United States Court of Appeals 1 for the Cighth Circuit

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	No.	24-1019	

Association for Accessible Medicines

Plaintiff - Appellee

v.

Keith M. Ellison, in his official capacity as Attorney General of the State of Minnesota

Defendant - Appellant

Appeal from United States District Court for the District of Minnesota

Submitted: October 23, 2024 Filed: June 12, 2025

Before COLLOTON, Chief Judge, GRUENDER and KOBES, Circuit Judges.

KOBES, Circuit Judge.

The Association for Accessible Medicines (AAM) is a trade organization whose members include generic prescription drug manufacturers. AAM sued Minnesota Attorney General Keith M. Ellison, challenging the state's law regulating

drug prices, Minn. Stat. § 62J.842 (the Act). The district court¹ granted AAM's motion for a preliminary injunction, finding that the Act likely violated the dormant Commerce Clause. We affirm.

I.

Drug manufacturers sell prescription drugs to nationwide wholesale distributors, who then resell to pharmacies, healthcare facilities, and other dispensers of prescription drugs. Generic drug manufacturers sell drugs in bulk to wholesale distributors under long-term, nationwide contracts. While manufacturers don't control the prices at which wholesalers or retailers sell their products or where they are eventually sold, manufacturers impact prices downstream by setting the wholesale acquisition cost. The wholesale acquisition cost is the baseline price wholesale distributors and retailers use to set their prices.

None of the AAM manufacturers are Minnesota entities. Nor are the three largest wholesalers. But AAM's members are licensed in Minnesota because all manufacturers and wholesalers in the supply chain must be licensed in the state for a drug to be distributed or sold there. Minn. Stat. § 151.252, subd. 1(g); Minn. Stat. § 151.47, subd. 1a(f); Minn. R. 6800.1400, subp. 3.

The Act prohibits manufacturers from "impos[ing], or caus[ing] to be imposed, an excessive price increase . . . on the sale of any generic or off-patent drug sold, dispensed, or delivered to any consumer in the state." Minn. Stat. § 62J.842 subd. 1. An "excessive price increase" is defined as a price increase that exceeds a certain percentage over the wholesale acquisition cost or that exceeds \$30 for a 30-day supply of the drug. *Id.*, subd. 2. The Act regulates only manufacturers, not wholesale distributors or pharmacies. *See id.*, subd. 3.

¹The Honorable Judge Patrick J. Schiltz, Chief Judge, United States District Court for the District of Minnesota.

AAM sought injunctive relief claiming, among other things, that the Act violates the dormant Commerce Clause's prohibition on state laws that regulate extraterritorially. In granting the preliminary injunction, the district court concluded that AAM was likely to succeed on the merits of its claim, that AAM's members faced a threat of irreparable harm, and that it was a wash whether AAM's harm was greater than any injury suffered by granting the injunction or whether the injunction would serve the public interest. Minnesota only appeals the likelihood of success on the merits and the balance of harms/public interest.

II.

"We review a district court's ultimate ruling on a preliminary injunction for abuse of discretion, though we review its underlying legal conclusions de novo." *Home Instead, Inc. v. Florance*, 721 F.3d 494, 497 (8th Cir. 2013). A party seeking to preliminarily enjoin the implementation of a state statute must show that it is likely to succeed on the merits, that there is a threat of irreparable harm to the movant if the injunction is not granted, that the balance of harms favors the movant, and that the injunction is in the public interest. *Dataphase Sys., Inc. v. C L Sys., Inc.*, 640 F.2d 109, 113 (8th Cir. 1981) (en banc); *Planned Parenthood Minn., N.D., S.D. v. Rounds*, 530 F.3d 724, 731–32 (8th Cir. 2008) (en banc). "Because our decision is predominantly one of determining whether the established facts fall within the relevant legal definition, albeit a constitutional definition, we apply a *de novo* standard of review in deciding whether there has been a violation of the commerce clause." *R & M Oil & Supply, Inc. v. Saunders*, 307 F.3d 731, 734 (8th Cir. 2002) (cleaned up) (citation omitted).

The Commerce Clause grants Congress the power "[t]o regulate Commerce . . . among the several States." U.S. Const. art. I, § 8, cl. 3. "Although the Clause is framed as a positive grant of power to Congress, we have long held that this Clause also prohibits state laws that unduly restrict interstate commerce." *Tenn. Wine & Spirits Retailers Ass'n v. Thomas*, 588 U.S. 504, 514 (2019) (cleaned up) (citation omitted). A state violates the so-called dormant Commerce Clause by

"(1) clearly discriminat[ing] against interstate commerce in favor of in-state commerce, (2) impos[ing] a burden on interstate commerce that outweighs any benefits received, or (3) ha[ving] the practical effect of extraterritorial control on interstate commerce." *Styczinski v. Arnold*, 46 F.4th 907, 912 (8th Cir. 2022) (cleaned up) (citation omitted). The third way of violating the dormant Commerce Clause—the extraterritoriality doctrine—is at issue here.

