2026 WL 2280929
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United States District Court, D. South Dakota.

ABBVIE INC., A DELAWARE CORPORATION; ALLERGAN, INC., A DELAWARE CORPORATION; DURATA THERAPEUTICS, INC., A DELAWARE CORPORATION; ABBVIE PRODUCTS LLC, A GEORGIA LIMITED LIABILITY COMPANY; PHARMACYCLICS LLC, A DELAWARE LIMITED LIABILITY COMPANY; AND ALLERGAN SALES, LLC, A DELAWARE LIMITED LIABILITY COMPANY; Plaintiffs,

v.

MARTY JACKLEY, IN HIS OFFICIAL CAPACITY AS ATTORNEY GENERAL OF THE STATE OF SOUTH DAKOTA; AND LARRY D. DEITER, IN HIS OFFICIAL CAPACITY AS DIRECTOR OF THE SOUTH DAKOTA DIVISION OF INSURANCE; Defendants.

PHARMACEUTICAL RESEARCH AND MANUFACTURERS OF AMERICA, Plaintiff,

v.

MARTY JACKLEY, IN HIS OFFICIAL CAPACITY AS ATTORNEY GENERAL OF THE STATE OF SOUTH DAKOTA; AND LARRY D. DEITER, IN HIS OFFICIAL CAPACITY AS DIRECTOR OF THE SOUTH DAKOTA DIVISION OF INSURANCE; Defendants.

ASTRAZENECA PHARMACEUTICALS LP, Plaintiff,

v.

MARTY J. JACKLEY, IN HIS OFFICIAL CAPACITY AS THE ATTORNEY GENERAL OF SOUTH DAKOTA; AND LARRY D. DEITER, IN HIS OFFICIAL CAPACITY AS DIRECTOR OF THE SOUTH DAKOTA DIVISION OF INSURANCE; Defendants.

3:25-CV-03006-RAL, 3:25-CV-03021-RAL, 4:25-CV-04156-RAL
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Filed 08/07/2026

OPINION AND ORDER GRANTING MOTIONS TO DISMISS

ROBERTO A. LANGE CHIEF JUDGE

***1** Before this Court are motions to dismiss the Complaints in three consolidated cases: AbbVie, Inc. et al. v. Jackley et al., Case No. 3:25-cv-03006-RAL; AstraZeneca Pharms. LP v. Jackley et al., Case No. 4:25-cv-04156-RAL; and Pharm. Rsch. & Mfrs. of Am. (PhRMA) v. Jackley et al., Case No. 3:25-cv-03021-RAL. Plaintiffs in these cases raise various challenges to South Dakota Senate Bill 154 (S.B. 154). Defendants Marty Jackley, in his official capacity as Attorney General of the State of South Dakota (Jackley), and Larry D. Deiter, in his official capacity as Director of the South Dakota Division of Insurance (Deiter), filed the motions to dismiss, which Plaintiffs oppose. Doc. 40 in 3:25-cv-03006-RAL; Doc. 26 in 4:25-cv-04156-RAL; Doc. 22 in 3:25-cv-03021-RAL. This Court conducted a hearing on March 27, 2026, on the motions to dismiss.[1] Because S.B. 154 does not function as a price regulation and is not federally preempted or otherwise unconstitutional or illicit, Plaintiffs have failed to state a claim, and the motions to dismiss are granted.

1 Following this hearing, the United States Court of Appeals for the Eighth Circuit published its opinion in Novartis Pharmaceuticals Corp. v. Hanaway, 180 F.4th 1097 (8th Cir. 2026), which addressed several issues present in this case.

I. Facts Plead and of Public Record

These three cases relate to pharmaceuticals subject to the federal 340B program, which Congress created to address in part the challenges that under-resourced healthcare facilities primarily serving low-income communities face across the country. A brief history of the 340B Program and the various federal and state laws at issue as set forth in the Complaint and case law suffices here.

In 1992, Congress enacted § 340B of the Public Health Service Act, 42 U.S.C. § 256b. Astra USA, Inc. v. Santa Clara Cnty., 563 U.S. 110, 113 (2011). The 340B program "imposes ceilings on prices drug manufacturers may charge for medications sold to specified health-care facilities[, ...] called '340B' or 'covered' entities, [which] include public hospitals and community health centers, many of them providers of safety-net services to the poor." Id.; see also Doc. 37 ¶ 34 in 3:25-cv-3006-RAL; Doc. 16 ¶ 1 in 4:25-cv-4156-RAL; Doc. 1-1 ¶ 12 in 3:25-cv-3021-RAL. The 340B program is supposed to help covered entities care for their typically low-income and rural patients in two ways: "First, it gives them extra revenue from serving insured patients: they turn a profit when insurance companies reimburse them at full price for drugs that they bought at the 340B discount. Second, it enables them to give uninsured patients drugs at little or no cost." Sanofi Aventis U.S. LLC v. U.S. Dep't of Health & Hum. Servs., 58 F.4th 696, 699 (3d Cir. 2023). However, "[e]ven though covered entities can obtain large quantities of 340B drugs at little cost, covered entities are not required to pass the discounts on to patients through free or subsidized medication," and "[i]nstead, Congress envisioned that covered entities would use 340B savings 'to stretch scarce Federal resources as far as possible, reaching more eligible patients and providing more comprehensive services.' " Hanaway, 180 F.4th at 1102 (first citing Notice Regarding Section 602 of the Veterans Health Care Act of 1992; Contract Pharmacy Services, 61 Fed. Reg. 43,549, 43,551 (Aug. 23, 1996); and then quoting H.R. Rep. No. 102-384(II), at 12 (102nd Cong., 2d Sess. 1992)).

***2** The 340B program is voluntary and administered by the Health Resources and Services Administration (HRSA), which is part of the United States Department of Health and Human Services (HHS). Id. at *1; Astra USA, Inc., 563 U.S. at 113; see also 42 U.S.C. § 256b(d). "Drug manufacturers opt into the 340B Program by signing a form Pharmaceutical Pricing Agreement (PPA) used nationwide." Astra USA, Inc., 563 U.S. at 113. Under the 340B Program, "[i]f drug manufacturers agree to make a bona fide offer to sell certain drugs at 340B prices to covered entities, those drugs would also be eligible for reimbursements under Medicare Part B and the federal share of Medicaid." Doc. 1-1 ¶ 13 in 3:25-cv-3021-RAL (emphasis omitted). The agreements between manufacturers and the federal government set a "ceiling price" "fixed by a statutory formula" as the amount to be paid to the manufacturer for the covered drugs sold to covered entities. See Novartis Pharms. Corp. v. Johnson, 102 F.4th 452, 456 (D.C. Cir. 2024) (citing 42 U.S.C. §§ 256b(a)(2), 1396r-8(c)); 42 C.F.R. § 10.10(b) (setting the ceiling price at $0.01 when the formula results in a price less than $0.01). "In exchange for offering 340B drugs to covered entities at these steep discounts, drug manufacturers receive access to lucrative Medicare and Medicaid markets." Hanaway, 180 F.4th at 1102 (citing 42 U.S.C. § 1396r-8(a)(1), (5)); see also Doc. 37 ¶ 36 in 3:25-cv-3006-RAL.

The 340B Program limits the recipients eligible to receive drugs at the 340B ceiling price and disallows multiple discounts on the same drug. Id. at *1–2; Novartis, 102 F.4th at 456. First, Section 340B defines covered entities to include only healthcare providers "such as black lung clinics, rural referral centers, and hospitals that primarily serve low-income patients." Novartis, 102 F.4th at 456 (citing 42 U.S.C. § 256b(a)(4)). Second, the statute protects manufacturers from having to sell discounted drugs outside of the terms agreed to in the PPA by prohibiting both " 'diversion,' which occurs when covered entities 'resell or otherwise transfer the drug to a person who is not a patient of the entity,' " and "duplicate discounts," which disallows "covered entities from receiving the section 340B discount on drugs also subject to a Medicaid rebate." Id. (citing 42 U.S.C. §§ 256b(a)(5)(B), 256b(a)(5)(A)(i)).

To ensure compliance, Section 340B provides an enforcement and remedial scheme. Id.; Astra USA, Inc., 563 U.S. at 115–16. If HHS determines that a manufacturer has breached its obligations under the 340B Program, HHS can terminate the PPA

and remove the manufacturer from the Program. Doc. 1-1 ¶ 70 in 3:25-cv-3021-RAL (citing 42 U.S.C. § 1396r-8(b)(4)(B)(v); 61 Fed. Reg. 65,406, 65,412–13 (Dec. 12, 1996)). Likewise, under 42 U.S.C. § 256b(a)(5)(C), either the HHS Secretary or a manufacturer may initiate an audit of a covered entity. Novartis, 102 F.4th at 456. "If the Secretary finds that a covered entity engaged in diversion or accepted duplicate discounts, the manufacturer may recover damages from the covered entity in administrative proceedings ... [and] may impose further penalties for intentional or systematic diversion." Id. (first citing 42 U.S.C. § 256b(a)(5)(D); and then citing 42 U.S.C. § 256b(d)(2)(B)(v)).

Although HHS has limited rulemaking authority under Section 340B, regulations promulgated by HHS establish an administrative process for the resolution of both covered entities and manufacturers' claims of 340B Program violations; a manufacturer is required to "conduct an audit of a covered entity pursuant to subsection (a)(5)(C) as a prerequisite to initiating administrative dispute resolution proceedings against a covered entity." 42 U.S.C. §§ 256b(d)(3)(A), 256b(d)(3)(B)(iv); see also AstraZeneca Pharms. LP v. Lopez, No. 25-00369, 2026 WL 497141, at *2 (D. Haw. Feb. 23, 2026) (highlighting that HHS's "rulemaking authority is limited to specific subjects, including the administrative dispute resolution (ADR) process, drug-pricing methodology, and monetary sanctions for violations"). Additionally, "a manufacturer may only initiate an audit when it can point to 'documentation which indicates that there is reasonable cause,' with 'reasonable cause' defined to mean 'that a reasonable person could believe that a covered entity may have violated' the prohibitions on diversion or duplicate discounting." Doc. 16 ¶ 25 in 4:25-cv-4156-RAL (quoting 61 Fed. Reg. 65,406, 65,409 (Dec. 12, 1996)).

***3** During the initial years of the 340B Program, many covered entities did not have in-house pharmacies, so they contracted with outside pharmacies, which would then directly receive the 340B drugs that the covered entities had ordered and paid for at the 340B ceiling price. Sanofi, 58 F.4th at 700. HHS expressly "allowed covered entities to partner with third-party contract pharmacies to distribute 340B drugs on the covered entity's behalf." Hanaway, 180 F.4th at 1103 (citing Final Notice Regarding Section 602 of the Veterans Health Care Act of 1992 Entity Guidelines, 59 Fed. Reg. 25,110, 25,113 (May 13, 1994) (permitting covered entities to use "purchasing agents")). Covered entities use contract pharmacies in large part because "building or maintaining a pharmacy is cost-prohibitive for many covered entities," and the use of contract pharmacies "has allowed for drug dispensation closer to where low-income patients reside." Pharm. Rsch. & Mfrs. of Am. (PhRMA) v. McClain, 95 F.4th 1136, 1139 (8th Cir. 2024), cert. denied, 145 S. Ct. 768 (2024). Contract pharmacies act as the covered entities' agent, and although "[t]he covered entity purchases the medication from the manufacturer and directs that the medication be delivered to the pharmacy," "[c]ontract pharmacies do not purchase the medication and title to the medication remains with the covered entity." Hanaway, 180 F.4th at 1103 (citing 61 Fed. Reg. at 43,554, 43,553, 43,552).

Despite lacking broad rulemaking authority, HHS may issue non-binding guidance on the 340B Program. AbbVie Inc. v. Skrmetti, No. 3:25-CV-00519, 2026 WL 542712, at *2 (M.D. Tenn. Feb. 26, 2026) (citing Novartis, 102 F.4th at 456). In 1996, HHS issued guidance allowing covered entities to contract with one outside pharmacy each. 61 Fed. Reg. 43,549 (Aug. 23, 1996). HHS changed course in 2010 and "issued new guidance, saying that covered entities could use an unlimited number of contract pharmacies," which in turn increased covered entities' use of contract pharmacies twentyfold. Sanofi, 58 F.4th at 700 (citing 75 Fed. Reg. 10,272 (Mar. 5, 2010)); Novartis, 102 F.4th at 457 (referring to Government Accountability Office Report No. 20-212 to note that the number of covered entities increased from about 9,700 to 13,000 locations between 2010 and 2019, while participating contract pharmacies increased from about 1,300 to 23,000 with Walgreens and CVS accounting for most of the market).[2]

2 See also Hanaway, 180 F.4th at 1103 ("After the issuance of the 2010 guidance, covered entities saw a significant arbitrage opportunity. Without the single-contract-pharmacy restriction, covered entities could partner with multiple contract pharmacies without regard to geographic proximity and maximize their distribution of 340B drugs. By increasing the volume of 340B drugs purchased at the ceiling price and sold to patients at full retail price, covered entities could maximize the profits available through the 340B Program.").

All Plaintiffs allege that the increased use of contract pharmacies led to the rise of the "replenishment model." Doc. 37 ¶¶ 61–65 in 3:25-cv-3006-RAL; Doc. 16 ¶¶ 33–47 in 4:25-cv-4156-RAL; Doc. 1-1 ¶¶ 88–91 in 3:25-cv-3021-RAL. Under the replenishment model, Plaintiffs allege contract pharmacies effectively comingle their stock of discounted drugs under the 340B Program with drugs they acquire at market rates and fill all prescriptions alike whether for patients of covered entities or non-

covered entities. Doc. 37 ¶ 62 in 3:25-cv-3006-RAL; Doc. 16 ¶ 32 in 4:25-cv-4156-RAL; Doc. 1-1 ¶ 88 in 3:25-cv-3021-RAL. Contract pharmacies subsequently determine which of the prescriptions were 340B eligible using a "black box algorithm." Doc. 37 ¶¶ 62–64 in 3:25-cv-3006-RAL; Doc. 16 ¶ 32 in 4:25-cv-4156-RAL; Doc. 1-1 ¶ 89 in 3:25-cv-3021-RAL. "Many pharmacies outsource this determination to third-party administrators, who often receive a larger fee for every prescription deemed eligible for the discount." Novartis, 102 F.4th at 457.[3] Following the determination of 340B prescriptions, the covered entity will order additional quantities of the drug at the 340B ceiling price and direct the manufacturer to replenish the contract pharmacy's inventory on the covered entity's behalf. Doc. 37 ¶¶ 62–64 in 3:25-cv-3006-RAL; Doc. 16 ¶ 32 in 4:25-cv-4156-RAL; Doc. 1-1 ¶ 89 in 3:25-cv-3021-RAL. The pharmacy, the covered entity, and third-party administrator all have "a financial incentive to catalog as many prescriptions as possible as eligible for the discount" because they "often divvy up the spread between the discounted price and the higher insurance reimbursement rate." Novartis, 102 F.4th at 457–58.[4] Plaintiffs allege that "[t]he replenishment model results in diversion, which the federal statute forbids," and makes it difficult to determine whether some drugs are subject to duplicate discounts as manufacturers typically do not have access to claims data for the individual prescriptions. See Doc. 37 ¶ 147 in 3:25-cv-3006-RAL; Doc. 16 ¶¶ 45, 70–72 in 4:25-cv-4156-RAL (noting "requests by manufacturers for participants in the system (including covered entities and contract pharmacies) to provide the necessary information on a voluntary basis have been consistently spumed"); Doc. 1-1 ¶ 103 in 3:25-cv-3021-RAL.

3 The D.C. Circuit provided illustrations of potential abuses leading to unlawful diversion and duplicate discounts:

> As to diversion, the concern is that pharmacies rely on manipulable algorithms to code whether prescriptions warrant the discount. For example, suppose a physician practices at a covered entity and somewhere else. The physician writes a prescription for a patient of his private practice. Yet the contract pharmacy, connecting the physician to the covered entity, classifies the prescription as eligible for the discount. As for duplicate discounts, the Inspector General found that some contract pharmacies do not track and exclude 340B-eligible prescriptions from Medicaid rebate claims, leading to impermissible duplication.

Novartis, 102 F.4th at 458 (citing S. Wright, Off. of the Inspector Gen., OEI-05-13-00431, Memorandum Report: Contract Pharmacy Arrangements in the 340B Program 10, 13 (2014)).

4 The court in Novartis cited one source that estimates that covered purchases under the 340B Program rose from $6.9 billion in 2012 to $24.3 billion by 2018. Novartis, 102 F.4th at 457 (citing A. Fein, Exclusive: 340B Program Purchases Reach $24.3 Billion—7% + of the Pharma Market—as Hospitals' Charity Care Flatlines, Drug Channels (May 14, 2019)). In oral argument, AbbVie's counsel called 340B pricing under the PPA "confiscatory." Without doubt, Plaintiffs have a strong financial incentive to sell drugs at market rather than 340B PPA pricing, while covered entities and their contract pharmacies have the inverse incentive.

***4** AstraZeneca additionally alleges that some large pharmacies are engaging in a more "brazen" iteration of the replenishment model, called "credit replenishment":

> Under this approach, the contract pharmacy's inventory is "virtually replenished" through a paper fiction—namely, by recharacterizing the prior transaction to make it appear as if the previously dispensed unit had been bought at the 340B price originally. To do so, the wholesaler simply credits the contract pharmacy for the commercial price; charges the 340B price to the covered entity; and then requests a refund from the manufacturer for the difference between the wholesale and 340B prices.

Doc. 16 ¶ 36 in 4:25-cv-4156-RAL.[5]

5 The 340B Program is meant to function in a way that allows the covered entities to use savings from the 340B Program to help fund its work in underserved communities. See Doc. 34 at 14–16 in 3:25-cv-3006-RAL (describing programs subsidized by savings from the 340B Program in South Dakota); Am. Hosp. Ass'n v. Becerra, 596 U.S. 724, 730 (2022) (noting that 340B "hospitals claimed that Members of Congress not only were aware, but actually intended for the 340B program's drug reimbursements to subsidize other services provided by 340B hospitals"). This is in part because "340B hospitals perform valuable services for low-income and rural communities but have to rely on limited federal funding for support." Becerra, 596 U.S. at 738. Defendants claim for instance that Sanford Health of South Dakota utilizes 340B cost savings to support vital programs such as assistance with medication costs, rural clinics and outreach, emergency air transportation, mobile mammogram clinics, and suicide prevention services. Doc. 23 at 10 in 3:25-cv-3021-RAL. Such a claim is outside of the well-pleaded allegations of the Plaintiffs and whether the 340B Program functions properly in South Dakota, or through Sanford Health as a covered entity, is outside the legal issues presented in the motions to dismiss.

Drug manufacturers raised concerns that contract pharmacies were diverting 340B drugs to ineligible patients and obscuring claims data, which drug manufacturers asserted were "driving up duplicate discounting and diversion." Sanofi, 58 F.4th at 700. AbbVie alleges that "[i]n recent years, commercial contract pharmacies have earned annually over $3.3 ***billion*** in 'spread.' " Doc. 37 ¶ 42 in 3:25-cv-3006-RAL (citing Eric Percher et al., Nephron Rsch. LLC, The 340B Program Reaches a Tipping Point: Sizing Profit Flows and Potential Disruption 3, 30, 31 (2020)). Manufacturers then began to adopt policies that limited covered entities' use of contract pharmacies. See Sanofi, 58 F.4th at 700–01 (summarizing drug manufacturers' distribution policies); Skrmetti, 2026 WL 542712, at *3; Doc. 16 ¶¶ 67, 73 in 4:25-cv-4156-RAL. But see McClain, 95 F.4th at 1139 (noting that some of these policies "caused covered entities dependent on contract pharmacies to become unable to serve patients in need").[6]

6 Amici submit that since manufacturers have begun limiting the use of contract pharmacies, Fall River Health Services, a covered entity in Hot Springs, South Dakota, "has lost a substantial majority of its 340B program savings [73%] .... forcing it to eliminate or reduce services that had been supported by 340B program savings—including eliminating its surgery department and reducing its psychiatry services." Doc. 34 at 16 in 3:25-cv-3006-RAL. Whether such dire consequences result from restricting use of contract pharmacies for the 340B Program drugs is outside the legal issues framed by the motions to dismiss.

***5** HHS responded by releasing "an Advisory Opinion declaring that Section 340B unambiguously requires drug makers to deliver 340B drugs to an unlimited number of contract pharmacies." Sanofi, 58 F.4th at 701 (citing HHS Off. Gen. Couns., Advisory Opinion 20-06 on Contract Pharmacies Under the 340B Program (Dec. 30, 2020)). Drug manufacturers successfully challenged this Advisory Opinion in the Third Circuit and D.C. Circuit, both of which upheld the drug manufacturers' limitations on contract pharmacies as lawful under the 340B statute. Sanofi, 58 F.4th at 706 ("These three drug makers' restrictions on delivery to contract pharmacies do not violate Section 340B. And we will enjoin HHS from enforcing against them its reading of Section 340B as requiring delivery of discounted drugs to an unlimited number of contract pharmacies."); Novartis, 102 F.4th at 460–61.

In the wake of Sanofi and Novartis, many state legislatures—South Dakota included—passed laws implementing the kind of requirements that the HHS sought to impose upon drug manufacturers in its Advisory Opinion to "prohibit[ ] manufacturers from limiting covered entities' ability to contract with outside pharmacies." See McClain, 95 F.4th at 1139 (summarizing Arkansas Act 1103).[7] Like many of its peer states, South Dakota adopted in S.B. 154 a law limiting restrictions drug manufacturers could impose on delivery of 340B drugs. S.B. 154 provides in part that

> [a] pharmaceutical manufacturer may not, directly or indirectly, deny, restrict, or prohibit the acquisition of a 340B drug or the delivery of a 340B drug to a location that is authorized to receive the drug by a 340B entity or pharmacy, unless receipt of the 340B drug is prohibited by federal law.
>
> Nothing in this section requires a pharmaceutical manufacturer to provide a 340B drug price discount to a pharmacy.
>
> Nothing in this section prohibits a pharmaceutical manufacturer from limiting distribution of a drug in accordance with 21 U.S.C. § 355-1 (January 1, 2025).

