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United States District Court, D. Colorado.

ASTRAZENECA PHARMACEUTICALS LP, Plaintiff,
v.
PHILIP J. WEISER, in his official capacity as the Attorney General of the State of Colorado, et al., Defendants.

Civil Action No. 25-cv-02685-PAB-STV
|
12/17/2025

PHILIP A. BRIMMER, Chief United States District Judge

ORDER

***1** This matter comes before the Court on Plaintiff's Motion for a Preliminary Injunction [Docket No. 25], wherein plaintiff seeks an injunction enjoining the Colorado 340B Contract Pharmacy Protection Act, Colorado Revised Statutes §§ 6-29-101 *et seq.* (2025) ("S.B. 71") from being enforced against it. Defendants oppose plaintiff's motion. Docket No. 48. The Court has jurisdiction pursuant to 28 U.S.C. § 1331.

I. BACKGROUND

In 1992, Congress created the so-called Section 340B program by enacting § 340B of the Public Health Service Act, 42 U.S.C. § 256b ("Section 340B"). *Astra USA, Inc. v. Santa Clara Cnty., Cal.*, 563 U.S. 110, 113 (2011). Section 340B "imposes ceilings on prices drug manufacturers may charge for medications sold to specified health-care facilities." *Id.* The Section 340B program was created "to ensure that uninsured and low-income individuals can access the medications they need and to ensure that medical providers serving these individuals receive crucial subsidies." *AbbVie, Inc. v. Fitch*, 152 F.4th 635 (5th Cir. 2025). The specified health-care facilities are known as "covered entities" and "include public hospitals and community health centers" which often provide "safety-net services to the poor." *Astra*, 563 U.S. at 113.

The Section 340B program "is superintended by the Health Resources and Services Administration (HRSA), a unit of the Department of Health and Human Services (HHS). Drug manufacturers opt into the 340B Program by signing a form Pharmaceutical Pricing Agreement (PPA) used nationwide." *Id.* PPAs are "uniform agreements that recite the responsibilities § 340B imposes." *Id.* One of these responsibilities requires that manufacturers "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." 42 U.S.C. § 256b(a)(1). Drug manufacturers cannot participate in Medicaid and Medicare Part B unless they participate in the Section 340B program. *Astra*, 563 U.S. at 113.

Section 340B also places certain restrictions on covered entities. *See* 42 U.S.C. § 256b(a)(5)(A)-(D); *see also Fitch*, 152 F.4th at 640 (listing the restrictions that Section 340B places on covered entities). Covered entities are forbidden to seek "duplicate discounts or rebates," meaning they cannot seek a Section 340B discount and a Medicaid rebate on the same drug. 42 U.S.C. § 256b(a)(5)(A). Covered entities are also forbidden from reselling or transferring a covered drug to a person who is not a patient of the covered entity. 42 U.S.C. § 256b(a)(5)(B). To ensure compliance with these restrictions, covered entities must permit the Secretary of Health and Human Services and the manufacturer of covered drugs to audit their records. 42 U.S.C. § 256b(a)(5)(C). If a covered entity fails to comply with these restrictions, it will be liable to the drug manufacturer for the amount improperly received. 42 U.S.C. § 256b(a)(5)(D).

Since Section 340B was first enacted, "covered entities have contracted with outside pharmacies, referred to as 'contract pharmacies,' for the distribution and dispensation of 340B drugs. This is in large part due to the fact that building or maintaining a pharmacy is cost-prohibitive for many covered entities. Additionally, the outsourcing of pharmacy services has allowed for drug dispensation closer to where low-income patients reside." *Pharm. Rsch. & Manufacturers of Am. v. McClain*, 95 F.4th 1136, 1139 (8th Cir. 2024).

***2** In 1996, HRSA issued guidance stating its belief that Section 340B is silent regarding how covered drugs were to be distributed, and that silence created a gap in the legislation. *Novartis Pharms. Corp. v. Johnson*, 102 F.4th 452, 456-57 (D.C. Cir. 2024) (citing Notice Regarding Section 602 of the Veterans Health Care Act of 1992; Contract Pharmacy Services, 61 Fed. Reg. 43,549, 43,549-50 (Aug. 23, 1996) ("1996 Guidance")). Seeking to fill that gap, "HRSA stated that a covered entity without an in-house pharmacy may contract with a single outside pharmacy to dispense drugs at a

single location." *Id.* at 457 (citing 1996 Guidance at 43,555). In 2010, HRSA issued new guidance stating that "covered entities may contract with an unlimited number of outside pharmacies and may do so regardless of whether the entities have in-house pharmacies." *Id.* (citing Notice Regarding 340B Drug Pricing Program—Contract Pharmacy Services, 75 Fed. Reg. 10,272, 10,272–73 (Mar. 5, 2010) ("2010 Guidance")). HRSA recognized that "contract pharmacies enable covered entities to 'create wider patient access by having more inclusive arrangements in their communities.' " *Id.* (quoting 2010 Guidance at 10,273). "After the 2010 guidance, the use of contract pharmacies skyrocketed." *Sanofi Aventis U.S. LLC v. United States Dep't of Health & Hum. Servs.*, 58 F.4th 696, 700 (3d Cir. 2023).

