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 is Defendant Mark A. Sorsaia's Rule 12(b)(1) and Rule 12(b)(6) Motion to Dismiss for Failure to State a Claim (ECF No. 17) and Defendant Patrick Morrisey's Motion to Dismiss (ECF No. 19). For the following reasons, the Motions are **DENIED** as to their arguments concerning standing. The Court holds in abeyance the remainder of the Motions.

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. This expressly includes abortions performed or induced via "medicine" or "drug." W. Va. Code § 16-2R-2. The UCPA 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-

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[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).

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).

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 their product to the FDA. Compl. ¶ 55. The FDA approved the proposed REMS in 2011. *Id*. The 2011 REMS[3] required that Mifeprex only be prescribed by certified physicians, 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]

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[3] U.S. Food & Drug Admin., NDA 20-687 MIFEPREX (mifepristone) Tablets, 200 mg, Risk Evaluation and Mitigation Strategy (REMS) (June 2011), https://www.fda.gov/media/164648/download.

[4] U.S. Food & Drug Admin., NDA 020687 MIFEPREX (mifepristone) Tablets, 200 mg, Risk Evaluation and Mitigation Strategy (REMS) (Mar. 2016), https://www.fda.gov/media/164649/download.

[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://www.fda.gov/media/164650/download.

Id. ¶¶ 60-61. 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 medication either by mail or from certified pharmacies. *Id*. ¶ 66.

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 that issue is now ripe for adjudication.

II. LEGAL STANDARD

Article III of the United States Constitution limits the jurisdiction of federal courts to "cases" and "controversies." U.S. Const. art. III, § 2. The Supreme Court has interpreted this as a

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[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://www.accessdata.fda.gov/scripts/cder/rems/index.cfm?event=RemsDetails.page&REMS=390 (last accessed Apr. 27, 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://www.accessdata.fda.gov/drugsatfda_docs/rems/Mifepristone_2023_03_23_REMS_Full.pdf [hereinafter 2023 REMS].

requirement that plaintiffs demonstrate an "irreducible minimum" to establish standing: (1) an injury in fact, (2) which is fairly traceable to the allegedly offensive conduct, and (3) which is likely to be redressed by a favorable decision from the court. *Lujan v. Defs. of Wildlife*, 504 U.S. 555, 560-61 (1992). "[E]ach element [of standing] must be supported in the same way as any other matter on which the plaintiff bears the burden of proof, i.e., with the manner and degree of evidence required at the successive stages of the litigation." *Id*. at 561. "A defendant may challenge standing at the motion-to-dismiss stage in one of two ways: facially or factually." *Wikimedia Foundation v. Nat'l Sec. Agency*, 857 F.3d 193, 208 (4th Cir. 2017) (quoting *Beck v. McDonald*, 848 F.3d 262, 270 (4th Cir. 2017)) (internal brackets omitted).

A "facial" challenge questions whether the allegations in the complaint are sufficient to sustain the court's jurisdiction. *Thigpen v. United States*, 800 F.2d 393, 401 n.15 (4th Cir. 1986), *rejected on other grounds*, *Sheridan v. United States*, 487 U.S. 392 (1988). If a "facial" challenge is made, the court must accept the allegations in the complaint as true and decide if the complaint is sufficient to confer subject matter jurisdiction. *Id*. On the other hand, a "factual" challenge contests the truthfulness of the factual allegations in the complaint upon which subject matter jurisdiction is based. In this situation, a "district court is to regard the pleadings' allegations as mere evidence on the issue and may consider evidence outside the pleadings without converting the proceeding to one for summary judgment." *Richmond, Fredericksburg & Potomac R.R. Co. v. United States*, 945 F.2d 765, 768 (4th Cir. 1991) (citing *Adams v. Bain*, 697 F.2d 1213, 1219 (4th Cir. 1982); *Trentacosta v. Frontier Pac. Aircraft Indus.*, 813 F.2d 1553, 1558 (9th Cir. 1987)).

