IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF NORTH DAKOTA

AbbVie Inc. et al. Plaintiffs, vs. Drew Wrigley, in his official capacity as the Attorney General of North Dakota, et al., Defendants.	Case No. 1:25-cv-00081
AstraZeneca Pharmaceuticals LP, Consolidated Plaintiff, vs. Drew Wrigley, in his official capacity as the Attorney General of North Dakota, et al., Defendants.	Case No. 1:25-cv-00182
Pharmaceutical Research and Manufacturers of America, Consolidated Plaintiff, vs. Drew Wrigley, in his official capacity as the Attorney General of North Dakota, et al., Defendants.	Case No. 1:25-cv-00204

ORDER ON MOTIONS

[¶ 1] THIS MATTER comes before the Court upon multiple Motions and Cross-motions for Summary Judgment and a Motion for Judgment on the Pleadings. AbbVie Inc. and co-Plaintiffs ("AbbVie")[1] and Pharmaceutical Research and Manufacturers of America ("PhRMA") filed for Summary Judgment in their respective cases on October 15, 2025. Doc. No. 28; Case 204, Doc. No. 15.[2] The Defendants[3] ("North Dakota") filed a combined Response to both Motions and a Cross-motion for Summary Judgment in both cases on November 17, 2025. Doc. No. 31; Case 204, Doc. No. 21. AbbVie and PhRMA filed Replies and Cross-motion Responses on December 17, 2025. Doc. Nos. 48–49; Case 204, Docs. No. 38–39. North Dakota filed Cross-motion Replies on January 20, 2026. Doc. No. 52; Case 204, Doc. No. 42. North Dakota filed a Motion for Judgment on the Pleadings in the case with AstraZeneca Pharmaceuticals LP ("AstraZeneca") on November 17, 2025. Case 182, Doc. No. 30. AstraZeneca filed a Response on December 23, 2025. Case 182, Doc. No. 47. North Dakota filed a Reply on January 20, 2026. Case 182, Doc. No. 52.[4]

[1] Co-Plaintiffs include Allergan, Inc.; Durata Therapeutics, Inc; AbbVie Products LLC; Pharmacyclics LLC; and Allergan Sales, LLC.

[2] Docket numbers without further attribution refer to the lead case AbbVie v. Wrigley, Case No. 1:25-cv-00081. Abbreviated case numbers will accompany docket numbers for the consolidated cases. "Case 182" will refer to AstraZeneca v. Wrigley, Case. No. 1:25-cv-00182. "Case 204" will refer to PhRMA v. Wrigley, Case No. 1:25-cv-00204.

[3] Defendants include Drew Wrigley, in his official capacity as Attorney General of North Dakota; Tanya Schmidt, in her official capacity as Board President of the N.D. Board of Pharmacy; Carolyn Bodell, Tyler Lannoye, Shane Wendell, Kevin Oberlander, Diane Halvorson, and Ron Horner, in their official capacities as Members of the N.D. Board of Pharmacy; and Mark Hardy, in his official capacity as Executive Director of the N.D. Board of Pharmacy.

[4] On December 29, 2025, the Court ordered all parties to show cause why the cases should not be consolidated. Doc. No. 50; Case 182, Doc. No. 46; Case 204, Doc. No. 40. All parties responded and the cases were consolidated on January 28, 2026. Doc. Nos. 51, 53–54; Case 182, Doc. Nos. 49–50, 55; Case 204, Doc. Nos. 41, 43–44.

A group of interested parties filed amicus briefs in each case. Doc. No. 47; Case 182, Doc. No. 44; Case 204, Doc. No. 37.[5] A hearing on the motions was held on March 27, 2026. Doc. No. 78.

[¶ 2] For the reasons set forth below, AbbVie's Motion for Summary Judgment is **GRANTED, in part, and found as MOOT, in part**. North Dakota's Cross-motion for Summary Judgment is **DENIED, in part, and found as MOOT, in part**. PhRMA's Motion for Summary Judgment is **GRANTED, in part, and DENIED, in part**. North Dakota's Cross-motion for Summary Judgment is **GRANTED, in part, and DENIED, in part**. North Dakota's Motion for Judgment on the Pleadings is **DENIED**.

INTRODUCTION

[¶ 3] Striking the balance between where federal authority ends and state authority begins is not always easy. Characterization of state law can cut to the core of federalism. H.B. 1473 and similar laws throughout the country purport to protect the underdogs, namely, facilities struggling to serve at-risk populations. The states defending these laws say those populations are the ones hurt when pharmaceutical companies put certain restrictions on delivery under the 340B program. However, a program meant to help American poor is being abused to provide a windfall to hospital conglomerates and participating pharmacies. North Dakota's law attempts to facilitate and sanction the graft by interfering with an area of federal law.

[¶ 4] The focus is not on the wording of the statute, which seemingly only prohibits interference with third-party contracts with pharmacies. The law wields the word "pharmacy" in an attempt to transform the issue from one of federal regulation of participants in a federal program into state regulation of the field of pharmacy. Arkansas was the first to pass a state law regulating 340B

[5] Amici parties include N.D. Hospital Association, American Society of Health System Pharmacists, 340B Health, and American Hospital Association.

manufacturers. However, Arkansas defined its law as only concerning delivery. When the case appeared before the Eighth Circuit, the state argued the law would only be enforced as to delivery. The Eighth Circuit dutifully deemed Arkansas's law as a delivery law.

[¶ 5] North Dakota would have this Court deem its law a delivery law too. But North Dakota did not define its law as a delivery law. And North Dakota does not argue it only pertains to delivery, instead arguing it directly alters manufacturer conditions.

[¶ 6] Here is what is really going on: a coordinated collusion between the state's covered entities and contract pharmacies to exploit Congress's inattention to a federal program. As a result, pharmacies and third-party administrators pocket billions of dollars each year. This scheme works because no one considers manufacturers as victims. Big pharma garners little sympathy. Manufacturers have money, medication prices are rapidly rising, and they love to litigate. These things may be true, but they do not mean manufacturers should be fleeced by enterprising states and hospital conglomerates that wield power in legislative lobbies.

[¶ 7] These laws also inhibit the 340B program as a whole. Already Bausch, a major manufacturer, has removed itself from participating in the 340B program because of these statutes. Bausch's medications are, therefore, not available for Medicaid and Medicare coverage. Ultimately, it is the patients who suffer as a result. Patients now must pay out-of-pocket prices that are far greater than their insurance copays. Oddly enough, because of the statute's artful crafting, patients don't have standing, insurance companies don't have standing, even pharmacies don't have standing. The only entities regulated by the statute are manufacturers that participate in a federal program. A program that allows conditions on offers.

[¶ 8] Sometimes discerning the line between a state's power and the federal government's can feel more like divination than legal reasoning. The line was different five years ago in Arkansas.

This time, under these facts with this North Dakota law, the situation is simple. The law does not promote or regulate the health and safety of its citizens; it only concerns the balance sheet of in-state entities. The 340B drug pricing program was meant to help the needy who require medication to live. H.B. 1473 benefits hospital conglomerates, and Joe Paycheck sees no difference in the price of his meds. H.B. 1473 is an infringement on federal programs masquerading as state governance.