Drug manufacturers believed that the proliferative use of contract pharmacies was increasing duplicate discounting and diversion. *Id.* Specifically, manufacturers worried that the "replenishment model" used by many contract pharmacies to stock Section 340B discounted drugs led to increased abuse of the Section 340B program. Docket No. 25 at 4-5; *Johnson*, 102 F.4th at 457-58. The D.C. Circuit explained how the replenishment model operates and how it can potentially be abused by contract pharmacies:

> While some contract pharmacies maintain separate inventories of section 340B drugs, most fill prescriptions from inventories that intermingle discounted and non-discounted drugs. Only after dispensing the drugs do these pharmacies attempt to discern whether individual customers were patients of covered entities—in other words, whether individual prescriptions were eligible for the discount. Many pharmacies outsource this determination to third-party administrators, who often receive a larger fee for every prescription deemed eligible for the discount. Once the pharmacy or the administrator categorizes a certain number of prescriptions as eligible, the pharmacy places an order to replenish its section 340B purchases. The covered entity, the pharmacy, and the third-party administrator often divvy up the spread between the discounted price and the higher insurance reimbursement rate. Each of these actors thus has a financial incentive to catalog as many prescriptions as possible as eligible for the discount.

Johnson, 102 F.4th at 457-58.

In 2020, attempting to combat this alleged abuse, manufacturers adopted policies limiting the use of contract pharmacies. *Id.* at 458. AstraZeneca Pharmaceuticals LP ("AstraZeneca") was one of the manufacturers who adopted such a policy, allowing 340B discounts at only a single designated contract pharmacy, and only for covered entities that lack an in-house pharmacy. Docket No. 25 at 5. In response to these new policies by drug manufacturers, "HHS issued an advisory opinion stating that section 340B requires manufacturers to deliver covered drugs to any contract pharmacies with which a covered entity chooses to partner." *Johnson*, 102 F.4th at 458. Drug manufacturers challenged HHS's interpretations in court. The Third Circuit and the D.C. Circuit held that Section 340B is silent about delivery, and therefore it does not require manufacturers to distribute discounted drugs to contract pharmacies. *Id.* at 464; *Sanofi Aventis*, 58 F.4th at 707. "HHS ultimately withdrew the advisory opinion." *Fitch*, 152 F.4th at 641.

***3** "Soon after, 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.* Nationwide, drug manufacturers have challenged these state statutes as unconstitutional; to date, courts have largely rejected those challenges. [1]

Like many other states, Colorado passed a statute, Senate Bill 25-071, which requires drug manufacturers to deliver drugs discounted under Section 340B to unlimited contract pharmacies. *Weiser*, 2025 WL 3041825, at *3-4. Senate Bill 25-071 is now codified as the Colorado 340B Contract Pharmacy Protection Act, Colorado Revised Statutes §§ 6-29-101 *et seq.* (2025). *Id.* at *1. S.B. 71 took effect on August 6, 2025. *Id.* at *1 n.1. The statute prohibits manufacturers from doing the following:

> (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.

Colo. Rev. Stat. § 6-29-105.

***4** On August 27, 2025, plaintiff AstraZeneca filed this lawsuit against defendants Philip J. Weiser, in his official capacity as the 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 ("defendants"), to challenge the constitutionality of S.B. 71.[2] Docket No. 1. On October 1, 2025, AstraZeneca filed a motion for a preliminary injunction seeking to enjoin S.B. 71 from being enforced against it. Docket No. 25. On October 30, 2025, defendants filed a response. Docket No. 48. On November 10, 2025, AstraZeneca filed a reply. Docket No. 57. The Court heard argument on the motion on December 2, 2025. Docket No. 67.

II. LEGAL STANDARD

To succeed on a motion for a preliminary injunction, the moving party must show (1) a likelihood of success on the merits; (2) a likelihood that the movant will suffer irreparable harm in the absence of preliminary relief; (3) that the balance of equities tips in the movant's favor; and (4) that the injunction is in the public interest. *RoDa Drilling Co. v. Siegal*, 552 F.3d 1203, 1208 (10th Cir. 2009) (citing *Winter v. Natural Res. Def. Council, Inc.*, 555 U.S. 7, 20 (2008)); *see Little v. Jones*, 607 F.3d 1245, 1251 (10th Cir. 2010). The third and fourth factors merge when the government is the opposing party. *Denver Homeless Out Loud v. Denver, Colo.*, 32 F.4th 1259, 1278 (10th Cir. 2022) (citation omitted). If a court finds against the movant on one factor, the other factors need not be addressed. *Dominion Video Satellite, Inc. v. Echostar Satellite Corp.*, 356 F.3d 1256, 1266 n. 8 (10th Cir. 2004); *see also Vill. of Logan v. U.S. Dep't of Interior*, 577 F. App'x 760, 766 (10th Cir. 2014) (unpublished) (a "plaintiff's failure to prove any one of the four preliminary injunction factors renders its request for preliminary injunctive relief unwarranted"). "[B]ecause a preliminary injunction is an extraordinary remedy, the right to relief must be clear and unequivocal." *Beltronics USA, Inc. v. Midwest Inventory Distrib., LLC*, 562 F.3d 1067, 1070 (10th Cir. 2009) (quoting *Greater Yellowstone Coal. v. Flowers*, 321 F.3d 1250, 1256 (10th Cir. 2003)) (internal quotation marks omitted). Granting such "drastic relief," *United States ex rel. Citizen Band Potawatomi Indian Tribe of Okla. v. Enter. Mgmt. Consultants, Inc.*, 883 F.2d 886, 888-89 (10th Cir. 1989), "is the exception rather than the rule." *GTE Corp. v. Williams*, 731 F.2d 676, 678 (10th Cir. 1984).

