IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF COLORADO

ASTRAZENECA PHARMACEUTICALS LP,

Plaintiff,

v.

PHILIP J. WEISER, in his official capacity as the ATTORNEY GENERAL OF THE STATE OF COLORADO; KRISTEN WOLF, in her official capacity as the President of the Colorado State Board of Pharmacy; RYAN LEYLAND, in his official capacity as the Vice President of the Colorado State Board of Pharmacy; and 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.

Case No. _____

COMPLAINT FOR DECLARATORY AND INJUNCTIVE RELIEF

INTRODUCTION

1. Section 340B of the federal Public Health Service Act, 42 U.S.C. § 256b, requires pharmaceutical manufacturers to "offer" their products at steeply discounted rates to an enumerated and clearly defined list of "covered entities." Because such price controls can disincentivize innovation and destabilize markets, Congress carefully crafted Section 340B and limited participation in the program to fifteen—and only fifteen—types of covered entities. Off-site, for-profit pharmacy chains that contract with covered entities to dispense 340B drugs were *not* included on the list of covered entities. Yet a number of States, including Colorado, have

recently passed laws purporting to require manufacturers to offer 340B-discounted pricing for sales at an unlimited number of these so-called "contract pharmacies." These provisions impose immense costs on manufacturers—and generate big profits for pharmacies—yet produce little benefit for patients.

2. Courts have rebuffed federal efforts to force manufacturers like AstraZeneca to offer 340B-discounted drugs for sales occurring through contract pharmacies. The U.S. Court of Appeals for the Third Circuit held that AstraZeneca's decision to restrict the offer of 340B-discounted drugs for contract pharmacy sales "do[es] not violate Section 340B," and it "enjoin[ed] [federal officials] from enforcing against" AstraZeneca any "reading of Section 340B" that would require AstraZeneca to make 340B discounts available for sales at "an unlimited number of contract pharmacies." *Sanofi Aventis U.S. LLC v. HHS*, 58 F.4th 696, 706 (3d Cir. 2023). The Third Circuit's decision was then incorporated into a permanent injunction, issued by the federal district court in Delaware, protecting AstraZeneca's right to proceed with its contract pharmacy policy.

3. The D.C. Circuit has joined the Third Circuit, similarly "reject[ing] [the] position that section 340B prohibits drug manufacturers from imposing any conditions on" the offer of "discounted drugs to covered entities" who use contract pharmacies. *Novartis Pharms. Corp. v. Johnson*, 102 F.4th 452, 459 (D.C. Cir. 2024). And the D.C. Circuit specifically upheld manufacturer policies requiring covered entities to provide claims data associated with 340B contract pharmacy orders, which allows manufacturers to prevent the improper diversion of their 340B-discounted medicines while imposing only "minimal" burdens on covered entities. *Id.* at 463-64.

4. The State of Colorado took the opposite side of that dispute. It filed amicus briefs in the Third and D.C. Circuits arguing that "[m]anufacturers should not be allowed to unilaterally restrict covered entities' use of contract pharmacies and thereby eliminate the significant revenue" that it generates. Br. of Amici Curiae States, *Sanofi Aventis*, 2022 WL 1617655, at *9; *see* Br. of Amici Curiae States, *Novartis Pharms.*, 2022 WL 1644996, at *2 (arguing manufacturers who "limit[] 340B covered entities to using a single retail community pharmacy" are thereby "flout[ing] their statutory obligation to offer safety-net providers 340B-discounted prices on critical prescription drugs.").

5. Dissatisfied with the scope of federal law, on May 30, 2025, Colorado enacted a statute seeking to achieve under state law precisely the same result that federal courts have resoundingly rejected. Known as SB 71, the Colorado statute targets what it describes as manufacturer policies that "unlawfully place restrictions on 340B covered entities using contract pharmacies," which the law says have caused covered entities to lose millions of dollars "in 340B program savings." SB 71 § 6-29-102(1)(n), (1)(j).[*]

6. SB 71 requires pharmaceutical manufacturers to offer 340B-discounted pricing for sales at an unlimited number of contract pharmacies. It prohibits manufacturers from "directly or indirectly[] deny[ing], restrict[ing], prohibit[ing], discriminat[ing] against, or otherwise limit[ing] 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." SB 71 § 6-29-105(1)(a). It also prohibits a manufacturer

[*] SB 71 is to be codified at Colo. Rev. Stat. §§ 6-1-105, 6-29-101 to -105, and 25-3-132. For clarity, provisions of the bill are cited herein using those designations.

from requiring covered entities or contract pharmacies, as a condition on its offer to sell drugs at 340B discounts, to submit claims data regarding 340B purchases. SB 71 § 6-29-105(1)(b).

7. SB 71 thus extends Section 340B's price caps beyond the scope of the federal program to reach unlimited contract pharmacy sales—in effect, vastly expanding discounts under the federal 340B program to an entirely new category of transactions. This expansion under state law directly conflicts with federal law.

8. Plaintiff AstraZeneca Pharmaceuticals LP brings this action to enjoin enforcement of SB 71. AstraZeneca argues that SB 71 cannot validly be enforced against AstraZeneca for four separate and independent reasons.

9. ***First***, SB 71 creates a conflict with—and thus is preempted by—federal law under the Supremacy Clause of the U.S. Constitution. *See* U.S. Const. art. VI, cl. 2. Rulings of the Third and D.C. Circuits make clear that the federal 340B statute does *not* obligate manufacturers to deliver discounted drugs to unlimited contract pharmacies. State officials may not impose this obligation on AstraZeneca either. Nor may any State engraft new, costly obligations under state law onto an existing federal benefits program—especially not one, like the 340B program, that involves nationally uniform standards and exclusive enforcement by federal agencies. And Colorado also may not preclude manufacturers from conditioning their sales offer under the federal program on the submission of claims data, which is necessary for manufacturers to meaningfully access the 340B program's audit and administrative dispute resolution procedures.

10. ***Second***, SB 71 creates a conflict with—and thus is preempted by—federal patent law. In *Biotechnology Industry Organization* (*BIO*) *v. District of Columbia*, the Federal Circuit squarely held that federal patent law "prohibits states from regulating the price of patented goods."

496 F.3d 1362, 1372 (Fed. Cir. 2007). Yet SB 71 does precisely that. It requires manufacturers like AstraZeneca to offer steeply discounted prices for the sale of their patented drugs, thereby extending federal price caps to an additional category of patented drug sales (contract pharmacy sales) that federal courts have held fall *outside* of the 340B program.

11. ***Third***, SB 71 violates the Contracts Clause of the U.S. Constitution. *See* U.S. Const. art. I, § 10, cl. 1. The 340B program is enforced through agreements between drug manufacturers and the Secretary of the U.S. Department of Health and Human Services (HHS). 42 U.S.C. § 256b(a)(1). SB 71 substantially interferes with the operation of those agreements, and with manufacturers' rights and obligations thereunder, by imposing costly new obligations only on manufacturers who sign such agreements.

12. ***Fourth***, SB 71 violates the U.S. Constitution's Takings Clause. *See* U.S. Const. amend. V. Under the Takings Clause, "the sovereign may not take the property of *A* for the sole purpose of transferring it to another private party *B*," a prohibition that applies regardless of whether "*A* is paid just compensation." *Kelo v. City of New London*, 545 U.S. 469, 477 (2005). But SB 71 requires manufacturers like AstraZeneca to transfer their property (prescription drugs) to other private parties (covered entities and the pharmacies with which they contract). This forced transfer would be unlawful even if manufacturers were paid just compensation for these contract pharmacy sales. But in fact they are not: Manufacturers are compensated at steeply discounted prices, well below fair market value.

13. AstraZeneca therefore seeks an order: (1) declaring that SB 71 is preempted by Section 340B; (2) declaring that SB 71 is preempted by federal patent law as applied to AstraZeneca's patented products; (3) declaring that SB 71 is unconstitutional as applied to

AstraZeneca under the federal Contracts Clause; (4) declaring that SB 71 is unconstitutional as applied to AstraZeneca under the federal Takings Clause; and (5) enjoining Defendant Colorado Attorney General Philip Weiser and any other Colorado officials from enforcing SB 71 against AstraZeneca through investigative demands, administrative proceedings, lawsuits seeking civil penalties or other relief, or in any other manner.

