UNITED STATES DISTRICT COURT
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. 0:23-cv-02024-PJS-JFD

PLAINTIFF'S COMBINED REPLY IN SUPPORT OF MOTION FOR A PRELIMINARY INJUNCTION AND OPPOSITION TO DEFENDANT'S MOTION TO DISMISS

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INTRODUCTION

The Act directly regulates the prices charged in wholly out-of-state transactions.[1] That is unconstitutional. The threat of massive penalties for violating the Act is injuring generic manufacturers and, if not enjoined, will harm the public's access to generic medicines. Defendant's response rests on a series of distortions—of the case law, of the Act, and of the Complaint's legal theory. The Court should grant AAM's motion for a preliminary injunction and allow this case to proceed.

The defense of the Act's extraterritorial price control rests almost entirely on Defendant's mistaken belief that after *National Pork Producers Council v. Ross*, 143 S. Ct. 1142 (2023), extraterritorial state laws do not violate the Commerce Clause unless they are independently discriminatory. That is not what *Ross* held. *Ross* did not disturb—indeed, it expressly preserved—existing case law invalidating nondiscriminatory state laws that "*directly* regulate[]" out-of-state commerce. *Id*. at 1157 n.1. And because those cases—including binding Eighth Circuit precedent—remain good law, the Act cannot stand. Defendant does not meaningfully try to reconcile the Act with those cases, and instead tries (Def. Br. 15, 28-29) to re-write the Act and the Complaint to make them look more like *Ross*. But by its plain terms, the Act *directly* regulates generic sales entirely outside Minnesota, and that problem is the basis for the Complaint's extraterritoriality claim. Compl. ¶¶ 60-63. The Act must be held "invalid." *Styczinski v. Arnold*, 46 F.4th 907, 913 (8th Cir. 2022).

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[1] Defined terms have the same meaning as in AAM's memorandum of law.

Defendant's arguments on the remaining preliminary-injunction factors fare no better. A constitutional violation is an irreparable injury; Defendant asks for an arbitrary exception for Commerce Clause violations but offers no justification. And the *financial* injury from the Act is both irreparable and certain. The declarations show, to the penny, that the Act is already preventing AAM members from adjusting their prices to respond to increased costs. That means the Act is causing AAM members to collect less revenue—which the State will never repay, even if AAM prevails. The injunction is necessary to halt that irreparable harm.

Enjoining this unconstitutional law is in the public interest. Defendant insists the Act will curb drug prices, but the very sources Defendant cites blame rising drug prices on *brand* manufacturers, who are exempt from the Act, and credit generics for *reducing* drug prices. And Defendant does not (and cannot) dispute that the Act's generic-only price control will exacerbate the severe drug shortages plaguing the healthcare system, making life-saving drugs *less* available and *more* costly.

The motion to dismiss should also be denied. The Act violates the Commerce Clause under settled Supreme Court and Eighth Circuit precedent, but the Commerce Clause is not the only constitutional restriction on attempts by one state to regulate activity within another. *First*, the Act violates the Due Process Clause because it exceeds Minnesota's legislative power: the State lacks the necessary "substantial" contact with out-of-state transactions. *McCluney v. Joseph Schlitz Brewing Co.*, 649 F.2d 578, 581 & n.3 (8th Cir. 1981), *aff'd*, 454 U.S. 1071 (1981). *Second*, for similar reasons, penalizing transactions that are lawful where they occur violates the "horizontal separation of powers"

implicit in the Constitution's design. *Ross*, 143 S. Ct. at 1156-57 & n.1. *Third*, the Act imposes unjustifiable burdens on interstate commerce, so it violates the Commerce Clause under the *Pike* balancing test. Defendant claims that test has been replaced by a bright-line rule—no discrimination, no problem—but six Justices rejected that argument in *Ross*. And the Act's burdens on the interstate generic drug market are indistinguishable from those the Court has previously found sufficiently substantial, including in *Ross* itself.

Just a few weeks after its enactment, the Act is already disrupting the generic market and endangering the generic industry's efforts to provide safe, lower-cost medications. This Court should enjoin the Act and deny the motion to dismiss.

ARGUMENT

I. AAM Is Entitled To A Preliminary Injunction.

A. AAM Is Likely To Succeed On Its Claims That The Act Violates The Constitution By Directly Regulating Out-Of-State Transactions.

AAM is likely to succeed in showing that the Act violates the Constitution, including the Commerce Clause's restraints on extraterritorial state regulation, because it directly regulates out-of-state transactions. AAM Br. 9-17. Defendant's contrary arguments rest on a series of misconceptions—and some outright misrepresentations—regarding the governing law and AAM's legal theory.

