STATE OF MINNESOTA **DISTRICT COURT**

COUNTY OF RAMSEY **SECOND JUDICIAL DISTRICT**

Pharmaceutical Research and Manufacturers of America,

Plaintiff,

vs.

The State of Minnesota, et al.,

Defendant.

Case Type: Other
Court File No. 62-CV-24-5744
Judge: Reynaldo A. Aligada

ORDER

Plaintiff Pharmaceutical Research and Manufacturers of America ("PhRMA") has filed a Complaint against the State of Minnesota and other named defendants. Defendants have moved to dismiss the Complaint. The Court heard oral argument on January 16, 2025. Philip J. Perry, Andrew D. Prins and Abid R. Qureshi of Latham & Watkins LLP and Barbara Podlucky Berens and Kari Berman, represent PhRMA. Peter J. Wenker, Assistant Attorney General and Peter J. Farrell, Deputy Solicitor General, represent Defendants. David W. Asp and Derek C. Waller, Lockridge Grindal Nauen PLLP represent Amici Curae the American Hospital Association, 340B Health, The Minnesota Hospital Association and The American Society of Health-System Pharmacists. Based upon the files, records, and proceedings herein, **IT IS HEREBY ORDERED** that

1. Defendants' motion to dismiss is **GRANTED**.
2. This Matter is **DISMISSED WITH PREJUDICE**.

LET JUDGMENT BE ENTERED ACCORDINGLY.

The attached Memorandum is incorporated into this Order.

Dated: 4/15/2025

BY THE COURT:

Aligada, Reynaldo (Judge)
Apr 15, 2025 3:33 PM

Reynaldo A. Aligada
Judge of District Court

MEMORANDUM

I. INTRODUCTION

PhRMA has brought this action against the State of Minnesota, the Attorney General, and members of the Minnesota Board of Pharmacy. Plaintiff challenges Minn. Stat. § 62J.96, which addresses the federal 340B program. Plaintiff's claims assert that § 62J.96 is preempted by federal law, violates the federal Commerce and Due Process Clauses, and violates the Minnesota Constitution's Single Subject and Title Clause. Defendants have moved to dismiss, arguing that each of Plaintiff's claims fails as a matter of law. The Court concludes Plaintiff has standing to bring this suit against each named defendant. However, the Court concludes that § 62J.96 is not preempted by federal law, does not engage unconstitutional extraterritorial regulation, and does not violate the Single Subject and Title Clause. For these reasons, the Court grants Defendants' motion to dismiss.

II. THE COMPLAINT

For the purpose of determining the motions to dismiss for failure to state a claim under Minnesota Rules of Civil Procedure Rule 12.02, the Court must "consider only the facts alleged in the complaint[,]…accept those facts as true[,] and construe all reasonable inferences in favor of" the plaintiff as the nonmoving party. *Hardin Cnty. Sav. Bank v. Hous. & Redevelopment Auth. of City of Brainerd*, 821 N.W.2d 184, 191 (Minn. 2012).

1. Parties

In the Complaint, PhRMA names the following defendants: The State of Minnesota, Keith Ellison, in his official capacity as Attorney General of Minnesota; Ronda Chakolis, in her official capacity as the President and a Member of the Minnesota Board of Pharmacy; Kendra Metz, in her official capacity as the Vice President and a Member of the Minnesota Board of Pharmacy; and the following individuals in their official capacities as a members of the

Minnesota Board of Pharmacy: James Bialke, Barbara Droher Kline, Michael Haag, Ben Maisenbach, Rabih Nahas, Amy Paradis, and John M. Zwier. Compl. ¶¶ 25–27.

2. Causes of action and relief sought

Through its Complaint, PhRMA alleges three claims for declaratory and injunctive relief on the following grounds: preemption (Claim I—Compl. ¶¶ 88–103), unconstitutional extraterritorial regulation (Claim II—Compl. ¶¶ 104–109) and Single Subject and Title Clause of the Minnesota Constitution (Claim III—Compl. ¶¶ 105–114). In its prayer for relief, PhRMA requests that the Court declare H.F. 4757 unconstitutional and enjoin the implementation and enforcement of H.F. 4757 against PhRMA's members, along with additional requested relief. Compl. at p. 43.

3. Facts alleged in the Complaint

Plaintiff PhRMA is a trade association representing biopharmaceutical research companies, and advocates for policies around pharmaceutical products. PhRMA's members manufacture and sell pharmaceutical products and participate in the federal 340B program. Compl. ¶ 24. Defendant State of Minnesota is a state and political entity. ¶ 25. Defendant Keith Ellison is the Attorney General of Minnesota, the chief law enforcement officer of the state. Compl. In that role, he has the authority to enforce the laws of Minnesota. Compl. ¶ 26. Defendant Ronda Chakolis is the President and a Member of the Minnesota Board of Pharmacy. Defendant Kendra Metz is the Vice President and a Member of the Minnesota Board of Pharmacy. Defendants James Bialke, Barbara Droher Kline, Michael Haag, Ben Maisenbach, Rabih Nahas, Amy Paradis, and John W. Zwier are all Members of the Minnesota Board of Pharmacy. The Minnesota Board of Pharmacy licenses drug manufacturers, and as part of that process requires that manufacturers certify they are complying with Minnesota law, which now includes H.F. 4757, or face criminal liability under Minn. Stat. §§ 151.252, 151.29. Compl. ¶ 27.