There are three types of preliminary injunctions that are disfavored: (1) injunctions that disturb the status quo, (2) injunctions that are mandatory rather than prohibitory, and (3) injunctions that provide the movant substantially all the relief it could feasibly attain after a full trial on the merits. *See Schrier v. Univ. Of Co.*, 427 F.3d 1253, 1260 (10th Cir. 2005). In seeking a disfavored injunction, "the movant must make a strong showing both with regard to the likelihood of success on the merits and with regard to the balance of harms." *Fish v. Kobach*, 840 F.3d 710, 724 (10th Cir. 2016) (quotations, alterations, and citation omitted); *see also Schrier*, 427 F.3d at 1259 (stating that such injunctions "must be more closely scrutinized to assure that the exigencies of the case support the granting of a remedy that is extraordinary even in the normal course" (citation omitted)).

III. ANALYSIS

***5** AstraZeneca argues that S.B. 71 is preempted by Section 340B and by federal patent laws. Docket No. 25 at 2. First, AstraZeneca asserts that any presumption against preemption does not apply in this case. *Id.* at 7. Second, it argues that Section 340B preempts S.B. 71 because (a) both laws regulate price; (b) S.B. 71 recalibrates the burdens and benefits of participating in Section 340B; (c) S.B. 71's enforcement regime conflicts with Section 340B's enforcement regime; and (d) S.B. 71's claims-data restriction conflicts with federal laws and regulations. *Id.* at 8-17. Third, AstraZeneca argues

that S.B. 71 is preempted by federal patent laws because it diminishes the rewards to patentees by capping the price at which patented drugs may be sold.

In their response, defendants raise two arguments of their own: (a) that AstraZeneca does not have standing; and (b) that AstraZeneca is seeking a disfavored injunction. Docket No. 48 at 3-6. The Court will first address whether AstraZeneca has standing. *See Colorado Env't Coal. v. Wenker*, 353 F.3d 1221, 1227 (10th Cir. 2004) (stating that standing is jurisdictional).

A. Standing

At its core, "standing is an essential and unchanging part of the case-or-controversy requirement of Article III." *Lujan v. Defenders of Wildlife*, 504 U.S. 555, 560 (1992). To establish standing, "a plaintiff must show: (1) that he has 'suffered an injury in fact'; (2) that the injury is 'fairly traceable to the challenged action of the defendant'; and (3) that it is 'likely' that the 'injury will be redressed by a favorable decision.' " *Am. Humanist Ass'n, Inc. v. Douglas Cty. Sch. Dist. RE-1*, 859 F.3d 1243, 1250 (10th Cir. 2017) (quoting *Ariz. Christian Sch. Tuition Org. v. Winn*, 563 U.S. 125, 133-34 (2011)). The party asserting federal jurisdiction has the burden of supporting each of these elements 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 the litigation." *Lujan*, 504 U.S. at 561. Thus, "[a]t the pleading stage, general factual allegations of injury...may suffice." *Id.*

Defendants argue that AstraZeneca does not have standing because its alleged injuries are not fairly traceable to S.B. 71. Docket No. 48 at 5. Defendants state that AstraZeneca's injuries are traceable to its voluntary participation in Section 340B. *Id.* at 5-6. However, AstraZeneca alleges that S.B. 71 makes participation in Section 340B more costly through its requirement to make Section 340B discounted drugs available at unlimited contract pharmacies. Docket No. 25 at 12. AstraZeneca projects this will result in it losing approximately $600,000 per month in sales. Docket No. 25-1 at 7, ¶ 28.

While these losses may ultimately stem from AstraZeneca's participation in Section 340B, the Court finds that AstraZeneca is incentivized to participate in Section 340B because otherwise it cannot participate in Medicaid and Medicare Part B. Thus, making participation in Section 340B more costly is a "concrete and particularized" injury that is fairly traceable to S.B. 71. *See Lujan*, 504 U.S. at 560 (stating that an injury in fact must be "concrete and particularized.") (citations omitted). Defendants also argue that any injury due to diversion or duplicate discounts is traceable to illegal transfers of Section 340B drugs, and not to S.B. 71. Docket No. 48 at 5. However, AstraZeneca alleges that illegal transfers of Section 340B drugs are more common in contract pharmacies, and are thus made more common by S.B. 71. Docket No. 25 at 4-5. Accordingly, the Court concludes that AstraZeneca has established that its injury is fairly traceable to S.B. 71. AstraZeneca therefore has standing to bring this action.

