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United States District Court, D. Colorado.

ABBVIE, INC., et al., Plaintiffs,
v.
Philip WEISER, et al., Defendants.

Civil Action No. 25-cv-1847-WJM-KAS
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Signed October 31, 2025

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ORDER DENYING PLAINTIFFS' MOTION FOR A PRELIMINARY INJUNCTION

William J. Martínez, Senior United States District Judge

***1** Plaintiffs AbbVie, Inc., Allergan, Inc., AbbVie Products LLC, Pharmacyclics LLC, and Allergan Sales, LLC (collectively, "Plaintiffs" or "AbbVie") bring this lawsuit against Defendants Philip Weiser, in his official capacity as Attorney General of the State of Colorado; and Kristen Wolf, Ryan Leyland, Patricia Evacko, Avani Soni, Michael Scruggs, Alexandra Zuccarelli, and Jayant Patel, in their official capacities as members of the Colorado State Board of Pharmacy (collectively, "Defendants"), to challenge the constitutionality of Colorado Senate Bill 25-071, now codified as the Colorado 340B Contract Pharmacy Protection Act, Colorado Revised Statutes (C.R.S.) §§ 6-29-101 *et seq.* (2025) (the "Act"). [1] (ECF No. 43.)

Currently before the Court is AbbVie's Motion for a Preliminary Injunction ("Motion"), by which it seeks to preliminarily enjoin enforcement of the Act. (ECF No. 7; *see also* ECF No. 43 at 65 ¶ 4.) The Motion has been fully briefed (ECF Nos. 33, 36, 52, 74), [2] and the Court presided over an evidentiary hearing on the Motion on September 19, 2025 (ECF No. 93). Thus, it is now ripe for adjudication.

For the reasons set forth below, the Motion is denied.

I. BACKGROUND [3]

A. Section 340B

In 1992, Congress enacted § 340B of the Public Health Service Act, 42 U.S.C. § 256b ("Section 340B")—thereby creating the "340B Program"—"to ensure that uninsured and low-income individuals can access the medications they need and to ensure that medical providers serving those individuals receive crucial subsidies." *AbbVie, Inc. v. Fitch,* 152 F.4th 635, 639 (5th Cir. 2025). The 340B Program accomplishes this by "impos[ing] ceilings on prices drug manufacturers may charge for medications sold to specified health-care facilities." *Astra USA, Inc. v. Santa Clara County, Cal.,* 563 U.S. 110, 113, 131 S.Ct. 1342, 179 L.Ed.2d 457 (2011). Those facilities, called "covered entities," "include public hospitals and community health centers, many of them providers of safety-net services to the poor." *Id.; see also* § 256b(a)(4) (defining "covered entity"). The 340B Program helps covered entities care for their 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).

***2** The 340B Program "is superintended by the Health Resources and Services Administration ('HRSA'), a unit of the Department of Health and Human Services ('HHS')." *Astra,* 563 U.S. at 113, 131 S.Ct. 1342. "Drug manufacturers opt into the 340B Program by signing a form Pharmaceutical Pricing Agreement ('PPA') used nationwide." *Id.* "PPAs are not transactional, bargained-for contracts." *Id.* Rather, "[t]hey are uniform agreements that recite the responsibilities § 340B imposes, respectively, on drug manufacturers and the Secretary of HHS." *Id.* Specifically, the PPA obligates manufacturers to "offer each covered entity covered outpatient drugs for purchase at or below the applicable ceiling price if such drug is made available to any other purchaser at any price." § 256b(a)(1). Manufacturers' eligibility to participate in Medicaid and Medicare Part B "is conditioned on their entry into PPAs for covered drugs purchased by [covered] entities." *Astra,* 563 U.S. at 113, 131 S.Ct. 1342.

Section 340B also prohibits covered entities from engaging in certain conduct:

> First, it bars 'duplicate discounts or rebates,' forbidding covered entities from seeking both the 340B discount and a Medicaid rebate on the same drug. [42 U.S.C.] § 256b(a)(5)(A). Second, it bars 'diversion,' providing that a covered entity 'shall not resell or otherwise transfer' a discounted drug 'to a person who is not a patient of the entity.' *Id.* § 256b(a)(5)(B). Third, it requires covered entities to permit [HHS] and drug manufacturers to 'audit' their records to assess compliance with the duplicate-discount and diversion bans. *Id.* § 256b(a)(5)(C). And fourth, it provides that a covered entity that violates the duplicate-discount or diversion bans 'shall be liable' to the drug manufacturer for the amount improperly received. *Id.* § 256b(a)(5)(D).

Fitch, 152 F.4th at 640.

B. Role of Contract Pharmacies

"When Congress first enacted Section 340B, few covered entities had pharmacies in house," *Sanofi Aventis,* 58 F.4th at 700, in substantial part because, for many, "building or maintaining [an in-house] pharmacy is cost-prohibitive," *PhRMA v. McClain,* 95 F.4th 1136, 1139 (8th Cir. 2024). Thus, "[s]ince the beginning, covered entities have contracted with outside pharmacies," or "contract pharmacies," "for the distribution and dispensation of 340B drugs." *Id.* For covered entities with large, rural service areas, "the outsourcing of pharmacy services [also] allowed for drug dispensation closer to where [their] low-income patients reside." *McClain,* 95 F.4th at 1139. "Covered entities using contract pharmacies would still order and pay for the drugs, but they would be shipped directly to the pharmacies." *Sanofi Aventis,* 58 F.4th at 700.

Noting covered entities' reliance on contract pharmacies and Section 340B's "silen[ce] as to permissible drug distribution systems" to patients, 61 Fed. Reg. 43, 549, 43,549 (Aug. 23, 1996), HRSA issued guidance in 1996 "permitting covered entities lacking an in-house dispensing pharmacy to contract with a single third-party commercial pharmacy to receive and dispense 340B drugs to their patients, so long as they abided by Section 340B's requirements and its duplicate-discount and diversion bans," *Fitch,* 152 F.4th at 640 (citing *id.* at 43,550–55). Then, in 2010, HRSA "changed course" and "issu[ed] new guidance permitting all covered entities—even those with an in-house dispensing pharmacy—to contract with an unlimited number of outside pharmacies to distribute Section 340B drugs to their patients." *Fitch,* 152 F.4th at 640; 75 Fed. Reg. 10,272, 10,273 (Mar. 5, 2010).