The federal 340B Drug Pricing Program, 42 U.S.C. § 256b ("340B"), requires that drug manufacturers whose products are eligible for reimbursement under Medicare Part B and the Federal share of Medicaid offer price reductions on covered outpatient drugs to 15 specified types of eligible healthcare providers ("covered entities"). 42 U.S.C. § 256b(a)(1). Compl. ¶ 2. The 340B program was created by Congress to help underserved patient populations who receive treatment at covered entities. Compl. ¶ 3. Under 340B, participating manufacturers shall offer each covered entity certain outpatient drugs at or below set ceiling prices, if such drugs are also offered to any other purchasers, meaning manufacturers must make a genuine offer to covered entities for purchase of 340B-priced drugs. 42 U.S.C. § 256b(a)(1). Compl. ¶ 39.

To meet the definition of a "covered entity" a provider may not engage in an unlawful transfer of 340B-priced drugs and may not seek or cause a duplicate Medicaid discount. 42 U.S.C. § 256b(a)(5). Compl. ¶ 40. Manufacturers must offer their covered outpatient drugs at or below the applicable ceiling price to "covered entities," and only "covered entities" may receive this pricing under the express terms of federal law. Compl. ¶ 42. The statute bars covered entities from "resell[ing] or otherwise transfer[ring]" a covered outpatient drug "to a person who is not a patient of the entity." 42 U.S.C. § 256b(a)(5)(B). Compl. ¶ 44.

The statute adopts a compliance framework by which the Secretary of the United States Department of Health and Human Services ("HHS") may terminate a Pharmaceutical Pricing Agreement contract ("PPA") with a manufacturer if HHS determines that the manufacturer breached its 340B obligations. Compl. ¶ 47. HHS has delegated 340B's oversight and enforcement to the Health Resources and Services Administration ("HRSA") a federal agency within HHS. Compl. ¶¶ 38, 48. The Complaint alleges that "[n]either the 340B statute nor any federal regulations promulgated under it authorize, envision, or create room for state regulation

of the 340B program." Compl. ¶ 48. Congress also created a mechanism for administering disputes and violations regarding 340B. That includes audits and administrative dispute resolution. Compl. ¶ 49. HHS may "review[] and finally resolv[e] claims" by covered entities or manufacturers in a process developed by HHS. Compl. ¶ 52.

340B requires that a manufacturer offer 340B pricing only to a "covered entity." 42 U.S.C. § 256b(a)(1). So-called "contract pharmacies" are not included and are ineligible to receive 340B pricing. Compl. ¶ 56. The Complaint alleges that some for-profit pharmacies have "sought to leverage 340B as a tool to enhance their profitability in a way that Congress never intended." Compl. ¶ 56. The Complaint alleges that these contract pharmacies use a "replenishment model" which allows most contract pharmacies to comingle "340B and non-340B drugs in one inventory and then dispending drugs from that inventory to all individuals—despite the fact that 340B-priced drugs are legally permitted to be dispensed only to patients of 340B covered entities." Compl. ¶ 57. The Complaint alleges that the result has been abuse and unlawful claims for 340B drugs. Compl. ¶ 59. As a result, PhRMA members adopted policies to address reported 340B abuses. Compl. ¶¶ 73. The policies include (A) limits on the number of contract pharmacies used and (B) requirements that claims data be provided if contract pharmacies are used. Compl. ¶¶ 80–81.

The Complaint alleges that after litigation before HHS and federal courts, Minnesota enacted Minnesota Session Law 2024, Chapter 121 H.F. 4757 on May 19, 2024. Compl. ¶ 84. The challenged provision is Minn. Stat. 62J.96, subd. 1, titled "ACCESS TO 340B DRUGS." Section 62J.96 defines the term "340B covered entity" by referencing 42 U.S.C. § 256, subd. 2; Compl. ¶ 84. Section 62J.96 provides:

> A manufacturer must not directly or indirectly restrict, prohibit, or otherwise interfere with the delivery of a covered outpatient drug to a pharmacy that is under

> contract with a 340B covered entity to receive and dispense covered outpatient drugs on behalf of the covered entity, unless the delivery of the drug to the pharmacy is prohibited under the 340B Drug Pricing Program.

Minn. Stat. § 62J.96, subd. 1; Compl. ¶ 84.

The Complaint alleges that § 62J.96 provides no geographical limitation and does not acknowledge HRSA's enforcement authority or 340B ADR procedures. Compl. ¶ 86. The Complaint also alleges that under Minnesota law, manufacturers must obtain a license from the Minnesota Board of Pharmacy and must certify that they comply with Minnesota law or face criminal liability. The Complaint alleges that Minnesota law provides for Board of Pharmacy enforcement authority against an entity engaging in "any unethical conduct" and "conduct likely to . . . harm the public." Compl. ¶ 86 (citing Minn. Stat. §§ 151.071, subd. 2(9), 151.252, 151.29).