B. Disfavored Injunction

***6** Defendants argue that AstraZeneca is seeking a disfavored injunction because enjoining the enforcement of S.B. 71 would alter the status quo and because the relief AstraZeneca seeks is coterminous with the relief it seeks at trial. Docket No. 48 at 3-4. However, the Court finds that enjoining the enforcement of S.B. 71 would not alter the status quo. In the context of a disfavored injunction, "the status quo is the last uncontested status between the parties which preceded the controversy." *Schrier*, 427 F.3d at 1260 (internal quotations and citation omitted). Thus, "[i]n the context of a newly enacted statute challenged on constitutional grounds, the status quo is the period prior to the statute's enactment." *Black Emergency Response Team v. Drummond*, 737 F. Supp. 3d 1136, 1145 (W.D. Okla. 2024). Therefore, the status quo was the period before S.B. 71 was enacted. Enjoining its enforcement would not alter the status quo.

Furthermore, the relief AstraZeneca seeks in its preliminary injunction motion is not the same as the relief it seeks at trial. AstraZeneca seeks to preliminarily enjoin enforcement of S.B. 71 against it. Docket No. 25 at 2. It is true that AstraZeneca also wants the Court to find S.B. 71 unconstitutional, and thus unenforceable. Docket No. 1 at 39. However, this is not the same relief as preliminarily enjoining enforcement because a prohibition on enforcing S.B. 71 could be undone after trial. *See Black Emergency Response Team*, 737 F. Supp. 3d at 1145-46 (citing *Prairie Band of Potawatomi Indians v. Pierce*, 253 F.3d 1234, 1247-58 (10th Cir. 2001)) ("a preliminary injunction would not irreversibly afford Plaintiffs all the relief they could recover at trial, because a prohibition on enforcing the Act could be undone at the conclusion of a determination on the merits."). Therefore, the relief AstraZeneca seeks is not the same as the relief it seeks at trial. Accordingly, it is not seeking a disfavored injunction.

The Court will now analyze whether AstraZeneca has shown a likelihood of success on the merits.

C. Preemption

Article VI, cl. 2 of the Constitution—known as the Supremacy Clause—provides that "the Laws of the United States...shall be the supreme Law of the Land...any Thing in the Constitution or Laws of any State to the Contrary notwithstanding." U.S. Const. art. VI, cl. 2. "Under this principle, Congress has the power to preempt state law." *Arizona v. United States*, 567 U.S. 387, 399 (2012). If a federal law regulates something "inherently federal in character," no presumption against preemption applies. *Buckman Co. v. Plaintiffs' Legal Comm.*, 531 U.S. 341, 347 (2001). However, if a state law regulates in an area within the historic police power of the States, courts must assume that it is not preempted "unless that was the clear and manifest purpose of Congress." *Arizona*, 567 U.S. at 400 (citation omitted). "This makes congressional intent 'the ultimate touchstone in every pre-emption case.' " *Bradshaw v. Am. Airlines, Inc.*, 123 F.4th 1168, 1173 (10th Cir. 2024) (citing *Wyeth v. Levine*, 55 U.S. 555, 565 (2009)). Congress can demonstrate its intent to preempt expressly, through enacting a statute containing a preemption provision. *Arizona*, 567 U.S. at 399. Preemption can also by implied through a statute's "structure and purpose." *Altria Grp., Inc. v. Good*, 555 U.S. 70, 76 (2008). Section 340B does not contain a preemption provision, so any preemption would have to be implied.

There are two types of implied preemption: field preemption and conflict preemption. *Fitch*, 152 F.4th at 645. 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 subject.' " *Bradshaw*, 123 F.4th at 1173 (citing *Arizona*, 567 U.S. at 399). "Conflict preemption occurs either when compliance with both the federal and state laws is a physical impossibility, or when the state law stands as an obstacle to the accomplishment and execution of the full purposes and objectives of Congress." *Keith v. Rizzuto*, 212 F.3d 1190, 1193 (10th Cir. 2000) (internal quotation and citation omitted).

D. Presumption Against Preemption

***7** AstraZeneca argues that the presumption against preemption does not apply in this case because S.B. 71 regulates something inherently federal in character. Docket No. 25 at 7-8 (citing *Buckman*, 531 U.S. at 347). Specifically, AstraZeneca cites *Buckman* to argue that, because S.B. 71 directly targets and depends on federal law, namely, Section 340B, it regulates a uniquely federal interest beyond the States' traditional police power. *Id.* However, *Buckman* "[does] not support the broad contention that there is necessarily a...preemption issue where a state law explicitly depends on a federal statute." *Weiser*, 2025 WL 3041825, at *7 (internal quotation omitted).

