This opinion is nonprecedential except as provided by Minn. R. Civ. App. P. 136.01, subd. 1(c).

STATE OF MINNESOTA
IN COURT OF APPEALS
A25-0805

Pharmaceutical Research and Manufacturers of America,
Appellant,

vs.

Keith Ellison, et al.,
Respondents.

Filed February 17, 2026
Affirmed
Wheelock, Judge

Ramsey County District Court
File No. 62-CV-24-5744

Barbara Podlucky Berens, Berens & Miller, PA, Minneapolis, Minnesota; and

Andrew D. Prins (pro hac vice), Latham & Watkins LLP, Washington, District of Columbia (for appellant)

Keith Ellison, Attorney General, Peter J. Farrell, Deputy Solicitor General, Peter Wenker, Assistant Attorney General, St. Paul, Minnesota (for respondents)

David W. Asp, Derek C. Waller, Lockridge Grindal Nauen PLLP, Minneapolis, Minnesota; and

William B. Schultz (pro hac vice), Zuckerman Spaeder LLP, Washington, District of Columbia (for amici curiae Minnesota Hospital Association, American Hospital Association, 340B Health, and American Society of Health-System Pharmacists)

Considered and decided by Reyes, Presiding Judge; Larkin, Judge; and Wheelock, Judge.

NONPRECEDENTIAL OPINION

WHEELOCK, Judge

Appellant association appeals the district court's grant of the state respondents' motion to dismiss its complaint challenging Minnesota Statutes section 62J.96 (2024) as unconstitutional. We affirm.

FACTS

Appellant Pharmaceutical Research and Manufacturers of America (PhRMA) is a trade association representing pharmaceutical manufacturers. PhRMA filed a complaint in district court seeking declaratory and injunctive relief against respondents State of Minnesota, the Minnesota Attorney General, and members of the Minnesota Board of Pharmacy.[1] PhRMA's complaint alleged that Minnesota Statutes section 62J.96 violates the Single Subject and Title Clause of the Minnesota Constitution, is preempted by federal law, and violates the dormant Commerce Clause of the United States Constitution. The district court granted the state's motion to dismiss the complaint, determining that all of PhRMA's claims failed to state a claim under Minn. R. Civ. P. 12.02.

To understand PhRMA's claims and the events that led to the underlying lawsuit, we summarize the federal 340B program and enactment of the statute PhRMA challenges before returning to the facts and procedural history of the present litigation.

The term "340B" refers to a federal drug-pricing program established by Congress in 1992. *See* Veterans Health Care Act of 1992, Pub. L. No. 102-585, § 602, 106 Stat.

[1] Respondents are referred to collectively as "the state" except when necessary to distinguish between parties.

4943, 4967-71 (incorporating section 340B of the Public Health Service Act, codified as 42 U.S.C. § 256b (2018)). The 340B program requires drug manufacturers, as a condition of participation in Medicaid and Medicaid Part B, to agree to offer drugs at discounted prices to statutorily defined "covered entities," which are, "dominantly, local providers of medical care for the poor." *Astra USA, Inc. v. Santa Clara County*, 563 U.S. 110, 131 (2011); *accord* 42 U.S.C. § 256b(a)(1), (4). These covered entities provide medical care to underserved populations but have limited federal funding for support, and the 340B program was designed in part to support this work. *Am. Hosp. Ass'n v. Becerra*, 596 U.S. 724, 738 (2022).

Under the 340B program, the Secretary of Health and Human Services (HHS) enters into a prescription pricing agreement with each manufacturer. Participating manufacturers agree to offer their drugs to any covered entity at a price no higher than the "ceiling price" if the drug is made available to any other purchaser at any price. A statutory formula sets the program's "ceiling price" for each drug, which is also referred to as the "340B price." 42 U.S.C. § 256b(a)(1), (4), (b)(1). In some instances, the 340B price can be as low as a penny per unit, and covered entities benefit financially through insurance reimbursements for the cost of drugs that exceeds the 340B price that a covered entity paid. *Novartis Pharms. Corp. v. Johnson*, 102 F.4th 452, 455-56 (D.C. Cir. 2024) (citing 340B Drug Pricing Program Ceiling Price and Manufacturer Civil Monetary Penalties Regulation, 82 Fed. Reg. 1210, 1211 (Jan. 5, 2017)).

Because operating an in-house pharmacy is cost-prohibitive for many covered entities, they regularly contract with outside pharmacies, referred to as "contract

pharmacies," to dispense drugs purchased through the 340B program ("340B drugs") to their patients. *Pharm. Rsch. & Mfrs. of Am. v. McClain*, 95 F.4th 1136, 1139 (8th Cir.), *cert. denied*, 145 S. Ct. 768 (2024). Recognizing the necessity of this practice, the Health Resources and Services Administration (HRSA) of HHS issued guidance in 1996 stating that covered entities without their own pharmacy may contract with one contract pharmacy. Contract Pharmacy Services, 61 Fed. Reg. 43,549, 43,549-50 (Aug. 23, 1996) (notice).

But in 2010, HRSA issued new guidance stating that covered entities may contract with an unlimited number of contract pharmacies. Notice Regarding 340B Drug Pricing Program—Contract Pharmacy Services, 75 Fed. Reg. 10,272, 10,272-73 (Mar. 5, 2010). This new guidance resulted in "significant expansion" of the 340B program. *Novartis*, 102 F.4th at 457. In 2024, the D.C. Circuit held in *Novartis* that section 340B allows manufacturers to contractually limit the distribution of discounted drugs, explaining that several Government Accountability Office reports indicated an approximately 34% increase in covered entity participation in the program between 2010 and 2019 but a 1,700% increase in the number of contract pharmacies during the same time period. *Id.*

It is this increase in contract-pharmacy use by covered entities that PhRMA alleges "has morphed [the federal program] into a money-making enterprise for national pharmacy chains and others who seek to enrich themselves at the expense of these underserved patients." PhRMA alleged in its complaint that contract pharmacies, although not allowed to profit from 340B pricing because they are not covered entities, have leveraged the program to enhance their profits by using a "replenishment model." This means, in essence, that the contract pharmacies commingle 340B and non-340B drugs in the same

inventory and sell 340B drugs to patients who may not be eligible for the discount. PhRMA alleges that the pharmacies then retroactively, and often incorrectly, identify which sales, if any, were to patients receiving the drugs through a covered entity and were thus eligible for the 340B price. After this retroactive determination, pharmacies request additional 340B drugs at the 340B price from the manufacturers to replenish their general inventory. PhRMA asserts that this creates a financial incentive for contract pharmacies to catalog as many prescriptions as possible as being eligible for the 340B price because the covered entity, contract pharmacy, and any third-party claims administrator divide and retain a portion of the difference in cost between the 340B price and the higher insurance reimbursement rate.

PhRMA also alleges that, because the "complex networks" of contract pharmacies make it difficult to obtain reliable data, the replenishment model can result in unlawful duplicate discounting if the manufacturer sells drugs at the 340B price and then also provides a rebate to the state Medicaid agency for the same sale. *See* 42 U.S.C. § 256b(a)(5)(A) (stating that it is unlawful to seek or cause a duplicate Medicaid discount).