SDCL § 58-29G-2. In another section, S.B. 154 prohibits drug manufacturers from requiring a covered entity or pharmacy "to submit any claim or utilization data, as a condition for allowing the acquisition of a 340B drug by, or delivery of a 340B drug to, a 340B entity, unless the claim or utilization data sharing is required by federal law." Id. § 58-29G-3. If a manufacturer violates any of these provisions, S.B. 154 allows a 340B entity or pharmacy to file a civil action requesting injunctive relief, damages, and attorneys' fees and costs. Id. § 58-29G-4. The statute also provides that, where the state has jurisdiction, it may initiate criminal and civil cases pursuant to the state's deceptive trade practices statute. Id. §§ 15-7-2, 37-24-6(17), 37-24-23, 37-24-26, 37-24-27, 37-24-29; see also Doc. 1-1 ¶¶ 134–35 in 3:25-cv-3021-RAL. However, S.B. 154 does not prohibit "a pharmaceutical manufacturer from conducting an audit of a 340B entity, in accordance with 42 U.S.C. § 256b(a)(5)(C) (January 1, 2025)." SDCL § 58-29G-3.

7 The Eighth Circuit recently tallied twenty-two states as having passed a statute like S.B. 154.

These 22 States are: Arkansas (Ark. Code Ann. § 23-92-604(c)); Colorado (Colo. Rev. Stat. § 6-29-105(1)(a)); Hawaii (Haw. Rev. Stat. § 481N-2(a)); Illinois (H.B. 2371 (104th Gen. Assemb. 2026)); Louisiana (La. Stat. Ann. § 40:2884(A)); Maine (Me. Stat. tit. 24-A, § 7753(1)); Maryland (Md. Code Ann., Health Occ. § 12-6C-09.1(c)(1)); Minnesota (Minn. Stat. § 62J.96(1)); Mississippi (Miss. Code Ann. § 41-149-7(1)); Missouri (Mo. Rev. Stat. 376.414.2); Nebraska (Neb. Rev. Stat. § 44-4620(1)); New Mexico (N.M. Stat. Ann. § 26-1-27(B)(1)); North Dakota (N.D. Cent. Code § 43-15.3-08(3)(b)(1)); Oklahoma (Okla. Stat. tit. 36, § 5403(A)); Oregon (Or. Rev. Stat. § 689.818(2)(a)); Rhode Island (5 R.I. Gen. Laws § 5-19.3-5(a)); South Dakota (S.D. Codified Laws § 58-29G-2); Tennessee (Tenn. Code Ann. § 47-18-136(c)); Utah (Utah Code Ann. § 31A-46-311(2)(a)); Vermont (Vt. Stat. Ann. tit. 18, § 4682(a)); Washington (2026 Wash. Sess. Laws Ch. 227, § 3(1)); and West Virginia (W. Va. Code § 60A-8-6a(b)(1)). Hanaway, 180 F.4th at 1105 n.5. See also Doc. 59 at 4 n.4 in 3:25-cv-3006-RAL (listing similar state statutes at the time of filing). Many of these statutes have been challenged in federal court. See infra Footnote 9.

***6** Drug manufacturers, including AbbVie and AstraZeneca, as well as the trade association PhRMA, have challenged the constitutionality of these state laws across the country, although much of this litigation has so far proven unsuccessful.[8] The circuit courts of appeal to have decided appeals so far have largely affirmed district court findings in favor of state defendants.[9] Pending appeals in the First, Fourth, Ninth, and Tenth Circuits remain undecided as of the time of this Opinion and Order.[10]

8 See Novartis Pharms. Corp. v. Brown, No. 1:24-cv-1557-MJM (D. Md. Sept. 5, 2024) (denying preliminary injunction as to Maryland law in consolidated cases Novartis Pharmaceutical Corp. v. Brown, Civ. No. MJM-24-1557; PhRMA v. Brown, Civ. No. MJM-24-1631; AbbVie Inc. v. Brown, Civ. No. MJM-24-1816; and AstraZeneca v. Brown, Civ. No. MJM-24-1868). vacated and remanded, AbbVie Inc. v. Brown, No. 24-1939, 2026 WL 1005576 (4th Cir. Apr. 14, 2026), reh'g en banc granted, 176 F.4th 830 (4th Cir. 2026); AbbVie Inc. v. Neronha, No. 1:25-cv-00388 (D.R.I. Sept. 30, 2025) (denying preliminary injunction as to Rhode Island law); AbbVie Inc. v. Frey, Nos. 1:25-cv-00407, 1:25-cv-00416, 2025 WL 2813787 (D. Me. Sept. 23, 2025) (same as to Maine law); AstraZeneca Pharms. LP v. Fitch, 766 F. Supp. 3d 657 (S.D. Miss. 2024) (same as to Mississippi law); Novartis Pharms. Corp. v. Fitch, 738 F. Supp. 3d 737 (S.D. Miss. 2024) (same); AbbVie Inc. v. Skrmetti, No. 3:25-cv-00519, 2025 WL 1805271 (M.D. Tenn. June 30, 2025) (same as to Tennessee law); Novartis Pharms. Corp. v. Bailey, No. 2:24-CV-04131, 2025 WL 595189 (W.D. Mo. Feb. 24, 2025) (same as to Missouri law), aff'd, Hanaway, 180 F.4th 1097 (affirming district court's denial of preliminary injunction concluding pharmaceutical company was unlikely to prevail on the merits of its dormant Commerce Clause and preemption claims); Novartis Pharms. Corp. v. Bailey, No. 2:24-CV-04131, 2025 WL 489881 (W.D. Mo. Feb. 13, 2025) (granting in part and denying in part motion to dismiss); AstraZeneca Pharms. LP v. Bailey, No. 2:24-cv-04143, 2025 WL 644285 (W.D. Mo. Feb. 27, 2025) (granting motion to dismiss manufacturer's claims that Missouri law was preempted and violated the Takings Clause); PhRMA v. Bailey, No. 2:24-CV-04144, 2025 WL 644281 (W.D. Mo. Feb. 27, 2025) (granting in part and denying in part motion to dismiss); AbbVie Inc. v. Bailey, No. 4:24-CV-00996, 2025 WL 1918948 (E.D. Mo. July 11, 2025) (dismissing for lack of standing); AbbVie, Inc. v. Ellison, 777 F. Supp. 3d 971 (D. Minn. 2025) (dismissing based on the finding of lack of standing and Eleventh Amendment immunity); PhRMA v. Murrill, Nos. 6:23-cv-00997, 6:23-cv-01042, 6:23-cv-01307, 2024 WL 4361597 (W.D. La. Sept. 30, 2024) (granting summary judgment in favor of State on manufacturers' claims that Louisiana law was preempted and violated the Takings Clause), aff'd sub nom., AbbVie. Inc. v. Murrill, 166 F.4th 528 (5th Cir. 2026). opinion withdrawn and superseded on reh'g, 180 F.4th 747 (5th Cir. 2026) (affirming summary judgment decision on field preemption, conflict preemption, physical taking, regulatory taking, and Contract Clause claims and reversing district court's decision on motion to intervene); AbbVie Inc. v. Fitch, No. 1:24-cv-184, 2024 WL 3503965 (S.D. Miss. July 22, 2024) (denying preliminary injunction as to Mississippi law), aff'd 152 F.4th 635 (5th Cir. 2025); PhRMA v. Fitch, No. 1:24-cv-160, 2024 WL 3277365 (S.D. Miss. July 1, 2024) (same); PhRMA v. McClain, 645 F. Supp. 3d 890 (E.D. Ark. 2022) (granting summary judgment in favor of Arkansas official on manufacturers' claim that Arkansas law was preempted), aff'd 95 F.4th 1136 (8th Cir. 2024), cert. denied, 145 S. Ct. 768 (2024); AbbVie Inc. v. Weiser, 811 F. Supp. 3d 1264 (D. Colo. Oct. 31, 2025) (denying motion for preliminary injunction as to Colorado law); AstraZeneca Pharms. LP v. Weiser, No. 25-CV-02685-PAB-STV, 2025 WL 3653161 (D. Colo. Dec. 17, 2025) (denying motion for preliminary injunction as to Colorado law); PhRMA v. Frey, No. 1:25-CV-00469-JCN, 2026 WL 184504 (D. Me. Jan. 23, 2026) (denying motion for preliminary injunction as to Maine law); AbbVie Inc. v. Hilgers, No. 4:25-cv-03089, 2025 WL 3688051 (D. Neb. Dec. 19, 2025) (denying preliminary injunction as to Nebraska law); PhRMA v. Ellison, No. A25-0805, 2026 WL 445719 (Minn. Ct. App. Feb. 17, 2026) (affirming district court's grant of state respondents' motion to dismiss its complaint challenging Minnesota statute); AstraZeneca Pharms. LP v. Lopez, No. CV 25-00369, 2026 WL 497141 (D. Haw. Feb. 23, 2026) (denying motion for preliminary injunction as to Hawaii law); AbbVie v. Skrmetti, No. 3:25-CV-00519, 2026 WL 542712 (M.D. Term. Feb. 26, 2026) (granting motion to dismiss).

But see AstraZeneca Pharms. LP v. Harris, No. 4:24-cv-00268 (E.D. Ark. Sept. 30, 2025), ECF No. 141 (denying judgment on the pleadings as to manufacturer's claim that Arkansas law violated Takings Clause); PhRMA v. Morrisey, 760 F. Supp. 3d 439, 452–

60 (S.D.W. Va. 2024) (granting preliminary injunction as to West Virginia law and denying the defendants' motion to dismiss in consolidated cases with Novartis v. Morrisey, No. 24-cv-272 and AbbVie Inc. v. Morrisey, 24-cv-298), aff'd, PhRMA v. McCuskey, 171 F.4th 675 (4th Cir.), reh'g en banc granted, 176 F.4th 830 (4th Cir. 2026); AbbVie Inc. v. Drummond, 808 F. Supp. 3d 1266 (W.D. Okla. 2025) (granting in part and denying in part motions for preliminary injunction as to Oklahoma law in consolidated case with Novartis v. Drummond, No. 25-cv-727 and AstraZeneca v. Drummond, No. 25-cv-1156); AbbVie Inc. v. Brown, 809 F. Supp. 3d 1341 (D. Utah 2025) (granting defendants' two of three motions to dismiss in part as to Utah law and denying one motion to dismiss in consolidated cases with Novartis v. Brown, 25-cv-284 and PhRMA v. Pike, 25-cv-308); AbbVie v. Lopez, Nos. 25-230, 25-292, 2026 WL 895705 (D. Haw. Feb. 19, 2026) (granting in part and denying in part motions to dismiss in consolidated cases); AbbVie Inc. v. Wrigley, No. 1:25-CV-00081, 2026 WL 1133457 (D.N.D. Apr. 27, 2026), abrogated in part by Hanaway, 180 F.4th 1097.

9 See AbbVie Inc. v. Fitch, Civil No. 1:24-cv-184, 2024 WL 3503965, at *12 (S.D. Miss. July 22, 2024) (denying preliminary injunction as to Mississippi law), aff'd 152 F.4th 635 (5th Cir. 2025); PhRMA v. Murrill, Nos. 6:23-cv-00997, 6:23-cv-01042, 6:23-cv-01307, 2024 WL 4361597, at *8–9, 13–15 (W.D. La. Sept. 30, 2024) (granting summary judgment in favor of State on manufacturers' claims concerning Louisiana law), aff'd sub nom. AbbVie, Inc. v. Murrill, 166 F.4th 528 (5th Cir. 2026), opinion withdrawn and superseded on reh'g, 180 F.4th (5th Cir. 2026) (affirming summary judgment decision on field preemption, conflict preemption, physical taking, regulatory taking, and Contract Clause claims and reversing district court's decision on motion to intervene); PhRMA v. McClain, 645 F. Supp. 3d 890 (E.D. Ark. 2022) (granting summary judgment in favor of Arkansas official on manufacturers' claim that Arkansas law was preempted), aff'd 95 F.4th 1136 (8th Cir. 2024), cert. denied, 145 S. Ct. 768 (2024); Novartis Pharms. Corp. v. Bailey, No. 2:24-CV-04131, 2025 WL 595189 (W.D. Mo. Feb. 24, 2025), aff'd, Hanaway, 180 F.4th 1097 (affirming district court's denial of a preliminary injunction as to Missouri law).

10 See AbbVie, Inc. v. Frey, No. 25-1914 (1st Cir.); PhRMA v. Frey, No. 26-1099 (1st Cir.); PhRMA v. McCuskey, 171 F.4th 675 (4th Cir.), reh'g en banc granted, 176 F.4th 830 (4th Cir. 2026) (vacating the panel's decision affirming the district court's preliminary injunction grant and motion to dismiss denial concerning the West Virginia law); AbbVie, Inc. v. Brown, No. 24-1939, 2026 WL 1005576 (4th Cir. Apr. 14, 2026), reh'g en banc granted, 176 F.4th 830 (4th Cir. 2026); AstraZeneca v. Lopez, No. 26-1172 (9th Cir.); AbbVie v. Weiser, No. 25-1439 (10th Cir.); AstraZeneca v. Weiser, No. 25-1466 (10th Cir.).

***7** In August 2025, HHS announced a new Pilot Program that allows qualifying drug manufacturers to switch to a rebate model for select 340B drugs. 340B Program Notice: Application Process for Rebate Model Pilot Program; Correction, 90 Fed. Reg. 36165 (Aug. 7, 2025). Under this Pilot Program model, "a covered entity would pay for the drug at a higher price upfront and then later receive a post-purchase rebate that reflects the difference between the initial higher price and the 340B price." Id. The qualifying drug manufacturer would use prescription-level claims data to determine what rebates it owed to covered entities. See Doc. 54 at 8–9 in 3:25-cv-03006-RAL. One of the Plaintiffs, AbbVie, applied for and was accepted into the initial Pilot Program for its drug, Imbruvica. Id. at 2, 6; Doc. 54-1; Doc. 54-2; Doc. 54-3. The initial Pilot Program was scheduled to begin on January 1, 2026, although the Pilot Program has been under reconsideration at HHS and appears to be revised as of July 31, 2026. See Doc. 54-1 ¶ 3; Doc. 54-3.[11]

11 Novartis challenged whether HRSA has the statutory authority to decide which manufacturers may use rebates under this Pilot Program, and the appeal is pending at the D.C. Circuit at the time of this Opinion and Order. See Novartis Pharms. Corp. v. Kennedy, No. 25-5177 (D.C. Cir.). Following the February 10, 2026, vacatur of the 340B Pilot Program in the District of Maine case challenging the program, HHS reconsidered the Rebate Pilot Program. See Letter, Doc. 2158427 in No. 25-5177 (D.C. Cir.). However, neither party argued that the questions presented on appeal were no longer justiciable. See id.; Letter, Doc. 2158962 in No. 25-5177 (D.C. Cir.).

The Plaintiffs in the three cases before this Court are either pharmaceutical manufacturers themselves or a trade association of pharmaceutical manufactures, all of whom participate in the federal Section 340B Program. Plaintiffs AbbVie Inc., Allergan, Inc., Durata Therapeutics, Inc., AbbVie Products LLC, and Allergan Sales, LLC (collectively, AbbVie) are pharmaceutical manufacturers who axe signatories to 340B PPAs, and/or successors-in-interest to executed 340B PPAs with HHS, HRSA. Doc. 37 ¶¶ 21–26 in 3:25-cv-3006-RAL. Plaintiff AstraZeneca is a pharmaceutical manufacturer who participates in the 340B Program. Doc. 16 ¶ 16 in 4:25-cv-4156-RAL. Plaintiff PhRMA is a trade association representing pharmaceutical manufacturers in its advocacy "for policies that encourage the discovery and development of important new pharmaceutical products." Doc. 1-1 ¶ 5 in 3:25-cv-3021-RAL. PhRMA's members participate in the 340B Program. Id.

Plaintiffs AbbVie and AstraZeneca allege federal jurisdiction under 28 U.S.C. § 1331, 42 U.S.C. § 1983, 28 U.S.C. § 1338(a), and the United States Constitution. Doc. 37 ¶¶ 15, 17, 19, 29–30 in 3:25-cv-3006-RAL; Doc. 16 ¶ 12 in 4:25-cv-4156-RAL. Plaintiff PhRMA originally filed in state court, but the Defendants removed the case under 28 U.S.C. § 1441(a) based on federal question jurisdiction under 28 U.S.C. § 1331. Doc. 1 in 3:25-cv-3021-RAL. Each Plaintiff asserts that S.B. 154 is preempted in some way by Section 340B and is invalid or defective on various other grounds.

In AbbVie, Inc. v. Jackley, AbbVie alleges the following claims: (1) S.B. 154 violates the Takings Clause of the United States Constitution; (2) S.B. 154 is preempted under the Supremacy Clause of the United States Constitution by Section 340B; (3) S.B. 154 is also preempted under the Supremacy Clause by the HRSA's Pilot Rebate Program; and (4) S.B. 154 violates the dormant Commerce Clause. Doc. 37 ¶¶ 132–83 in 3:25-cv-03006-RAL.[12] AbbVie seeks declaratory relief that S.B. 154 effects an impermissible taking, is preempted by federal law and unconstitutional under the Supremacy Clause, and violates the Commerce Clause as well as "[a] declaration, order, and judgment holding that the 340B statute does not require drug manufacturers to provide 340B pricing to contract pharmacies or transfer or cause their discounted covered outpatient drugs to be transferred to contract pharmacies," and preliminary and injunctive relief enjoining enforcement of S.B. 154. Id. at 57–58. This Court previously denied AbbVie's Motion for a Preliminary Injunction because S.B. 154 does not impede AbbVie's participation in the Pilot Rebate Program. Doc. 61 in 3:25-cv-03006-RAL.

12 The Court previously granted a Motion for Leave to Amend Complaint filed on behalf of Plaintiffs AbbVie Inc. (AbbVie), Allergan, Inc. (Allergan), Durata Therapeutics, Inc. (Durata Therapeutics), AbbVie Products LLC (AbbVie Products), Pharmacyclics LLC (Pharmacyclics), and Allergan Sales, LLC (Allergan Sales). See Docs. 35, 36.

***8** In AstraZeneca Pharmaceuticals LP v. Jackley, AstraZeneca alleges the following claims: (1) S.B. 154 is preempted by federal patent law; (2) S.B. 154's restriction on manufacturers' data collection is preempted by Section 340B; (3) S.B. 154 violates the Contracts Clause of the United States Constitution; and (4) S.B. 154 violates the Takings Clause of the United States Constitution. Doc. 16 ¶¶ 90–147 in 4:25-cv-04156-RAL. AstraZeneca seeks declaratory relief on each of its claims and both preliminary and permanent injunctive relief to prevent "Defendants from implementing or enforcing S.B. 154 against AstraZeneca or any of its affiliates." Id. ¶ 11, at 44.

In the final case, PhRMA v. Jackley, PhRMA alleges the following: (1) enforcement of S.B. 154 is barred by state law; (2) S.B. 154 is preempted by federal law; and (3) S.B. 154 constitutes unconstitutional extraterritorial regulation. Doc. 1-1 ¶¶ 160–218 in 3:25-cv-03021-RAL. PhRMA seeks declaratory judgment "that S.B. 154 does not apply where there are no actual 340B drug purchases by a '340B entity' in South Dakota," or alternatively, that S.B. 154 is "preempted and otherwise unconstitutional under the U.S. Constitution, and parallel injunctive relief prohibiting such enforcement against PhRMA's members." Id. ¶¶ 1, 4.

Absent relief, Plaintiffs all assert that they, or their members, face a credible threat of prosecution or risk financial harm because, among other things, S.B. 154 requires sales of additional 340B discounted drugs beyond what would be required in the absence of S.B. 154. Doc. 37 ¶ 1 in 3:25-cv-03006-RAL; Doc. 1-1 ¶¶ 44–45 in 3:25-cv-3021-RAL; Doc. 16 ¶¶ 94–95, 118, 124, 129–30 in 4:25-cv-4156-RAL. As one of the complaints puts it, S.B. 154 requires manufacturers "to transfer[ ] its pharmaceutical products unconditionally to certain commercial pharmacies at substantially discounted prices," which "significantly increases the costs of participation in" the 340B Program, "on pain of criminal penalties," Doc. 37 ¶ 1 in 3:25-cv-03006-RAL. All Plaintiffs allege that S.B. 154 prevents them from imposing offer conditions on covered entities that they or their members would otherwise impose to safeguard themselves against diversion and duplicate discounts in the 340B Program.

Defendants have filed motions to dismiss arguing that the Plaintiffs lack standing and have failed to state a claim. Doc. 40 in 3:25-cv-03006-RAL; Doc. 26 in 4:25-cv-04156-RAL; Doc. 22 in 3:25-cv-03021-RAL. Defendants in their motion to dismiss AbbVie's Amended Complaint argue that Plaintiffs lack standing and fail to state a claim because S.B. 154 does not result in a taking, S.B. 154 is not preempted by federal law, and S.B. 154 does not violate the dormant Commerce Clause. Doc. 41 in 3:25-cv-3006-RAL. In their consolidated motion to dismiss AstraZeneca and PhRMA's Complaints, Defendants make similar arguments concerning lack of standing and failure to state a claim concerning the Takings Clause, Supremacy Clause, and Commerce Clause claims, and attack additional claims brought by PhRMA and AstraZeneca by arguing that S.B. 154 is not

preempted by federal patent law, S.B. 154 does not violate the Contracts Clause, and enforcement of S.B. 154 is not barred by state law. Doc. 23 in 3:25-cv-3021-RAL. Amicus Parties 340B Health, American Hospital Association, American Society of Health-System Pharmacists, and South Dakota Association of Healthcare Organizations have filed an amicus brief in support of the motions to dismiss. See Doc. 18 in 3:25-cv-3006-RAL; Doc. 32 in 3:25-cv-3021-RAL; Doc. 36 in 4:25-cv-4156-RAL.