In *Buckman*, the state law at issue attempted to police fraud against federal agencies. *Buckman*, 531 U.S. at 347. The *Buckman* court determined that this was not "a field which the States have traditionally occupied." *Id.* (citation omitted). Conversely, public health is a matter within a state's traditional police powers. *See Medtronic, Inc. v. Lohr*, 518 U.S. 470, 475 (1996) ("Throughout our history, the several States have exercised their police powers to protect the health and safety of their citizens. Because these are primarily, and historically,...matter[s] of local concern. The States traditionally have had great latitude under their police powers to legislate as to the protection of the lives, limbs, health, comfort, and quiet of all persons.") (citations and internal quotations omitted). Thus, unlike the state law in *Buckman*, the state law here does not implicate a uniquely federal interest. Accordingly, the presumption against preemption applies.

E. Whether S.B. 71 is Preempted by Section 340B

AstraZeneca asserts that S.B. 71 is preempted by Section 340B, noting that a state law is preempted if it " 'stands as an obstacle to the accomplishment and execution of the full purposes and objectives of Congress.' " Docket No. 25 at 11 (quoting *Crosby v. Nat'l Foreign Trade Council*, 530 U.S. 363, 373 (2000)). This is a conflict preemption argument.[3] *See Keith*, 212 F.3d at 1193 ("Conflict preemption occurs...when the state law stands as an obstacle to the accomplishment and execution of the full purposes and objectives of Congress.") (citation and internal quotation omitted). Specifically, AstraZeneca asserts that S.B. 71 is preempted by Section 340B because: (1) both laws regulate price; (2) S.B. 71 recalibrates Congress's balancing of the burdens and benefits of participating in Section 340B; (3) S.B. 71's enforcement regime conflicts with Section 340B's enforcement regime; and (4) S.B. 71's claims-data restriction conflicts with federal laws and regulations. Docket No. 25 at 8-17. The Court will analyze each argument in turn.

1. Whether S.B. 71 Regulates Price or Delivery

AstraZeneca argues that S.B. 71 regulates drug pricing, not delivery. *Id.* at 8. It is not entirely clear to the Court why that matters to the preemption analysis. Apparently, AstraZeneca's argument is that, if S.B. 71 and Section 340B both regulate price, they necessarily conflict such that S.B. 71 is preempted. However, AstraZeneca fails to explain what conflict would ensue if S.B. 71 and Section 340B both regulate price. *See id.* at 8-11. The Court does not find that any such conflict exists. Section 340B sets discounted drug prices for eligible patients. S.B. 71 mandates that those Section 340B-discounted drugs must be distributed to unlimited contract pharmacies. The Court fails to see how those two requirements conflict with one another; if anything, they seem to complement each other. The federal government, acting through HHS, attempted to enact the same requirement as S.B. 71 through its 2020 guidance. *Johnson*, 102 F.4th at 459. The Third Circuit and D.C. Circuit, however, held that Section 340B is silent about delivery and therefore does not contain such a requirement. *Johnson*, 102 F.4th at 464; *Sanofi Aventis*, 58 F.4th at 707. Colorado and other states attempted to fill the gap through state legislation that mirrors the earlier guidance of HHS. Such legislation does not create a conflict, regardless of whether S.B. 71 is considered to regulate price or to regulate delivery.

***8** In any event, the Court finds that S.B. 71 does not regulate price. Other courts agree. *Weiser*, 2025 WL 3041825, at *11 ("the Court...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, [S.B. 71] purports to regulate pricing."); *Fitch*, 152 F.4th at 647 (stating that a law substantially similar to S.B. 71 regulates the distribution of drugs, not the pricing of those drugs); *McClain*, 95 F.4th at 1145 (same).

AstraZeneca's arguments to the contrary are unpersuasive. AstraZeneca notes that S.B. 71 identifies the drugs it regulates in terms of their price. For example, S.B. 71 states that manufacturers "shall not...prohibit...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." Colo. Rev. Stat. § 6-29-105(1)(a). A 340B drug is defined as any drug discounted under the Section 340B program that has been purchased by a covered entity. Colo. Rev. Stat. § 6-29-103(2). In AstraZeneca's view, the fact that these drugs are identified by their price is enough to make S.B. 71 a regulation of price. But S.B. 71 is clear that it is Section 340B that sets the price of the discounted drugs; S.B. 71 merely dictates that those drugs must be made available at more locations, namely, at unlimited contract pharmacies.