III. LEGAL ANALYSIS

Defendants have moved to dismiss PhRMA's Complaint. Under Minn. R. Civ. P. 12.02(e), a defendant may move to dismiss a complaint for "failure to state a claim upon which relief can be granted." Minnesota's notice-pleading standard allows "short and general statements of fact and does not ask for detailed factual allegations." *Demskie v. U.S. Bank Nat'l Ass'n*, 7 N.W.3d 382, 387 (Minn. 2024) (quotation omitted). "A claim survives a Rule 12.02(e) motion to dismiss if it is possible on any evidence which might be produced, consistent with the pleader's theory, to grant the relief demanded." *Sterry v. Minn. Dep't of Corr.*, 8 N.W.3d 224, 235 (Minn. 2024) (quotation omitted). A complaint "will be dismissed only if it appears to a certainty that no facts, which could be introduced consistent with the pleading, exist which would support granting the relief demanded." *DeRosa v. McKenzie*, 936 N.W.2d 342, 346 (Minn. 2019) (quotation omitted). The Court must "look only to the facts alleged in the complaint, accepting those facts as true." *Hansen v. U.S. Bank Nat'l Ass'n*, 934 N.W.2d 319, 325 (Minn.

2019) (citation omitted). In doing so, a court must "construe all reasonable inferences from the facts in favor of the plaintiff." *Id*. (citation omitted).

A. Standing/Subject Matter Jurisdiction

Defendants argue that the Complaint fails to plead a justiciable case or controversy because it fails to plead a redressable injury traceable to Defendants. Defendants argue that PhRMA does not plead a direct and imminent injury that is traceable to any Defendant. Standing is a jurisdictional prerequisite. *Scheffler v. City of Anoka*, 890 N.W.2d 437, 451 (Minn. Ct. App. 2017), *rev. denied* (Minn. Apr. 26, 2017); *see also Garcia-Mendoza v. 2003 Chevy Tahoe*, 852 N.W.2d 659, 663 (Minn. 2014). To have standing, "a party must have a sufficient stake in the controversy to seek relief from the court." *Webb Golden Valley, LLC v. State*, 865 N.W.2d 689, 693 (Minn. 2015). A party has standing when it is an aggrieved party that has suffered an injury-in-fact. *Garcia-Mendoza*, 852 N.W.2d at 663. "To demonstrate an injury-in-fact, the plaintiff must point to an injury that is fairly traceable to the defendants' challenged action and that is likely to be redressed by a favorable decision." *Scheffler*, 890 N.W.2d at 451 (citing *Garcia-Mendoza*, 852 N.W.2d at 663).

Defendants first argue that the State of Minnesota is not a proper party because the state may only act through its agencies and a plaintiff must directly sue an agency that is alleged to have caused harm. Defendants argue that the Attorney General is not a proper party because PhRMA does not allege that the Attorney General has taken any enforcement action against it or its members, or that he is likely to do so in the future. Further, Defendants argue that no provision of H.F. 4757 or § 62J.96 empowers the Attorney General to civilly, criminally, or administratively enforce § 62J.96. Defendants argue that the Board defendants are not proper defendants because it is not sufficient for PhRMA to allege that the Board requires

manufacturers to certify compliance with H.F. 4757. Defendants assert that the Board does not have the authority to enforce § 62J.96 against PhRMA's members.

Plaintiff responds that it is undisputed that § 62J.96 is aimed at prohibiting PhRMA's members' policies and it does not matter if the text of § 62J.96 does not contain an enforcement provision. Plaintiff argues that it is undisputed that § 62J.96 will harm PhRMA's members by requiring them to provide substantially discounted pricing where they would not otherwise be required to under federal law. Plaintiff argues that the Attorney General has broad common law and statutory power, and Minn. Stat. §§ 8.01 and 8.31 allow the Attorney General to sue for unlawful practices in commerce. Plaintiff argues that the Board defendants are appropriate parties because the Board asserts enforcement authority over licensees in cases of unethical conduct or conduct likely to harm the public. Plaintiff argues that the State of Minnesota is an appropriate defendant because case law provides that when a party seeks a declaration that a statutory provision violates of the Minnesota Constitution, the State is a proper defendant.

