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STATE OF MINNESOTA **DISTRICT COURT**

COUNTY OF RAMSEY **SECOND JUDICIAL DISTRICT**

Pharmaceutical Research and Manufacturers of America,

Plaintiff,

v.

State of Minnesota, et al.,

Defendants.

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

BRIEF OF *AMICI CURIAE* AMERICAN HOSPITAL ASSOCIATION, 340B HEALTH, MINNESOTA HOSPITAL ASSOCIATION, AND AMERICAN SOCIETY OF HEALTH-SYSTEM PHARMACISTS IN SUPPORT OF DEFENDANTS' MOTION TO DISMISS

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INTERESTS OF *AMICI CURIAE*

Proposed *Amici* include three hospital associations with members in Minnesota that receive 340B discounts for drugs that they purchase, many of which are dispensed through contract pharmacies, and one organization that represents pharmacists, many located in Minnesota, who serve patients in hospitals, health systems, ambulatory clinics, and other healthcare settings many of which benefit from the 340B program. *Amici* and their members are committed to improving the health of the communities they serve through the delivery of high-quality, efficient, and accessible health care and the discounts provided by the 340B program are essential to achieving this goal. *Amici* therefore have a strong interest in the success of Minnesota legislative efforts to protect the 340B program.

The **American Hospital Association** (AHA) represents nearly 5,000 hospitals, healthcare systems, and other healthcare organizations nationwide. AHA members are committed to helping ensure that healthcare is available to and affordable for all Americans. AHA promotes the interests of its members by participating as *amicus curiae* in cases with important and far-ranging consequences for their members, including cases related to the 340B program.

340B Health is a national, not-for-profit organization founded in 1993 to advocate for 340B hospitals—a vital part of the nation's healthcare safety net. 340B Health represents over 1,600 public and private nonprofit hospitals and health systems participating in the 340B program.

The **Minnesota Hospital Association** (MHA) is an organization representing non-profit hospitals and health systems across the state to advance the health of individuals and communities through leadership, advocacy, and collaboration. Over 100 MHA members participate in the 340B program.

The **American Society of Health-System Pharmacists** (ASHP) is the largest association of pharmacy professionals in the United States. ASHP advocates and supports the professional

practice of pharmacists in hospitals, health systems, ambulatory care clinics, and other settings spanning the full spectrum of medication use. For over 80 years, ASHP has championed innovation in pharmacy practice; advanced education and professional development; and served as a steadfast advocate for members and patients.

BACKGROUND

More than four years ago, amid a devastating pandemic, multiple drug companies broke with decades of precedent and began to undermine the 340B drug discount program. Under that program, drug companies that participate in Medicaid and Medicare Part B must provide discounts on drugs sold to patients of certain nonprofit or public hospitals and community health centers. *See* 42 U.S.C. § 256b(a)(1)–(4). Before 2020, drug companies had provided drug pricing discounts to eligible 340B providers for drugs dispensed *both* through in-house pharmacies and community pharmacies with which the providers had contracts. *See Pharm. Rsch. & Mfrs. of Am. (PhRMA) v. McClain*, 95 F.4th 1136, 1139 (8th Cir. 2024) *cert. denied*, --- S. Ct. ----, 2024 WL 5011712 (Mem Dec. 9, 2024) ("For 25 years, drug manufacturers . . . distributed 340B drugs to covered entities' contract pharmacies.").[1] But in July 2020, one drug company made an about-face and refused to provide these discounts for drugs if dispensed to 340B patients at community pharmacies (or contract pharmacies). Recognizing an opportunity to boost their own bottom lines, 38 other major drug companies, including many members of Plaintiff Pharmaceutical Research and Manufacturers of America (PhRMA) followed suit.[2]

[1] Eighth Circuit precedent is persuasive authority in Minnesota courts. *Regner v. Nw. Airlines, Inc.*, 652 N.W.2d 557, 563 (Minn. Ct. App. 2002).

[2] Collectively, 19 of these companies made more than $660 billion in profits in 2021. *See* 340B Informed, *Drugmakers Cutting 340B Discounts Reported Record Revenues in 2021* (updated Jan. 13, 2023), https://340binformed.org/2023/01/updated-drugmakers-cutting-340b-discounts-reported-record-revenues-in-2021/.

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The contract pharmacy arrangements that drug companies honored for almost 30 years helped sustain 340B providers and their patients. Prior to the implementation of contract pharmacy restrictions, discounts on drugs dispensed at community and specialty contract pharmacies made up about one-quarter of overall 340B savings for hospitals participating in 340B. Of the 103 Minnesota hospitals participating in the 340B drug program, 91 contract with at least one community pharmacy to dispense drugs to patients.[3] The drug company restrictions have substantially cut the savings from the 340B program, which is devasting for hospitals in Minnesota that provide 88% of all hospital care that is provided to Medicaid patients.[4]

For example, 340B savings allow Fairview Health Services, a health system headquartered in Minneapolis, to provide critical care to patients throughout the metropolitan area at three Health Commons locations in economically and culturally diverse neighborhoods. The Health Commons locations are responsible for almost 11,000 patient visits annually and 340B savings has allowed Fairview Health Services to provide health education through an onsite community nurse, offer wellness classes, and distribute free meals, fresh produce, diapers, and more to those in need. 340B savings have also allowed the Cedar Riverside Health Commons location to provide training on how to administer naloxone (medication that reverses opioid drug poisoning) and to become a Naloxone Access Point.