II. Failure to State a Claim Standard

***9** Defendants argue that Plaintiffs have failed to state a claim in their Complaints. On a motion to dismiss under Rule 12(b)(6), courts must accept a plaintiff's factual allegations as true and construe all inferences in the plaintiff's favor but need not accept a plaintiff's legal conclusions. Retro Television Network, Inc. v. Luken Commc'ns, LLC, 696 F.3d 766, 768–69 (8th Cir. 2012). To survive a motion to dismiss for failure to state a claim, a complaint must contain "a short and plain statement of the claim showing that the pleader is entitled to relief." Fed. R. Civ. P. 8(a)(2). Although detailed factual allegations are unnecessary, the plaintiff must plead "sufficient factual matter, accepted as true, to 'state a claim to relief that is plausible on its face.' " Ashcroft v. Iqbal, 556 U.S. 662, 678 (2009) (quoting Bell Atl. Corp. v. Twombly, 550 U.S. 544, 570 (2007)). A claim is plausible on its face "when the plaintiff pleads factual content that allows the court to draw the reasonable inference that the defendant is liable for the misconduct alleged," Iqbal, 556 U.S. at 678, "even if it strikes a savvy judge that actual proof of those facts is improbable, and 'that a recovery is very remote and unlikely,' " Twombly, 550 U.S. at 556 (quoting Scheuer v. Rhodes, 416 U.S. 232, 236 (1974)). Still, "conclusory statements" and "naked assertion[s] devoid of further factual enhancement" do not satisfy the plausibility standard. Iqbal, 556 U.S. at 678 (alteration in original) (citation and internal marks omitted).

The parties presented legal arguments in briefing and oral argument. Neither Plaintiffs nor Defendants identified any issue of fact on which discovery ought to occur. Plaintiffs referred generally to conducting discovery not from Defendants but perhaps from others that would bolster their allegations. This Court takes the well-pleaded facts in Plaintiffs' Complaints as true in ruling on the motions to dismiss. This Court first addresses Plaintiffs' standing to bring claims against Defendants Jackley and Deiter and then addresses the sufficiency of constitutional and statutory claims pleaded.

III. Standing

Defendants have challenged Plaintiffs' standing to pursue the present litigation. "Article III of the Constitution limits the jurisdiction of federal courts to 'Cases' and 'Controversies.' " Murthy v. Missouri, 603 U.S. 43, 56 (2024); see also Clapper v. Amnesty Int'l USA, 568 U.S. 398, 408 (2013). Federal courts do not "operate as an open forum for citizens 'to press general complaints about the way in which government goes about its business.' " FDA v. All. for Hippocratic Med., 602 U.S. 367, 379 (2024) (quoting Allen v. Wright, 468 U.S. 737, 760 (1984)). Courts implement this limit through different justiciability doctrines, including standing and ripeness. DaimlerChrysler Corp. v. Cuno, 547 U.S. 332, 352 (2006).

Broadly speaking, the standing inquiry concerns whether the plaintiff is the appropriate party to bring a particular suit Raines v. Byrd, 521 U.S. 811, 818 (1997): Flast v. Cohen, 392 U.S. 83, 99–100 (1968). The three requirements for standing are (1) an injury in fact, (2) a causal connection between the injury and the challenged law, and (3) a likelihood that a favorable decision will redress the injury. All. for Hippocratic Med., 602 U.S. at 380; Animal Legal Def. Fund v. Vaught, 8 F.4th 714, 718 (8th Cir. 2021) (citing Lujan v. Defenders of Wildlife, 504 U.S. 555, 560–61 (1992)). Standing is jurisdictional, requiring a federal court to consider all standing defects, even those parties may overlook. See Young Am.'s Found. v. Kaler, 14 F.4th 879, 887 (8th Cir. 2021) (requiring the court raise the "threshold issue" of standing "sua sponte if need be" (cleaned up and citations omitted)).

To satisfy Article III standing, an injury in fact "must be concrete and particularized and actual or imminent, not conjectural or hypothetical." Susan B. Anthony List v. Driehaus, 573 U.S. 149, 158 (2014) (cleaned up and citation omitted). A "concrete" injury means "that it must be real and not abstract." All. for Hippocratic Med., 602 U.S. at 381. A "particularized" injury means that it "must affect 'the plaintiff in a personal and individual way' and not be a generalized grievance." Id. (quoting Lujan, 504 U.S. at 560 n.1). "Moreover, the injury must be actual or imminent, not speculative—meaning that the injury must have already occurred or be likely to occur soon." Id. "An allegation of future injury may suffice if the threatened injury is certainly impending, or there is a substantial risk that the harm will occur." Susan B. Anthony List, 573 U.S. at 158 (cleaned up and

citation omitted); see also Minn. Chapter of Associated Builders & Contractors, Inc. v. Blissenbach, 155 F.4th 1015, 1020–21 (8th Cir. 2025) ("Because the [plaintiffs] allege specific conduct that the Act targets, and because state officials have not disavowed enforcing it, the [plaintiffs] have standing."). "Risk of direct financial harm establishes injury in fact," even if the timing and extent of a plaintiff's financial injury remains to be determined. Nat'l Parks Conservation Ass'n v. U.S. E.P.A., 759 F.3d 969, 975 (8th Cir. 2014).

***10** The Supreme Court of the United States has recognized that the "second and third standing requirements—causation and redressability—are often 'flip sides of the same coin.' " All. for Hippocratic Med., 602 U.S. at 380 (citation omitted). Causation requires a plaintiff to show an "injury likely was caused or likely will be caused by the defendant's conduct." Id. at 382. "[T]he causation requirement screens out plaintiffs who were not injured by the defendant's action." Id. at 383. For causation, "the plaintiff must show a predictable chain of events leading from the government action to the asserted injury—in other words, that the government action has caused or likely will cause injury in fact to the plaintiff." Id. at 385. "Government regulations that require or forbid some action by the plaintiff almost invariably satisfy both the injury in fact and causation requirements." Id. at 382. Where the defendant's action caused injury, redressability—the third element of standing—typically exists through injunctive action or an award of damages. Id. at 381.

A plaintiff bears the burden of establishing standing as of the time the lawsuit was brought and throughout the pendency of the case. See Carney, 592 U.S. at 59. "[S]tanding is not dispensed in gross," TransUnion LLC v. Ramirez, 594 U.S. 413, 431 (2021), but requires a plaintiff to "demonstrate standing for each claim that they press against each defendant, and for each form of relief that they seek," Murthy, 603 U.S. at 61 (cleaned up and citation omitted). "Because these requirements are 'an indispensable part of the plaintiff's case, each element must be supported in the same way as any other matter on which the plaintiff bears the burden of proof, *i.e.*, with the manner and degree of evidence required at the successive stages of litigation. ['] " Young Am.'s Found., 14 F.4th at 887 (quoting Bernbeck v. Gale, 829 F.3d 643, 646 (8th Cir. 2016)). At the pleading stage, "the plaintiff may rely on 'general factual allegations of injury resulting from the defendant's conduct.' " Id. at 888 (quoting Lujan, 504 U.S. at 561).

Defendants have argued that Plaintiffs have failed to establish an injury in fact as S.B. 154 does not mandate any additional sales of 340B drugs beyond what is required by the 340B Program; S.B. 154 complies with the 340B Program and causes no injury on that basis; Plaintiffs are under no compulsion to comply with S.B. 154, or the 340B Program, because the program is voluntary, and therefore, there is no injury through compelled transfer of property; and Plaintiffs' alleged injuries are not fairly traceable to the conduct of Defendants Jackley or Deiter because Plaintiffs are not under a present threat of enforcement from either. Doc. 41 at 10–11 in 3:25-cv-3006-RAL; Doc. 27 at 12–21 in 4:25-cv-4156-RAL.

Each of the Plaintiffs have standing to bring their claims. "An injury in fact exists when the plaintiffs allege an intention to engage in a course of conduct arguably affected with a constitutional interest, but proscribed by statute, and there exists a credible threat of prosecution thereunder." Iowa Migrant Movement for Just. v. Bird, 157 F.4th 904, 914 (8th Cir. 2025) (cleaned up and citation omitted); see also All. for Hippocratic Med., 602 U.S. at 382 ("Government regulations that require or forbid some action by the plaintiff almost invariably satisfy both the injury in fact and causation requirements. So in those cases, standing is usually easy to establish."). AbbVie and AstraZeneca, as individual drug manufacturers, have pleaded that they wish to engage in conduct that is directly prohibited[13] by the newly-passed statute, S.B. 154. At oral argument, Plaintiffs made clear that they want to restrict covered entities to only one contract pharmacy and want to impose data collection requirements to facilitate detection and audits to combat diversionary or duplicate discounting. Further, AbbVie and AstraZeneca have alleged that due to S.B. 154 they will lose significant funds due to covered entities' use of multiple contract pharmacies and due to increased diversion and duplicate discount practices by contract pharmacies without certain data collection. Defendants have not disavowed preemptive enforcement of S.B. 154, though Defendants read S.B. 154 more narrowly than do Plaintiffs.

13 PhRMA has a state-law declaratory judgment claim that seeks a declaration that S.B. 154 does not inhibit the practices Plaintiffs wish to impose. Thus for purposes of one claim, PhRMA urges a very narrow reading of S.B. 154, though for the other claims, Plaintiffs broadly read S.B. 154 to conflict with constitutional provisions.

***11** The Eighth Circuit recently rejected a similar standing argument in Hanaway, concluding that a pharmaceutical manufacturer challenging a regulation like S.B. 154 as causing "financial loss" had standing. 180 F.4th at 1106 n.6 (citing All. for Hippocratic Med., 602 U.S. at 382 ("Government regulations that require or forbid some action by the plaintiff almost invariably satisfy both the injury in fact and causation requirements. So in those cases, standing is usually easy to establish.")).[14] AbbVie and AstraZeneca's allegations concerning their credible risk of prosecution and risk of financial injury are sufficient to establish an injury-in-fact. Id.; Susan B. Anthony List, 573 U.S. at 158; Blissenbach, 155 F.4th at 1020–21; Nat'l Parks Conservation Ass'n., 759 F.3d at 975.

14 A decision in the Eastern District of Missouri found an absence of standing in a similar case, AbbVie Inc. v. Bailey, No. 4:24-CV-00996, 2025 WL 1918948 (E.D. Mo. July 11, 2025), but that decision seems to be an outlier and since abrogated by the Eighth Circuit's decision in Hanaway, see supra note 8; Hanaway, 180 F.4th at 1106 n.6.

Additionally, AbbVie and AstraZeneca have referenced statutory provisions in their allegations concerning Jackley's and Deiter's respective roles in enforcing S.B. 154. See SDCL §§ 37-24-23, 37-24-26, 37-24-20, 37-24-31, 58-4-5, 58-4-7; see also Doc. 44 at 10, 10 n. 3 in 3:25-cv-3006-RAL; Doc. 37 ¶¶ 27–28 in 3:25-cv-3006-RAL. "For purposes of the Eleventh Amendment and Ex parte Young, a state official's requisite connection with the enforcement of a statute may arise out of 'the general law' or be 'specially created by the act itself.' " Calzone v. Hawley, 866 F.3d 866, 870 (8th Cir. 2017) (quoting Ex parte Young, 209 U.S. 123, 157 (1908)). Because both named Defendants have statutory authority to enforce S.B. 154, AbbVie and AstraZeneca have standing for the claims alleged against Jackley and Deiter.

PhRMA, claiming representational standing, has pleaded that its members wish to engage in conduct that is directly prohibited by S.B. 154, and that they will lose significant funds due to increased diversion and duplicate discount practices by contract pharmacies. See Doc. 1-1 ¶ 5 in 3:25-cv-3021-RAL. To have representational standing, an organization must demonstrate "that (a) its members would otherwise have standing to sue in their own right; (b) the interests it seeks to protect are germane to the organization's purpose; and (c) neither the claim asserted nor the relief requested requires participation of individual members in the lawsuit.' " Iowa Migrant Movement for Just., 157 F.4th at 916 (quoting Students for Fair Admissions, Inc. v. President & Fellows of Harv. Coll., 600 U.S. 181, 199 (2023)).

PhRMA satisfies all three requirements for representational standing. First, PhRMA's members, which include AstraZeneca, and Novartis, a manufacturer that has sued to enjoin other states' 340B drug delivery laws, would have standing to sue in their own right. Second, the interests PhRMA seeks to protect are germane to its purpose: PhRMA "advocates for policies that encourage the discovery and development of important new pharmaceutical products," which PhRMA alleges is impeded by contract pharmacies' workarounds to 340B Program limitations. Doc. 1-1 ¶ 5 in 3:25-cv-3021-RAL. PhRMA alleges S.B. 154 is a further impediment to its members' ability to address and prevent diversion and duplicate discounts, which contravenes the interests PhRMA seeks to protect as part of PhRMA's purpose. Third, this case, in which PhRMA seeks declaratory and injunctive relief, does not require the participation of individual members. Warm v. Seldin, 422 U.S. 490, 515 (1975) ("If in a proper case the association seeks a declaration, injunction, or some other form of prospective relief, it can reasonably be supposed that the remedy, if granted, will inure to the benefit of those members of the association actually injured."); see also Worth v. Jacobson, 108 F.4th 677, 686 (8th Cir. 2024). PhRMA, like AbbVie and AstraZeneca, has established standing at this stage of the litigation.

IV. Supremacy Clause and Preemption Claims

***12** Plaintiffs raise various claims that federal law preempts S.B. 154. "Article VI of the 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." McClain, 95 F.4th at 1140 (cleaned up) (quoting Cipollone v. Liggett Grp., Inc., 505 U.S. 504, 516 (1992); see also Hanaway, 180 F.4th at 1111. Therefore, "any state law conflicting with federal law has no effect." Lefaivre v. KV Pharm. Co., 636 F.3d 935, 938 (8th Cir. 2011) (cleaned up and citation omitted). Congress may expressly or impliedly preempt state law. Oneok, Inc. v. Learjet, Inc., 575 U.S. 373, 376–77 (2015). If Congress does not expressly preempt, or invalidate, a state law

through federal legislation, it may still "impliedly preempt state law either through field pre-emption or conflict preemption." McClain, 95 F.4th at 1140 (cleaned up and citation omitted).

"Field preemption exists where 'Congress has forbidden the State to take action in the *field* that the federal statute pre-empts.' " Id. (quoting Oneok, Inc., 575 U.S. at 377); see also Hanaway, 180 F.4th at 1112. Conflict preemption "exists where 'compliance with both state and federal law is impossible,' " known as impossibility preemption, "or where 'the state law stands as an obstacle to the accomplishment and execution of the full purposes and objectives of Congress," known as obstruction preemption. Id. (quoting Oneok, Inc., 575 U.S. at 377); see also Hanaway, 180 F.4th at 1113; Lefaivre, 636 F.3d at 939 (citing Wis. Pub. Intervenor v. Mortier, 501 U.S. 597, 605 (1991)). In either scenario, "federal law must prevail." McClain, 95 F.4th at 1140. However, any Supremacy Clause analysis concerning laws within the realm of states' historic police powers begins with the "presumption that state or local regulation of matters related to health and safety is not invalidated under the Supremacy Clause." Hillsborough Cnty. v. Automated Med. Lab'ys, Inc., 471 U.S. 707, 715 (1985); McClain, 95 F.4th at 1140 ("Notwithstanding the supremacy of federal law, consideration of issues arising under the Supremacy Clause starts 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." (cleaned up and citation omitted)).

All Plaintiffs allege that S.B. 154 violates the Supremacy Clause because it is preempted by the 340B statute itself as well as the related regulations. See Doc. 37 in 3:25-cv-03006-RAL ¶¶ 141–58; Doc. 16 ¶¶ 131–35 in 4:25-cv-04156-RAL; Doc. 1-1 ¶¶ 169–205 in 3:25-cv-03021-RAL. In addition, AbbVie alleges that S.B. 154 is preempted by the Pilot Rebate Program, and AstraZeneca separately alleges that S.B. 154 is preempted by patent law. Doc. 37 in 3:25-cv-03006-RAL ¶¶ 159–66; Doc. 16 ¶¶ 127–30 in 4:25-cv-04156-RAL. Finally, in their responses to the state Defendants' motions to dismiss, Plaintiffs AstraZeneca and PhRMA contend that S.B. 154 is preempted by the Supremacy Clause itself under the intergovernmental immunity doctrine, though their complaints did not expressly allege so.[15] Each of the Plaintiffs have failed to state a viable preemption claim under any of the legal theories raised, and therefore, Defendants' Motions to Dismiss the Supremacy Clause claims are granted.

15 Defendants highlight in their Reply that Plaintiffs AstraZeneca and PhRMA assert in their respective responses that S.B. 154 violates the intergovernmental immunity doctrine for the first time as this "new preemption theory [has] not [been] previously presented to this Court." Doc. 48 at 9 in 4:25-cv-4156-RAL. Defendants argue that Plaintiffs' invocation of the intergovernmental immunity doctrine in their responses circumvents Federal Rule of Civil Procedure 15 and is an untimely amendment to their Complaints. Id. at 9 n.2. This claim was briefed and argued at the hearing, is closely related to if not embraced within the AstraZeneca and PhRMA complaints and could be plead in an Amended Complaint were this Court to read the complaints narrowly. Therefore, this Court will consider this argument.

A. Preemption Under Section 340B

***13** AbbVie alleges that Section 340B preempts S.B. 154 under both theories of field and obstacle preemption, alleging (1) S.B. 154 "expressly and impliedly protects the use of the replenishment model" because "the replenishment model results in diversion," which Section 340B forbids; (2) "S.B. 154 creates an irreconcilable conflict with federal law and obstructs the objectives of the federal 340B program" by disallowing the collection of claims data; (3) S.B. 154 may not regulate or change the conditions of participating in the federal 340B program; (4) Congress meant for the 340B federal program to be a comprehensive federal healthcare program and S.B. 154 is an impermissible price regulation; and (5) Congress comprehensively defined who was entitled to administer the 340B Program as well as the tools the HRSA is allowed to use in ensuring compliance and S.B. 154 may not impermissibly intrude on HRSA's exclusive administration. See Doc. 37 in 3:25-cv-03006-RAL ¶¶ 141–58.

AstraZeneca alleges that S.B. 154's data-collection restriction is preempted by the 340B statute under the theory of conflict preemption because it "creates an obstacle to the accomplishment and execution of Congress's objective for the 340B statute" by "inhibit[ing] manufacturers' access to Congress's enforcement regime" and "prevent[ing] manufacturers from enforcing their federal right to avoid paying duplicate discounts under the 340B program and the [Inflation Reduction Act]." Doc. 16 ¶ 133 in 4:25-cv-04156-RAL.

PhRMA alleges that federal law preempts S.B. 154 under both theories of field and conflict preemption because (1) "Congress created a comprehensive federal program in 340B and centralized control of that program exclusively within HHS to safeguard the delicate balance Congress struck"; (2) S.B. 154 "compels manufacturers to allow the purchase of 340B-priced drugs even though the offered conditions were *not accepted*"; (3) S.B. 154's claims data restriction conflicts with Congress's allowance for data-related conditions in an offer; (4) S.B. 154 is preempted by both the federal oversight and remedial regimes, including that S.B. 154 impermissibly allows for additional adjudication and penalties; and (5) S.B. 154 conflicts with the federal Medicare Drug Price Negotiation Program in the Inflation Reduction Act. Doc. 1-1 ¶¶ 169–205 in 3:25-cv-03021-RAL.

1. Field Preemption

Defendants seek dismissal of the field preemption claims by relying on McClain where the Eighth Circuit upheld the constitutionality of a similar Arkansas statute imposing delivery restrictions on drug manufacturers participating in the 340B program. See Doc. 41 at 20 in 3:25-cv-3006-RAL; Doc. 27 at 26 in 4:25-cv-4156-RAL. The Eighth Circuit recently applied McClain to a statute similar to S.B. 154, noting that the plaintiff drug manufacturer's "field preemption claims are foreclosed by McClain." Hanaway, 180 F.4th at 1113 (finding no abuse of discretion in district court's denial of motion for preliminary injunction on field preemption claim); see also Bailey, 2025 WL 644281, at *2–3 (Western District of Missouri case applying McClain to dismiss field preemption claim for failure to state a claim in case involving statute akin to S.B. 154). Plaintiffs' field preemption claims here are similarly foreclosed. Hanaway, 180 F.4th at 1113.

The upheld portion of the Arkansas statute at issue in McClain reads:

> 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). See also McClain, 95 F.4th at 1140 ("For purposes of this appeal, PhRMA takes issue with Ark. Code Ann. § 23-92-604(c), arguing that it is preempted by Section 340B and the FDCA and is therefore unconstitutional."). The Eighth Circuit concluded that the 340B program did not preempt the state statute under a theory of field preemption because the federal program was not "so pervasive ... that Congress left no room for the States to supplement it" given its silence on delivery of drugs to patients, and "the practice of pharmacy is an area traditionally left to state regulation." McClain, 95 F.4th at 1143 (first quoting Arizona v. United States, 567 U.S. 387, 399 (2012); then citing Sanofi, 58 F.4th at 703; and then quoting Pharm. Care Mgmt. Ass'n v. Wehbi, 18 F.4th 956, 972 (8th Cir. 2021)).

***14** McClain expressly rejected the plaintiff PhRMA's arguments to the contrary. McClain first disagreed with PhRMA's assertion that Congress intended to create a closed system within the statute and the Arkansas statute impermissibly added pharmacies as 340B entities entitled to discount pricing; McClain concluded instead that "[p]harmacies do not purchase 340B drugs, and they do not receive the 340B price discounts[, and] [c]overed entities purchase and maintain title to the 340B-discounted drugs, while contract pharmacies dispense these drugs to covered entities' patients." Id. at 1144 (citing Sanofi, 58 F.4th at 700). AbbVie argues that McClain is distinguishable because, contrary to the Eighth Circuit's reasoning in McClain, AbbVie has pleaded that covered entities do not maintain title to 340B discounted drugs or have an agency relationship with its pharmacies. Doc. 44 at 28 in 3:25-cv-03006-RAL (quoting Doc. 37 ¶¶ 66, 93).