The Court concludes that Plaintiff has standing to bring this action, and that Defendants are all proper parties. As a trade association, PhRMA may bring an action to seek redress for its members. "An organization can assert standing if its members' interests are directly at stake or if its members have suffered an injury-in-fact." *Builders Ass'n of Minnesota v. City of St. Paul*, 819 N.W.2d 172, 177 (Minn. Ct. App. 2012) (citing *State ex rel. Humphrey v. Philip Morris Inc*., 551 N.W.2d 490, 497–98 (Minn. 1996) and *Minneapolis Fed'n of Teachers, Local 59 v. Special Sch. Dist. No. 1*, 512 N.W.2d 107, 109 (Minn. Ct. App. 1994). PhRMA's members "have a sufficient stake in the controversy to seek relief from the court." *Webb Golden Valley*, 865 N.W.2d at 693. Section 62J.96 impacts drugs PhRMA's members sell. Under either theory advanced by the parties—whether the statute impacts pricing or delivery of drugs—the Complaint alleges an

injury to PhRMA's members through limits on their ability to conduct a commercial transaction. "Economic injury may be sufficient to establish standing, so long as it is not abstract or speculative." *Builders Ass'n of Minnesota*, 819 N.W.2d at 176 (citing *State v. Knutson*, 523 N.W.2d 909, 911 (Minn. Ct. App. 1994), *rev. denied* (Minn. Jan. 13, 1995)). Because Plaintiff's claims relate to drugs that its manufacturer members sell, it has standing to bring this action.

Further, the Complaint alleges that PhRMA's members will suffer injury that is attributable to each of the defendants, and that its requested relief would redress that injury. *Scheffler*, 890 N.W.2d at 451. The Court is not persuaded that just because § 62J.96 lacks an enforcement mechanism that names each of the defendants, Plaintiff cannot have standing. Rather, taking the allegations in the Complaint as true, each of the parties sued by PhRMA are the entities that have the authority to enforce § 62J.96. The Attorney General "has broad powers at common law" and "broad statutory powers." *State ex rel. Hatch v. Am. Family Mut. Ins. Co*., 609 N.W.2d 1, 3 (Minn. Ct. App. 2000). The Attorney General "may institute, conduct, and maintain all such actions and proceedings as he deems necessary for the enforcement of the laws of this state, the preservation of order, and the protection of legal right." *Id*. (citation omitted). Further as defendants argue, Minn. Stat. § 8.31 specifically gives the Attorney General the ability "to sue" based on the violation "of the law[s] of [Minnesota] respecting unfair, discriminatory, and other unlawful practices in business, commerce, or trade." Minn. Stat. §§ 8.31, subd. 1, 3. As discussed below, the delivery of drugs constitutes commerce, and the Attorney General's statutory authority to enforce laws, including § 62J.96, gives Plaintiff standing.

The Board also has authority over matters addressed by § 62J.96. The Board has authority to regulate the "manufacture [and] wholesale" of drugs in Minnesota and requires the licensing of drug manufacturers. *See* Minn. Stat. § 151.06, subd. 1(2). It also asserts enforcement

authority over licensees. Minn. Stat. § 151.071, subd. 2(9) (Board can revoke licenses and impose civil monetary penalties on licensee where Board finds licensee "engage[d] in any unethical conduct" or conduct "likely to … harm the public"). Because the Board has statutory authority over the subject matter of § 62J.96 and has enforcement authority over drug manufacturers, Plaintiff has standing to sue members of the Board in their official capacities.

With regard to the State, the Court is persuaded by PhRMA that its challenge to the constitutionality of H.F. 4757 and § 62J.96 makes the State an appropriate party to this litigation. Standing is about justiciability, and justiciability was at issue in *Cruz-Guzman v. State*, 916 N.W.2d 1 (Minn. 2018). In *Cruz-Guzman* the plaintiffs sued the State and alleged that the State failed to meet its obligations under the Education Clause of the Minnesota Constitution. The Minnesota Supreme Court, concluding that the matter was justiciable, held that "the judiciary is asked to determine whether the Legislature has violated its constitutional duty under the Education Clause. We conclude that the courts are the appropriate domain for such determinations and that appellants' Education Clause claims are therefore justiciable." *Id*. at 9. Similarly, in Claim III, PhRMA alleges that the Legislature violated the Single Subject and Title Clause of the Minnesota Constitution and seeks declaratory and injunctive relief. This Court concludes that this is a justiciable claim, and the State is an appropriate party.

In a notice of supplemental authority, the parties have provided their positions on a decision in the United States District Court for the District of Minnesota, where the court dismissed a challenge to § 62J.96 based on a lack of standing and Eleventh Amendment Immunity. *See Abbie Vie. et. al., v. Keith M Ellison*, Civil No. 24-2605 and *AstraZeneca Pharmaceuticals LP v. Keith M Ellison, et. al*., Civil No. 24-2621, ECF # 52 (D. Minn. April 3, 2025). Based upon the record and arguments in this matter, this Court reaches a different

conclusion. The Court concludes that PhRMA has standing to sue each of the named defendants. Having established justiciability, the Court now turns to the merits of the parties' arguments.