JURISDICTION AND VENUE

14. This Court has jurisdiction pursuant to 28 U.S.C. § 1331 (action arising under the Constitution of the United States) and 28 U.S.C. § 1338(a) (civil action arising under any Act of Congress relating to patents). An actual controversy exists between the parties within the meaning of 28 U.S.C. § 2201(a), and this Court may grant declaratory relief, injunctive relief, and other relief pursuant to 28 U.S.C. §§ 2201-02.

15. This Court also has inherent equitable powers to enjoin actions of state officials that contradict the federal Constitution or federal law. *See Ex parte Young*, 209 U.S. 123, 159-60 (1908); *accord, e.g.*, *Larson v. Domestic & Foreign Com. Corp.*, 337 U.S. 682, 689 (1949).

16. Venue is proper in this Court under 28 U.S.C. § 1391(b)(2) because this action challenges a Colorado law that applies to and purports to regulate the sale of AstraZeneca's products in Colorado. AstraZeneca makes its drugs available and offers its products to multiple 340B-covered entities in Colorado, and these entities maintain multiple contract pharmacy arrangements. The challenged law (if not invalidated) would apply to conduct and property in Colorado, including AstraZeneca's, and would be subject to enforcement here.

17. Venue is also proper in this Court under 28 U.S.C. § 1391(b)(1) because Defendants maintain offices in this District, through which Defendants would enforce the law challenged in this action.

PARTIES TO THE ACTION

18. Plaintiff AstraZeneca Pharmaceuticals LP is a limited partnership organized under the laws of the State of Delaware with its principal place of business in Wilmington, Delaware. AstraZeneca is a biopharmaceutical company focusing on the discovery, development, manufacturing, and commercialization of medicines. AstraZeneca participates in the 340B program.

19. Defendant Philip Weiser is the Attorney General of Colorado. In that role, he enforces the challenged legislation. This suit is brought against him in his official capacity only. The Attorney General maintains an office in Denver, Colorado.

20. Defendants Kristen Wolf, Ryan Leyland, Patricia Evacko, Avani Soni, Michael Scruggs, Alexandra Zuccarelli, and Jayant Patel are, respectively, the President, Vice President, and Members of the Colorado State Board of Pharmacy. In that capacity, they enforce the challenged legislation. This suit is brought against each of them in their official capacities only.

FACTUAL ALLEGATIONS

The Federal 340B Program Caps Drug Prices for Enumerated Covered Entities that Provide Healthcare to Certain Underserved Populations

21. Section 340B of the Public Health Service Act established a federal program that "imposes ceilings on prices drug manufacturers may charge for medications sold to specified health-care facilities," known as covered entities, that provide healthcare to certain underserved populations. *Astra USA, Inc. v. Santa Clara Cnty.*, 563 U.S. 110, 113 (2011).

22. As a condition of receiving coverage and reimbursement for its drugs under Medicaid and Medicare Part B, a pharmaceutical manufacturer must enter into a pharmaceutical pricing agreement with HHS. 42 U.S.C. § 256b(a)(1). In that agreement, the manufacturer must "offer each covered entity covered outpatient drugs for purchase" at a specified discount price "if such drug is made available to any other purchaser at any price." *Id.* This is known as Section 340B's "must-offer" requirement. Manufacturers that "knowingly and intentionally charge[] a covered entity a price for purchase of a drug that exceeds the [340B discount price]" are subject to civil monetary penalties. *Id.* § 256b(d)(1)(B)(vi)(III). The 340B statute also regulates covered entities, which may not obtain 340B pricing on units of drugs for which a manufacturer pays a Medicaid rebate (known as "duplicate discounts"), nor resell or otherwise transfer such drugs to persons other than their patients (known as "diversion"). *Id.* § 256b(a)(5)(A), (B).

23. Congress enacted Section 340B to give covered entities access to prescription drugs at below-market prices, thereby helping them serve their uninsured and indigent patients. H.R. Rep. No. 102-384, pt. 2, at 7 (1992). Balanced against its goal of increasing access, however, Congress also recognized the need to "assure the integrity of the drug price limitation program." *Id.* at 16.

24. Congress has added to the list of 340B-covered entities over time, and today there are fifteen delineated categories of covered entities. 42 U.S.C. § 256b(a)(4)(A)-(*O*).

25. Notably, Congress has *never* included contract pharmacies in the statutorily defined list of facilities that qualify as covered entities. Indeed, in drafting what would become the 340B statute, Congress considered proposed language that would have permitted covered entities to dispense 340B drugs through *on-site* contractors providing pharmacy services. *See* S. Rep. No.

102-259, at 1-2 (1992) (requiring manufacturers to provide a discounted price for drugs that are "purchased and dispensed by, or under a contract entered into for *on-site pharmacy services* with" certain enumerated covered entities) (emphasis added). But that provision was not enacted.

26. The 340B program has its own federal enforcement provisions and administrative dispute-resolution process. Congress required the Secretary of HHS to establish an adjudicatory body to resolve disputes among participants in the 340B program, including "claims by covered entities that they have been overcharged for drugs purchased under this section [340B], and claims by manufacturers … of violations" by covered entities. 42 U.S.C. § 256b(d)(3)(A). Under that statutory mandate, the Health Resources and Services Administration (HRSA), the subagency of HHS that oversees the 340B program, has established "requirements and procedures for the 340B Program's administrative dispute resolution (ADR) process." 85 Fed. Reg. at 80,632 (Dec. 14, 2020). The ADR Rule authorizes panels of federal officers to resolve claims for "monetary damages," as well as other unspecified "equitable relief" sought by claimants. 42 C.F.R. § 10.21(a). And it empowers ADR panels to address a range of factual and legal disputes, including "those having to do with covered entity eligibility, patient eligibility, or manufacturer restrictions on 340B sales." 85 Fed. Reg. at 80,636.

27. Importantly, before a manufacturer may access the ADR process, HRSA requires the manufacturer to first audit a covered entity. *See* 42 U.S.C. § 256b(d)(3)(B)(iv); 89 Fed. Reg. 28,643, 28,645 (Apr. 19, 2024) ("[M]anufacturers are required to audit a covered entity prior to filing an ADR claim"). And under HRSA regulations, a manufacturer may only initiate an audit when it can point to "documentation which indicates that there is reasonable cause," with "reasonable cause" defined to mean "that a reasonable person could believe that a covered entity

may have violated" the prohibitions on diversion or duplicate discounting. 61 Fed. Reg. 65,406, 65,409 (Dec. 12, 1996). Thus, absent such "documentation," the ADR process is unavailable to a manufacturer.

28. HRSA revised the ADR Rule last year. *See* 89 Fed. Reg. at 28,643. Among other things, the revised rule gives "340B ADR Panel[s]" responsibility to resolve disputes related to "overcharge[s]," which include claims that a manufacturer has "limited [a] covered entity's ability to purchase covered outpatient drugs at or below the 340B ceiling prices." 42 C.F.R. §§ 10.3, 10.21.

Contract Pharmacy Use Leads to Abuse and Profiteering

29. Section 340B does not require manufacturers to offer 340B-discounted drugs to contract pharmacies—or indeed, to *any* entity not specifically enumerated in the statute. In the decades since the enactment of the program, however, HRSA has issued two non-binding "guidance" documents purporting to authorize covered entities to enter into agreements with contract pharmacies to dispense outpatient drugs under Section 340B.

30. In 1996, HRSA issued guidance providing that "eligible covered entities that do not have access to appropriate 'in-house' pharmacy services" could now enter into an agreement with a *single* outside pharmacy of its choice to provide such services for 340B drugs. 61 Fed. Reg. 43,549, 43,555 (Aug. 23, 1996) (1996 Guidance).

31. Then, in 2010, HRSA released new guidance stating that covered entities could now "use multiple pharmacy arrangements"—that is, an *unlimited* number of contract pharmacies, without any geographic limits—"as long as they comply with guidance developed to help ensure against diversion and duplicate discounts and the policies set forth regarding patient definition."