A rural health system headquartered in Duluth, Essentia Health (Essentia) has 14 hospitals throughout Minnesota, North Dakota, and Wisconsin, which care for a service area that is classified as 84% rural. All of these hospitals, including seven critical access hospitals in

[3] Health Res. & Servs. Admin, Off. of Pharmacy Affairs, *340B OPA Info. Sys.*, https://340bopais.hrsa.gov/coveredentitysearch.

[4] Dobson DaVanzo Health Economics Consulting, *Minnesota 340B Hospitals Serve More Patients With Low Incomes, Who Live With Disabilities, and/or Identify as Black* 1, https://www.340bhealth.org/files/MN-340B-Low-Income15021.pdf.

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Minnesota, are 340B covered entities that leverage 340B savings to ensure the rural and underserved communities they serve have access to comprehensive, local health care services, such as 24/7 emergency care, intensive care, mental and behavioral health services, and primary and specialty care. As a rural safety-net hospital system that cares for some of the State's most vulnerable patients, Essentia relies heavily upon the 340B program.

Winona Health, an independent, rural hospital, has likewise been hit hard by increased drug costs resulting from manufacturers' restrictive contract pharmacy policies. Winona Health uses 340B savings to subsidize programs that don't generate revenue, and the hospital has had to dip into investments to pay operating costs and cut back on capital investments because of these losses. For example, Winona Health recently almost had to close its dialysis department. Although private donations have saved the dialysis program for the next three years, severe financial challenges remain, and they will be compounded if Minnesota's statute is invalidated.

Contract pharmacy arrangements are especially important because fewer than half of 340B hospitals operate in-house pharmacies.[5] This is why 340B hospitals have relied on contract pharmacies since the beginning of the program.[6] In addition, many payors require that certain specialty drugs be filled only at a PBM-owned "specialty pharmacy." Such "specialty" drugs are typically used to treat chronic, serious, or life-threatening conditions, and are often priced much higher than non-specialty drugs.[7] Only one in five 340B hospitals have in-house "specialty"

[5] 340B Health, *Drugmakers Pulling $8 Billion Out of Safety-Net Hospitals: More Expected as Growing Number Impose or Tighten 340B Restrictions* (July 2023), https://www.340bhealth.org/files/Contract_Pharmacy_Financial_Impact_Report_July_2023.pdf.

[6] *See* Notice Regarding Section 602 of the Veterans Health Care Act of 1992 Contracted Pharmacy Services, 60 Fed. Reg. 55,586 (Nov. 1, 1995).

[7] Adam J. Fein, *Insurers + PBMs + Specialty Pharmacies + Providers: Will Vertical Consolidation Disrupt Drug Channels in 2020?*, Drug Channels Institute (Dec. 12, 2019), https://www.drugchannels.net/2020/05/insurers-pbms-specialty-pharmacies.html; U.S. Dep't of

pharmacies. Thus, 340B hospitals typically *must* contract with at least one specialty pharmacy to receive the 340B discount for their patients' high-priced specialty drugs.[8] In fact, for seven of the 21 drug companies with restrictive contract pharmacy policies as of June 1, 2023, specialty drugs make up more than three-quarters of the savings associated with restricted drugs.[9]

Savings from contract pharmacy relationships are especially important for another reason: the fragile state of 340B hospital finances. In stark contrast to the pharmaceutical industry, 340B hospitals typically operate with razor-thin (and often negative) margins.[10] This is not surprising: 340B hospitals provide a disproportionate amount of uncompensated care to the country's most vulnerable patients.[11] Savings from the 340B program help to offset the cost of providing uncompensated health care. As the Supreme Court recognized, "340B hospitals perform valuable services for low-income and rural communities but have to rely on limited federal funding for support." *Am. Hosp. Ass'n v. Becerra*, 596 U.S. 724, 738 (2022).

Health & Hum. Servs. Off. Of Inspector Gen., *Specialty Drug Coverage and Reimbursement in Medicaid*, https://oig.hhs.gov/reports-and-publications/workplan/summary/wp-summary-0000255.asp.

[8] 340B Health, *supra* note 5, at 7 (citing Fein, *supra* note 7).

[9] *Id*. at 6.