B. Preemption

Defendants argue that this case must be dismissed because 340B does not preempt § 62J.96. Defendants assert that because § 62J.96 regulates the delivery of drugs to contract pharmacies, that regulation is within the authority of the State of Minnesota to protect the health and safety of its citizens. "Federal law can preempt state law in three ways: through (1) field preemption, (2) express preemption, and (3) conflict preemption[.]" *Hous. & Redev. Auth. of Duluth v. Lee*, 852 N.W.2d 683, 687 (Minn. 2014) (citations omitted). Whichever of those theories a defendant pursues, "the purpose of Congress is the ultimate touchstone in every pre-emption case." *Medtronic, Inc. v. Lohr*, 518 U.S. 470, 485 (1996) (cleaned up). Express preemption occurs when Congress's intent to preempt state law "is explicitly stated in [a] statute's language." *Morales v. Trans World Airlines, Inc*., 504 U.S. 374, 383 (1992). Field preemption describes the circumstance in which "[s]tates are precluded from regulating conduct in a field that Congress, acting within its proper authority, has determined must be regulated by its exclusive governance." *Arizona v. United States*, 567 U.S. 387, 399 (2012).

Defendants argue that § 62J.96 is not field preempted because §62J.96 regulates the delivery and distribution of drugs and does not invade the drug pricing field. Plaintiff argues that it has sufficiently pled that § 62J.96 is field preempted because 340B is exclusively federal, and Congress left no room for state supplementation. Plaintiff argues that § 62J.96 intrudes into an exclusively federal field, both substantively and procedurally. The parties' briefing focuses on two federal cases and the applicability of those decisions to H.F. 4757. Defendants rely on *Pharm. Rsch. & Mfrs. of Am. v. McClain*, 95 F.4th 1136 (8th Cir. 2024). Plaintiff relies on

Pharm. Rsch. & Manufacturers of Am. v. Morrisey, --- F.Supp.3d ----, No. 2:24-CV-00271, 2024 WL 5147643 (S.D.W. Va. Dec. 17, 2024).

In *McClain*, PhRMA challenged an Arkansas law, arguing Section 340B preempts it. *Id*. at 1139-40. The district court granted summary judgment against PhRMA, and the Eighth Circuit affirmed. *Id*. The challenged provision, Ark. Code Ann. § 23-92-604(c) (Arkansas Act 1103) has two relevant subsections.

> The first subsection of section 23-92-604(c) prohibits pharmaceutical manufacturers from interfering in a covered entity's agreement with a contract pharmacy by denying the pharmacy access to a covered entity's 340B drugs. The second subsection prohibits pharmaceutical manufacturers from interfering in a covered entity's agreement with a contract pharmacy by denying 340B drug pricing to covered entities who use contract pharmacies for distribution.

Id. at 1143

In *McClain*, PhRMA argued that 340B "preempts the field because Congress intended to create a 'closed system' with the statute." 95 F.4th at 1144. The McClain court responded: "This misconstrues what Act 1103 does. Pharmacies do not purchase 340B drugs, and they do not receive the 340B price discounts. Covered entities purchase and maintain title to the 340B-discounted drugs, while contract pharmacies dispense these drugs to covered entities' patients." *Id*. (citing *Sanofi Aventis U.S. LLC v. U.S. Dep't of Health & Hum. Servs*., 58 F.4th 696, 700 (3d Cir. 2023). The *McClain* court also held that "[p]harmacy has traditionally been regulated at the state level, and we must assume that absent a strong showing that Congress intended preemption, state statutes that impact health and welfare are not preempted." 95 F.4th at 1144. Further, the Eighth Circuit held that pharmacies have always been participants in the 340B program and Congress's decision not to legislate on pharmacies engaging in distribution demonstrates that Section 340B was not intended to preempt the field. *Id*. at 1143. The *McClain* court concluded that "[t]he case for federal pre-emption is particularly weak where Congress has indicated its

awareness of the operation of state law in a field of federal interest, and has nonetheless decided to stand by both concepts and to tolerate whatever tension there [is] between them." *Id*. at 1144 (quotation omitted) Thus, as to field preemption, the Eighth Circuit concluded that "the 340B Program is not so pervasive that Congress left no room for the States to supplement it," given that the statute is "'silent about delivery' of drugs to patients." *Id*. at 1143 (quoting *Arizona*, 567 U.S. at 399 and *Sanofi Aventis U.S. LLC v. U.S. Dep't of Health & Hum. Servs*., 58 F.4th 696, 703 (3d Cir. 2023)).

As to conflict preemption, the Eighth Circuit held the Arkansas law did not require manufactures to provide 340B pricing discounts to contract pharmacies and did not set or enforce discount pricing, and therefore the law did not create an obstacle to enforce the 340B program. *McClain,* 95 F.4th at 1145. Because Act 1103 "does not require manufacturers to provide 340B pricing discounts to contract pharmacies," and "does not set or enforce discount pricing," the Eighth Circuit held that "the delivery of a covered entity's 340B drugs to contract pharmacies for dispensing creates no obstacle. *Id*. at 1145. "There is no obstacle for pharmaceutical manufacturers to comply with both Act 1103 and Section 340B." *Id*.