In response to their concerns about contract pharmacies and these billing practices, some PhRMA members began adopting policies "to address the 340B abuses." One of those policies is a limitation on the number and location of contract pharmacies to which manufacturers are willing to ship 340B drugs; another is requiring certain claims data to be provided to manufacturers as a condition of sale. In 2020, HHS issued an advisory opinion stating that federal law requires manufacturers to deliver 340B drugs to any contract pharmacy that a covered entity chooses without limitation on the number of

contract pharmacies a covered entity may use. U.S. Dep't of Health & Hum. Servs., Off. Gen. Counsel, Advisory Opinion No. 20-06 (Dec. 30, 2020); *see also Novartis*, 102 F.4th at 458. HRSA then sent enforcement letters to manufacturers indicating that a manufacturer's duty under the 340B program to provide the 340B drugs to a covered entity cannot be qualified or restricted based on how a covered entity chooses to distribute 340B drugs to their patients. *Novartis*, 102 F.4th at 458-59. HHS withdrew advisory opinion 20-06 in June 2021. U.S. Dep't of Health & Hum. Servs., Off. Gen. Counsel, Withdrawing Advisory Opinion 20-06 on Contract Pharmacies under the 340B Program (June 18, 2021) (notice).

In recent cases, however, federal courts have ruled that a manufacturer's duty to offer 340B drugs to covered entities under the manufacturer's agreement with HHS does not encompass an unlimited number of contract pharmacies. *See Novartis*, 102 F.4th at 464 (holding that the 340B program does not prohibit manufacturers from imposing reasonable conditions on distribution); *Sanofi Aventis U.S. LLC v. U.S. Dep't of Health & Hum. Servs.*, 58 F.4th 696, 707 (3d Cir. 2023) (concluding that HRSA's enforcement of HHS advisory opinion 20-06 overstepped the 340B program's bounds because Congress did not say manufacturers must deliver to an unlimited number of contract pharmacies). PhRMA alleges that the states were "dissatisfied with the outcomes" of these lawsuits in federal court, which were contrary to HHS's advisory opinion, and that, in response, states, including Minnesota, began enacting legislation to prevent manufacturers from interfering with covered entities' agreements with contract pharmacies.

In 2024, the legislature passed Minnesota Statutes section 62J.96, which says, in its entirety:

> Subdivision 1. Manufacturers. A manufacturer must not directly or indirectly restrict, prohibit, or otherwise interfere with the delivery of a covered outpatient drug to a pharmacy that is under contract with a 340B covered entity to receive and dispense covered outpatient drugs on behalf of the covered entity, unless the delivery of the drug to the pharmacy is prohibited under the 340B Drug Pricing Program.
>
> Subd. 2. Definitions. (a) For purposes of this section, the following definitions apply.
>
> (b) "340B covered entity" has the meaning provided in section 340B(a)(4) of the Public Health Service Act.
>
> (c) "Covered outpatient drug" has the meaning provided in section 1927(k) of the Social Security Act.
>
> (d) "Manufacturer" has the meaning provided in section 151.01, subdivision 14a.
>
> Subd. 3. Expiration. This section expires July 1, 2027.

2024 Minn. Laws ch. 121, art. 4, § 3, p. 2155 (codified at Minn. Stat. § 62J.96). The statute prohibits manufacturers from preventing delivery of a covered entity's 340B drugs to contract pharmacies for dispensing to the covered entity's patients. PhRMA has since brought the underlying lawsuit seeking to invalidate this statute.

Returning to the present litigation, in addition to filing a motion to dismiss for failure to state a claim in the district court, the state also asserted that PhRMA lacked standing. The district court rejected that argument and determined that PhRMA has organizational standing to bring its claims against each respondent. It then determined that PhRMA failed to state a claim because section 62J.96 does not violate the Single Subject or Title Clause of the Minnesota Constitution, is not preempted by federal law, and does not violate the

dormant Commerce Clause of the United States Constitution. Based on those determinations, the district court then granted the state's motion to dismiss PhRMA's complaint.

PhRMA appeals.

DECISION

PhRMA argues that each of the claims in its complaint is sufficient to withstand a motion to dismiss, and it asks this court to reverse the district court's order dismissing them. The state argues that the district court erred when it determined that PhRMA has standing and asks that this court affirm dismissal for that reason, and in the alternative, it argues the district court correctly determined that PhRMA's pleadings fail to state a claim and that we should affirm dismissal on that ground. Because "[s]tanding is a threshold consideration in determining whether a litigant is entitled to have the courts determine the merits of a dispute," we address it first. *Hanson v. Woolston*, 701 N.W.2d 257, 261 (Minn App. 2005); *accord In re Consol. Hosp. Surcharge Appeals*, 883 N.W.2d 778, 784 (Minn. 2016).

We then address PhRMA's argument that each of the following claims survives a motion to dismiss: first, that section 62J.96 violates the Single Subject and Title Clause of the Minnesota Constitution because the bill the legislature passed that contained section 62J.96 was not germane to drug regulation and its title was too broad; second, that we should depart from federal caselaw and conclude that section 62J.96 is preempted by federal law; and third, that section 62J.96 violates the extraterritoriality doctrine of the dormant Commerce Clause. Ultimately, we conclude that PhRMA has standing but that

its claims fail as a matter of law and thus the district court did not err in granting the state's motion to dismiss.

I. PhRMA has standing.

"Standing is a legal requirement that a party have a sufficient stake in a justiciable controversy to seek relief from a court." *Lorix v. Crompton Corp.*, 736 N.W.2d 619, 624 (Minn. 2007) (citing *Sierra Club v. Morton*, 405 U.S. 727, 731-32 (1972)); *Webb Golden Valley, LLC v. State*, 865 N.W.2d 689, 693 (Minn. 2015). Because it is a question of law, we review standing de novo. *Minn. Sands, LLC v. County of Winona*, 940 N.W.2d 183, 192 (Minn. 2020); *see also Surcharge Appeals*, 883 N.W.2d at 784 ("[W]e evaluate decisions on standing de novo." (Quotation omitted.)).

"An organization can assert standing if its members' interests are directly at stake or if its members have suffered an injury-in-fact." *Builders Ass'n of Minn. v. City of St. Paul*, 819 N.W.2d 172, 177 (Minn. App. 2012) (citing *State by Humphrey v. Philip Morris Inc.*, 551 N.W.2d 490, 497-98 (Minn. 1996)). "To demonstrate an injury-in-fact, the plaintiff must point to an injury that is fairly traceable to the defendants' challenged action and that is likely to be redressed by a favorable decision." *Scheffler v. City of Anoka*, 890 N.W.2d 437, 451 (Minn. App. 2017), *rev. denied* (Minn. Apr. 26, 2017). Economic injury may be sufficient to establish standing, so long as it is not abstract or speculative. *Builders Ass'n of Minn.*, 819 N.W.2d at 176 (citing *State v. Knutson*, 523 N.W.2d 909, 911 (Minn. App. 1994), *rev. denied* (Minn. Jan. 13, 1995)).