BACKGROUND

I. 340B Program Evolution

[¶ 9] In 1990, Congress created the Medicaid Drug Rebate Program to help Medicaid clients with the cost of their prescriptions. Nicholas C. Fisher, The 340B Program: A Federal Program in Desperate Need of Revision After Two-and-a-Half Decades of Uncertainty, 22 J. Health Care L. & Pol'y 25, 28–30 (2019). Before the program, manufacturers offered discounts voluntarily. Id. After the program, the voluntary discounts resulted in larger rebates to Medicaid, so the discounts stopped and drug prices rose, the opposite of what Congress intended. See id.

[¶ 10] In 1992, the 340B Drug Pricing Program was the solution. See id.; see also 42 U.S.C. § 256b. To participate in Medicare and Medicaid, drug manufacturers must "offer" certain drugs at a discounted price to qualified health-care providers, called "covered entities." See 42 U.S.C. § 256b. These covered entities generally provide care to underserved populations. See Fisher, at 32–33. Eligibility for covered entities is prescribed by statute, as is the price of these so-called 340B drugs. Id.; see also 42 U.S.C. § 256b. In some cases, the discount is so steep hospitals pay "a penny per unit." Novartis Pharms. Corp. v. Johnson, 102 F.4th 452, 456 (D.C. Cir. 2024). AstraZeneca's Farxiga, for example, sells for "hundreds of dollars" commercially but "less than a dollar" with the 340B discount. Case 182, Doc. No. 11, ¶ 51.

[¶ 11] Congressional intent was for covered entities "to stretch scarce Federal resources as far as possible, reaching more eligible patients and providing more comprehensive services." Fisher, at 30 (quoting H.R. Rep. No. 102-384, pt. 2, at 12 (1992)). A hospital is reimbursed by insurance (either private or Medicare/Medicaid) at the full prescription price, and since these drugs were bought at a lower price, they pocket the difference. Id. at 26–27. There is no statutory requirement for how the covered entities use the 340B revenue. See 42 U.S.C. § 256b.

[¶ 12] Manufacturers join the 340B program (and are therefore eligible for Medicare and Medicaid reimbursement) by contracting with the Department of Health and Human Services ("HHS") through a form contract called a Pharmaceutical Pricing Agreement. Astra USA, Inc. v. Santa Clara Cnty., 563 U.S. 110, 113 (2011). Manufacturers are subject to penalties for overcharging covered entities, and covered entities may not resell prescriptions (known as diversion) or receive duplicate discounting by receiving the 340B discount and getting reimbursed through other government programs like Medicaid. 42 U.S.C. § 256b.

[¶ 13] The Health Resources and Services Administration ("HRSA") oversees the 340B program under the authority of the HHS Secretary; however, neither the Secretary nor HRSA have rulemaking authority. Novartis, 102 F.4th at 456. Instead, HRSA issues "guidance documents interpreting and implementing the scheme." Id.

II. Introduction of Contract Pharmacies

[¶ 14] In 1994, HRSA guidance allowed covered entities to use "purchasing agent[s].". Novartis, 102 F.4th at 456. The covered entities would buy the medications, but the stock would be shipped to agents first before going to the covered entity's in-house pharmacy for distribution to patients. Id.

[¶ 15] In 1996, HRSA guidance stated the statute "is silent as to permissible drug distribution systems" and allowed covered entities without an in-house pharmacy to contract with one outside pharmacy. Id. at 456–57. HRSA was clear the covered entities should retain title to the medication and maintain liability for diversion or duplicate discounting. Id. at 457.

[¶ 16] In 2010, HRSA expanded this provision and allowed covered entities to contract with an unlimited number of contract pharmacies. Id. At the same time, Congress expanded the categories of health-care providers that qualified as covered entities and allowed drugs dispensed in an outpatient setting (i.e., not a hospital) to participate in the program. See Patient Protection and Affordable Care Act, Pub. L. No. 111-148, tit. VII, § 7101(a), 124 Stat. 119, 821–22 (2010).[6]

[¶ 17] These changes greatly increased participation in the 340B program, though in a disproportionate way. Between 2010 and 2019, covered entities "increased from about 9,700 to 13,000" and contract pharmacy participation "increased from about 1,300 to 23,000." Novartis, 102 F.4th at 457. 340B purchases are estimated to have increased "from roughly $6.9 billion in 2012 to $24.3 billion by 2018." Id. (citing Adam J. Fein, Exclusive: 340B Program Purchases Reach $24.3 Billion—7%+ of the Pharma Market—as Hospitals' Charity Care Flatlines, Drug Channels (May 14, 2019)); see also Doc. No. 28-13 (same article). The same source estimated sales in 2024 alone to total $80 billion. Adam J. Fein, Drug Channels News Roundup, June 2025, Drug Channels (June 24, 2025).

III. Current System

[¶ 18] Covered entities obtain 340B-priced medication, generally, in one of two ways. Pharmacies (on behalf of a covered entity) order 340B-priced drugs, keep the stock separate in their inventory,

[6] The 340 Program only applies to outpatient medication; medication for inpatient services is not covered. Fisher, at 45.

and dispense the medication to patients who are identified as 340B eligible at the time the prescription is filled. Doc. No. 28-17, ¶ 23–27. This is nationally uncommon but is used by Family HealthCare in Fargo. Doc. No. 31-11, ¶ 6.

[¶ 19] More commonly, the pharmacies use a "replenishment model." Doc. No. 28-17, ¶¶ 24–26. Pharmacies fill prescriptions at full price (with no discount for those in need). Id. Covered entities contract with third-party administrators ("TPAs") to comb through the filled prescriptions and patient records to identify 340B-eligible prescriptions. Id. Once enough prescriptions are found, the pharmacy (on behalf of the covered entity) places an order for 340B-priced prescriptions to "replenish" the stock. Id. This new stock is placed in the general inventory to be dispensed at full price. Id. The pharmacies and TPAs take either a percentage of the revenue or a flat fee per script. Id.; see also Doc. No. 28-8, p. 3. To make the transaction look correct on paper, "the wholesaler credits the pharmacy for the commercial price; charges the 340B price to the covered entity; and then requests a refund from the manufacture for the difference." Case 182, Doc. No. 11, ¶ 36. This is sometimes called a chargeback. See Doc. No. 28-14, p. 8.

[¶ 20] HRSA Guidance approved of the replenishment model in 2015 if the covered entity remains in compliance with the program and only orders based on actual prior usage. 80 Fed. Reg. 52300, 52308, 52319. HRSA anticipated "a covered entity's frequent monitoring of compliance to identify purchasing errors . . . and communicating with the manufacturer." Id. at 52308. Errors are to be remedied within 30 days. Id. at 52305.

[¶ 21] Each year HRSA audits approximately 200 covered entities (out of an estimated 13,000). Doc. No. 31-7, ¶ 6. The audit includes selecting a random sample of dispensed medication and requiring the covered entity to provide records that show it was 340B eligible.