1. Defendant's opposition to AAM's motion rests almost entirely on his insistence that after *Ross*, laws that regulate extraterritorially violate the Commerce Clause only if they are independently *discriminatory*. Def. Br. 14, 16-17. But *Ross* held no such thing: the California law "barr[ed the] *in-state sales*" of pork, Def. Br. 15 (emphasis

added), and the plaintiffs challenged that law, not as *directly* regulating out-of-state commerce, but instead as having that "*practical effect*," 143 S. Ct. at 1154. *Ross* thus addressed a specific type of law—nondiscriminatory laws regulating *in-state* sales—and rejected a specific legal challenge to such laws—that their extraterritorial effects *alone* render them unconstitutional.

Ross did not give states license to penalize conduct outside their borders so long as they avoid overt discrimination, as Defendant argues. Def. Br. 16-17. *Ross* itself made that clear by expressly distinguishing its holding from the plurality opinion in *Edgar v. MITE Corp.*, 457 U.S. 624 (1982), which addressed an Illinois law that *did not* discriminate against interstate commerce. *See Ross*, 143 S. Ct. at 1157 n.1; *id*. at 1166 (Sotomayor, J., concurring in part). While the Illinois law "*directly* regulated out-of-state transactions," the California law "regulates only products that companies choose to sell 'within' California." *Id*. at 1157 n.1 (majority opinion). If *Ross* truly held that even laws that *directly* regulate out-of-state commerce are impermissible only if they are also discriminatory, its careful distinction of the *Edgar* plurality would make no sense.[2]

2. Defendant also seeks to distort both the Act and AAM's allegations to fit within *Ross*'s actual holding. Defendant argues that the Act is no different than the California law because "both laws … prohibit … the *in-state* distribution of certain

[2] *New Jersey Staffing Alliance v. Fais*, No. 1:23-cv-02494, 2023 WL 4760464 (D.N.J. July 26, 2023), merely recognized that after *Ross* "extraterritorial *effects* alone are no longer sufficient." *Id*. at *9 (emphasis added). AAM has never argued that they are, because the Act directly regulates out-of-state transactions on its face.

consumer products." Def. Br. 28-29 (emphasis added). That is incorrect. California's law targets in-state sales, but Minnesota's does not. Rather, the Act targets and directly regulates the wholly *out-of-state* sales between manufacturers and wholesalers. And while its coverage is triggered by a sale within Minnesota, a resale by a third party suffices, and the Act *exempts* the in-state resale from liability. AAM Br. 7, 15. The Act thus does exactly what Defendant denies (Def. Br. 17): it directly "regulate[s] 'wholly' out-of-state prices" and penalizes transactions that are lawful where they occur.

Equally flawed is Defendant's assertion that AAM's claim is "functionally identical to the pork producers' claim rejected in *Ross*," because (Defendant contends) AAM is alleging that the Act "has '*the practical effect* of extraterritorial control on interstate commerce.'" Def. Br. 15 (emphasis added). That is plainly incorrect. The only paragraph of the Complaint Defendant cites addressing AAM's extraterritoriality claim says nothing about "practical effects." Compl. ¶ 61. The others either relate to different claims (and do not mention "practical effects" either) (Compl. ¶¶ 65, 70), pertain to AAM's *Pike* claim, where effects *are* relevant (Compl. ¶¶ 44, 74), or supply background information about the pharmaceutical market (Compl. ¶ 24). The Complaint's extraterritoriality claim is clear: "[t]he Act directly regulates out-of-state commerce" and "therefore violates the Commerce Clause." Compl. ¶¶ 62-63.

3. The Act's fate is sealed by the long line of cases invalidating state laws that directly regulated wholly out-of-state transactions. AAM Br. 11-12, 15-16 & n.18. Defendant's response rests mainly on his already-debunked distortion of *Ross*.

The *Edgar* plurality concluded that the Illinois law violated the Commerce Clause

because it sought to "directly regulate[] *transactions* which t[ook] place … wholly outside … Illinois"—*i.e.*, purchase offers communicated and accepted entirely outside the State. 457 U.S. at 641 (plurality opinion) (emphasis omitted); *see also id*. at 643. That is exactly what the Minnesota law does, too. *See* pp. 4-5, *supra*. Defendant attempts to dismiss that opinion as only a plurality view, but as AAM has already pointed out (Br. 11), the Supreme Court later recognized the *Edgar* plurality as "significantly illuminat[ing] the contours of the constitutional prohibition on extraterritorial legislation." *Healy v. Beer Inst., Inc.*, 491 U.S. 324, 333 n.9 (1989). Defendant has no response. Instead, Defendant argues that the direct-regulation rule applies only to "transactions by those with *no* connection to the State." Def. Br. 29 (quoting *Ross*, 143 S. Ct. at 1157 n.1). But that overreads *Ross*'s footnote summary. The shareholders in *Edgar* clearly had *some* connection to Illinois by virtue of owning shares of "a publicly held Illinois corporation," but that connection was inadequate to save the Illinois statute. 457 U.S. at 642 (plurality opinion). The Act regulates transactions even less connected to Minnesota.