At the pleading stage, general factual allegations of injury resulting from the defendant's conduct may suffice, "for on a motion to dismiss we presume that general

allegations embrace those specific facts that are necessary to support the claim." *Forslund v. State*, 924 N.W.2d 25, 32 (Minn. App. 2019) (quoting *Lujan v. Defs. of Wildlife*, 504 U.S. 555, 561 (1992)).

PhRMA's complaint alleged that its members, who manufacture and sell pharmaceutical products and participate in the 340B program, have adopted policies restricting contract pharmacy use by covered entities but will be required to deliver 340B drugs they produce to more pharmacies at a steeply reduced price because of section 62J.96. It alleged that, because the federal statute does not require the members to deliver their 340B drugs to an unlimited number of contract pharmacies, section 62J.96's requirement that they do so will cause economic loss. It also asserts that such injuries would be redressed by a court declaring section 62J.96 unconstitutional.

It is undisputed that section 62J.96 is aimed at prohibiting PhRMA's members' policies on restricting the delivery of their 340B drugs to contract pharmacies. Accordingly, PhRMA's members' interests are directly at stake. *See Builders Ass'n of Minn.*, 819 N.W.2d at 177. PhRMA alleges that section 62J.96 affects its members' ability to conduct commercial transactions that are otherwise in accordance with federal law. This alleged injury is not abstract or speculative, and thus, it is sufficient to establish standing. *See Knutson*, 523 N.W.2d at 911 ("A party must have more than an abstract concern and the injury must not be merely speculative.").

The state argues that, because it has not enforced section 62J.96 against PhRMA's members and the statute contains no explicit enforcement provision giving any state respondent authority to enforce it, PhRMA has failed to plead a sufficient injury to establish

standing.[2] We conclude that the state respondents each have authority to enforce the statute, and we reject this argument.

The attorney general has broad powers and may "institute, conduct, and maintain all such actions and proceedings as he deems necessary for the enforcement of the laws of this state, the preservation of order, and the protection of legal right." *State by Hatch v. Am. Fam. Mut. Ins. Co.*, 609 N.W.2d 1, 3 (Minn. App. 2000), *rev. denied* (Minn. June 13, 2000); *see also* Minn. Stat. § 8.31, subd. 2 (2024) (stating that the attorney general has power to investigate and take such steps as are necessary to cause the arrest and prosecution of any person for violation of laws respecting unfair, discriminatory, or other unlawful practices in business, commerce, or trade). The board of pharmacy has the authority to regulate the manufacture and wholesale of drugs in Minnesota. Minn. Stat. § 151.06, subd. 1(2) (2024). It further has enforcement authority over licensed drug manufacturers. Minn. Stat. § 151.071, subd. 2(9) (2024) (providing that the board can revoke licenses and impose civil monetary penalties).

[2] The state relies on a federal district court decision to support its argument. In *AbbVie, Inc. v. Ellison*, the District of Minnesota dismissed pharmaceutical manufacturer AbbVie's constitutional claims challenging section 62J.96, determining that, because the statute did not empower either the attorney general or the board to enforce it, AbbVie did not have standing for purposes of federal "injury." 777 F. Supp. 3d 971, 977 (D. Minn. 2025). But Minnesota courts are "not bound by the standing constraints of Article III of the United States Constitution," even when claims are based on federal law. *Growe v. Simon*, 2 N.W.3d 490, 499 n.6 (Minn. 2024); *see also Lorix*, 736 N.W.2d at 626 (recognizing a "desire for harmony" between federal and state courts on substantive law but emphasizing that Minnesota is not bound by federal standing law); *All. for Metro. Stability v. Metro. Council*, 671 N.W.2d 905, 913 (Minn. App. 2003) (recognizing that Minnesota has adopted liberal standards for standing).

Because PhRMA has demonstrated that its members have suffered injuries-in-fact—including an economic impact and limit on their ability to conduct commercial transactions—that is traceable to the enactment of section 62J.96, we conclude that PhRMA has standing.

Having resolved the threshold question of standing, we next consider whether the district court erred when it dismissed the complaint for failure to state a claim.

II. The district court did not err when it determined that each of PhRMA's claims must be dismissed for failure to state a claim.

"We review de novo whether a complaint sets forth a legally sufficient claim for relief. We accept the facts alleged in the complaint as true and construe all reasonable inferences in favor of the nonmoving party." *Walsh v. U.S. Bank, N.A.*, 851 N.W.2d 598, 606 (Minn. 2014) (citation omitted).

A claim is sufficient to withstand a motion to dismiss for failure to state a claim if it is possible, on any evidence which might be produced consistent with the pleader's theory, to grant the relief demanded. *Id.* at 603. Under this rule, a pleading will be dismissed only if it appears to a certainty that no facts that could be introduced consistent with the pleading would support granting the relief demanded. *Id.* at 602. We consider each of PhRMA's claims in turn.

A. PhRMA has not pleaded a viable claim that section 62J.96 violates the Single Subject and Title Clause requirements of the Minnesota Constitution.

PhRMA argues that it sufficiently pleaded that section 62J.96 violates the Minnesota Constitution. First, it argues that, because the bill that enacted section 62J.96

includes several provisions about cannabis regulation, the subject of the bill is actually cannabis, and the inclusion of section 62J.96 in the bill violates the single-subject requirement. It further contends that, as section 62J.96 purports to regulate the federal 340B program, this statute is not germane to the subject of cannabis. Second, it argues, as to the title requirement, that the use of "commerce" in the title of the bill was too broad to be informative.

When determining whether a statute is constitutional, we proceed with the presumption that it is constitutional and we exercise the power to declare a statute unconstitutional with extreme caution. *Assoc. Builders & Contractors v. Ventura*, 610 N.W.2d 293, 298-99 (Minn. 2000). The challenger has an "extraordinary burden of persuasion in order to overcome the general presumption of constitutional validity." *Otto v. Wright County*, 910 N.W.2d 446, 459 (Minn. 2018) (quoting *Blanch v. Suburban Hennepin Reg'l Park Dist.*, 449 N.W.2d 150, 157 (Minn. 1989) (Popovich, C.J., concurring)).

Article IV, section 17 of the Minnesota Constitution states: "No law shall embrace more than one subject, which shall be expressed in its title." The first clause is the Single Subject Clause, and the second clause is the Title Clause. Minn. Const. art. IV, § 17. The two clauses "serve independent though interrelated purposes." *Wass v. Anderson*, 252 N.W.2d 131, 134 (Minn. 1977). We consider each clause below.

1. Single Subject Clause

The supreme court has identified two purposes for the Single Subject Clause. The first purpose is to prevent "log-rolling a legislative process by which a number of different

and disconnected subjects are united in one bill." *Otto*, 910 N.W.2d at 456 (quotations omitted). The second purpose is "to prevent surprise and fraud upon the people and the legislature by failing to provide notice of the nature of the proposed legislation and the interests likely to be affected." *Id.* The clause is construed liberally. *Id.*

The test for a challenge under this clause is "germaneness." *Id.* at 458. The test and the clause are satisfied if the bill is germane to one general subject. *Assoc. Builders*, 610 N.W.2d at 299. The supreme court has explained the broad nature of this test:

> The term "subject," as used in the constitution, is to be given a broad and extended meaning . . . . All that is necessary is that the act should embrace . . . some one general idea, be so connected with or related to each other, either logically or in popular understanding, as to be parts of, or germane to, one general subject.