However, the Eighth Circuit has been clear that in the 340B Program, "title to the medication remains with the covered entity." Hanaway, 180 F.4th at 1103 (citing 61 Fed. Reg. at 43,554, 43,553, 43,552). In determining that covered entities retain legal title to 340B drugs, McClain and Hanaway relied on HRSA's 1996 Guidance on covered entities, including that contract pharmacies become agents of the covered entity "with the authorization to 'dispense 340B drugs to patients of the covered entity pursuant

to a prescription.' " McClain, 95 F.4th at 1142 (quoting 61 Fed. Reg. at 43,550); Hanaway, 180 F.4th at 1103 (citing 61 Fed. Reg. at 43,554, 43,553, 43,552); see also Sanofi, 58 F.4th at 700 ("Covered entities using contract pharmacies ... still order and pay for the drugs, but they [are] shipped directly to the pharmacies."). As noted in HRSA guidance, because covered entities maintain legal title, allowing covered entities to enter into agreements with contract pharmacies "does not in any way extend this pricing to entities which do not meet [340B] program eligibility." 61 Fed. Reg. at 43,500. HRSA's 2010 update to its guidance allowing covered entities to contract with an unlimited number of outside pharmacies did not alter that covered entities "must maintain title to and responsibility for the drugs." Novartis, 102 F.4th at 457 (citing 2010 Guidance at 10,277).

While Plaintiffs have alleged that contract pharmacies are disregarding federal law on legal title to pharmaceuticals, that allegation does not justify disregarding McClain. Other courts have rejected this same argument. See Bailey, 2025 WL 1918948, at *7 (concluding that neither Section 340B nor the Missouri statute require AbbVie to transfer title of discounted drugs); Fitch, 766 F. Supp. 3d at 666–67 ("The covered entity's retention of title was only one basis for the McClain court's finding that the Arkansas statute was not preempted.").[16]

16 The district court in Harris entertained this argument, but that decision predated the Eighth Circuit's most recent opinion in Hanaway. Compare Harris, No. 4:24-cv-00268, Doc. 141 at 12 (distinguishing McClain on the grounds that "AstraZeneca alleges that covered entities do not actually retain title to the 340B drugs and that contract pharmacies are actually independent contractors, instead of agents of the covered entities, facts that AstraZeneca claims are different from what the Eighth Circuit based its ruling in the PhRMA Case .... those facts were not developed or litigated in that case."), with Hanaway, 180 F.4th at 1103, 1113.

Since the oral argument in this case, the Eighth Circuit expressly declined an invitation to reconsider McClain and, as noted above, concluded McClain foreclosed another pharmaceutical manufacturer's field preemption claims concerning a statute similar to S.B. 154. Hanaway, 180 F.4th at 1113 ("Recognizing that its field preemption argument is foreclosed, Novartis contends McClain was wrongly decided and should be overturned. We decline Novartis's request to reconsider McClain."). McClain is precedent here, and pleading and arguing that McClain misunderstood the realities of the 340B Program drug distribution does not justify ignoring McClain's holding, especially when the Eighth Circuit has so recently reaffirmed this holding on 340B field preemption. Hanaway, 180 F.4th at 1113.

***15** McClain also rejected the plaintiff's second argument that the Arkansas statute impermissibly creates its own oversight and enforcement scheme contravening HHS's exclusive 340B jurisdiction. Hanaway, 180 F.4th at 1112. "Section 340B does not preempt the field of 340B regulation and ... the 340B Program's enforcement mechanisms do not preempt the field of 340B enforcement." Id. (citing McClain, 95 F.4th at 1143–44). The state statute on delivery "ensures that covered entities can utilize contract pharmacies for their distribution needs and authorizes the [state] to exact penalties and equitable relief if manufacturers deny 340B drugs to covered entities' contract pharmacies," whereas the 340B Program regulates discount pricing, not delivery; therefore, "HHS has jurisdiction over different disputes." McClain, 95 F.4th at 1144. Relying both on "Congress's decision not to legislate the issue of pharmacy distribution" and Congress's awareness "of the role of pharmacies and state pharmacy law in implementing 340B," McClain concluded that "Congress did not intend to preempt the field." Id. at 1143–44.

Plaintiffs AbbVie and PhRMA argue that McClain does not apply to the field preemption claim because, unlike the Arkansas statute, S.B. 154 is a price regulation. AbbVie argues this is demonstrated in part by S.B. 154's use of the word "acquisition," and refers to the statute's definition of "340B drug"[17] to argue S.B. 154 "regulates 'delivery at a given price, not delivery per se.' " Doc. 44 at 25–26 in 3:25-cv-03006-RAL (quoting Morrisey, 760 F. Supp. 3d at 455). Further, AbbVie argues that "no presumption against preemption can apply where a state law explicitly depends on a federal statute." Id. at 25 (citing Buckman Co. v. Plaintiffs' Legal Comm., 531 U.S. 341, 347–48 (2001); Boyle v. United Techs. Corp., 487 U.S. 500, 507–08 (1988)). PhRMA similarly asserts that McClain does not control this case and no presumption against preemption applies in part because McClain does not hold that a state law regulating 340B pricing would be preempted. Doc. 42 at 37 in 3:25-cv-03021-RAL. Without S.B. 154, PhRMA members could decline to sell drugs at 340B prices to covered entities that refuse to agree to certain conditions; therefore, it argues, S.B. 154 is "a mandate on when and under what conditions manufacturers must sell drugs at

340B prices." Id. at 39. If S.B. 154 is a state law on sale and price, PhRMA argues, McClain does not apply and neither does the presumption against preemption because it is not a "health and safety" regulation within the state's traditional police power. Id.

17 S.B. 154 defines "340B drug" as "a drug purchased through the 340B drug discount program by a 340B entity." SDCL § 58-29G-1(3).

When reviewing S.B. 751, a Missouri statute with language much closer to S.B. 154 than the Arkansas statute at issue in McClain, the Eighth Circuit confirmed that these kinds of state statutes regulate delivery and not price:

> The price at which 340B drugs are offered to covered entities is set by federal statutory formula. State laws like Arkansas Act 1103 and Missouri S.B. 751 do not alter that pricing formula or otherwise set the price of 340B drugs; rather, these laws provide that, once 340B drugs are offered to covered entities at the ceiling price, drug manufacturers cannot prevent covered entities from directing the delivery of those drugs to its contract pharmacies.

Hanaway, 180 F.4th at 1113 (citing 42 C.F.R. § 10.10(a)).

Further, the Arkansas statute at issue in McClain had more to do with pricing than S.B. 154 does. The Arkansas Legislature called the subchapter the "340B Drug Pricing Nondiscrimination Act" after all. Ark. Code Ann. § 23-92-601. Under the Arkansas statute, which the Eighth Circuit interpreted to only concern delivery, a manufacturer could neither "[p]rohibit 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," nor "[d]eny 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." Id. § 23-92-604(c). The Arkansas statute clearly contemplates barring manufacturers from imposing *any* conditions on covered entities to receive access to drugs at 340B pricing.

***16** Under S.B. 154, meanwhile, a "manufacturer may not, directly or indirectly, deny, restrict, or prohibit the acquisition of a 340B drug or the delivery of a 340B drug to a location that is authorized to receive the drug by a 340B entity or pharmacy, unless receipt of the 340B drug is prohibited by federal law," subject to certain limitations, including that "[n]othing in this section requires a pharmaceutical manufacturer to provide a 340B drug price discount to a pharmacy." SDCL § 58-29G-2. Plaintiffs focus on the use of "acquisition" in S.B. 154 to argue that it regulates pricing and is preempted, and is thereby distinguishable from the Arkansas statute at issue in McClain. This argument falls flat when considering that the Arkansas statute twice mentions "340B drug pricing," unlike the South Dakota statute, and still was deemed in McClain to not be preempted.

Given the parallels between the statutes, Plaintiffs' interpretations of S.B. 154 is at odds with how the Eighth Circuit read the Arkansas and Missouri statutes. Like the statute upheld in McClain, this portion of S.B. 154, codified at SDCL § 58-29G-2, only regulates the delivery[18] of 340B drugs by preventing the imposition of conditions on covered entities to receive access to 340B drugs and not price. See Lopez, 2026 WL 497141, at *7 ("The statute's operation depends on price only because the federal program does—not because Hawai'i is regulating price."). McClain and Hanaway are binding upon this Court and clear that such a state law on delivery to pharmacies is not field preempted by the 340B Program.

18 This Court recognizes that more than delivery is addressed in S.B. 154, the Arkansas statute at issue in McClain, the Missouri statute in the Hanaway decision, the Mississippi statute in Fitch, the Louisiana statute in Murrill and those like it. Those statutes address the silence of federal law on the question and in the wake of Sanofi and Novartis, whether pharmaceutical manufacturers get to impose such things as a one-contract-pharmacy-per-covered-entity rule and to require sharing with them claim and utilization data to assist them in controlling and reducing the amount of drugs sold through the 340B program. Courts of course are ill-equipped to make such policy decisions, which remain in the purview of Congress and, at least to some extent, state legislatures and HHS rule makers.

S.B. 154 contains a provision that the Arkansas statute and the Missouri statute lack, specifically that a "manufacturer may not, directly or indirectly, require a 340B entity or pharmacy to submit any claim or utilization data, as condition for allowing the acquisition of a 340B drug by, or delivery of a 340B drug to, a 340B entity," except for data sharing required by federal law. SDCL § 58-29G-3. McClain directs considering the portion of S.B. 154 codified at SDCL § 58-29G-2 as related to delivery and it would be awkward to characterize SDCL § 58-29G-3 any differently. Both provisions regulate "acquisition of a 340B

drug" and "delivery of a 340B drug." Neither relate to the drug's pricing. And the portion of S.B. 154 restricting "claim or utilization data" expressly allows such claim or utilization data sharing required by federal law and states that nothing in the section prohibits an audit of a 340B entity under federal law.[19] SDCL § 58-29G-3. Plaintiffs have failed to state a claim upon which relief can be granted regarding field preemption as these are foreclosed by McClain and Hanaway.[20]

19 One argument during the motion hearing was that HHS regulations, particular 42 C.F.R. § 10.21, permit claims to the federal Office of Pharmacy Affairs (OPA) by covered entities about not only overcharging, but also "claims that a manufacturer has limited the covered entity's ability to purchase covered outpatient drugs at or below the 340B ceiling price." 42 C.F.R. § 10.21(a)(1). Allowing such claims to the OPA does not render McClain nugatory or trigger preemption.

20 Before the Eighth Circuit ruled in Hanaway, the district courts to have considered field preemption questions in the 340B context post-McClain, including district courts within the Eighth Circuit, ruled against plaintiff manufacturers finding that Congress did not intend for the 340B program to preempt the state statute under a theory of field preemption, and many noted that laws of this kind regulate delivery of 340B drugs, not price. See Brown, No. 1:24-cv-01557, Doc. 59 at 117 (denying preliminary injunction as to Maryland law); Neronha, No. 1:25-cv-00388, Doc. 39 at 56 (same as to Rhode Island law); Frey, 2025 WL 2813787, at *7–8 (same as to Maine law); Fitch, 766 F. Supp. 3d at 665 (same as to Mississippi law); Fitch, 738 F. Supp. 3d at 751–52 (same); Skrmetti, 2025 WL 1805271, at *12–13 (same as to Tennessee law); Bailey, 2025 WL 595189, at *3 (same as to Missouri law); Bailey, 2025 WL 489881, at *4 (same); Bailey, 2025 WL 644285, at *2–3 (same); Murrill, 2024 WL 4361597, at *4–8 (granting summary judgment in favor of state defendants); Fitch, 2024 WL 3503965, at *15–16 (denying preliminary injunction as to Mississippi law); Fitch, 2024 WL 3277365, at *11–12 (same); Weiser, 811 F. Supp. 3d at 1274–77 (denying motion for preliminary injunction as to Colorado law); Frey, 2026 WL 184504, at *8–9 (denying motion for preliminary injunction as to Maine law); Skrmetti, 2026 WL 542712, at *10–11 (granting motion to dismiss). See also Ellison, 2026 WL 445719, at *8–13 (affirming state district court's grant of state respondents' motion to dismiss its complaint challenging Minnesota statute). But see Lopez, No. 1:25-cv-230, Doc. 81 at 16 (finding that plaintiff had sufficiently pleaded allegations of field preemption and denying motion to dismiss).
Those few district courts denying motions to dismiss or granting preliminary injunctions on preemption claims typically relied on the theory of conflict preemption. See Morrisey, 760 F. Supp. 3d at 450–60 (granting preliminary injunction as to West Virginia law); Drummond, 808 F.Supp.3d at 1278 (granting in part motions for preliminary injunction as to Oklahoma law); Brown, 809 F. Supp. 3d at 1358–59 (declining to infer field preemption but finding plaintiff had adequately alleged that Utah law violates the Supremacy Clause under a theory of conflict preemption).

2. Conflict Preemption

***17** Defendants seek to dismiss the conflict preemption claims by again primarily relying on McClain. See Doc. 41 at 20–21 in 3:25-cv-03006-RAL; Doc. 27 at 26 in 4:25-cv-04156-RAL. Defendants argue that, as with the Arkansas statute in McClain, S.B. 154 "helps to fulfill the purpose of the 340B program, as opposed to frustrating it, because S.B. 154 prohibits harmful interference to access the 340B program," and it "does not mandate pricing discounts.... [r]ather, this legislation attempts to deter pharmaceutical manufacturers from interfering with agreements between covered entities and contract pharmacies." Doc. 41 at 20–21 in 3:25-cv-3006-RAL; see also Doc. 27 at 26–28 in 4:25-cv-04156-RAL.

McClain concluded that the statute at issue was not unconstitutional under a theory of obstacle preemption because, as the McClain court saw it, the Arkansas statute assisted in fulfilling the purpose of the 340B program, and Hanaway recently reaffirmed this. 95 F.4th at 1144–45; 180 F.4th at 1113–14.[21] Reviewing whether a state law creates "a sufficient obstacle is a matter of judgment, to be informed by examining the federal statute as a whole and identifying its purpose and intended effects." Crosby v. Nat'l Foreign Trade Council, 530 U.S. 363, 373 (2000). "If the purpose of the act cannot otherwise be accomplished—if its operation within its chosen field else must be frustrated and its provisions be refused their natural effect—the state law must yield to the regulation of Congress within the sphere of its delegated power." Id. (citation omitted). Again, the Eighth Circuit determined that the Arkansas statute did not require manufacturers to provide discounts to pharmacies *themselves*, only covered entities, "[a]s such, the delivery of a covered entity's 340B drugs to contract pharmacies for dispensing creates no obstacle." McClain, 95 F.4th at 1145. Finally, because the state statute's "penalties are aimed at activity that falls outside of the purview of 340B" by "simply deterring" manufacturers from interfering with contracts between covered entities and their

pharmacies, the statute posed no obstacle for manufacturers to comply with both state and federal law. Id. Therefore, "[b]ecause state laws like Arkansas Act 1103 and Missouri S.B. 751 regulate an area beyond the purview of federal law and do not pose an obstacle for drug manufacturers to comply with both federal and state law, such state laws are not conflict preempted." Hanaway, 180 F.4th at 1113–14.[22]

21 As McClain was an appeal of a summary judgment decision, the Eighth Circuit highlighted that PhRMA had additionally presented no evidence of an obstacle. 95 F.4th at 1144–45.

22 The Fifth Circuit has agreed with this position when reviewing a similar statute. Murrill, 180 F.4th at 761–62.

McClain also rejected the argument that the statute was unconstitutional because of impossibility preemption. Id. at 1145. "Impossibility preemption exists when it is 'impossible for a private party to comply with both state and federal requirements,' " id. (quoting PLIVA, Inc. v. Mensing, 564 U.S. 604, 618 (2011)), asks "whether the private party could independently do under federal law what state law requires of it," PLIVA, Inc., 564 U.S. at 620, and "arises when compliance with both federal and state regulations is a physical impossibility," Hillsborough Cnty., 471 U.S. at 713 (cleaned up and citation omitted). Rejecting PhRMA's argument that it was impossible to comply with the state statute regulating delivery and the FDCA's Risk Evaluation and Mitigation Strategies (REMS) Program, 23 U.S.C. § 355-1, the Eighth Circuit noted, "[p]roviders, manufactures, and pharmacies are subject to many legal and regulatory requirements in the area of drug distribution," and "[j]ust because a medication is subject to multiple legal requirements does not make it impossible to comply with" the Arkansas statute governing delivery to pharmacies and the REMS program regulating high-risk products to ensure safe distribution. McClain, 95 F.4th at 1145.[23]

23 The Eighth Circuit explained that the Arkansas statute

> prohibits drug manufacturers from denying 340B covered entities the ability to contract with third-party pharmacies for dispensation of 340B drugs. If a 340B drug is also subject to REMS safety requirements and the covered entity wants to contract with a pharmacy for dispensation, the covered entity bears the responsibility of contracting with a pharmacy that meets the REMS requirements.

McClain, 95 F.4th at 1145.

***18** All Plaintiffs challenge S.B. 154's limitation on claims data as conflicting with manufacturers' abilities to audit covered entities and initiate ADR under the 340B statute. Doc. 44 at 21 in 3:25-cv-03006-RAL; Doc. 43 at 31–32 in 4:25-cv-04156-RAL; Doc. 42 at 44 in 3:25-cv-03021-RAL.[24] As noted above, the 340B Program includes remedial measures. As a part of that remedial scheme, under 42 U.S.C. § 256b(a)(5)(C), a manufacturer may audit a covered entity to ensure that the covered entity or its pharmacy is not engaging in diversion or duplicate discounts. Additionally, a manufacturer is required to "conduct an audit of a covered entity pursuant to subsection (a)(5)(C) as a prerequisite to initiating administrative dispute resolution proceedings against a covered entity." 42 U.S.C. § 256b(d)(3)(B)(iv). But under McClain, a state is "allowed to promulgate rules concerning the delivery and acquisition of 340B drugs based on the silence of the federal 340B program and because the practice of pharmacy is traditionally left to state regulation," including with terms regarding claims data policies. Bailey, 2025 WL 644281, at *3 (dismissing conflict preemption claim for failure to state a claim); Hanaway, 180 F.4th at 1113–14.

24 PhRMA also argues that S.B. 154 is conflict preempted because S.B. 154 eliminates the discretion that the 340B Program grants manufacturers to impose reasonable conditions on their offers, which PhRMA believes was congressional silence reflecting an intentional choice to preclude state regulation, and that S.B. 154 does not help fulfill the purpose of the 340B Program. Doc. 42 at 41–44 at 3:25-cv-3021-RAL. However, these issues were decided contrary to PhRMA's position in McClain, which is binding precedent here. McClain, 95 F.4th at 1144–45.

The text of S.B. 154 does not prevent the limited claims data collection authorized by federal law. Section 4 of S.B. 154 provides,

> A pharmaceutical manufacturer may not, directly or indirectly, require a 340B entity or pharmacy to submit any claim or utilization data, as a condition for allowing the acquisition of a 340B drug by, or delivery of a 340B drug to, a 340B entity, *unless the claim or utilization data sharing is required by federal law.*

> *Nothing in this section prohibits a pharmaceutical manufacturer from conducting an audit of a 340B entity, in accordance with 42 U.S.C. § 256b(a)(5)(C).*

SDCL § 58-29G-3 (emphasis added).

To the extent that any of the Plaintiffs, or their members in the case of PhRMA, may be required to collect certain claims data from covered entities by federal law, S.B. 154 poses no barrier to that data collection. At least two other federal courts have considered a similar issue on a motion for preliminary injunction that stemmed in part from concerns over a drug manufacturer's ability to participate in a Pilot Program, which contemplated limited claims data collection. See Doc. 61 at 10–11 in 3:25-cv-03006-RAL; Weiser, 2025 WL 3041825, at *11–12; Hilgers, 4:25-cv-3089, Doc. 73.[25] The courts in those cases denied the drug manufacturer's request to enjoin similar state statutes on the same grounds as this Court did in its earlier order denying a preliminary injunction. See Weiser, 2025 WL 3041825, at *11–12 (finding that because the Colorado act did not pose a barrier to participation where the state law "does not prohibit a manufacturer from requiring health information or other data that a covered entity is required to furnish to the manufacturer under applicable federal law," the plaintiff drug manufacturer had "not established a substantial likelihood of success that the [state law] 'stands as an obstacle' to the implementation of the Pilot Program"); Hilgers, 4:25-cv-3089, Doc. 73 at 7 (denying motion for preliminary injunction where the Nebraska statute "does not establish a blanket ban on obtaining claims data from covered entities and ... contains a clause that expressly provides that nothing in the Act [ ]shall be construed or applied to conflict with federal law or any other law of the State of Nebraska"). The Colorado statute, the Nebraska statute, and S.B. 154 all contain similar provisions.

25 HRSA is currently considering whether to implement the model rebate pilot program.

***19** S.B. 154 also does not change how audits are conducted on covered entities under § 256b(a)(5). As one court reasoned, "claims data polices that condition the sale of 340B drugs on transfer of data collected at the expenses and effort of covered entities," like the ones that the drug manufacturers allege that they are prevented from including in their initial offers to covered entities, "would be directly contrary to the 340B statutes [sic] provision that audits occur only at the expense of the Secretary or manufacturer." Bailey, 2025 WL 644281, at *3. As another court rejecting the same conflict preemption argument concerning a claims data provision noted, "[b]ecause federal law never expressly *required* covered entities to provide claims data, AbbVie cannot explain how the state law expressly conflicts with federal law." Skrmetti, 2026 WL 542712, at *11 (dismissing conflict preemption claim for failure to state a claim).[26]

26 This observation is particularly relevant where the Tennessee law, like S.B. 154, stipulated that manufacturers could not require the submission of claims or utilization data unless it was explicitly required by federal or state law. Skrmetti, 2026 WL 542712, at *11. Defendants also note, "Between 2019 and 2024, six manufacturers have followed the department's guidelines to request an audit, and each of those requests has been granted." Doc. 48 at 15 in 3:25-cv-03006-RAL (citing 340B Drug Pricing Program; Administrative Dispute Resolution Regulation, 89 Fed. Reg. 28,646 (Apr. 19, 2024)).