AstraZeneca further argues that the "replenishment model" is indicative that S.B. 71 regulates price. Docket No. 25 at 10-11. Under the replenishment model, discounted and non-discounted drugs are intermingled on the shelves of the pharmacy, and it is not determined by the pharmacy which drugs are discounted under Section 340B until they are already dispensed. *Johnson*, 102 F.4th at 457-58. As a result, AstraZeneca asserts that, " '[b]ecause the drug is already in the hands of the contract pharmacy before the patient arrives at the pharmacy, the question is not about delivery of the drug.' " Docket No. 25 at 11 (quoting *Morrisey*, 760 F. Supp. 3d at 455). However, "[r]eplenishment inventory systems are commonplace [and]...pharmaceuticals distribution often relies on pharmaceuticals' fungibility to facilitate efficiency." *Fitch*, 2024 WL 3503965, at *14 (citation omitted). Thus, the Court agrees that the replenishment model is a means of efficient distribution, and AstraZeneca's argument reflects a "technicality," which does not suddenly make S.B. 71 a regulation of price. *See id.* at *15 (stating that the replenishment model facilitates efficient distribution of Section 340B drugs and that reality cannot "be undercut by technicality"). Accordingly, S.B. 71 does not regulate price and, even if it did, that would not necessarily mean it is preempted by Section 340B.

2. Recalibration of the Burdens and Benefits

AstraZeneca argues that S.B. 71 is an obstacle to the purposes and objectives of Congress because it recalibrates the benefits and burdens of participation in Section 340B. Docket No. 25 at 11. According to AstraZeneca, Congress "carefully balanced the benefits and burdens of participation in the 340B program," and S.B. 71 upsets that balance. *Id.* However, AstraZeneca provides no evidence that Congress considered whether drug manufacturers would participate in Section 340B if the program was too expensive.

Conversely, there is evidence that Section 340B was enacted so healthcare providers could " 'reach[ ] more eligible patients and provid[e] more comprehensive services.' " 340B Drug Pricing Program; Administrative Dispute Resolution Regulation, 89 FR 28643-01 ("ADR Rule"), at 28,643 (April 19, 2024) (quoting H.R. Rep. No. 102-384(II), at 12

(1992)); *see also Sanofi Aventis*, 58 F.4th at 699 (stating that Section 340B helps providers care for low-income and rural persons). S.B. 71 helps accomplish this purpose by making Section 340B drugs more accessible to more patients. Thus, as noted by the Eighth Circuit when analyzing a similar Arkansas law, the state statute "does not create an obstacle for pharmaceutical manufacturers to comply with 340B, rather it does the opposite: [the statute] assists in fulfilling the purpose of 340B." *McClain*, 95 F.4th at 1144-45. AstraZeneca does not directly support its argument to the contrary. Instead, AstraZeneca argues that S.B. 71 interferes with federal objectives "because it specifically targets federal law—applying *only* to 340B participants, *only* to 340B drugs, and *only* to pharmacies that contract with 340B-covered entities. Docket No. 25 at 12. "The Supreme Court, however, has never adopted a categorical rule that requires a finding of preemption whenever a state law is addressed directly to those participating in a federal program where the federal statute does not rely on the state to implement the program." *Frey*, 2025 WL 2813787, at *10. S.B. 71 does not interfere with Section 340B's objectives, but instead helps to achieve them. Thus, there is no preemption issue raised by S.B. 71 attaching itself to Section 340B.

***9** AstraZeneca also claims that, if Colorado is allowed to add to the burdens of participating in Section 340B, then so may other states. Docket No. 25 at 13. It argues that such laws run the risk of conflicting adjudications which would "frustrate[ ] Congress's goal of a national, uniform 340B program." *Id.* However, AstraZeneca does not provide evidence that Congress intended the Section 340B program to be nationally uniform and, in any event, states are increasingly passing laws that are substantially similar to S.B. 71. Thus, laws like S.B. 71 are becoming the norm rather than the exception. While AstraZeneca asserts that all of these laws are slightly different, it does not explain what those differences are or how they create an obstacle to the purposes and objectives of Congress. [4]

3. Enforcement Schemes

AstraZeneca notes that Section 340B contains a federal enforcement regime. Docket No. 25 at 13-14. In *Astra*, the Supreme Court observed that, in certain circumstances, private entities bringing suit under Section 340B would interfere with the administration and enforcement of the program. 563 U.S. at 120. AstraZeneca points out that S.B. 71 authorizes the Colorado Attorney General and district attorneys to bring civil actions to enjoin violations and recover penalties. Docket No. 25 at 14. Thus, relying on *Astra*, AstraZeneca argues that S.B. 71's state enforcement scheme encroaches on the federal government's Section 340B enforcement scheme. *Id.* However, S.B. 71 does not create new enforcement authority over Section 340B; rather, it creates enforcement authority for violations of S.B. 71 itself. *See* Colo. Rev. Stat. § 6-29-105(3)(a) ("The attorney general may investigate a complaint concerning a violation of *this article 29*. A person that violates *this article 29*...is subject to the enforcement provisions, civil penalties, and damages set forth in article 1 of this title 6.") (emphasis added). Thus, S.B. 71's enforcement scheme does not impact enforcement of Section 340B, and there is no conflict between the two. *See Weiser*, 2025 WL 3041825, at *9 (finding that S.B. 71 only penalizes activity that falls outside the purview of Section 340B). Other courts have come to the same conclusion about state law enforcement schemes like the one found in S.B. 71. *See id.* (collecting cases).

