UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF MINNESOTA

ASSOCIATION FOR ACCESSIBLE MEDICINES,

Plaintiff,

v.

KEITH ELLISON,
in his official capacity as Attorney General of the State of Minnesota,

Defendant.

Case No. 23-cv-2024

REPLY IN SUPPORT OF DEFENDANT'S MOTION TO DISMISS

INTRODUCTION

Generic Drugmakers knowingly and willfully avail themselves of the Minnesota marketplace. More than simply registering an agent or filing corporate papers with the secretary of state, Generic Drugmakers agreed to comply with Minnesota law when they voluntarily obtained drug manufacturer or distributor licenses to engage in the very conduct the Act regulates. The Act simply updates the rules of the game for manufacturers granted the privilege of distributing, dispensing, or selling generic drugs to consumers in Minnesota. Now, Generic Drugmakers may not impose excessive price increases on sales in Minnesota. Act, § 23.

Despite conceding that liability under the Act is *only* triggered by an in-state sale of an excessively priced generic drug (Resp. at 8), Plaintiff claims this valid exercise of Minnesota's police power is unconstitutional because "several" manufacturers want to engage in excessive price hikes elsewhere. (Compl. ¶ 36.) Plaintiff erroneously contends

the Act directly regulates out-of-state transactions that have no connection with Minnesota based on a willful misreading of *Edgar v. MITE Corp.*, 457 U.S. 624 (1982), that is clearly inapplicable to parties who, like Generic Drugmakers, sought out licenses from a state's regulatory regime to access in-state consumers. Accordingly, Plaintiff fails to articulate plausible constitutional claims and its complaint must be dismissed.

ARGUMENT

I. THE ACT DOES NOT DIRECTLY REGULATE OUT-OF-STATE TRANSACTIONS WITHOUT CONNECTIONS TO MINNESOTA.

Plaintiff argues that it has pled a "plausible claim of extraterritoriality," (Response at 15), but the Supreme Court recently extinguished this claim. *Nat'l Pork Producers Council v. Ross*, 598 U.S. 356, 371-376 (2023). Therefore, Plaintiff cannot state a plausible claim for relief solely on the Act's extraterritorial effects.[1]

Plaintiff couples reliance on *Edgar*, a 40-year-old plurality decision, with a self-serving narrow definition of 'commerce,' to conclude the Act directly regulates out-of-state conduct. (Response at 3-8.) But the Court's description of prohibited extraterritorial regulation there, does not apply here.

[1] Plaintiff's belated allegation that the Act is discriminatory because it exempts "pharmacies and wholesale distributors" that "are more likely to be located in Minnesota" than manufacturers is meritless. (Resp. at 9.) Even though Plaintiff alleges that 90% of the market is controlled by wholesalers incorporated or headquartered outside Minnesota, (Compl. ¶ 26), Plaintiff's concern is irrelevant. *CTS Corp. v. Dynamics Corp. of Am.*, 481 U.S. 69, 88 (1987) (rejecting argument that law was discriminatory because it applied more frequently to out-of-state entities). Plaintiff's new argument fails to present cognizable discrimination.

First, because the initial transaction in the prescription drug supply chain (manufacturer-to-distributor) often – though not always – occurs outside Minnesota, Plaintiff asserts the Act directly regulates conduct "wholly outside" the state, violating the Commerce Clause. (Response, at 9.) But Plaintiff concedes the Act is only triggered when excessively-priced drugs are distributed, dispensed, or sold *in Minnesota*.[2] (Response, at 8); Act, § 23, subd. 3; *accord Star Scientific v. Beales*, 278 F.3d 339, 355-56 (4th Cir. 2002) (rejecting extraterritoriality challenge to law requiring cigarette *manufacturer* to make payments on cigarettes sold in Virginia, regardless of whether they were distributed or sold by out-of-state third-party distributors). The Act's in-state sales limitation is fatal to Plaintiff's extraterritoriality claim.