***3** After the 2010 guidance, the use of contract pharmacies proliferated, and pharmaceutical manufacturers became increasingly concerned that "contract pharmacies were driving up duplicate discounting and diversion." *Sanofi Aventis,* 58 F.4th at 700; *see also Novartis Pharms. Corp. v. Johnson,* 102 F.4th 452, 457 (D.C. Cir. 2024) (citing governmental report indicating that "the number of contract pharmacies participating in the program increased from about 1,300 to 23,000" between 2010 and 2019). So, manufacturers began adopting policies "that limited or prohibited covered entities from contracting with outside pharmacies for the dispensation of 340B drugs to patients." *McClain,* 95 F.4th at 1139.

AbbVie adopted one such policy, its "340B Program Integrity Initiative," in 2023. (ECF No. 7-1 at 3 ¶ 4.) Under the current iteration of AbbVie's policy, last updated in February 2025, "hospital covered entities" "*without* an in-house outpatient pharmacy may designate a single contract location" "within 40 miles of the HRSA registered covered entity parent site" to receive "orders of 340B priced medicines," provided that the covered entity also "submits limited claims data on 340B

utilization" for that contract pharmacy location. (*Id.* at 51–52 (emphasis in original).) *See also Fitch,* 152 F.4th at 641 (noting "AbbVie's contract-pharmacy policy ... essentially follows HRSA's 1996 guidance").

"HHS acted quickly to prohibit drug manufacturers from imposing these restrictive contract-pharmacy policies." *Id*. In December 2020, HHS issued an advisory opinion concluding that, "to the extent contract pharmacies are acting as agents of a covered entity, a drug manufacturer in the 340B Program is obligated to deliver its covered outpatient drugs to those contract pharmacies and to charge the covered entity no more than the ceiling price for those drugs." OIG Advisory Op. No. No. 20-06, 2020 WL 11422965, at *1 (Dec. 30, 2020).

Manufacturers sued. Ultimately, the Third and D.C. Circuits upheld the manufacturers' policies because "Congress never said that drug makers must deliver discounted 340B drugs to an unlimited number of contract pharmacies." *Sanofi Aventis,* 58 F.4th at 707; *Novartis Pharms.*, 102 F.4th at 455 (agreeing that "section 340B does not prohibit manufacturers from limiting the distribution of discounted drugs by contract"). [4] HHS withdrew the advisory opinion. *Fitch,* 152 F.4th at 641.

C. State Legislatures Weigh In

Following the Third and D.C. Circuits decisions, "several states passed laws to protect covered entities' partnerships with contract pharmacies, attempting to do by statute what HHS had done in its advisory opinion." *Id.*

As pertinent here, the Act was signed into Colorado law on May 30, 2025. (ECF No. 33-1 at 10.) Its operative provision prohibits manufacturers from undertaking the following acts:

> (a) Unless the receipt of the 340B drugs is prohibited by the federal department of health and human services, a manufacturer, third-party logistics provider, or repackager, or an agent, contractor, or affiliate of a manufacturer, third-party logistics provider, or repackager, including an entity that collects or processes health information, shall not, directly or indirectly, deny, restrict, prohibit, discriminate against, or otherwise limit the acquisition of a 340B drug by, or delivery of a 340B drug to, a 340B covered entity, a pharmacy contracted with a 340B covered entity, or a location otherwise authorized by a 340B covered entity to receive and dispense 340B drugs.
>
> (b) A manufacturer shall not directly or indirectly require, including as a condition, a 340B covered entity, a pharmacy contracted with a 340B covered entity, or any other location authorized to receive 340B drugs by a 340B covered entity to submit any health information, claims or utilization data, purchasing data, payment data, or other data that does not relate to a claim submitted to a federal health care program, unless such data is voluntarily furnished by such covered entity or otherwise required to be furnished under applicable federal law.

***4** § 6-29-105(1). A violation of the Act is an unfair or deceptive trade practice under the Colorado Consumer Protection Act ("CCPA"), and the violator is subject to CCPA enforcement provisions and penalties, including monetary fines of up to $20,000 per violation. § 6-29-105(3)(a).

Pharmaceutical manufacturers have filed many lawsuits challenging state laws comparable to the Act. Unlike their earlier challenges to the 2020 HHS guidance, the very large majority of these lawsuits have been unsuccessful to date. [5]

D. Procedural History

AbbVie filed this lawsuit challenging the constitutionality of the Act on June 12, 2025 (ECF No. 1) and moved for a preliminary injunction one day later (ECF No. 7). After setting oral argument on the Motion, AbbVie requested an evidentiary hearing so that it could proffer the testimony of three witnesses in support of its requested relief. (ECF No. 31.) The Court set an evidentiary hearing at AbbVie's behest. (ECF No. 32.)

During the September 19, 2025 hearing, the Court heard the testimony of five witnesses in total. First, AbbVie called expert witness Alice Chen, Ph.D., a professor of public policy at the University of Southern California, to generally "testify about ... how the [340B] program operates in practice" and "explain the growth of contract pharmacies." (ECF No. 111 at 19:11–20; *see also* ECF No. 36-2.) Second, AbbVie called Mr. Edward Scheidler, its corporate representative, to "explain that, in fact, AbbVie will not sell its drugs at the 340B price unless [its] conditions are agreed to, which [AbbVie avers] is a complete answer to the State's position on takings." (ECF No. 111 at 20:1–6.) And lastly, AbbVie called expert witness Dr. Amitabh Chandra, a professor of public policy at Harvard University, to "explain where the research shows that 340B profits go," which, according to AbbVie, "is not to charity care, to uncompensated care, or to benefit patients." (*Id.* at 20:7–11; *see also* ECF No. 36-1.)

***5** Defendants, for their part, proffered testimony from "two witness who work for Colorado hospital systems that are 340B covered entities," both of whom were called to generally testify "about how their systems have been impacted by the drug company restrictions and how they expect it to change under the new law." (ECF No. 111 at 23:13–14.) Those witnesses included Dr. Kevin Forbush, "a pharmacist who runs the 340B program at Intermountain Health," and Kevin Stansbury, the CEO of Lincoln Health, "a county governmental hospital system" located in the rural town of Hugo, Colorado. (*Id.* at 23–25.)