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

In his Memorandum of Law in Support of his Motion to Dismiss, Defendant Morrisey argues that Plaintiff GenBioPro lacks Article III standing to pursue its claims, contesting GenBioPro's asserted injury in fact and the alleged redressability of that injury. *See* Mem. in Supp. of Mot. to Dismiss at 6-8, ECF No. 20. Defendant Sorsaia has raised similar arguments in his Motion to Dismiss, and additionally asserts that the injury GenBioPro has raised cannot be traced to his

actions. Mem. of Law in Supp. of Def. Sorsaia's Mot. to Dismiss at 3-4, ECF No. 18. For the following reasons, the Court **DENIES** both Motions as to standing.

A. Injury in Fact

Injuries in fact must be "concrete and particularized" and "actual or imminent" rather than "conjectural or hypothetical." *Lujan*, 504 U.S. at 560. For an injury to be "particularized" it "must affect the plaintiff in a personal and individual way." *Spokeo, Inc. v. Robins*, 578 U.S. 330, 339 (2016). The Supreme Court has also characterized this requirement as not "undifferentiated," *United States v. Richardson*, 418 U.S. 166, 177 (1974) and "distinct," *Whitmore v. Arkansas*, 495 U.S. 149, 155 (1990). For an injury to be "concrete" it must be "de facto," or "real" rather than "abstract"—though not necessarily "tangible." *Spokeo*, 578 U.S. at 340; *see Friends of the Earth v. Laidlaw Environmental Servs., Inc.*, 528 U.S. 167, 181-84 (2000) (involving recreational and aesthetic injuries). In contrast, an injury is not "actual or imminent" when it relies upon so-called "some day" intentions which are too indefinite to confer standing. *Lujan*, 504 U.S. at 564; *Doe v. Obama*, 631 F.3d 157, 162-63 (4th Cir. 2011).

Defendant Morrisey argues that GenBioPro's alleged injury is neither particularized nor concrete, as GenBioPro does not allege "that it has ever sold [medication] abortion drugs in West Virginia, nor does it allege any specific plan to do so." Def. Morrisey's Mem. in Supp. of Mot. to Dismiss at 7. Rather, GenBioPro alleges an injury premised upon its lessened "opportunity and ability to market, promote, and sell" its product within the state, leading to "lost sales, customers, and revenue." Compl. ¶¶ 15, 79. Defendant Morrisey argues this is insufficient, likening GenBioPro's asserted injuries to the insufficient "some day" intentions in *Lujan*. Def. Morrisey's Mem. in Supp. of Mot. to Dismiss at 7. In Response, GenBioPro argues that its injuries are

appropriately alleged economic harm, as well as credibly threatened enforcement of the UCPA against itself or its vendees. Pl.'s Opp'n to Def. Morrisey's Mot. to Dismiss at 3-5. The Court will first consider the parties' arguments as to the alleged economic injury.

"[F]inancial harm is a classic and paradigmatic form of injury in fact." *Air Evac EMS, Inc. v. Cheatham*, 910 F.3d 751, 760 (4th Cir. 2018) (quoting *Cottrell v. Alcon Labs.*, 874 F.3d 154, 163 (3d Cir. 2017)); *see also Adkins v. Rumsfeld*, 464 F.3d 456, 465 (4th Cir. 2006), *cert. denied*, 127 S. Ct. 2972 (2007) (finding an injury which "allegedly inflicts a direct economic harm upon [the plaintiff] is concrete and not hypothetical."). "[W]here a plaintiff alleges financial harm, standing is often assumed without discussion." *Cottrell*, 874 F.3d at 163 (internal quotation omitted). "Any monetary loss suffered by the plaintiff satisfies the injury-in-fact element; even a small financial loss suffices." *Id*. (quoting *Carter v. HealthPort Techs., LLC*, 822 F.3d 47, 55 (2d Cir. 2016)). Applying this principal, the Supreme Court has found that physicians who performed abortions had standing to challenge restrictions on Medicaid payment for abortions, as fewer reimbursed abortions would lead to a loss in physician revenue. *Singleton v. Wulff*, 428 U.S. 106, 113 (1976); *see also Reprod. Health Servs. v. Strange*, 3 F.4th 1240, 1251-52 (11th Cir. 2021) (finding physicians had standing to challenge restrictions on minor patients where less abortions on minors would lead to loss of revenue).