Johnson v. Harrison, 50 N.W. 923, 924 (Minn. 1891), *cited with approval in Otto*, 910 N.W.2d at 458 n.11. If the germaneness test is met, there is no need to consider legislative history. *Otto*, 910 N.W.2d at 457 n.10; *see also Unity Church of St. Paul v. State*, 694 N.W.2d 585, 597 (Minn. App. 2005) ("What the Minnesota Constitution requires is germaneness. It does not require the absence of legislative maneuvering to enact unpopular, but germane, bills."). In considering a single-subject challenge, we may look at the title of a bill because "it presents words and phrases suggesting the common thread among the provisions." *Defs. of Wildlife v. Ventura*, 632 N.W.2d 707, 713 n.1 (Minn. App. 2001), *rev. denied* (Minn. Oct. 24, 2001).

Here, H.F. 4757, the bill that enacted section 62J.96, states it is "[a]n act relating to commerce"; in full, the bill is identified as follows:

> An act relating to commerce; modifying appropriations to the Office of Cannabis Management and the Department of Health; modifying cannabis provisions; modifying fees assessed by the Department of Commerce; adding and modifying consumer protection provisions; establishing the Minnesota Consumer Data Privacy Act; authorizing rulemaking; classifying data; making technical changes; requiring reports; appropriating money; [remainder listing additions and amendments].

2024 Minn. Laws ch. 121, at 2041.

Notwithstanding that the title of H.F. 4757—"An act relating to commerce"—identifies the general subject of the bill as "commerce," PhRMA contends that its subject is actually cannabis and that section 62J.96's regulation of the 340B program is not germane to cannabis. In making this argument, PhRMA primarily relies on *Associated Builders*, an opinion in which the supreme court concluded that an amendment on prevailing wage law that was included in a bill violated the single-subject requirement because the subject of the bill was taxation and government operations and the wage–law amendment was not sufficiently related to taxation and government operations to be germane. 610 N.W.2d at 304. The supreme court observed that, if it were to uphold the amendment, which had no connection to the other subjects and required that certain wages be paid regardless of whether a project was publicly funded or not, its decision "would push the mere filament to a mere figment." *Id.* at 303.

Associated Builders is materially different. The provision that was struck down was contained in a bill entitled in part, "[a]n act relating to the financing and operation of state

and local government." *Id.* at 297 (quotation omitted). The title contained no reference to labor, wages, or anything that would suggest the presence of a prevailing-wage-law amendment. *Id.* at 304; *see Defs. of Wildlife*, 632 N.W.2d at 713 n.1 (addressing the title in a single-subject challenge to identify the "common thread"). Moreover, in *Otto*, its most recent decision addressing the single-subject requirement, the supreme court clarified that its decision in *Associated Builders* was narrowly focused on the connection between the title and the alleged subject in that case, which counsels against its broad application here. *Otto*, 910 N.W.2d at 457 (discussing *Assoc. Builders*, 610 N.W.2d at 295-304).

In *Otto*, the appellant raised a single-subject challenge to a law by focusing on the title of that bill—"an act relating to the operation of state government"—to argue that the subject "operation of state government" was too broad to be a single subject that connected the provisions of the bill. 910 N.W.2d at 456. The supreme court, however, rejected that argument, reasoning that "[a] provision that allows counties to choose between the State Auditor and a private . . . firm for the annual audit required by statute . . . is clearly germane to the subject of state government operations." *Id.* at 457. It further explained that categorizing it as too broad would be "inconsistent with our earlier cases that define 'subject' with a 'broad and extended meaning,' encompassing one general matter that falls 'under some one general idea.'" *Id.* (quoting *Johnson*, 50 N.W. at 924). The supreme court thus concluded, "Consistent with our precedent, the subject—'the operation of state government'—is not too broad to pass constitutional muster in a challenge to legislation that addresses the roles and responsibilities of state entities." *Id.*

The subject of H.F. 4757 is commerce. The bill consists of five articles, and section 62J.96 is located in article 4, titled "Commerce Policy." Like other bills upheld against a single-subject challenge, H.F. 4757 includes provisions on a limited number of topics: appropriations, cannabis policy, commerce policy, and consumer data privacy. *Cf. Defs. of Wildlife*, 632 N.W.2d at 713 (noting the challenged bill contained only seven topics). PhRMA urges us to determine that, instead of commerce, the subject of H.F. 4757 is cannabis, seemingly because the article containing cannabis-related provisions is the longest part of the bill. But PhRMA does not meaningfully dispute that the regulation of 340B drug delivery, like the regulation of cannabis, is included within the common thread of commerce. *See id.* (considering title to identify the common thread of provisions in a bill).

Based on *Otto*, the term "commerce" is a general subject with a broad and extended meaning that is logically related to the delivery of goods—which is precisely what section 62J.96 purports to regulate. To determine that "commerce" is too broad would be inconsistent with binding supreme court precedent. PhRMA thus has failed to meet the "extraordinary burden" required to overcome the presumption of constitutional validity, *Otto*, 910 N.W.2d at 459, and section 62J.96 does not violate the Single Subject Clause.

2. Title Clause

The function of the title requirement is to provide notice of the interests likely to be affected by the law and "to prevent surprise and fraud upon the people and the legislature by including provisions in a bill whose title gives no intimation of the nature of the proposed legislation." *Wass*, 252 N.W.2d at 134-35 (quotation omitted). "[T]he generality

of the title of an act is not grounds for invalidation as long as the title gives notice of the general subject because the title was never intended to be an index of the law." *Assoc. Builders*, 610 N.W.2d at 300 (quotation omitted). "It is not essential that the best or even an accurate title be employed, if it be suggestive in any sense of the legislative purpose." *Wass*, 252 N.W.2d at 137 (quotation omitted). Every reasonable presumption should be in favor of the title's constitutionality. *Id.*

PhRMA argues that nothing in the title of H.F. 4757 relates to sections 62J.96 or 340B, that "commerce" is far too broad, and that "consumer protection" does not accurately describe the statute because it benefits only commercial entities like covered entities and contract pharmacies, not patients. But generality is not grounds for invalidation, and the title need not be perfect or an index of the law. *Wass*, 252 N.W.2d at 137; *Assoc. Builders*, 610 N.W.2d at 300. While "commerce" and "consumer protection" may be general, neither is misleading. *See Wass*, 252 N.W.2d at 137 ("'Transportation' is a general term. But no legislator could be misled by it."). Regulating the delivery of goods within a commerce bill is not a "surprise" or "fraud." *Otto*, 910 N.W.2d at 456. And a statute designed to prevent interference with the distribution of drugs to underserved patients is not so far afield of "consumer protection" as to be misleading.

Accordingly, section 62J.96 also does not violate the Title Clause, and the district court did not err in granting the state's motion to dismiss PhRMA's claim that the statute violates the Minnesota Constitution.