Defendant also fails to differentiate the Act from the law the Eighth Circuit struck down in *Styczinski*. *See* AAM Br. 11-12. Defendant claims that the law "discriminated against out-of-state bullion traders," Def. Br. 30-31, but that again is inaccurate. The law applied to *both* in-state and out-of-state dealers, and it subjected the in-state dealers to *more* onerous regulation. 46 F.4th at 910, 912-913. Unsurprisingly, then, the plaintiff did not assert a "discrimination" claim and the Eighth Circuit did not consider one.

Instead, *Styczinski* held the law unconstitutional because it regulated transactions "anywhere in the world." 46 F.4th at 913. Defendant suggests (Def. Br. 30) that

constitutional flaw would dissipate if the product were later resold into Minnesota in a *separate* transaction between *separate* parties. That ignores *Styczinski*'s reasoning, which neither said nor suggested any such thing: the law was invalid because it regulated a "wholly out-of-state transaction." *Id.*; *see Pitman Farms v. Kuehl Poultry LLC*, --- F. Supp. 3d ---, 2023 WL 3853411, at *8 (D. Minn. June 6, 2023) (reading *Styczinski* to hold that a law is invalid if it "controls wholly out-of-state commerce" (quoting 46 F.4th at 914)). The Act is invalid for the same reason.

Styczinski also rejected the argument that "by domiciling in Minnesota," companies "subject themselves to Minnesota regulation," 46 F.4th at 914—which puts to rest Defendant's assertion (Def. Br. 29-30 & n.20) that AAM's members being licensed in Minnesota neutralizes the Commerce Clause violation, *see* AAM Br. 16-17. As the Supreme Court has long held, even where a business registers in a particular state and consents to suit there, that does not empower the state to regulate the entity's activity worldwide in derogation of the Commerce Clause. *See Davis v. Farmers' Co-op Equity Co.*, 262 U.S. 312, 314-17 (1923); *see also Mallory v. Norfolk S. Ry. Co.*, 143 S. Ct. 2028, 2051-55 (2023) (Alito, J., concurring in part and concurring in the judgment).[3] Defendant never even attempts to respond to this point.

Nor does the licensing procedure give Minnesota permission to violate the Commerce Clause. Agreeing generally "to operate in a manner prescribed by federal and

[3] Defendant incorrectly argues (Def. Br. 18-19) that the other decisions AAM cited applied the "practical effects" theory rejected in *Ross*. Each of those cases invalidated laws because they *directly* regulated out-of-state conduct. *See* AAM Br. 12 n.18, 15-16.

state law and according to Minnesota Rules," Minn. Stat. Ann. § 151.252(d), is not consent to otherwise-unconstitutional nationwide regulation by Minnesota.[4] A state may not violate the Constitution "under the guise of a surrender of a right in exchange for a valuable privilege which the state threatens otherwise to withhold." *Frost & Frost Trucking Co. v. R.R. Comm'n*, 271 U.S. 583, 593 (1926); *accord Koontz v. St. Johns River Water Mgmt. Dist.*, 570 U.S. 595, 601-02, 604-09 (2013) (discussing "unconstitutional conditions" doctrine). In particular, a state may not condition access to its market on the imposition of regulations that violate the Commerce Clause, such as a tax on out-of-state operations. *Western Union Telegraph Co. v. Kansas ex rel. Coleman*, 216 U.S. 1, 33-37 (1910) (plurality opinion); *see Western & Southern Life Ins. Co. v. State Bd. of Equalization*, 451 U.S. 648, 662 & n.14 (1981).

Defendant's attempt to distinguish *Association for Accessible Medicines v. Frosh*, 887 F.3d 664 (4th Cir. 2018)—which the Supreme Court cited approvingly in *Ross*—is equally flawed. He argues (Def. Br. 31) that *Frosh* is distinct because the Maryland law regulated the price of "transaction[s] that did not result in a single pill being shipped to Maryland." 887 F.3d at 671. But the same is true of the Act: it regulates sales by manufacturers to wholesalers, which occur entirely outside Minnesota (AAM Br. 4-5), and *those* wholly out-of-state sales likewise "d[o] not result in a single pill being shipped [in]to [Minnesota]." That the Act is *triggered* by an in-state sale is irrelevant, because liability is

[4] Nor is it the kind of *irrevocable* consent that would be needed to justify the Act's penalty for leaving the Minnesota market.

imposed on the *out-of-state* transaction.[5] Indeed, *Frosh* made this exact point: it held that the Maryland law violated the Commerce Clause "*[e]ven if* [it] … require[d] a nexus to an actual sale in Maryland," as the district court had believed, because it "measured" the lawfulness of a sale "according to the price the manufacturer or wholesaler charges *in the initial sale of the drug*" outside Maryland. 887 F.3d at 671 (first emphasis added); *see also Pharm. Rsch. & Mfrs. of Am. v. District of Columbia*, 406 F. Supp. 2d 56, 69-70 (D.D.C. 2005) (similar); AAM Br. 14-16.