[¶ 22] Manufacturers may request an audit if they have "documentation which indicates there is reasonable cause" to suspect diversion or double discounting. The "reasonable cause" is if a reasonable person would suspect diversion or double discounting to be happening. 61 Fed. Reg. 65406, 65409 (Dec. 12, 1996). Documentation does not have to be in the form of claims data or solid proof but instead it may consist of drug orders with significant changes in quantity or complaints from patients or manufacturers. Id. at 65406. HRSA said in 2024 that the standard is "not overly burdensome," and they have not denied a single manufacturer request for an audit in the last five years. 89 Fed. Reg. 28643, 28646 (Apr. 19, 2024). HRSA expects more documentation to be produced during the audit process that may be used for future alternative dispute resolution proceedings. Id. at 28652. See also 42 U.S.C. §§ 256b(a)(5)(C), 256b(d)(3) (detailing the process). Covered entities also internally audit their pharmacies. Doc. Nos. 31-11, ¶ 11; 31-12, ¶ 9.

IV. Manufacturer Action and State Reply

[¶ 23] Since the text of 340B only requires manufacturers to "offer" the drugs for sale at a certain price, in 2020 manufacturers added conditions to those offers: they would require claims data for delivery and only deliver medications to one contract pharmacy, and only if the covered entity did not have an in-house pharmacy. Sanofi Aventis U.S. LLC v. HHS, 58 F.4th 696, 700–01 (3d Cir. 2023). HHS issued an advisory opinion telling the manufacturers to let the covered entities contract with whomever they wanted, that the law required delivery to anywhere the covered entity requests including "the lunar surface." Id. at 704 (quoting Contract Pharmacies Under the 340B Program, HHS Off. Gen. Couns, Advisory Opinion 20-06, 2–3 (Dec. 30, 2020)). A district court in Delaware held the advisory opinion was arbitrary because the statute is silent on delivery and therefore, manufacturers were allowed to add these conditions. Id. at 702. The opinion was withdrawn and HHS sent enforcement letters ordering the same outcome as the opinion. Id. The letters were

vacated in New Jersey, and the Third Circuit affirmed, holding 340B was silent on delivery and therefore does not require delivery to unlimited pharmacies. Id. at 704–05, 707. ("Legal duties do not spring from silence."). Manufacturer conditions do not violate the 340B program. Id. The D.C. Circuit came to the same conclusion and held the specific conditions of limiting contract pharmacies and requiring data were valid. Novartis, 104 F.4th at 455.

[¶ 24] Meanwhile, about half of the states decided to enter the conversation and enact state laws doing what federal courts said HHS could not. Litigation surrounding these statutes is still playing out all over the country. Arkansas was the first state to pass its statute, and the Eighth Circuit held that statute was not preempted by federal law because it regulated delivery and not price. PhRMA v. McClain, 95 F.4th 1136, 1145–46 (8th Cir. 2024). A denial of a preliminary injunction against Missouri's law is currently pending in the Eighth Circuit. Novartis Pharms. Corp. v. Hanaway, Case No. 25-1619 (8th Cir. argued Jan. 15, 2026).

V. North Dakota Passes H.B. 1473

[¶ 25] North Dakota's 340B law ("H.B. 1473") took effect August 1, 2025, and states:

> a. For purposes of this subsection:
> (1) "Contract pharmacy" means a pharmacy that has a contract with a covered entity to receive and dispense drugs to the covered entity's patients on its behalf.
> (2) "Covered entity" means an entity participating or authorized to participate in a federal drug discount program under 42 U.S.C. 256b.
> (3) "Drug" means a drug purchased under reduced pricing under section 340B of the federal Public Health Service Act [42 U.S.C. 201 et seq.] by a covered entity.
> b. Except as otherwise provided under section 43-15.3-09, it is a class B misdemeanor for a manufacturer, an agent or affiliate of that manufacturer, virtual manufacturer, or third-party logistics provider of a manufacturer's drugs, to:
> (1) Directly or indirectly deny, restrict, prohibit, or otherwise interfere with the acquisition of a drug by a contract pharmacy on behalf of a covered entity unless receipt of the drug is prohibited by federal law.
> (2) Prohibit a contract pharmacy from dispensing a drug by denying access to the drug.
> (3) Require a covered entity or contract pharmacy to submit any claims, encounter, or utilization data as a condition for acquiring or receiving a drug,

> unless the claims, encounter, or utilization data sharing is required by federal law.
> (4) Interfere with the ability of a covered entity or contract pharmacy to dispense a drug to an eligible patient of the covered entity.
> (5) Offer or otherwise make available a drug in the form of a rebate, unless in the form of a discount at the time of sale and authorized under federal law.

N.D.C.C. § 43-15.3-08(3).

[¶ 26] Unlike Arkansas's law, H.B. 1473 carries civil and criminal penalties. Class B misdemeanors have a "maximum penalty of thirty days' imprisonment, a fine of one thousand five hundred dollars, or both," id. § 12.1-32-01(6), and can be enforced by the Attorney General's general prosecutorial power. Id. §§ 54-12-01(2), 54-12-02 (power to institute actions in which the state is a party). The Board of Pharmacy also has power to revoke licenses and impose civil penalties. Id. § 43-15.3-09.

VI. Pilot Rebate Program

[¶ 27] HRSA announced a Pilot Rebate Program in August 2025, but it was preliminary enjoined in December 2025, then vacated and remanded to the agency in February 2026. Am. Hosp. Ass'n v. Kennedy, No. 2:25-cv-00600-LEW, 2026 WL 372131 (D. Me. Feb. 10, 2026). HRSA did not sufficiently consider reliance interests and costs. Id. at *1. HRSA already completed a new notice and comment period to remedy these errors, which closed March 19, 2026. 91 Fed. Reg. 7287 (Feb. 17, 2026).

[¶ 28] The rebate program (as it was laid out before) allowed claims data requirements and after-purchase rebates instead of pre-purchase discounts to help implement a new Medicare Drug Price Negotiation Program, which sets a "maximum fair price" for drugs that (1) are not eligible for 340B pricing or (2) if the 340B price is lower than the fair price. See 90 Fed. Reg. 36163, 36163–65 (Aug. 1, 2025); 42 U.S.C. §§ 1320f-2(d), 1320f-3(a). Manufacturers must indicate if a claim

qualifies for the fair price, which seems to indicate they must know what claims are eligible for the 340B program. CMS, Medicare Drug Price Negotiation Program: Draft Guidance 48 (2024).

VII. Procedural Posture

[¶ 29] AbbVie and North Dakota move for Summary Judgment on five counts: I – Takings Clause violation, II – conflict preemption with the 340B statute, III – conflict preemption with Pilot Rebate Program, IV – Due Process violation, and V – dormant Commerce Clause violation. Doc. Nos. 28, 31. PhRMA and North Dakota move for Summary Judgment on three counts: I – plain text interpretation, II – field preemption with 340B statute, and III – dormant Commerce Clause violation. Case 204, Doc. Nos. 15, 31. North Dakota moves for Judgment on the Pleadings on four counts: I – field preemption with patent law, II – conflict preemption with 340B statute, III – Contracts Clause violation, IV – Takings Clause violation. Case 182, Doc. No. 30. The Court will discuss the issues on summary judgment, then turn to the judgment on the pleadings.