B. PhRMA has not pleaded a viable claim that section 62J.96 is preempted by federal law.

PhRMA's second claim is based on its allegations that section 62J.96 is preempted by federal law. To support this claim, PhRMA makes two distinct arguments, contending that (1) section 62J.96 is in direct conflict with the federal scheme because it operates as more than a mere regulation of delivery obligations in two ways: first, it "impermissibly regulates 340B pricing" by setting or enforcing discount pricing and, second, it "expand[s] the federal subsidy" by requiring manufacturers to provide 340B pricing discounts to contract pharmacies; and (2) section 62J.96 "conflicts with and intrudes on 340B's exclusive federal administration and enforcement regime." Based on these arguments, PhRMA asserts that section 62J.96 fails under two different theories of preemption: conflict preemption and field preemption. We consider whether PhRMA's preemption claim under either theory survives a motion to dismiss and conclude that it does not. To facilitate that analysis, however, we lead with a discussion of the presumption against preemption and of statutes and federal caselaw that are relevant to the question of preemption.

Presumption Against Preemption

Article VI of the United States Constitution provides that the laws of the United States "shall be the supreme Law of the Land; . . . any Thing in the Constitution or Laws of any state to the Contrary notwithstanding." U.S. Const. art. VI, cl. 2. "The preemption of state law may operate impliedly . . . because a federal statute conflicts with a state statute

or because the scope of a federal statute indicates that Congress intended federal law to occupy a field exclusively." *Surcharge Appeals*, 867 N.W.2d at 517 (quotations omitted).[3]

But the United States Supreme Court has explained that "[c]onsideration of issues arising under the Supremacy Clause 'start[s] with the assumption that the historic police powers of the States [are] not to be superseded by Federal Act unless that [is] the clear and manifest purpose of Congress.'" *Cipollone v. Liggett Grp., Inc.*, 505 U.S. 504, 516 (1992) (quoting *Rice v. Santa Fe Elevator Corp.*, 331 U.S. 218, 230 (1947)). "Preemption of state law is not favored 'in the absence of persuasive reasons—either that the nature of the regulated subject matter permits no other conclusion or that the Congress has unmistakably so ordained.'" *Blackburn v. Doubleday Broad. Co.*, 353 N.W.2d 550, 554 (Minn. 1984) (quoting *Fla. Lime & Avocado Growers, Inc. v. Paul*, 373 U.S. 132, 142 (1963)).

"Health and safety" is an area of state law that is "traditionally included within a state's police power," and accordingly, the party alleging preemption bears "the considerable burden of overcoming" the presumption that Congress does not intend to preempt the state law. *Surcharge Appeals*, 883 N.W.2d at 786 (citing *De Buono v. NYSA-ILA Med. & Clinical Servs. Fund*, 520 U.S. 806, 814 (1997)). State regulation of the business of pharmacy "under the police power cannot well be questioned." *State v. Hovorka*, 110 N.W. 870, 871 (Minn. 1907). And Minnesota has long recognized the "relationship between the sale of drugs and the public health" and that the state can "validly exercise its police power by a statute regulating such sales." *State v. Red Owl Stores, Inc.*,

[3] Though PhRMA does not allege it here, Congress may also expressly preempt certain state laws by stating so in express terms. *Id.*

115 N.W.2d 643, 658 (Minn. 1962). Accordingly, we apply the presumption against preemption here.

Statutes and Relevant Federal Caselaw

Next, we must recall the statutory framework of the 340B program to evaluate its breadth and its intersections, if any, with section 62J.96. Section 340B requires manufacturers to "offer each covered entity covered outpatient drugs for purchase" at or below a specified ceiling price. 42 U.S.C. § 256b(a)(1). We recognize that the "340B program 'has three basic parts: (1) a cap on drug makers' prices, (2) restrictions on covered entities, and (3) compliance mechanisms for both covered entities and manufacturers.'" *McClain*, 95 F.4th at 1141 (quoting *Sanofi*, 58 F.4th at 699). When disputes over payment, pricing, diversion, or discounts arise between manufacturers and covered entities, section 340B mandates that parties engage in HHS's dispute-resolution process to resolve the issue. 42 U.S.C. § 256b(d)(3) (2018). Congress made HHS the sole enforcer of 340B. *See Astra*, 563 U.S. at 120.

On the other hand, section 62J.96 prohibits manufacturers from interfering "with the delivery of a covered outpatient drug to a pharmacy that is under contract with a 340B covered entity to receive and dispense covered outpatient drugs on behalf of the covered entity." Minn. Stat. § 62J.96, subd. 1. But section 62J.96 says nothing about price and does not require manufacturers to provide 340B drugs to contract pharmacies at the 340B price. Pharmacies are not covered entities and are not eligible to receive the 340B price. *See* 42 U.S.C. § 256b(a)(4) (defining "covered entity"). Section 62J.96, by its plain language, makes clear that pharmacies under contract with a 340B covered entity

may receive and dispense covered drugs "on behalf of the covered entity." Minn. Stat. § 62J.96, subd. 1. But it is the covered entity that pays the 340B price, and the statute merely prevents manufacturers from interfering with the contract pharmacy's dispensing of the drugs to the covered entity's patients. By its plain language, section 62J.96 does not attempt to enforce or impose penalties for violations of 340B. And section 62J.96 does not give the state any jurisdiction over payment, pricing, diversion, or discount disputes between manufacturers and covered entities.

Given the disagreements about aspects of the 340B program, there are a number of significant cases to which the parties cite as persuasive authority. PhRMA cites two federal appellate opinions—*Sanofi* and *Novartis*. In these cases, the Third Circuit in 2023 and the D.C. Circuit in 2024 addressed HHS advisory opinion 20-06 and subsequent HRSA enforcement letters in which the agency interpreted section 340B to require drug manufacturers to deliver 340B drugs to an unlimited number of contract pharmacies and opined that manufacturer policies that limit delivery to contract pharmacies are unlawful. *Sanofi*, 58 F.4th at 701-03; *Novartis*, 102F.4th at 458-59.

In conducting statutory interpretation of section 340B, the court in *Novartis* reached the same conclusion for the same reasons as the court in *Sanofi*. *Novartis*, 102 F. 4th at 461. Both courts held that section 340B is silent regarding delivery and thus that HHS's reading of section 340B as requiring delivery to an unlimited number of contract pharmacies was incorrect. *Sanofi*, 58 F.4th at 703-07 (stating that "[l]egal duties do not spring from silence"); *Novartis*, 102 F.4th at 460-61 (stating "we agree entirely" with the reasoning and conclusion in *Sanofi* that, "because section 340B is silent about delivery,

HRSA erred in concluding that the statute requires drug makers to deliver drugs to an unlimited number of contract pharmacies" (quotation omitted)). In *Novartis*, the D.C. Circuit interpreted the language of 340B in terms of the contractual relationship it requires between manufacturers and covered entities and explained that the statutory silence of section 340B on delivery preserves the ability of manufacturers to impose "at least some delivery conditions." 102 F.4th at 460.