Both the Fourth Circuit and the Supreme Court have found that lost business opportunities are a form of economic injury. *Md. Shall Issue, Inc. v. Hogan*, 971 F.3d 199, 211 (4th Cir. 2020) (citing *Craig v. Boren*, 429 U.S. 190, 194 (1976)). In *Hogan*, the Fourth Circuit found that a firearms store had standing to challenge a state handgun license requirement, due to the business's allegations of lost sales. *Id*. In turn, *Craig* held that a beer vendor had standing to challenge a law limiting the sale of beer to adolescent men, where the vendor could either "heed the statutory

discrimination, thereby incurring a direct economic injury through the constriction of her buyers' market" or suffer potential "sanctions and perhaps loss of license." 429 U.S. at 194. GenBioPro reasons that it has suffered direct economic harm due to its loss of business opportunities to sell mifepristone within West Virginia, and therefore, it is akin to the handgun and beer vendor challenging laws limiting the sale of those goods. Pl.'s Opp'n. to Def. Morrisey's Mot. to Dismiss at 3.

Defendants do not dispute GenBioPro's business interest in selling mifepristone generally. Rather, they argue that because GenBioPro's complaint does not allege the company has ever sold in West Virginia prior to the passage of the UCPA, its claim that it wishes to enter the market now is purely speculative. Reply in Supp. of Mot. to Dismiss at 2-3, ECF No. 45. The Court interprets this as a facial challenge as to whether the allegations in the complaint are sufficient to sustain the court's jurisdiction. *See Thigpen*, 800 F.2d at 401 n.15. Defendant Morrisey emphasizes that the plaintiffs in *Hogan* and *Craig* had past sales in the market they argued was now restricted by statute. Reply in Supp. of Mot. to Dismiss at 2-3. At oral argument, Plaintiff underscored that other courts have found injuries based on market constriction where plaintiffs were not already operating in the targeted market, citing *Ezell v. City of Chicago*, 651 F.3d 684 (7th Cir. 2011), and *303 Creative LLC v. Elenis*, 6 F.4th 1160 (10th Cir. 2021). Upon consideration, the Court agrees that there is no per se requirement to show past sales in order to demonstrate economic injury caused by statutes which constrict potential markets. *See Ezell*, 651 F.3d at 692, 696 (granting a national firing range vendor standing to challenge state firing range restrictions where they merely expressed a desire to open a firing range in Chicago); *303 Creative*, 6 F.4th at 1172 ("Although Appellants have not yet offered wedding website services" their past general website services and intent to offer wedding websites demonstrated standing to challenge statutory restrictions). Absent

any such per se requirement of past presence in the market, the Court applies "its judicial experience and common sense" to determine whether the Complaint plausibly alleges an intent to sell in West Virginia which has been constricted by the challenged statutes. *See Iqbal*, 556 U.S. at 679.

GenBioPro is a well-established manufacturer of a nationally distributed and federally approved product. Compl. ¶ 2. The company's only revenue producing products are medication abortion drugs. *Id*. ¶ 23. Plaintiff attests that it spent nearly a decade working to attain FDA approval for its generic mifepristone. *Id*. ¶¶ 2, 60. GenBioPro's FDA approval allows it to sell mifepristone nationwide. *Id*. ¶ 77. Since Plaintiff received approval from the FDA to sell generic mifepristone, it has sold approximately 850,000 units of the drug. *Id*. ¶ 3. Accordingly, Plaintiff has demonstrated how any constriction of the market for mifepristone would affect it in a particularized manner. *See Spokeo*, 578 U.S. at 339 (discussing particularization of injuries).