AstraZeneca argues that the federal and state enforcement schemes conflict because S.B. 71 would require state adjudicators to "consider and resolve questions of federal law in order to determine whether a manufacturer has violated the statute." Docket No. 25 at 14. However, "state courts are regularly and rightly called on to decide questions of federal law, as they have throughout our history." *In re C & M Props., L.L.C.*, 563 F.3d 1156, 1167 (10th Cir. 2009). Accordingly, AstraZeneca has not shown a likelihood of success on the merits based on its claim that S.B. 71's enforcement scheme is preempted by Section 340B.

4. Claims-Data Restriction

AstraZeneca's final argument that S.B. 71 is preempted by Section 340B is based on Colo. Rev. Stat. § 6-29-105(1)(b). Docket No. 25 at 16. This provision prohibits manufacturers from requiring covered entities or contract pharmacies 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." Colo. Rev. Stat. § 6-29-105(1)(b). AstraZeneca argues that this restriction conflicts with federal law in three ways. Docket No. 25 at 14-16.

***10** First, Astra Zeneca notes that manufacturers must audit covered entities or contract pharmacies prior to manufacturers filing an alternative dispute resolution ("ADR") claim. *Id.* at 14-15 (citing ADR Rule at 28,644). However, before auditing,

manufacturers need documentation from the covered entity or pharmacy that indicates that there is reasonable cause to support a request for an audit. Manufacturer Audit Guidelines and Dispute Resolution Process 0905-ZA-19, 61 FR 65406-01 ("Audit Guidelines"), at 65409 (Dec. 12, 1996). Because S.B. 71 restricts manufacturers' ability to get this documentation, AstraZeneca argues that it is preempted. Docket No. 25 at 14-16. Courts addressing this argument, however, have found that manufacturers have not demonstrated that the "reasonable cause" standard is particularly burdensome, or that manufacturers cannot find reasonable cause to perform an audit without requiring claims-data from covered entities or contract pharmacies. *See Skrmetti*, 2025 WL 1805271, at *15-16; *Frey*, 2025 WL 2813787, at *12. As one court observed, "if a manufacturer has an articulable basis for suspecting that a covered entity is engaging in prohibited conduct, it likely will have reasonable cause to request an audit." *Skrmetti*, 2025 WL 1805271, at *16. Therefore, AstraZeneca has not shown a likelihood of success on its argument that S.B. 71's claim-data restriction prevents manufacturers from conducting the audits needed for filing ADR claims.

Second, AstraZeneca asserts that, under the Drug Price Negotiation Program, 42 U.S.C. §§ 1320f *et seq.*, manufacturers have a duty to prevent duplicate price reductions by identifying when a drug is dispensed as a Section 340B drug. Docket No. 25 at 15 (citing CMS, Medicare Drug Price Negotiation Program: Final Guidance, at 58-60 (Oct. 2, 2024), http://bit.ly/3Y719J0). Therefore, AstraZeneca argues that S.B. 71 "bars manufacturers from obtaining the data they need to conduct this federally required de-duplication." *Id.* This argument lacks merit because S.B. 71's claim-data restriction does not apply if the data is required to be furnished under applicable federal law. Colo. Rev. Stat. § 6-29-105(1)(b).

Finally, AstraZeneca argues that the claims-data restriction prevents manufacturers from participating in a federal pilot program under which manufacturers may receive sales data from covered entities before paying Section 340B rebates. Docket No. 25 at 15-16. Judge Martinez held that there is no conflict, because Colo. Rev. Stat. § 6-29-105(5) allows data to be collected if it is required to be furnished under federal law. *Weiser*, 2025 WL 3041825, at *12. AstraZeneca, however, argues that this exception would not apply to the pilot program because participation is voluntary, not required. Docket No. 57 at 11 n.2. Even if true, AstraZeneca has not shown that manufacturers could not participate in the pilot program, since S.B. 71 does not prohibit them from requesting covered entities to provide data. The language of the pilot program discusses the type of data that manufacturers can "request." 340B Program Notice: Application Process for the 340B Rebate Model Pilot Program; Correction, 90 FR 38165-01, at 38,167 (Aug. 7, 2025). Accordingly, none of these three arguments show a likelihood of success on the claim that S.B. 71's claim-data restriction provision is preempted.

> **F. Whether S.B. 71 is Preempted by Federal Patent Laws** AstraZeneca's final argument is that S.B. 71 is preempted by federal patent laws.

Docket No. 25 at 17-18. In support of this argument, AstraZeneca notes that patent laws incentivize inventors by carefully balancing their rewards and incentives with the public interest. *Id.* at 17 (citing *Biotech Indus. Org. v. District of Columbia* ("*BIO*"), 496 F.3d 1362, 1373 (Fed. Cir. 2007)). AstraZeneca argues that laws capping the price of patented drugs skews that balance and are " 'contrary to the goals established by Congress in the patent laws." [5] *Id.* (citing *BIO*, 496 F.3d at 1374). This argument fails because S.B. 71 does not cap the price of patented drugs—Section 340B does.