4. The Act is therefore unconstitutional because it directly regulates prices charged in wholly out-of-state transactions. But even under Defendant's misreading of *Ross*, the Act still would be invalid because it "discriminates against interstate commerce … in effect," by "favor[ing] in-state economic interests over out-of-state interests." *IESI AR Corp. v. Nw. Ark. Reg'l Solid Waste Mgmt. Dist.*, 433 F.3d 600, 604, 605 (8th Cir. 2006).

The Act imposes liability on AAM's members who are generic manufacturers, all of whom are based outside Minnesota and sell their products predominantly to a small number of large wholesalers also based outside Minnesota. AAM Br. 4. But the Act shields pharmacies and wholesale distributors, which are more likely to be located in Minnesota. *See* Act §§ 23(1), (3); Howard Decl. ¶ 17. The Act's burdens will thus be overwhelmingly felt *outside* Minnesota by entities engaged in transactions *outside* Minnesota, while in-state

[5] That is why AAM's proposed order specifically seeks to enjoin imposing liability on out-of-state transactions. Defendant's speculation that perhaps some transactions occur in-state therefore attacks a straw man.

transactions involving in-state entities are more likely to be immunized. *See* AAM Br. 14-15. Thus, even if the Commerce Clause's extraterritoriality doctrine applied solely to laws with some discriminatory feature, the Act would still be unconstitutional given its discriminatory impact on out-of-state transactions.

B. AAM's Members Will Suffer Irreparable Harm Absent An Injunction.

The Act imposes unconstitutional regulations and makes AAM's members bear unrecoverable economic harms. Both are irreparable injuries. AAM Br. 17-20.

1. Defendant recognizes the binding precedent that the deprivation of *other* constitutional rights constitutes irreparable harm and concedes that this Court has held that violations of the Commerce Clause presumptively cause irreparable harm. Def. Br. 32 & n.23. Defendant urges this Court to reject those holdings and make an exception for Commerce Clause violations, but never explains why this type of constitutional harm should be treated differently. It should not: the Constitution's allocation of authority over interstate commerce is just another example of how "federalism secures to citizens the liberties that derive from the diffusion of sovereign power." *Bond v. United States*, 564 U.S. 211, 221 (2011) (citation omitted).

Defendant appeals to the accurate-but-inapposite principle that a state "suffers … a form of irreparable injury" if a court enjoins one of its duly enacted laws. Def. Br. 32-33 (quoting *Maryland v. King*, 567 U.S. 1301, 1303 (2012) (Roberts, C.J., in chambers)). That principle may help the State when it is the movant seeking a stay, but it does not immunize state statutes from being enjoined. It is "the threat of irreparable harm *to the movant*" that matters for this prong of the preliminary-injunction standard. *Eggers v. Evnen*, 48 F.4th

561, 564 (8th Cir. 2022) (emphasis added; citation omitted). Since Defendant gives no reason why the Commerce Clause should be treated less favorably than, say, the Equal Protection Clause, *see* Def. Br. 32, he appears to be arguing that a state's interest in enforcing its statutes always outweighs the harm when one of those statutes violates the Constitution. That is not the law. *See, e.g.*, *Libertarian Party of Ark. v. Thurston*, 962 F.3d 390, 405 (8th Cir. 2020) (constitutional harm "outweighed the lesser harm to the State in enjoining [a law]").

2. AAM's members also will suffer irreparable economic harm. Defendant does not dispute that unrecoverable financial losses (whether in the form of lost revenues, financial penalties, or compliance costs) qualify as irreparable harm, nor that the financial losses described in the Teva and Sandoz declarations will be unrecoverable due to sovereign immunity. *See* AAM Br. 18-19.[6] Instead, Defendant repeatedly claims that Teva's and Sandoz's financial losses are "speculative." Def. Br. 21, 33, 34, 35. They are anything but. As Defendant admits, both companies identified specific prices, down to the penny, that they had "intended" to charge for specific products, but which they now "will refrain from" charging. Def. Br. 33-34. They did so "[s]olely" because of the Act's price control. de Gavre Decl. ¶¶ 14, 16; Galownia Decl. ¶¶ 10-11, 15-16. Those facts show that the Act is causing concrete financial injury, which will increase as compliance costs

[6] Defendant is wrong to "presum[e]" that the Act will "have no negative impact on the revenues" of AAM's other members. Def. Br. 33 n.25. The Act went into effect after many prices were set for the calendar year, yet within weeks it inflicted harm on the declarants. The harm will only compound as more companies adjust their prices.

mount.[7]

Instead of disputing *whether* the Act prevented the companies from changing their prices, Defendant questions whether increased costs "require[d]" these specific price changes. Def. Br. 34. That does not matter: the Act penalizes manufacturers *whether or not* price changes are driven entirely by higher costs, and manufacturers are injured by losing revenue *whether or not* the loss pushes the product into the red. AAM Br. 19. But even if increased costs were necessary for irreparable harm, the declarations explain that the price increases were planned "in light of the increased cost of manufacturing" the products and give details about what costs increased, why, and how much. Galownia Decl. ¶¶ 10, 14-15; de Gavre Decl. ¶¶ 11, 14.