[10] Am. Hosp. Ass'n, *340B Drug Pricing Program: Fact vs. Fiction* 2 (Apr. 2023), https://www.aha.org/system/files/2018-04/340BFactvsFiction.pdf; Allen Dobson *et al.*, *The Role of 340B Hospitals in Serving Medicaid and Low-income Medicare Patients* 12–13 (July 10, 2020), https://www.340bhealth.org/files/340B_and_Medicaid_and_Low_Income_Medicare_Patients_Report_7.10.2020_FINAL_.pdf.

[11] *See* L&M Policy Research, LLC, *Analysis of 340B Disproportionate Share Hospital Services to Low-Income Patients* 1 (Mar. 12, 2018), https://www.340bhealth.org/files/340B_Report_03132018_FY2015_final.pdf; AHA, *supra* note 10, at 2; Dobson et al., *supra* note 10, at 13–17.

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ARGUMENT

In late May 2024, the Minnesota legislature acted to address the drug industry's unprecedented assault on its health care safety net. PhRMA now seeks to halt Minnesota's lawful exercise of its police power to protect public health and safety. PhRMA's complaint should be dismissed because all three claims in the Complaint fail to state a claim for relief.

First, Minnesota's law is not preempted because Congress did not create or occupy any field through its 340B legislation, nor does it conflict with the 340B statute. At bottom, PhRMA takes the position that whenever Congress creates a detailed federal program, that comprehensiveness wrests traditional police power from the States. That has never been the rule in our federal system. PhRMA's argument is especially inapplicable here because, as the Eighth Circuit explained earlier this year, "[p]harmacy has traditionally been regulated at the state level, and [courts] must assume that absent a strong showing that Congress intended preemption, state statutes that impact health and welfare are not preempted." *PhRMA v. McClain*, 95 F.4th at 1144 (citing *Pharm. Care Mgmt. Ass'n v. Wehbi*, 18 F.4th 956, 972 (8th Cir. 2021)); *see MacDonald v. Monsanto Co*., 27 F.3d 1021, 1023 (5th Cir. 1994). For this reason, six out of seven courts that have considered the issue have rejected PhRMA's preemption claims regarding materially similar state laws. *See PhRMA v. McClain*, 95 F.4th at 1143–45; *Novartis Pharms. Corp. v. Fitch*, ___ F. Supp. 3d ___, No. 1:24-cv-00164-HSO-BWR, 2024 WL 3276407, at *6 (S.D. Miss. July 1, 2024), *appeal docketed*, No. 24-60342 (5th Cir. July 9, 2024); *Pharm. Rsch. & Mfrs. of Am. v. Fitch*, No. 1:24-cv-00160-HSO-BWR, 2024 WL 3277365, at *8 (S.D. Miss. July 1, 2024), *appeal docketed*, No. 24-60340 (5th Cir. July 5, 2024); *AbbVie Inc. v. Fitch*, No. 1:24-cv-00184-HSO-BWR, 2024 WL 3503965, at *7 (S.D. Miss. July 22, 2024), *appeal docketed*, No. 24-60375 (5th Cir. July 24, 2024); *Pharm. Rsch. & Mfrs. of Am. v. Murrill*, No. 6:23-cv-00997, 2024 WL 4361597, at *9 (W.D. La. Sept. 30, 2024) (*PhRMA v. Murrill*), *appeal docketed*, No. 24-30673 (5th Cir. Oct. 21,

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2024); *AstraZeneca Pharms. LP v. Fitch*, No. 1:24-cv-196-LG-BWR, slip op. at 7–19, ECF No. 36 (Dec. 23, 2024); *Novartis Pharms. Corp. v. Brown*, No. 24-cv-01557-MJM, ECF No. 57 (D. Md. Sept. 5, 2024). As discussed below, the single decision overturning a state law protecting 340B contract pharmacies, *Pharm. Rsch. & Mfrs. of Am. v. Morrissey*, Civ. Nos. 2:24-cv-00271, 2:24-cv-00272, 2:24-cv-00298, 2024 WL 5147643 (S.D. W. Va. Dec. 17, 2024), was based on a fundamental misunderstanding of the 340B program. This Court should ignore the flawed, out-of-State analysis of the Southern District of West Virginia.

Second, the Minnesota statute is not an unconstitutional extraterritorial regulation. PhRMA's sweeping reading of the dormant Commerce Clause was recently rejected by the Supreme Court. *Nat'l Pork Producers Council v. Ross*, 598 U.S. 356, 375 (2023). Like the petitioners there, PhRMA advocates an "'almost *per se*' rule against laws that have the 'practical effect' of 'controlling' extraterritorial commerce [which] would cast a shadow over laws long understood to represent valid exercises of the States' constitutionally reserved powers." *Id.*

Third, § 62J.96 does not run afoul of the Minnesota Constitution's single-subject clause because it easily meets the "germaneness test." *Townsend v. Minnesota*, 767 N.W.2d 11, 13 (Minn. 2009).

