IN THE UNITED STATES DISTRICT COURT
FOR THE NORTHERN DISTRICT OF ILLINOIS
EASTERN DIVISION

NOVARTIS PHARMACEUTICALS CORPORATION, *Plaintiff*, v. KWAME RAOUL, in his official capacity as ATTORNEY GENERAL OF ILLINOIS, *Defendant*.	)	Case No.

VERIFIED COMPLAINT

Novartis Pharmaceuticals Corporation (Novartis) brings this complaint against Defendant Kwame Raoul, in his official capacity as Attorney General of Illinois, seeking preliminary and permanent injunctive relief and a declaratory judgment preventing the enforcement of Illinois's recently enacted H.B. 2371. Novartis alleges as follows:

NATURE OF THE ACTION

1. When Congress carefully delineates the costs and benefits imposed on participants in a voluntary federal program, states are not free to second-guess its judgment. But H.B. 2371 attempts to do just that. Federal law purposely limits the obligations imposed on manufacturers that participate in the 340B Drug Pricing Program, including by allowing manufacturers to impose reasonable conditions on access to discounted drugs.

2. H.B. 2371 purports to outlaw the very same reasonable conditions that federal law authorizes. H.B. 2371 violates the Supremacy and dormant Commerce Clauses of the U.S. Constitution.

3. Drug manufacturers must participate in the federal 340B Program as a condition of having their drugs covered by Medicaid and Medicare Part B. The 340B Program requires manufacturers to offer to sell deeply discounted units of drugs to select non-profit hospitals and clinics called "covered entities." The 340B Program subsidizes these covered entities by allowing them to buy drugs cheaply—as low as a penny per unit—while charging patients the drug's full commercial price. Because covered entities can pocket the difference, they have sought to maximize the number of drug sales categorized as part of the 340B Program; every additional transaction completed at the 340B price boosts their bottom line.

4. Congress, though, sought to balance two competing goals in creating the 340B Program: (1) subsidizing covered entities, but (2) not making the subsidy so large that it dissuades manufacturers from participating in Medicaid and Medicare Part B. To ensure careful calibration of these objectives, Congress gave a single federal agency centralized oversight of both Medicaid and the 340B Program. *Astra USA, Inc. v. Santa Clara County*, 563 U.S. 110, 119-120 (2011).

5. In recent years, covered entities have tried to game the system. To supersize the number of 340B discounts they claim, covered entities started contracting with third-party pharmacies ("contract pharmacies") located all over the country—often large, for-profit chain pharmacies like CVS or Walgreens. Covered entities hire data-crunchers called "third-party administrators" to retroactively analyze prescriptions previously filled at contract pharmacies, looking for pharmacy customers covered entities could argue they treated at some point in the past. For each such connection the third-party administrator purports to find, the covered entity (or one of its for-profit partners) arranges for the pharmacy to acquire a discounted drug—the "replenishment" unit—to make up for the fact that the unit actually dispensed was purchased at commercial prices. The pharmacy then sells the replenishment unit at full price to the next

customer who walks in the door, whether or not that person is a patient of the covered entity. The covered entity, third-party administrator, and pharmacy all split the resulting profit.

6. The 340B statute does not mention contract pharmacies, and for good reason: Because drugs purchased outside of the 340 Program are purchased at the commercial price, hospitals have no financial incentive to ship those drugs to pharmacies around the country. Their patients can purchase drugs at any pharmacy that stocks them, and the dispense involves a one-way transaction between the pharmacy and its customer, with no commercial incentive for the hospital to get involved. After the 340B statute was enacted, however, the federal agency responsible for the 340B Program opined that covered entities may claim 340B discounts on drugs dispensed by *one* contract pharmacy—solely so covered entities without an in-house pharmacy could participate in the Program. In other words, a contract pharmacy arrangement is a legal fiction that allows the covered entity to associate itself with a sale between a pharmacy and one of the pharmacy's customers, under the pretense that the pharmacy was acting on the covered entity's behalf.

7. When the federal agency later changed its policy to allow covered entities to use *unlimited* contract pharmacies, the volume of 340B discount claims skyrocketed. This trend ultimately led some drug manufacturers (including Novartis) to introduce their own reasonable limits on the use of contract pharmacies as conditions of offering 340B pricing.

8. Two federal appeals courts have now confirmed that Congress intentionally preserved manufacturers' discretion to recognize only one contract pharmacy and to require covered entities to submit basic claims data. *Novartis Pharms. Corp. v. Johnson*, 102 F.4th 452, 460 (D.C. Cir. 2024); *Sanofi Aventis U.S. LLC v. HHS*, 58 F.4th 696, 704-706 (3d Cir. 2023).