The Court refers to some of that hearing evidence where relevant to its analysis below. But ultimately, it finds it unnecessary to recount much of the testimony put forth at the evidentiary hearing. In general, the Court concurs with Defendants' view that the testimony presented a compelling case that Section 340B is in dire need of legislative reform, but it did not significantly move the needle on the issues immediately before the Court—namely, whether AbbVie is substantially likely to succeed in demonstrating that the Act is preempted by federal law or effects an unconstitutional taking.

II. LEGAL STANDARD

"Because a preliminary injunction is an 'extraordinary remedy never awarded as of right,' ... the movant must make a 'clear and unequivocal' showing it is entitled to such relief." *Colorado v. U.S. Envtl. Protection Agency,* 989 F.3d 874, 883 (10th Cir. 2021) (quoting *Winter v. Natural Res. Def. Council,* 555 U.S. 7, 24, 129 S.Ct. 365, 172 L.Ed.2d 249 (2008)); *Port City Props. v. Union Pac. R.R. Co.,* 518 F.3d 1186, 1190 (10th Cir. 2008) (internal citation omitted). "To obtain a preliminary injunction, the movant must show (1) it 'is substantially likely to succeed on the merits,' (2) it 'will suffer irreparable injury if the injunction is denied,' (3) its 'threatened injury outweighs the injury the opposing party will suffer under the injunction,' and (4) 'the injunction would not be adverse to the public interest.' " *Colorado,* 989 F.3d at 883 (quoting *New Mexico Dep't of Game & Fish v. U.S. Dep't of Interior,* 854 F.3d 1236, 1246 (10th Cir. 2017)). The third and fourth factors merge when the government is the opposing party. *Denver Homeless Out Loud v. Denver, Colorado,* 32 F.4th 1259, 1278 (10th Cir. 2022) (citation omitted).

III. ANALYSIS

AbbVie contends that the Act is unconstitutional because (1) it is preempted by federal law pursuant to the Supremacy Clause and/or (2) it effects a taking in violation of the Takings Clause. (*See generally* ECF Nos. 7, 43.) For the reasons explained below, the Court finds that AbbVie has not established a substantial likelihood of success on the merits of either claim. Accordingly, the Court does not proceed to consider the remaining preliminary injunction factors. *See Vill. of Logan v. U.S. Dep't of Interior,* 577 F. App'x 760, 766 (10th Cir. 2014) (a "plaintiff's failure to prove any one of the four preliminary injunction factors renders its request for preliminary injunctive relief unwarranted"); *Dominion Video Satellite, Inc. v. Echostar Satellite Corp.,* 356 F.3d 1256, 1266 n. 8 (10th Cir. 2004) (concluding "the other preliminary injunction factors" "need not [be] address[ed]" after finding against the movant on one factor).

A. Preemption

"Congress has the power to preempt state law" pursuant to the Supremacy Clause, which "provides a clear rule that federal law 'shall be the supreme Law of the Land ... any Thing in the Constitution or Laws of any state to the Contrary notwithstanding.' " *Arizona v. United States,* 567 U.S. 387, 399, 132 S.Ct. 2492, 183 L.Ed.2d 351 (2012) (quoting U.S. Const., Art. VI, cl. 2.) "[A]ny preemption inquiry begins with the presumption that federal law does not override 'the historic police powers of the States,' without the 'clear and manifest' intent of Congress." *Bradshaw v. Am. Airlines, Inc.,* 123 F.4th 1168, 1173 (10th Cir. 2024) (quoting *Arizona,* 567 U.S. at 400, 132 S.Ct. 2492). Thus, congressional intent is "the ultimate touchstone in every pre-emption case." *Wyeth v. Levine,* 555 U.S. 555, 565, 129 S.Ct. 1187, 173 L.Ed.2d 51 (2009) (citation omitted).

***6** "The party claiming preemption ... bears the burden of showing with specificity that Congress intended to preempt state law." *Day v. SkyWest Airlines,* 45 F.4th 1181, 1184 (10th Cir. 2022) (internal citation and quotation marks omitted). "Congress's intent to preempt state law can be shown 'through a statute's express language' or implied 'through its structure and purpose.' " *Bradshaw,* 123 F.4th at 1173 (quoting *Altria Grp., Inc. v. Good,* 555 U.S. 70, 76, 129 S.Ct. 538, 172 L.Ed.2d 398 (2008)). Here, AbbVie does not argue that Section 340B expressly preempts the Act. (*See generally* ECF No. 7.) Instead, it contends that the Act is impliedly

"preempted because it intrudes on a federal field and conflicts with the text and purpose of the 340B statute." (*Id.* at 7.)

Notably, categories of preemption are not "rigidly distinct." *English v. Gen. Elec. Co.,* 496 U.S. 72, 79 n.5, 110 S.Ct. 2270, 110 L.Ed.2d 65 (1990). "Indeed, field pre-emption may be understood as a species of conflict pre-emption: A state law that falls within a pre-empted field conflicts with Congress' intent ... to exclude state regulation." *Id.* That sentiment rings true here, where it is, at times, difficult to distinguish between AbbVie's arguments in support of its field preemption and conflict preemption theories. Nevertheless, the Court endeavors to disentangle those arguments and address AbbVie's field and conflict preemption theories separately below.

1. Field Preemption

Field preemption "exists where 'a framework of regulation' of a field is 'so pervasive' that it leaves no space for state supplementation or where the federal interest is 'so dominant' that the existence of a federal scheme can 'be assumed to preclude enforcement of state laws on the same subject.' " *Bradshaw,* 123 F.4th at 1173 (quoting *Arizona,* 567 U.S. at 399, 132 S.Ct. 2492). AbbVie has not demonstrated that it is substantially likely to succeed in demonstrating that either inference applies here.

At the outset, AbbVie argues that Congress intended to preempt the field because, through Section 340B, it created "a single comprehensive federal scheme that governs every detail" of "the federally occupied 340B field," "from covered-entity eligibility to manufacturer obligations and enforcement ...." (ECF No. 7 at 7–8 (emphasis added).) Though AbbVie's briefing does not specifically define the "340B field," AbbVie's counsel seemed to affirm at the evidentiary hearing that it views the relevant regulatory field quite broadly: "the field of the 340B program, itself." (ECF No. 111 at 290:1–4.)