Shifting gears, Defendant argues that irreparable harm is lacking because AAM has not "alleged any imminent enforcement of the Act." Def. Br. 35. But a regulated party challenging an unconstitutional law need not "expose [it]self to liability before bringing suit." *Susan B. Anthony List v. Driehaus*, 573 U.S. 149, 158-59 (2014) (citation omitted). The Act specifies what price changes it prohibits, and "when a course of action is within the plain text of a statute, a 'credible threat of prosecution' exists." *Alexis Bailly Vineyard, Inc. v. Harrington*, 931 F.3d 774, 778 (8th Cir. 2019) (citation omitted) (Commerce Clause case). Defendant never denies that he would enforce the Act against Teva or Sandoz if they implemented their price changes. *See Susan B. Anthony List*, 573 U.S. at 165 (noting that

[7] Defendant says the evidence of compliance costs is "speculative," Def. Br. 33 n.24, but cannot seriously argue that the tasks the Act imposes on manufacturers will be cost-free.

the government "ha[d] not disavowed enforcement"); *Religious Sisters of Mercy v. Becerra*, 55 F.4th 583, 605 (8th Cir. 2022) (similar). Nor could any generic or biosimilar company expect a lack of enforcement: Defendant advocated passage of the Act (Lewellen Decl., Ex. F at 9; Def. Br. 1-2), which specifically targets the generic and biosimilar manufacturers AAM represents. The threat of enforcement is thus far from "imaginary or wholly speculative." *Susan B. Anthony List*, 573 U.S. at 160 (quotation marks omitted). Defendant cites only *Morales v. Trans World Airlines, Inc.*, 504 U.S. 374 (1992), an inapplicable preemption case involving an effort to enjoin states from enforcing their catchall consumer-protection laws against airlines; that case did not address injunctive relief from an unconstitutional statute that expressly bars the plaintiff's desired conduct. *Id*. at 380, 381-83. *Morales* narrowed a portion of an injunction based on a "conjectural" threat of enforcement, *id.* at 382; here, the threat that Defendant will enforce the Act is not conjectural at all.

Finally, Defendant contends that Teva (and only Teva) will not be irreparably harmed because it "is not currently licensed" as a manufacturer in Minnesota. Def. Br. 34. That is incorrect for multiple reasons. Minnesota requires a license for each "facility" where drugs are manufactured (Minn. Stat. Ann. § 151.252(g); Minn. R. 6800.1400(3); Howard Decl. ¶ 3)—*except* those "located outside the United States," Howard Decl., Ex. B at 1. One of the Teva products at issue is manufactured outside the United States, as the declarant explained. Galownia Decl. ¶ 8. The other is manufactured at a facility operated by a Teva subsidiary, which has a Minnesota license. Galownia Decl. ¶ 13; Declaration of Brian Savage ¶¶ 1-2 (filed concurrently herewith); *see* Howard Decl., Ex. A at 9 (listing

the subsidiary as licensed). And most importantly, for both products, it is Teva that "impose[s]" or "cause[s] to be imposed" the prices charged for the specific generic drugs. Act § 23(1); *see* Galownia Decl. ¶¶ 10, 15. That fact—which Defendant does not dispute—means that Teva is subject to the Act.

In any event, Defendant concedes that Sandoz is currently licensed as a manufacturer in Minnesota and is subject to the Act. Def. Br. 34. Defendant offers no reason or authority why establishing irreparable harm to Sandoz would be insufficient.

C. The Balance Of Hardships And Public Interest Support An Injunction.

The balance of hardships and the public interest likewise support an injunction. AAM Br. 20-22. Defendant ignores the on-point case law AAM cited, and relies on *Carson v. Simon*, 978 F.3d 1051 (8th Cir. 2020), but that case *imposed* an injunction against *executive* action that unconstitutionally overrode a Minnesota election law. *Id*. at 1059-63. To be sure, the enforcement of a *valid* state statute is in the public interest, *id*. at 1061, but the enforcement of an *unconstitutional* law is not. AAM Br. 21.

Defendant insists that the Act's price controls will benefit the public interest (Def. Br. 36), but he does not deny that the Act will exacerbate the severe drug shortages plaguing the U.S. healthcare system, forcing withdrawal of generics and *reducing* patient access to affordable medicines. AAM Br. 21-22.