Defendants argue that Arkansas Act 1103 is substantially identical to § 62J.96, and therefore following the reasoning of *McClain*, § 62J.96 is not preempted by field or conflict preemption. The Court agrees. Similar to Act 1103, § 62J.96, prohibits a manufacturer from prohibiting the delivery of a covered outpatient drug to a contract pharmacy. Minn. Stat. § 62J.96, subd. 1. Given the similarity of the statutory provisions at issue, the Court is persuaded by the *McClain* court's preemption analysis. The State of Minnesota has authority to regulate health and safety matters, including the practice of pharmacy. *McClain*, 95 F.4th at 1143-44. Because Congress has decided not to legislate on the issue of pharmacies engaging in

distribution, Section 340B was not intended to preempt the field. *Id*. at 1143. Further, because § 62J.96 "does not require manufacturers to provide 340B pricing discounts to contract pharmacies," and "does not set or enforce discount pricing," there is no conflict preemption by 340B. *Id*. at 1145.

Defendants cite several federal court decisions that have followed the *McClain* holding in similar challenges to state statutes. *See, e.g. Pharm. Rsch. & Manufacturers of Am. v. Murrill*, No. 6:23-CV-00997, 2024 WL 4361597 (W.D. La. Sept. 30, 2024) (Louisiana statute); *AbbVie v. Fitch*, No. 1:24-cv-184-HSO-BWR, 2024 WL 3503965 (S.D. Miss. July 22, 2024) (Mississippi statute).

In support of its argument for preemption, Plaintiff relies on a federal district court decision in *Pharm. Rsch. & Manufacturers of Am. v. Morrisey*, --- F.Supp.3d ----, No. 2:24-CV-00271, 2024 WL 5147643, at *16 (S.D.W. Va. Dec. 17, 2024). In *Morrisey*, a federal district court enjoined enforcement of West Virginia Code § 60A-8-6a (S.B. 325), ruling that its "No-Audits" and enforcement provisions are preempted by the federal 340B program. *Id*. at *7. S.B. 325's No-Audits provision "restricts a drug manufacturer's ability to acquire claims and utilization data by stating that no manufacturer shall directly or indirectly 'require a 340B entity to submit any claims or utilization data as a condition for allowing the acquisition of a 340B drug by, or delivery of a 340B drug to, a 340B entity unless' the data is required to be shared by federal law." *Id*. at 3 (citing W. Va. Code § 60A-8-6a(b)(2)). As Defendants argue, § 62J.96 does not contain a No-Audits provision or any other language restricting manufacturers' from acquiring claims data from covered entities.

S.B. 325's enforcement provisions imposed penalties for violation of S.B. 325's "No-Restrictions" or "No-Audits" provisions. *Morrisey*, 2024 WL 5147643 at *3. Those penalties include

> "a civil penalty of $50,000 per violation; investigatory power and civil suit authorization in the West Virginia Attorney General; enforcement under the general unfair trade practice laws of West Virginia; civil suit referral powers in the West Virginia Board of Pharmacy; rulemaking authority in the West Virginia Board of Pharmacy; and the ability to 'discipline, or suspend[ ], or revok[e] the license or permit of any [drug] manufacturer' who is found to be non-compliant.

Id. at *3 (citing W. Va. Code § 60A-8-6a(c)(1)–(3)). Similar enforcement provisions are not found in § 62J.96.

As of the date of the filing of this order, this Court found only one case which cited *Morrisey*, and that court declined to follow its holding because of textual distinctions between the challenged state statutes. In A*straZeneca Pharms. LP v. Fitch*, --- F.Supp.3d ----, No. 1:24CV196-LG-BWR, 2024 WL 5345507, at *8 (S.D. Miss. Dec. 23, 2024) a federal district court in Mississippi held that "[s]ince Mississippi's H.B. 728 does not contain a provision equivalent to S.B. 325's 'No-Audits' provision, it is not necessary for this Court to address that portion of the *Morrisey* court's decision." *Id*.

Defendants argue that because the West Virginia legislation at issue in *Morrisey* contains a "No-audits" provision and enforcement provisions, the *Morrisey* case's reasoning is irrelevant to PhRMA's preemption claims as to § 62J.96. The Court agrees. The *Morrisey* court's reasoning focused primarily on the "No-audits" provision and enforcement provisions in concluding that federal law preempted the West Virginia statute. Plaintiff argues that the *Morrisey* court correctly held that what is at issue is pricing, and the *McClain* court erred in concluding that delivery is at issue. Plaintiff argues that it has sufficiently pled conflict preemption because § 62J.96 (1) impermissibly expands the scope of manufacturers' obligations

and creates new pricing obligations; (2) practically eliminates manufacturers' ability to utilize 340B's enforcement scheme, and (3) conflicts with 340B's enforcement scheme. Opp. at 23. Even treating the allegations in the Complaint as true, this Court relies on the language of § 62J.96, which only mentions the "delivery" of drugs, and says nothing of the prices of those drugs. *See* Minn. Stat. § 62J.96, subd. 1 ("A manufacturer must not directly or indirectly restrict, prohibit, or otherwise interfere with the delivery of a covered outpatient drug[.]") This Court concludes that there is no conflict preemption.