AbbVie alleges that there is conflict preemption because S.B. 154 "expressly and impliedly protects the use of the replenishment model" and because "the replenishment model results in diversion," which Section 340B forbids. Doc. 37 ¶ 147 in 3:25-cv-03006-RAL. But S.B. 154 certainly does not mandate, let alone mention, the replenishment model or legalize any activity that is currently forbidden by the 340B Program, like diversion and duplicate discounts. See 42 U.S.C. § 256b(a)(5). Instead, as observed by the Fifth Circuit about a similar law passed in Mississippi challenged in a lawsuit brought by AbbVie,

> [a]s we understand it, AbbVie's grievance is this: it believes that when covered entities are allowed to distribute Section 340B drugs via contract pharmacies, those contract pharmacies cause covered entities to place orders for larger quantities of discounted drugs than they are actually entitled to, and the contract pharmacies then improperly resell those discounted drugs in ways that increase their profits. AbbVie avers that [the Mississippi statute] has the practical effect of allowing this type of illicit activity to occur.
>
> AbbVie is essentially alleging that the real problem with [the statute] is not a *feature* of the law, but rather a *bug*.

Fitch, 152 F.4th at 648 (affirming district court's denial of preliminary injunction, including AbbVie's conflict preemption claim).

Like the statute at issue in McClain, S.B. 154's "penalties are aimed at activity that falls outside the purview of 340B" by "simply deterring" manufacturers from interfering with contracts between covered entities and their pharmacies, and therefore, the statute poses no obstacle for manufacturers to comply with both state and federal law. McClain, 95 F.4th at 1145; Hanaway, 180 F.4th at 1113–14. Additionally, although the Arkansas statute at issue in McClain did not explicitly address claims data, the language is broad enough to contemplate that a drug manufacturer would not be permitted to condition its offer to a covered entity on the kind of claim data submission requirements that all three Plaintiffs wish to deploy. See Ark. Code Ann. § 23-92-604(c). And unlike the subsection upheld as constitutional in McClain, S.B. 154 includes express provisions that claim or utilization data sharing must be provided when it is "required by federal law" and that "[n]othing in this section prohibits a pharmaceutical manufacturer from conducting an audit of a 340B entity, in accordance with 42 U.S.C. § 256b(a)(5)(C)." SDCL § 58-29G-3.

***20** Finally, PhRMA alleges that S.B. 154 "compels manufacturers to allow the purchase of 340B-priced drugs even though the offered conditions were not accepted" and that S.B. 154 conflicts with the federal Medicare Drug Price Negotiation Program in the Inflation Reduction Act because the data claims limitations frustrate a manufacturer's ability to avoid duplicate discounts under the IRA and 340B programs. Doc. 1-1 ¶¶ 169–205 in 3:25-cv-03021-RAL. This argument fails as well.

First, as the Eighth Circuit explained in McClain, it is permissible for a state to regulate the delivery of 340B drugs, which was not held to be compelled purchase in the same context. McClain, 95 F.4th at 1144–45. The Fifth Circuit more directly rejected AbbVie's assertion that a state law regulating delivery was conflict preempted as

> simply incorrect. [The statute] does not expand Section 340B's list of covered entities to include contract pharmacies. By its plain text, [it] requires drug manufacturers to give custody of discounted drugs to contract pharmacies only insofar as they have partnered with covered entities to distribute the drugs to patients. It *does not compel* manufacturers to "offer" discounted drugs to contract pharmacies in the way that Section 340B compels them to "offer" these drugs to covered entities.

Fitch, 152 F.th at 647 (emphasis added).

Second, "[j]ust because a medication is subject to multiple legal requirements does not make it impossible to comply with" both state and federal statutes. McClain, 95 F.4th at 1145. Under 42 U.S.C. § 1320f-2(d), manufacturers must provide access to certain drugs at "maximum fair prices," except for those that are provided under the 340B program (and that 340B price is lower than the "maximum fair price" under the Inflation Reduction Act). For the same reasons that its claims data limitation is constitutionally permissible, S.B. 154 does not conflict with the provisions of the federal Medicare Drug Price Negotiation Program.

S.B. 154 is not unconstitutional under any theory of obstacle preemption advanced by the Plaintiffs relating to the 340B Program itself. If the Arkansas statute in McClain and the Missouri statute in Hanaway can be viewed as assisting in fulfilling the purpose of the 340B program, then so can S.B. 154. See McClain, 95 F.4th at 1144–45; Hanaway, 180 F.4th at 1113–14; see also Lopez, 2026 WL 497141, at *8 ("In short, price governs the economic terms of exchange; delivery governs access. Regulating one does not inherently regulate the other."). Therefore, Plaintiffs have failed to state a claim upon which relief can be granted and Plaintiffs' claims on conflict preemption must be dismissed.[27]

27 Before the Eighth Circuit's opinion in Hanaway, the majority of district courts to have considered conflict preemption questions in the 340B context post-McClain, including district courts within the Eighth Circuit, ruled against plaintiff manufacturers in finding that the state statute is not preempted under a theory of obstacle or conflict preemption. See Brown, No. 1:24-cv-01557, Doc. 59 at 119 (denying preliminary injunction as to Maryland law); Neronha, No. 1:25-cv-00388, Doc. 39 at 56 (same as to Rhode Island law); Frey, 2025 WL 2813787, at *8–12 (same as to Maine law); Fitch, 766 F. Supp. 3d at 663–64 (same as to Mississippi law); Fitch, 738 F. Supp. 3d at 747–51 (same); Skrmetti, 2025 WL 1805271, at *13–17 (same as to Tennessee law); Bailey, 2025 WL 644281, at *2–5 (granting motion to dismiss on conflict preemption claims concerning Missouri law); Bailey, 2025 WL 489881, at *4 (same); Bailey, 2025 WL 595189, at *3 (denying preliminary injunction of Missouri law); Murrill, 2024 WL 4361597, at *8–9 (granting summary judgment in favor of state defendants); Fitch, 2024 WL 3503965, at *8–15 (denying preliminary injunction as to Mississippi law); Fitch, 2024 WL 3277365, at *7–11 (same); Weiser, 811 F. Supp. 3d at 1277–78 (denying motion for preliminary injunction as to

Colorado law); Frey, 2026 WL 184504, at *8–12 (same as to Maine law); Lopez, 2026 WL 497141, at *6–18 (denying motion for preliminary injunction as to Hawaii law on federal preemption claims); Skrmetti, 2026 WL 542712, at *11–12 (granting motion to dismiss); Hilgers, No. 25-cv-03089, Doc. 73 at 7 (denying motion for preliminary injunction as to Nebraska law). See also Ellison, 2026 WL 445719, at *10–11 (affirming state district court's grant of state respondents' motion to dismiss its complaint challenging Minnesota statute).

Five district courts denying motions to dismiss or granting preliminary injunctions on preemption claims relied on a theory of conflict preemption. See Lopez, No. 1:25-cv-230, Doc. 81 at 18 (finding that plaintiff had sufficiently pleaded allegations of conflict preemption and denying motion to dismiss); Morrisey, 760 F. Supp. 3d at 450–60 (granting preliminary injunction as to West Virginia law); Drummond, 808 F. Supp. 3d at 1278 (granting in part motions for preliminary injunction as to Oklahoma law); Brown, 809 F. Supp. 3d at 1355–60 (declining to infer field preemption but finding plaintiff had adequately alleged that Utah law violates the Supremacy Clause under a theory of conflict preemption); Harris, No. 4:24-cv-268, Doc. 141 at 12 (denying judgment on pleadings on conflict preemption claim concerning patent law).

B. Preemption under the Pilot Program

***21** The next question—whether S.B. 154 is an obstacle to drug manufacturer participation and data collection in the federal Pilot Program—was covered in the Order Denying Plaintiff AbbVie's Motion for a Preliminary Injunction. Doc. 61 in 3:25-cv-03006-RAL. The Pilot Program modifies the 340B program for certain drugs, and this Court's previous decision reviewed the origin and policy arguments behind the initiation of the Pilot Program. Id. AbbVie alleges in its Amended Complaint that S.B. 154 prevents it from asking covered entities for prescription-level claims data that it needs to determine which claims for Imbruvica are eligible for a rebate under the Pilot Program. Doc. 37 ¶¶ 159–66 in 3:25-cv-03006-RAL. Without that data, AbbVie argues, it cannot make these determinations and participate in the Pilot Program. Id. ¶ 166. Both PhRMA and AstraZeneca have raised parallel concerns around participation in the Pilot Program and argue that S.B. 154 is preempted but do not raise a separate claim based on the Pilot Program. See Doc. 1-1 ¶ 126 in 3:25-cv-03021-RAL; Doc. 16 ¶ 106 in 4:25-cv-04156.

The Pilot Program's existence and future appears uncertain. On December 29, 2025, the District of Maine preliminarily enjoined the Rebate Model Pilot Program in American Hospital Association v. Kennedy, No. 2:25-cv-600. Am. Hospital Ass'n v. Kennedy, No. 2:25-cv-600 (D. Me. Dec. 29, 2025), Doc. 90. On February 10, 2026, the district court vacated and remanded to HHS the 340B Rebate Model Pilot Program Application Notice, 90 Fed. Reg. 36,163 (Aug. 1, 2025), the Corrected 340B Rebate Model Pilot Program Application Notice, 90 Fed. Reg. 38,165 (Aug. 7, 2025), and the approvals of applications from drug manufacturers submitted pursuant to those notices (announced between October 30 and November 14, 2025). At oral argument, AbbVie's counsel acknowledged that HHS's reconsideration of the Pilot Program renders this claim no longer ripe. Therefore, this Court dismisses the preemption claims based on participation in the Pilot Program as not ripe. Texas v. United States, 523 U.S. 296, 300 (1998) ("A claim is not ripe for adjudication if it rests upon contingent future events that may not occur as anticipated, or indeed may not occur at all." (cleaned up and citation omitted)).

C. Patent Law

AstraZeneca has separately alleged that S.B. 154 is preempted by patent law because S.B. 154 forces manufacturers to offer 340B discounts for unlimited contract pharmacy sales and therefore caps the price and limits the benefits manufacturers can take of their patented drugs' terms, which impermissibly rebalances the "rewards and incentives" embodied in federal patent laws beyond a state's powers. Doc. 16 ¶¶ 127–30 in 4:25-cv-04156-RAL (quoting Biotechnology Indus. Org. (BIO) v. D.C., 496 F.3d 1362, 1372–74 (Fed. Cir. 2007)). More simply, AstraZeneca asserts, "S.B. 154 is preempted by the federal patent laws because it regulates the prices at which patented drugs may be sold." Id. ¶ 91. Defendants seek dismissal of this count by arguing that S.B. 154 is not a price regulation and that there is no forced sale as the 340B Program is entirely voluntary. Doc. 27 at 31–32 in 4:25-cv-04156-RAL.

"[S]tate regulation of intellectual property must yield to the extent that it clashes with the balance struck by Congress in our patent laws." Bonito Boats, Inc. v. Thunder Craft Boats, Inc., 489 U.S. 141, 152 (1989). Yet AstraZeneca has not alleged

that S.B. 154 authorizes any activities generally prohibited under patent law or somehow allows competitors to make or sell AstraZeneca's patented drugs.

AstraZeneca's reliance on BIO is inapt as S.B. 154 does not impermissibly rebalance the rewards and incentives protected by federal patent law. See Lopez, 2026 WL 497141, at *17 (distinguishing BIO because the challenged state statute at issue on 340B drug delivery "leaves the patent bargain intact"). AstraZeneca's argument for preemption under patent law hinges on S.B. 154 capping or fixing the prices at which patented drugs are sold, but as discussed above, S.B. 154 is not a price regulation. See Doc. 16 ¶ 94 in 4:25-cv-04156-RAL; Hanaway, 180 F.4th at 1113 ("State laws like Arkansas Act 1103 and Missouri S.B. 751 do not alter that pricing formula or otherwise set the price of 340B drugs."). See also Brown, No. 1:24-cv-01557, Doc. 59 at 120–21 (denying preliminary injunction on patent claim) ("Even if patented drugs fall within the scope of 340B drugs, HB1056 does not set prices for those drugs. The federal 340B statute does that.")

***22** Unlike the statue at issue in BIO, S.B. 154 "neither caps the price of patented drugs nor penalizes high prices as such, and it applies regardless of whether the drugs are subject to patent." Lopez, 2026 WL 497141, at *17. Any allegations concerning the ability of AstraZeneca to profit from its patent due to covered entities utilizing a greater number of contract pharmacies or those contract pharmacies potentially engaging in diversion or duplication do not stem from "interference with the patent right itself" and separately have a remedy under the federal 340B Program. Id. (citing Pfizer, Inc. v. Heckler, 735 F.2d 1502, 1513 (D.C. Cir. 1984) ("While the patent holder may exercise control over the supply of the product to the market and the number of suppliers, its lawful power to exclude others does not include the power to prevent consumers from responding prudently to any competitive market conditions created by the patent holder.")). Therefore, this count fails to state a claim, and the patent law preemption claim in AstraZeneca's Amended Complaint is dismissed.[28]

28 Of the other courts to consider patent law preemption challenges to similar state laws, seven of the eight decisions known to this Court have decided these issues in favor of state defendants in preliminary rulings relying on the conclusion that these laws do not lower prices on any drugs already discounted under the 340B Program. See Brown, No. 1:24-cv-01557, Doc. 59 at 121 (denying preliminary injunction as to Maryland law); Fitch, 766 F. Supp. 3d at 664–65 (same as to Mississippi law); Fitch, 738 F. Supp. 3d at 752–53 (same); Bailey, 2025 WL 595189, at *2–3 (same as to Missouri law) ("S.B. 751 makes no mention of exclusivity periods, patent terms, or even deals with pricing discounts."); Bailey, 2025 WL 644285, at *2–3 (granting motion to dismiss manufacturer's claims that Missouri law was preempted); Bailey, 2025 WL 489881, at *3 (same); Weiser, 2025 WL 3653161, at *5, *10–11 (denying motion for preliminary injunction as to Colorado law) ("Here, a law that neither caps the price of a patented drug nor specifically targets patented drugs cannot justifiably be found preempted under *BIO*. This is particularly true because such a finding would inhibit Colorado's ability to protect public health, an area long recognized as a traditional police power."); Lopez, 2026 WL 497141, at *17. But see Harris, No. 4:24-cv-268, Doc. 141 at 18 (denying motion on the pleadings on the patent law preemption count).

D. Intergovernmental Immunity Doctrine

In their responses to Defendants' joint motion to dismiss, AstraZeneca and PhRMA both raise a new argument that S.B. 154 is preempted by the Supremacy Clause itself under the intergovernmental immunity doctrine. Doc. 43 at 14 (citing United States v. Washington, 596 U.S. 832, 838 (2022)) in 4:25-cv-4156-RAL; Doc. 42 at 27 (citing Washington, 596 U.S. at 838–39) in 3:25-cv-3021-RAL. AstraZeneca argues S.B. 154 violates the Supremacy Clause itself because it "unconstitutionally discriminates against federal contractors—manufacturers who sign Pharmaceutical Pricing Agreements with the Secretary of HHS to participate in the 340B program—by requiring them (and only them) to sell their products at reduced rates *because of* their contractual relationship with the federal government." Doc. 43 at 14 in 4:25-cv-4156-RAL. PhRMA argues S.B. 154 violates the Supremacy Clause itself because it targets and discriminates against manufacturers based on their entry into PPAs with the federal government, directly regulates and burdens the operations of the federal government, and intrudes on the federal government's core powers by regulating an area of uniquely federal interest. Doc. 42 at 29–37 (citing Washington, 596 U.S. at 838–39; Cassirer v. Thyssen-Bornemisza Collection Found., 596 U.S. 107, 116 (2022)) in 3:25-cv-3021-RAL.

The intergovernmental immunity doctrine is rooted in McCulloch v. Maryland, 17 U.S. 316 (1819). Under the Supremacy Clause, "the States have no power, by taxation or otherwise, to retard, impede, burden, or in any manner control, the operations

of the constitutional laws enacted by congress to carry into execution the powers vested in the general government." McCulloch, 17 U.S. at 436. Over time, this doctrine has evolved from "barring any state law whose 'effect ... was or might be to increase the cost to the Federal Government of performing its functions,' including laws that imposed costs on federal contractors," to "prohibiting state laws that *either* 'regulat[e] the United States directly *or* discriminat[e] against the Federal Government or those with whom it deals' (e.g., contractors)." Washington, 596 U.S. at 838 (first quoting United States v. County of Fresno, 429 U.S. 452, 460 (1977); and then quoting North Dakota v. United States, 495 U.S. 423, 435 (1990) (plurality opinion)).

***23** "[A] state law discriminates against the Federal Government or its contractors if it 'single[s them] out' for less favorable 'treatment,' or if it regulates them unfavorably on some basis related to their governmental 'status.' " Id. at 839 (citing Washington v. United States, 460 U.S. 536, 546 (1983); North Dakota, 495 U.S. at 438 (plurality opinion)). See also Goodyear Atomic Corp. v. Miller, 486 U.S. 174, 181 (1988) (noting that "a federally owned facility performing a federal function is shielded from direct state regulation, even though the federal function is carried out by a private contractor, unless Congress clearly authorizes such regulation"). In Washington, the Court concluded the state law at issue singled out the federal government for unfavorable treatment by on its face only applying to "a person, including a contractor or subcontractor, who was engaged in the performance of work, either directly or indirectly, for the United States," and by imposing costs upon the federal government "that state or private entities do not bear." 596 U.S. at 839 (cleaned up and citation omitted). Because the relevant federal statute did not clearly and unambiguously waive the federal government's immunity from discriminatory state laws, the state law at issue was unconstitutional under the Supremacy Clause. Id. at 844.

AstraZeneca argues that S.B. 154 facially discriminates against manufacturers participating in the 340B Program because "every single relevant provision of the Act depends on the participants' 340B status," and that the statute increases costs for the federal government because "[i]t applies only to manufacturers who participate in the 340B program (not all manufacturers), requiring them to provide discounts to 340B covered entities (not all hospitals) for unlimited sales to pharmacies that contract with covered entities (not all pharmacies)." Doc. 43 at 17 in 4:25-cv-4156-RAL. Further, AstraZeneca argues that S.B. 154 impermissibly requires "qualifications for those doing government work in addition to those that the Government has pronounced sufficient," and threatens to "deny those failing to meet its own qualification the right to perform the functions within the scope of federal authority." Id. at 18 (cleaned up and quoting Geo Grp., Inc. v. Newsom, 50 F.4th 745, 754 (9th Cir. 2022)).

PhRMA likewise argues that S.B. 154 specifically targets and restricts the conduct of manufacturers if and only if they participate in the federal 340B Program. Doc. 42 at 29 in 3:25-cv-3021-RAL. S.B. 154 therefore, PhRMA argues, violates the Supremacy Clause because "states may not 'control' federal operations by directly regulating—let alone discriminating against—those that partner with the federal government to advance federal objectives." Id. at 30 (citing Washington, 596 U.S. at 838–39). PhRMA next argues that "S.B. 154 impermissibly regulates the federal government itself" as it " 'overrides federal contracting decisions' by forcing drug manufacturers to sell their drugs at 340B prices when federal law does not require them to do so" under the PPAs, and it "substantially expand[s] HRSA's regulatory responsibilities." Id. at 32 (quoting GEO Grp., 50 F.4th at 760). PhRMA argues that S.B. 154 similarly interferes with the implementation of a federal program. Id. at 33–34 (citing Forest Park II v. Hadley, 336 F.3d 724, 728–32 (8th Cir. 2003)). Finally, PhRMA argues that S.B. 154 is unconstitutional under the Supremacy Clause because it "intrudes on an enclave of 'uniquely federal interests' .... in defining—clearly—the limits of multiple of its spending programs," including the 340B Program, Medicaid, and Medicare Part B. Id. at 35–37.

In their reply, Defendants quibble with AstraZeneca and PhRMA raising but not expressly pleading in their Complaints the intergovernmental immunity doctrine as an effort to circumvent Federal Rule of Civil Procedure 15 and an untimely amendment to their complaints. Doc. 48 at 9 n.2 in 4:25-cv-04156-RAL. Addressing the merits of the argument, Defendants assert that AstraZeneca and PhRMA have failed to demonstrate that 340B drug manufacturers are federal employees or contractors, and instead, "Plaintiffs are merely participants in a government program." Id. at 10–11. Relying on Astra USA, Inc., Defendants assert that "PPAs are not transactional, bargained-for contracts" and " 'merely "recite" the statutory obligations of manufacturers and the HHS Secretary.' " Id. at 11 (first quoting Astra USA, Inc., 563 U.S. at 113; and then quoting Murrill, 166 F.4th at 535).