But it cannot be that Congress has enacted a scheme that governs "every detail" of the 340B Program. *Four* federal Circuit Courts of Appeal now concur that Section 340B "is silent about delivery," *Sanofi Aventis,* 58 F.4th at 703; *Novartis Pharms.,* 102 F.4th at 461 ("agree[ing] entirely"); *McClain,* 95 F.4th at 1143 (relying on *Sanofi Aventis*), and thus "regulates neither the distribution of drugs to patients nor the role of pharmacies in this distribution," *Fitch,* 152 F.4th at 646. The Court is further inclined to think that the manner of distribution of 340B drugs to patients is a relevant "detail" of the 340B Program of which Congress is well-aware, given that (1) "[p]harmacies have always been an essential part of the 340B Program" and (2) Congress *did* "directly address distribution by third-party wholesalers." *McClain,* 95 F.4th at 1143 (citing 42 U.S.C. § 256b(a)(8)); *see also Fitch,* 152 F.4th at 646 ("Congress 'knew how to impose delivery-related requirements' and regulate distribution, because Section 340B does authorize distribution of drugs by manufacturers and third-party wholesalers." (quoting *Sanofi Aventis,* 58 F.4th at 704)). That "Congress chose not regulate distribution to patients ... indicat[es] that it did not intend to occupy the entire field in this area." *Fitch,* 152 F.4th at 646.

***7** Second, AbbVie suggests that there is necessarily a field preemption issue because the Act "could not exist but for the *federal* 340B statute." (ECF No. 7 at 8 (emphasis in original); *see also* ECF No. 111 at 290:1–4 (arguing that the Act facially "targets the regulation of a federal program, and that intrudes on a federal field").) The Court presumes that AbbVie endeavors to show through this argument that there is a "federal interest ... 'so dominant' that the existence of a federal scheme can 'be assumed to preclude enforcement of state laws on the same subject.' " *Bradshaw,* 123 F.4th at 1173 (quoting *Arizona,* 567 U.S. at 399, 132 S.Ct. 2492).

AbbVie failed to direct the Court to any authority related to this argument in its Motion. (*See id.*) However, in its reply, AbbVie cited two authorities for the somewhat-related proposition that "there is no presumption against preemption where a state law explicitly depends on a federal statute": *Buckman Co. v. Plaintiffs' Legal Comm.,* 531 U.S. 341, 121 S.Ct. 1012, 148 L.Ed.2d 854 (2001) and *Boyle v. United Techs. Corp.,* 487 U.S. 500, 108 S.Ct. 2510, 101 L.Ed.2d 442 (1988). (ECF No. 36 at 4–5.) Moreover, at the evidentiary hearing, AbbVie's counsel likened the Act to an impermissible state "regulation of a federal instrumentality, like in *M'Culloch v. Maryland*." (ECF No. 111 at 289:10–15.)

Buckman and *Boyle* may be a closer fit for AbbVie's argument that the Act is in tension with Section 340B's enforcement scheme, but those authorities do not support the broad contention that there is necessarily a field preemption issue where "a state law explicitly depends on a federal statute." (ECF No. 36 at 4.) Rather, the Supreme Court held in those cases that state-law causes of action were impliedly preempted by federal common law because there was a "uniquely federal interest" at stake, like "the civil liabilities arising out of the performance of federal procurement contracts," *Boyle,* 487 U.S. at 506, 108 S.Ct.

2510 (government contractors immune from liability under state tort law), or "the relationship between a federal agency and the entity it regulates," *Buckman,* 531 U.S. at 347, 121 S.Ct. 1012 (state tort law fraud-on-the-FDA claims impliedly preempted). AbbVie has not identified a "uniquely federal interest" here.

This case is also unlike *M'Culloch v. Maryland,* where the direct subject of state regulation was itself a federal instrumentality. 17 U.S. 316, 4 Wheat. 316, 4 L.Ed. 579 (1819). Here, it is the non-governmental participants and beneficiaries of the 340B Program—namely, pharmaceutical manufacturers and covered entities—that are the subject of state regulation. And "the Supreme Court ... has never adopted a categorical rule that requires a finding of preemption whenever a state law is directly addressed to those participating in a federal program where the federal statute does not rely on the state to implement the program." *AbbVie Inc. v. Frey,* 2025 WL 2813787, at *10 (D. Me. Sept. 23, 2025). To the contrary, "matters left unaddressed in [ ] a [federal] scheme are presumably left subject to the disposition provided by state law." *O'Melveny & Myers v. F.D.I.C.,* 512 U.S. 79, 85, 114 S.Ct. 2048, 129 L.Ed.2d 67 (1994).

The fundamental problem with AbbVie's argument that the Act is preempted because it depends on a federal statute is that it is backwards. As the Court understands it, AbbVie essentially argues that "the existence of a federal scheme" necessarily establishes there is a sufficiently dominant "federal interest" from which it can be assumed that Congress intended to "preclude enforcement of state laws on the same subject." *Bradshaw,* 123 F.4th at 1173 (citation omitted). But that is not the law, and AbbVie cannot circumvent its burden to identify a compelling federal interest warranting preemption by pointing to the mere existence of a federal statute.

***8** Lastly, AbbVie argues that the Act "goes to the very heart of the federally occupied field: [i]t overrides the *offer* structure Congress established, eliminates manufacturers' federally permitted discretion, and dictates the terms under which entities receive discounted drugs." (ECF No. 7 at 8.) To the extent AbbVie is arguing that the relevant field is defined more narrowly—"the terms by which manufacturers must offer discounted drugs under the 340B program"—"there would still be no field preemption." *Frey,* 2025 WL 2813787, at *8. "[B]ecause 340B does not dictate many of the terms regarding manufacturers' obligation to offer and provide the drugs, the language of 340B is insufficient to imply a congressional intent to preclude all state regulation in the field." *Id.* (citing *Sanofi Aventis,* 58 F.4th at 704 (observing, as to the terms of an offer, that the 340B statute "imposes only a price term for drug sales to covered entities, leaving all other terms blank")). Congress's intent to preempt the field cannot be inferred solely from the fact that it left certain "terms" to manufacturers' discretion. AbbVie's discretion to set those terms—namely, where it is willing to deliver 340B drugs—is derived from Congress's silence. *See Novartis Pharms.,* 102 F.4th at 460 ("Section 340B is ... silent about delivery conditions.") And "Congressional silence will not be presumed to mandate preemption." *Paul v. Monts,* 906 F.2d 1468, 1475 n.8 (10th Cir. 1990) (internal citation and quotation marks omitted).