Furthermore, the Complaint provides evidence of the growing market for mifepristone, which now accounts for more than half of abortions in the United States. *Id*. ¶ 76. Plaintiff asserts that several nationwide pharmacy chains—some of which have locations in Putnam County—have evinced a desire to sell mifepristone but are prevented from doing so by West Virginia's statutes and Defendants' threatened legal action. *Id*. ¶¶ 75, 78, 80. While mifepristone is approved by the FDA for medication abortion up to ten weeks gestation, West Virginia's UCPA limits "medicine" abortion to an extremely narrow set of circumstances. *See id*. ¶ 83; W. Va. Code § 16-2R-3. The prior restrictions on prescription of mifepristone via telemedicine likewise conflict with the REMS. *See* Compl. ¶¶ 66, 86, 88; W. Va. Code §§ 30-3-13a(g)(5); 30-1-26(b)(9). The Court concludes that there is nothing "conjectural or hypothetical" about GenBioPro's affirmations that it would be selling its product to a wider market in West Virginia were it not for the UCPA and prior

restrictions. *See Spokeo*, 578 U.S. at 339. Accordingly, the Court finds that GenBioPro's Complaint plausibly alleges a sufficiently concrete intent to access the market in West Virginia, which arguably is stymied by the UCPA and prior restrictions.

GenBioPro has plausibly asserted a sufficiently concrete and particularized injury in fact. As the Court has found that GenBioPro has plausibly alleged injury in fact based on economic harms, it need not determine whether the UCPA's provisions are sufficiently vague to subject Plaintiff to potential criminal liability.

B. Redressability

It is insufficient to show merely that Plaintiff has been injured; that injury must be traceable to Defendants and redressable by the relief requested from the Court. *Lujan*, 504 U.S. at 560-61. Here, the relief requested by GenBioPro is a declaratory judgment that both the UCPA and the prior restrictions are invalid under the Constitution. Compl. at 32. Defendants have argued that Plaintiff's injury would not be redressed by this relief, as (1) redressability is impermissibly dependent on the third-party action of "medical professionals," and (2) the Comstock Act bars relief. Def. Morrisey's Mem. in Supp. of Mot. to Dismiss at 7-8. Further, Defendant Morrisey asserts that the alleged injuries caused by the pre-UCPA restrictions on dispensation of mifepristone cannot be redressable, as those restrictions are not currently operative. *Id*. at 8. In rebuttal, Plaintiff reiterates that if this Court were to find West Virginia's statutes to be unconstitutional, then the statutory restrictions on the market for their products would be eased. Pl.'s Opp'n. to Def. Morrisey's Mot. to Dismiss at 5-7.

In determining whether standing exists, "[t]he relevant inquiry is whether … the plaintiff has shown an injury to himself that is likely to be redressed by a favorable decision." *Simon v. E. Ky.*

Welfare Rights Org., 426 U.S. 26, 38 (1976). However, redressability does not require that the injury be completely ameliorated. *See Massachusetts v. EPA*, 549 U.S. 497, 526 (2007).

a. Alleged Dependence on Third-Party Action

Defendant Morrisey argues that Plaintiff's injury is not redressable by the relief requested, as invalidation of the statutes does not necessarily entail that "medical professionals" will prescribe or purchase mifepristone from GenBioPro. Therefore, he argues the relief requested is impermissibly dependent on third-party action. Def. Morrisey's Mem. in Supp. of Mot. to Dismiss at 7-8.

The Court disagrees. None of the cases in which doctors, contraceptive providers, or other vendors were found by the Supreme Court to have standing found that relief was impermissibly premised on third-party customer sales. *See, e.g.*, *Singleton*, 428 U.S. at 113 (finding that doctors providing abortion care had standing where they would suffer economic loss due to restrictions on abortion); *Carey v. Population Servs. Int'l*, 431 U.S. 678, 682–84 (1977) (finding contraceptive vendor had standing to challenge restriction on contraceptive sales); *Craig*, 429 U.S. at 194 (finding beer vendor had standing to challenge restriction on beer customers). Just as the Supreme Court has in the past assumed that people will continue to seek beer, contraceptives, and abortion, the Court finds here that it is reasonable to assume pharmacies and doctors will continue to prescribe and purchase abortion medication. This inference is supported by the fact that medication abortion is the most common form of abortion in the United States. Compl. ¶ 76. Furthermore, the Complaint alleges that pharmacies with locations in West Virginia have stated they would sell mifepristone, absent the statutory restrictions. *Id*. ¶ 78. At the motion to dismiss stage, the Court accepts these factual allegations as true. *See Iqbal*, 556 U.S. at 678.