As discussed above, the Court concludes that the *McClain* decision is persuasive on the question of field preemption. This Court agrees with the *McClain* holding that "the 340B Program is not 'so pervasive ... that Congress left no room for the States to supplement it.'" *McClain*, 95 F.4th at 1143 (quoting *Arizona v. United States*, 567 U.S. 387, 401 (2012)). Further, the *McClain* court's holding regarding the Arkansas statute applies with equal force in Minnesota: "Pharmacy has traditionally been regulated at the state level, and we must assume that absent a strong showing that Congress intended preemption, state statutes that impact health and welfare are not preempted." *McClain*, 95 F.4th at 1144. The Court concludes that there is neither field preemption nor conflict preemption by Section 340B as to § 62J.96. Therefore, the Court concludes that § 62J.96 is not preempted by federal law.

C. Commerce Clause and extraterritorial regulation

PhRMA's Claim II alleges that § 62J.96 violates the Commerce Clause's bar on extraterritorial state regulation. Defendants argue that § 62J.96 is not extraterritorial legislation. In particular, Defendants argue that (1) Minnesota laws presumptively operate only within the State's boundaries, (2) Minnesota laws are not generally enforceable outside of the territory of the State, and (3) nothing in the plain language of Section 62J.96 expresses an intent to operate outside Minnesota. Plaintiffs respond that § 62J.96 impermissibly regulates wholly

extraterritorial transactions because it bans manufacturers who have no presence in Minnesota from interfering with the delivery of drugs to pharmacies and the state regulates pharmacies outside of Minnesota that dispense drugs for Minnesota residents.

"Minnesota's laws are not generally enforceable outside of the territory of the State." *Matter of Minnesota Power's Petition for Approval of EnergyForward Res. Package*, 958 N.W.2d 339, 349 (Minn. 2021) (citing Minn. Stat. § 1.01); *see also In re Pratt*, 219 Minn. 414, 18 N.W.2d 147, 153 (1945) ("The laws of one state of their own vigor have no extraterritorial effect."). The Commerce Clause gives Congress the power to regulate interstate commerce. U.S. Const. art. I, § 8, cl. 3. This grant of power to Congress also "contains a further, negative command, one effectively forbidding the enforcement of certain state economic regulations even when Congress has failed to legislate on the subject." *Nat'l Pork Producers Council v. Ross*, 598 U.S. 356, 368 (2023) (cleaned up). This negative command—the dormant Commerce Clause—prohibits states from directly regulating out-of-state transactions. *Id*. at 376 n.1. In *Pork Producers*, the Supreme Court described a key principle of its dormant commerce clause jurisprudence: "antidiscrimination ... lies at the very core of [the Court's] dormant Commerce Clause jurisprudence." *Id*. at 369 (cleaned up). The Supreme Court rejected an argument that there was an "almost per se rule forbidding enforcement of state laws that have the practical effect of controlling commerce outside the State, even when those laws do not purposely discriminate against out-of-state economic interests." *Id*. at 371 (cleaned up). Stated another way, in *Pork Producers*, the Supreme Court clarified that a state law does not necessarily violate the dormant Commerce Clause merely because its regulation of in-state activity has out-of-state effects. *Pork Producers*, 598 U.S. at 371-76.

Defendants argue that § 62J.96 does not contain language demonstrating an intent to operate outside of Minnesota. Defendants argue that Plaintiff's reliance on Minn. R. § 6800.0300—which regulates pharmacies outside of Minnesota that dispense drugs for Minnesota residents—is misplaced. Defendants argue that the plain language of both of those provisions does not purport to regulate out-of-state pharmacies or apply outside of the boundaries of Minnesota. The Court agrees with Defendants. Plaintiff does not allege in the Complaint that § 62J.96 directly regulates out-of-state pharmacies. At best, Plaintiff seems to argue that the statute has the practical effect of regulating out-of-state manufacturers, but this is not a dormant Commerce Clause violation pursuant to the holding of *Pork Producers*. 598 U.S. at 371-76. The Court concludes that Plaintiff's citation to Minn. R. § 6800.0300 is unpersuasive. As Defendants argue, that rule simply states that "[n]o person or persons shall conduct a pharmacy in or outside of Minnesota that dispenses legend drugs for Minnesota residents and mails, ships, or delivers the legend drugs into this state unless the pharmacy is licensed by the Board of Pharmacy." Minn. R. § 6800.0300. As Defendants correctly argue, this provision requires any pharmacy that conducts business in Minnesota to be licensed in Minnesota whether it is an in-state or out-of-state pharmacy. Nothing in the text of the rule suggests extraterritorial state regulation. The Court concludes that PhRMA's dormant commerce clause claim fails as a matter of law.

D. Single Subject and Title Clause

Claim III of the Complaint alleges that H.F. 4757 violates the Minnesota Constitution's Single Subject and Title Clause. Defendants argue that H.F. 4757 does not violate the Single Subject and Title Clause, and so Claim III must be dismissed with prejudice because it fails as a matter of law.