I. SECTION 62J.96 IS NOT PREEMPTED.

In determining a federal statute's preemptive reach, "'[t]he purpose of Congress is the ultimate touchstone' of pre-emption analysis." *Cipollone v. Liggett Grp., Inc.*, 505 U.S. 504, 516 (1992) (quoting *Malone v. White Motor Corp.*, 435 U.S. 497, 504 (1978)). In every preemption case, "and particularly in those in which Congress has 'legislated in a field which the States have traditionally occupied,'" *Medtronic, Inc. v. Lohr*, 518 U.S. 470, 485 (1996), courts "start with the assumption that the historic police powers of the States were not to be superseded by the Federal Act unless that was the clear and manifest purpose of Congress," *Columbus v. Ours Garage &*

Wrecker Serv., Inc., 536 U.S. 424, 432 (2002)). PhRMA has the burden to show that Congress intended to preempt Section 62J.96. *See Pharm. Rsch. & Mfrs. of Am. v. Walsh*, 538 U.S. 644, 661–62 (2003).

The Eighth Circuit recently rejected both of PhRMA's arguments supporting the same preemption claim. *PhRMA v. McClain*, 95 F.4th at 1143–45. And for good reason. Like in that case, PhRMA does not claim that Section 62J.96 is expressly preempted. Nor does it deny that States have police power over public health policy, including the regulation of healthcare. *See, e.g.*, *N.Y. State Conf. of Blue Cross & Blue Shield Plans v. Travelers Ins. Co.*, 514 U.S. 645, 655 (1995) (healthcare is a "field[] of traditional state regulation"); *Pharm. Care Mgmt. Ass'n v. Wehbi*, 18 F.4th 956, 972 (8th Cir. 2021) ("[T]he practice of pharmacy is an area traditionally left to state regulation."). Thus, unlike state laws that intrude into uniquely federal areas such as immigration and foreign relations that PhRMA has cited during this litigation, Section 62J.96 is presumptively *not* preempted.[12] PhRMA therefore must demonstrate Congress's "clear and manifest purpose" to supersede Minnesota's historic authority to regulate in the public health arena, *Medtronic*, 518 U.S. at 485 (citation omitted), which it cannot do.

A. Congress Did Not Create or Occupy a Field When It Established the 340B Program.

Field preemption occurs only in rare instances, "when federal law occupies a 'field' of regulation 'so comprehensively that it has left no room for supplementary state legislation.'" *Murphy v. Nat'l Collegiate Athletic Ass'n*, 584 U.S. 453, 479 (2018) (citation omitted). Indeed, "[t]he subjects of modern social and regulatory legislation often by their very nature require intricate and complex responses from the Congress, but without Congress necessarily intending its

[12] *See, e.g.*, *Arizona v. United States*, 567 U.S. 387 (2012); *Crosby v. Nat'l Foreign Trade Council*, 530 U.S. 363 (2000).

enactment as the exclusive means of meeting the problem." *N.Y. State Dep't of Soc. Servs. v. Dublino*, 413 U.S. 405, 415 (1973). Thus, the Supreme Court has rejected "the contention that pre-emption is to be inferred merely from the comprehensive character" of federal provisions. *Id.* With the 340B program, "a detailed statutory scheme was both likely and appropriate, completely apart from any questions of pre-emptive intent." *Dublino*, 413 U.S. at 415.

Ignoring this well-established precedent, PhRMA relies on what it describes as the "comprehensive federal program" of the 340B statute to support its argument that the federal government intended to occupy a field with the 340B program. *See* Compl. ¶ 92. But PhRMA fails to cite any authority—from the statute, governing regulations, or legislative history—for its assertions about Congress's *intent* to create (or occupy) this purported 340B "field."

In addition to repeatedly (and wrongly) asserting that Congress created a comprehensive federal scheme through the 340B program, PhRMA relies primarily on *Astra USA, Inc. v. Santa Clara Cnty.*, 563 U.S. 110 (2011), an inapposite precedent. *Astra* addressed *only* whether covered entities could use a third-party beneficiary theory to enforce the 340B statute's federal requirements and does not ever mention the question of whether the 340B program preempts state law. *See Astra*, 563 U.S. at 113. The only mention of preemption in *Astra* is in a footnote concerning a different federal program, the Medicaid Drug Rebate Program. *Id.* at 120 n.5.

PhRMA nevertheless asserts that *Astra*'s discussion of the 340B program's centralized enforcement scheme proves the statute's preemptive effect. But nothing about *Astra* displaced the Supreme Court's well-established principle that "the mere existence of a federal regulatory or enforcement scheme . . . does not by itself imply pre-emption of state remedies." *English v. Gen. Elec. Co.*, 496 U.S. 72, 87 (1990). Moreover, PhRMA's reliance on *Astra* is further undermined by the federal government's decades-old recognition of State authority over contract

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pharmacy arrangements.[13] Thus, the *Astra* Court's hesitance to allow "potentially thousands of covered entities" to sue to correct "errors in manufacturers' price calculations" has no bearing on whether *States* can legislate as Minnesota did here to restore contract pharmacies as an outlet for 340B drugs. *Astra,* 563 U.S. at 114. Even if Congress had created a "340B field," PhRMA would have to further demonstrate that Section 62J.96 intrudes into that field, which it has failed to do.