The counter inference to AbbVie's arguments is that the Act does not intrude on a federal field but instead implicates "traditional general areas of state regulation," like "public health," *Fitch,* 152 F.4th at 647 (citing *Gobeille v. Lib. Mut. Ins. Co.,* 577 U.S. 312, 325, 136 S.Ct. 936, 194 L.Ed.2d 20 (2016) (noting "the State's traditional power to regulate in the area of public health")), and "the practice of pharmacy," *McClain,* 95 F.4th at 1143 (citation omitted). The "assumption that the historic police powers of the States [are] not to be superseded by the Federal Act unless that was the clear and manifest purpose of Congress," *Altria Grp.,* 555 U.S. at 77, 129 S.Ct. 538 (citation omitted), "applies with greater force when the alleged conflict is in an area traditionally occupied by the States," *Ramsey Winch Inc. v. Henry,* 555 F.3d 1199, 1204 (10th Cir. 2009). At this stage, AbbVie has failed to adduce sufficient evidence to persuade the Court that it is substantially likely to succeed in demonstrating that (1) this presumption against preemption does not extend to the Act in the first instance and/or (2) that the presumption is overcome by "a strong showing that Congress intended preemption." *McClain,* 95 F.4th at 1144.

2. Conflict Preemption

A state law provision will "also preempted if it conflicts with federal law, either because (1) 'compliance with both federal and state regulations is a physical impossibility,' " "or because the provision (2) 'stands as an obstacle to the accomplishment and execution of the full purposes and objectives of' federal law." *United States v. Supreme Court of New Mexico,* 839 F.3d 888, 918 (10th Cir. 2016) (quoting *Arizona,* 567 U.S. at 399, 132 S.Ct. 2492).

Here, AbbVie argues that the Act "stands as an obstacle" to Congress's objectives for three reasons. (ECF No. 7 at

8–9; ECF No. 52 at 4.) Whether these alleged conflicts are "a sufficient obstacle" to warrant a finding of conflict preemption "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, 120 S.Ct. 2288, 147 L.Ed.2d 352 (2000).

a. *Enforcement*

AbbVie first contends that the Act "stands as an obstacle" to Congress's objectives because it "contravenes HRSA's exclusive enforcement authority." (ECF No. 7 at 8.) On this record, the Court is unpersuaded.

AbbVie asserts that "[f]ederal law vests enforcement solely in HHS and lays out the precise tools available: audits, dispute resolution, and civil penalties." (*Id.* at 9 (citing §§ 256b(d)(l)(B)(v), (vi), (d)(3)).) By contrast, it notes that "[s]tate enforcement mechanisms" under the Act include "civil suits by third parties, the Attorney General, or the Board of Pharmacy." (*Id.*) AbbVie thus contends that the federal and state enforcement frameworks are in direct conflict insofar as the Act vests enforcement authority in actors *other* than HRSA.

***9** Following the Supreme Court's decision in *Astra,* there can be little debate that Section 340B decidedly does *not* authorize a private right of action for violations of the federal statute. Indeed, the parties conceded in that case that covered entities had "no [private] right to sue for overcharges under [§ 340B] itself," and the Supreme Court proceeded to hold "that suits by [covered] entities to enforce ceiling-price contracts [the PPAs] running between drug manufacturers and the Secretary of HHS [were also] incompatible with the statutory regime." 563 U.S. at 113, 131 S.Ct. 1342.

But this does not end the inquiry. " 'Conflict is imminent' when 'two separate remedies are brought to bear *on the same activity.*' " *Crosby,* 530 U.S. at 373, 120 S.Ct. 2288 (quoting *Wis. Dep't of Indus. v. Gould, Inc.,* 475 U.S. 282, 286, 106 S.Ct. 1057, 89 L.Ed.2d 223 (1986)) (emphasis added); *see also Arizona,* 567 U.S. at 402, 132 S.Ct. 2492 ("Permitting the State to impose its own penalties for the *federal offenses* here would conflict with the careful framework Congress adopted." (emphasis added)). AbbVie has identified two separate remedies, but it does not discuss in its briefing the activities those remedies are intended to redress.

Numerous federal courts have now considered the same argument that AbbVie sets forth here, and nearly all have found that state law enforcement schemes like that found in the Act "do[ ] not conflict with Section 340B's enforcement scheme." *E.g., Fitch,* 152 F.4th at 647. Though "true that Congress made HHS the sole enforcer of Section 340B," the Fifth and Eighth Circuits reasoned that the comparable state laws before them "d[id] not intrude upon this authority because [they did] not impose penalties for *violations of Section 340B*, like failing to offer discounted drugs to covered entities or engaging in diversion." *Id.* at 647–48 (emphasis added); *McClain,* 95 F.4th at 1144 ("HHS has jurisdiction over different disputes: disputes between covered entities and manufacturers regarding pricing, overcharges, refunds, and diversion of 340B drugs to those who do not qualify for discounted drugs."). Rather, the state laws "impose[d] penalties when drug manufacturers [*violated the state law*] by interfering with the distribution of Section 340B drugs pursuant to covered entities' partnerships with contract pharmacies." *Fitch,* 152 F.4th at 648; *McClain,* 95 F.4th at 1145 (reasoning the Arkansas law's penalties were aimed at "deterring pharmaceutical manufacturers from interfering with a covered entity's contract pharmacy arrangements"). Put simply, the state law penalties were "aimed at activity that falls outside the purview of 340B." *McClain,* 95 F.4th at 1145.

The same is true of the Act here. *See* § 6-9-105(3)(a) ("A person that violates *this [Act]* ... is subject to the enforcement provisions, civil penalties, and damages set forth in Article 1 of this Title 6." (emphasis added)).