75 Fed. Reg. 10,272, 10,273 (2010 Guidance). The 2010 Guidance thus purported to authorize a covered entity to enter into an unlimited number of contract pharmacy arrangements anywhere in the United States.

32. The 2010 Guidance triggered a massive surge in the number of contract pharmacies receiving and distributing 340B drugs. *See Novartis Pharms.*, 102 F.4th at 457 (noting a "significant expansion"). In 2018, the Government Accountability Office reported that the number of contract pharmacies had ballooned from 1,300 in 2010, to nearly 20,000 in 2017. U.S. Gov't Accountability Off., GAO-18-480, *Drug Discount Program: Federal Oversight of Compliance at 340B Contract Pharmacies Needs Improvement* 2 (June 2018) (2018 GAO Report), https://www.gao.gov/assets/700/692697.pdf. These numbers have continued to grow. Today, more than 33,000 different pharmacies participate in the 340B program, with more than 194,000 individual contracts. Adam J. Fein, Drug Channels Inst., *Exclusive: For 2023, Five For-Profit Retailers and PBMs Dominate an Evolving 340B Contract Pharmacy Market* (Jul. 11, 2023), https://www.drugchannels.net/2023/07/exclusive-for-2023-five-for-profit.html. The vast majority of these contract pharmacies (75% as of 2018) are for-profit retail chain pharmacies; and the five largest national pharmacy chains—CVS, Walgreens, Walmart, Rite-Aid, and Kroger—accounted for a combined 60% of all 340B contract pharmacies, even though these chains represent only 35% of all pharmacies nationwide. 2018 GAO Report at 20-21.

33. Make no mistake, the boom in contract pharmacies has been fueled by the prospect of outsized profit margins on 340B-discounted drugs. As the D.C. Circuit explained:

> 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.

Novartis Pharms., 102 F.4th at 457-58; *see* Decl. of Krista M. Pedley ¶¶ 5-9, *Sanofi-Aventis U.S., LLC v. HHS*, No. 3:21-cv-634 (D.N.J. June 24, 2021), ECF No. 93-2. Since a 340B discount is applied for the contract pharmacy sale—even though the sale has *also* benefitted from the full insurance reimbursement—this dynamic results in substantial arbitrage revenues. *See Sanofi*, 58 F.4th at 699 ("[T]hey turn a profit when insurance companies reimburse them at full price for drugs that they bought at the 340B discount."). And though the pharmacy may share some of its windfall with the covered entity (or the covered entity's vendor), *the patient* has still paid the full out-of-pocket amount designated under his or her insurance policy.

34. As Senator Chuck Grassley put it in a letter to HRSA, for-profit pharmacies "are reaping sizeable 340B discounts on drugs and then turning around and upselling them to fully insured patients covered by Medicare, Medicaid, or private health insurance in order to maximize their spread." Letter from Sen. Chuck Grassley, S. Comm. on the Judiciary, to Mary K. Wakefield, Adm'r, HRSA (Mar. 27, 2013), https://www.grassley.senate.gov/download/2013-03-27-ceg-to-hrsa-340b-oversight-3. This "spread" means contract pharmacies retain up to $5 billion in annual profits from 340B sales. *See* Neal Masia, *340B Drug Pricing Program: Analysis Reveals $40 Billion in Profits in 2019*, Alliance for Integrity & Reform (May 2021), http://bit.ly/4bM7sHE; Laura Joszt, *340B, Biosimilars, and More in the Future of Specialty Pharmacy*, Am. J. of Managed

Care (May 4, 2022), https://bit.ly/4c61Do6 (five contract pharmacies "earn about $3.2 billion in gross profits from 340B"); Walgreens Boots Alliance, Inc., Form 10-K (Oct. 15, 2020), https://bit.ly/3KveDrI (noting that "[c]hanges in pharmaceutical manufacturers' . . . distribution policies . . . in connection with the federal 340B drug pricing program[] could . . . significantly reduce [Walgreens's] profitability"); Rebecca Pifer, *Hospitals, PBMs Say Drugmaker Restrictions on 340B Discounts Stifling Finances*, HealthcareDive (May 5, 2020), https://bit.ly/3P9xmdF (reporting that CVS Health "said its 340B product lines were stagnant" after contract-pharmacy restrictions were imposed).

35. Although some of the money generated through contract pharmacy sales is passed on to covered entities, most of these profits are *not* going to federally qualified health centers or other federal grantees that provide services to underserved populations (such as black lung clinics, hemophilia treatment centers, urban Indian health organizations, and AIDS drug purchasing assistance programs). Instead, they are being captured by 340B hospitals and contract pharmacies, which are responsible for nearly 90% of all 340B purchases. Aaron Vandervelde et al., Berkeley Rsch. Grp., *For-Profit Pharmacy Participation in the 340B Program* 7 (Oct. 2020), https://bit.ly/3owtUwa.

36. Nor are these huge profits being passed on to patients. For example, in response to a 2018 GAO survey, 45% of covered entities admitted they do not pass along *any* discount to *any* patients that use *any* of their contract pharmacies. 2018 GAO Report at 30. As for the remaining 55%, the GAO noted that entities using contract pharmacies may provide discounts to patients only in limited cases. *Id*. Likewise, the HHS Office of Inspector General found in 2014 that some contract pharmacies do not offer 340B-discounted prices to uninsured patients at all. HHS-OIG,

Memorandum Report: Contract Pharmacy Arrangements in the 340B Program, OEI-05-13-00431, at 2 (Feb. 4, 2014) (2014 OIG Report), https://oig.hhs.gov/oei/reports/oei-05-13-00431.pdf. As a result, "uninsured patients pay the full non-340B price for their prescription drugs at contract pharmacies." *Id.* By contrast, the GAO noted that 17 of 23 of the surveyed covered entities that had *in-house* pharmacies reported offering discounts at those pharmacies. 2018 GAO Report at 30 n.46. Most recently, a report by the Senate Committee on Health, Education, Labor & Pensions found that major covered entities do not directly pass on 340B discounts to patients, with one entity stating to the Committee that "reducing patients' drug expenses is not the purpose of the 340B Program." S. Comm. on Health, Educ., Labor & Pensions, *Congress Must Act to Bring Needed Reforms to the 340B Drug Pricing Program* 9 (Apr. 2025), https://www.help.senate.gov/imo/media/doc/final_340b_majority_staff_reportpdf.pdf.

37. In short, the widespread proliferation of contract pharmacy arrangements since 2010 has transformed the 340B program from one intended to assist vulnerable patients into a multi-billion-dollar arbitrage scheme.

38. At the same time, the explosive growth of contract pharmacy arrangements also has facilitated increased diversion and duplicate discounts. *See Novartis Pharms.*, 102 F.4th at 458. A 2011 report from the Government Accountability Office warned that "[o]perating the 340B program in contract pharmacies creates more opportunities for drug diversion compared to in-house pharmacies." U.S. Gov't Accountability Off., GAO-11-836, *Drug Pricing: Manufacturer Discounts in the 340B Program Offer Benefits, but Federal Oversight Needs Improvement* 28, (Sept. 23, 2011), https://www.gao.gov/assets/330/323702.pdf. The report further found that

"HRSA's oversight of the 340B program is inadequate because it primarily relies on participants' self-policing to ensure compliance." *Id.* at 21.

39. These structural problems have only intensified over time, as the use of multiple contract pharmacies has become rampant. The 2014 OIG report determined that self-policing by covered entities has been insufficient to stop these abuses, since "most covered entities . . . do not conduct all of the oversight activities recommended by HRSA." 2014 OIG Report at 2. The 2018 GAO Report similarly criticized the continuing "weaknesses in HRSA's oversight [that] impede its ability to ensure compliance with 340B Program requirements at contract pharmacies." 2018 GAO Report at 45.

