar. 27, 2008). The fact that Congress did not specify that mifepristone is to be used for abortion when it incorporated the drug into the REMS scheme is of no more import than its lack of specification

[9] This is not a case where the regulatory agency relied upon an implied grant of authority. This list consisted of only 17 previously approved drugs and Congress undoubtedly knew that one, mifepristone, was used only for medication abortion.

as to isotretinoin's usage as an acne medication. *See id*. Each medicine listed in the FDA's 2008 Notice was approved for an indicated use via Subpart H, and Congress stated that those approvals were to be carried over into the new REMS schema (subject to eventual FDA re-evaluation). An order to regulate an express list of prescription medicines under a second list of articulated criteria is about as granular a grant of authority as Congress ever gives an agency.

Accordingly, the Court finds that this is not a major questions case, and the major questions doctrine does not bar Plaintiff's arguments as to preemption and the dormant Commerce Clause. Whether the UCPA or prior restrictions violate either the Supremacy or Commerce Clause is a different question and is considered below.

B. Preemption

The Supremacy Clause provides that federal law "shall be the supreme Law of the Land; and the Judges in every State shall be bound thereby, any Thing in the Constitution or Laws of any state to the Contrary notwithstanding." U.S. Const., art. VI, cl. 2. It follows inexorably that "Congress has the power to preempt state law." *Arizona v. United States*, 567 U.S. 387, 399 (2012) (citing *Crosby v. Nat'l Foreign Trade Council*, 530 U.S. 363, 372 (2000); *Gibbons v. Ogden*, 9 Wheat. 1, 210–211, 6 L.Ed. 23 (1824)). Accordingly, "the purpose of Congress is the ultimate touchstone in every preemption case." *Medtronic, Inc. v. Lohr*, 518 U.S. 470, 485 (1996) (internal quotation omitted). "Congress may indicate pre-emptive intent through a statute's express language or through its structure and purpose." *Altria Grp., Inc. v. Good*, 555 U.S. 70, 76 (2008). However, there is a presumption against preemption, especially in a field traditionally occupied by the States. *Wyeth v. Levine*, 555 U.S. 555, 565 (2009).

Generally, there are three types of preemption: (1) express preemption, (2) conflict preemption, and (3) field preemption. *Murphy v. Nat'l Collegiate Athletic Ass'n*, 138 S. Ct. 1461, 1480 (2018); *Mayor & City Council of Balt. v. BP P.L.C.*, 31 F.4th 178, 198 n.2 (4th Cir. 2022). Both "conflict" and "field" are considered types of implied preemption. *Kurns v. Railroad Friction Prods. Corp.*, 565 U.S. 625, 630-31 (2012). On occasion, the Supreme Court has delineated further, treating "impossibility" and "obstacle" preemption as two separate entities within "conflict" preemption. *See Arizona*, 567 U.S. at 399-400. The Court has admitted that it "sometimes use[s] different labels" but that "these categories are not rigidly distinct." *Va. Uranium, Inc. v. Warren*, 139 S. Ct. 1894, 1901 (2019) (quoting *Crosby*, 530 U.S. at 372, n.6). This Opinion considers both whether the challenged state provisions "conflict" with or provide an "obstacle" to federal law, treating these as one form of "conflict" preemption, in accordance with *e.g.*, *Murphy*, 138 S. Ct. at 1480.

The FDCA does not include an express preemption provision. *See Wyeth*, 555 U.S. at 574 ("If Congress thought state-law suits posed an obstacle to its objectives, it surely would have enacted an express preemption provision at some point during the FDCA's 70–year history.") The 1962 Amendments to the FDCA, however, include an express preemption saving clause. *See* Drug Amendments of 1962, § 202, 76 Stat. 793 ("Nothing in the amendments made by this Act to the Federal Food, Drug, and Cosmetic Act shall be construed as invalidating any provision of State law . . . unless there is a direct and positive conflict between such amendments and such provision of State law"). Of further import, regulation of health and safety is a field that States have traditionally occupied. *Hillsborough Cnty., Fla. v. Automated Med. Labs., Inc.*, 471 U.S. 707, 716 (1985). The Supreme Court has made it clear that regulating abortion is a matter of health and safety upon which States may appropriately exercise their police power. *See*

Dobbs, 142 S. Ct. at 2279. Regulation of medical professionals—which the UCPA directly accomplishes—is arguably a field in which the States have an even stronger interest and history of exercising authority. *See id*. at 2284 (emphasizing the States' interest in "the preservation of the integrity of the medical profession"); *Dent v. West Virginia*, 129 U.S. 114 (1889) (holding that West Virginia has the authority to regulate medical licensure).

Keeping these principles in mind, the Court will consider the arguments as to implied preemption.

a. Conflict Preemption

As an antecedent matter, the Court cannot find any evidence of Congressional intent in the FDCA or FDAAA amendments to preempt state laws of the type challenged here. Again, "the purpose of Congress is the ultimate touchstone in every preemption case." *Wyeth*, 555 U.S. at 565 (quoting *Medtronic*, 518 U.S. at 485). Congressional intent must be determined in context, as "our interpretation of [statutory] language does not occur in a contextual vacuum." *Medtronic*, 518 U.S. at 485.

In determining the purpose of the contested FDAAA "access" provisions, the Court "begin[s] by analyzing the statutory language" as "[w]e must enforce plain and unambiguous statutory language according to its terms." *Hardt v. Reliance Standard Life Ins. Co.*, 560 U.S. 242, 251 (2010). The relevant portion of the statute reads as follows:

> **(f) Providing safe access for patients to drugs with known serious risks that would otherwise be unavailable**
>
> **(1) Allowing safe access to drugs with known serious risks**
>
> The Secretary, in consultation with the offices described in subsection (c)(2), may require that the risk evaluation and mitigation strategy for a drug include such elements as are necessary to assure safe use of the drug, because of its inherent toxicity or potential harmfulness, if the Secretary determines that—

> **(A)** the drug, which has been shown to be effective, but is associated with a serious adverse drug experience, can be approved only if, or would be withdrawn unless, such elements are required as part of such strategy to mitigate a specific serious risk listed in the labeling of the drug; and
>
> **(B)** for a drug initially approved without elements to assure safe use, other elements under subsections (c), (d), and (e) are not sufficient to mitigate such serious risk.