Nevertheless, at the evidentiary hearing, AbbVie highlighted that, in response to regulatory comments from stakeholders like Dr. Forbush, HRSA recently modified the 340B Administrative Dispute Resolution Regulation to explain that the 340B ADR Panel is permitted to hear "[c]laims by a covered entity that it has been overcharged by a manufacturer for a covered outpatient drug, including claims that a manufacturer has limited the covered entity's ability to purchase covered outpatient drugs at or below the 340B ceiling price." 89 Fed. Reg. 28,643, 28,657 (Apr. 19, 2024). (*See also* ECF No. 111 at 105–108.) Dr. Forbush agreed during his testimony that he, personally, "wanted the government to clarify that it counts as an overcharge of a drug when a manufacturer imposes limits or conditions on a covered entity's ability to purchase drugs at the 340B price." (*Id.* at 105:24–106:3.)

***10** Notably, though, HRSA expressly declined to promulgate "an explicit definition of the term 'overcharge,' " instead choosing to explain only that "[w]hen an overcharge claim is presented before a 340B ADR Panel, the Panel will follow the 340B statute" and "relevant case law," among other sources. 89 Fed. Reg. at 28,649. Given the Third and D.C. Circuits have held that manufacturers do not violate Section 340B when they restrict a covered entity's ability to distribute drugs to patients through contract pharmacies, it is difficult to see how that conduct "could be challenged as a limitation on the ability to purchase drugs at or below the ceiling price *under federal law*" before the ADR Panel. *Frey,* 2025 WL 2813787, at *11 (emphasis added). At the very most, "the alleged conflict is too speculative" at this stage "to support a finding that [AbbVie] is likely to prevail on [its] claim" that the Act is preempted because it contains a conflicting enforcement mechanism. *Id.*

For these reasons, the Court concludes that AbbVie has not demonstrated a likelihood of success on the merits of its preemption claim based on a purported conflict between the enforcement mechanisms of Section 340B and the Act.

b. *340B Drug Pricing*

Next, AbbVie argues that Section 340B and the Act are in conflict because, "like the federal statute, [the Act] regulates *pricing,* not 'delivery' ...." (ECF No. 7 at 9.) The Court is unpersuaded.

Much of AbbVie's argument originates with the Act's definition of a "340B drug," which is as follows:

> ... a drug that:
>
> (a) Is a covered outpatient drug within the meaning set forth in 42 U.S.C. sec. 256b;
>
> (b) Has been subject to any offer for reduced prices by a manufacturer pursuant to 42 U.S.C. sec. 256b(a)(1);
>
> (c) Is purchased by a covered entity. As used in this subsection (2)(c), a drug is considered "purchased" if it would have been purchased but for the restriction or limitation described in section 6-29-105.

§ 6-29-103(2) (emphasis added).

First, AbbVie argues that the Act "by its very text cannot escape the word 'price.' " (ECF No. 7 at 9.) However, as concisely put by the *Amici,* "[t]he fact that [the Act] includes 'the word price' ... does not mean that it *regulates* price." (ECF No. 34-1 at 7 (emphasis in original).) Indeed, the cited definition makes clear that the price is set "*pursuant to [Section 340B].*" § 6-29-103(2)(b) (emphasis added); *cf., e.g., McClain,* 95 F.4th at 1145 (concluding substantially similar Arkansas statute "does not set or enforce discount pricing"); *PhRMA v. Murrill,* 2024 WL 4361597, at *9 (W.D. La. Sept. 30, 2024) ("[D]iscounts are set by the federal government, not the State of Louisiana or Act 358."); *AbbVie Inc. v. Skrmetti,* 2025 WL 1805271, at *18 (M.D. Tenn. June 30, 2025) ("The amount of the discount is not at issue and is not affected by the state scheme.").

Second, AbbVie emphasizes that the Act defines a 340B drug as inclusive of one that "*would have been purchased* but for the restriction or limitation" imposed by AbbVie's policy. § 6-29-103(2) (emphasis added).[6] In this way, the Court understands AbbVie to argue that the Act conflicts with Section 340B because it compels AbbVie to make sales it otherwise would have refused to make by "attach[ing] 340B discounts to drugs shipped to for-profit pharmacies or other 'authorized' locations." (ECF No. 7 at 9.) Put still another way, AbbVie insists that the Act conflicts with Section 340B because it "grants contract pharmacies expanded access to 340B pricing." (ECF No. 36 at 3.)

Like the Fifth Circuit, the Court understands AbbVie's concern is that the involvement of contract pharmacies comes with an increased risk of abuse of the 340B Program. *See Fitch,* 152 F.4th at 648 (noting AbbVie's grievance is that "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"). But, to again borrow the words of the Fifth Circuit, AbbVie's suggestion that the Act facially requires it to sell 340B drugs to non-covered entities

> ***11** is simply incorrect. [The Act] does not expand Section 340B's list of covered entities to include contract pharmacies. By its plain text, [the Act] 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.

Id. at 647. On this record, the Court is further unconvinced that the Act will have the practical effect of requiring AbbVie to make sales to non-covered entities in conflict with Section 340B, such that a preliminary injunction is warranted. *Cf. id.* at 648 ("AbbVie is essentially alleging that the real problem with [the Mississippi law] is not a *feature* of the law, but rather a *bug*. And on this record, we cannot say that this potential bug in [the state law] merits a preliminary injunction.").

For these reasons, the Court also concludes that AbbVie has not demonstrated a substantial likelihood of success on the merits of its preemption claim based on its assertion that, like Section 340B, the Act purports to regulate pricing.

c. *Pilot Program*

Third, AbbVie avers that the Act's claims data restriction conflicts with the impending 340B Rebate Model Pilot Program (the "Pilot Program"), which HRSA announced shortly after AbbVie filed the Motion. (ECF No. 52 at 2.) *See also* 90 Fed. Reg. 36,163 (Aug. 1, 2025).