In addition to the federal appellate opinions addressing challenges to HHS's interpretation of section 340B, two federal courts of appeal recently have addressed drug manufacturers' challenges to state laws similar to section 62J.96 that prohibit restrictions by manufacturers on, among other things, delivery of 340B drugs. The state cites these cases, in which the drug manufacturers asserted, in part, that state laws were preempted by federal law, but the courts, applying the presumption against preemption, upheld the state laws after determining that the federal drug-pricing program—the 340B program—did not preempt the state laws under theories of field or conflict preemption. *See McClain*, 95 F.4th at 1143 (holding that Arkansas law prohibiting drug manufacturers from limiting covered entities' ability to contract with outside pharmacies was not preempted by 340B statutory scheme under either a conflict or field preemption theory); *AbbVie, Inc. v. Fitch*, 152 F.4th 635, 645 (5th Cir. 2025) (affirming denial of injunctive relief to drug

manufacturers challenging Mississippi law prohibiting interference with acquisition or delivery of a 340B drug to a contract pharmacy and rejecting preemption claims).[4,5]

Against this backdrop, we consider PhRMA's arguments on preemption as to section 62J.96.

1. Conflict Preemption

Conflict preemption may arise in two ways. First, it may exist if a party cannot simultaneously comply with both state and federal law. *In re Est. of Barg*, 752 N.W.2d 52, 64 (Minn. 2008) (citing *Fla. Lime & Avocado Growers, Inc.*, 373 U.S. at 142-43). Second, it may exist when the state law is an obstacle to the accomplishment of Congress's purpose and objectives. *Id.* Because PhRMA argues conflict preemption only on the basis that section 62J.96 is an obstacle to the accomplishment of Congress's purpose and objectives in establishing the 340B program,[6] our inquiry is focused there.

---

[4] Some federal district courts have come to the opposite conclusion. *AbbVie Inc. v. Drummond*, No. 25-CV-726 (W.D. Okla. Oct. 31, 2025), *AbbVie, Inc. v. Weiser*, No. 25-CV-1847-WJM KAS, 2025 WL 3041825, at *1 (D. Colo. Oct. 31, 2025); *Pharm. Rsch. & Mfrs. of Am. v. Morrisey*, 760 F. Supp. 3d 439, 448 (S.D. W. Va. 2024). We acknowledge that a circuit split may arise later on this issue but find persuasive that one does not exist now.

[5] We observe that as recently as this past week, the Fifth Circuit decided *AbbVie, Inc. v. Murrill*, ___ F.4th___, ___, No. 24-30645, slip op. at 13-16 (5th Cir. Feb. 9, 2026), in which it relied on its preemption analysis in *Fitch*, 152 F.4th at 646-48, to conclude that a Louisiana law prohibiting manufacturers from interfering with delivery of 340B drugs to contract pharmacies was not preempted by federal law.

[6] We note that PhRMA does not allege that it cannot comply with both federal law and state law simultaneously, and we interpret its brief to assert only that section 62J.96 presents an obstacle to the 340B program.

PhRMA argues that section 62J.96 conflicts with the 340B scheme by compelling manufacturers to provide 340B-priced drugs to contract pharmacies in circumstances where federal law does not. We understand PhRMA's argument to be that section 62J.96 operates in a manner determined by the D.C. Circuit in *Novartis* to be in conflict with section 340B, insofar as the text of section 340B does not support any requirement that a manufacturer deliver to an unlimited number of contract pharmacies and that a state law including such a requirement impermissibly conflicts with section 340B. We disagree with the premise upon which PhRMA's argument relies—that section 62J.96 compels drug manufacturers to offer 340B-priced drugs to contract pharmacies.

The opinion in *Novartis*, addressing HHS's advisory opinion 20-06, held that the text of section 340B does not support the proposition that manufacturers are categorically prohibited from imposing conditions on the distribution of 340B drugs to covered entities. 102 F.4th at 464. The D.C. Circuit explained that the statutory silence of section 340B on delivery preserves the ability of manufacturers to impose "at least some delivery conditions." *Id.* at 460. But *Novartis* did not hold that a state law restriction on manufacturer delivery to contract pharmacies created a pricing mandate. Indeed, *Novartis* did not address state law at all. We cannot read *Novartis* as implying that because 340B does not affirmatively prohibit manufacturers from imposing conditions on distribution, it must mean that states are prohibited from imposing such conditions.

And while PhRMA argues that section 62J.96 alters the bargain that Congress struck with manufacturers in creating the 340B scheme, it does not. A manufacturer participating in the 340B program must agree to "offer" each covered entity their drugs at the ceiling

price. 42 U.S.C. § 256b(a)(1). Section 62J.96 does not change the 340B obligation; a manufacturer is still required to offer the drugs at the 340B price. A manufacturer is still free to choose not to opt in to the program. *See Astra*, 563 U.S. at 115 (referring to the 340B program creating an "opt-in mechanism" for manufacturers).

PhRMA makes the same arguments here that were rejected in *McClain*. 95 F. 4th at 1143-45. In *McClain*, the Arkansas law at issue was similar to section 62J.96 in that it addressed delivery to contract pharmacies. *See id.* at 1142-43. The state law authorized the state insurance division to exact penalties and equitable relief if manufacturers denied delivery to a covered entity's contract pharmacy. *Id.* at 1144. The Eighth Circuit determined that section 340B provided HHS with jurisdiction over all pricing-related disputes and the state law merely addressed distribution to contract pharmacies. *Id.* It therefore concluded that the Arkansas law "does not set or enforce discount pricing. As such, the delivery of a covered entity's 340B drugs to contract pharmacies for dispensing creates no obstacle" and was not conflict preempted. *Id.* at 1145.

PhRMA asserts the *McClain* analysis is inapplicable because it was decided before the decision in *Novartis* and that, because it did not apply the "offer" framework PhRMA urges us to now apply, it is not persuasive. PhRMA fails to acknowledge, however, that *McClain* was decided after *Sanofi*—in fact, it cites *Sanofi* numerous times, *McClain*, 95 F.4th at 1141-45; that the court in *Novartis* applied the same reasoning and reached the same conclusion as the court in *Sanofi*, *see Novartis*, 102 F. 4th at 461 (stating "we agree entirely" with the conclusion in *Sanofi*); and that both *Sanofi* and *Novartis* discussed the meaning of "offer" in the language of section 340B, *Sanofi*, 58 F.4th at 703; *Novartis*,

102 F.4th at 460. For these reasons, we conclude that the analysis in *McClain* is not inconsistent with the holding in *Novartis*.

We are also not persuaded that the mere existence of any effects of section 62J.96 on PhRMA's members' commercial transactions means that section 62J.96 is an obstacle to section 340B. The purpose of section 340B is to increase access to medications for entities that provide medical care to underserved populations. *Becerra*, 596 U.S. at 738. Rather than creating an obstacle to 340B's purpose, section 62J.96 complements it by ensuring that more patients have adequate access to pharmacies that can dispense the 340B drugs necessary for their healthcare. *See McClain*, 95 F.4th at 1144-45 ("Act 1103 does not create an obstacle for pharmaceutical manufacturers to comply with 340B, rather it does the opposite: Act 1103 assists in fulfilling the purpose of 340B.").

