2025 WL 3706066
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United States District Court, D.
South Dakota, Central Division,
CENTRAL DIVISION.

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.

3:25-CV-03006-RAL
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Attorneys and Law Firms

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Grant M. Flynn, Office of the Attorney General, Pierre, SD, for Defendants.

OPINION AND ORDER DENYING PLAINTIFFS' MOTION FOR A PRELIMINARY INJUNCTION

ROBERTO A. LANGE CHIEF JUDGE

***1** Plaintiffs AbbVie Inc., Allergan, Inc., Durata Therapeutics, Inc., AbbVie Products LLC, and Allergan Sales, LLC (collectively, AbbVie) bring this lawsuit against Defendants 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, to challenge and enjoin the enforcement of a recently enacted South Dakota law known as Senate Bill 154 (S.B. 154). Doc. 37. S.B. 154 restricts certain practices by pharmaceutical manufacturers, renders some practices to be deceptive trade practices, and grants a private right of action for violations of the law. Since initiating this lawsuit, AbbVie has been accepted into the recently announced federal 340B Rebate Model Pilot Program (Pilot Program), which begins on January 1, 2026. Doc. 54-1 ¶ 3; Doc. 54-3.

Before this Court is AbbVie's motion for a preliminary injunction to prevent Defendants from enforcing S.B. 154 in a way that obstructs AbbVie from participating in the Pilot Program. Doc. 52. Defendants maintain that S.B. 154 does not impede or prohibit AbbVie's participation in the Pilot Program. Because this Court similarly does not read S.B. 154 to pose a barrier to AbbVie's participation in the Pilot Program, AbbVie's motion for a preliminary injunction is denied.

I. Background

This case concerns 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 full recounting of this history is not necessary to decide the pending motion, but the focus and origin of the various federal and state laws at issue guide this Court's analysis.

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. The 340B program helps 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). The program is administered by the Health Resources and Services Administration (HRSA), which is a

unit of the Department of Health and Human Services (HHS). 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," and "[m]anufacturers' eligibility to participate in State Medicaid programs is conditioned on their entry into PPAs for covered drugs purchased by 340B entities." Astra USA, Inc., 563 U.S. at 113.

***2** During the initial years of the 340B program, many covered entities did not have in-house pharmacies, so they contracted with outside pharmacies, who 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. 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)).

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." Id. Drug manufacturers began to adopt policies that limited covered entities' use of contract pharmacies. See id. at 700–01 (summarizing one drug manufacturer's distribution policy). 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." Id. 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 ("So the Violation Letters and Advisory Opinion are unlawful. 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 Pharms. Corp. v. Johnson, 102 F.4th 452, 460–61 (D.C. Cir. 2024).

In the wake of Sanofi and Novartis, many state legislatures —South Dakota included with S.B. 154—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 PhRMA v. McClain, 95 F.4th 1136, 1139 (8th Cir. 2024) (summarizing Arkansas Act 1103). In response, drug manufacturers, including AbbVie, have challenged the constitutionality of these state laws across the country, although much of this litigation has so far proven unsuccessful.[1] Both circuit courts of appeal to have weighed in on state-law preemption challenges have affirmed lower court findings in favor of state defendants. 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. 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).

***3** In August 2025, HHS announced a new Pilot Program that will allow 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 manufacturers would use prescription-level claims data to determine what rebates it owed to covered entities. See Doc. 54 at 8–9. AbbVie applied for and was accepted into the Pilot Program for its drug called Imbruvica. Id. at 2, 6; Doc. 54-1; Doc. 54-2; Doc. 54-3.

Like many of its peer states, in 2025, South Dakota adopted in S.B. 154 a law limiting restrictions drug manufacturers could impose on delivery of 340B drugs. In one section, S.B. 154 prevents 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." S.D.C.L. § 58-29G-3. AbbVie's Amended Complaint alleges that S.B. 154 as a whole is preempted by both § 340B of the Public Health Service Act, 42 U.S.C. § 256b, and the new HHS Pilot Program announced earlier this year. Doc. 37 ¶¶ 141–66.

AbbVie requests declaratory relief invalidating S.B. 154 and a permanent injunction preventing enforcement of S.B. 154 in its entirety. Id. at 57–58. In this motion, though, AbbVie only asks for a preliminary injunction to enjoin enforcement of S.B. 154 "in any manner that would stop AbbVie from collecting claims data required for participation" of its drug Imbruvica in the new Pilot Program. Doc. 54 at 1.