Novartis crafted its contract pharmacy policy with those decisions in mind, and its policy has repeatedly been found by the federal government to comply with federal law.

9. H.B. 2371 eliminates the discretion Congress preserved for manufacturers to impose reasonable limits on covered entities' purchases. By prohibiting manufacturers from imposing any restrictions or conditions not explicitly spelled out in the 340B statute, H.B. 2371 prohibits the very same manufacturer limits endorsed by *Novartis* and *Sanofi*: restricting the number of contract pharmacy arrangements manufacturers recognize, and requiring claims data about the specific units for which 340B discounts are sought. And because H.B. 2371 cannot be enforced without addressing a number of thorny questions regarding the federal 340B requirements, the Illinois law destroys the federal government's ability to administer the program "on a uniform, nationwide basis." *Astra*, 563 U.S. at 120.

10. H.B. 2371 cannot coexist with federal law. The state law consciously sets out to restructure the burdens and obligations imposed by the federal 340B program. But the federal government has overriding interests in regulating manufacturers' 340B obligations and in preserving the uniformity of 340B enforcement. The federal 340B statute's pervasive regulation of the 340B Program leaves no room for state supplementation. H.B. 2371 separately frustrates Congress's goals in three ways: (a) outlawing conduct Congress chose to allow; (b) upsetting Congress's delicate balance of interests in the 340B Program; and (c) inviting inconsistent adjudications regarding manufacturers' 340B obligations. For these reasons, the federal government itself has explained that laws like H.B. 2371 violate the Supremacy Clause.

11. H.B. 2371 independently violates the dormant Commerce Clause. The statute caps the price manufacturers may charge for their drugs that end up at pharmacies located anywhere in the United States that have a contract with an Illinois covered entity. But manufacturers sell their

drugs to wholesalers outside of Illinois, and those wholesalers then resell the drugs to pharmacies. When covered entities located in Illinois demand 340B pricing on replenishment units bound for contract pharmacies, the wholesaler provides the 340B discount and then asks the manufacturer for reimbursement in a distinct transaction that takes place wholly outside Illinois's borders. Under H.B. 2371, manufacturers would be forced to provide that reimbursement. This extraterritorial regulation is impermissible.

12. Absent immediate judicial intervention enjoining Defendant from enforcing H.B. 2371, Novartis will suffer irreparable harm. Because the law took effect on **August 7, 2026**, Novartis already risks violating Illinois law—and incurring serious penalties—merely by maintaining a 340B policy that has been declared lawful by federal courts applying the federal 340B statute.

13. Novartis therefore requests preliminary and permanent injunctive relief preventing enforcement of H.B. 2371 against Novartis, as well as a declaratory judgment establishing that H.B. 2371 violates the Supremacy and dormant Commerce Clauses of the U.S. Constitution.

PARTIES

14. Plaintiff Novartis Pharmaceuticals Corporation is a corporation organized in Delaware with its principal place of business at 59 Route 10, East Hanover, New Jersey 07936. Novartis's mission is to reimagine medicine to improve and extend people's lives.

15. Defendant Kwame Raoul is the Attorney General of Illinois and is responsible for administering and enforcing H.B. 2371. Defendant Raoul maintains an office at 500 South Second Street, Springfield, IL 62701. Defendant is sued in his official capacity only.

JURISDICTION AND VENUE

16. This Court has jurisdiction under 28 U.S.C. § 1331 because this civil action arises under the laws and Constitution of the United States. *Verizon Md., Inc. v. Public Serv. Comm'n of Md.*, 535 U.S. 635, 642 (2002); *Shaw v. Delta Air Lines, Inc.*, 463 U.S. 85, 96 n.14 (1983).

17. This Court also has inherent equitable power to enjoin the actions of state officials that violate the U.S. Constitution and federal law. *Ex parte Young*, 209 U.S. 123, 159-160 (1908); *MCI Telecomms. Corp. v. Illinois Bell Tel. Co.*, 222 F.3d 323, 345 (7th Cir. 2000).

18. Venue is proper in this Court under 28 U.S.C. §§ 1391(b)(1) and (2) because one or more defendants reside in this district and because a substantial part of the events giving rise to Novartis's claims occurred in this district. The challenged state law also purports to govern contract pharmacy arrangements in this district.

LEGAL AND FACTUAL BACKGROUND

I. Statutory and Regulatory Background

19. H.B. 2371 refers to the federal 340B statute five times and incorporates the federal 340B statute into key definitions. *See, e.g.*, H.B. 2371 §§ 5(2), 10 (citing 42 U.S.C. § 256b). To understand what H.B. 2371 requires, it is necessary to first understand the federal landscape into which it inserts itself.