Relying on decisions made in connection with claims that there is a *federal* statutory requirement to honor contract pharmacies, PhRMA also asserts that the omission of a contract pharmacy requirement in the 340B statute reflects a deliberate choice by Congress to forbid States from imposing additional requirements on manufacturers. Compl. ¶¶ 12–16.

But PhRMA distorts those decisions. Contrary to PhRMA's argument, the Third Circuit and D.C. Circuit both found that the 340B statute's "text is silent about delivery," and accordingly, the U.S. Department of Health and Human Services (HHS) lacked authority under the statute to require drug companies to honor contract pharmacy arrangements. *Sanofi Aventis v. U.S. Dep't of Health & Hum. Servs.*, 58 F.4th 696, 703, 707 (3d Cir. 2023); *Novartis Pharms. Corp. v. Johnson*, 102 F.4th 452, 459 (D.C. Cir. 2024). Neither court said anything about what *States* may do in the face of the federal law's "silence." And as the Eighth Circuit and other courts have held, statutory silence cannot be spun into preemptive substance. *See PhRMA v. McClain*, 645 F. Supp. 3d. 890, 899 (E.D. Ark 2022), *affirmed*, 95 F.4th 1136, 1144 (8th Cir. 2024); *see also Chinatown*

[13] *See* Notice Regarding Section 602 of the Veterans Health Care Act of 1992; Contract Pharmacy Services, 61 Fed. Reg. 43,549, 43,550 (Aug. 23, 1996) (noting that, "[a]s a matter of State law, . . . covered entities have the right to contract with retail pharmacies for the purpose of dispensing 340B drugs," and that, "[b]y issuing guidelines in this area, [the federal agency] is not seeking to create a new right but rather is simply recognizing an existing right that covered entities enjoy under State law").

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Neighborhood Ass'n v. Harris, 794 F.3d 1136, 1143 (9th Cir. 2015); *Frank Bros., Inc. v. Wis. Dep't of Transp*., 409 F.3d 880, 891 (7th Cir. 2005); *PhRMA v. Murrill*, 2024 WL 4361597, at *7.

B. Section 62J.96 Does Not Conflict with the 340B Statute.

PhRMA also claims that Section 62J.96 is preempted because it conflicts with the federal 340B statute. But PhRMA is not able to identify any actual conflict between Section 62J.96 and that statute, particularly because Section 62J.96 only requires drug companies to continue a practice (*i.e.*, recognition of multiple contract pharmacy arrangements) that had been in place since 2010. No one, including PhRMA, disputes that 340B hospitals are entitled to discounts under the 340B statute if the 340B drugs are dispensed at a hospital pharmacy. Section 62J.96 simply allows 340B hospitals to prescribe discounted drugs to eligible patients to be dispensed at pharmacies with which they have contractual relationships. Section 62J.96 does not change the prices that PhRMA may charge for these drugs.

Nor does Section 62J.96 change the character of the contract pharmacies, which function as the covered entities' pharmacies, not covered entities themselves. Consequently, PhRMA cannot meet the "high threshold [that] must be met if a state law is to be preempted for conflicting with the purposes of a federal Act." *Chamber of Com. of U.S. v. Whiting*, 563 U.S. 582, 607 (2011) (citation omitted).

Ultimately, PhRMA's conflict preemption arguments miss the forest for the trees. The 340B program was designed to allow covered entities "to stretch scarce Federal resources as far as possible, reaching more eligible patients and providing more comprehensive services." H.R. Rep. No. 102-384(II), at 12 (1992); *see*, *Am. Hosp. Ass'n v. Azar*, 967 F.3d 818, 822 (D.C. Cir. 2020) (quoting same), *rev'd on other grounds sub nom. Am. Hosp. Ass'n v. Becerra*, 596 U.S. 724 (2022). Section 62J.96, in turn, enables 340B providers to continue to benefit from contract pharmacy arrangements and thereby offer improved and expanded health care to their patients.

Therefore, not only does Section 62J.96 not interfere with Congress's 340B scheme; it "furthers" it. *CTS Corp. v. Dynamics Corp. of Am.*, 481 U.S. 69, 82 (1987); *PhRMA v. McClain*, 95 F.4th at 1144–45.

C. The Single Court To Find Preemption Did So on the Basis of a Flawed Legal Analysis and a Misunderstanding of the 340B Program.

The West Virginia district court's analysis finding that West Virginia's contract pharmacy law is preempted both ignores the presumption against preemption, *Lohr*, 518 U.S. 470 (1996), and is based on both a flawed interpretation of the federal 340B statute and a flawed understanding of how the program operates. That outlier, out-of-jurisdiction decision should carry no weight with this Court, just as it carried no weight in the Southern District of Mississippi, which specifically rejected the West Virginia decision's reasoning only days later. *AstraZeneca v. Fitch*, slip op. at 16–19 (refusing to "disregard mainstream decisions and the Eighth Circuit's ruling in McClain without clear precedential support").