Second, for the same reasons, Plaintiff's reliance on *Edgar* is entirely misplaced. In *Edgar*, an Illinois' law was struck down because it "could be applied to regulate a tender offer which would not affect a single Illinois shareholder." 457 U.S. at 642. Courts note *Edgar's* application is limited to situations where states attempt to regulate conduct that "would not affect a single [in-state] shareholder." *See, e.g.*, *Rosenblatt v. City of Santa Monica*, 940 F.3d 439, 446 (9th Cir. 2019) (citations omitted). Where a law applies "only [to] products that companies choose to sell 'within' [the state]," *Edgar* does not apply. *Ross*, 598 U.S. at 376, n.1. And here, the Act applies only to those manufacturers who choose to allow their generic drugs to be distributed and sold in Minnesota, they do not

[2] Plaintiff's attempt to distinguish the Act from the law in *Ross* is futile because both laws are only triggered by in-state sales.

violate the Act by distributing or selling excessively-priced drugs in any other state.[3] The Generic Drugmakers do not claim that Minnesota's licensing scheme is extraterritorial, and the Act is simply a component of their preexisting, in-state regulatory relationship.[4]

Third, Plaintiff's view of the economic activity being regulated by the Act is 'unjustifiably narrow.' *See Swanson v. Integrity Advance, LLC*, 870 N.W.2d 90, 94-96 (Minn. 2015) (Stras, J.) (citing *Gonzales v. Raich*, 545 U.S. 1, 25-26 (2005) and holding that 'commerce' includes the entire transaction of 'production, distribution, and consumption of commodities'.) Like the law capping interest rates on payday loans in *Swanson*, the Act falls well-within Minnesota's power to regulate goods brought into the state through the stream of commerce. *Id.* at 94-96; Act, § 23. Because Generic Drugmakers can distribute and sell excessively-priced drugs in other states without violating the Act, Minnesota does not "project its legislation onto other states" or otherwise impermissibly regulate extraterritorial "commerce" occurring "wholly" beyond its borders. *Cotto Waxo Co. v. Williams*, 46 F.3d 790, 794 (8th Cir. 1995) (finding law prohibiting in-

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[3] Plaintiff complains that its members cannot control unauthorized third-party resale. (Compl. ¶¶ 44-45; Resp. at 21), but also admits its members can contract to limit subsequent geographical distribution of its drugs, (Compl. ¶¶ 24, 45-46.) and can presumably include defense and indemnification clauses. Plaintiff, however, does not challenge the Act's enforcement against its members for unauthorized third-party sales.

[4] Plaintiff claims the licensing application purportedly exempts manufacturers' international sites, but "manufacturer" bears a broader definition than simply compounding and creation. Minn. Stat. § 151.01, subd. 14 (including packaging, repackaging, labeling, and relabeling). To "manufacture" a drug for purchase in Minnesota, an entity must be licensed. Minn. Stat. § 151.252.

state sale of products lacked impermissible extraterritorial reach despite effecting out-of-state distribution).

Notably, the Act's regulatory reach is identical to Minnesota's prescription drug manufacturing and distribution licensure regime, but Plaintiff does not challenge the reach of these licensure laws. Plaintiff's erroneous extraterritoriality arguments, if accepted, would call into question long-standing police power regulations Minnesota applies to out-of-state manufacturers, including production standards, inspections, and prohibitions on the manufacture, delivery, or sale of misbranded or adulterated drugs. *See, e.g.*, Minn. Stat. §§ 151.252, subd. 1(h); 151.34. Plaintiff's legal challenge, if successful, would leave Minnesota residents at the whim of whatever safety precautions existed in each manufacturer's home state. That result is absurd; the dormant Commerce Clause does not "force all of the states to accept the lowest standard for conducting the business permitted by one of them." *Robertson v. California*, 328 U.S. 440, 460 (1946).