Nor does Defendant justify targeting *only* generic manufacturers. Defendant's own task-force report acknowledges that generics are the primary driver behind price *reductions*, bringing prices "down by 80% to 85%," and that Minnesota itself has sought to "lower prescription drug costs" through legislation "encouraging the use of generic

drugs." Lewellen Decl., Ex. F at 28, 37. And the cited Minnesota Department of Health report found that of the 698 price increases (covering "686 unique drugs") that triggered the reporting requirement in Minnesota's separate "drug price transparency" law, "*only nine* were for generic drugs." Lewellen Decl., Ex. G at 22 (emphasis added). By contrast, Defendant's task-force report puts the blame for higher drug prices on the practices of brand manufactures and other market actors, especially those that block, delay, or discourage patients from using generics. Lewellen Decl., Ex. F at 7-8, 16, 36-38, 40, 42-47. The public interest is not served by imposing burdensome price regulations exclusively on the entities responsible for *hundreds of billions* in annual healthcare savings nationwide, AAM Br. 4, while exempting the brand manufacturers that Defendant himself concedes are responsible for skyrocketing drug prices.

* * *

The Court should grant AAM's motion for a preliminary injunction.

II. The Court Should Deny Defendant's Motion To Dismiss.

A. The Complaint Plausibly Alleges That The Act Violates The Commerce Clause's Prohibition On Extraterritorial State Laws (Count I).

AAM has stated a plausible claim of unconstitutional extraterritoriality. *See* Part I.A, *supra*.

B. The Complaint Plausibly Alleges A Due Process Claim (Count II).

AAM has plausibly alleged that the Act's regulation of wholly out-of-state transactions violates the Due Process Clause's restrictions on extraterritorial state legislation. Compl. ¶¶ 50-51, 64-68.

1. The Due Process Clause restricts a state's "power … to apply its laws to any given set of facts," to prevent "infring[ing] upon the legitimate interests that other states may have in the transaction." *McCluney*, 649 F.2d at 581 n.3, 582. For a state to exercise its "legislative jurisdiction" consistent with due process, it "must have a substantial factual contact with the parties or the transaction giving rise to the litigation." *Id.* at 581; *accord Gerling Glob. Reinsurance Corp. of Am. v. Gallagher*, 267 F.3d 1228, 1236 (11th Cir. 2001). A state violates this rule when it "regulate[s] and control[s] activities wholly beyond its boundaries." *Watson v. Employers Liab. Assurance Corp.*, 348 U.S. 66, 70 (1954); *see Home Ins. Co. v. Dick*, 281 U.S. 397, 407-10 (1930); *BMW of N. Am., Inc. v. Gore*, 517 U.S. 559, 571-73 (1996) (because each "State's power" is "constrained by the need to respect the interests of other States," states have no power "to punish [actors] for conduct that was lawful where it occurred").

Minnesota lacks the necessary "substantial … contact[s]" with AAM's members' out-of-state sales, *McCluney*, 649 F.2d at 581, but the Act directly regulates those sales anyway, Compl. ¶¶ 26-31. Indeed, Defendant acknowledges that, for purposes of due process, Minnesota "lack[s] contact[s] with [AAM's members] regarding [the] *specific* transaction[s]" made wholly outside Minnesota. Def. Br. 23 (emphasis added). AAM has thus plausibly alleged that the Act violates the Due Process Clause because it "regulate[s] and control[s] activities wholly beyond [Minnesota's] boundaries." *Watson*, 348 U.S. at 70.

2. Defendant offers two theories for why Minnesota can regulate transactions with which it has no substantial contacts, but both are incorrect.

Defendant first suggests that if AAM members sell *some* drugs "directly to entities in the state," that entitles Minnesota to regulate their transactions involving *other* drugs *outside* Minnesota. Def. Br. 24. But Defendant cannot bootstrap from a company's unrelated contacts with Minnesota; due process requires "a connection to the activity itself," not just "the actor." *Allied-Signal, Inc. v. Dir., Div. of Tax.*, 504 U.S. 768, 777 (1992) (discussing unconstitutional tax on activity); *Gerling*, 267 F.3d at 1236 (connection must be with the "regulated subject matter," not just the "regulated party"). Nor can that connection come from a subsequent *resale* into Minnesota by someone else: "the unilateral act of a third party is not sufficient to create the requisite contacts." *Am. Charities for Reasonable Fundraising Regul., Inc. v. Pinellas Cnty.*, 221 F.3d 1211, 1216 (11th Cir. 2000).

Defendant relies principally on *Ford Motor Co. v. Montana Eighth Judicial District Court*, 141 S. Ct. 1017 (2021). Def. Br. 23. But *Ford* only addressed state courts' adjudicative jurisdiction—and *specific* jurisdiction at that, 141 S. Ct. at 1024-25, despite Defendant's incorrect claim that *Ford* allowed states to exercise "*general* jurisdiction" over a business simply because it operates there, Def. Br. 23 (emphasis added). Adjudicative jurisdiction is "entirely distinct" from legislative jurisdiction, *i.e.*, a state's power to regulate activities or transactions. *Phillips Petroleum Co. v. Shutts*, 472 U.S. 797, 821 (1985); *see McCluney*, 649 F.2d at 581 n.3. Legislative jurisdiction (the issue in this case) requires sufficient "contacts" with the "regulated subject matter" or "transaction." *Gerling*, 267 F.3d at 1236; *McCluney*, 649 F.2d at 582.