A. The 340B Program, Medicaid, and Medicare Part B

20. Congress created the Medicaid Drug Rebate Program (MDRP) in 1990.[1] In exchange for near-universal Medicaid coverage of their products, manufacturers in the MDRP must offer state Medicaid plans the "best price" given to any other purchaser. H.R. Rep. No. 102-

[1] Medicaid & CHIP Payment & Access Comm'n, *The 340B Drug Pricing Program & Medicaid Drug Rebate Program: How They Interact* 1-2 (May 2018) (MACPAC Report), https://tinyurl.com/43uum74c.

384(II), *9-10 (1992). This design inadvertently discouraged drug manufacturers from continuing their longstanding practices of offering steep discounts to charitable hospitals—because those sales would often amount to the "best price" charged to any purchaser, and therefore set the rate owed to state Medicaid plans on *all* drugs dispensed to patients covered by Medicaid. *Id.*; *see also* Milt Freudenheim, *Big Costs Imposed on Drug Makers*, N.Y. Times (Nov. 6, 1990) at D2, https://tinyurl.com/368umt5y.

21. Congress created the 340B Program to address that problem. H.R. Rep. No. 102-384(II), *12 (1992). As a condition of having their drugs covered by Medicaid and Medicare Part B, manufacturers must offer to sell their products to certain healthcare providers at rock-bottom prices, but those prices would be excluded from the Medicaid "best price" determinations. *See* 42 U.S.C. § 256b(a)(1); *id.* §§ 1396r-8(a)(1), (a)(5)(A); 42 C.F.R. § 447.508(a)(1).

22. The select providers entitled to these discounts—called "covered entities"—are carefully described in the 340B statute. 42 U.S.C. § 256b(a)(4). 340B prices, too, are set by federal law under a statutory formula that references MDRP pricing. *Id.* §§ 256b(a)(1)-(2).

23. 340B prices can drop as low as a penny. 82 Fed. Reg. 1,210, 1,215 (Jan. 5, 2017). Critically, though, covered entities need not pass on these discounts to their patients,[2] and they usually do not.[3] Instead, a covered entity typically uses the 340B discount to generate a "spread":

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[2] Karen Mulligan, *The 340B Drug Pricing Program: Background, Ongoing Challenges, & Recent Developments* 2 (2021), https://tinyurl.com/5n6chhm6; Rena M. Conti & Peter B. Bach, *Cost Consequences of the 340B Drug Discount Program*, 309 JAMA 1995, 1995 (2013), https://tinyurl.com/yc2t8b35.

[3] Rory Martin & Kepler Illich, IQVIA, *Are Discounts in the 340B Drug Discount Program Being Shared with Patients at Contract Pharmacies?* 11-12 (2022), https://tinyurl.com/4bfbz7yz; *see also, e.g.*, Senate Health Educ. Lab. & Pensions Comm., *Congress Must Act to Bring Needed Reforms to the 340B Drug Pricing Program* 9-10 (April 2025) (HELP Comm. Report), https://tinyurl.com/2e642hru.

It bills "the patient's insurance—whether commercial, Medicare or Medicaid—at customary reimbursement rates that do not account for the 340B discount" and then pockets the difference.[4]

24. Covered entities may use that revenue for purposes that have nothing to do with the 340B Program—or even with treating patients. Recent reporting has noted examples where covered entities used 340B revenue to make "deals with minor-league and college sports teams for naming rights," to launch "a film company," to fuel "consolidation" that "has increased prices and insurance premiums,"[5] and to build "a luxury apartment and office complex" while "slashing services" in lower-income areas.[6] All of this, of course, comes at a great cost to drug manufacturers.

25. The 340B Program is deeply interwoven with other federal healthcare programs, especially Medicaid. As explained above, when a unit of a drug is sold at the 340B price, that sale is exempted from the statutory formula that determines how much Medicaid pays for all units of the drug. *See* 42 C.F.R. § 447.508(a)(1). And manufacturers need not pay Medicaid rebates on a particular unit of a drug for which a covered entity paid the 340B price. 42 U.S.C. § 256b(a)(5)(A).

26. For the latter reason, the federal government can be adversely impacted when a unit of a drug is deemed 340B eligible. When a covered entity claims a 340B discount on a unit of a drug that was dispensed to certain Medicaid recipients, the Medicaid plan faces a greater expenditure because it does "not receive drug rebates."[7] States and the federal government share

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[4] Ryan Long et al., *Cui Bono? Misaligned Incentives in the 340B Program* § IV (Sep. 2025), https://tinyurl.com/msb3zn96.