The Minnesota Constitution's Single Subject and Title Clause states: "No law shall embrace more than one subject, which shall be expressed in its title." Minn. Const. art. IV, § 17.

The first clause is referred to as the Single Subject Clause, and the second clause as the Title Clause. The two clauses "serve independent though interrelated purposes." *Wass v. Anderson*, 252 N.W.2d 131, 134 (Minn. 1977).

The Single Subject Clause "should be interpreted liberally and the restriction [is] met if the bill [is] germane to one general subject[.]" *Associated Builders & Contractors v. Ventura*, 610 N.W.2d 293, 299 (Minn. 2000); *see also Johnson v. Harrison*, 50 N.W. 923, 924 (Minn. 1891) ("The term 'subject,' as used in the constitution, is to be given a broad and extended meaning .... All that is necessary is that the act should embrace ... some one general idea, be so connected with or related to each other, either logically or in popular understanding, as to be parts of, or germane to, one general subject."). The Single Subject Clause thus "ensures that each piece of legislation receives separate and individual consideration on the merits by prohibiting insertion of wholly unrelated matters." *Unity Church v. State*, 694 N.W.2d 585, 592 (Minn. Ct. App. 2005), *review dismissed* (Minn. June 9, 2005). But it is "not intended to preclude the enactment of comprehensive legislation addressing related topics within a general subject area." *Id*. "[N]ongermaneness is "the key word" that demonstrates a violation the Single Subject Clause. *Id*. at 592 n.3. "Legislation that someone claims is 'log-rolling legislation' has always been permissible when *similar* subjects are united in one bill and the bill is passed by a combination of legislators, all of whom are united in wanting their part of the bill to go through." *Id.* (emphasis original).

The Title Clause is "intended to prevent fraud or surprise upon the legislature and the public by prohibiting the inclusion of provisions in a bill whose title gives no intimation of the nature of the proposed legislation." *Assoc. Builders*, 610 N.W.2d at 300 (quotation omitted). The Title Clause should be accorded "the same liberal construction as the single subject provision"

and "[e]very reasonable presumption should be in favor of the title." *Id*. (alteration in original) (quotation omitted). "[T]he generality of the title of an act is not grounds for invalidation as long as the title gives notice of the general subject because the title was never intended to be an index of the law." *Id*. (quotation omitted).

H.F. 4757 provides that it is "[a]n act relating to commerce[.]" The Complaint notes that the remainder of its title is over 380 words long. Compl. ¶ 113. Defendants argue that Section 62J.96 is germane to H.F. 4757's subject: commerce. Defendants argue that delivery is a necessary component of commerce. Further, Defendants argue that § 62J.96 is germane to commerce because it prevents drug manufacturers from interfering with the delivery of drugs to Minnesota consumers. Defendants argue that H.F. 4757's title is sufficiently clear because it gives adequate notice of its subject and purpose by noting that it is related to commerce, and provides an article-by-article description of its contents.

Plaintiff argues that that H.F. 4757 violates the single-subject provision because it includes disparate subjects that lack a legitimate connection to one another. Plaintiff argues that the legislation's primary focus is on cannabis, which is unrelated to 340B, and that 140 of the 186 pages of the bill address the regulation of cannabis. Plaintiff argues that the remaining topics in the bill were disparate and do not relate to a single subject. Plaintiff argues that "commerce" is too broad of a subject, and its use violates the single subject requirement.

The Court concludes that § 62J.96 and H.F. 4757 do not violate the Single Subject and Title Clause. Even taking the allegations in the Complaint as true, this Court must liberally construe both clauses. The Court agrees with Defendants that the subject of H.F. 4757—commerce—is directly addressed in the text of § 62J.96. There can be no question that the delivery of drugs from a manufacturer to a pharmacy is a commercial transaction. By its very

nature, a commercial transaction is "commerce." Section 62J.96 is therefore germane to H.F. 4757's subject. The Court also concludes that H.F. 4757's title is sufficiently clear. H.F. 4757 describes both its primary topic—commerce—and then specifically describes the other topics addressed in the legislation. While it is true that commerce is a general description, that is not dispositive. *Assoc. Builders*, 610 N.W.2d at 300 ("generality of the title of an act is not grounds for invalidation as long as the title gives notice of the general subject because the title was never intended to be an index of the law") (quotation omitted). Given the liberal construction this Court must apply, the Court cannot conclude that H.F. 4757 "gives no intimation of the nature of the proposed legislation." *Id*. (quotation omitted). The Court concludes that the H.F. 4757 does not violate the Minnesota Constitution's Single Subject and Title Clause and Claim III of the Complaint fails as a matter of law.

IV. CONCLUSION

Based upon the Court's file, and records in the proceeding, and the arguments of Counsel, Defendant's Motion to Dismiss is granted. This matter is dismissed with prejudice.

LET JUDGMENT BE ENTERED ACCORDINGLY.

Dated: 4/15/2025

BY THE COURT:

Aligada, Reynaldo (Judge)
Apr 15, 2025 3:33 PM

Reynaldo A. Aligada
Judge of District Court