In sum, we conclude that section 62J.96 does not compel manufacturers to provide 340B-priced drugs to contract pharmacies in circumstances where federal law does not, and we conclude that it is not conflict preempted by federal law.

2. Field Preemption

PhRMA contends that "field preemption is also an appropriate lens through which to evaluate [whether] section 62J.96" is preempted by federal law. Field preemption applies when Congress "intend[s] 'to foreclose any state regulation in the [regulated] *area*,' irrespective of whether state law is consistent or inconsistent with 'federal standards.'" *Oneok, Inc. v. Learjet, Inc.*, 575 U.S. 373, 377 (2015) (quoting *Arizona v. United States*, 567 U.S. 387, 401 (2012)). Congress's intent to preempt a field "can be inferred from a framework of regulation 'so pervasive . . . that Congress left no room for the States to

supplement it'" or a "federal interest . . . so dominant that the federal system will be assumed to preclude enforcement of state laws on the same subject." *Arizona*, 567 U.S. at 399 (quoting *Rice*, 331 U.S. at 230). A reviewing court must determine whether the congressional act "manifest[s] the intention to occupy the entire field" such that the only logical inference left is that the state has no room to legislate the same subject. *Kurns v. R.R. Friction Prods. Corp.*, 565 U.S. 625, 631 (2012) (quotation omitted). Field preemption "should not be inferred, however, simply because the agency's regulations are comprehensive." *R.J. Reynolds Tobacco Co. v. Durham County*, 479 U.S. 130, 149 (1986).

PhRMA's theory of field preemption is that the statutory scheme underlying the 340B program is "so pervasive . . . that Congress left no room for the States to supplement it" and thus section 62J.96 violates the Supremacy Clause.[7] To support its argument and

[7] Although PhRMA pointed out that a state law may be field preempted when there is a "federal interest . . . so dominant that the federal system will be assumed to preclude enforcement of state laws on the same subject," *Arizona*, 567 U.S. at 399, it limits its discussion of caselaw related to this argument to a footnote in which it relies on the concept of a unique federal interest primarily to challenge whether the presumption against preemption applies here, not to argue that the delivery of 340B drugs to contract pharmacies presents a unique federal concern. The Supreme Court has held that certain areas involving "uniquely federal interests" are "so committed by the Constitution and laws of the United States to federal control that state law is preempted and replaced" by federal common law. *Boyle v. United Techs. Corp.*, 487 U.S. 500, 504 (1988). However, such a uniquely federal interest has been found in only a few circumstances. *Id.* at 505 (collecting prior cases on the civil liability of federal officials for actions taken in the course of duty), 506 (government contractor civil liability arising out of performance of federal procurement contracts was a uniquely federal interest); *United States v. Locke*, 529 U.S. 89, 97, 99 (2000) (regulation of maritime vessels); *Buckman Co. v. Plaintiffs' Legal Comm.*, 531 U.S. 341, 347 (2001) (state tort claims for fraud on a federal agency). We are neither persuaded that we should not apply the presumption against preemption nor that a unique federal interest exists that supports a determination that section 62J.96 is field preempted here, where section 62J.96 regulates in the area of public health and pharmacy,

demonstrate the pervasive nature of the statutory scheme, PhRMA points to components of the 340B program, including compliance mechanisms, penalties for noncompliance or abuse by manufacturers and covered entities, and a dispute resolution process through HHS.[8] *See, e.g.*, *Astra*, 563 U.S. at 115-16 (explaining how the 340B program operates and is enforced); *Sanofi*, 58 F.4th at 701-02 (same). When preemption is alleged, the ultimate touchstone of our analysis is whether Congress's "clear and manifest purpose" was to supersede the historic police powers of the state. *Cipollone*, 505 U.S. at 516; *Barg*, 752 N.W.2d at 63 (stating that whether federal law preempts state law is primarily an issue of statutory interpretation).

The opinion in *McClain* again provides useful guidance. The Eighth Circuit rejected PhRMA's field-preemption arguments, determining that, because HHS has jurisdiction over disputes between covered entities and manufacturers, any dispute over delivery at the state level is not an intrusion into HHS jurisdiction. *McClain*, 95 F.4th at 1143-44. It concluded that the Arkansas law was simply deterring manufacturers from interfering with

---

areas that within the state's police power. *See Surcharge Appeals*, 883 N.W.2d at 786; *Red Owl Stores, Inc.*, 115 N.W.2d at 658.

Furthermore, establishing "an area of uniquely federal interest does not . . . end the inquiry" because that is merely "a necessary, not a sufficient, condition for the displacement of state law." *Boyle*, 487 U.S. at 507. State law will only be displaced where a "significant conflict exists between an identifiable federal policy or interest and the operation of state law," or when state law would frustrate "specific objectives of federal legislation." *Id.* (quotations omitted). And here, as we have observed, section 62J.96 furthers the objectives of the 340B program.

[8] When disputes over payment, pricing, diversion, or discount arise between manufacturers and covered entities, section 340B mandates that parties engage in HHS's dispute-resolution process to resolve the issue. 42 U.S.C. § 256b(d)(3).

a covered entity's contract-pharmacy arrangements. *Id.* at 1145. And it also interpreted "congressional silence on pharmacies in the context of 340B [as an indication] that Congress did not intend to preempt the field." *Id.* at 1144.

We find the reasoning in *McClain* persuasive. While the compliance mechanisms in section 340B are comprehensive, section 62J.96 does not intrude on them. Section 340B does not address disputes between manufacturers and pharmacies, and pharmacies are not covered entities. Section 340B does not address delivery to pharmacies at all. We cannot say this logically leads to the conclusion that Congress intended to occupy the entire field, especially when section 340B is silent on the subject of pharmacies.

Although the statutory scheme of the 340B program, including compliance mechanisms, penalties for noncompliance or abuse by manufacturers and covered entities, and the HHS dispute-resolution provision are comprehensive, they do not demonstrate such a pervasive nature that Congress had as its "clear and manifest purpose" to supersede the historic police powers of the states, including Minnesota. We therefore conclude that section 62J.96 is not field preempted by federal law.

Because section 62J.96 is not preempted by federal law, the district court did not err in granting the state's motion to dismiss PhRMA's claim based on preemption.

C. PhRMA has failed to plead a viable dormant Commerce Clause claim.

PhRMA alleges it has sufficiently pleaded a claim under what is known as the "extraterritoriality doctrine" of the dormant Commerce Clause of the United States Constitution because section 62J.96 seeks to operate wholly outside the state of Minnesota.

We first explain dormant Commerce Clause jurisprudence and then address each of PhRMA's specific allegations of how section 62J.96 violates the clause.

The Commerce Clause states that Congress may "regulate Commerce . . . among the several States." U.S. Const. art. I, § 8. The Supreme Court has long understood that this affirmative grant of authority includes a "negative or dormant implication." *Gen. Motors Corp. v. Tracy*, 519 U.S. 278, 287 (1997).