(2) ***Assuring access and minimizing burden***

Such elements to assure safe use under paragraph (1) shall—

> **(A)** be commensurate with the specific serious risk listed in the labeling of the drug;
>
> **(B)** within 30 days of the date on which any element under paragraph (1) is imposed, be posted publicly by the Secretary with an explanation of how such elements will mitigate the observed safety risk;
>
> **(C)** considering such risk, *not be unduly burdensome on patient access* to the drug, considering in particular—
>
> > **(i)** patients with serious or life-threatening diseases or conditions;
> >
> > **(ii)** patients who have difficulty accessing health care (such as patients in rural or medically underserved areas); and
> >
> > **(iii)** patients with functional limitations; and
>
> **(D)** to the extent practicable, *so as to minimize the burden on the health care delivery system—*
>
> > **(i)** conform with elements to assure safe use for other drugs with similar, serious risks; and
> >
> > **(ii)** be designed to be compatible with established distribution, procurement, and dispensing systems for drugs.

21 U.S.C. § 355-1(f) (italics added, bold in original).

Plaintiff argues that this language—repeatedly emphasizing ensuring access and minimizing undue burden—shows Congressional intent to designate access determinations for drugs subject to a REMS with elements to assure safe use to the FDA, thus preempting any conflicting state access determinations. Admittedly, Section 355-1(f)(2) requires the FDA to consider patient access and burden. However, this requirement is plainly a limitation on the FDA's *own restrictions* on a drug, rather than a command that the FDA assure access for all patients: "[s]uch elements to assure safe use *under paragraph (1)* shall" not be "unduly burdensome." Accordingly, Congress's purpose in directing the FDA to consider burden and access when promulgating REMS with elements to assure safe use was to ensure that the elements *themselves* would not be unduly burdensome upon patient access.

The context in which the FDAAA was passed confirms this interpretation. At the time Congress passed the FDAAA in 2007, mifepristone was approved for usage up to 49 days of pregnancy under the Subpart H regulatory scheme. Compl. ¶¶ 39, 58. In 2007, *Planned Parenthood v. Casey*'s "undue burden" or "substantial obstacle" standard was the touchstone for assessment of the constitutionality of abortion restrictions, and the Court recognized "the right of the woman to choose to have an abortion before viability." 505 U.S. at 846; *see Stenberg v. Carhart*, 530 U.S. 914, 921 (2000) (providing that "a law designed to further the State's interest in fetal life which imposes an undue burden on the woman's decision before fetal viability is unconstitutional" (internal quotation marks omitted)); *Cincinnati Women's Servs., Inc. v. Taft*, 468 F.3d 361, 367-69 (6th Cir. 2006) (discussing and applying *Casey*). While debate over the ethics of abortion roiled the nation, no Congressperson in 2007 could have credibly doubted that abortion was legal up to 49 days of pregnancy, long before the point of viability. In fact, in 2006, the Sixth Circuit upheld a district court's preliminary injunction on an Ohio ban of off-label

usage of mifepristone as unconstitutional under *Casey* and *Carhart*. *Planned Parenthood Cincinnati Region v. Taft*, 444 F.3d 502, 508-09, 518 (6th Cir. 2006). Consequently, while Congress deemed mifepristone to have in effect a REMS, and included language concerning access in the REMS scheme, it is not plausible to infer an intent from this language to preclude state abortion law by granting mifepristone access decisions to the FDA. In 2007, the issue of access to abortion up to 49 days of pregnancy was conclusively determined (so we thought) by the Supreme Court, and an appellate court had applied that standard to mifepristone. Absent express language to the contrary, the Court finds it difficult to conclude that Congress intended for the FDAAA access language to preempt state abortion restrictions which would have been unconstitutional at the time the FDAAA was passed.

Therefore, the Court finds that the UCPA and abortion restrictions do not pose 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 omitted); *Hines v. Davidowitz*, 312 U.S. 52, 67 (1941) (seminal case finding obstacle preemption). As discussed above, "conflict" preemption has been variously deconstructed into "conflict," "impossibility," and "obstacle" preemption. Some Supreme Court decisions have elevated obstacle preemption to sit alongside field and conflict preemption, treating the later as synonymous with "impossibility" preemption, while others conflate "obstacle" and "conflict" preemption. *Compare, e.g., Virginia Uranium*, 139 S. Ct. at 1907 (treating "conflict" and "obstacle" preemption as synonymous), *with Arizona*, 567 U.S. at 399 (delineating two types of "conflict" preemption as "impossibility" and "obstacle" preemption). Regardless of taxonomies, both parties treat "conflict" or "impossibility" preemption and "obstacle" preemption as distinct pathways to an implied preemption holding,

and the Court will consider those claims as they have arisen before it. *See* Def. Morrisey's Mem. of Law in Supp. of Mot. to Dismiss at 11; Pl.'s Opp'n to Def. Morrisey's Mot. to Dismiss at 14.

The Court finds that while the FDAAA requires the FDA to consider accessibility in making REMS determinations, the plain language of the statute indicates that "access" considerations are made with regards to the FDA's own limitations it imposes upon obtaining medications subject to a REMS, rather than broadly legislating geographical access to the entire population. The context in which the FDAAA was passed confirms this interpretation of the objectives of Congress. Any additional or incidental burden West Virginia has placed upon patients wishing to obtain mifepristone does not provide an unconstitutional "obstacle" to the FDAAA's unambiguous directive to the FDA.

Congruently, the Court rejects Plaintiff's assertion of "direct" or "impossibility" type conflict preemption. Conflict preemption may occur when "compliance with both federal and state regulations is a physical impossibility." *Arizona*, 567 U.S. at 399 (quoting *Fla. Lime & Avocado Growers, Inc. v. Paul*, 373 U.S. 132, 142-143 (1963)). The Supreme Court has "long recognized that state laws that conflict with federal law are 'without effect.'" *Altria Group*, 555 U.S. at 76 (quoting *Maryland v. Louisiana*, 451 U.S. 725, 746 (1981)). Theoretically—regardless of the intent of the FDAAA—the mifepristone REMS could directly conflict with West Virginia's restrictions, thereby creating a system in which individuals regulated by both federal and state law could not comply with both mandates. *See Mut. Pharm. Co. v. Bartlett*, 570 U.S. 472, 486-87 (2013) (finding preemption due to direct conflict between state tort law and FDCA labelling requirements); *PLIVA, Inc. v. Mensing*, 564 U.S. 604, 624 (2011) (same).