SUMMARY JUDGMENT

I. Legal Standard

[¶ 30] Summary judgment is appropriate when the evidence, viewed in a light most favorable to the non-moving party, indicates no genuine issues of material fact exist and the moving party is entitled to judgment as a matter of law. See Davison v. City of Minneapolis, 490 F.3d 648, 654 (8th Cir. 2007); see also Fed. R. Civ. P. 56(a). Summary judgment is not appropriate if there are factual disputes that may affect the outcome of the case under applicable substantive law, such that the evidence would allow a reasonable jury to return a verdict for the non-moving party. Anderson v. Liberty Lobby, Inc., 477 U.S. 242, 248 (1986).

[¶ 31] The Court must inquire whether the evidence presents sufficient disagreement to require submission of the case to a factfinder or, alternatively, if the law demands one party must prevail.

Diesel Mach., Inc. v. B.R. Lee Indus., Inc., 418 F.3d 820, 832 (8th Cir. 2005). The moving party bears the burden of demonstrating there are no genuine issues of material fact. Forrest v. Kraft Foods, Inc., 285 F.3d 688, 691 (8th Cir. 2002). The non-moving party may not merely allege factual disputes exist or otherwise deny the movant's assertions, instead, it must specify which facts create a genuine issue for trial. Id.

II. Standing

[¶ 32] While no parties contest standing in this case,[7] it has been an issue elsewhere. See AbbVie v. Bailey, Case No. 4:24-cv-00996-SRC, 2025 WL 1918948 (E.D. Mo. July 11, 2025). Standing requires an injury, causation, and redressability. Minn. Ch. Associated Builders & Contractors, Inc. v. Blissenbach, 155 F.4th 1015, 1020 (8th Cir. 2025). A future injury must be "certainly impending" or have a "substantial risk" of occurring. Id. (quoting Susan B. Anthony List v. Driehaus, 573 U.S. 149, 158 (2014)). Generally, if a state statute is challenged, injury can come from the law prohibiting conduct and lack of disavowal of enforcement. Id. The law at issue in Builders & Contractors carried civil and criminal penalties, as does H.B. 1473. "Because the Contractors allege specific conduct that the Act targets, and because state officials have not disavowed enforcing it, the Contractors have standing." Id. All plaintiffs allege conduct targeted by North Dakota's law. State officials have not disavowed enforcing it. Therefore, all parties have standing.

[7] On March 10, 2026, the Court ordered supplemental briefing on the issues of standing and North Dakota-specific evidence from the record; those briefs were filed on March 23, 2026. Doc. Nos. 66, 70–75. Various notices, supplemental authority, and responses were filed in March 2026. Doc. Nos. 65, 67–69, 76.

III. Plain Text Interpretation

[¶ 33] PhRMA asks for declaratory judgment in Count I of its Complaint that the plain text meaning of the North Dakota law does not restrict the contract pharmacy policies, since "drug" is defined in the statute as "a drug purchased under reduced pricing . . . by a covered entity," N.D.C.C. § 43-15.3-08(3)(a)(3), the law is regulating items post-purchase, not the manufacturers' pre-purchase offers to the covered entities. Case 204, Doc. 1-1, ¶ 155. North Dakota argues the intended construction "defines a temporally continuous category" including a drug that "is purchased or is to be purchased" or is available for purchase at those prices. Doc. No. 31-1, p. 54.

[¶ 34] The Court uses North Dakota's rules of interpretation when reviewing North Dakota law. Roubideaux v. N.D. Dep't of Corr. & Rehab., 570 F.3d 966, 972 (8th Cir. 2009). While the "primary goal in statutory construction is to ascertain the intent of the legislature," the Court must "first look to the plain language of the statute and give each word of the statute its ordinary meaning." State v. Fasteen, 2007 ND 162, ¶ 8, 740 N.W.2d 60. When alternative definitions are given, the words "are to be understood as thus explained." N.D.C.C. § 1-02-02. "When the wording of a statute is clear and free of all ambiguity, the letter of it is not to be disregarded under the pretext of pursuing its spirit." Id. § 1-02-05. If "the strict letter of the statute would lead to an absurd or ludicrous result, a court may resort to extrinsic aids, such as legislative history, to interpret the statute." Fasteen, 2007 ND, ¶ 8. A statute is ambiguous if multiple meanings can be understood rationally. Id.

[¶ 35] On its face, H.B. 1473's statutory definition of "drugs" unambiguously refers to those purchased (past tense) under the pricing scheme. North Dakota argues a "manufacturer's drugs" are mentioned in the statute, and if the law only referred to post-sale, then the drugs wouldn't be the manufacturer's anymore. But that language is used as an adjective describing an entity's role,

namely a "third-party logistics provider of a manufacturer's drugs," not the drugs themselves. N.D.C.C. § 43-15.3-08(3)(b).

[¶ 36] North Dakota also argues the law references distribution requirements under 21 U.S.C. § 355-1, which only applies to manufacturers, not purchasers of the medication. However, distribution is always done after a sale. Therefore, if anything, reference to distribution standards is evidence the law contemplates actions after a sale is complete.

[¶ 37] Finally, North Dakota argues the plain text interpretation would subvert the intent of the legislature. But, if the text is plain and clear, that is where the Court's interpretation stops. See Fasteen, 2007 ND, ¶ 8. "To be purchased" is in the text, nor is any other indication the law refers to medications pre-sale. Further, if the statute really regulates delivery instead of price, then it would inevitably only deal with medications post-purchase. Therefore, the Court finds the statute only applies to medications purchased under the 340B scheme, not those "to be purchased."

[¶ 38] However, this plain text interpretation does not resolve the case as PhRMA argues. North Dakota covered entities may have signed contracts with manufacturers agreeing to conditions on delivery, but that does not mean those conditions are legal in North Dakota. Just like non-compete clauses are prohibited within North Dakota, this law could invalidate the conditions on delivery. See N.D.C.C. § 9-08-01 ("Any provision of a contract is unlawful if it is: 1. Contrary to an express provision of law . . . ."); E. Cent. Water Dist. v. City of Grand Forks, 2024 ND 135, ¶ 17, 9 N.W.3d 705 ("An unlawful contract is generally void.").

[¶ 39] Even under a plain text interpretation of the statute, the state law prohibits manufacturer policies about conditions on offers to sell 340B medications. Therefore, Summary Judgment is **DENIED** as to Count I of PhRMA's Motion for Summary Judgment and **GRANTED** as to North Dakota's Cross-motion.

IV. Supremacy Clause and Preemption

[¶ 40] AbbVie and PhRMA each bring preemption arguments, arguing H.B. 1473 is either field or conflict/obstacle preempted by federal law. Doc. No. 1; Case 204, Doc. No. 1-1. North Dakota argues McClain either forecloses these arguments explicitly, or the reasoning holds true, and the arguments still fail. Doc. No. 52, pp. 15–16. AbbVie argues McClain does not control because the statutes are materially different. Doc. No. 29, p. 28. PhRMA argues McClain did not address the arguments presented in this case. Case 204, Doc. No. 16, p. 42.