While most dormant Commerce Clause jurisprudence focuses on whether the challenged law discriminates against out-of-state interests or excessively burdens interstate commerce, PhRMA makes a less-common argument under the extraterritoriality doctrine. *See Swanson v. Integrity Advance, LLC*, 870 N.W.2d 90, 94 (Minn. 2015) (referring to the extraterritoriality doctrine as "[a]n additional, related limitation on state regulation of commerce"); *In re Licensure of Griepentrog*, 888 N.W.2d 478, 494, 495 (Minn. App. 2016) (describing the extraterritoriality doctrine's limited use in "rare cases" and observing that, in analyzing these cases, courts employ a different test).

The extraterritoriality doctrine provides that states may not enact laws that control commercial activity occurring wholly outside the boundary of a state. *See Healy v. Beer Inst.*, 491 U.S. 324, 337 (1989) (holding that a state statute was unlawful when it had the "undeniable effect of controlling commercial activity occurring wholly outside the boundary of the State"); *see also Brown-Forman Distillers Corp. v. N.Y. State Liquor Auth.*, 476 U.S. 573, 581-82 (1986) (citing *Healy* and determining the dormant Commerce Clause was violated when a state statute required distillers to ensure their in-state prices were no higher than their out-of-state prices). The focus is whether "the practical effect of

the regulation is to control conduct beyond the boundaries of the State." *Healy*, 491 U.S. at 336. To determine a statute's "practical effect," we must consider not only the effects of the challenged statute itself, but also how it "may interact with the legitimate regulatory regimes of other States and what effect would arise if not one, but many or every, State adopted similar legislation." *Id.*; *see also Swanson*, 870 N.W.2d at 94 (describing and employing this test).

"The extraterritoriality doctrine applies only when its narrow parameters are met; when a law, typically price regulation, controls commerce totally outside its borders."[9] *Griepentrog*, 888 N.W.2d at 495 (recognizing that the Supreme Court has relied upon the doctrine only in the context of price-control laws); *see also Baldwin v. G.A.F. Seelig, Inc.*, 294 U.S. 511, 521-22 (1935) (striking down act prohibiting dealer from selling, in the state, milk produced out of the state, at less than minimum price fixed for similar milk produced within the state).

PhRMA makes two main allegations under this doctrine. The first is that section 62J.96 governs transactions between out-of-state manufacturers and out-of-state pharmacies. PhRMA admits that, if section 62J.96 does not require manufacturers to provide 340B-priced drugs to contract pharmacies located outside of Minnesota, it does

[9] If a case does not fit into those narrow confines, the traditional Commerce Clause analysis is appropriate. *Swanson*, 870 N.W.2d at 94. But PhRMA does not argue that the traditional analysis—involving *Pike v. Bruce Church, Inc.*—applies. 397 U.S. 137, 142 (1970). Thus, our analysis rests solely on the extraterritoriality doctrine.

not implicate the dormant Commerce Clause in this manner. At oral argument, the state agreed that section 62J.96 does not apply to delivery to pharmacies in other states.[10]

PhRMA's second allegation is that section 62J.96 governs transactions between out-of-state manufacturers and out-of-state distributors. Prior to the Supreme Court's May 2023 decision in *National Pork Producers Council v. Ross*, 598 U.S. 356, some federal appellate courts considered that laws that had the practical effect of controlling commerce outside the state were almost per se invalid. *See, e.g.*, *North Dakota v. Heydinger*, 825 F.3d 912, 919 (8th Cir. 2016); *Int'l Dairy Foods Ass'n v. Boggs*, 622 F.3d 628, 645 (6th Cir. 2010); *All. of Auto. Mfrs. v. Gwadosky*, 430 F.3d 30, 35 (1st Cir. 2005). In *Pork Producers*, the Supreme Court expressly rejected an almost-per-se rule. 598 U.S. at 374-75. The Supreme Court stated that it "has already described '[t]he rule that was applied in *Baldwin* and *Healy*' as addressing 'price control or price affirmation statutes' that tied 'the price of . . . in-state products to out-of-state prices.'" *Id.* at 374 (quoting *Pharm. Rsch. & Mfrs. of Am. v. Walsh*, 538 U.S. 644, 669 (2003)). The challenged statutes in those cases "had a *specific* impermissible extraterritorial effect—they deliberately prevent[ed out-of-state firms] from undertaking competitive pricing or deprive[d] businesses and consumers in

[10] The state contends that PhRMA's entire dormant Commerce Clause argument fails due to PhRMA's concession on its first issue because PhRMA makes a "facial challenge" and, therefore, it was required to show that section 62J.96 is unconstitutional in all applications. The state did not argue to the district court that PhRMA's arguments fail as a facial challenge, and we decline to address that contention here. *See Thiele v. Stich*, 425 N.W.2d 580, 582 (Minn. 1988) (stating that appellate courts generally address only those questions previously presented to and considered by the district court).

other States of whatever competitive advantages they may possess." *Id.* (quotations omitted).

PhRMA primarily relies on *Association for Accessible Medicines v. Ellison*. 140 F.4th 957 (8th Cir. 2025). *Accessible Medicines* determined that *Pork Producers* preserved 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.'" *Id.* at 960 (quoting *Pork Producers*, 598 U.S. at 374). It further stated 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." *Id.* (quotations omitted). Accordingly, the Eighth Circuit rejected the state's argument that *Pork Producers* created a presumption against dormant Commerce Clause challenges when a law does not discriminate. *Id.* at 961.

We find the Eighth's Circuit's reasoning persuasive because, in Minnesota, before the decision in *Pork Producers*, the extraterritoriality doctrine was understood as not strictly requiring discrimination. *See Swanson*, 870 N.W.2d at 94 (referring to extraterritoriality as "[a]n additional, related limitation" where the party does not argue that a law is discriminatory or that it excessively burdens interstate commerce); *Griepentrog*, 888 N.W.2d at 494 (explaining extraterritoriality as a "discrete subset" of cases without reference to discrimination).

Accessible Medicines determined that a Minnesota law violated the extraterritoriality doctrine when it prohibited 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." 140 F.4th at 959; *see* Minn. Stat. § 62J.842, subd. 1 (2024). On this point, *Accessible Medicines* is distinguishable. *Accessible Medicines* addressed a law that directly controlled the price of any generic or off-patent drug sold to any consumer in the state. Section 62J.96 has no such mandate and does not address price at all. The price of the drugs and the consumers eligible to receive the 340B drugs are still controlled by federal law under section 340B.[11]

Section 62J.96 does not control the price of manufacturer-to-distributor sales occurring outside of Minnesota. Federal law under section 340B controls the price of manufacturer sales both in and outside of Minnesota. Section 62J.96 merely prevents a manufacturer from interfering with the delivery of drugs at the 340B price to Minnesota contract pharmacies. Accordingly, the district court did not err in dismissing PhRMA's dormant Commerce Clause claim.

Because no facts that could be introduced consistent with the pleading would support granting the relief demanded, we conclude that PhRMA's complaint did not set forth a legally sufficient claim for relief as to any of its three claims. Thus, the district court did not err in dismissing PhRMA's claims.

Affirmed.

[11] The effect of the extraterritoriality doctrine on 340B state "delivery" laws has not yet been addressed by federal courts of appeals.