Yet, the Court finds that GenBioPro is not subject to a catch-22, whereby it may either comply with the UCPA or the REMS regulations. In fact, GenBioPro is not regulated by the

UCPA *at all*. The UCPA regulates "licensed medical professionals," defined as persons licensed under either West Virginia Code § 30-3-1 *et seq.* or § 30-14-1 *et seq*., which govern licensure of the practice of medicine, surgery, podiatry, and osteopathic medicine or surgery for physicians and physicians' assistants. W. Va. Code §§ 16-2R-2; 16-2R-3. As discussed above, the UCPA prohibits licensed medical professionals from performing, inducing, or attempting to perform or induce an abortion by any means, subject to a limited series of exceptions. W. Va. Code § 16-2R-3. The prohibited act is further defined as "an act or the omission of an act that, under the circumstances as the person so acting or omitting to act believes them to be, constitutes a substantial step in a course of conduct intended to culminate in an abortion." W. Va. Code § 16-2R-2. Whether this definition could include GenBioPro's sale of mifepristone to doctors and pharmacies is debatable, but the Court need not decide that question today, as GenBioPro is not a "licensed medical professional" under either West Virginia Code § 30-3-1 *et seq.* or § 30-14-1 *et seq*. Accordingly, GenBioPro is not caught between obeying state and federal law in a manner which would offend the Supremacy Clause.[10]

However, this Court has found that GenBioPro may assert the interests of its vendees, who are subject to the strictures of the UCPA. Mem. Op. & Order at 18-22, ECF No. 54. GenBioPro sells to doctors and pharmacies nationwide and would like to sell to those same vendees in West Virginia. Compl. ¶¶ 77-79. While the Court's previous opinion focused on the ability of GenBioPro to represent the interests of its vendees who fall outside the UCPA's definition of "licensed medical professional," there is no doubt that many of GenBioPro's vendees would be "licensed medical professionals" under the UCPA. *See* Mem. Op. & Order at 21-22;

[10] As an aside, the Court rejects Defendants' argument that GenBioPro may simply choose to stop selling mifepristone in West Virginia, and thus avoid any conflict between state and federal law. *See Bartlett*, 570 U.S. at 488 (rejecting a "stop-selling rationale").

Compl. ¶ 71. So, the question remains: does the UCPA conflict with the REMS such that licensed medical professionals cannot lawfully comply with both?

The REMS specify the methods by which mifepristone may be prescribed. For example, the REMS indicate which providers may prescribe the drug, whether it may be prescribed remotely or in person, and what diagnostic criteria is appropriate for prescribing mifepristone. 2023 REMS; *see also* 21 U.S.C. § 355-1(f)(3) (indicating which elements to assure safe use may be included in a REMS). The UCPA, on the other hand, instructs licensed medical professionals in the State of West Virginia to only perform abortions when certain extrinsic criteria are present—both medical and non-medical—such as an ectopic pregnancy, or reported rape or incest. W. Va. Code § 16-2R-3(a), (b). The additional state law restrictions include an active prohibition on telemedicine prescription of mifepristone and a dormant set of restrictions mostly involving informational disclosure requirements. *See* W. Va. Code §§ 16-2I-2; 16-2R-9; 30-3-13a(g)(5); 30-1-26(b)(9). A licensed medical professional in West Virginia, therefore, must surmount several hurdles to prescribe mifepristone: first ascertaining whether a patient may obtain an abortion under the UCPA, then whether mifepristone is appropriate for that patient under the REMS, and finally, the method by which mifepristone may be prescribed to the patient in consideration of both the REMS and the West Virginia restrictions. This scheme coheres with traditional conceptions of the practice of medicine and the scope of physicians' authority as state matters. *See, e.g.*, *Dent*, 129 U.S. at 122 (describing the "time immemorial" power of the State to regulate the practice of physicians).

Accordingly, the Court finds that the UCPA is a restriction on the incidence of abortion, rather than a state directive in direct conflict with the logistical REMS regulations. The Supreme Court has repeatedly indicated that similarly broad state regulations are not preempted by

intricate federal regulatory systems. For instance, in *Virginia Uranium*, mining companies and owners of uranium-rich land sued Virginia, alleging that a state law preventing uranium mining was preempted by the federal Atomic Energy Act's regulations on the practice of uranium mining. *Virginia Uranium*, 139 S. Ct. at 1901. As the decision to disallow uranium mining is separate from the regulations on the act of mining itself—and in an area of authority traditionally left to the States—the Court found that the Atomic Energy Act did not preempt state bans on uranium mining. *Id*. at 1903, 1907-08. Similarly, the Court has found that state bans on horsemeat are not preempted by the federal regulatory scheme dictating how horses are to be slaughtered. *Nat'l Meat Ass'n v. Harris*, 565 U.S. 452, 467 (2012).[11] Here, West Virginia's UCPA has limited *when* an abortion may be performed, without touching *how* medication abortion is to be performed. The mifepristone REMS only concern themselves with the latter.[12] As the Court found States may ban uranium mining despite a federal scheme of uranium mining regulation, or horsemeat in the face of a federal scheme of horse slaughter regulation, so this Court is compelled to find that federal regulation of medication abortion prescription does not conflict with severe state limitations on abortion.

[11] While *National Meat Association v. Harris* decided that the Federal Meat Inspection Act (FMIA) preempted a California law regulating the slaughter of non-ambulatory pigs, the Court emphasized that its holding on the pigs did not imply that state laws banning horse meat would be similarly preempted by the FMIA, stating: "A ban on butchering horses for human consumption works at a remove from the sites and activities that the FMIA most directly governs. When such a ban is in effect, no horses will be delivered to, inspected at, or handled by a slaughterhouse, because no horses will be ordered for purchase in the first instance." 565 U.S. at 467. The Court has reiterated this dictum as to the legality of bans on horse slaughter in subsequent cases. *Virginia Uranium*, 139 S. Ct. at 1914 (Ginsburg, J., concurring); *see also Nat'l Pork Prod. Council v. Ross*, 143 S. Ct. 1142, 1163 (2023) (discussing state horsemeat bans).