Finally, cases Plaintiff cites do not support its extraterritoriality claim. For example, *Stycinski* is distinguishable because it does not involve a manufacturer availing itself to particular state markets through third-party distributors.[5] *Ross* and *Star Scientific* both rejected manufacturer claims that laws were unconstitutionally extraterritorial because they

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[5] As previously explained, *Frosh*'s majority analysis relied on an erroneously broad reading of the Supreme Court's pre-*Ross* extraterritoriality decisions and an unjustifiably narrow definition of "commerce" this Court should reject. *See Ass'n for Accessible Medicines v. Frosh*, 887 F.3d 664, 681-83 (4th Cir. 2018) (dissent, J. Wynn) (correctly recognizing Maryland's law only effects upstream sales in streams of commerce that end in Maryland and thus, does not regulate economic activity that does not enter Maryland's borders).

affected out-of-state distribution processes used to access the in-state market. Those laws were upheld because they only prescribed the conditions or requirements (for police power purposes) the manufacturer was required to meet before bringing its product into the regulating state's market, and only that state's market. The Act regulates in this same permissible way—for police power purposes, it prohibits generic manufacturers from injecting excessively priced drugs into Minnesota's market, and only Minnesota's market.

II. PLAINTIFF FAILS TO ALLEGE A PLAUSIBLE *PIKE* VIOLATION.

Courts "rarely invoke[] *Pike* balancing to invalidate state regulation under the Commerce Clause." *So. Union Co. v. Missouri Pub. Svc. Com'n.*, 289 F.3d 503, 509 (8th Cir. 2002). Non-specific alleged burdens on interstate commerce like "time and money" or contract amendments do not establish a substantial burden under *Pike*. *So. Union Co.*, 289 F.3d at 509. Here, Plaintiff refuses to describe any burden beyond contracting and amorphous "costs." (*See, e.g.*, Compl. ¶¶ 44-45.) Moreover, Plaintiff concedes these nebulous burdens only apply to a minority of manufacturers engaged in excessive pricing, but alleged burdens only affecting individual manufacturers, rather than the generic market writ large, do not establish plausible Commerce Clause claims. *Exxon Corp. v. Gov. of Maryland*, 437 U.S. 117, 127-28 (1978) (holding that the Commerce Clause "protects the interstate market, not particular interstate firms, from prohibitive or burdensome regulations").

Minnesota's substantial state interest in securing affordable generic prescription drugs for consumers in Minnesota is undisputed. *Pike v. Bruce Church, Inc.*, 397 U.S. 137, 142 (1970); (Lewellen Decl. Ex. C at 11-13.) Plaintiff's speculation that the Act will

decrease the availability of drugs to Minnesotans is unfounded and irrelevant. (Resp. at 23.) And the dormant Commerce Clause prohibits "second-guess[ing] the empirical judgments of lawmakers concerning the utility of legislation." *CTS Corp.*, 481 U.S. at 92 (quotation omitted). Indeed, Plaintiff made the same argument before the Act's passage.[6] Minnesota lawmakers rejected it.

Plaintiff's proposed less burdensome regulatory alternatives are not serious. First, Plaintiff's request that Minnesota provide a pass-through defense to manufacturers too would render the Act a dead letter by immunizing every actor in the distribution chain, including manufacturers who control the list price of generic drugs. (Compl. ¶¶ 23-26, 77.) Second, Plaintiff's suggestion that Minnesota "limit[] regulation to in-state transactions" is superfluous because the Act already *does* limit its regulation to in-state drug transactions. (Compl. ¶ 77); Act § 23, subd. 1. In short, Plaintiff's proposed "less restrictive" alternatives boil down to no regulation at all.[7]

Any *Pike* balancing here is simple. On the one hand, Minnesota's law is intended to curb well-documented industry abuses[8] and ensure access to reasonably-priced generic

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[6] (Defendant's Brief, at 8 n.11, ECF Doc. No. 25.)