[¶ 41] The Supremacy Clause states federal law supersedes contrary state law. U.S. Const. art. VI, cl. 2. Congress can preempt state law in three ways: (1) explicitly through legislation or implicitly by either (2) occupying the field or (3) setting up a conflict between the two laws. McClain, 95 F.4th at 1140. Field preemption occurs either when a regulation's framework is "so pervasive . . . that Congress left no room for the States to supplement it" or a dominant federal interest. Id. at 1143 (quoting Arizona v. United States, 567 U.S. 387, 399 (2012)).

a. PhRMA v. McClain

[¶ 42] In McClain, PhRMA challenged Arkansas's law under field and obstacle preemption with the 340B statute and impossibility preemption with the Risk Evaluation and Mitigation Strategies Program ("REMS"). See 95 F.4th at 1146. Arkansas's 340B statute states:

> A pharmaceutical manufacturer shall not:
> (1) Prohibit a pharmacy from contracting or participating with an entity authorized to participate in 340B drug pricing by denying access to drugs that are manufactured by the pharmaceutical manufacturer; or
> (2) Deny or prohibit 340B drug pricing for an Arkansas-based community pharmacy that receives drugs purchased under a 340B drug pricing contract pharmacy arrangement with an entity authorized to participate in 340B drug pricing.

Ark. Code Ann. § 23-92-604(c) (2024). "340B drug pricing" is defined as "the program established under section 602 of the Veteran Health Care Act of 1992," meaning the 340B program. Id. § 23-

92-602. The Arkansas Insurance Department promulgated a rule further defining "340B drug pricing" as "**the acquisition and delivery** of 340B-priced drugs." 23-152-101 Ark. Code. R. § (1) (2024) (23 CAR § 152-101(1)) (emphasis added).

[¶ 43] McClain held the law was not field preempted by the 340B statute because the federal statute was silent as to delivery. 95 F.4th at 1143. Arkansas's law explicitly governed delivery, which fell under the traditionally state-regulated area of pharmacy. Id. The court found no obstacle preemption because the enforcement mechanisms covered different areas: one concerned offers to covered entities and the other concerned delivery of medication to pharmacies. Id. at 1144. Further, there was no impossibility preemption because manufacturers gave no evidence they couldn't comply with 340B and the state law and the REMS program. Id. at 1145.

[¶ 44] The Court finds the Arkansas law is materially distinguishable from the North Dakota law. Even though the language is similar, the two laws have been interpreted by their states very differently. Arkansas formally defined its law only to apply to medication delivery and indicated it would only be enforced as to delivery. In the briefing of McClain, the State averred "the final rule, as ultimately promulgated, resulted in limiting the application of the Act to the **acquisition and delivery** of 340B drugs," "Act 1103 is indubitably an **acquisition and delivery** statute," "Arkansas is only governing the **physical delivery** of the drugs," Brief for Alan McClain at 26–27, 36, PhRMA v. McClain, 95 F.4th 1136 (8th Cir. 2024) (No. 22-3675) (emphasis added). The state also argued that the state-level penalties only applied to "*delivery* of the drugs to the pharmacy." Id. at 39.

[¶ 45] In contrast, North Dakota has not promulgated any rules further defining statutory language. At times in its briefing, the State described the law as a delivery law similar to other

states, but it also argued "H.B. 1473[] can only plausibly refer to pre-sale conditions imposed on distribution of drugs *available to be purchased* at 340B program prices." Doc. No. 31-1, p. 54.

[¶ 46] North Dakota argues H.B.1473 protects the contracts between covered entities and pharmacies, like in McClain. Doc. 31-1, p. 43. However, if that were the case, the manufacturers' contracts with covered entities would not be at issue. Manufacturers, by federal law, are allowed to put conditions on their offers. See Sanofi, 58 F.4th at 702. As this Court has held, the North Dakota law applies post-purchase to sales already completed. At that point, the covered entity has agreed to the delivery conditions placed on them by the manufacturers, otherwise the sale would not have been completed. H.B. 1473 kicks in only if those conditions include requirements for claims data and delivery to one pharmacy. The law makes illegal in the state of North Dakota the delivery condition in the contract between the manufacturer and the covered entity.

[¶ 47] Nothing about this situation affects the contracts between covered entities and pharmacies. The covered entities may still send medications to any facility they choose. It is only when covered entities want to contract with a specific manufacturer for **specific pricing** that the calculus changes. North Dakota's H.B. 1473 is not a delivery statute; it regulates manufacturers, not pharmacies.

[¶ 48] Additionally, even if McClain was not distinguishable based on statutory language, the case did not address field preemption regarding Congress's spending power. Therefore, the Court finds McClain is not controlling in the present case.

b. Field Preemption

[¶ 49] PhRMA argues H.B. 1473 impermissibly adds conditions to a program enacted under Congress's spending power, and therefore, is field preempted. Doc. No. 16, pp. 25–26. North Dakota argues the field of pharmacy is not a unique federal interest, therefore, there is a presumption of no preemption; and additionally, the State argues doctrines like intergovernmental

immunity do not apply because manufacturers are not acting on behalf of the federal government. Doc. No. 52, pp. 15–16.[8]

i. Presumption

[¶ 50] A "presumption [exists] that state or local regulation of matters related to health and safety is not invalidated under the Supremacy Clause." Id. (quoting Hillsborough Cnty. v. Automated Med. Lab'ys, Inc., 471 U.S. 707, 715 (1985)). No presumption exists in matters of uniquely federal interests, such as obligations and rights of the United States in its contracts. Boyle v. United Techs. Corp., 487 U.S. 500, 504 (1988); see also United States v. Locke, 529 U.S. 89, 108 (2000) ("An assumption of nonpre-emption is not triggered when the State regulates in an area where there has been a history of significant federal presence." (citation modified)).

[¶ 51] The Court finds the presumption against preemption does not apply to H.B. 1473. As stated above, the Court interprets the law to regulate 340B manufacturers and not the field of pharmacy. The 340B program is an area with "a history of significant federal presence." Locke, 529 U.S. at 108. As AbbVie points out, "H.B. 1473 cannot operate without federal law: if Congress repealed the 340B statute tomorrow, H.B. 1473 would regulate nothing." Doc. No. 48, p. 4 (citing Buckman Co. v. Plaintiffs' Legal Comm., 531 U.S. 341, 347 (2001)). Without "significant federal presence," the law would be dead on arrival.

[8] North Dakota argues intergovernmental immunity was not properly pled in PhRMA's Complaint. Doc. No. 68. New claims should not be raised in passing in an opposition brief at the Summary Judgment stage. InfoDeli, LLC v. W. Robidoux, Inc., 136 F.4th 792, 801 n.6 (8th Cir. 2025). In this case, the issue of intergovernmental immunity is discussed in relation to the claimed issue of preemption under Congress's spending powers and not as an independent issue. See Case 204, Doc. Nos. 1-1, ¶¶ 169–75; 16, pp. 8–9, 26–27. Therefore, the Court finds North Dakota had fair notice of Spending Clause preemption, and the issue was sufficiently pled for consideration.

ii. Spending power

[¶ 52] Legislation enacted under Congress's spending power has long been analogized to a contract: Congress gives federal funds and entities agree with federally imposed conditions. Mo. Child Care Ass'n v. Cross, 294 F.3d 1034, 1041 (8th Cir. 2002). In these programs, "the key is not what a majority of the Members of both Houses intend but what the [participants in the program] are clearly told." Medina v. Planned Parenthood S. Atlantic, 606 U.S. 357, 381 (2025) (citation modified). The guiding idea is the federal government may induce action, not coerce it. Nat'l Fed. of Indep. Bus. v. Sebelius, 567 U.S. 519, 537 (2012) (plurality opinion). The typical remedy for violations of the federal program is directly tied to the spending power, namely the cutting off of federal funding. Planned Parenthood S. Atlantic, 606 U.S. at 384.