[12] The Court is aware that the REMS do dictate "when" an abortion may be performed with mifepristone, in the sense of gestational limits and locations. But there are different kinds of "when." West Virginia creates pre-requisites to accessing abortion care, while the REMS delineate logistical safety standards once a patient has sought medication abortion.

b. Field Preemption

Likewise, the Court rejects Plaintiff's arguments as to field preemption.

Field preemption precludes States from "regulating conduct in a field that Congress, acting within its proper authority, has determined must be regulated by its exclusive governance." *Arizona*, 567 U.S. at 399 (citing *Gade v. Nat'l Solid Wastes Mgmt. Ass'n*, 505 U.S. 88, 115 (1992) (Souter, J., dissenting)). To put it another way, field preemption "occurs when federal law occupies a 'field' of regulation 'so comprehensively that it has left no room for supplementary state legislation.'" *Murphy*, 138 S. Ct. at 1480 (quoting *R.J. Reynolds Tobacco Co. v. Durham Cty.*, 479 U.S. 130, 140 (1986)). Where Congress has made this determination, States may not regulate in the same "field," even where those regulations might be "parallel to federal standards." *Arizona*, 567 U.S. at 401.

Plaintiff has argued that Congress occupied the field specifically as to drugs subject to a REMS which include "elements to assure safe use." Pl.'s Opp'n to Def. Morrisey's Mot. to Dismiss at 9.[13] A subset of REMS must contain "elements to assure safe use," if the Secretary determines that the regulated drug requires such elements "as part of [a] strategy to mitigate a specific serious risk listed in the labeling of the drug." 21 U.S.C. § 355-1(f)(1). These drugs, Plaintiff asserts, are subject to a more "pervasive framework" than other drugs regulated under the FDCA, utilizing the imperative "shall" when instructing the FDA to consider patient "access" in making REMS determinations. Pl.'s Opp'n to Def. Morrisey's Mot. to Dismiss at 9. Essentially, once the FDA concludes a REMS including such elements is necessary for a drug, the FDA is required to take a series of steps in promulgating a REMS including elements to

[13] While Plaintiff's Opposition appears to argue that Congress occupied the field as to all drugs subject to a REMS, at oral argument GenBioPro clarified that its field preemption argument is only as to drugs subject both to a REMS and to additional elements to assure safe use. *See* Tr. of Proceedings at 34-35, ECF No. 62.

assure safe use. *See* 21 U.S.C. §§ 355-1(a), (c), (f), (h). Plaintiff believes this requirement is sufficient to demonstrate that Congress has "occupied the field" when it comes to such drugs.

In reply, Defendant Morrisey points to the FDCA's 1962 express saving clause, demonstrating Congressional intent for state law to play a complementary role in the field. Reply in Supp. of Mot. to Dismiss at 6, ECF No. 45. Defendant Morrisey notes that "the presence of a savings provision 'is fundamentally incompatible with complete field preemption.'" *Id*. (quoting *Farina v. Nokia Inc.*, 625 F.3d 97, 121 (3d Cir. 2010); *Aldridge v. Miss. Dept. of Corr.*, 990 F.3d 868, 874-75 (5th Cir. 2021); *In re NOS Commc'ns*, 495 F.3d 1052, 1058 (9th Cir. 2007)). Included in the 1962 Amendments to the FDCA, the saving clause has been interpretated to allow for state tort law's complementary role in shaping safety standards for products regulated under the FDCA. *See Wyeth*, 555 U.S. 555. Accordingly, the Court agrees that the 1962 saving clause has foreclosed any argument for complete field preemption. However, Plaintiff has been clear in its assertion that Congress has only occupied the field as to a subsection of drugs subject to a REMS with elements to assure safe use. *See* Pl.'s Opp'n to Def. Morrisey's Mot. to Dismiss at 9.

Nevertheless, Plaintiff's argument fails for want of Congressional intent in the FDAAA amendments, as discussed in depth above. Where Congress acts in a field traditionally occupied by the States, the presumption against preemption is strongest. *Wyeth*, 555 U.S. at 565. There is no disputing that health, medicine, and medical licensure are traditional areas of state authority. *See, e.g.*, *Hillsborough*, 471 U.S. at 716. Furthermore, the Supreme Court has repeatedly held that the FDCA does not preempt state action in the field of healthcare or medicine, absent a direct conflict. *Compare Wyeth,* 555 U.S. at 581 (not finding preemption because state tort law did not directly conflict with FDCA), *with Bartlett*, 570 U.S. at 486-87 (finding preemption due

to direct conflict between state tort law and FDCA labelling requirements). While the Supreme Court has yet to address the wrinkles of the REMS provision, Plaintiff has not advanced a convincing argument that the Court would treat that statutory subsection differently than any other portion of the FDCA.

To that end, Plaintiff cites *United States v. Locke*, 529 U.S. 89 (2000). In *Locke*, Washington State passed more stringent regulations on oil tankers than existed under the national regulatory scheme. *See id*. at 97. Washington's personnel qualifications for oil tanker employees were found to be preempted by federal requirements, given historical federal occupation of the field. *Id*. at 112-15. In reaching this conclusion, the *Locke* Court emphasized that the Coast Guard was given non-discretionary authority to ensure oil tanker personnel met the minimum federal requirements. *Id*. at 115-16. Here, Plaintiff argues that the FDA is subject to a similarly non-discretionary requirement that it ensure drugs which require both a REMS and elements to assure safe use consider access in promulgating those elements. *See* Pl.'s Opp'n to Def. Morrisey's Mot. to Dismiss at 9; 21 U.S.C. § 355-1(f)(1)-(3). Therefore, just as the *Locke* Coast Guard only must ensure oil tanker employees meet minimum qualification requirements, GenBioPro asserts that the FDA has been commanded to ensure mifepristone is available subject only to its REMS.