Simply put, the Court finds the argument that no medical practitioner or pharmacy in the state of West Virginia would ever prescribe or sell mifepristone to be facially implausible. More abstractly, the underlying injury asserted by Plaintiff is constriction of the market it sells within, and the relief requested would redress that market constriction—even if every "medical professional" in the state declined to buy from Plaintiff, it would still have an increased opportunity to "market its product in West Virginia." *See* Compl. ¶ 77. Accordingly, the Court rejects Defendant Morrisey's argument.

b. The Comstock Act

Next, Defendant Morrisey argues that even if the Court were to grant the relief requested, Plaintiff's business would still be illegal under the Comstock Act, thereby negating redressability. Def. Morrisey's Mem. in Supp. of Mot. to Dismiss at 7-8. The Court finds that this argument is without merit.

The Comstock Act of 1873 declares that "[e]very article or thing designed, adapted, or intended for producing abortion," as well as "[e]very article, instrument, substance, drug, medicine, or thing which is advertised or described in a manner calculated to lead another to use or apply it for producing abortion," is "nonmailable matter" that the United States Postal Service ("USPS") may not lawfully deliver. 18 U.S.C. § 1461. While the plain language of the statute arguably encompasses GenBioPro's business model, the Comstock Act is currently understood to apply only to use of the mails in an illegal manner. Courts have held this consistently since 1915. *See Bours v. United States*, 229 F. 960 (7th Cir. 1915); *Davis v. United States*, 62 F.2d 473 (6th Cir. 1933); *United States v. One Package*, 86 F.2d 737 (2d Cir. 1936); *Consumers Union of United States, Inc. v. Walker*, 145 F.2d 33 (D.C. Cir. 1944). The Department of Justice's current

enforcement interpretation concurs. Dept. of Justice, Application of the Comstock Act to the Mailing of Prescription Drugs that Can Be Used for Abortions, Mem. Op. for the Gen. Couns. USPS (Dec. 23, 2022).

While Defendant Morrisey has obliquely threatened legal action against pharmacies willing to distribute mifepristone in West Virginia, he does not have the authority to enforce federal law. *See* Compl. ¶ 75. To reiterate, the entity with that enforcement authority—the Department of Justice—has stated that it will not enforce the Comstock Act against legal vendors of mifepristone. Dept. of Justice, Application of the Comstock Act to the Mailing of Prescription Drugs that Can Be Used for Abortions, Mem. Op. for the Gen. Couns. USPS (Dec. 23, 2022). Accordingly, this Court declines to find that a widely abrogated 19th century statute which the federal government will not enforce bars redressability here.

c. Redressability as to the Prior Restrictions

Finally, Defendant Morrisey argues that Plaintiff cannot challenge provisions which are not currently in effect, i.e., the restrictions on prescription of mifepristone extant prior to the passage of the UCPA. Def. Morrisey's Mem. in Supp. of Mot. to Dismiss at 8. In support, Defendant Morrisey cites *California v. Texas* for the proposition that "[t]o find standing … to attack an unenforceable statutory provision would allow a federal court to issue what would amount to 'an advisory opinion without the possibility of any judicial relief.'" 141 S. Ct. 2104, 2116 (2021) (internal citation omitted). Plaintiff's Response emphasizes that *California v. Texas* dealt with a "toothless law" that had "no means of enforcement," while the provisions here would spring back into effect were the Court to declare the UPCA unconstitutional. Pl.'s Opp'n. to Def. Morrisey's Mot. to Dismiss at 7.

The Court agrees with Plaintiff. The prior provisions were superseded by the UCPA,[8] which suspends their enforceability so long as the UCPA is in effect. W. Va. Code § 16-2R-9. However, the UCPA includes a provision that should it be found unconstitutional the older provisions would once again become enforceable. *Id*. Had GenBioPro challenged the prior provisions without challenging the UCPA, it may not have had standing. But as Plaintiff has challenged the UCPA, it also may challenge the provisions which would spring back into enforceability if this Court were to find the UCPA unconstitutional. Of course, if the Court were to find that the statute is constitutional, it would not consider GenBioPro's challenges to the other provisions.