According to the West Virginia district court, its law is likely an obstacle to the implementation of the federal 340B statute since it "hampers the ability of drug manufacturers to formulate the 'reasonable cause' necessary to conduct an audit," which the manufacturer must do to "access the administrative dispute resolution process." *Pharm. Rsch. & Mfrs. of Am. v. Morrissey*, 2024 WL 5147643, at *6 (S.D. W. Va. Dec. 17, 2024). This conclusion flows from a basic misunderstanding of the federal 340B audit process. Under the federal statute, audits may be initiated by HRSA or manufacturers. When manufacturers wish to conduct an audit of a covered entity, they must make demonstrate "reasonable cause,'' defined broadly to mean that a reasonable person could believe that a covered entity *may* have violated a requirement of section 340B(a)(5)(A) or (B) of the PHS Act. *See* 61 Fed. Reg, 65,406, 65,409 (Dec. 12, 1996).

HRSA's guidance and practice confirm that the "reasonable cause" showing that a drug manufacturer must make to obtain authority to audit a covered entity is a modest one. Manufacturers can satisfy this standard in various ways, including by pointing to "[s]ignificant changes in quantities of specific drugs ordered by a covered entity and complaints from patients/other manufacturers about activities of a covered entity," according to long-standing HRSA guidance. 61 Fed. Reg at 65,406. Critically, HRSA has *never* required the claims or utilization data that the pharmaceutical companies now demand to initiate an audit. Nor has HRSA ever expected that a manufacturer would have access to claims data until *after* it conducted an audit. Tellingly, PhRMA *does not point to a single instance* of HRSA rejecting a manufacturer's audit plan due to the absence of claims data, and we are aware of none.

The West Virginia district court's reasoning turns the audit process upside down. There is no role in the audit process for a drug company requiring covered entities *prospectively* to turn over massive amounts of data as a precondition to receiving 340B discounts. Instead, the purpose of an audit is to *retrospectively* measure a covered entity's compliance *after* 340B transactions have occurred. *See* 59 Fed. Reg. 25,110, 25,113 (May 13, 1994). In fact, longstanding HRSA guidance makes clear that "[a] manufacturer may not condition the offer of statutory discounts upon an entity's assurance of compliance with section 340B provisions." Final Notice Regarding Section 602 of the Veterans Health Care Act of 1992 Entity Guidelines, 59 Fed. Reg. at, 25,113; *see* Health Resources and Services Administration, Release No. 2011 – 1.1, Clarification of Non-Discrimination Policy (2012) (same); *see generally Loper Bright v. Raimondo*, 144 S. Ct. 2244, 2258 (2024) (an agency interpretation "issued roughly contemporaneously with enactment of the statute" and held "consistent over time" is entitled to a court's "most respectful consideration"). The same agency that established and oversees the "reasonable cause" standard takes the position

that manufacturers *cannot* condition discounts on 340B compliance—exactly what PhRMA admits it wishes to do with its claims-data-precondition. It is therefore difficult to understand how the West Virginia district court concluded that its state law—which barred such preconditions—is an obstacle to the HRSA's compliance and audit processes. The West Virginia court also erred by ruling that the enforcement provision in the state statute is likely preempted. In its view, the West Virginia law would require state actors to determine questions of federal law if a drug manufacturer refuses delivery of a drug to a contract pharmacy when it believes that drug is being diverted within the meaning of the federal 340B statute. *PhRMA v. Morrissey*, 2024 WL 5147643, at *7. But under the statute, 340B's anti-diversion provisions are enforced either by HRSA directly or in the *post hoc* Alternative Dispute Resolution process. 42 U.S.C. §§ 256b(d)(2)(B)(vi) & (3). The statute does not permit manufacturers to take the law into their own hands and refuse delivery. This is true for delivery of 340B drugs in contract pharmacies *or* in-house hospital pharmacies—any claims of diversion are addressed after-the-fact by HRSA or in the ADR process. As such, state laws that require drug companies to deliver drugs to contract pharmacies (on the same terms as they deliver to in-house hospital pharmacies) will never raise questions of diversion since those will be addressed, per the 340B statute, in the federal processes *after* the drugs have been delivered.

As a factual matter, moreover, the hypothetical posed in the West Virginia case whereby a drug company would decline delivery would never come to pass. At the time 340B drugs are delivered, drug companies do not have contemporaneous information about the patients who receive the drugs. Their claims-data-precondition wouldn't provide such information. Thus, manufacturers have no practical ability to deny the 340B discount based on some in-the-moment belief that diversion is occurring.