However, *Locke* is distinguishable for several reasons. First, the *Locke* Court repeatedly emphasized that regulating interstate navigation is historically an area of federal concern, dating back to the Constitutional Convention; here, the Court has found the opposite is true. *Id*. at 99-100; *see Hillsborough*, 471 U.S. at 716; *Dobbs*, 142 S. Ct. at 2248-55 (discussing the history of abortion laws). Second, much of *Locke* circled around a preemption savings clause in the Oil Pollution Act of 1990, which indicated Congress only intended to leave room for complementary state action in a specified area of discretionary federal authority. 529 U.S. at 105-06. In contrast,

the Supreme Court has found the 1962 FDCA saving clause to contain breadth, given the general language of the clause, the historical state police powers implicated, and the fact Congress included express preemption provisions in a different amendment to the FDCA. *Wyeth*, 555 U.S. at 567. Conversely, *Locke* found that a particular sub-field of an area of historical federal concern had been fully occupied by Congress, given the existence of a separate preemption saving clause indicating a differing sub-field would permit complementary state action. The limited language in the *Locke* opinion focusing on the Coast Guard command must be read in this broader context, which stands in stark contrast to the manner in which the Court has treated how traditional state authority over healthcare has been affected by the FDCA.

Accordingly, the Court finds that Congress has not expressed an intent to occupy the field of drugs subject to a REMS in a manner which would preempt West Virginia's abortion restrictions.

c. Telemedicine Restriction

There is one provision which is unambiguously preempted by the 2023 REMS: the prior restriction on prescribing mifepristone via telemedicine. *See* W. Va. Code §§ 30-3-13a(g)(5); 30-1-26(b)(9). Unlike the other prior restrictions, the telemedicine provision is still in effect. *See* W. Va. Code § 16-2R-9. Accordingly, the Court's finding that the UCPA is not preempted by the REMS is irrelevant to consideration of the telemedicine restriction. The 2023 REMS reflects a determination by the FDA that when mifepristone is prescribed, it may be prescribed via telemedicine.[14]

[14] Again, the Court notes that the Fifth Circuit's recent decision in *Alliance for Hippocratic Medicine* stayed the 2023 REMS and the 2021 FDA decision to allow prescription of mifepristone via telemedicine. *See* 2023 WL 5266026, at *1-2. Therefore, this Court's decision as to the West Virginia telemedicine restriction will not change the current Fifth Circuit injunction prohibiting telemedicine, subject to the Supreme Court's order. *See id*. at 4.

The telemedicine restriction is not "upstream" from the REMS, in the manner of the UCPA. Rather than indicating what procedures are allowed in West Virginia, the telemedicine restriction dictates the manner in which mifepristone may be prescribed. This is a determination which Congress has allocated to the FDA. 21 U.S.C. § 355-1(f)(3)(C) (stating that a REMS may include a restriction specifying that "the drug be dispensed to patients only in certain health care settings, such as hospitals."). The FDA has evaluated the criteria Congress designated and has come to the reasoned conclusion that mifepristone may be prescribed via telemedicine. 2023 REMS. This conflict between the REMS and the state statute creates the kind of impossibility preemption discussed above—a licensed medical professional prescribing mifepristone could not comply with both the access determination made by the FDA and the access determination made by West Virginia as to telehealth.

The other prior restrictions might be likewise preempted by direct conflict with the REMS, as they similarly dictate the way mifepristone may be prescribed. *See* W. Va. Code § 16-2I-2. Regardless, the Court has not found that the UCPA is unconstitutional. As none of these prior restrictions are currently in effect, this Court may not issue an advisory opinion as to the constitutionality of a law not presently operative.

Accordingly, Defendants' Motions to Dismiss Count I are **DENIED,** as to the telemedicine restriction, and **GRANTED**, as to the UCPA and other prior restrictions.

C. Dormant Commerce Clause

The Commerce Clause grants Congress the power to regulate interstate commerce. U.S. Const. Art. I, § 8, cl. 3. The Supreme Court has long recognized that the Commerce Clause contains a corollary command, "effectively forbidding the enforcement of certain state economic

regulations even when Congress has failed to legislate on the subject." *Nat'l Pork Prod. Council v. Ross*, 143 S. Ct. 1142, 1152 (2023) (quoting *Okla. Tax Comm'n v. Jefferson Lines, Inc.*, 514 U.S. 175, 179 (1995)) (cleaned up). Known as the "dormant Commerce Clause," this doctrine has previously been characterized as forbidding States from enacting laws which either discriminate against interstate commerce or regulate extraterritorially. *See, e.g.*, *Ass'n for Accessible Medicines v. Frosh*, 887 F.3d 664, 667-69 (4th Cir. 2018) (relying on *Healy v. Beer Inst.*, 491 U.S. 324, 335–36 (1989); *Brown-Forman Distillers Corp. v. N.Y. State Liquor Auth.*, 476 U.S. 573, 582–83 (1986); *Edgar v. MITE Corp.*, 457 U.S. 624, 642–43 (1982) (plurality opinion); *Baldwin v. G.A.F. Seelig, Inc.*, 294 U.S. 511, 521 (1935)). Even if a law did not discriminate or regulate extraterritorially, it could still fail the "balancing test" announced in *Pike v. Bruce Church*, 397 U.S. 137 (1970). Under this standard, if plaintiffs can demonstrate that the challenged law burdens interstate commerce, then the Court determines "whether the State's interest is legitimate and whether the burden on interstate commerce clearly exceeds the local benefits." *Id*. at 142; *see Nat'l Pork*, 143 S. Ct. at 1165-66 (Sotomayor, J., concurring) (discussing the threshold burden requirement for *Pike* balancing).