II. Legal Standard

"A district court considering injunctive relief evaluates [1] the movant's likelihood of success on the merits, [2] the threat of irreparable harm to the movant, [3] the balance of the equities between the parties, and [4] whether an injunction is in the public interest." Powell v. Ryan, 855 F.3d 899, 902 (8th Cir. 2017) (citing Dataphase Sys., Inc. v. C L Sys., Inc., 640 F.2d 109, 114 (8th Cir. 1981) (en banc)). These four considerations are commonly known within the Eighth Circuit as the "Dataphase factors," and the moving party bears the burden of proof on all of them. Watkins Inc. v. Lewis, 346 F.3d 841, 844 (8th Cir. 2003). Although "[n]o single factor is dispositive, ... in deciding whether to grant a preliminary injunction, likelihood of success on the merits is most significant." Turtle Island Foods, SPC v. Thompson, 992 F.3d 694, 699 (8th Cir. 2021) (cleaned up and citations omitted). If plaintiffs "challenge a state statute 'based on presumptively reasoned democratic processes,' they must show they are 'likely to prevail on the merits.' " Id. (quoting Planned Parenthood Minn., N.D., S.D. v. Rounds, 530 F.3d 724, 732–33, 732 n.4 (8th Cir. 2008) (en banc)). "Ultimately, '[t]he primary function of a preliminary injunction is to preserve the status quo until, upon final hearing, a court may grant full, effective relief.' " Missouri v. Trump, 128 F.4th 979, 990 (8th Cir. 2025) (quoting Wilbur-Ellis Co., LLC v. Erikson, 103 F.4th 1352, 1355 (8th Cir. 2024)).

III. Analysis

AbbVie asserts that it is likely to succeed on the merits and prove that the Pilot Program preempts S.B. 154 because the HHS has "identified twenty-two categories of claims data AbbVie could require covered entities to provide" as a participant in the Pilot Program, but S.B. 154 prevents AbbVie from "requir[ing] covered entities to 'submit any claim or utilization data'—precisely the data AbbVie needs for" the Pilot Program. Doc. 54 at 9 (first citing Doc. 54-3, then quoting S.D.C.L. § 58-29G-3). Defendants oppose grant of a preliminary injunction, do not oppose AbbVie's participation in the Pilot Program, and assert that S.B. 154 permits data collection "required by federal law." Doc. 59. AbbVie notes that Defendants would not assure it previously that they would not enforce S.B. 154 upon AbbVie's collection of data for the Pilot Program, and Defendants could change their minds or AbbVie could face private enforcement of S.B. 154. Doc. 54 at 7, 12–13.

***4** "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 (quoting Cipollone v. Liggett Grp., Inc., 505 U.S. 504, 516 (1992) (citing Art. VI, cl. 2)) (cleaned up). 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).

In seeking a preliminary injunction, AbbVie argues that it is likely to succeed on the merits of its Pilot Program conflict preemption claim. Doc. 54 at 7. 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. McClain, 95 F.4th at 1140 (quoting Oneok, Inc., 575 U.S. at 377); see also Lefaivre, 636 F.3d at 939 (citing Wis. Pub. Intervenor v. Mortier, 501 U.S. 597, 605 (1991)). 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).

The question then is whether S.B. 154 is an obstacle to drug manufacturer participation and data collection in the federal Pilot Program. The Pilot Program modifies the 340B program for certain drugs. Under the 340B program, participating drug manufacturers provide drugs to covered entities at the 340B ceiling price. To address drug manufacturers' concerns

about "340B and Maximum Fair Price (MFP) deduplication ... [and] 340B Medicaid duplicate discounts and diversion," the HHS recently announced the 340B Rebate Model Pilot Program. 90 Fed. Reg. 36165.[2] "[T]he 340B Program has traditionally operated as an upfront discount program," where the covered entity purchases the covered outpatient drug at the 340B ceiling price from the drug manufacturer, but under the rebate model, a covered entity will purchase the drug at the market price upfront from the drug manufacturer "and then later receive a post-purchase rebate." Id. The Office of Pharmacy Affairs (OPA) has approved certain data fields that drug manufacturers may request from covered entities claiming 340B rebates to allow manufacturers to determine which reimbursements they are required to make. See Doc. 54-3 at 2 (listing OPA-approved pharmacy claims data fields and medical claims data fields). The OPA has specified "that [manufacturers'] data requests are limited to these approved fields," some of which are optional, "and that no rebate claims may be denied for the absence of the optional fields." Id.

***5** AbbVie applied for and was accepted into the Pilot Program for its drug, Imbruvica, which is subject to the 340B program as well as an MFP. Doc. 54 at 6. AbbVie, beginning on January 1, 2026, will issue rebates for Imbruvica to covered entities, who will have purchased the 340B drug at market price, rather than selling the drug to the covered entities at the outset at the 340B ceiling price. Id. Under the Pilot Program, AbbVie "will collect 340B claims data from covered entities and contract pharmacies and compare that to MFP claims data to determine which price concession (if any) is appropriate." Id. at 5.

AbbVie fears 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. Without that data, AbbVie argues, it cannot make these determinations and participate in the Pilot Program. Doc. 54 at 2. In arguing for a preliminary injunction, AbbVie asserts that it is likely to succeed on the merits of the Pilot Program preemption claim because S.B. 154 is an obstacle to participation in the Pilot Program, AbbVie will suffer irreparable harm if it cannot participate in the federal program and must pay duplicate discounts under § 340B and the Inflation Reduction Act, and the equities and public interest favor the granting of the preliminary injunction. Id. at 3, 8. Defendants counter that S.B. 154 does not prevent AbbVie from collecting data as "the Pilot Program sets forth precisely what data must be collected," and therefore this federally-imposed data requirement qualifies for the exception under S.B. 154, which expressly allows manufacturers to require data from covered entities in order "to comply with federal law, such as the Pilot Program." Doc. 59 at 8–9 (first citing 90 Fed. Reg. 36164–65, then citing S.D.C.L. § 58-29G-3).