This is true under the replenishment model discussed by the West Virginia district court because the 340B discount is provided when the pharmacy's stock is replenished with 340B discounted drugs to replace the drugs already distributed to 340B patients. There is no patient information involved in this transaction other than the covered entity's representation that the discount is being provided for drugs distributed to 340B patients. As a result, state authorities will never be called upon to determine the meaning of diversion because drug companies do not have a factual basis, as the West Virginia district court wrongly assumed, to decline delivery based on a belief that diversion is occurring.

Finally, the West Virginia court wrongly concluded that its state statute regulated 340B drug price and not delivery. The court stated that under the replenishment model, "[b]ecause the drug is already in the hands of the contract pharmacy even before the patient arrives at the pharmacy, the question is not about the delivery of the drug." *PhRMA v. Morrissey*, 2024 WL 5147643, at *8. But this puts form over substance. If a contract pharmacy received each 340B drug at the 340B price and then dispensed the drug, one-by-one, directly to the patient at the contract pharmacy, the West Virginia court would logically have to conclude that the law does not regulate price because the price was set by the 340B statute. The only difference with the replenishment model is that the drug is dispensed at a contract pharmacy and is then replenished. In both cases, the price is set by federal statute and in neither case is the state law establishing the price. All the state law is doing is ensuring that drug companies continue to deliver drugs to contract pharmacies, where those drugs can be dispensed to patients on equal terms as if they were delivered to and dispensed at hospital pharmacies. Viewed from a different lens, there is no question that 340B drugs may be sold at hospital pharmacies using the replenishment model. PhRMA has never disputed this. All the state law allows for is the hospital to warehouse the drug at a contract

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pharmacy. Thus, by refusing to deliver to those contract pharmacies, the drug companies are imposing *delivery* restrictions—namely, they are saying, "We will deliver to your hospital but not your functional warehouse that makes it easier to get those drugs into the hands of needy patients." Ultimately, the only impact of state laws like West Virginia's and Minnesota's is to ensure that manufacturers deliver 340B drugs purchased by the 340B covered entity at the federally-mandated price, regardless of whether the covered entity is using an in-house pharmacy or an outside pharmacy. This is undoubtedly a question of delivery rather than price. The West Virginia court failed to understand this important fact. It is yet another reason why this Court should disregard that erroneous decision and instead follow the overwhelming number of courts that have upheld similar state statutes as regulations of drug delivery.

II. SECTION 62J.96 IS NOT AN UNCONSTITUTIONAL EXTRATERRITORIAL REGULATION.

PhRMA also claims that Section 62J.96 runs afoul of the dormant Commerce Clause because it "directly regulates wholly out-of-state transactions." Compl. ¶ 21. But that claim is squarely foreclosed by *National Pork Producers*. *E.g.*, *PhRMA v. Fitch*, 2024 WL 3277365, at *13.

As a factual matter, the Minnesota law applies *only* to drugs dispensed to patients of *Minnesota* 340B providers. Like "many (maybe most) state laws," Section 62J.96 may indirectly impact "extraterritorial behavior" for drug companies that are headquartered outside of Minnesota. *Nat'l Pork Producers*, 598 U.S. at 374. But Section 62J.96 does not target the regulation of extraterritorial activities. To the contrary, it is focused entirely on drug dispensing to patients of 340B providers that are *inside* of Minnesota's borders. Even if PhRMA had a valid legal theory about extraterritorial effects, it would not apply to Section 62J.96 on the facts. *See id*. at 375 (quoting *Hoyt v. Sprague*, 103 U. S. 613, 630 (1880)).

But PhRMA has no valid legal theory. *National Pork Producers* flatly rejected the "almost *per se*" extraterritoriality rule that PhRMA seeks, holding that the dormant Commerce Clause does *not* forbid "enforcement of state laws that have the "practical effect of controlling commerce outside the State[.]"598 U.S. at 371. Instead, the "very core" of its dormant Commerce Clause jurisprudence is the "antidiscrimination principle," *i.e*., whether a state engages in "economic protectionism" by privileging in-state competitors over out-of-state competitors. *Id*. at 369. PhRMA's attempt to revive the "extraterritoriality doctrine" so soon after the Supreme Court rejected it, *id.* at 371, is foreclosed by *National Pork Producers*.[14]

For the same reasons, the Southern District of Mississippi rejected PhRMA's extraterritoriality challenge to that State's materially identical law. Applying the presumption against extraterritoriality, which also exists in Minnesota, *see Matter of Minn. Power's Pet. for Approval of EnergyForward Res. Package*, 958 N.W.2d 339, 349 (Minn. 2021), the district court found that the Mississippi law "does not exhibit a clear intent to regulate out-of-state conduct." *Fitch*, 2024 WL 3277365, at *13. As a result, the Mississippi court held that that statute's "'general words' referring to 340B entities, manufacturers, and pharmacies are prima facie operative only as to persons or things within the territorial jurisdiction of Mississippi." *Id.* (internal citation and quotation marks omitted). The same is true of Section 62J.96.