On May 11, 2023, the Supreme Court issued its decision in *National Pork Producers Council v. Ross*, 143 S. Ct. 1142 (2023). *National Pork* affirmed a lower court decision to dismiss a pork industry plaintiff's challenge to a California law limiting the sale of certain kinds of pork in the State. The pork plaintiffs argued that the law violated the dormant Commerce Clause by forcing them to broadly change their business practices. *Id*. at 1151. As a preliminary matter, the Court rejected plaintiff's interpretation of *Healy*, *Brown-Forman*, *Edgar*, and *Baldwin* as engendering an "almost per se rule" against extraterritoriality.[15] *Id*. at 1154-57. Accordingly, this Court finds

[15] The Court appeared to limit dormant Commerce Clause extraterritoriality claims to statutes

that to whatever extent the Fourth Circuit's dormant Commerce Clause jurisprudence employed a similar "principle against extraterritoriality" founded in those same cases, it has been abrogated by *National Pork*. *See Ass'n for Accessible Med.*, 887 F.3d at 667-69. While Justice Gorsuch's majority opinion could not come to a consensus on the application of the *Pike* balancing test to the pork industry group's claims, in three partial concurrences a minimum of six Justices[16] upheld some form of *Pike* balancing. *See id*. at 1165-72. At least a plurality held that "derivative harms" of legislation may be considered when employing the *Pike* balancing test. *Id*. at 1169 (Roberts, C.J., concurring in part); *see id*. at 1165-66 (Sotomayor, J., concurring in part) (potentially supporting usage of derivative harms as a factor in *Pike* analysis). Throughout, the opinions emphasize that an "antidiscrimination principle lies at the 'very core' of our dormant Commerce Clause jurisprudence," forbidding States from enacting statutes "driven by economic protectionism." *Id*. at 1153 (majority).

In its Opposition to Defendant Morrisey's Motion to Dismiss, Plaintiff argues that the challenged statutes "violate the Clause by imposing an undue burden on interstate commerce, by regulating extraterritorially, and by functionally banning an article of commerce." Pl.'s Opp'n to Def. Morrisey's Mot. to Dismiss at 23. However, following the decision in *National Pork*, this

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that discriminate against interstate commerce by tying in-state prices to out-of-state prices. *Id*. at 1154-55 (relying on *Healy*, 491 U.S. 324).

[16] As this Court reads *National Pork*, Justices Sotomayor and Kagan upheld *Pike*'s balancing test with no further elaboration, stating only that plaintiff had failed to meet the threshold requirement for consideration under *Pike*. *Id*. at 1165-66. Chief Justice Roberts and Associate Justices Alito, Kavanaugh, and Jackson applied *Pike* to the facts of the case, further interpreting the balancing test. *Id*. at 1167-72.

Justices Gorsuch, Barrett, and Thomas's view might be interpreted as upholding *Pike* as applying only to cases in which commensurate values could be balanced. *Id*. at 1159-61; 1166-67 (Barrett, J., concurring). Whether one considers that view to be upholding traditional *Pike* balancing or as partially overturning *Pike* likely depends on whether one agrees with the arguments made by those Justices. Regardless, this opinion is clearly the minority and will not be applied here.

Court ordered the parties to file supplemental briefing addressing how *National Pork*'s holding applied to the instant allegations. ECF No. 55. GenBioPro's Supplemental Brief admits that *National Pork* forecloses the Complaint's argument that West Virginia has violated the dormant Commerce Clause by regulating extraterritorially. Pl.'s Supp. Br. at 14-15, ECF No. 58. This Brief further re-categorizes GenBioPro's argument that the Clause was violated by "functionally banning an article of commerce" as a factor of consideration under the *Pike* balancing test, rather than as an independent means by which West Virginia could have violated the Clause. *Compare* Pl.'s Opp'n to Def. Morrisey's Mot. to Dismiss at 27, *with* Pl. Supp. Br. at 11-12. Therefore, the Court will only consider whether the Complaint has plausibly alleged that the challenged laws fail the *Pike* balancing test, in light of any recent refinement of *Pike* by *National Pork*.

Post-*National Pork*, Plaintiff asserts that West Virginia's laws fail that test for three reasons: "(1) they intrude on an area in which Congress requires nationally uniform regulation; (2) they functionally ban a product for its indicated use; and (3) they inflict 'derivative harms' by imperiling the health and safety of pregnant West Virginians and the national market for medications." Pl.'s Supp. Br. at 7. The Court will consider each asserted ground in turn.[17] But first, the Court notes that *National Pork* made clear that *Pike* balancing is meant to "serve[] as an important reminder that a law's practical effects may also disclose the presence of a discriminatory purpose." 143 S. Ct. at 1157. While the Court recognized that "a small number of our cases have invalidated state laws that appear to have been genuinely nondiscriminatory,"

[17] The Court acknowledges Defendant Morrisey's analysis of the potentially conflicting concurrences in *National Pork*, and their implications to the present dispute. *See* Def.'s Supp. Br., ECF No. 59. In fact, Defendant's Supplemental Brief contains a more prudent jurisprudential approach to applying *National Pork* to Plaintiff's Complaint. However, at the Motion to Dismiss stage, the Court takes care to draw all reasonable inferences in favor of the non-moving party and therefore employs Plaintiff's proffered post-*Pork* approach in dismissing its claims. Accordingly, Defendant Morrisey's crisp application of conflicting doctrine is valued but not utilized here.

they referred to ferreting out discriminatory laws as the "heartland" of the *Pike* test. *Id*. GenBioPro's claim falls far outside of this heartland, declining to assert that West Virginia was motivated by economic protectionism or that it had a discriminatory intent in passing the UCPA. As with the pork plaintiffs, this "is not an auspicious start." *Id*.

a. Required Nationally Uniform Regulation

Plaintiff distinguishes the holding in *National Pork*, arguing that while the pork plaintiff was merely concerned with the "cost of compliance," GenBioPro is concerned about "an area where there is a compelling need for national uniformity." Pl.'s Supp. Br. at 8 (quoting *Yamaha*, 401 F.3d at 572).

Yet again, regulation of health, medicine, and the medical profession are areas in which the States have traditionally exercised authority. *E.g.*, *Hillsborough*, 471 U.S. at 716. Accordingly, the Supreme Court has repeatedly found that there is a complementary role for state law, even where Congress has acted to regulate health and medicine. *E.g.*, *Wyeth,* 555 U.S. at 581. If Congress had created a system mandating national uniformity, the Court would expect to see some evidence of intent to preempt historical complementary state action. As analyzed in depth above, here there is no such expressed intent to occupy the field. A "compelling need for national uniformity" could exist absent field preemption, of course, but GenBioPro has not plausibly alleged any such need.