As pertinent background, AbbVie explains that the Pilot Program concerns the interplay between the 340B Program and the Inflation Reduction Act's Drug Price Negotiation Program ("DPNP"), 42 U.S.C. §§ 1320f *et seq.* (*Id.*) Whereas the 340B Program "requires manufacturers to offer drugs to certain 'covered entities' at a statutorily calculated 'ceiling price,' " the DPNP "requires HHS to set a 'maximum fair price' ('MFP') for certain selected drugs," which manufacturers must then make "available to certain Medicare-covered individuals at the MFP." (*Id.* (citing §§ 1320f(a)(3), (c)(2), 1320f-2(a)(3)).) Under the DPNP's "nonduplication" provision, manufacturers must provide the lower of the two price concessions—the 340B ceiling price or the MFP—but not both. (*Id.* (citing § 1320f-2(d))). According to AbbVie, manufacturers, rather than HHS, "shoulder the task" of "identifying and deduplicating 340B dispenses." (*Id.*)

In response to "widespread concern about the nonduplication and compliance problems" facing manufacturers, AbbVie states that "HRSA announced the Pilot Program to test a rebate model for effectuating the 340B price to covered entities." (*Id.* (citing 90 Fed. Reg. at 36,163–65).) As pertinent here, the Pilot Program allegedly permits "manufacturers ... to request from covered entities—and covered entities are expected to provide—claims data" to better enable manufacturers "[t]o determine which price concession (if any) is appropriate" under the new rebate model. (*Id.* at 3.) AbbVie believes that the Act poses a barrier to its participation in the Pilot Program because it restricts manufacturers "from requiring 340B covered entities and contract pharmacies to 'submit any health information, claims or utilization data, purchasing data, payment data, or other data.' " (ECF No. 52 at 3 (quoting § 6-29-105(b)).) [7]

***12** The Court is not persuaded. Even setting aside the standing and ripeness issues Defendants raised (ECF No. 74 at 2), there appears to be no conflict between the Act's plain text and the Pilot Program as far as claims data is concerned. AbbVie selectively quoted the Act's prohibitory language on the collection of claims data but ignored its further qualification that the prohibition applies "*unless such data is ... otherwise required to be furnished under applicable federal law.*" § 6-29-105(1)(b) (emphasis added). This caveat is further reinforced by § 6-29-105(5), which provides:

> (5) **Data exclusions.** Subsection (1) of this section 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, including data relating to an audit in accordance with procedures established by the Federal Department of Health and Human Services under 42 U.S.C. § 256b(a)(5)(C).

§ 6-29-105(5).

Thus, to the extent the Pilot Program requires covered entities to provide certain claims data, it appears at this point that the

Act poses no barrier. For at least this reason, the Court easily concludes that AbbVie has also not established a substantial likelihood of success in demonstrating the Act "stands as an obstacle" to the implementation of the Pilot Program.

B. Takings Clause

AbbVie's second claim is that the Act runs afoul of the Takings Clause "because it compels AbbVie and other manufacturers to make sales at 340B-discounted prices under terms they would otherwise never agree to." (ECF No. 7 at 11.)

"The Takings Clause of the Fifth Amendment, applicable to the States through the Fourteenth Amendment, provides: '[N]or shall private property be taken for public use, without just compensation.' " *Cedar Point Nursery v. Hassid,* 594 U.S. 139, 147, 141 S.Ct. 2063, 210 L.Ed.2d 369 (2021). As a general matter, a government taking may occur when the government "physically acquires private property for a public use," or where, "rather than appropriate private property for itself or a third party," the government "instead imposes regulations that restrict an owner's ability to use his own property." *Id.* at 147–48, 141 S.Ct. 2063. In the Motion, AbbVie appears to argue only the former—that the Act effects a *per se* taking of its private property. (*See* ECF No. 36 at 8–9 (discussing Supreme Court authority holding that "when there has been a physical appropriation, 'we do not ask ... whether it deprives the owner of all economically valuable use' of the item taken," *Horne v. Dep't of Agriculture,* 576 U.S. 350, 363, 135 S.Ct. 2419, 192 L.Ed.2d 388 (2015) (internal citation omitted)).) Accordingly, the Court does not analyze herein whether the Act effects a taking as a "use restriction" under the *Penn Central* test. *Cedar Point,* 594 U.S. at 148, 141 S.Ct. 2063.

Critically, "[a] demand for personal property" is not a taking where "it involve[s] a voluntary exchange for a government benefit." *Valancourt Books, LLC v. Garland,* 82 F.4th 1222, 1232 (D.C. Cir. 2023). So long as "the property owner is 'aware of the conditions' of an exchange," "the conditions are 'rationally related to a legitimate Government interest,' " and "the purported 'benefit' is [not] illusory," "presenting the exchange poses no takings problem." *Id.* (quoting *Ruckelshaus v. Monsanto Co.,* 467 U.S. 986, 1007, 104 S.Ct. 2862, 81 L.Ed.2d 815 (1984)); *see also Baker County Med. Servs., Inc. v. U.S. Atty. Gen.,* 763 F.3d 1274, 1276 (11th Cir. 2014) (collecting cases "instruct[ing] that no taking occurs where a person or entity voluntarily participates in a regulated program or activity").

***13** As especially pertinent here, numerous Circuit Courts of Appeal have found that regulatory requirements imposed as a condition of participation in Medicaid and Medicare do not effect a taking. *See, e.g., Baker County Med. Servs.,* 763 F.3d at 1279 (rejecting hospital's takings challenge to "its rate of compensation in a regulated industry for an obligation it voluntarily undertook ... when it opted into Medicare and became subject to" federal statute requiring hospitals to treat all people who seek treatment in emergency departments); *Burditt v. U.S. Dep't of Health & Hum. Servs.,* 934 F.2d 1362, 1376 (5th Cir. 1991) (similar); *Minn. Ass'n of Health Care Facilities, Inc. v. Minn. Dep't of Public Health Welfare,* 742 F.2d 442, 446 (8th Cir. 1984) (nursing home's voluntary decision to participate in Medicaid "forecloses the possibility that the statute could result in an imposed taking of private property").

Extending that rationale to the precise circumstances here, courts have found that the voluntariness of the 340B program poses an obvious impediment to pharmaceutical manufacturers' Takings Clause challenges to state legislation like the Act. *See, e.g., 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."); *Astrazenca Pharms. LP v. Bailey,* 2025 WL 644285, at *4 (W.D. Mo. Feb. 27, 2025) ("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 to just compensation."). The Court agrees and adopts the rationale of these decisions, and finds AbbVie's voluntary participation in the 340B program, at least at this early juncture of these proceedings, to present a nearly insurmountable obstacle to the success of their Takings claim.

Still, while AbbVie acknowledges that "[v]oluntarily accepting a government benefit in exchange for giving up property rights can extinguish a takings claim against the government who conferred the bargained-for benefit," it argues that its voluntarily participation in a federal program "cannot justify separate state-imposed requirements where no state benefit is conferred." (ECF No. 7 at 13.) The authorities upon which AbbVie relies to support this assertion, however, are inapposite.