***24** The intergovernmental immunity doctrine does not preempt or render S.B. 154 invalid. The allegations in AstraZeneca and PhRMA's Complaints do not support the conclusion that S.B. 154 directly or indirectly regulates the federal government. Nor does the 340B Program render drug manufacturers contractors of the federal government. See Lopez, 2026 WL 497141, at *15. When presented with Plaintiffs' exact intergovernmental immunity argument on a parallel state statute in Hawai'i, the court in Lopez was unconvinced. The Lopez court observed that there was "no persuasive argument" that the Hawai'i statute directly regulated the federal government, and "[a] state enforcement action compelling such a drug manufacturer to stop acting in a certain way within a state's boundaries would directly regulate the manufacturer." Id. at *15. Therefore, the Lopez court reasoned, "if the manufacturer was not acting at the direction or instruction of the federal government, then the manufacturer is being regulated for its own conduct, not for conduct it has undertaken as an instrumentality of the United States." Id. Because the federal government has not required manufacturers to impose certain delivery conditions now prohibited by laws like S.B. 154, the court reasoned these laws are aimed at manufacturers' private conduct. Id. The court also did not foresee that the federal government would bear the costs of the Hawai'i statute. Id. at *16.[29]

29 The court observed,

> [W]hile AstraZeneca makes a persuasive argument that Act 143 is not generally applicable, that argument does not aid AstraZeneca in showing a likelihood of success on the merits, precisely because the question of general applicability is not implicated if the federal government does not bear the financial burden of the state law in the first place. As noted, AstraZeneca has not—at least to this point in the case—shown that the federal government bears, either directly or indirectly, any amount of the costs of Act 143 on the manufacturers. To the contrary, the evidence at this stage suggests that AstraZeneca is bearing these costs entirely itself—which is, in fact, precisely the reason it argues that it faces irreparable injury from Act 143.

Lopez, 2026 WL 497141, at *16.

S.B. 154 differs from instances where state law violated the intergovernmental immunity doctrine. For instance, in Washington, the workers' compensation state law discriminated against "people employed by private companies under contract with the Federal Government" as well as federal employees working to clean up a nuclear site, and imposed costs upon the federal government because "the statute create[d] a causal presumption that certain diseases and illnesses are caused by the cleanup work," and as "the Federal Government pays workers' compensation claims for federal contractors ... [the state] law increases workers' compensation costs for the Federal Government." 596 U.S. at 836, 839 (describing the law as facially applying only to "a person, including a contractor or subcontractor, who was engaged in the performance of work, either directly or indirectly, for the United States"). Similarly, in Goodyear Atomic Corp., the state law at issue there attempted to regulate "a federally owned facility[, which was] performing a federal function ... even though the federal function is carried out by a private contractor." 486 U.S. at 181.[30]

30 In Goodyear Atomic Corp., the Supreme Court concluded that 40 U.S.C. § 290 unambiguously authorized the additional award provision of Ohio's workers' compensation law and therefore did not run afoul of the Supremacy Clause. See 486 U.S. at 186.

The same cannot be said for drug manufacturers participating in the 340B Program. At the core of the drug manufacturers' claims is the concern that S.B. 154 reduces Plaintiffs' ability to restrict the replenishment model and has the effect of expanding the amount of drugs they must sell at a discount under the 340B Program, which in turn reduces the amount of drugs the manufacturers otherwise would sell at the market price in their capacity as private companies. The federal government, however, has not required manufacturers to impose their own conditions on covered entities for delivery to contract pharmacies now frustrated by S.B. 154. In short, S.B. 154 is aimed at manufacturers' private conduct, and AstraZeneca and PhRMA, to the extent their complaints include this claim, do not allege that the federal government would bear the costs of S.B. 154. See Lopez, 2026 WL 497141, at *15–16. Further, for the reasons explained in this Court's analysis of Plaintiffs' field preemption claims, unlike the state statute at issue in Forest Park II, S.B. 154 does not interfere with the 340B Program, see 336 F.3d at 728–32, nor intrude upon a uniquely federal enclave.

***25** For the reasons outlined above, Defendants' Motions to Dismiss AbbVie, AstraZeneca, and PhRMA's preemption claims are granted, and those claims are dismissed.

V. Takings Clause

The Fifth Amendment Takings Clause prohibits the government from taking "private property ... for public use, without just compensation." U.S. Const. amend. V. The "[t]wo kinds of takings are: (1) per se, involving the 'direct government appropriation of or physical invasion of private property'; and (2) regulatory, where a regulation affecting private property 'goes too far.' " Hawkeye Commodity Promotions, Inc. v. Vilsack, 486 F.3d 430, 440 (8th Cir. 2007) (quoting Lingle v. Chevron U.S.A., Inc., 544 U.S. 528, 537–38 (2005) (quoting Pa. Coal Co. v. Mahon, 260 U.S. 393, 415 (1922))); see also Palazzo v. Rhode Island, 533 U.S. 606, 617 (2001) (citing Chicago, B. & Q.R. Co. v. Chicago, 166 U.S. 226 (1897)) (noting that "t[h]e Takings Clause of the Fifth Amendment[ ] [is] applicable to the States though the Fourteenth Amendment"). Per se and regulatory takings entitle the property owner to just compensation. Cedar Point Nursey v. Hassid, 594 U.S. 139, 147–49 (2021); see also Williamson Cnty. Reg'l Plan. Comm'n v. Hamilton Bank of Johnson City, 473 U.S. 172, 194 (1985), overruled on other grounds by Knick v. Twp. of Scott, Pa., 588 U.S. 180 (2019) ("The Fifth Amendment does not proscribe the taking of property; it proscribes taking without just compensation.").

However, when a plaintiff "voluntarily [chooses] to participate" in a federal program, Se. Ark. Hospice, Inc. v. Burwell, 815 F.3d 448, 450 (8th Cir. 2016), "[t]his voluntariness forecloses the possibility that the statute could result in an imposed taking of private property which would give rise to the constitutional right of just compensation ...." Minn. Ass'n of Health Care Facilities, Inc. v. Minn. Dep't of Pub. Welfare, 742 F.2d 442, 446 (8th Cir. 1984). See also Ruckelshaus v. Monsanto Co., 467 U.S. 986, 1007 (1984); Garelick v. Sullivan, 987 F.2d 913, 916 (2d Cir. 1993) ("[W]here a service provider voluntarily participates in a price-regulated program or activity, there is no legal compulsion to provide service and thus there can be no taking."). Participation is voluntary even if "business realities" motivate that decision to participate. Minn. Ass'n of Health Care Facilities, Inc., 742 F.2d at 446 ("Despite the strong financial inducement to participate in Medicaid, a nursing home's decision to do so is nonetheless voluntary."). Defendants assert that Plaintiffs AbbVie and AstraZeneca[31] fail to state a claim that S.B. 154 violates the Takings Clause of the Fifth Amendment, as incorporated to the states by the Fourteenth Amendment. Doc. 41 at 14–18 in 3:25-cv-03006-RAL and Doc. 27 at 38–44 in 4:25-cv-04156-RAL.

31 Plaintiff PhRMA did not challenge S.B. 154 as unconstitutional under the Takings Clause. See Doc. 1-1 in 3:25-cv-03021-RAL.

A. Neither AbbVie nor AstraZeneca Have Shown a Per Se Taking

Both AbbVie and AstraZeneca allege that S.B. 154 violates the Takings Clause because it results in a forced transfer of private property from the manufacturers to the pharmacies without just compensation. See Doc. 37 ¶¶ 132–37 in 3:25-cv-3006-RAL; Doc. 16 ¶¶ 121–26, 142–47 in 4:25-cv-4156-RAL. However, S.B. 154 does not result in a per se taking because S.B. 154 does not require any additional sales of 340B drugs outside of the federal 340B Program, which both AbbVie and AstraZeneca voluntarily chose to participate in.

***26** "A per se taking occurs '[w]hen the government physically acquires private property for a public use,' including 'when the government physically takes possession of property without acquiring title to it.' " Astrazenca Pharms. LP v. Bailey, No. 2:24-cv-04143, 2025 WL 644285, at *4 (WD. Mo. Feb. 27, 2025) (quoting Cedar Point Nursey, 594 U.S. at 147). A per se taking can occur even if the government itself does not physically take possession of the property but rather forces an A to B transfer of private property for the benefit of a particular private party without serving a broader public purpose. See Kelo v. City of New London, 545 U.S. 469, 477–80 (2005) (highlighting that "it has long been accepted that the 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" and that "it is equally clear that a State may transfer property from one private party to another if future 'use by the public' is the purpose of the taking").

The majority of district courts reviewing the constitutionality of similar state statutes challenged by pharmaceutical manufacturers have concluded that no per se taking occurs when state laws require manufacturers to deliver 340B-priced drugs to covered entities under the relevant federal law and in turn to those covered entities' contract pharmacies. See Neronha, No. 1:25-cv-387, Doc. 39 at 57[32]; Bailey, 2025 WL 644285, at *4; Murrill, 2024 WL 4361597, at *14–15 (W.D. La. Sep. 30, 2024).

aff'd, 180 F.4th 747 (5th Cir. 2026); Fitch, 2024 WL 3503965, at *16–20, aff'd, 2025 WL 2630900 (5th Cir. Sep. 12, 2025) (per curiam), and aff'd, 152 F.4th 635 (5th Cir. 2025) (per curiam); Frey, 2025 WL 2813787, at *14; Weiser, 811 F. Supp. 3d at 1281–83; see also Skrmetti, 2025 WL 1805271, at *7–10, 19–20 (finding that AbbVie does not have standing to challenge the section of the Tennessee state law it argued allowed for an unconstitutional taking because of the statute's grandfather clause but noting that it was persuaded by other holdings rejecting nearly identical takings challenges). But see Brown, 809 F. Supp. 3d at 1360–62, 1362 n.142 (D. Utah 2025); Drummond, 808 F. Supp. 3d at 1279–80; Lopez, No. 1:25-cv-230, Doc. 81 at 21 (finding that plaintiff had sufficiently pleaded allegations of a per se taking and denying motion to dismiss); Harris, No. 4:24-cv-268, Doc. 141 at 17–18 (finding that plaintiff had sufficiently pleaded allegations of a per se taking and denying motion for judgment on the pleadings).[33] Four of the courts rested on the manufacturers' voluntary 340B Program participation in finding that the laws did not present an unconstitutional taking. See Neronha, No. 1:25-cv-388, Doc. 39 at 57 ("Voluntary government programs like the 340B program do not give rise to unconstitutional takings."); Bailey, 2025 WL 644285, at *4 ("Plaintiff voluntarily chose to participate in a federal program, and as Eighth Circuit precedent has noted, it forecloses the possibility that the federal 340B program, or S.B. 751, results in an imposed taking of private property which would give right to the constitutional right of just compensation."); Frey, 2025 WL 2813787, at *14 ("Because AbbVie can choose not to participate in the 340B program, AbbVie has not demonstrated a likelihood of success on its takings claim."); Weiser, 811 F. Supp. 3d at 1282 (finding "AbbVie's voluntary participation in the 340B program ... to present a nearly insurmountable obstacle to the success of their Takings claim."). Though the weight of authority is against allowing a per se takings claim to proceed in such a case, this Court will analyze AbbVie and AstraZeneca's per se takings claims.

32 The Honorable John J. McConnell, Jr., Chief Judge of the District of Rhode Island, made the following finding on the record at the preliminary injunction hearing in the case before him:

> AbbVie believes that it is compelled to make sales at 340B discounted prices to private third parties and is being forced to follow a state law for which it receives no benefit. The obligation to sell drugs is to covered entities at discounted prices, however, is a consequence of AbbVie's voluntary participation in the 340B program, not the Rhode Island law. Voluntary government programs like the 340B program do not give rise to unconstitutional takings.

Neronha, No. 1:25-cv-387, Doc. 39 at 57. See also Brown, No. 1:24-cv-01557, Doc. 59 at 108–09 (denying preliminary injunction as to Maryland law).

33 Of the decisions that found that the state statute at issue effected a taking without just compensation in violation of the Fifth Amendment as incorporated by the Fourteenth Amendment, the District of Utah decision is distinguishable from the issue presented at hand because the text of the Utah statute differs in meaningful ways from that of S.B. 154. See Brown, 809 F. Supp. 3d at 1360–62, 1362 n.142. The Utah statute expands the relevant definition of "340B entity" to include a pharmacy contracting with a 340B entity as opposed to the more limited federal definition for 340B entities, primarily medical clinics and hospitals serving low-income patients, contained in 42 U.S.C. § 256b(a)(4). Compare Utah Code § 31A-46-102(3) (defining "340B entity" to include "a pharmacy of an entity participating in the 340B drug discount program" or "a pharmacy contracting with an entity participating in the 340B drug discount program") with SDCL § 58-29G-1(2), (5) (defining "pharmacy" as "any place within or outside this state, licensed by the State Board of Pharmacy, where drugs are dispensed, and pharmaceutical care is provided to residents of this state" and "340B entity" as "a covered entity as defined in 42 U.S.C. § 256b(a)(4) (January 1, 2025)").

Neither the court in Drummond nor Lopez is bound by relevant Eighth Circuit precedent on the voluntary participation doctrine. See Drummond, 808 F. Supp. 3d at 1280; Lopez, No. 1:25-cv-230, Doc. 81 at 21. The court in Harris, which is bound by Eighth Circuit precedent, agreed that voluntary participation in a federal program forecloses a takings clause. Harris, No. 4:24-cv-268, Doc. 141 at 16–17 (citing Ark. Hospice, 815 F.3d at 450; Minn. Ass'n of Health Care Facilities, 742 F.2d at 446). However, the Harris court concluded that the plaintiff had sufficiently alleged a claim under the Takings Clause by raising a genuine question as to whether its participation should be considered involuntary with respect to the Arkansas statute at issue. Id. As explained below, this Court respectfully disagrees with the reasoning and conclusions in Harris, Drummond, and Lopez.

***27** Both AbbVie and AstraZeneca frame S.B. 154 as compelling increased sales at discount prices to other private parties, which qualifies as a per se taking. See Doc. 44 at 12–16 in 3:25-cv-03006-RAL; Doc. 43 at 41–42 in 4:25-cv-4156-RAL. AbbVie and AstraZeneca argue that they are permitted under federal law to include reasonable non-price terms in 340B offers. See Doc. 44 at 13–15 in 3:25-cv-3006-RAL (citing Novartis, 102 F.4th at 460; Sanofi, 58 F.4th at 703); Doc. 43 at 43 in 4:25-cv-4156-RAL (citing Sanofi, 58 F.4th at 703). AbbVie and AstraZeneca further argue that the voluntary participation doctrine does not apply because South Dakota has offered no benefit in exchange for this taking, South Dakota may not impose new conditions

on participation in a federal program, and neither AbbVie nor AstraZeneca have voluntarily chosen to participate in the 340B program in South Dakota specifically. See Doc. 44 at 16–18 in 3:25-cv-03006-RAL; Doc. 43 at 43 in 4:25-cv-04156-RAL (citing Drummond, 808 F. Supp. 3d at 1279). Finally, AbbVie argues that even assuming South Dakota has extended a benefit in exchange for its property, South Dakota lacks a legitimate interest that bears an essential nexus and rough proportionality to the impact of the proposed use of the property, and any dispute about who benefits from the law supports allowing the case to proceed to discovery rather than dismissal. See Doc. 44 at 18–19 in 3:25-cv-03006-RAL (citing Cedar Point Nursey, 594 U.S. at 161).

First, under S.B. 154, neither AbbVie nor AstraZeneca is required to sell any additional medications beyond the ones authorized under Section 340B to the appropriate covered entities, as defined in 42 U.S.C. § 256b(a)(4), and therefore, there is no per se taking. See Fitch, 152 F.4th at 643; see also Murrill, 180 F.4th at 763 (no physical taking as the statute "applies only '*after* [covered entities] have purchased' the discounted drugs and directed their delivery" (quoting Fitch, 152 F.4th at 643)).[34] Second, as discussed in McClain, despite the Third Circuit's holding in Sanofi Aventis that *federal* law did not impose an obligation on participating 340B manufacturers to sell to an unlimited number of pharmacies, a state may constitutionally impose delivery obligations on manufacturers in a state law that is not otherwise preempted. See McClain, 95 F.4th 1142–46.

34 The covered entities serve certain patients eligible for 340B-priced drugs, whom they then provide with those drugs at one or more pharmacies. The number of pharmacies that a covered entity contracts with, or any limitations placed by S.B. 154 on delivery, do not increase the number of eligible patients at 340B covered entities who are permitted under the federal statutes to access a drug at the lower price negotiated by the federal government *or* the price of those drugs under 340B. Although AbbVie alleges numerous and concerning issues relating to apparent widespread abuses of the 340B statutory scheme, "AbbVie has more likely identified a public policy issue, and not a Takings Clause violation." Weiser, 811 F. Supp. 3d at 1283.

As the Western District of Louisiana court observed, Plaintiffs' characterization of the state statute "as compelling direct, confiscatory sales to private pharmacies" is incorrect because the 340B-priced "[d]iscounted drugs are sold to *covered entities* under the terms and conditions of the PPAs and the Section 340B program—they are not sold to pharmacies that enter into contracts to dispense the drugs on behalf of covered entities." Murrill, 2024 WL 4361597, at *14, aff'd, 180 F.4th 747. The Louisiana statute, like the South Dakota statute at issue here, "only prevents pharmaceutical companies from restricting the ability of covered entities to contract with multiple pharmacies to dispense Section 340B drugs to their patients," and therefore, because the state statues "do[ ] not compel Plaintiffs to directly sell 340B drugs to pharmacies, it is not a taking for purposes of the Takings Clause." Id. See also Hanaway, 180 F.4th at 1113–14. Affirming the district court's conclusion that the similar Mississippi statute did not violate the Takings Clause, the Fifth Circuit noted that the statute "does not impose on drug manufacturers a positive obligation to directly transfer or sell their drugs to anyone[ ] [n]or does it require them to sell larger quantities of their drugs at discounted prices than Section 340B requires and thereby deprive them of sales at full market price." Fitch, 152 F.4th at 643. Therefore, because the drug manufacturer "still receives payment of the full discounted amounts to which it is entitled under Section 340B," a statute imposing "a negative obligation of non-interference with covered entities' arrangements with contract pharmacies" does not effectuate a physical taking. Id.

***28** Under S.B. 154, a manufacturer is not required to sell any additional drugs beyond the ones authorized under Section 340B to the appropriate covered entities, as defined in 42 U.S.C. § 256b(a)(4). Fitch, 152 F.4th at 643. As noted by the Southern District of Mississippi, "§ 256b's text does not prohibit distribution through contract pharmacies, and that such distribution has long been understood not to constitute diversion," and "entities, under any distribution system, must comply with the statutory prohibition against diversion [and duplicate discounts.]" Fitch, 2024 WL 3503965, at *14–15 (quoting August 1996 Guidance at 43,549–43,550). Therefore, S.B. 154 does not effectuate a per se taking.

Finally, AbbVie and AstraZeneca's per se takings claims are foreclosed by the voluntary participation doctrine under relevant Eighth Circuit precedent. Bailey, 2025 WL 644285, at *4 (citing Se. Ark. Hospice, Inc., 815 F.3d at 450) (granting motion to dismiss on physical appropriation claim). Like the plaintiffs in Bailey, Southeast Arkansas Hospice, and Minnesota Association of Health Care Facilities, AbbVie and AstraZeneca opted into the 340B program by signing the PPA agreement to offer their drugs to covered entities at the 340B price, and the subsequent state law tied to that 340B program imposing delivery

requirements on AbbVie does not constitute an imposed taking of private property. See Hanaway, 180 F.4th at 1102 ("Drug manufacturers' participation in the 340B Program is voluntary."). And AbbVie and AstraZeneca's participation is voluntary even if "business realities" motivate that decision to participate. See Minn. Ass'n of Health Care Facilities, Inc., 742 F.2d at 446 ("Despite the strong financial inducement to participate in Medicaid, a nursing home's decision to do so is nonetheless voluntary."); Hanaway, 180 F.4th at 1102 ("In exchange for offering 340B drugs to covered entities at these steep discounts, drug manufacturers receive access to lucrative Medicare and Medicaid markets." (citing 42 U.S.C. § 1396r-8(a)(1), (5))).[35] AbbVie and AstraZeneca voluntarily participate in the 340B program, and "[w]hen an entity voluntarily participates in a federal program, it forecloses the possibility that the statute could result in an imposed taking of private property which would give rise to the constitutional right of just compensation." Bailey, 2025 WL 644285, at *4 (citing Se. Ark. Hospice, Inc., 815 F.3d at 450) (granting motion to dismiss on physical appropriation claim); see also Brown, No. 1:24-cv-01557, Doc. 59 at 108; Neronha, No. 1:25-cv-387, Doc. 39 at 57; Murrill, 2024 WL 4361597, at *15; Frey, 2025 WL 2813787, at *14; Weiser, 811 F. Supp. 3d at 1282. Therefore, even taking the well-pleaded allegations in the Complaints as true, AbbVie and AstraZeneca have failed to state a claim of a per se taking.

35 AbbVie unsuccessfully seeks to distinguish Minnesota Association of Health Care Facilities as concerning a state statute "where nursing homes voluntarily participated in ***state*** Medicaid program." See Doc. 44 at 17 in 3:35-cv-03006-RAL (citing Minn. Ass'n of Health Care Facilities, Inc., 742 F.2d at 444–46) (emphasis in original). First, a state Medicaid program is a joint federal and state government program. See Minn. Ass'n of Health Care Facilities, Inc., 742 F.2d at 444–46; see also Md. Dep't of Health & Mental Hygiene v. Ctrs. For Medicare & Medicaid Servs., 542 F.3d 424, 429 (4th Cir. 2008) ("Designed to provide medical assistance to persons whose income and resources are insufficient to meet the costs of necessary medical care, the Medicaid program functions as a partnership between the federal government and the states.") (citing 42 U.S.C. § 1396a(a)(10)). The Second Circuit was not persuaded by a similar argument in Garelick, noting that "even if the alleged compulsion to serve Medicare patients [from New York state law] were imputed to the federal government, the ... takings claim would fail" because "physicians are required to provide services to Medicare beneficiaries only if they practice in hospitals," so "anesthesiologists can avoid treating Medicare beneficiaries by practicing on an outpatient basis." 987 F.2d at 917. "[A]s the law presently stands, economic hardship is not equivalent to legal compulsion for purposes of takings analysis." Id. Finally, Bailey, the other 340B Program takings decision in this circuit, similarly relied on Arkansas Hospice, Inc. and Minnesota Association of Health Care Facilities to find that Eighth Circuit precedent foreclosed the plaintiff pharmaceutical manufacturer's per se takings claim given its voluntary participation in the federal 340B program. 2025 WL 644285, at *4.
AbbVie further relies on an out-of-circuit district court case, Virginia Hospital & Healthcare Association v. Roberts, to argue that while Defendants may have explained why the federal government may not be liable under the Takings Clause, they have failed to address South Dakota's liability. Doc. 44 at 17–18 in 3:25-cv-03006-RAL (citing Va. Hosp. & Healthcare Ass'n v. Roberts, 671 F. Supp. 3d 633, 644, *666* (E.D. Va. 2023) as "recognizing that the voluntariness of a federal program does not establish that a state law is voluntary for purposes of the Takings Clause"). But Roberts is distinguishable given the notable differences between S.B. 154, which mandates delivery to all contract pharmacies of a 340B covered entity for manufacturers already voluntarily participating in the 340B program, and the Virginia COPN program, which "legally compels any healthcare system with an acute care hospital in Virginia to participate in Medicare and Medicaid." Roberts, 671 F. Supp. 3d at 667. See also Weiser, 811 F. Supp. 3d at 1283 (distinguishing Roberts by noting "[t]here, the plaintiffs' Takings Clause claim was based on the contention that the Virginia program at issue 'legally compelled [them] to participate in Medicaid and Medicare programs,' " but "AbbVie does not argue [here] that the Act purports to compel its participation in the 340B Program").