Most importantly, it's unclear where *National Pork* or its predecessors indicate that a "compelling need for national uniformity" entails a dormant Commerce Clause violation pursuant to *Pike*. Plaintiff points to language in the Chief Justice's concurrence. *See Nat'l Pork*, 143 S. Ct. at 1170 ("The *Pike* balance may well come out differently when it comes to interstate transportation, an area presenting a strong interest in 'national uniformity.'"). However, the

majority opinion dispensed of this interpretation. *Id*. at 1158 n.2. ("[T]his Court has only rarely held that the Commerce Clause itself pre-empts an entire field from state regulation, and then only when a lack of national uniformity would impede *the flow* of interstate goods." (internal quotation marks omitted, emphasis in original)). There is no argument that the UCPA or other restrictions impede *the flow* of mifepristone nationally.

b. Banning an Article of Commerce

GenBioPro's argument that the UCPA fails the *Pike* test by functionally banning an article of commerce is misplaced. In making this argument, Plaintiff leans heavily upon an 1898 case in which the Court found that the dormant Commerce Clause forbids States from banning "oleomargarine" as an "article of commerce." Pl.'s Supp. Br. at 11 (citing *Schollenberger v. Pennsylvania*, 171 U.S. 1 (1898)). In *Schollenberger*, the Court stated that

> The general rule to be deduced from the decisions of this court is that a lawful article of commerce cannot be wholly excluded from importation into a state from another state where it was manufactured or grown. A state has power to regulate the introduction of any article, including a food product, so as to insure [sic] purity of the article imported, but such police power does not include the total exclusion even of an article of food.

171 U.S. at 12. Be that as it may, the Court finds that *National Pork* put to rest any debate over whether States may enact product bans under their police power. Without acknowledging the existence of the oleomargine case, the various fractured opinions in *National Pork* made it clear that state bans of products as diverse as horsemeat, fireworks, and plastic bags do not offend the United States Constitution. 143 S. Ct. at 1163 (plurality); 1171 (Roberts, C.J., concurring) (responding to the plurality by arguing the broader market is affected by California's economy, rather than arguing a per se rule against banning products); 1150 (majority) ("While the Constitution addresses many weighty issues, the type of pork chops California merchants may sell is not on that list."). Circuit Courts have upheld both partial and full bans of foie gras,

horsemeat, and shark fins in the face of dormant Commerce Clause challenges. *See Ass'n des Eleveurs de Canards et d'Oies du Quebec v. Harris*, 729 F.3d 937 (9th Cir. 2013) (foie gras); *Cavel Int'l, Inc. v. Madigan*, 500 F.3d 551 (7th Cir. 2007) (horsemeat); *Chinatown Neighborhood Ass'n v. Harris*, 794 F.3d 1136 (9th Cir. 2015) (shark fins). Relevant to the instant case is the fact that many of the bans upheld by the Appellate Courts and name-checked by the Supreme Court plurality were enacted under state police power to regulate the health and morality of the community—the same authority under which the UCPA and other provisions were enacted. *See, e.g.*, *Cavel Int'l,* 500 F.3d at 555, 557 (finding a ban on horsemeat to be within the state's power to regulate animal welfare); *Nat'l Pork*, 143 S. Ct. at 1163 (plurality; citing *Cavel Int'l*).

Plaintiff attempts to distinguish product bans which *National Pork* found acceptable from the "ban" of mifepristone,[18] arguing that "(1) the products involved are not necessities," "(2) they often cause severe harms or offer little public benefit, and (3) Congress did not subject these items to an integrated, and inherently national, system . . . much less limit 'burdens' on that system." Pl.'s Supp. Br. at 11. First, the Court finds that the determination that any given product is a "necessity" invites the Court to engage in second-guessing of state legislatures, with no limiting principle. Second, and similarly, the conclusion that any given product causes "severe harms or offer[s] little public benefit" is surely one for the legislative body enacting any given statutory ban—not for this Court. Furthermore, at oral argument in *National Pork*, the plaintiff pressed the Court to distinguish bans enacted for health and safety from bans enacted solely pursuant to a State's moral authority; the Court declined. *See Nat'l Pork*, 143 S. Ct. at 1160.

[18] Plaintiff characterizes the UCPA and other restrictions as a "functional ban" of mifepristone. Pl.'s Supp. Br. at 11-12. Given the exceptions enumerated within the UCPA (and the fact mifepristone is not regulated directly by any of the challenged provisions), the Court is skeptical of this claim. *See* W. Va. Code § 16-2R-3(a) & (b).

Finally, while Plaintiff claims "[h]orsemeat and shark fins fit those three criteria," this is incorrect; both animal products are subject to an "inherently national system," demonstrating that such products may be subject to state bans. *See, e.g.*, FMIA, 21 U.S.C. § 601 *et seq.* (regulating horsemeat); Shark Conservation Act of 2010, Pub. L. 111–348; 124 Stat. 3668 (regulating shark fins).[19] More fundamentally, the Court cannot find any support in *National Pork* for the proposition that any of these criteria should be considered when considering state law limitations on the sale of consumer goods.

Accordingly, the Court finds that impeding the sale of an "article of commerce" is not an intrinsic violation of the dormant Commerce Clause, and that *Schollenberger* has been abrogated.[20] If West Virginia has "functionally banned" mifepristone, it was well within its rights to do so.

c. Derivative Harms

Next, Plaintiff argues that, under *Pike*, non-economic "derivative harms" caused by the UCPA and challenged restrictions should be weighed against the putative benefits or interests of the State in enacting the legislation. Pl.'s Supp. Br. at 12-14.

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[19] The Shark Conservation Act of 2010 ("SCA") amended the High Seas Driftnet Fishing Moratorium Protection Act and the Magnuson-Stevens Fishery Conservation and Management Act ("MSA") to require all sharks caught in the United States be brought to shore with their fins naturally attached. Pub. L. 111–348; 124 Stat. 3668. The SCA is the most recent in a series of actions taken by the federal government to regulate shark finning. *See, e.g.*, The Shark Finning Prohibition Act of 2000, Pub. L. 106-557; 114 Stat. 2772. The caselaw referenced by Plaintiff found that a ban on possession of shark fins—even when those fins were obtained legally pursuant to the federal finning scheme—was neither preempted by the MSA nor in violation of the dormant Commerce Clause. *See Chinatown Neighborhood Association*, 794 F.3d 1136. As might be inferred, the parallels between *Chinatown* and the instant case are not particularly favorable to GenBioPro.