[¶ 53] The Court finds H.B. 1473 is field preempted by the 340B statute. State laws like North Dakota's inhibit the ability of the government to exercise its spending power by deterring manufacturers from participating in the program. Doc. Nos. 28-18, ¶ 32; 70-1, ¶ 2 (both noting Bausch Health withdrew from the 340B program in October 2025). This inhibition is especially strong when North Dakota, unlike other states, adds criminal penalties and makes violations a class B misdemeanor. N.D.C.C. §§ 43-15.3-08, 12.1-32-01(6). Manufacturers are forced to decide between violation of a state law or participation in a federal program with additional costs, which amount to the millions. AbbVie estimates North Dakota's change to its participation in the 340B program cost the company $10 million in 2025 and will cost another $35 million in 2026 in discounted sales it would not make but for the law. Doc. No. 75, ¶ 9. This added cost and interference constitutes an impermissible insertion into a federal program that Congress did not invite.

iii. Intergovernmental immunity

[¶ 54] The intergovernmental immunity doctrine says that state laws may not "regulate the United States directly or discriminate against the Federal Government or those with whom it deals." United States v. Washington, 596 U.S. 832, 838 (2022) (quoting North Dakota v. United States, 495 U.S. 423, 435 (1990) (plurality opinion)) (citation modified). "[A] state law discriminates . . . if it singles them out for less favorable treatment or if it regulates them unfavorably on some basis related to their governmental status." Id. (citations omitted).

[¶ 55] While the doctrine does not apply here because the manufacturers are not agents of the federal government, the Court finds persuasive the reasoning in PhRMA v. McCuskey from the Fourth Circuit. 171 F.4th 675, 688 (4th Cir. 2026).[9] "Even when the intergovernmental-immunity doctrine doesn't directly apply, a state law may still implicate the preemption doctrine, which provides that federal interests edge out state interests when federal and state law 'clash.'" Id.

[¶ 56] McCuskey considered a law from West Virginia that prohibits interference with delivery or acquisition of 340B drugs, which are defined as medications bought through the 340B program. Id. at 687. Even though the West Virginia law explicitly mentions delivery, which North Dakota's law does not, the Fourth Circuit still found it was "anything but a traditional health-and-safety regulation." Id. at 689. The West Virginia law does not target pharmacies, but "injects the State into 'the relationship between a federal agency and the entity it regulates,' which is 'inherently federal in character because the relationship originates from, is governed by, and terminates according to federal law.'" Id. (quoting Buckman, 531 U.S. at 347).

[9] Unlike the dissent's argument in McCuskey, Congress's spending power has been squarely argued in the present case. See Case 204, Doc. Nos. 1-1, ¶¶ 169–75.

[¶ 57] The 340B program does not invite supplementation through a collaborative framework of cooperative federalism. See McCuskey, 2026 WL 898259, at 7. The program has existed for thirty years with only federal regulation. The statute was silent as to pharmacies, which have been historically regulated by states. McClain, 95 F.4th at 1143. For laws like Arkansas's that regulate delivery, that silence is meaningful. However, North Dakota's law regulates manufacturer participation in the 340B program, not pharmacies.

[¶ 58] The deal between Congress and manufacturers, even if it is not a traditional bargained-for contract, has terms: participate in 340B by offering your drugs at a lower price and your company can participate in Medicare and Medicaid. North Dakota's law, as much as it avers otherwise, changes those terms. The law requires **only** 340B program participants to change their contracts with covered entities to what **the state** deems acceptable. See Sanofi, 58 F.4th at 702 (finding manufacturers can add conditions under federal law).

iv. Conclusion

[¶ 59] The offer a 340B manufacturer makes to a 340B covered entity is governed by the 340B program and Congress. States have no part in that relationship. H.B. 1473 is not defined as a law regulating delivery. North Dakota argues it applies to offers. Therefore, the Court finds H.B. 1473 is field preempted by 340B as legislation enacted under Congress's spending power and **GRANTS** PhRMA's Motion for Summary Judgment as to Count II and **DENIES** North Dakota's Cross-motion on Count II.

[¶ 60] This finding alone renders the law invalid and the remaining counts moot. However, even if the law is not preempted, the Commerce Clause independently bars the law's application.

V. Commerce Clause

[¶ 61] AbbVie and PhRMA argue H.B. 1473 has an extraterritorial effect on interstate commerce and, therefore, violates the Commerce Clause. Doc. No. 29, p. 47; Case 204, Doc. No. 16, p. 44. North Dakota argues the law must be construed to preserve constitutionality and it has no intention of enforcing the regulation outside of North Dakota. Doc. No. 52, p. 30.

[¶ 62] The Commerce Clause includes "'a further, negative command,' one effectively forbidding the enforcement of 'certain state economic regulations even when Congress has failed to legislate on the subject.'" Nat'l Pork Producers Council v. Ross, 598 U.S. 356, 368 (2023) (quoting Okla. Tax Comm'n v. Jefferson Lines, Inc., 514 U.S. 175, 179 (1995)) (citation modified). A statute "violates the so-called dormant Commerce Clause by '(1) clearly discriminating against interstate commerce in favor of in-state commerce, (2) imposing a burden on interstate commerce that outweighs any benefits received, or (3) having the practical effect of extraterritorial control on interstate commerce.'" Ass'n for Accessible Meds. v. Ellison, 140 F.4th 957, 960 (8th Cir. 2025) (quoting Styczinski v. Arnold, 46 F.4th 907, 912 (8th Cir. 2022)) (citation modified).

[¶ 63] The Eighth Circuit has held "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. (quoting PhRMA v. Walsh, 538 U.S. 644, 669 (2003)) (citation modified). Association for Accessible Medicines held invalid a Minnesota law that prohibited manufacturers from "imposing, or causing 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." Id. at 959 (quoting Minn. Stat. § 62J.842 subd. 1) (citation modified). In that case, "a Colorado manufacturer would be penalized if it sold drugs to a New Jersey distributor at prices above those proscribed by the Act and those drugs ended up in Minnesota." Id. at 960.

[¶ 64] While the North Dakota law says it governs the contract between the covered entity and a contract pharmacy (many of which are located outside the state), the law in reality regulates the transactions between the manufacturers and out-of-state wholesalers. Manufacturers sell medications to wholesalers at full price, then covered entities buy those medications, also at full price. After 340B-eligible transactions are identified after the fact, the covered entity buys more medication at the lower price. Then the wholesalers ask for a refund or "chargeback" from the manufacturers for the difference. But for H.B. 1473, this chargeback would not occur due to offer conditions that manufacturers are allowed by federal law to implement.

[¶ 65] North Dakota argues "virtually all state laws create ripple effects beyond their borders." Doc. No. 31-1, p. 51 (quoting Nat'l Pork Producers, 598 U.S. at 390). However, the Supreme Court in Nat'l Pork Producers was discussing the parties' request for an almost *per se* rule against laws with extraterritorial effects. The law here does not incidentally create a ripple effect on out-of-state actors. By prohibiting these manufacturer policies, the law directly regulates the amount and price of sales between out-of-state manufacturers and out-of-state wholesalers.