40. Indeed, HRSA's own audits of covered entities continue to identify numerous instances of abuse. The 2018 GAO Report observed that "66 percent of the 380 diversion findings in HRSA audits [between 2012 and 2017] involved drugs distributed at contract pharmacies." *Id.* at 44. And based on information from HRSA's website, over 25% of covered entities audited since 2017 have had at least one finding related to contract pharmacy noncompliance. Indeed, out of 199 audits conducted in 2019, HRSA discovered dozens of instances of duplicate discounts, as well as evidence that at least 19 covered entities had permitted diversion of 340B drugs through contract pharmacies. *See* HRSA, *Program Integrity: FY19 Audit Results*, https://www.hrsa.gov/opa/program-integrity/audit-results/fy-19-results.

AstraZeneca's 340B Policy and Resulting Litigation

41. Against this legal and factual backdrop, in August 2020, AstraZeneca announced to covered entities that, effective October 1, 2020, it would revert to the contract pharmacy approach set forth in HRSA's 1996 Guidance.

42. Under this policy, AstraZeneca continues to make its products available at 340B-discounted prices—in unlimited quantities—to all covered entities. For covered entities that do not maintain their own on-site dispensing pharmacy, AstraZeneca offers discounted drugs for sales at a single contract pharmacy site for each covered entity. But AstraZeneca no longer makes 340B discounts available for drugs sold at an unlimited number of contract pharmacies.

43. AstraZeneca's policy is consistent with the letter and intent of the 340B program—limiting the potential for abuse, while still enabling all covered entities and their patients to continue to access AstraZeneca's medicines at 340B prices. Under AstraZeneca's policy, over 13,000 covered entities that lack an on-site pharmacy have registered a contract pharmacy to which AstraZeneca continues to make 340B discounts available, including numerous covered entities in Colorado. AstraZeneca is committed to working with all covered entities to ensure that every patient can obtain needed medicines at prices they can afford.

44. In response to AstraZeneca's new contract pharmacy policy and other manufacturers' adoption of similar policies, HHS and HRSA issued an Advisory Opinion on December 30, 2020, asserting that the 340B statute requires manufacturers to offer 340B-discounted drugs for sales at unlimited contract pharmacies.

45. In early 2021, AstraZeneca filed suit in the U.S. District Court for the District of Delaware against HHS and HRSA, challenging the Advisory Opinion. On June 16, 2021, the court issued a detailed opinion finding the Advisory Opinion unlawful. *AstraZeneca Pharms. LP v. Becerra*, 543 F. Supp. 3d 47 (D. Del. 2021). The court concluded that Section 340B "says nothing about the permissible role (if any) of contract pharmacies," and that, in light of this "total omission," the Advisory Opinion's attempt to impose an obligation on AstraZeneca to make

discounted drugs available for sales at unlimited contract pharmacies was "legally flawed." *Id.* at 59. The agency withdrew the Advisory Opinion following the court's ruling.

46. In a second ruling, the court addressed AstraZeneca's challenge to a "violation letter" issued by HRSA, which adopted the same position as the Advisory Opinion. The court again rejected the agency's view that Section 340B obligates drug manufacturers to make 340B-discounted drugs available for unlimited contract pharmacy sales. *AstraZeneca Pharms. LP v. Becerra*, No. 21-cv-27, 2022 WL 484587 (D. Del. Feb. 16, 2022). The court reiterated "key points" from its prior opinion, including that Congress "did not clearly intend for drug manufacturers to be required to facilitate sales of covered drugs for dispensing by an unlimited number of contract pharmacies." *Id.* at *5-*6.

47. On January 30, 2023, the U.S. Court of Appeals for the Third Circuit affirmed. In a consolidated opinion addressing AstraZeneca's case and appeals in parallel actions by other manufacturers, the Third Circuit held that the Advisory Opinion and violation letter are "unlawful," and it "enjoin[ed] HHS from enforcing [it] against" AstraZeneca. *Sanofi*, 58 F.4th at 706. The court of appeals also held that AstraZeneca's policy of not offering discounts for sales at unlimited "contract pharmacies do[es] not violate Section 340B." *Id.*

48. The government neither sought en banc review of the Third Circuit's decision nor filed a petition for certiorari in the U.S. Supreme Court.

49. On May 5, 2023, the Delaware district court issued a final judgment in AstraZeneca's case, to which the government stipulated. The court's order provides that it is:

a. "DECLARED that Advisory Opinion 20-06 and the Violation Letter from the Health Resources and Services Administration to Plaintiff AstraZeneca Pharmaceuticals LP (AstraZeneca), dated May 17, 2021 (Violation Letter), are unlawful;

b. DECLARED that AstraZeneca's policy limiting the use of contract pharmacies under Section 340B of the Public Health Service Act (Section 340B), 42 U.S.C. § 256b—namely, that covered entities may use an in-house pharmacy and, if they do not have an in-house pharmacy, they may use one contract pharmacy—does not violate Section 340B;

c. ORDERED that the Violation Letter is VACATED as contrary to law pursuant to 5 U.S.C. § 706;

d. ORDERED that Defendants, including their officers, agents, and employees, are ENJOINED from enforcing against AstraZeneca the agency's reading of Section 340B as requiring delivery of discounted drugs to an unlimited number of contract pharmacies."

Final Judgment at 1, *AstraZeneca*, No. 1:21-cv-27 (D. Del. May 5, 2023), ECF No. 123.

50. The Third Circuit's ruling and the injunction entitled AstraZeneca to proceed with its lawful contract pharmacy policy.

51. More recently, AstraZeneca has further modified its contract pharmacy policy to promote program integrity. On October 1, 2024, AstraZeneca updated the policy to require covered entities to report a limited set of claims data for contract pharmacy dispenses that were replenished using 340B-priced drugs.

52. AstraZeneca's collection of limited 340B claims data enables AstraZeneca to better detect and prevent violations of the 340B statute's program integrity provisions, including its prohibition on duplicate discounts. A duplicate discount occurs when a manufacturer pays a separate rebate to a payer for a drug that was purchased, credited, or replenished at the 340B price. The 340B statute expressly prohibits duplicate discounts under Medicaid. 42 U.S.C. § 256b(a)(5)(A).

53. Other types of duplicate discounts are prohibited under payer-manufacturer contracts or other federal laws. For instance, the Inflation Reduction Act requires HHS to "negotiate" with manufacturers for a "maximum fair price" that Medicare will pay for certain drugs, which must include a discount of at least 20%. *Id.* § 1320f-3(a). Under the IRA, each manufacturer must make its drug available at the "maximum fair price"—but *not* if the drug is available at a lower 340B price. *Id.* § 1320f-2(d). To ensure compliance with the IRA and prevent duplicative price reductions under Section 340B and the IRA, the Centers for Medicare and Medicaid Services (CMS) has charged manufacturers with identifying instances where a drug has been dispensed as a 340B drug. *See* CMS, Medicare Drug Pricing Negotiation Final Guidance 58-60 (Oct. 2, 2024), https://www.cms.gov/files/document/medicare-drug-price-negotiation-final-guidance-ipay-2027-and-manufacturer-effectuation-mfp-2026-2027.pdf.

54. If AstraZeneca's access to claims data is cut off, however, AstraZeneca will lack sufficient information to adequately identify and prevent these and other duplicate discounts. That is because the information AstraZeneca needs to directly connect payer rebates to 340B dispenses is *not* otherwise available to AstraZeneca as part of the 340B purchasing process. And requests by

manufacturers for participants in the system (including covered entities and contract pharmacies) to provide the necessary information on a voluntary basis have been consistently spurned.

55. Manufacturers like AstraZeneca do have a statutory right to conduct audits of covered entities regarding compliance with the statute's anti-duplication requirement, and they may compel the reporting of some data in connection with those audits. 42 U.S.C. § 256b(a)(5)(C). But HRSA regulations provide that a manufacturer may only initiate an audit when it can furnish "documentation which indicates that there is reasonable cause" for such an audit, with "reasonable cause" defined to mean "that a reasonable person could believe that a covered entity may have violated" the prohibitions on diversion or duplicate discounting. 61 Fed. Reg. at 65,409. As a result, a manufacturer must already have "documentation" showing that a covered entity has engaged in duplicate discounting before it may obtain permission to audit that entity.

56. Covered entities generally do not voluntarily provide manufacturers with the information or data required to establish "reasonable cause." And without the ability to establish reasonable cause, AstraZeneca is effectively unable it access its audit rights.