[7] Confusingly, Plaintiff alleges that the Act exempts in-state sales. (Resp. at 22.) That is flatly incorrect—the Act only targets in-state sales and certainly applies to in-state sales by manufacturers. *See generally*, Act. Indeed, Plaintiff's proposed order for a preliminary injunction seeks no injunction of application of the Act to in-state sales. (Pl. Proposed Order at 2.)

[8] Indeed, just this week Teva admitted to participating in a generic drug price-fixing conspiracy, paying a record $225 million criminal penalty. *See* https://perma.cc/L42T-KBW4.

drugs. On the other, the Act minimally burdens individual manufacturers, not a particular industry, any individualized burden is vague in severity, and concededly within manufacturers' considerable means to adapt. Because *Pike* balancing weighs in favor of the State and falls well outside *Pike's* discrimination "heartland," Plaintiff has not stated a plausible claim. *Ross*, 598 U.S. at 378-80.

III. PLAINTIFF HAS NOT PLAUSIBLY ALLEGED A DUE PROCESS CLAIM.

The Act does not violate the Constitution's substantive Due Process limitation on a state's police power. A "state's power to regulate" does not depend on "a conceptualistic discussion of theories of the place of contracting or of performance," but gives "great weight" to the in-state "consequences" of the regulated activities. *Travelers Health Ass'n. v. Virginia*, 339 U.S. 643, 648 (1950). Thus "[t]he forum State does not exceed its powers under the Due Process Clause if it asserts personal jurisdiction over a corporation that delivers its products into the stream of commerce with the expectation that they will be purchased by consumers in the forum State" and those products subsequently injure forum consumers. *Burger King Corp. v. Rudzewicz*, 471 U.S. 462, 473 (1985). Plaintiff cannot wield the Due Process clause as a territorial shield to avoid interstate obligations they voluntarily assumed. *Id*. at 474.

The Act is part and parcel of Minnesota's drug manufacturer and distributor licensing scheme. Plaintiff's members are not required to be here, but choose to become Minnesota-licensed drug manufacturers and distributors, and follow Minnesota law, in order to access Minnesota consumers. *Allstate Ins. Co. v. Hague*, 449 U.S. 302, 318 (1981) ("Particularly since the company was licensed to do business in the forum state] it must

have known it might be sued there, and that [the forum's] courts would feel bound by [forum] law."); *McCluney v. Joseph Schlitz Brewing Co.*, 649 F.2d 578, 581 (8th Cir.) (1981) ("*Hague* is consistent with the Court's earlier legislative jurisdiction cases and its more recent decisions in the area of judicial jurisdiction.").

Accordingly, Plaintiff fails to state a plausible Due Process claim.

IV. PLAINTIFF FAILS TO STATE A PLAUSIBLE "HORIZONTAL" SEPARATION OF POWERS CLAIM.

Because the Act only applies to Minnesota-licensed manufacturers when their drugs are distributed, dispensed, or sold *in* Minnesota, it does not disturb the Constitution's horizontal separation of powers between states. *Cf.* Section I, *supra*. The Act does not conflict with the laws of any other state, Generic Drugmakers are free to excessively price drugs as permitted by other states. It does not "abrogate the rights of parties beyond its borders having no relation to anything done or to be done within them." *Phillips Petroleum Co. v. Shutts*, 472 U.S. 797, 822 (1985) (citations omitted). Accordingly, the Act does not violate the Constitution's horizontal separation of powers.

CONCLUSION

The Act is a constitutional exercise of Minnesota's police power to seek "lower prices for its consumers." *Brown-Forman Distillers Corp. v. New York State Liquor Authority*, 476 U.S. 573, 579 (1986). The Commerce Clause does not protect Plaintiff's preferred "methods of operation." *Exxon Corp.*, 437 U.S. at 127. Accordingly, the Court should grant Defendant's motion and dismiss Plaintiff's complaint with prejudice.

Dated: August 23, 2023

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