In National Pork Producers Council v. Ross, the Supreme Court rejected the argument that the extraterritoriality doctrine created an "almost per se rule forbidding enforcement of state laws that have the practical effect of controlling commerce outside the State." 598 U.S. 356, 371 (2023) (Pork Producers) (cleaned up). The Court instead upheld the challenged law, distinguishing it from laws that "had a specific impermissible 'extraterritorial effect." Id. at 374 (quoting Healy v. Beer Inst., Inc., 491 U.S. 324, 339 (1989)). Unlike the statute in Pork Producers, the laws the Court had previously struck down in its extraterritoriality cases like Baldwin, Brown-Forman, and Healy had the specific impermissible extraterritorial effect of "deliberately 'prevent[ing] out-of-state firms from undertaking competitive pricing' or 'depriv[ing] businesses and consumers in other States of "whatever competitive advantages they may possess."" Id. (quoting Healy, 491 U.S. at 338-339 (quoting Brown-Forman Distillers Corp. v. N.Y. State Liquor Auth., 476 U.S. 573, 580 (1986))) (cleaned up); see also Baldwin v. G.A.F. Seelig, Inc., 294 U.S. 511, 521 (1935). The Court did not overturn "the rule that was applied in *Baldwin* and *Healy*," preserving its precedent that a state violates the extraterritoriality principle when it enacts "price control or price affirmation statutes that tie[] the price of in-state products to out-of-state-prices." Pork Producers, 598 U.S. at 374 (cleaned up) (citation omitted). So the "classic observation that '[a state] has no power to project its legislation into [another state] by regulating the price to be paid in that state" for drugs sold there remains good law. See Pharm. Rsch. & Mfrs. of Am. v. Walsh, 538 U.S. 644, 669 (2003) (quoting Baldwin, 294 U.S. at 521).

We conclude the Act has the specific impermissible extraterritorial effect of controlling prices outside of Minnesota. Minnesota insists that the Act does not

restrict pricing or set policy in other states. But, like our sister circuit when posed with a challenge to a nearly identical Maryland law, we find this argument unavailing. See Ass'n for Accessible Meds. v. Frosh, 887 F.3d 664, 672 (4th Cir. 2018). Minnesota argues that because the drugs must eventually end up in Minnesota for a manufacturer to be subject to liability, the Act is not a price control and does not set the price of transactions in other states. But Minnesota concedes that a Colorado manufacturer would be penalized if it sold drugs to a New Jersey distributor at prices above those proscribed by the Act and those drugs ended up in Minnesota. Minnesota "cannot, even in an effort to protect its consumers from skyrocketing prescription drug costs, impose its preferences in this manner." Id. at 673.

The Supreme Court's decision in *Walsh* confirms our conclusion that Minnesota's law has the specific impermissible extraterritorial effect of controlling prices under *Baldwin* and *Healy*. There, the Court considered a Maine law challenged under the extraterritoriality doctrine and concluded that "[t]he rule that was applied in *Baldwin* and *Healy*" did not apply because Maine was not "regulat[ing] the price of any out-of-state transaction," "insist[ing] that manufacturers sell their drugs to a wholesaler for a certain price," or "tying the price of its in-state products to out-of-state prices." *Walsh*, 538 U.S. at 669 (citation omitted). But under the Act, Minnesota regulates the price of out-of-state transactions, insists that out-of-state manufacturers sell their drugs to wholesalers for a certain price, and ties the price of in-state products—prescription drugs—to the price that out-of-state manufacturers charge their wholesalers. *See* Minn. Stat. § 62J.842, subd. 1, 2.

Minnesota argues that *Pork Producers* created a "practical presumption against dormant Commerce Clause challenges where a state law does not discriminate." But the Court did not overturn its cases that applied the dormant Commerce Clause to invalidate statutes that have the specific impermissible extraterritorial effect of controlling prices, nor did it once use the word "presumption." We cannot conclude that the Court created this presumption while

admittedly "say[ing] nothing new" about the extraterritoriality doctrine. *Pork Producers*, 598 U.S. at 374. We also find the facts in this case analogous to those in *Edgar v. MITE Corp.*, 457 U.S. 624, 641 (1982) (plurality opinion). Here, as there, the law "'directly regulate[s] transactions which [take] place . . . wholly outside the State." *Pork Producers*, 598 U.S. at 376 n.1 (quoting *Edgar*, 457 U.S. at 641). Because discrimination is not required when a statute has the specific extraterritorial effect of controlling the price of wholly out-of-state transactions, we think AAM is likely to succeed on the merits of its claim.

Moving to the balance of harms and public interest, these factors "merge" since Minnesota is the nonmoving party. *Eggers v. Evnen*, 48 F.4th 561, 564–65 (8th Cir. 2022). The district court found the balance of the harms and the public interest to be "a wash." Minnesota insists that the district court erred by finding a "public interest to protect constitutional rights," by failing to weigh Minnesota's interest in enforcing its laws, and by not considering that the Act serves the public interest by making prescription drugs cheaper.

We find no abuse of discretion below. Although Minnesota is right that the public interest is generally "served by maintaining the ability to enforce the law adopted by the Minnesota Legislature," *Carson v. Simon*, 978 F.3d 1051, 1061 (8th Cir. 2020), it is also "always in the public interest to protect constitutional rights," *id.* (quoting *Phelps-Roper v. Nixon*, 545 F.3d 685, 694 (8th Cir. 2008), *overruled on other grounds by Phelps-Roper v. City of Manchester*, 697 F.3d 678, 692 (8th Cir. 2012) (en banc)). And the balance of harms is not as clear as Minnesota insists. While the Act might make generic prescription drugs more affordable, it could also backfire and, for example, force generic manufacturers to pull out of the market. All

²Minnesota also argues that the district court erred by citing *Carson* for this proposition, since that case was about First Amendment rights. But we have considered upholding constitutional rights in the public interest in other contexts too. *See, e.g., D.M. ex rel. Bao Xiong v. Minn. State High Sch. League*, 917 F.3d 994, 1003 (8th Cir. 2019) (Equal Protection Clause and Title IX).

told, the district court did not abuse its discretion by finding that the remaining factors were neutral and in granting the preliminary injunction based on AAM's likelihood of success on the merits—"the most important of the *Dataphase* factors"—and irreparable harm. *Craig v. Simon*, 980 F.3d 614, 617 (8th Cir. 2020) (per curiam) (cleaned up) (citation omitted).

	III.
Affirmed.	