57. Given these challenges, AstraZeneca's contract pharmacy policy of October 1, 2024, requires covered entities to submit limited claims data for 340B purchases and dispenses at contract pharmacies. The data that AstraZeneca requires covered entities to submit was already required of pharmacies when they submit claims to payers; and HRSA requires covered entities to maintain the same data in the regular course of business, with one minor exception for the unique identification number of the covered entity.

58. In *Novartis Pharmaceuticals*, the D.C. Circuit upheld a manufacturer claims data policy that was materially identical to AstraZeneca's current policy. 102 F.4th at 464. Among other

things, the court explained that the request for information was consistent with HRSA guidance, under which "drug manufacturers may require [such] 'standard information' from covered entities." *Id.* at 463 (quoting 59 Fed. Reg. 25,114). The Court also emphasized that "record evidence" showed "the burden of providing the claims data is 'minimal.'" *Id.*

Colorado Enacts Legislation Requiring Manufacturers to Make 340B-Discounted Drugs Available for Unlimited Contract Pharmacy Sales

59. On May 6, 2025, the Colorado Legislature passed SB 71, which Governor Jared Polis signed into law on May 30, 2025. The law took effect on August 6, 2025. *See* SB 71 § 5.

60. SB 71's sole regulatory object is Section 340B. The statute is expressly directed at modifying operation of the 340B program—and altering the behavior of those who participate in the federal program—by adding requirements and restrictions that Congress did not.

61. SB 71 provides that a drug manufacturer "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" unless "the receipt of the 340B drugs is prohibited by the federal Department of Health and Human Services." SB 71 § 6-29-105(1)(a).

62. SB 71 defines its basic terms by reference to federal law. It defines "340B drug" to mean "a covered outpatient drug within the meaning set forth in 42 U.S.C. sec. 256b" that "has been subject to any offer for reduced prices by a manufacturer pursuant to 42 U.S.C. sec. 256b (a)(1)" and "is purchased by a covered entity." SB 71 § 6-29-103(2). "[A] drug is considered 'purchased' if it would have been purchased but for [a] restriction or limitation" prohibited by the new statute. SB 71 § 6-29-103(2)(c). SB 71 also defines "340B covered entity" to have "the

meaning set forth in section 340B (a)(4) of the Federal 'Public Health Service Act'"—that is, as set forth in 42 U.S.C. § 256b(a)(4). SB 71 § 6-29-103(1).

63. SB 71 also restricts manufacturers' ability to collect data regarding the purchase and dispensing of 340B drugs by covered entities and contract pharmacies. The statute provides that drug manufacturers may 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." SB 71 § 6-29-105(1)(b). SB 71 does not acknowledge that collecting such claims data is a critical means for manufacturers to develop the "reasonable cause" that HRSA guidance requires before a manufacturer may audit a covered entity, 61 Fed. Reg. at 65,409, and is also necessary to identify sales that are eligible for the Medicare Drug Price Negotiation Program under the Inflation Reduction Act (IRA), s*ee* 42 U.S.C. § 1320f-2(d), in order to avoid duplicate discounts under both the 340B program and the IRA.

64. SB 71's sweeping prohibitions also contain no geographic limitations. *See* SB 71 § 6-29-103(1) (defining "340B covered entity" to have "the meaning set forth in Section 340B (a)(4) of the Federal 'Public Health Service Act,'" which makes no reference to state boundaries).

65. SB 71 does not prohibit diversion or otherwise require that drugs purchased at 340B-discounted prices be dispensed only to patients of a covered entity. *See* 42 U.S.C. § 256b(a)(5)(B) ("[A] covered entity shall not resell or otherwise transfer the drug to a person who

is not a patient of the entity."). Nor does SB 71 account for HRSA's enforcement authority or for the congressionally mandated procedures for administrative dispute resolution. *See id.* § 256b(d)(3).

66. SB 71 empowers the Colorado Attorney General to "investigate a complaint concerning a violation of" the statute. SB 71 § 6-29-105(3)(a). Violations of SB 71 are deemed "unfair or deceptive trade practice[s]," and violators are subject to the enforcement provisions, civil penalties, and damages set forth in the Colorado Consumer Protection Act. SB 71 §§ 6-1-105, 6-29-105(3)(a). The Consumer Protection Act, in turn, authorizes civil penalties up to $20,000 per violation. Colo. Rev. Stat. § 6-1-112(1)(a). Each package of a 340B drug "constitutes a separate violation." SB 71 § 6-29-105(3)(b). The Colorado Attorney General and district attorneys "may bring a civil action on behalf of the state to seek the imposition" of such penalties. Colo. Rev. Stat. § 6-1-112(1)(a). They may also seek restraining orders and other forms of injunctive relief to enforce SB 71. *E.g.*, *id.* §§ 6-1-107, 6-1-110.

67. Separately, SB 71 empowers the Colorado State Board of Pharmacy to "discipline" regulated entities for violating the statute. SB 71 § 6-29-105(3)(d). The Board may, therefore, "[d]eny, suspend, or revoke licenses, certifications, or registrations" and "obtain restraining orders and injunctions" to enforce SB 71. Colo. Rev. Stat. § 12-280-108(1)(c)-(d).

68. Finally, SB 71 incorporates the private right of action created by the Colorado Consumer Protection Act. *See id.* § 6-1-113. As a result, any person, corporation, partnership, or any other "legal or commercial entity" may sue for damages stemming from alleged violations of SB 71. *See id.* § 6-1-102(6).

LEGAL ALLEGATIONS

SB 71 Is Preempted by Section 340B

69. The Supremacy Clause of the U.S. Constitution provides that the "Constitution, and the Laws of the United States which shall be made in Pursuance thereof," are "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. The doctrine of federal preemption that arises out of the Supremacy Clause requires that "[a]ny state law, however clearly within a State's acknowledged power, which interferes with or is contrary to federal law, must yield." *Arnold v. Duchesne Cnty.*, 26 F.3d 982, 986 (10th Cir. 1994) (quoting *Felder v. Casey*, 487 U.S. 131, 138 (1988))).

70. Under the Supremacy Clause, SB 71 is preempted by Section 340B because its mandates for drug manufacturers, and its associated enforcement mechanisms, conflict with the 340B statute and impermissibly interfere with important federal policies and objectives.

71. *First*, by requiring drug manufacturers to offer 340B pricing for unlimited contract pharmacy sales—thereby drastically increasing their costs of participating in the 340B program—SB 71 impermissibly "stands as an obstacle to the accomplishment and execution of the full purposes and objectives of Congress." *In re MDL 2700 Genentech Herceptin (Trastuzumab) Mktg. & Sales Pracs. Litig.*, 960 F.3d 1210, 1230 (10th Cir. 2020) (quoting *Crosby v. Nat'l Foreign Trade Council*, 530 U.S. 363, 372-73 (2000)).

72. Covered entities, and their contract pharmacy partners, use 340B discounts to "turn a profit," by reselling discounted drugs at full price to insured patients. *Sanofi*, 58 F.4th at 699. But such discounts impose corresponding costs on drug manufacturers. Prior to SB 71's enactment, manufacturers were obligated to offer such discounts only for sales directly to covered entities

themselves: Federal courts determined that Section 340B does *not* obligate manufacturers to "help [covered entities] maximize their 340B profits" by offering discounts for contract pharmacy sales. *Id.* at 704; accord *Novartis*, 102 F.4th at 459.

73. SB 71 is designed to counteract those rulings, by requiring manufacturers who participate in the 340B program to offer those very discounts under state law. Under the law, a manufacturer must offer 340B discounts for unlimited contract pharmacy sales—despite the Third and D.C. Circuits' holdings that federal law imposes no such requirement. Imposing such a requirement will enable covered entities and their associated contract pharmacies to "squeeze [more] revenue out of" the federal program. *Id.* at 704. But in so doing, the law imposes a corresponding cost on manufacturers, significantly increasing the burdens of participating in a federal program beyond those that Congress intended when it crafted the program.