AbbVie has not established a likelihood of success in demonstrating that S.B. 154 is an obstacle to AbbVie's participation in the Pilot Program. Setting aside issues of standing and ripeness, the plain text of S.B. 154 does not conflict with the Pilot Program or prevent the limited claims data collection authorized by federal law for Imbruvica, the only drug AbbVie manufactures currently enrolled in the Pilot Program. 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.*

S.D.C.L. § 58-29G-3 (emphasis added). To the extent that AbbVie is required to collect certain claims data from covered entities under the Pilot Program, S.B. 154 plainly poses no barrier to that data collection. At least one other federal district court has considered a similar motion for a preliminary injunction that stemmed in part from concerns over a drug manufacturer's ability to participate in the Pilot Program. See Weiser, 2025 WL 3041825, at *11–12. The court in that case denied the drug manufacturer's request to enjoin a similar state statute on the same grounds as this Court. Id. (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"). The Colorado statute and S.B. 154 contain similar provisions. See id.

***6** AbbVie has not shown that it is likely to prevail on the merits of its claim, so this Court does not need to consider

the remaining preliminary injunction factors and denies the request for a preliminary injunction. See Lewis, 346 F.3d at 844; Turtle Island Foods, SPC, 992 F.3d at 699. If Defendants take steps to enforce S.B. 154 against AbbVie based on AbbVie's participation in the Pilot Program and collection of data on Imbruvica prescriptions authorized by the Pilot Program, AbbVie can seek a temporary restraining order or renew its request for a preliminary injunction.

IV. Conclusion

For the foregoing reasons, it is hereby

ORDERED that Plaintiffs' Motion for Preliminary Injunction, Doc. 52, is denied.

DATED this 22nd day of December, 2025.

All Citations

Slip Copy, 2025 WL 3706066

Footnotes

1 See 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, at *1 (D. Me. Sept. 23, 2025) (same as to Maine law); AstraZeneca Pharms. LP v. Fitch, 766 F. Supp. 3d 657, 664–65 (S.D. Miss. 2024) (same as to Mississippi law); Novartis Pharms. Corp. v. Fitch, 738 F. Supp. 3d 737, 749–50 (S.D. Miss. 2024) (same); AbbVie Inc. v. Skrmetti, No. 3:25-cv-00519, 2025 WL 1805271, at *18, 25 (M.D. Term. June 30, 2025) (same as to Tennessee law); Novartis Pharms. Corp. v. Bailey, No. 2:24-CV-04131, 2025 WL 595189, at *7 (W.D. Mo. Feb. 24, 2025) (same as to Missouri law); Astrazenca Pharms. LP v. Bailey, No. 2:24-cv-04143, 2025 WL 644285, at *3–5 (W.D. Mo. Feb. 27, 2025) (granting motion to dismiss manufacturer's claims that Missouri law was preempted and violated the Takings Clause); AbbVie, Inc. v. Ellison, 777 F. Supp. 3d 971, 977 (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, at *8–9, 13–15 (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); AbbVie Inc. v. Fitch, 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. Fitch, No. 1:24-cv-160, 2024 WL 3277365, at *11 (S.D. Miss. July 1, 2024) (same); PhRMA v. McClain, 645 F. Supp. 3d 890, 902 (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, No. 25-cv-1847, 2025 WL 3041825, at *5–14 (D. Colo. Oct. 31, 2025) (denying motion for preliminary injunction as to Colorado law). 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); AbbVie Inc. v. Drummond, No. 5:25-cv-00726 (W.D. Okla. Oct. 31, 2025), ECF No. 79 (granting in part and denying in part motions for preliminary injunction as to Oklahoma law); AbbVie Inc. v. Brown, No. 2:25-cv-00271 (D. Utah Nov. 19, 2025), ECF No. 95 (granting defendants' two of three motions to dismiss in part as to Utah law and denying one motion to dismiss in consolidated cases).

2 As explained by AbbVie in its brief, the Pilot Program addresses concerns with "two overlapping federal drug-pricing programs": the 340B Program and the Inflation Reduction Act's Drug Price Negotiation Program (DPNP), which requires HHS to set a maximum fair price (MFP) for certain drugs. Doc. 54 at 3. When a drug is subject to both programs, "manufacturers must provide the lower of the two price concessions (MFP or 340B ceiling price)" to eligible individuals, "but not both." Id. at 4 (citing 42 U.S.C. § 1320f-2(d)) (emphasis omitted).

AbbVie has argued that it is difficult to comply with both programs without providing duplicate discounts under the current system. See id. at 5.

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