B. Neither AbbVie nor AstraZeneca Have Shown a Regulatory Taking

***29** Both AbbVie and AstraZeneca plead in the alternative that S.B. 154 violates the Takings Clause as a regulatory taking. See Doc. 37 ¶¶ 138–40 in 3:25-cv-3006-RAL; Doc. 16 ¶ 146 in 4:25-cv-4156-RAL. However, S.B. 154 does not deprive AbbVie or AstraZeneca of all economically beneficial uses, and therefore, AbbVie and AstraZeneca have failed to state a claim for a regulatory taking.

"[W]hile property may be regulated to a certain extent, if regulation goes too far it will be recognized as a taking." Pa. Coal Co. v. Mahon, 260 U.S. 393, 415 (1922). A law effectuates a regulatory taking when it "goes too far" in "impos[ing] regulations that restrict an owner's ability to use his own property." Cedar Point Nursery, 594 U.S. at 148. Courts consider the following factors under the Penn Central balancing test to determine whether a regulation constitutes a taking: (1) "[t]he economic impact of the

regulation on the claimant," (2) "the extent to which the regulation has interfered with distinct investment-backed expectations," and (3) "the character of the government action." Penn Cent. Transp. Co. v. City of New York, 438 U.S. 104, 124 (1978); Cedar Point Nursery, 594 U.S. at 148; see, e.g., Becker v. City of Hillsboro, Missouri, 125 F.4th 844, 857–59 (8th Cir.), cert. denied, 145 S. Ct. 2777 (2025) (applying Penn Central test).

To the extent that the regulatory takings doctrine applies,[36] AbbVie argues that it has stated a plausible claim under the Penn Central factors, namely

> (1) S.B. 154 imposes significant financial losses on AbbVie and other manufacturers, (2) S.B. 154 interferes with drug manufacturers' reasonable investment backed expectations, and (3) S.B. 154 serves no valid government purpose because it deprives manufacturers of the full use and control of their property on a continual basis for the commercial benefit of private parties.

Doc. 44 at 20 in 3:25-cv-03006-RAL (quoting Doc. 37 ¶ 140) (quotation marks omitted). AstraZeneca's regulatory takings claim is similar. See Doc. 16 ¶ 146 in 4:25-cv-4156-RAL.

36 AbbVie pleads in the alternative that S.B. 154 effectuates a "partial regulatory taking." Doc. 44 at 19 in 3:25-cv-3006-RAL.

In terms of the first factor, AbbVie argues that "S.B. 154 compels a higher number of discounted sales," however, nothing in the text of S.B. 154 changes anything about the definition or eligibility of the covered entities themselves, who are entitled to prescription medications at the 340B price, or the patients at the covered entities, who are the only ones eligible to receive the discounted drugs under the 340B program.[37] Doc. 44 at 20 in 3:25-cv-03006-RAL. The Amended Complaints by AbbVie and AstraZeneca invite this Court to read S.B. 154 as endorsing and illicitly furthering "the replenishment model," but diversion and duplicate discounts are specifically disallowed under the federal statutory scheme. Even taking the well-pleaded allegations as true that the manufacturers will have to provide a greater quantity of drugs at a discount price due to S.B. 154, as the Fifth Circuit concluded in its analysis of a nearly identical law under this factor, "for most drugs, manufacturers will still receive a large percentage of the market price," and therefore, this factor weighs against a finding of a regulatory taking. Fitch, 152 F.4th at 644 (reviewing Mississippi law); Murrill, 180 F.4th at 762–64 (relying on Fitch to reach same conclusion as to Louisiana law).

37 AstraZeneca's argument in its response to Defendants' Motion to Dismiss focuses primarily on its per se taking claim. See Doc. 43 at 39–42 in 4:25-cv-4156-RAL.

***30** Turning to the second factor, the extent to which the advent of S.B. 154 "has interfered with distinct investment-backed expectations" also does not weigh in favor of Plaintiffs. HHS first approved the use of contract pharmacies in 1996, and then lifted limitations on that use as early as 2010 when it allowed covered entities to contract with multiple pharmacies. 61 Fed. Reg. 43,549 (Aug. 23, 1996); Sanofi, 58 F.4th at 700 (citing 75 Fed. Reg. 10,272 (Mar. 5, 2010)). Therefore, S.B. 154 does not significantly interfere with investment-backed expectations. See also Fitch, 152 F.4th at 644; Murrill, 180 F.4th at 762–64; see also Fitch, 2024 WL 3503965, at *20 (quoting Pace Res., Inc. v. Shrewsbury Two., 808 F.2d 1023, 1033 (3d Cir. 1987) ("[I]nvestment-backed expectations are reasonable only if they take into account the power of the state to regulate in the public interest.")).

Finally, "the character of the government action" weighs against the Plaintiffs' arguments. S.B. 154 imposes restrictions on the delivery of medications to ensure that covered entities in South Dakota may use multiple contract pharmacies to serve their patients. See Doc. 41 at 16 in 3:25-cv-3006-RAL. This law and others similar to it seek to "ensur[e] that low-income and rural patients have access to discounted medications." Murrill, 180 F.4th at 764; see also Fitch, 152 F.4th at 644.

Again, other district courts that have confronted this exact question concerning similar state laws have found that these laws do not amount to a regulatory taking, and two of those decisions have now been affirmed on appeal. Bailey, 2025 WL 644285, at *6; Murrill, 2024 WL 4361597, at *15, aff'd, 180 F.4th 747; Fitch, 2024 WL 3503965, at *20, aff'd, 152 F.4th 635. But see Lopez, No. 1:25-cv-230, Doc. 81 at 21–22 (finding that plaintiff had sufficiently pleaded allegations of a regulatory taking and denying motion to dismiss); Harris, No. 4:24-cv-268, Doc. 141 at 18 (finding that plaintiff had sufficiently pleaded allegations

of a regulatory taking and denying motion for judgment on the pleadings). As with the per se takings claim, AbbVie and AstraZeneca's voluntary participation in the 340B Program forecloses the "possibility that the statute could result in an imposed taking of private property which would give rise to the constitutional right of just compensation." Minn. Ass'n of Health Care Facilities, Inc., 742 F.2d at 446. Even taking the allegations as true for the purposes of a motion to dismiss, the Plaintiffs have failed to state a claim of a regulatory taking.

For the reasons stated above, the Defendants' Motions to Dismiss AbbVie's Takings Claim, its First Claim for Relief, and AstraZeneca's Takings Claim, its Fourth Claim for Relief, are granted.

VI. Dormant Commerce Clause

"The Commerce Clause grants Congress the power '[t]o regulate Commerce ... among the several States." Ass'n for Accessible Meds. v. Ellison, 140 F.4th 957, 959 (8th Cir. 2025) (quoting U.S. Const. art. I, § 8, cl. 3). In addition to a "positive grant of power to Congress," "this Clause also prohibits state laws that unduly restrict interstate commerce," which doctrine is known as the dormant Commerce Clause. Tenn. Wine & Spirits Retailers Ass'n v. Thomas, 588 U.S. 504, 514 (2019) (cleaned up and citation omitted). A state may violate the dormant Commerce Clause in three ways: "(1) clearly discriminat[ing] against interstate commerce in favor of in-state commerce, (2) impos[ing] a burden on interstate commerce that outweighs any benefits received, or (3) ha[ving] the practical effect of extraterritorial control on interstate commerce." Ass'n for Accessible Meds., 140 F.4th at 960 (quoting Styczinski v. Arnold, 46 F.4th 907, 912 (8th Cir. 2022) (cleaned up) (citation omitted)). "Preventing state officials from enforcing a democratically adopted state law in the name of the dormant Commerce Clause is a matter of 'extreme delicacy,' something courts should do only where the infraction is clear." Nat'l Pork Producers Council v. Ross, 598 U.S. 356, 390 (2023) (cleaned up and citation omitted).

***31** AbbVie alleges that S.B. 154 violates the dormant Commerce Clause by discriminating against interstate commerce in favor of in-state commerce, imposing a burden on interstate commerce that outweighs any conceivable benefit to in-state commerce, and having the practical effect of extraterritorial control on interstate commerce. Doc. 37 ¶¶ 167–83 in 3:25-cv-03006-RAL. PhRMA alleges that S.B. 154 constitutes unconstitutional extraterritorial regulation in violation of the dormant Commerce Clause, including references to alleged discrimination and undue burden. Doc. 1-1 ¶¶ 206–18 in 3:25-cv-3021-RAL. Defendants argue that Plaintiffs AbbVie and PhRMA fail to state a claim regarding the dormant Commerce Clause because the law does not regulate price and South Dakota laws are interpreted to apply within South Dakota unless the legislature has clearly expressed an alternate intent. Doc. 41 at 25–30 in 3:25-cv-03006-RAL (citing Knapp v. Hamm & Phillips Serv. Co., 824 N.W.2d 785, 789 (S.D. 2012)); Doc. 23 at 35–38 in 3:25-cv-3021-RAL (citing Knapp, 824 N.W.2d at 789). Each of Plaintiffs' dormant Commerce Clause claims fail based on the reasoning in Hanaway, 180 F.4th 1097.

A. Discrimination

AbbVie and PhRMA argue that S.B. 154 is discriminatory in violation of the dormant Commerce Clause because it privileges in-state hospitals over out-of-state manufacturers. See Doc. 44 at 29 (citing Doc. 37 ¶ 172) in 3:25-cv-3006-RAL; Doc. 1-1 ¶ 216 in 3:25-cv-3021-RAL (alleging S.B. 154 is discriminatory and "privileges in-state interests by providing them monetary benefit not contemplated by Congress, while imposing a significant burden on out-of-state manufacturers"). "Discrimination in this context refers to 'differential treatment of in-state and out-of-state economic interests that benefits the former and burdens the latter.' " S.D. Farm Bureau, Inc. v. Hazeltine, 340 F.3d 583, 593 (8th Cir. 2003) (quoting Waste Sys., Inc. v. Dep't of Envtl. Quality, 511 U.S. 93, 99 (1994)). The Supreme Court has recognized three indicators of discrimination: (1) "where the evidence in the record demonstrates that the law has a discriminatory purpose"; (2) where the law "facially discriminate[s] against out-of-state interests"; or (3) where the law has "a discriminatory effect." Id. (citing Bacchus Imports, Ltd. v. Dias, 468 U.S. 263, 270 (1984); Chem. Waste Mgmt. v. Hunt, 504 U.S. 334, 342 (1992); Maine v. Taylor, 477 U.S. 131, 148 n.19 (1986)). If the law is "discriminatory, it is '*per se* invalid' unless the Defendants 'can demonstrate, under rigorous scrutiny, that [they have]

no other means to advance a legitimate local interest.' " Id. (quoting C & A Carbone, Inc. v. Town of Clarkstown, N.Y., 511 U.S. 383, 392 (1994)).

The dormant "Commerce Clause prohibits the enforcement of state laws driven by ... economic protectionism—that is, regulatory measures designed to benefit in-state economic interests by burdening out-of-state competitors." Nat'l Pork Producers Council, 598 U.S. at 369 (cleaned up and citation omitted). One "fundamental element of dormant Commerce Clause jurisprudence [is] the principle that 'any notion of discrimination assumes a comparison of substantially similar entities.' " Dep't of Revenue of Ky. v. Davis, 553 U.S. 328, 342 (2008) (United Haulers Ass'n, Inc. v. Oneida-Herkimer Solid Waste Mgmt. Auth., 550 U.S. 330, 342 (2007)). "[W]hen the allegedly competing entities provide different products, as here, there is a threshold question whether the companies are indeed similarly situated for constitutional purposes." Gen. Motors Corp. v. Tracy, 519 U.S. 278, 299 (1997).

The Eighth Circuit in Hanaway recently said a parallel state statute regulating 340B drug delivery did "not facially discriminate against interstate commerce because it does not refer to in-state or out-of-state manufacturers or otherwise indicate a preference for in-state entities." 180 F.4th at 1108 (comparing Mo. Rev. Stat. § 376.414.2 (applying equally to all pharmaceutical manufacturers, their agents, and affiliates) with Healy v. Beer Inst., Inc., 491 U.S. 324, 341 (1989) (invalidating statute that "applies solely to interstate brewers or shippers of beer" and not to "brewers and shippers engaging in solely domestic sales")). The Eighth Circuit disagreed with the drug manufacturer's argument that "because no drug manufacturers have a physical presence in Missouri, the entire burden of S.B. 751 falls on out-of-state commerce," and instead concluded, "[b]ecause Missouri's entire prescription drug supply comes from out-of-state, 'such claims of disparate treatment between interstate and local commerce [are] meritless.' " Id. (quoting Exxon Corp. v. Governor of Md., 437 U.S. 117, 125 (1978) (holding that a Maryland law prohibiting fuel producers and refiners from operating retail service stations did not discriminate against interstate commerce when there were no producers or refiners of gasoline within the state)). The Eighth Circuit also rejected the pharmaceutical manufacturer's attempt to compare in-state hospitals and pharmacies with out-of-state drug manufacturers because "[d]rug manufacturers, hospitals, and pharmacies, while all part of an interconnected healthcare system, are not substantially similar such that they can be said to operate in economic competition with one another." Id. at 1109. The Eighth Circuit concluded in Hanaway that the pharmaceutical manufacturer had not shown a discriminatory purpose or effect as the Missouri statute "regulates the distribution of 340B drugs without affecting their price," and thus the statute did not discriminate against out-of-state economic interests or affect the price of 340B drugs. Id.

***32** S.B. 154, like the Missouri statute at issue in Hanaway, does "not facially discriminate against interstate commerce because it does not refer to in-state or out-of-state manufacturers or otherwise indicate a preference for in-state entities." Id. at 1108. S.B. 154 "does not make any distinction between in-state and out-of-state" entities, "thus avoiding violation of the dormant Commerce Clause" on discrimination grounds. Grand River Enters. Six Nations, Ltd., 574 F.3d at 942; Hanaway, 180 F.4th at 1108. Plaintiffs' groupings of in-state hospitals and pharmacies against out-of-state manufacturers are not "substantially similar entities" because "the allegedly competing entities provide different products." Gen. Motors Corp., 519 U.S. at 298–99; see also id. at 300 ("Thus, in the absence of actual or prospective competition between the supposedly favored and disfavored entities in a single market there can be no local preference, whether by express discrimination against interstate commerce or undue burden upon it, to which the dormant Commerce Clause may apply."); Hanaway, 180 F.4th at 1108. Finally, S.B. 154 does not discriminate against interstate commerce as it "regulates the distribution of 340B drugs without affecting their price." Hanaway, 180 F.4th at 1109. Therefore, AbbVie and PhRMA fail to state a claim that S.B. 154 is discriminatory on its face, has a discriminatory purpose, or has a discriminatory effect.

B. Undue Burden

AbbVie alleges that S.B. 154 imposes a burden on interstate commerce by "plac[ing] an improper thumb on the scale and tilt[ing] the bargaining power in favor of in-state pharmacies and covered entities at the expense of out-of-state manufacturers," and that this burden outweighs any conceivable benefit to in-state commerce. Doc. 37 ¶¶ 175–79 in 3:25-cv-03006-RAL. Specifically,

AbbVie alleges "S.B. 154 effectively compels manufacturers to sell discounted drugs nationwide based on South Dakota's mandates, imposing an economic burden," and if manufacturers cannot impose conditions to stop abuses, it will "result in covered entities requiring insured patients to pay more for their prescription at contract pharmacies so the covered entity can generate 340B funds." Id. ¶¶ 178–79 (cleaned up and citation omitted).

Pike v. Bruce Church, Inc., 397 U.S. 137 (1970) established a balancing test to determine whether state legislation is valid under the dormant Commerce Clause. See also Nat'l Pork Producers Council, 598 U.S. at 380 (upholding past applications of the Pike test but declining to extend it) (plurality opinion); id. at 391–93 (Sotomayor, J., concurring in part) (affirming the judgment because petitioners fail to allege a substantial burden on interstate commerce as required by Pike); Hanaway, 180 F.4th at 1110 (observing "Pike balancing remains a valid approach when considering dormant Commerce Clause challenges"). The Pike test asks whether "the statute regulates even-handedly to effectuate a legitimate local public interest, and its effects on interstate commerce are only incidental." Pike, 397 U.S. at 142. A court should uphold such a state statute "unless the burden imposed on such commerce is clearly excessive in relation to the putative local benefits." Grand River Enters. Six Nations, Ltd., 574 F.3d at 942 (citation omitted).

Applying the Pike test in cases like Minnesota v. Clover Leaf Creamery Co., "the Court found no impermissible burden on interstate commerce because, looking to the law's effects, 'there [was] no reason to suspect that the gainers' would be in-state firms or that 'the losers [would be] out-of-state firms.' " Nat'l Pork Producers Council, 598 U.S. at 378 (quoting 449 U.S. 456, 473 (1981)). But a complaint may fail to state a dormant Commerce Clause violation even without a parallel "in-state" industry. In Exxon Corp., where petroleum producers challenged a Maryland law that prohibited them from operating gas stations in the state, the Supreme Court found the allegations in the complaint insufficient as a matter of law to demonstrate a substantial burden on interstate commerce where Exxon had argued that because "Maryland had no in-state petroleum producers, ... the law's 'divestiture requirements' fell 'solely on interstate companies' and threatened to force some to 'withdraw entirely from the Maryland market' or incur new costs to serve that market." Nat'l Pork Producers Council, 598 U.S. at 383 (quoting Exxon Corp., 437 U.S. at 125–27). Although the "law favored one business structure ... over another" and "some [ ] question[ed] its 'wisdom,' " the law "welcomed competition" from other gas station chains and its " 'practical effect' wasn't to protect in-state producers; it was to shift market share from one set of out-of-state firms (vertically integrated businesses) to another (retail gas station firms)." Id. at 383–84 (quoting Exxon Corp., 437 U.S. at 124–27). "If the dormant Commerce Clause protects the 'interstate market ... from prohibitive or burdensome regulations,' ... it does not protect 'particular ... firms' or 'particular structure[s] or methods of operation.' " Id. at 384 (quoting Exxon Corp, 437 U.S. at 127–28); see also id. at 385 ("That goes for pigs no less than gas stations.").

***33** Turning to the local public interest, the Eighth Circuit has noted that "[u]nquestionably, the State possesses a legitimate public interest in the health of its citizens," Grand River Enters. Six Nations, Ltd., 574 F.3d at 942, and more specifically noted in the 340B Program context that "pharmacies have always been important participants in delivering 340B drugs to patients," and "[p]harmacy has traditionally been regulated at the state level," McClain, 95 F.4th at 1142, 1144. See also R & M Oil & Supply, Inc. v. Saunders, 307 F.3d 731, 737 (8th Cir. 2002) ("State statutes passed for the protection of the public's health and safety are generally constitutional despite the incidental burden they may impose on interstate commerce."). In addition, "the public interest is generally 'served by maintaining the ability to enforce the law adopted by the [state] [l]egislature." Ass'n for Accessible Meds., 140 F.4th at 961 (quoting Carson v. Simon, 978 F.3d 1051, 1061 (8th Cir. 2020)).

When considering Missouri's statute on 340B drug delivery, the Eighth Circuit in Hanaway applied the Pike balancing test to conclude the pharmaceutical manufacturer had "not shown, at this stage in litigation," a motion for a preliminary injunction, "that the burdens of S.B. 751 are excessive in relation to the statute's potential benefits." Hanaway, 180 F.4th at 1111. The Eighth Circuit perceived the pharmaceutical manufacturer's argument to be akin to the one rejected by the Supreme Court in Exxon Corp., because the burdens the pharmaceutical manufacturer identified, including that it " 'must now contend with a patchwork of state laws' that 'will cost it millions of dollars per year' to comply with" were insufficient to prevail under the Pike balancing test. Id. at 1110. Although the pharmaceutical manufacturer highlighted studies on how covered entities profit from the 340B Program, the Eighth Circuit concluded that "[e]ven if Novartis is correct that some covered entities do, in fact, pocket the entire

profit from the sale of 340B drugs, many other covered entities use 340B drug revenues to provide better services to their patients," which was enough of a potential local benefit. Id. (citing U.S. Gov't Accountability Off., Drug Pricing: Manufacturer Discounts in the 340B Program Offer Benefits, but Federal Oversight Needs Improvement at 17 (Sep. 23, 2011) (describing how covered entities use excess 340B revenue to expand services or maintain services that might otherwise be cut)).