74. In effect, Colorado has used manufacturers' participation in the federal 340B program as leverage to extract additional money from them under state law. The result is to "exert an extraneous pull on the scheme established by Congress," thus "skew[ing]" the "delicate balance of statutory objectives." *Buckman Co. v. Plaintiffs' Legal Comm.*, 531 U.S. 341, 348, 353 (2001).

75. Other States have defended similar contract pharmacy laws by claiming that they regulate only drug distribution, which the 340B statute does not address.

76. Even if that were true, and SB 71 regulated delivery rather than pricing, that would not save the law from preemption. Imposing a costly new delivery obligation on transactions under a federal program just as readily "discourage[s]" participation in the program and impermissibly disrupts Congress's careful design. *Id.* at 350.

77. But in fact it is *not* true: Although it refers to the "acquisition" and delivery" of 340B drugs, SB 71 regulates drug *pricing*. The law dramatically expands the range of transactions in which manufacturers must provide access to their products at prices that have been reduced under the formula prescribed by Section 340B.

78. By prohibiting manufacturers from restricting 340B-priced sales to contract pharmacies, SB 71 on its face regulates pricing—and insofar as manufacturers are affected, *only* regulates pricing. The statute does not affect any aspect of drug acquisition or delivery, such as packaging requirements, shipping conditions, shipping costs, or other logistics and specifications. To the contrary, whether a contract pharmacy pays a commercial price or the 340B price is the *only* thing that distinguishes a sale that complies with SB 71 from a sale that violates SB 71.

79. The Supremacy Clause prohibits States from engrafting new, costly state law obligations like SB 71 onto an existing federal program and overturning the careful balance of benefits and burdens that Congress established.

80. *Second*, the Supremacy Clause prohibits States from establishing parallel regimes that encroach on the federal government's authority to set and define federal enforcement priorities. *See id.* at 349-51.

81. SB 71 directly interferes with the robust federal enforcement regime that Congress has enacted for the 340B program, which includes the ADR process, required auditing provisions for manufacturers and covered entities, and the possibility of civil monetary penalties in the event of a manufacturer overcharge or diversion by a covered entity.

82. Indeed, SB 71 expressly *prevents* manufacturers from using the federal enforcement regime. "[M]anufacturers are required to audit a covered entity prior to filing an ADR

claim," 89 Fed. Reg. at 28,645; *see* 42 U.S.C. § 256b(d)(3)(B)(iv), but a manufacturer must have "documentation" indicating diversion or duplicate discounts before it may initiate such an audit, 61 Fed. Reg. at 65,409. Yet SB 71 restricts manufacturers' ability to collect necessary claims data regarding the purchase and dispensing of 340B drugs by covered entities and contract pharmacies, because it forbids them from requiring the submission of such data as a condition of their "offer" under the 340B program. SB 71 § 6-29-105(1)(b).

83. Without this claims data, manufacturers are unable to adequately identify duplicate discounts or diversion. They are likewise significantly hampered in establishing the "reasonable cause" required to conduct audits of covered entities, as is their statutory right. *See* ¶¶ 27, 55-56, *supra*.

84. "By restricting the very method by which data collection is made," SB 71 "frustrates drug manufacturers' ability to take the initial steps necessary to start the very audit required to access the alternative dispute resolution system." *PhRMA v. Morrisey*, 760 F.Supp.3d 439, 453 (S.D. W. Va. 2024).

85. The data-collection restriction conflicts with federal law in other ways, too. Under the Inflation Reduction Act, Congress has instructed HHS to "negotiate" with manufacturers regarding the "maximum fair price" that Medicare will pay for certain drugs. 42 U.S.C. § 1320f-3(a). A manufacturer whose drug is selected for "negotiation" must make the drug available at the "maximum fair price" unless it is available at a lower 340B price. *Id.* § 1320f-2(d). To ensure compliance with the IRA and to prevent duplicative price reductions under Section 340B and the IRA, the Centers for Medicare and Medicaid Services (CMS) has charged manufacturers with identifying instances where a drug has been dispensed as a 340B drug. *See* CMS, Medicare Drug

Pricing Negotiation Final Guidance 58-60 (Oct. 2, 2024), https://www.cms.gov/files/document/medicare-drug-price-negotiation-final-guidance-ipay-2027-and-manufacturer-effectuation-mfp-2026-2027.pdf. But SB 71 restricts manufacturers' ability to obtain the data that manufacturers need to make those identifications. It therefore inhibits manufacturers' ability to avoid such unlawful duplicate price reductions under Section 340B and the IRA, conflicting with federal law. *See* 42 U.S.C. § 1320f-2(d) (providing that manufacturers "shall not be required" to provide duplicate discounts).

86. SB 71 interferes with enforcement of the 340B program in yet another respect: It requires state officials to adjudicate disputes about the meaning and application of federal terms and provisions.

87. SB 71 enables both the Colorado Attorney General and private entities to bring a civil action to enforce violations of the statute. *See* SB 71 §§ 6-1-105, 6-29-105(3)(a); Colo. Rev. Stat. §§ 6-1-112, 6-1-113.

88. In any state enforcement proceeding, a state adjudicator would be required to consider and resolve questions of federal law in order to determine whether a manufacturer has violated SB 71. Among other things, the adjudicator would need to decide whether the 340B drugs to which the manufacturer allegedly denied or restricted access were intended for a "a patient of the entity," as required for eligibility under the 340B program. 42 U.S.C. § 256b(a)(5)(B). That question turns on the definition of "patient of the entity" under federal law. The adjudicator would also be required to determine whether a particular covered entity continues to qualify for participation in the 340B program, which depends on whether the entity sells or transfer 340B-drugs to anyone other than its patients or seeks duplicate discounts. *See id.* § 256b(a)(4) (defining

"'covered entity'" to "mean[] an entity that meets the requirements described in paragraph (5)," which includes the prohibitions on diversion and duplicate discounts). These issues are often disputed and have been the subject of federal litigation. *See, e.g.*, *Amgen Inc. v. Becerra*, No. 1:24-cv-3571 (D.D.C. filed Dec. 20, 2024).

89. In *Astra USA, Inc. v. Santa Clara County*, the Supreme Court held that private entities may not bring actions under state contract law to enforce the provisions of manufacturers' 340B pharmaceutical pricing agreements. 563 U.S. at 113-14. "Congress made HHS administrator of … the 340B Program." *Id.* at 120. Suits by private entities, the Court explained, "would undermine the agency's efforts" to administer the program "harmoniously and on a uniform, nationwide basis." *Id.* "With HHS unable to hold the control rein, the risk of conflicting adjudications would be substantial." *Id.*

90. SB 71 makes that risk unavoidable. By inserting Colorado, its officials, and private entities into the program that Congress adopted, the law frustrates the accomplishment of Congress's objectives and interferes with Congress's chosen method of oversight.

SB 71 Is Preempted by Federal Patent Law as Applied to AstraZeneca's Patented Products

91. As applied to AstraZeneca's patented products, SB 71 is also preempted by the federal patent laws because it regulates the prices at which patented drugs may be sold.

92. The Constitution gives Congress exclusive authority to establish a system of incentives "[t]o promote the Progress of Science and useful Arts." Art. I, § 8, cl. 8. Under the federal patent law, inventors are "impelled to invest in creative effort" on the promise that they will obtain "a federally protected 'exclusive right'" to sell their inventions for a limited period. *BIO*, 496 F.3d at 1372. The public can benefit from immediate access to new inventions during

the exclusivity period; and after the period expires, the public gets "lower price[s] through unfettered competition." *Id.* at 1373. The States are not free to upset that finely calibrated system: "Where it is clear how the patent laws strike that balance in a particular circumstance, that is not a judgment the States may second-guess." *Bonito Boats, Inc. v. Thunder Craft Boats, Inc.*, 489 U.S. 141, 152 (1989).