***11** Moreover, the case AstraZeneca cites in support of this argument—*BIO*—is inapposite for other reasons as well. In *BIO*, the disputed law operated exclusively within the scope of patent laws and applied only to patented drugs. 496 F.3d at 1374-75. Conversely, S.B. 71 does not operate only within the scope of patent laws. Rather, it applies to patented and unpatented drugs alike. While *BIO* did set limits on a state's ability to cap the price of patented drugs, "Congress never intended that the patent laws should displace the police powers of the States." *Webber v. State of Virginia*, 103 U.S. 344, 347-48 (1880). 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. *Medtronic*, 518 U.S. at 475. Accordingly, AstraZeneca has not shown a likelihood of success on the merits as to its claim that S.B. 71 is preempted by federal patent laws. [6]

IV. CONCLUSION

Therefore, it is

ORDERED that Plaintiff's Motion for a Preliminary Injunction [Docket No. 25] is **DENIED**.

DATED December 17, 2025.

BY THE COURT:

PHILIP A. BRIMMER

Chief United States District Judge

All Citations

Slip Copy, 2025 WL 3653161

Footnotes

1 *See Fitch*, 152 F.4th at 648 (affirming order denying preliminary injunction); *McClain*, 95 F.4th at 1146 (affirming order granting summary judgment to state); *Abbvie, Inc. v. Weiser*, No. 25-cv-01847-WJM-KAS, 2025 WL 3041825 (D. Colo. Oct. 31, 2025); *Novartis Pharms. Corp. v. Frey*, 2025 WL 2813787 (D. Me. Sept. 23, 2025) (denying preliminary injunction); *AbbVie Inc. v. Skrmetti*, 2025 WL 1805271 (M.D. Tenn. June 30, 2025) (same); *AstraZeneca Pharms. LP v. Bailey*, 2025 WL 644285 (W.D. Mo. Feb. 27, 2025) (granting in part and denying in part state's motion to dismiss, with denial limited to contract clause argument); *Novartis Pharms. Corp. v. Bailey*, 2025 WL 595189 (W.D. Mo. Feb. 24, 2025) (denying preliminary injunction); *Pharm. Rsch. & Manufacturers of Am v. Murrill*, 2024 WL 4361597 (W.D. La. Sept. 30, 2024) (granting summary judgment to state); *AstraZeneca Pharms. LP v. Fitch*, 766 F. Supp. 3d 657 (S.D. Miss. 2024) (denying preliminary injunction); *AbbVie Inc. v. Fitch*, 2024 WL 3503965 (S.D. Miss. July 22, 2024) (same), *aff'd*; *Novartis Pharms. Corp. v. Fitch*, 738 F. Supp. 3d 737 (S.D. Miss. 2024) (same); *Pharm. Rsch. & Manufacturers of Am v. Fitch*, 2024 WL 3277365 (S.D. Miss. July 1, 2024) (same); *but see Pharm. Rsch. & Manufacturers of Am v. Morrisey*, 760 F. Supp. 3d 439 (S.D. W. Va. 2024) (granting preliminary injunction); *AbbVie Inc. v. Drummond*, 2025 WL 3048929 (W.D. Okla. Oct. 31, 2025) (granting preliminary injunction in part).

2 In its complaint, AstraZeneca brings claims that S.B. 71 is unconstitutional because it (1) is preempted by Section 340B; (2) is preempted by federal patent laws; (3) violates the Contracts Clause, U.S. Const. art. I § 10, cl. 1; and (4) violates the Takings Clause, U.S. Const., amend. V. Docket No. 1 at 35-39, ¶¶ 112-131. However, AstraZeneca only discusses the first two claims in its motion for a preliminary injunction. *See generally* Docket No. 25. The Court assumes that its motion is limited to these claims.

3 While AstraZeneca does not make a field preemption argument against S.B. 71, one court in this district has already ruled that Congress did not intend to preempt the field when enacting Section 340B. *Weiser*, 2025 WL 3041825, at *6-8.

4 AstraZeneca argues that the differences between S.B. 71 and similar laws could frustrate Section 340B's enforcement scheme. Docket No. 25 at 13. The Court will address the enforcement scheme in the next subsection.

5 Five district courts have already rejected this argument as it relates to state laws similar to S.B. 71. *See Fitch*, 677 F. Supp. 3d at 664-65; *Bailey*, 2025 WL 644285, at *2-3; *Novartis Pharms. Corp. v. Bailey*, 2025 WL 489881, at *2-3 (W.D. Mo. Feb. 13, 2025); *Murrill*, 2024 WL 4361597, at *9; *Fitch*, 738 F. Supp. 3d at 753.

6 Because AstraZeneca has not shown a likelihood of success on the merits as to any of its claims, the Court will not address the other preliminary injunction factors. *See* *Dominion Video Satellite*, 356 F.3d at 1266 n.8 (refusing to address other preliminary injunction factors after finding that one factor was not met).

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