Accordingly, the Court finds that GenBioPro's economic injuries are traceable to the statutes complained of and would be redressed by the relief requested from the Court.

C. Traceability as to Defendant Sorsaia

While the Court has found GenBioPro has standing as to Defendant Morrisey, "the standing inquiry must be evaluated separately as to each defendant." *Disability Rights S.C. v. McMaster*, 24 F.4th 893, 901-02 (4th Cir. 2022) (citing *Bostic v. Schaefer*, 760 F.3d 352, 370–71 (4th Cir. 2014)).

As discussed above, "traceability" is one the three "irreducible" prongs of Article III standing. *Lujan*, 504 U.S. at 560-61. A plaintiff's injury satisfies the traceability element of standing when there is "a causal connection between the injury and the [defendant's] conduct complained of by the plaintiff." *Air Evac*, 910 F.3d at 760 (internal quotation marks omitted). "While the defendant's

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[8] The Court notes that West Virginia Code § 30-3-13a(g)(5) and § 30-1-26(b)(9) remain in effect. Accordingly, the analysis in this section is directed only towards GenBioPro's challenge as to West Virginia Code § 16-2I-2.

conduct need not be the last link in the causal chain, the plaintiff must be able to demonstrate that the alleged harm was caused by the defendant, as opposed to the 'independent action of some third party not before the court.'" *Id.* at 760 (quoting *Frank Krasner Enters., Ltd. v. Montgomery Cnty.*, 401 F.3d 230, 234 (4th Cir. 2005)). Further, "an injury resulting from the application or threatened application of an unlawful enactment remains fairly traceable to such application." *Fed. Election Comm'n. v. Cruz*, 142 S. Ct. 1638, 1647 (2022).

Defendant Sorsaia argues that GenBioPro lacks standing as to him as a defendant, as the injury Plaintiff complains of cannot be traced to his actions or inaction. Mem. of Law in Supp. of Def. Sorsaia's Mot. to Dismiss at 4. The Fourth Circuit addressed a similar argument in *Disability Rights South Carolina v. McMaster*. 24 F.4th at 901-02. In *McMaster*, the Appeals Court held that mere public endorsement of a statute by a state official was insufficient to demonstrate traceability, where the defendant governor did not have the authority to enforce the statute. *Id*. Rather, *McMaster* held that "[t]o establish standing, '[a] plaintiff who challenges a statute must demonstrate a realistic danger of sustaining a direct injury as a result of the statute's operation or enforcement.'" *Id*. at 902 (quoting *Babbitt v. United Farm Workers Nat'l Union*, 442 U.S. 289, 298 (1979)). In other words, "[a] controversy exists not because the state official is himself a source of injury but because the official represents the state whose statute is being challenged as the source of injury." *Mobil Oil Corp. v. Atty. Gen. of Va.*, 940 F.2d 73, 76 n.2 (4th Cir. 1991) (quoting *Wilson v. Stocker*, 819 F.2d 943, 947 (10th Cir. 1987)). But "[w]hen a defendant has no role in enforcing the law at issue, it follows that the plaintiff's injury allegedly caused by that law is not traceable to the defendant." *McMaster*, 24 F.4th at 901-02.

The Court has found that the source of GenBioPro's alleged injury is the UCPA and prior restrictions on abortion in the state. As the Prosecuting Attorney of Putnam County, Defendant

Sorsaia is charged with enforcing the UCPA's criminal penalties, and the Complaint plausibly asserts that he has indicated that he will enforce the UCPA. W. Va. Code § 7-4-1(a); Compl. ¶ 24. GenBioPro has alleged an intent to distribute its product within the state and to specific pharmacies within the county. Compl. ¶ 78. Unlike the governor in *McMaster*, therefore, the statute challenged as the source of GenBioPro's alleged injury within Putnam County is traceable to the enforcement authority of Defendant Sorsaia.

Accordingly, Defendant Sorsaia's Motion is **DENIED** as to the issue of standing.