[¶ 66] North Dakota argues its laws must be construed to avoid unconstitutional readings. "[W]hen a statute is susceptible of two constructions, one of which renders it unconstitutional and the other constitutional, it is the duty of the court to adopt the construction which, without doing violence to the fair meaning of the statute, will render it valid." State v. Julson, 202 N.W.2d 145, 151 (N.D. 1972). However, here there are not two ways of reading this statute. By its plain meaning the statute regulates out-of-state manufacturers and out-of-state wholesalers. If the State intends not to enforce the statute against out-of-state transactions, then the law would never be enforced.

[¶ 67] Therefore, the Court **GRANTS** AbbVie's Motion for Summary Judgment on Count V, PhRMA's Motion for Summary Judgment on Count III, and **DENIES** North Dakota's Cross-

motions on the same counts. The Court finds the remaining issues presented on Summary Judgment **MOOT**.

VI. Remedy

[¶ 68] AbbVie and PhRMA request declaratory judgments and permanent injunctions against H.B. 1473.

a. Declaratory Judgment

[¶ 69] Declaratory judgment is appropriate when the issue is "definite and concrete, touching the legal relations of parties having adverse legal interests, real and substantial, and admit of specific relief through a decree of conclusive character." Yeransian v. B. Riley FBR, Inc., 984 F.3d 633, 637 (8th Cir. 2021) (quoting McLeod v. General Mills, Inc., 856 F.3d 1160, 1166 (8th Cir. 2017)).

[¶ 70] The Court has granted Summary Judgment on AbbVie's Count V and PhRMA's Counts II and III. The requested declaratory judgments of unconstitutionality are definite and concrete and would give specific relief.

[¶ 71] North Dakota argues the proper remedy is severance. Doc. No. 31-1, p. 55. North Dakota law presumes severability. N.D.C.C. § 1-02-20 (stating an invalid clause does not invalidate the rest of the title). Severance is proper when the remaining clauses "are sufficiently distinct to operate independently from the invalid provisions." Nw. Landowners Ass'n v. State, 2022 ND 150, ¶ 40, 978 N.W.2d 679. The Court has found the entire law's focus and operation violates the Commerce Clause and the Supremacy Clause by singling out entities solely because they participate in a federal program enacted under the Spending Clause. Therefore, no provision can

act independently, and severance is not available. The Court finds declaratory judgment proper as to AbbVie's Count V and PhRMA's Counts II and III.[10]

b. Permanent Injunction

[¶ 72] The standard for issuing a permanent injunction is essentially the same as a preliminary injunction but with one key difference: actual success on the merits instead of a fair chance. Miller v. Thurston, 967 F.3d 727, 735–36 (8th Cir. 2020). "If actual success is found, courts must then consider . . . (1) the threat of irreparable harm to the moving party; (2) the balance of harms with any injury an injunction might inflict on other parties; and (3) the public interest." Id. (quoting Oglala Sioux Tribe v. C&W Enters., Inc., 542 F.3d 224, 229 (8th Cir. 2008)). While no one factor is dispositive, success on the merits is most important. Brakebill v. Jaeger, 905 F.3d 553, 557 (8th Cir. 2018). The balance of harms and public interest factors merge when the government is the opposing party. Nken v. Holder, 556 U.S. 418, 435 (2009). The burden to demonstrate the necessity of injunctive relief rests with the movant. General Motors Corp. v. Harry Brown's, LLC, 563 F.3d 312, 316 (8th Cir. 2009).

[¶ 73] The Court found AbbVie and PhRMA succeeded on the merits of their claims against H.B. 1473; therefore, actual success is satisfied. North Dakota is a government entity and, so, the balance of harms and public interest are merged. The effect of invalidating this statute has no effect on the price patients pay for their medication. See 42 U.S.C. § 256b. Further, there is no requirement that the revenue going to the facilities is spent on patients. See id. Therefore, the Court does not find sufficient evidence that the public interest will be affected by the injunction. The Court finds the factors support a permanent injunction as to AbbVie and PhRMA.

[10] While the Court grants Summary Judgment to North Dakota on PhRMA's Count I, North Dakota did not request declaratory judgment as a relief. See Doc. No. 31-1, p. 55.

JUDGMENT ON THE PLEADINGS

[¶ 74] Courts grant judgment on the pleadings when the moving party is entitled to judgment as a matter of law. Fed. R. Civ. P. 12(c). The Court assumes all facts pled in the Complaint are true, construing inferences in favor of the plaintiff. Spagna v. Phi Kappa Psi, Inc., 30 F.4th 710, 715 (8th Cir. 2022). The Eighth Circuit standard is if there are "enough facts to state a claim to relief that is plausible on its face." Id. (quoting Bell Atl. Corp. v. Twombly, 550 U.S. 544, 570 (2007)).

I. Patent Law Preemption

[¶ 75] North Dakota argues H.B. 1473 is not preempted by patent law because there exists a presumption of no preemption in pharmacy regulation and the law does not change the price. AstraZeneca argues the as-applied challenge shows the law interferes with its federal patent rights.

[¶ 76] Under the Supremacy Clause, state laws that interfere or are contrary to federal law are preempted. See U.S. Cost. art. VI, cl. 2; Felder v. Casey, 487 U.S. 131, 138 (1988). The U.S. Constitution also gives Congress the exclusive authority to manage incentives for inventors for "the Progress of Science and useful Arts." U.S. Const. art. I., § 8, cl. 8. Patent holders have exclusive rights to set prices and sell their products for a certain period of time. Biotechnology Indus. Org. v. District of Columbia, 496 F.3d 1362, 1372 (Fed. Cir. 2007) ("BIO"). In BIO, the Federal Circuit struck down a D.C. law that prohibited excessive prices for patented medications. Id. at 1365. The court held Congress struck a balance between consumer access and manufacturer incentive and states could not disrupt that balance. Id. at 1374.

[¶ 77] AstraZeneca alleges the obligation of H.B. 1473 caps the prices manufacturers may offer their drugs during the patent period. As explained above, the presumption against preemption does not exist in areas of unique federal interest, for which patent law certainly qualifies. Even though the wording of the law does not change the price of a medication, the effect of the law is to limit

the offers manufacturers would otherwise be able to make under federal law. Taking AstraZeneca's allegations as true, it has raised a right to relief above a speculative level. Therefore, the Court **DENIES** North Dakota's Motion for Judgment on the Pleadings as to Count I.

II. Data-collection Preemption

[¶ 78] North Dakota argues the claims-data restriction does not conflict with audit or enforcement provisions. AstraZeneca alleges the data-collection restriction creates an obstacle to the 340B statute and imposes new costs for participating in a federal benefits program, upsetting the balance of the 340B program. It further alleges its previous requests for claims data from covered entities "have been consistently spurned." Case 182, Doc. No. 11, ¶ 71.[11]

[¶ 79] The 340B program requires manufacturers to guard against duplicative discounts. Without claims data AstraZeneca has no way of verifying the reasoning behind a refund to a wholesaler and differentiating between 340B and other rebates. Claims data is not required to have good reason to conduct an audit; however, requiring claims data as a condition of delivery is a method available to manufacturers under federal law, which the North Dakota law denies only to participants of the 340B program. Without this data, manufacturers risk violating the program's prohibition of duplicate discounts, which is punishable by removal from the program.