93. State laws that cap or fix the prices at which patented drugs may be sold are accordingly preempted by federal patent law, as the Federal Circuit has explained, because they "re-balance the statutory framework of rewards and incentives . . . in effect diminishing the reward to patentees in order to provide greater benefit to . . . drug consumers." *BIO*, 496 F.3d at 1374. In *BIO*, the Federal Circuit struck down a District of Columbia law that prohibited patented drugs from "being sold in the District for an excessive price." *Id.* at 1365. The court explained that, notwithstanding "the District's judgment" that drug manufacturers were charging "excessive prices" that "threaten[ed] the health and welfare of the residents of the District as well as the District government's ability to ensure that all residents receive the health care they need," the law was "contrary to the goals established by Congress in the patent laws." *Id.* at 1365, 1374 (quoting D.C. Code § 28-4551). The District's law was therefore preempted because "[t]he underlying determination about the proper balance between innovators' profit and consumer access to medication . . . is exclusively one for Congress to make." *Id.* at 1374.

94. The same analysis applies to SB 71. Like the District of Columbia law invalidated in *BIO*, SB 71 restricts the prices at which manufacturers must offer their patented drugs by requiring them to make 340B discounts available for unlimited contract pharmacy sales. Whereas Section 340B caps drug prices with respect to sales to a limited set of specifically enumerated

covered entities, SB 71 purports to extend those price caps to a category of sales—unlimited contract pharmacy sales—where federal courts have held that manufacturers are *not* required to offer them under the federal program. Accordingly, SB 71 functions as a price cap for unlimited contract pharmacy sales, impermissibly constraining manufacturers' "opportunity" to take advantage of the benefit of exclusivity conferred by Congress "during the patent's term." *Id.* at 1372.

95. SB 71 is thus preempted by federal patent law as applied to AstraZeneca's patented products. States are not permitted to set the prices of patented drugs or to "re-balance" the "rewards and incentives" embodied in the federal patent laws, as Colorado has done here. *Id.* at 1374.

SB 71 Violates the Contracts Clause

96. SB 71 also violates the Contracts Clause of the U.S. Constitution. Article I, section 10, clause 1 of the Constitution provides that "No State shall . . . pass any . . . Law impairing the Obligation of Contracts." Courts have interpreted the Contracts Clause to require a three-part inquiry to balance the State's obligation not to impair contracts with the State's interest in public welfare. S*tillman v. Tchrs. Ins. & Annuity Ass'n Coll. Ret. Equities Fund*, 343 F.3d 1311, 1321 (10th Cir. 2003). First, the court asks whether the state law has "operated as a substantial impairment of a contractual relationship." *Boyz Sanitation Serv., Inc. v. City of Rawlins*, 889 F.3d 1189, 1195 (10th Cir. 2018) (quoting *Gen. Motors Corp. v. Romein*, 503 U.S. 181, 186 (1992)). Second, if the court finds substantial impairment, it must examine whether the State has a "significant and legitimate public purpose behind the [law]." S*tillman*, 343 F.3d at 1321 (quoting *Energy Rsrvs. Grp., Inc. v. Kan. Power & Light Co.*, 459 U.S. 400, 411 (1983)). Third, if the State presents a legitimate justification for the impairment, the court must determine whether the law "is

based upon reasonable conditions and is of a character appropriate to the public purpose justifying the legislation's adoption." *Id.* (cleaned up) (quoting *Energy Rsrvs. Grp.*, 459 U.S. at 412).

97. SB 71 fails at every stage of this test. SB 71 substantially impairs a contractual relationship. As explained above, the 340B program operates through contracts, which are called pharmaceutical pricing agreements (PPAs). PPAs are "uniform agreements that recite the responsibilities § 340B imposes . . . on drug manufacturers and the Secretary of HHS." *Astra USA*, 563 U.S. at 113. While PPAs are not "transactional, bargained-for contracts," *id.*, they nonetheless announce the parties' rights and obligations like any other contract, and manufacturers like AstraZeneca are entitled to rely on the PPA's terms when developing their business. Among those terms is the requirement that manufacturers offer discounted drugs only for sales to a specifically delineated set of "covered entities." As the Third Circuit held, and the D.C. Circuit later underscored, neither the 340B statute nor the PPA requires AstraZeneca to make 340B discounts available for sales at "an unlimited number of contract pharmacies." *Novartis Pharms.*, 102 F.4th at 461 (quoting *Sanofi Aventis*, 58 F.4th at 706).

98. SB 71 operates as a substantial impairment of AstraZeneca's PPA with the HHS Secretary. AstraZeneca joined the 340B program with the expectation and understanding that it would be required to offer discounts only for a limited category of sales, and it accepted that obligation. SB 71 seeks to unilaterally expand AstraZeneca's obligations under that contract—without AstraZeneca's consent—by requiring AstraZeneca to offer discounts for an entirely new category of sales: contract pharmacy sales.

99. The U.S. Supreme Court has held that similar expansions of beneficiaries to a contract constitute substantial impairment under the Contracts Clause. *See Allied Structural Steel*

Co. v. Spannaus, 438 U.S. 234, 245-46 (1978) (Contracts Clause prohibited State from requiring company to provide additional pension benefits after it had agreed to provide pension benefits under specific contractual conditions); *see also United Healthcare Ins. Co. v. Davis*, 602 F.3d 618, 630 (5th Cir. 2010) (Contracts Clause prohibited state from enacting legislation increasing obligations on companies that had agreed to insure state employees under specific conditions).

100. SB 71 impairs AstraZeneca's contracts in other ways, too. AstraZeneca agreed by contract to participate in a regulatory regime that allowed it to conduct audits to facilitate ADR claims. But SB 71's data-collection restriction severely limits AstraZeneca's ability to gather information necessary for pre-ADR audits, frustrating another critical component of its contractual agreement under the PPA and further increasing the burdens of participating in the 340B program.

101. Any justification Colorado might offer for SB 71 would be insufficient under the Contracts Clause. Colorado cannot claim that its law is necessary to provide access to 340B drugs to covered entities and their patients, because AstraZeneca's policy already ensures that every covered entity is offered those drugs at a discounted price. Indeed, AstraZeneca's policy goes further, allowing covered entities to designate a single contract pharmacy if it does not have an on-site pharmacy.

102. Colorado has no legitimate justification for requiring discounts for unlimited contract pharmacy sales, which will advance the economic interests of for-profit entities at the expense of companies like AstraZeneca, particularly where Congress itself has not required them.

103. Nor can Colorado justify SB 71 as a cost-reduction mechanism for patients. Studies show that most 340B discounts to contract pharmacies are *not* passed on to patients, who must pay full price for their drugs. *See* ¶ 34, *supra*.

104. Finally, even if Colorado could articulate a legitimate justification for SB 71's impairment of AstraZeneca's PPA, that justification would not be reasonable and necessary to achieve the State's goals.

SB 71 Violates the Takings Clause

105. The Takings Clause of the U.S. Constitution provides that "private property" may not "be taken for public use, without just compensation." U.S. Const. amend. V.

106. Under the Takings Clause, although the government may take private property "for public use" so long as it pays "just compensation," the government may never take private property for *private* use, regardless of the amount of compensation paid. As the U.S. Supreme Court has explained, "the sovereign may not take the property of *A* for the sole purpose of transferring it to another private party *B*," a prohibition that applies regardless of whether "*A* is paid just compensation." *Kelo*, 545 U.S. at 477. Such takings for private use are always unlawful, since "[n]o amount of compensation can authorize such action." *Lingle v. Chevron U.S.A. Inc.*, 544 U.S. 528, 543 (2005).

107. SB 71 takes the private property of manufacturers like AstraZeneca for private, not public, use. The law forces manufacturers to transfer their prescription drugs to other private (non-governmental) entities—namely, to covered entities and the pharmacies with which they contract—at prices that AstraZeneca would not otherwise offer (and is not required to offer under federal law).

108. This forced transfer would be unlawful even if manufacturers were paid just compensation for these contract pharmacy sales. *See id.* But manufacturers are *not* justly

compensated for the forced transfers covered by the law: The law requires manufacturers to make these transfers at steeply discounted prices, well below fair market value.

109. This forced transfer results in the "physical appropriation" of manufacturers' prescription drugs by contract pharmacies and covered entities, and it therefore constitutes "a *per se* taking." *Cedar Point Nursery v. Hasid*, 594 U.S. 139, 149 (2021).