[20] This is not the first Court to conclude that a literal interpretation of *Schollenberger* would be anomalous and out-of-step with modern dormant Commerce Clause jurisprudence. *See Association des Eleveurs*, 729 F.3d at 949-50 (implicitly interpreting *Schollenberger* to apply only where a "nationally uniform business" and national system of regulation are implicated).

GenBioPro asserts derivative harms "to pregnant West Virginians by depriving them of essential medicine." Pl.'s Supp. Br. at 13. First, while this Court has granted Plaintiff third-party standing to pursue the interests of its vendees, it has not granted GenBioPro third-party standing as to "pregnant West Virginians." Nor has Plaintiff petitioned the Court to consider these interests prior to this Supplemental Brief. The Court does not doubt, however, that there are substantial derivative harms to pregnant West Virginians caused by a decrease in access to mifepristone.

Unfortunately, the Court cannot consider any such holistic derivative harms to pregnant West Virginians under *Pike* balancing. As fractured as *National Pork* is, the scant emphasis on "derivative harms" within the concurring opinion clarifies that—in the context of the dormant Commerce Clause—such harms are primarily economic in nature. *See* 143 S. Ct. at 1169 ("Our precedents have long distinguished the costs of complying with a given state regulation from *other economic harms to the interstate market*." (emphasis added)). The concurrence focused on harms to interstate commerce and interstate trade generally—such as difficulties in interstate shipping and employment—rather than harms to individuals within the challenged State. *Id*. (discussing *Bibb v. Navajo Freight Lines, Inc.*, 359 U.S. 520 (1959)). Again, in discussing application of *Pike*, the Chief Justice's concurrence emphasizes that these are derivative "harms to the interstate market" which are "in no sense noneconomic." *Id*. (internal quotation marks omitted). Accordingly, this Court concludes that derivative harms to pregnant West Virginians are not the type of harm it may consider when employing the *Pike* balancing test.

Plaintiff also argues that the UCPA and restrictions "upend the national market for drugs." Pl.'s Supp. Br. at 13. A state law which spawned chaos in the national prescription drug market would likely cause the type of derivative economic and interstate harm which could be

considered under the *Pike* balancing test. But the Court is not convinced that Plaintiff has plausibly pled facts to support any "upending" of the national market for mifepristone caused by West Virginia's legislation. Further, as alluded to above, many States restrict abortion in a manner which likely limits the sale of mifepristone. *See, e.g.*, Miss. Code Ann. § 97-3-3(1) (banning abortion with very limited exceptions). Plaintiff has not alleged that the national prescription drug market has been upended by the incidental restriction of mifepristone in many States.

d. *Pike* Threshold Showing

The Court appreciates the gravity of Plaintiff's claims and has taken pains to address them at length above—but even if Plaintiff were correct that national uniformity, functionally banning an article of commerce, and the various alleged derivative harms were sufficient to swing the *Pike* balance in GenBioPro's favor, the Court remains skeptical that Plaintiff could meet the threshold burden necessary to invoke *Pike*. Admittedly, it's unclear what exactly a party would need to do to meet the threshold to be considered under the *Pike* balancing test, as muddled by *National Pork*. Justice Sotomayor's concurrence in *National Pork* averred that the pork producers had failed to meet this threshold burden, without elaboration into the facts of the case. 143 S. Ct. at 1165. This confusion is another reason the Court has considered the *Pike* claims at length above.

Regardless of whether it met the threshold burden, the pork producer plaintiff in *National Pork* plausibly alleged significant disruption to the national pork industry. *See id*. at 1151-52. Due to the size of the California market, the national producers of pork alleged they would be compelled to alter their national production standards in order to continue to sell within California. *Id*. And yet, it appears a majority of the Justices found this insufficient to meet the threshold "burden on interstate commerce" required under *Pike*. Here, Plaintiff has undoubtedly

alleged less of a burden on interstate commerce than was alleged by the pork producers. None of West Virginia's laws require Plaintiff to alter its national production methods in order to access the State's market. Nor will compliance with the UCPA and other restrictions entail broad re-working of the entire pharmaceutical industry. At most, Plaintiff has plausibly alleged that one prescription medication will be prescribed less for one indicated purpose within one State.

Another comparison: in *Association for Accessible Medicine v. Frosh*, the Fourth Circuit found that a Maryland statute regulating pharmaceutical price-gouging burdened interstate commerce in prescription drugs in violation of the dormant Commerce Clause. 887 F.3d at 673. There, the Court of Appeals found that the challenged statute "set[] prescription drug prices in a way that 'interfere[s] with the natural function of the interstate market' by superseding market forces that dictate the price of a good." *Id*. (quoting *McBurney v. Young*, 569 U.S. 221, 235 (2013)). Accordingly, if many States adopted laws analogous to the Maryland act, there was the potential to create "the kind of competing and interlocking local economic regulation that the Commerce Clause was meant to preclude." *Id*. at 674 (quoting *Healy*, 491 U.S. at 337). There is no such potential here. The UCPA can hardly be characterized as an economic regulation, and even if every State adopted a differing regulation on when abortion is permissible—and, to be frank, *this has already happened*—it would not entail competition on mifepristone pricing between the States.

States enact laws pursuant to their police power to regulate public health and morality. Morality-based laws often curtail the sale of goods. The vendors of curtailed goods may lose sales opportunities. Outraged, vendors can feel the laws must somehow be unconstitutional. And yet, the Supreme Court and Courts of Appeals have repeatedly affirmed that morality-based

product bans do not intrinsically offend the dormant Commerce Clause. Accordingly, Defendants' Motions to Dismiss Count II are **GRANTED**.

IV. CONCLUSION

Defendant Mark A. Sorsaia and Defendant Patrick Morrisey's Motions to Dismiss (ECF Nos. 17 & 19) are **GRANTED,** in part, and **DENIED** in part.

The Court **DIRECTS** the Clerk to send a copy of this Order to counsel of record and any unrepresented parties.

ENTER: August 24, 2023

ROBERT C. CHAMBERS
UNITED STATES DISTRICT JUDGE