In any event, Ford's contacts with the forum states far exceeded those alleged here

and relied on by Defendant. In particular, the Court emphasized that Ford "systematically" marketed "the very vehicles" at issue, throughout both states. 141 S. Ct. at 1028. That offers no support for Defendant's position that Minnesota can regulate any out-of-state transaction involving a company that happens to sell "similar products" (whatever that means), in unspecified quantities, in Minnesota. Def. Br. 23.

Defendant next argues that the Court "need not parse [AAM's] contacts in Minnesota" because AAM's members "voluntarily agreed to comply with Minnesota law" when applying for licensure. Def. Br. 24. Defendant appears to contend that Minnesota can enact any law it wants to regulate licensed (or "previously" licensed) companies, anywhere in the world. Def. Br. 24-25. Defendant cites no authority to support this sweeping proposition—or, indeed, any case law at all, which "is reason enough to deny" dismissal. *Vill. Pizza House, Inc. v. EIC Agency, LLC*, No. 13-cv-12293, 2014 WL 1232978, at *1 (D. Mass. Mar. 26, 2014) (citation omitted).

Even if "consent" could waive a due-process challenge to a state's exercise of *legislative* power, no AAM member consented to the Act after "clear notice." *Mallory*, 143 S. Ct. at 2049 (Alito, J., concurring in part and concurring in the judgment). In *Mallory*, "Norfolk Southern ha[d] agreed to … answer any suit [in Pennsylvania] *for more than 20 years*" and there was "no[] dispute that it appreciated the jurisdictional consequences attending these actions." *Id*. at 2037, 2043 (majority opinion) (emphasis added). Nothing like that is present here. The Act was signed into law on May 24 and took effect on July 1. Compl. ¶ 27. AAM's members plainly did not have "clear notice" when applying for licenses that Minnesota would—sometime in the future—seek to subject them to

unconstitutional extraterritorial legislation *and* to penalize them if they responded to the constitutional violation by leaving the Minnesota market.

C. The Complaint Plausibly Alleges The Act Violates The Horizontal Separation Of Powers (Count III).

The Complaint also plausibly alleges that the Act violates the horizontal separation of powers implicit in the Constitution's federal design. Compl. ¶¶ 52-57, 69-71.

Our federal system "restricts a State's power to reach out and regulate conduct that has little if any connection with the State's legitimate interests." *Mallory*, 143 S. Ct. at 2049 (Alito, J., concurring in part and concurring in the judgment). This "horizontal separation of powers," *Ross*, 143 S. Ct. at 1156-57 & n.1, is an "'obviou[s]' and 'necessary result' of our constitutional order" that "is not confined to any one clause or section but is expressed in the very nature of the federal system … and in numerous provisions that bear on States' interactions with one another." *Mallory*, 143 S. Ct. at 2049 (Alito, J., concurring in part and concurring in the judgment) (citation omitted); *see also Ross*, 143 S. Ct. at 1175-76 (Kavanaugh, J., concurring in part and dissenting in part); *see also* Compl. ¶¶ 52-57.

Under these federalism principles, Minnesota may not directly regulate transactions that occur wholly outside its borders: a state law that "directly … assert[s] extraterritorial jurisdiction over persons and property … offend[s] sister States and exceeds the inherent limits of the State's power." *Edgar*, 457 U.S. at 643 (plurality opinion) (citation and internal quotation marks omitted); *see also Ross*, 143 S. Ct. at 1157 n.1. Defendant's motion reduces to an argument that the Act does not engage in this form of impermissible

regulation. Def. Br. 25-27. That position ignores the Act's plain text (*see* pp. 5, 8-9, *supra*; AAM Br. 9-17), and Defendant's motion to dismiss this claim should therefore be denied.

D. The Complaint Plausibly Alleges A *Pike* Claim (Count IV).

Finally, the Court should deny Defendant's motion to dismiss AAM's *Pike* claim. AAM plausibly alleges that the Act imposes a substantial burden on interstate commerce that is "clearly excessive in relation to [any] putative local benefits." *Pike v. Bruce Church, Inc.*, 397 U.S. 137, 142 (1970).

1. Defendant's argument for dismissing AAM's *Pike* claim starts from the flawed premise that *Ross* limited *Pike* claims to laws that are discriminatory or burden instrumentalities of commerce. Def. Br. 18-19 & n.17. But *six* Justices (including the two who concurred in the judgment on the narrowest grounds) concluded that a plaintiff's "failure to allege discrimination or an impact on instrumentalities of commerce does not doom their *Pike* claim." 143 S. Ct. at 1166 (Sotomayor, J., concurring in part); *id*. at 1168 (Roberts, C.J., concurring in part and dissenting in part). As those Justices recognized, the Court has previously invalidated *non*discriminatory state laws under *Pike*. *Id*. at 1166 (Sotomayor, J., concurring in part) (citing *Edgar*, 457 U.S. at 643-46 (majority opinion)).[8]

2. The Complaint alleges that the Act compels every generic manufacturer to either: (a) "make every sale nationwide comply with Minnesota's rules," (b) "attempt somehow to restructure pricing and supply processes to segregate drug products for sale in

[8] *Exxon Corp. v. Governor of Maryland*, 437 U.S. 117 (1978), did not hold that *Pike* claims are limited to discriminatory laws. *Contra* Def. Br. 18-19. *Exxon* rejected a discrimination claim because the law was not discriminatory, and then separately rejected a *Pike* claim for lack of a substantial burden. 437 U.S. at 125-27.