HRSA released guidance allowing covered entities to use multiple contract pharmacies over fifteen years ago, and pharmaceutical manufacturers only began to implement conditional offers limiting the use of contract pharmacies in recent years. Despite pharmaceutical manufacturers wanting to add delivery conditions on 340B Program drugs to covered entities and exercise a greater degree of control overall, the dormant Commerce Clause does not protect particular firms, structures, or methods of operation. Nat'l Pork Producers Council, 598 U.S. at 384. Because the burdens imposed by S.B. 154 are "not clearly excessive in relation to the legitimate interest received, it does not violate the Commerce Clause."[38] Grand River Enters. Six Nations, Ltd., 574 F.3d at 942. Further, S.B. 154, like the Missouri law, "assists in fulfilling the purpose of [the] 340B [ ] program to provide qualified health care providers, with pricing discounts on certain drugs prescribed to individuals and families whose income falls below the federal poverty level." Bailey, 2025 WL 595189, at *4; Hanaway, 180 F.4th at 1110–11. Therefore, South Dakota has a legitimate interest in regulating the delivery of 340B drugs ultimately dispensed to its citizens, and S.B. 154 is of a kind of "state statute[ ] that impact[s] health and welfare." McClain, 95 F.4th at 1144. AbbVie has failed to allege that the burdens of S.B. 154 are excessive in relation to the statue's potential benefits.

38 One district court dismissed an undue burden claim concerning the parallel Utah statute and another denied a preliminary injunction in a challenge to the Maryland statute. See Brown, 809 F. Supp. 3d at 1365–66; Brown, No. 1:24-cv-01557, Doc. 59 at 128.

C. Extraterritorial Control

***34** Both AbbVie and PhRMA assert that S.B. 154 impermissibly exerts extraterritorial control in violation of the dormant Commerce Clause. AbbVie alleges that because "covered entities often enter contract pharmacy arrangements with pharmacies located outside the states," S.B. 154 has the practical effect of extraterritorial control on interstate commerce. Doc. 37 ¶ 180 in 3:25-cv-03006-RAL. PhRMA alleges that drug manufacturers primarily sell their drugs that end up in South Dakota through distributors, who are located outside of South Dakota, and out-of-state distributors then sell drugs to healthcare facilities and pharmacies, some of which are in South Dakota. Doc. 1-1 ¶¶ 212–13 in 3:25-cv-03021-RAL.

> Additionally, in some circumstances where a South Dakota covered entity or pharmacy receives the 340B price on a drug from an out-of-state distributor, the out-of-state distributor then seeks the difference between the lower 340B price and the original price paid by the out-of-state distributor to the out-of-state manufacturer, including PhRMA's members, in a subsequent transaction. The subsequent transaction also occurs wholly outside South Dakota.

Id. ¶ 214. Therefore, "S.B. 154 tells out-of-state manufacturers that they cannot condition their upstream sales to out-of-state distributors at the 340B price on compliance with contract pharmacy policies." Id. ¶ 215. PhRMA finally alleges that "the extraterritorial reach of S.B. 154 is heightened by the remedies available for violations of S.B. 154," including "prohibitory orders and injunctions." Id. ¶ 217.

Any "statute that directly controls commerce occurring wholly outside the boundaries of a State exceeds the inherent limits of the enacting State's authority and is invalid regardless of whether the statute's extraterritorial reach was intended by the legislature." Healy, 491 U.S. at 336. However, there is no per se rule against state laws with extraterritorial effects; a state law is unconstitutional when it has a "specific impermissible extraterritorial effect—[it] deliberately prevented out-of-state firms from undertaking competitive pricing or deprived businesses and consumers in other States of whatever competitive advantages they may possess." Nat'l Pork Producers Council, 598 U.S. at 374 (cleaned up and citation omitted).[39] In other words, "the rule that was applied in Baldwin and Healy" addressed "price control or price affirmation statutes that tied the price of ... in-state products to out-of-state prices." Id. (cleaned up and citing PhRMA v. Walsh, 538 U.S. 644, 669 (2003)) (referring to Baldwin v. G.A.F. Seelig, Inc., 294 U.S. 511 (1935); Healy, 491 U.S. 324). "A state has no power to project its legislation into another

state by regulating the price to be paid in that state." Ass'n for Accessible Meds., 140 F.4th at 960 (cleaned up and citation omitted).[40] The Eighth Circuit has affirmed the dismissal of extraterritorial control claims under Rule 12(b)(6) where the state statute at issue was not based on or tied to sales outside of the state and there was no showing by the plaintiff that conduct required by the state statute had "any effect, either directly or indirectly, on [ ] prices in other states." Grand River Enters. Six Nations, Ltd., 574 F.3d at 944.

39 Additionally, in rejecting an expanded reading of Healy, Justice Gorsuch noted, "Petitioners' 'almost *per se*' rule against laws that have the 'practical effect' of 'controlling' extraterritorial commerce would cast a shadow over laws long understood to represent valid exercises of the States' constitutionally reserved powers." Nat'l Pork Producers Council, 598 U.S. at 375. As recognized in McClain, states have long regulated pharmacies. See 95 F.4th at 1143–44.

40 "[D]iscrimination is not required when a statute has the specific extraterritorial effect of controlling the price of wholly out-of-state transactions." Ass'n for Accessible Meds., 140 F.4th at 961.

***35** The Supreme Court's most recent case on the extraterritoriality doctrine, National Pork Producers Council v. Ross, upheld the challenged California law, which "forbids the in-state sale of whole pork meat that comes from breeding pigs (or their immediate offspring) that are 'confined in a cruel manner,' " 598 U.S. at 365–66, by "distinguishing it from laws that 'had a *specific* impressible "extraterritorial effect,' "" Ass'n for Accessible Meds., 140 F.4th at 960 (quoting 598 U.S. at 374). Following National Pork Producers Council, the Eighth Circuit affirmed a district court's grant of a preliminary injunction enjoining the enforcement of a Minnesota law that regulates "the price of out-of-state transactions, insists that out-of-state manufacturers sell their drugs to wholesalers for a certain price, and ties the price of in-state products—prescription drugs—to the price that out-of-state manufacturers charge their wholesalers," and agreed that the plaintiff was likely to succeed on the merits of its dormant Commerce Clause claim where "the law directly regulates transactions which take place ... wholly outside the State." Id. 961 (cleaned up and citations omitted). But that Minnesota law was far different from S.B. 154, and the Missouri law (S.B. 751) akin to S.B. 154, which was at issue in the recent Hanaway decision.

In Hanaway, the Eighth Circuit distinguished S.B. 751 from other laws struck down in Styczinski v. Arnold, 46 F.4th 907 (8th Cir. 2022) and Association for Accessible Medicines v. Frosh, 887 F.3d 664 (4th Cir. 2018) because it "applies only to the delivery of 340B drugs to covered entities and contract pharmacies located in Missouri and does not target out-of-state transactions between drug manufacturers and wholesalers." Hanaway, 180 F.4th at 1107–08. The Eighth Circuit determined that the Missouri 340B delivery statute "resembles the law upheld in Pork Producers.... [because] while S.B. 751 may incidentally bear on out-of-state transactions, it does not have a specific impermissible extraterritorial effect and directly regulates only the delivery of 340B drugs to covered entities and their contract pharmacies." Id. at *7. The Eighth Circuit disagreed with the pharmaceutical manufacturer's interpretation of S.B. 751 because the statute only regulated delivery to pharmacies partnered with a Missouri covered entity and did not purport to regulate transactions between manufacturers and wholesalers. Id. at 1107–08. "Even assuming S.B. 751 has some incidental effect on out-of-state transactions, '[i]n our interconnected national marketplace, many (maybe most) state laws have the "practical effect of controlling" extraterritorial behavior' without violating the Commerce Clause." Id. at 1107 (quoting Nat'l Pork Producers Council, 598 U.S. at 374).

S.B. 154, like S.B. 751 "may incidentally bear on out-of-state transactions, [but] it does not have a specific impermissible extraterritorial effect and directly regulates only the delivery of 340B drugs to covered entities and their contract pharmacies," and S.B. 154 is consistent with South Dakota's "power to regulate conduct occurring within its borders." Hanaway, 180 F.4th at 1108. S.B. 154 does not directly regulate price, see supra, unlike the Minnesota law at issue in Association for Accessible Medicines, and therefore does not have a protectionist intent or effect. See Ass'n for Accessible Meds., 140 F.4th at 960. Therefore, despite its potential, *incidental* extraterritorial effects, S.B. 154 does not violate the dormant Commerce Clause. Hanaway, 180 F.4th at 1107–08. Defendants' Motions to Dismiss AbbVie's dormant Commerce Claim, its Fourth Claim for Relief, and PhRMA's dormant Commerce Claim, its Third Claim for Relief, are granted.

VII. Contracts Clause

AstraZeneca seeks a declaratory judgment that S.B. 154 violates the Contracts Clause. Doc. 16 ¶¶ 136–41 in 4:25-cv-04156-RAL. The Contracts Clause "restricts the power of States to disrupt contractual arrangements," Sveen v. Melin, 584 U.S. 811, 818 (2018), and provides that "[n]o State shall ... pass any ... Law impairing the Obligation of Contracts." U.S. Const. art. 1, § 10, cl. 1. "Although it once was an absolute ban on state interference, the prohibition has since diminished and is no longer 'the Draconian provision that its words might seem to imply.' " Heights Apartments, LLC v. Walz, 30 F.4th 720, 728 (8th Cir. 2022) (first citing Sturges v. Crowninshield, 17 U.S. 122, 206 (1819), then quoting Allied Structural Steel Co. v. Spannaus, 438 U.S. 234, 240 (1978)). See Melendez v. N.Y.C., 16 F.4th 992, 1016–20 (2d Cir. 2021) (reviewing the jurisprudential evolution of the Contract Clause). Under the modern interpretation of the Contracts Clause, "states have some leeway to alter parties' contractual relationships to safeguard the vital interests of [their] people," and "[i]ndeed, parties contract with an expectation of possible regulation—especially ... in highly regulated industries." Murrill, 180 F.4th at 764 (cleaned up and citations omitted).

***36** Courts apply a two-step test to determine if a law violates the Contracts Clause. Sveen, 584 U.S. at 819; Heights Apartments, LLC, 30 F.4th at 728. First, the court determines whether the law has substantially impaired the contractual relationship at issue by considering "the extent to which the law undermines the contractual bargain, interferes with a party's reasonable expectations, and prevents the party from safeguarding or reinstating his rights." Sveen, 584 U.S. at 819 (citing Allied Structural Steel Co., 438 U.S. at 246). When evaluating parties' reasonable expectations, courts have looked at both the contractual terms as well as the federal and state regulations of the market at the time the parties entered into the contract. See Energy Rsrvs. Grp., Inc. v. Kan. Power & Light Co., 459 U.S. 400, 413–14 (1983) (concluding that supplemental state regulation did not violate parties' contractual rights in part due to "the fact that the parties are operating in a heavily regulated industry .... [and] [a]t the time of the execution of these contracts, [the state] did not regulate natural gas prices specifically, but its supervision of the industry was extensive and intrusive.") "If such factors show a substantial impairment, the inquiry turns to the means and ends of the legislation." Sveen, 584 U.S. at 819. However, if there is not a showing of substantial impairment, the court "may stop after step one." Id.

AstraZeneca argues that S.B. 154 substantially impairs its contractual relationship with the federal government under the PPA because "AstraZeneca joined the 340B program with the expectation and understanding that it would be required to offer discounts only for a limited category of sales," but S.B. 154 expands AstraZeneca's obligations under the PPA "by requiring AstraZeneca to offer discounts for an entirely new category of sales: contract pharmacy sales." Doc. 16 ¶ 114 in 4:25-cv-04156-RAL. In addition, AstraZeneca argues S.B. 154 disrupts the PPA because "AstraZeneca agreed by contract to participate in a regulatory regime that allowed it to conduct audits to facilitate ADR claims," which is impaired by S.B. 154's data-collection restriction. Id. ¶ 116. Defendants assert that this argument fails for the same reason that many of Plaintiffs' other arguments have failed: namely, that S.B. 154 regulates delivery and does not impact the price of 340B drugs. Doc. 27 at 38–40 in 4:25-cv-4156-RAL.

Of the four district courts to consider a Contracts Clause claim brought in this 340B context, where manufacturers challenge similar state laws regulating delivery of 340B drugs to pharmacies, one dismissed the claim on a motion to dismiss, Bailey, 2025 WL 644281, at *6, one granted summary judgment in favor of the state defendants, which was subsequently affirmed by the Fifth Circuit, Murrill, 2024 WL 4361597, at *12–13, aff'd, 180 F.4th 747, but two have found that the complaints sufficiently alleged a claim to survive a motion to dismiss as well as a motion for judgment on the pleadings, Bailey, 2025 WL 644285, at *3–4; Harris, No. 4:24-cv-268, Doc. 141 at 15.

In affirming the Western District of Louisiana's grant of summary judgment on the Contracts Clause claim, the Fifth Circuit focused on the purpose of the statute at issue. There, AstraZeneca made a substantially similar Contracts Clause argument against a Louisiana statute with parallel provisions as S.B. 154. Murrill, 180 F.4th at 764–65. The Fifth Circuit disagreed with AstraZeneca's characterization of the statute and highlighted that the statute "does not alter the terms, rights, or obligations of AstraZeneca's PPA with the federal government" and instead "regulates relationships between covered entities and their contract pharmacies—relationships to which AstraZeneca is not a party." Id. at 765.

The Fifth Circuit also rejected AstraZeneca's assertion that the statute expanded AstraZeneca's obligations to "provide discounts for unlimited contract pharmacy sales." Id. The Fifth Circuit distinguished the Louisiana 340B delivery statue from the statute held to be unconstitutional in Allied Structural Steel Co. v. Spannaus, which had imposed retroactive pension obligations. Id. In the 340B context, "delivery logistics were never part of the federal pricing agreements, a covered entity's decision to use a contract pharmacy—and [the Louisiana statute's] requirement that manufacturers not interfere with that choice—does not alter the contractual bargain between AstraZeneca and the federal government." Id. The parties' reasonable exceptions reinforced this conclusion because the parties entered the PPA "within a heavily regulated industry in which state and federal oversight have long coexisted." Id. at 766; see also Hanaway, 180 F.4th at 1102–04 (reviewing HHS guidance from 1994 and 2010 on the 340B Program and the use of contract pharmacies). Therefore, even though the PPA did not address delivery terms, "that silence cuts against AstraZeneca, not in its favor .... [because] AstraZeneca could not reasonably expect that delivery obligations would arise exclusively from federal law." Id.

***37** AstraZeneca has failed to state a claim under the Contracts Clause because S.B. 154 does not substantially impair AstraZeneca's contractual obligations under its PPA with the federal government. Indeed, S.B. 154 does not alter AstraZeneca's PPA with the federal government at all. AstraZeneca argues that S.B. 154 expands its obligations under its PPA with the federal government because it "requir[es] AstraZeneca to offer 340B discounts for unlimited contract pharmacy sales," including to the extent that it "requir[es] AstraZeneca to offer 340B discounts for sales at contract pharmacies that do not qualify as covered entities" within the scope of the PPA. Doc. 16 ¶¶ 138, 141 in 4:25-cv-4156-RAL. However, as a delivery regulation, S.B. 154 does not compel any additional sales to pharmacies that a manufacturer is not already legally obligated to offer to a covered entity under its PPA. See supra Section V. A.1. This Court agrees with the Fifth Circuit's reasoning that a bill like S.B. 154 does not change the terms, rights or obligations of AstraZeneca's PPA with the federal government.

Further, as a delivery regulation, S.B. 154 "regulates relationships between covered entities and their contract pharmacies—relationships to which AstraZeneca is not a party," Murrill, 180 F.4th at 765; specifically, the statute imposes "a negative obligation of *non-interference* with covered entities' arrangements with contract pharmacies," Fitch, 152 F.4th at 643 (emphasis added). Murrill and this case involve the same PPA that AstraZeneca executed with the federal government in the same market operating "within a heavily regulated industry in which state and federal oversight have long coexisted." Murrill, 180 F.4th at 766. Just as with the Louisiana law, when signing the PPA at issue, "AstraZeneca could not reasonably expect that delivery obligations would arise exclusively from federal law." Id.

AstraZeneca's allegations are not sufficient to satisfy the first prong for a cognizable claim under the Contract Clause, so this Court "may stop after step one." Sveen, 584 U.S. at 819. AstraZeneca has failed to state a claim under the Contracts Clause, and the Defendants' Motion to Dismiss AstraZeneca's Contracts Clause Claim, its Third Claim for Relief, is granted.

VIII. Enforcement Barred by South Dakota State Law

Finally, PhRMA seeks a declaratory judgment under state law that S.B. 154 is unenforceable. PhRMA argues that "S.B. 154 should not be interpreted to limit the contract pharmacy and claims data conditions that PhRMA's members impose in their offers to sell 340B-priced drugs" because such restrictions are impermissible. Doc. 1-1 ¶¶ 162–63 in 3:25-cv-3021-RAL. PhRMA asserts that the PPA with the federal government only requires manufacturers to "offer" 340B-priced drugs, and as explained by Sanofi and Novartis, under federal law, manufacturers may include delivery conditions. Id. ¶ 164. According to PhRMA's interpretation of the law, "[t]he 340B pricing obligation attaches only where covered entities accept the terms of the offer, at which point drugs are purchased through the 340B program." Id. PhRMA points to S.B. 154's definition of a 340B drug—"a drug purchased through the 340B drug discount program by a 340B entity"—and argues that "[w]here a 340B entity does not accept manufacturer conditions on 340B sales ..., there is no 340B drug purchase, either legally or factually." Id. ¶¶ 165–66. Therefore, under PhRMA's interpretation, "S.B. 154 simply does not apply to PhRMA's members' conduct described herein, namely, the imposition of contract pharmacy and claims data conditions in their 340B offers," and any alternative construction would render it unconstitutional. Id. ¶¶ 167–68.

Defendants argue that PhRMA is not entitled to the declaratory judgment it seeks because "PhRMA cannot simply bypass South Dakota's statutes by bargaining around them." Doc. 23 at 34 in 3:25-cv-3021-RAL. As Defendants highlight, "illegal contract terms either void the contract or make it unenforceable." Id. at 15, 34–35 (citing Sturzenbecher v. Sioux Cnty. Ranch, LLC, 20 N.W.3d 419, 428 (S.D. 2025) (holding that "[a]mong the requirements for all valid contracts is conformity with the public policy of our State, as expressed in our published decisions, statutes enacted by the Legislature, and our constitution"); Two Eagle v. Avel Ecare, LLC, 17 N.W.3d 242, 249 (S.D. 2025) (quoting Oesterreich v. Canton-Inwood Hosp., 511 N.W.2d 824, 827 (S.D. 1994)) ("The primary sources for declarations of public policy in South Dakota are the constitution, statutes, and judicial decisions."); SDCL § 53-9-1 (stating a contract whose provisions are "contrary to an express provision of law ... is unlawful"). Therefore, Defendants argue, "[s]hould PhRMA[41] choose to enter into such a contract in direct contradiction to South Dakota public policy, those provisions of the contract that violate SB 154 would be simply unenforceable." Id. at 34–35.

41 PhRMA itself does not enter into any PPA under the 340B Program, though its members do.

***38** PhRMA did not respond to Defendants' arguments on this count or address the count at all in response to Defendants' motion to dismiss. See Doc. 42 in 3:25-cv-3021-RAL. "A litigant's complete failure to respond to an opposing party's argument is often construed as a waiver." Doll v. Trellis Walnut Towers LLC, No. 24-CV-136, 2024 WL 4355084, at *3 (D. Minn. Sep. 30, 2024) (collecting cases); Mark v. Ault, 498 F.3d 775, 786 (8th Cir. 2007) (holding that failure to raise or address an issue constitutes abandonment). Even if there is no waiver of this argument, this claim fares no better on the merits.

South Dakota law does not permit contracts that contravene "the public policy of [the] State, as expressed in [its] published decisions, statutes enacted by the Legislature, and [its] constitution." Sturzenbecher, 20 N.W.3d at 428. S.B. 154 expressly disallows pharmaceutical manufacturers from imposing delivery conditions in their 340B Program offers to covered entities. PhRMA shrewdly urges an interpretation that "S.B. 154 simply does not apply to PhRMA's members' conduct described herein, namely, the imposition of contract pharmacy and claims data conditions in their 340B offers" because it argues that the law takes effect after the purchase of a 340B discount drug, which necessarily has to come after the offer has been accepted. See Doc. 1-1 ¶¶ 162–68 in 3:25-cv-3021-RAL. If that were the case and PhRMA's interpretation were correct, then S.B. 154 threatens no harm to PhRMA or its members.

PhRMA effectively is seeking a declaratory judgment that S.B. 154 should be read out of existence, and such a claim can be dismissed. And as explained above, interpreting S.B. 154 to disallow the imposition of contract pharmacy and claims data conditions in manufacturers' 340B offers is not unconstitutional. PhRMA has failed to state a claim under state law, and the Defendants' Motion to Dismiss PhRMA's state law claim, Claim I, is granted.

IX. Conclusion

For the foregoing reasons, it is

ORDERED that Defendants' Motion to Dismiss the Amended Complaint, Doc. 40 in 3:25-cv-3006-RAL, is granted, and Defendants' Motion to Dismiss Complaint, Doc. 14 in 3:25-cv-3006-RAL, is denied as moot. It is further

ORDERED that AbbVie's Amended Complaint, Doc. 37 in 3:25-cv-3006-RAL, is dismissed without prejudice. It is further

ORDERED that Defendants' Motion to Dismiss the Complaint, Doc. 22 in 3:25-cv-3021-RAL, is granted. It is further

ORDERED that PhRMA's Complaint, Doc. 1-1 in 3:25-cv-3021-RAL, is dismissed without prejudice. It is further

ORDERED that Defendants' Motion to Dismiss the Amended Complaint, Doc. 26 in 4:25-cv-4156-RAL, is granted. It is further

ORDERED that AstraZeneca's Amended Complaint, Doc. 16 in 4:25-cv-4156-RAL, is dismissed without prejudice.

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DATED this 7th day of August, 2026.

All Citations

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