110. But even if SB 71 did not involve a physical appropriation, it would still constitute a regulatory taking because it (1) has a profound economic impact on the value of the property subject to the law; (2) significantly interferes with manufacturers' investment-backed expectations; and (3) forces manufacturers to transfer title to their property, depriving them of the full use and enjoyment of that property. *See Penn Central Transp. Co. v. City of New York*, 438 U.S. 104, 124 (1978).

111. SB 71 accordingly violates the Takings Clause of the U.S. Constitution.

CLAIMS FOR RELIEF

FIRST CLAIM FOR RELIEF

(Declaratory/Injunctive Relief – SB 71 is Preempted by Section 340B Supremacy Clause, U.S. Const. art. VI, cl. 2)

112. Plaintiff realleges and incorporates by reference all prior and subsequent paragraphs.

113. The Supremacy Clause, U.S. Const. art. VI, cl. 2, prohibits a State from enacting any law "which interferes with or is contrary to federal law," *Arnold*, 26 F.3d at 986 (quoting *Felder*, 487 U.S. at 138). The mandates imposed on drug manufacturers by SB 71, and its associated enforcement mechanisms, are preempted by the 340B statute under the Supremacy Clause.

114. SB 71 creates an obstacle to the accomplishment and execution of Congress's objectives for the 340B statute. It imposes significant new costs for participating in a federal benefits program, thereby "exert[ing] an extraneous pull on the scheme established by Congress" and "skew[ing]" the "delicate balance of statutory objectives." *Buckman*, 531 U.S. at 348, 353. In addition, Section 340B includes a comprehensive regime for enforcement and management of the program, which includes the ADR process, audits, and civil monetary penalties. SB 71's attempt to insert into Congress's program a layer of enforcement by state officials under Colorado law frustrates Congress's purposes and interferes with the carefully specified federal regime it created.

115. For these reasons, SB 71's provisions requiring manufacturers to offer 340B discounts for unlimited contract pharmacy sales, barring manufacturers from obtaining claims data from covered entities and pharmacies, and empowering Defendants to pursue purported violations of the statute, are preempted by federal law under the Supremacy Clause.

SECOND CLAIM FOR RELIEF

(Declaratory/Injunctive Relief – SB 71 is Preempted by Federal Patent Law Supremacy Clause, U.S. Const. art. VI, cl. 2)

116. Plaintiff realleges and incorporates by reference all prior and subsequent paragraphs.

117. The Supremacy Clause, U.S. Const. art. VI, cl. 2, prohibits a State from enacting any law "which interferes with or is contrary to federal law." *Arnold*, 26 F.3d at 986 (quoting *Felder*, 487 U.S. at 138). Moreover, the Constitution assigns exclusive authority to regulate patents to the U.S. Congress. With respect to pharmaceuticals, Congress has enacted comprehensive legislation establishing the scope of patent rights under federal law. Thus, state laws that cap or fix drug prices are preempted by federal patent law because they "re-balance the statutory

framework of rewards and incentives . . . in effect diminishing the reward to patentees in order to provide greater benefit to . . . drug consumers." *BIO*, 496 F.3d at 1374.

118. SB 71 requires manufacturers to make 340B discounts available for unlimited contract pharmacy sales, and it empowers Defendants to pursue purported violations of the statute. As applied to AstraZeneca's patented products, those provisions are preempted by federal patent law under the Supremacy Clause.

119. The obligation imposed by SB 71 on manufacturers—to offer 340B discounts for unlimited contract pharmacy sales—caps the prices at which manufacturers can offer their patented drugs and constrains manufacturers' "opportunity" to take advantage of the benefits of exclusivity "during the patent's term." *Id.* at 1372. The Act therefore impermissibly seeks to "re-balance" the "rewards and incentives" embodied in the federal patent laws in a manner that is beyond a state's powers. *Id.* at 1374. SB 71 is therefore preempted by federal patent law under the Supremacy Clause as applied to AstraZeneca's patented products.

THIRD CLAIM FOR RELIEF

(Declaratory/Injunctive Relief – SB 71 Violates the Contracts Clause, U.S. Const. art. I, § 10, cl. 1)

120. Plaintiff realleges and incorporates by reference all prior and subsequent paragraphs.

121. Under the Contracts Clause, U.S. Const. art. I, § 10, cl. 1, "[n]o State shall . . . pass any . . . Law impairing the Obligation of Contracts." The Contracts Clause thus prohibits States from enacting legislation that "operate[] as a substantial impairment of a contractual relationship." *Boyz Sanitation Serv.*, 889 F.3d at 1195 (quoting *Gen. Motors*, 503 U.S. at 186).

122. SB 71 violates the Contracts Clause. It substantially impairs AstraZeneca's PPA with the HHS Secretary by requiring AstraZeneca to offer 340B discounts for unlimited contract pharmacy sales, thus purporting to substantially expand AstraZeneca's obligations under the agreement beyond what the agreement itself provides.

123. Colorado has no valid justification for impairing AstraZeneca's PPA. AstraZeneca's policy ensures that every covered entity is offered 340B drugs at statutorily required prices. The policy also allows covered entities without an on-site pharmacy to utilize a single contract pharmacy, which is more than the statute requires. Compelling AstraZeneca to offer 340B-discounted drugs for unlimited contract pharmacy sales advances the economic interests of for-profit pharmacies at AstraZeneca's expense, with little to no benefit to 340B patients.

124. Even if Colorado could identify a legitimate justification for impairing AstraZeneca's PPA, it would not be reasonable and necessary to achieve the State's goals.

125. SB 71 is also unconstitutional under the Contracts Clause to the extent it requires AstraZeneca to offer 340B discounts for sales at contract pharmacies that do not qualify as covered entities, and which therefore are not included within the anticipated or actual scope of the PPA that AstraZeneca signed with the HHS Secretary.

FOURTH CLAIM FOR RELIEF

(Declaratory/Injunctive Relief – SB 71 Violates the Takings Clause, U.S. Const., amend. V)

126. Plaintiff realleges and incorporates by reference all prior and subsequent paragraphs.

127. Under the Takings Clause of the Fifth Amendment of the U.S. Constitution, the government may not take "private property" for private use—such as requiring the transfer of ownership from one private party to another—even if just compensation is paid.

128. SB 71 takes private property for private use by forcing manufacturers to transfer 340B-discounted drugs—including relinquishing title and control of the drugs—to private, non-governmental entities (covered entities and their contract pharmacies) at non-commercial prices that AstraZeneca would not otherwise offer.

129. SB 71 also denies manufacturers just compensation because it requires that their drugs be transferred to these private entities at below-market prices.

130. The forced transfer of drugs under SB 71 constitutes a taking per se or, in the alternative, a regulatory taking.

131. SB 71 is therefore unconstitutional under the Takings Clause.

PRAYER FOR RELIEF

NOW, THEREFORE, AstraZeneca requests a judgment in its favor against the Colorado Attorney General as follows:

A. Declare that SB 71 is preempted by Section 340B and is therefore null, void, and unenforceable;

B. Declare that SB 71 is preempted by federal patent law, and therefore null, void, and unenforceable, as applied to AstraZeneca's patented products;

C. Declare that SB 71 is unconstitutional as applied to AstraZeneca under the Contracts Clause of the U.S. Constitution;

D. Declare that SB 71 is unconstitutional as applied to AstraZeneca under the Takings Clause of the U.S. Constitution;

E. Declare that AstraZeneca is not required to offer 340B discounts for unlimited contract pharmacy sales under Colorado law;

F. Issue preliminary and permanent injunctive relief preventing Defendants from implementing or enforcing SB 71 against AstraZeneca or any of its affiliates, officers, agents, or contractors;

G. Issue preliminary and permanent injunctive relief preventing Defendants from seeking civil penalties, equitable relief, or any other remedy based on any alleged violation of SB 71 by AstraZeneca or any of its affiliates, officers, agents, or contractors;

H. Award AstraZeneca reasonable attorneys' fees and costs, as appropriate; and

I. Grant such other and further relief as the Court may deem appropriate.

Dated: August 27, 2025

Respectfully submitted,

/s/ Colin M. O'Brien

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