Minnesota, resulting in significant compliance costs and disruptions to the drug-supply chain," or (c) "'defend itself' in Minnesota 'with reference to all transactions,' including those with no forum connection." Compl. ¶ 74 (citations omitted); *see also id*. ¶¶ 43-47. Defendant never disputes that the last constitutes a substantial burden, and his arguments regarding the first two fail.

Defendant does not seriously dispute that the burden of making all sales *nationwide* comply with Minnesota's price regulations would be substantial. Def. Br. 19. For good reason: *Edgar* held that a law with a similarly sweeping "nationwide reach" was an "obvious burden" on interstate commerce. 457 U.S. at 643 (majority opinion).

Instead, Defendant fights the premise—arguing that manufacturers can avoid nationwide compliance by "restricting the geographical resale of batches of drugs they sell to wholesalers." Def. Br. 19. But Defendant's speculation that restructuring the entire market is as "simpl[e]" as "putting pen to paper," Def. Br. 20, is contrary to the Complaint's allegation that segregating products on a state-by-state basis "may well be impossible," especially because manufacturers cannot control where their products are *resold* by third parties. Compl. ¶ 44. Even if such geographic segregation were possible, restructuring "pricing and supply processes" (Compl. ¶ 74) will impose "substantial costs" on manufacturers, "place increased upward pressure on the cost of delivering prescription drugs to patients throughout the United States," and ultimately "create enormous inefficiencies" that "result[] in significant delays and disruptions." Compl. ¶¶ 45-46. These are far greater than mere "compliance costs," Def. Br. 19-20; they are substantial burdens that afflict the *national* drug-supply chain. Compl. ¶¶ 46-47, 74.

Defendant contends that the Act's alleged burdens are comparable to those in *Ross*. But five Justices in *Ross* concluded the plaintiffs *had* plausibly alleged a substantial burden. The California law imposed "sweeping extraterritorial effects" by "forc[ing]" out-of-state producers "as far flung as Indiana and North Carolina" to comply with the California law, "whether or not they sell in California," 143 S. Ct. at 1170-71 (Roberts, C.J., concurring in part and dissenting in part), and those "costs" were "pervasive, burdensome, and w[ould] be felt primarily (but not exclusively) outside California," *id*. at 1167 (Barrett, J., concurring in part). Similarly here, the Act allegedly will impose a nationwide price control whose burdens "will fall overwhelmingly on interstate commerce." Compl. ¶ 75.

Defendant complains that if this claim is cognizable, states could never "regulate the *in-state* sale of any commercial products." Def. Br. 20 (emphasis added). But this Act does not target in-state sales; it expressly exempts them. Recognizing the substantial burdens that extraterritorial price controls impose on interstate commerce does not convert *Pike* into a *per se* rule.

3. Finally, AAM plausibly alleges that the Act's alleged substantial burdens are "clearly excessive" in relation to its putative local benefits. Compl. ¶¶ 74-79. Defendant relies on its "interest in … ensuring that generic drugs are not priced out of reach" for Minnesotans, Def. Br. 21-22, but Minnesota has no interest in regulating wholly out-of-state activity, and therefore "there is nothing to be weighed in the balance to sustain the law." *Edgar*, 457 U.S. at 644. Moreover, Defendant fails to address the Complaint's allegations that the Act will *undermine* the Act's purported benefit of increasing patient access by lowering prices. As alleged, the Act will exacerbate the already-severe supply

shortages for generic drugs, pressuring generic and biosimilar manufacturers to withdraw from the market and driving up prices for remaining products—all of which will make it *more* difficult for Minnesotans to access affordable medicines. Compl. ¶¶ 12, 22, 78. Where a law undermines the putative benefits it is meant to advance, those "benefits" do not outweigh the law's substantial burdens on interstate commerce. *See Edgar*, 457 U.S. at 644. And Defendant never addresses the Complaint's allegation (Compl. ¶ 77) that there are "less burdensome alternative[s]" to achieving Minnesota's interest in lowering drug prices. *See U & I Sanitation v. City of Columbus*, 205 F.3d 1063, 1070 (8th Cir. 2000) ("the availability of a less burdensome alternative is relevant to the inquiry that *Pike* requires").

CONCLUSION

The Court should grant AAM's motion for a preliminary injunction and deny Defendant's motion to dismiss.

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Respectfully submitted,

s/ David L. Hashmall

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