[¶ 80] Taking AstraZeneca's allegations as true, it has raised a right to relief above a speculative level. Therefore, the Court **DENIES** North Dakota's Motion for Judgment on the Pleadings as to Count II.

[11] AstraZeneca additionally alleges the claims-data restriction runs afoul of the Pilot Rebate program. This program was vacated and is in process of agency revision. See 91 Fed. Reg. 7287 (Feb. 17, 2026). This theory of preemption is, therefore, moot; however, the remaining theories are still active.

III. Contracts Clause

[¶ 81] North Dakota argues H.B. 1473 does not expand AstraZeneca's obligations because it only governs contracts with pharmacies; it is the 340B program that requires sales to covered entities. AstraZeneca alleges in its Amended Complaint that H.B. 1473 impairs its contract by requiring unlimited pharmacy sales.

[¶ 82] The Contracts Clause prohibits state law from impairing contract obligations. U.S. Const. art. I, § 10, cl. 1. The Eighth Circuit looks at if the law is a "substantial impairment on pre-existing contractual relationships." Equip. Mfrs. Inst. v. Janklow, 300 F.3d 842, 850 (8th Cir. 2002). If so, courts look to whether there a "significant and legitimate public purpose behind the regulation." Id. (quoting Educ. Emps. Credit Union v. Mut. Guar. Corp., 50 F.3d 1432, 1438 (8th Cir. 1995)). The law is upheld only if "the adjustment of 'the rights and responsibilities of contracting parties is based upon reasonable conditions and is of a character appropriate to the public purpose justifying the'" law. Id. (quoting Energy Rsrvs. Grp., Inc. v. Kan. Power & Light Co., 459 U.S. 400, 412 (1983)) (citation modified).

[¶ 83] The contract in question is between AstraZeneca and the federal government. That contract allows for conditions on delivery. The North Dakota law prohibits these conditions. This prohibition results in a significant impairment to the relationship, requiring sales that otherwise would not be completed due to the conditions. North Dakota argues the funds are for the health and safety of its citizens; however, with no requirement for how the money is spent, there is insufficient connection between the law and that purpose. Further, medication sales are not limited under AstraZeneca's policy. Facilities may still submit as many claims as previously, just with one pharmacy instead of hundreds or thousands.

[¶ 84] Taking AstraZeneca's allegations as true, it has raised a right to relief above a speculative level. Therefore, the Court **DENIES** North Dakota's Motion for Judgment on the Pleadings as to Count III.

IV. Takings

[¶ 85] North Dakota argues H.B. 1473 does not constitute a *per se* taking because it does not require sale; rather, it only prohibits contract interference and AstraZeneca voluntarily participates in the 340B program. AstraZeneca argues sales to more than one contract pharmacy would not occur but for the North Dakota law because federal law allows for contract conditions on delivery.

[¶ 86] The Fifth and Fourteenth Amendments provide that the federal government may not take private property for public use without just compensation. U.S. Const. amends. V, XIV. Generally concerning real property, "physical appropriations constitute the 'clearest sort of taking.'" Cedar Point Nursery v. Hassid, 594 U.S. 139, 148 (2021) (quoting Palazzolo v. Rhode Island, 533 U.S. 606, 617 (2001)). These are *per se* takings. A "sovereign may not take the property of *A* for the sole purpose of transferring it to another private party *B*, even though *A* is paid just compensation." Kelo v. City of New London, 545 U.S. 469, 477 (2005). Voluntary participation in a federal program "forecloses the possibility that the statute could result in an imposed taking of private property." Se. Ark. Hospice, Inc. v. Burwell, 815 F.3d 448, 450 (8th Cir. 2016) (quoting Minn. Ass'n of Health Care Facilities, Inc., 742 F.2d 442, 446 (8th Cir. 1984)).

[¶ 87] AstraZeneca alleges that some sales to covered entities would not occur but for H.B. 1473. Taken as true, this constitutes a *per se* taking. Voluntary participation in a federal program does not indicate voluntary participation to state law restricting the program, especially when no state law has governed the program in the past 30 years. Taking AstraZeneca's allegations as true, it has

raised a right to relief above a speculative level. Therefore, the Court **DENIES** North Dakota's Motion for Judgment on the Pleadings as to Count IV.

CONCLUSION

[¶ 88] For the foregoing reasons, the Court rules as follows: AbbVie's Motion for Summary Judgment (Doc. No. 28) is **GRANTED** as to Count V – dormant Commerce Clause violation and Counts I, II, III, and IV are **found as MOOT**; North Dakota's Cross-motion (Doc. No. 31) is **DENIED** as to Count V – dormant Commerce Clause violation and Counts I, II, III, and IV are **found as MOOT**; PhRMA's Motion for Summary Judgment (Case 204, Doc. No. 15) is **DENIED** as to Count I – plain text interpretation and **GRANTED** as to Counts II – field preemption with 340B statute and III – dormant Commerce Clause violation; North Dakota's Cross-Motion (Case 204, Doc. No. 21) is **GRANTED** as to Count I – plain text interpretation and **DENIED** as to Counts II – field preemption with 340B statute and III – dormant Commerce Clause violation; and finally, North Dakota's Judgment on the Pleadings (Case 182, Doc. No. 30) is **DENIED** on all counts.

[¶ 89] The Court **DECLARES** H.B. 1473 is unconstitutional and violates the Supremacy Clause and the Commerce Clause. The Court **PERMANENTLY ENJOINS AND RESTRAINS** North Dakota and its agents from enforcing H.B. 1473 against AbbVie; Allergan, Inc.; Durata Therapeutics, Inc; AbbVie Products LLC; Pharmacyclics LLC; Allergan Sales, LLC; and PhRMA's members and members' affiliates, officers, agents, representatives, or contractors. To come within this permanent injunction, PhRMA members must: be a member of PhRMA at the time of the alleged violation, not yet be protected from the laws at issue here, be approved by PhRMA for meeting membership criteria, the membership criteria has not substantively changed

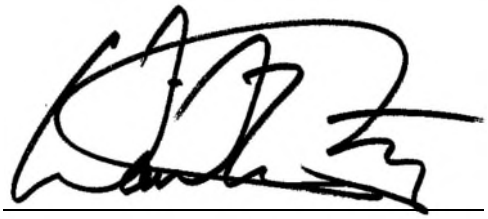
since filing this Complaint, and the member is not subject to an adverse ruling on the merits in another case involving the laws at issue here.

[¶ 90] This order disposes of the lead case AbbVie v. Wrigley, 1:25-cv-81, and consolidated case PhRMA v. Wrigley, 1:25-cv-204. Therefore, the Court **SEVERS** AstraZeneca v. Wrigley, 1:25-cv-182. This order and all future filings for AstraZeneca shall be entered in Case No. 1:25-cv-182.

[¶ 91] The Court retains jurisdiction of this matter as necessary for enforcing this Court's order.

[¶ 92] **IT IS SO ORDERED.**

DATED April 27, 2026.



Daniel M. Traynor, District Judge
United States District Court