D. Third-Party Standing

GenBioPro argues that it may assert the rights of third parties to whom it wishes to sell mifepristone within West Virginia. Pl.'s Opp'n to Def. Morrisey's Mot. to Dismiss at 7-8; Pl.'s Opp'n to Def. Sorsaia's Mot. to Dismiss at 12-14. Defendant Morrisey counters that "in order to assert the interests of a third party, a vendor plaintiff must first satisfy the requirements of Article III standing itself." Reply in Supp. of Mot. to Dismiss at 3 (citing *Hogan*, 971 F.3d at 214-15). While the Court agrees with Defendant Morrisey's interpretation of *Hogan* and related cases, it has already found that Plaintiff has satisfied the requirements of Article III standing as to itself, above. While Plaintiff raised the same argument as to Defendant Sorsaia, he neglected to file a Reply. Therefore, the Court will consider whether Plaintiff has met the requirements to assert third-party standing on behalf of its vendees.

A "plaintiff generally must assert his own legal rights and interests, and cannot rest his claim to relief on the legal rights or interests of third parties." *Warth v. Seldin*, 422 U.S. 490, 499 (1975); *see Hogan*, 971 F.3d at 214. This rule is meant to ensure that parties appearing before the court have "the appropriate incentive to challenge (or not challenge) governmental action and to do so

with the necessary zeal and appropriate presentation." *Kowalski v. Tesmer*, 543 U.S. 125, 129 (2004). And yet, the Supreme Court has found circumstances in which plaintiffs may have standing to assert the rights of others. *See id*. at 129-30.

One widely recognized ground for third-party standing is the vendor-vendee relationship, where the vendor independently has established its own standing. *See Craig*, 429 U.S. at 195 ("As a vendor with standing to challenge the lawfulness of [the relevant statutes], appellant [] is entitled to assert those concomitant rights of third parties that would be 'diluted or adversely affected' should her constitutional challenge fail and the statutes remain in force."). "[V]endors and those in like positions have been uniformly permitted to resist efforts at restricting their operations by acting as advocates of the rights of third parties who seek access to their market or function." *Id*.; *see also Carey*, 431 U.S. at 682–84 (granting third-party standing to a nationwide mail-order contraceptive vendor to challenge a state prohibition on contraceptive sales by asserting vendee right to privacy); *Eisenstadt v. Baird*, 405 U.S. 438, 443-446 (1972) (granting third-party standing to plaintiff prosecuted for illegal distribution of contraceptives to assert equal protection rights of unmarried persons denied access to contraceptives). "Courts have invariably found that a vendor has a sufficiently close relationship with its customers when a challenged statute prevents that entity from transacting business with them." *Hogan*, 971 F.3d at 216 (citing *Craig*, 429 U.S. at 192–97; *Lepelletier v. F.D.I.C.*, 164 F.3d 37, 43–44 (D.C. Cir. 1999)). Furthermore, the Fourth Circuit has held that "a vendor has third-party standing to pursue claims on behalf of its customers, regardless of whether a vendor's customers are hindered in bringing their own claims." *Id*. at 216 (collecting cases).

Here, GenBioPro is a vendor of mifepristone. Compl. ¶ 3. Under the current REMS, its customers include certified healthcare providers and pharmacies nationwide. *See id*. ¶¶ 66, 71;

2023 REMS. Plaintiff has plausibly alleged an intention to sell to this group of vendees in West Virginia. *See id*. ¶¶ 78-79. The Court has held above that GenBioPro has plausibly alleged that the UCPA restricts its sales to these vendees in the state and that this restriction is sufficient to constitute an economic injury in fact. Accordingly, the Court holds that GenBioPro may assert the third-party rights of the certified healthcare providers and pharmacies who seek access to its market but are prevented by the UCPA from transacting business with GenBioPro.