[14] *National Pork Producers* also fatally undermines PhRMA's reliance on *Association for Accessible Medicines v. Frosh*, 887 F.3d 664, 674 (4th Cir. 2018) and *Association for Accessible Medicines v. Ellison*, No. 23-cv-2024, 2023 WL 8374586 (D. Minn. Dec. 4, 2023). As the Supreme Court explained, *Frosh* stands for the principle that one State may not tie "the price of . . . in-state products to out-of-state prices." *Nat'l Pork Producers*, 598 U.S. at 374; *see Ass'n for Accessible Meds. v. Ellison*, 2023 WL 8374586 (analyzing a similar statute). H.F. 4757 does no such thing. It simply requires manufacturers to distribute 340B drugs to the pharmacies with which Minnesota 340B hospitals have contracted. There is no tie to prices set by any other State, thereby refuting PhRMA's reliance on *Frosh* and *Ellison*.

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III. SECTION 62J.96 DOES NOT VIOLATE THE MINNESOTA CONSTITUTION'S SINGLE-SUBJECT CLAUSE.

The challenged provision also does not violate the Minnesota Constitution's single-subject and title clause. Minn. Const. art. IV, § 17; Compl. ¶¶ 110–14. A provision of a law satisfies the Single Subject Clause if it meets the "germaneness test," which means the challenged provisions are "parts of, or germane to, one general subject." *Townsend*, 767 N.W.2d at 13. It is well-established that a general subject should be construed very broadly. *Johnson v. Harrison*, 50 N.W. 923, 578 (Minn. 1891). In fact, the Minnesota Supreme Court has "upheld the legislation at issue in all but one of the single-subject challenges that have reached [it] in the last 40 years." *Otto v. Wright Cnty.*, 910 N.W.2d 446, 458–59 (Minn. 2018).[15] PhRMA relies heavily on that single case, *Associated Builders & Contractors v. Ventura*, 610 N.W.2d 293 (Minn. 2000), but advances an overly broad reading that the Minnesota Supreme Court recently rejected in *Otto*. 910 N.W.2d at 548.

The general subject of Section 62J.96 is the regulation of drugs. Article I of the law addresses appropriations for drug enforcement and health-related agencies, and Article II extensively addresses cannabis policy. Those Articles occupy 147 pages of a 181-page law. The challenged provisions regarding 340B drugs and contract pharmacies are undoubtedly germane to their "one general idea," *Otto*, 910 N.W.2d at 457 (quotation marks omitted), as they too expressly

[15] *See, e.g.*, *Otto*, 910 N.W.2d at 455 (upholding a provision governing audits of State counties in an omnibus bill addressing topics "ranging from appropriations, to provisions that adopt a symbol to represent the State's commitment to honoring members of the military, to railroad condemnation powers and regulation of cosmetologists"); *Townsend*, 767 N.W.2d at 13–14 (noting that legislation addressing postconviction remedies, while part of "a wide-ranging bill," was related to the subject of "public safety"); *Blanch v. Suburban Hennepin Reg'l Park Dist.*, 449 N.W.2d 150, 155 (Minn. 1989) (holding that a law permitting the acquisition of park land without public consent "is germane to the broad subject of appropriations *for the operation of state government*" (emphasis added)).

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govern access to drugs. "Given the broad view" that the Minnesota Supreme Court has "taken of germaneness," *Otto*, 910 N.W. at 457, PhRMA's claim that provisions of Section 62J.96 dealing with the distribution of 340B drugs are not germane to a law that generally addresses the regulation of drugs falls flat.

PhRMA emphasizes provisions in the remaining 35 or so pages of the law that do not address drugs. Even if PhRMA were correct about those *unchallenged* provisions of Section 62J.96, they are irrelevant to this case. Those provisions are not before this Court. Courts "will not strike down a germane provision of a law simply because other provisions in the law are not germane. To do so would undermine the presumption of constitutionality that [courts] afford to legislation and risk 'overstepping [their] judicial bounds.'" *Otto*, 910 N.W. at 458 (quoting *Associated Builders*, 610 N.W.2d at 305).

Thus, PhRMA's citations to the provisions of Section 62J.96 addressing scrap metal dealers or consumer data privacy provide no support for its single-subject argument because the 340B provisions that PhRMA actually challenges are plainly germane to the subject of drug regulation. Accordingly, the Court should dismiss this claim because the challenged provisions easily satisfy the Minnesota Supreme Court's forgiving germaneness test.

CONCLUSION

For the foregoing reasons, *Amici* respectfully request that the Court grant Defendants' motion to dismiss.

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Respectfully submitted,

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[16] Attorneys William B. Schultz, Margaret M. Dotzel, and Alyssa Howard Card of Zuckerman Spaeder LLP in Washington, D.C. intend to serve as counsel of record for *Amici* in this matter. Their *pro hac vice* motions are forthcoming.