In *Valancourt Books,* the D.C. Circuit concluded that a provision of the *federal* Copyright Act "requiring copyright owners to provide physical copies of books" effected a taking because "copyright owners receive[d] no additional benefit for the works they forfeit[ed] pursuant to [the] deposit requirement." 82 F.4th at 1232. The D.C. Circuit reasoned that "[m]andatory deposit is not required to secure the benefits of copyright." *Id.* Rather, authors obtained the benefit of copyright immediately upon fixation of the work, and the "mandatory deposit [provision] grant[ed] no additional benefits." *Id.* at 1233. Unlike copyright protection, however, AbbVie has no automatic right to receive the benefits incidental to its participation in Medicare and Medicaid. And it cites no case law supporting that each time the government (whether federal or state) imposes a new regulatory requirement upon Medicaid and Medicare participants, it must *also* confer some increased "benefit" of participation. *Cf. Frey,* 2025 WL 2813787, at *14 ("AbbVie does not provide any persuasive authority to support the contention that each new regulatory condition must be accompanied by a separate benefit to maintain the voluntary nature of the program for purposes of a takings claim").

***14** *Virginia Hospital & Healthcare Association v. Roberts* is also distinguishable. 671 F. Supp. 3d 633 (E.D. Va. 2023). There, 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." *Id.* at 666;[8] *see also Garelick v. Sullivan,* 987 F.2d 913, 917 (2d Cir. 1993) (where the plaintiffs argued the voluntary participation doctrine was inapplicable "because New York law compels them to render services to Medicare beneficiaries"). Here, AbbVie does not argue that the Act purports to compel its participation in the 340B Program. To the contrary, it has affirmed that it remains free, in its sole discretion, to withdraw from the Program. (ECF No. 111 at 261:4–7 ("one day laws like this are going to force manufacturers to withdraw on a manufacturers to withdraw on a nationwide basis Medicare and Medicaid"); *see also* ECF No. 98 (AbbVie's notice of supplemental authority informing the Court that "a large drug manufacturer announced that it will withdraw from both 340B and Medicaid next week").) Though that would be an unfortunate result, it appears at this juncture that AbbVie has more likely identified a public policy issue, and not a Takings Clause violation.

For these reasons, and most importantly because AbbVie's participation in the 304B Program is wholly voluntary, the Court finds that AbbVie has not established a substantial likelihood of success in demonstrating that the Act effects a *per se* taking. Accordingly, the Court does not reach AbbVie's arguments that the Act runs afoul of the Takings Clause "public use" requirement, nor Defendants' argument that "AbbVie cannot bring a takings claim for injunctive relief against state officers in federal court." (ECF No. 33 at 10.)

IV. CONCLUSION

For all the foregoing reasons, Plaintiffs' Motion for a Preliminary Injunction (ECF No. 7) is DENIED.

All Citations

--- F.Supp.3d ----, 2025 WL 3041825

Footnotes

1 The Act went into effect on August 6, 2025. (*See* ECF No. 33-1 at 9.)

2 With the Court's leave, *Amici Curiae* American Hospital Association, 340B Health, Colorado Hospital Association, and American Society of Health-System Pharmacists (collectively, the "*Amici*") also filed a brief in opposition to the Motion. (ECF No. 34-1.)

3 Numerous federal courts have now had occasion to summarize the history of the 340B Program and related HHS guidance relevant to this lawsuit, including the Supreme Court and four Circuit Courts of Appeal. *See Astra USA, Inc. v. Santa Clara County, Cal.,* 563 U.S. 110, 131 S.Ct. 1342, 179 L.Ed.2d 457 (2011); *AbbVie, Inc. v. Fitch,* 152 F.4th 635 (5th Cir. 2025); *PhRMA v. McClain,* 95 F.4th 1136 (8th Cir. 2024); *Novartis Pharms. Corp. v. Johnson,* 102 F.4th 452 (D.C. Cir. 2024); *Sanofi Aventis U.S. LLC v. U.S. Dep't of Health*

& Hum. Servs., 58 F.4th 696 (3d Cir. 2023). The Court leverages the factual background set forth in those decisions where applicable and adds further detail from the parties' briefing on the Motion where needed. All citations to docketed materials are to the page number in the CM/ECF header, which sometimes differs from a document's internal pagination.

4 A third appeal is currently pending before the Seventh Circuit. *See Eli Lilly & Co. v. HHS, et al.*, No. 21-3405 (7th Cir.).

5 *See AbbVie Inc. v. Neronha,* 1:25-cv-00388-JJM-AEM (D.R.I. Sept. 30, 2025) (denying preliminary injunction as to Rhode Island law); *AbbVie, Inc. v. Frey,* 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,* 2025 WL 1805271, at *18 (M.D. Tenn. June 30, 2025) (same as to Tennessee law); *Astrazenca Pharms. LP v. Bailey,* 2025 WL 644285, at *3 (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. Murrill,* 2024 WL 4361597, at *8–9 (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,* 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,* 2024 WL 3277365, at *11 (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* —— U.S. ——, 145 S.Ct. 768, 220 L.Ed.2d 272 (2024); *but see AstraZeneca Pharms. LP v. Harris,* No. 4:24-cv-00268-KGB (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).

6 In substantial part, this argument appears to be a repackaging of AbbVie's argument that Congress has preempted the field when it comes to the terms that manufacturers may or may not attach to their offers of 340B drugs. The Court's analysis as to that issue above applies with equal force to the extent AbbVie bases its conflict preemption claim on the same grounds. (*See* Section III.A.1 *infra.*)

7 Just before the Court issued this Order, AbbVie filed a notice informing the Court that HRSA had "officially approved" its application to participate in the Pilot Program, which is expected to commence on January 1, 2026. (ECF No. 112.)

8 Notably, the district court ultimately did "not fully determine whether Virginia's [ ] program amount[ed] to legal compulsion" because the plaintiffs' Takings Clause claim against the state defendant was barred by the Eleventh Amendment in any event. *Id.* at 667. Defendants similarly raise an Eleventh Amendment issue here, though, as noted below, the Court does not reach that issue.