GenBioPro wishes to assert its customers' interests in not being subjected to criminal penalties due to West Virginia's enforcement of allegedly unconstitutional statutory provisions. Pl.'s Opp'n to Def. Morrisey's Mot. to Dismiss at 7-8; Pl.'s Opp'n to Def. Sorsaia's Mot. to Dismiss at 6-8, 13. Where no criminal enforcement action has been initiated, "a plaintiff satisfies the injury-in-fact requirement where he alleges 'an intention to engage in a course of conduct arguably affected with a constitutional interest, but proscribed by a statute, and there exists a credible threat of prosecution thereunder.'" *Susan B. Anthony List v. Dreihaus*, 573 U.S. 149, 159 (2014) (quoting *Babbitt*, 442 U.S. at 298). Where such a credible threat of enforcement exists, plaintiffs "should not be required to await and undergo a criminal prosecution as the sole means of seeking relief." *Babbitt*, 442 U.S. at 298. However, where the government has "disavowed enforcement," there is no credible threat of prosecution. *See Susan B. Anthony List*, 573 U.S. at 163; *Holder v. Humanitarian Law Project*, 561 U.S. 1, 16 (2010) (emphasizing that the government did not disavow future enforcement of the challenged statute).

GenBioPro has alleged that West Virginia's limitations on the sale of mifepristone violate the Supremacy and Commerce Clauses of the Constitution. Compl. at 28-32. The Court finds this sufficient to satisfy the alleged "intention to engage in a course of conduct arguably affected with a constitutional interest." *See Susan B. Anthony List*, 573 U.S. at 159. While the Court has declined

to determine whether GenBioPro itself could be subject to criminal liability pursuant to the UCPA, it is more than arguable that at least some of the pharmacies and medical personnel who could distribute mifepristone under the 2023 REMS also could be prosecuted for that distribution under West Virginia law. GenBioPro's vendees include non-physicians and pharmacies, who can be certified to distribute mifepristone under the current REMS. *See* Compl. ¶¶ 58, 71; 2023 REMS. The Complaint alleges that national pharmacy chains with locations in Putnam County, West Virginia have expressed a desire to sell mifepristone. *Id*. ¶ 78. Accordingly, as County Prosecutor for Putnam County and Attorney General of West Virginia, Defendants could prosecute GenBioPro's customers under § 61-2-8(a). Further, rather than "disavowing enforcement," both Defendants have affirmatively expressed that they will enforce the relevant criminal provisions. *Id*. ¶¶ 24, 75.

At oral argument, Defendant Sorsaia underscored that West Virginia's criminal penalties for performing illegal abortions do not apply to "licensed medical professionals," who he implied are the majority of GenBioPro's customers. "Licensed medical professionals" who would violate the UCPA by prescribing mifepristone for abortion care outside of the limited exceptions would only be subject to licensure revocation, rather than criminal prosecution. W. Va. Code § 16-2R-7. The UCPA defines "licensed medical professional" as a person 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. Therefore, registered professional nurses and nurse practitioners are not "licensed medical professionals" for the purposes of the UCPA, as they are subject to different statutory schemes under West Virginia Code § 30-7-1, *et seq*. and § 30-7A-1, *et seq*. Nor would pharmacists or pharmacies be considered "licensed medical professionals," as they are governed by West Virginia

Code § 30-5-1, *et seq*. *See also* W. Va. Code § 30-5-22 (outlining registration requirements for pharmacies). Accordingly, registered professional nurses, nurse practitioners, pharmacists, and pharmacies who could be certified under the mifepristone REMS would be subject to the criminal penalties of § 61-2-8(a), rather than the license revocation of § 16-2R-7, were they to violate § 16-2R-3.

Therefore, the Court finds that GenBioPro has plausibly alleged that its vendees have suffered an injury in fact sufficient for Article III standing in the form of a credible threat of enforcement, and that GenBioPro may assert the third-party rights of its vendees, due do its independent standing and its relationship with them as a vendor.

IV. CONCLUSION

For the forgoing reasons, the Court concludes that Plaintiff has sufficiently alleged Article III standing for this Court to hear the instant case or controversy. Accordingly, the Court **DENIES** each Motion to Dismiss in part and holds in abeyance the remainder of the Motions. The Court **DIRECTS** that counsel to appear in person on **May 23, 2023,** at **1:30 p.m.** to argue the remaining issues raised in the Motions.

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

ENTER: May 2, 2023

ROBERT C. CHAMBERS
UNITED STATES DISTRICT JUDGE