[5] Editorial, *A Good Idea to Cut Drug Costs*, WALL ST. J. (Sep. 21, 2025), https://tinyurl.com/y3k63v3z.

[6] Katie Thomas & Jessica Silver-Greenberg, *How a Hospital Chain Used a Poor Neighborhood to Turn Huge Profits*, N.Y. TIMES (Sep. 24, 2022), https://tinyurl.com/4cxjukf4.

[7] Long et al., *supra* n.4, at § VI(C).

Medicaid rebates, so this effect directly increases what the federal government must spend to support Medicaid.[8] The added costs can be substantial; one recent estimate found that 340B discounts displaced $6.5 *billion* in Medicaid rebates in a single year—of which "the federal government's share" would have been $4.2 *billion*.[9] Further "legislative expansion" of the 340B Program "increas[es] these costs by millions of dollars annually."[10]

27. The 340B Program also serves as the "price of admission to participate in Medicaid and Medicare Part B." *AbbVie Inc. v. Drummond*, 808 F. Supp. 3d 1266, 1273 (W.D. Okla. 2025). Because the 340B Program was enacted under Congress's spending power,[11] manufacturers' participation is voluntary and works "much in the nature of a contract," *see Pennhurst State Sch. & Hosp. v. Halderman*, 451 U.S. 1, 17 (1981). Congress must spell out program conditions unambiguously so participants can understand in advance what they are agreeing to do. *Cummings v. Premier Rehab Keller, P.L.L.C.*, 596 U.S. 212, 219 (2022). If 340B burdens become too large, manufacturers could withdraw from the program entirely—reducing participation in Medicaid and Medicare Part B, too. *Pharmaceutical Rsch. & Mfrs. of Am. (PhRMA) v. McCuskey*, 171 F.4th 675, 693 (4th Cir. 2026), *vacated and rehearing en banc granted*, 2026 WL 1493394 (4th Cir. May 28, 2026); *Drummond*, 808 F. Supp. 3d at 1277 & n.65; *AbbVie Inc. v. Wrigley*, _ F. Supp. 3d _, 2026 WL 1133457, at *2, *10 (D.N.D. 2026).

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[8] *See* MACPAC Report, *supra* n.1, at 1–2; Centers for Medicare & Medicaid Servs., *Medicaid Drug Rebate Program (MDRP)* (last updated May 26, 2026), https://tinyurl.com/yaajfmvv.

[9] Eleanor Blalock & Carlee Launsbach, *The Financial Impact to Medicaid from the 340B Drug Pricing Program* 2 (July 2025), https://tinyurl.com/s7p6u3z2; *see also* Kolton Gustafson et al., *Impacts of 340B on State Medicaid Programs & Patient OOP Costs*, Avalere (Feb. 12, 2025) (similar), https://tinyurl.com/54p2vnf7.

[10] Chuan Sun, Harish Karne, & Rory Martin, *The Cost of 340B to State Employee Health Benefit Plans* 9 (Feb. 6, 2026), https://tinyurl.com/2vhy9djr.

[11] *See Talevski ex rel. Talevski v. Health & Hosp. Corp. of Marion Cnty.*, 6 F.4th 713, 724 (7th Cir. 2021) (noting that the 340B Program was created under the Spending Clause).

B. HRSA's Uniform, Nationwide Enforcement Mechanisms

28. To manage the interactions among these federal healthcare programs, Congress gave control over all three programs to one federal agency: the U.S. Department of Health and Human Services (HHS), which houses both the Centers for Medicare & Medicaid Services (CMS) and the Health Resources and Services Administration (HRSA).

29. HRSA currently oversees the 340B Program's day-to-day administration. For example, HRSA enters into Pharmaceutical Pricing Agreements (PPAs) with manufacturers to memorialize the terms of the bargain for manufacturers wishing to participate in 340B. 42 U.S.C. § 256b(a)(1); *see also* HHS, *Example PPA*, https://tinyurl.com/4nshe96y. A PPA lists seven discrete responsibilities that manufacturers assume by joining the program, *Example PPA*, *supra* ¶ 29, § II, lays out three discrete responsibilities for HRSA, *id.* § III, and provides that these obligations must be "construed in accordance with Federal common law," *see id.* § VII(g).

30. The Supreme Court has stressed the importance of leaving HRSA "in control of § 340B's drug-price prescriptions." *Astra*, 563 U.S. at 114. In *Astra*, a county that operated multiple covered entities sued drug manufacturers, alleging it had been deprived of access to 340B pricing it was entitled to receive. *Id.* at 116. All agreed that the 340B statute does not authorize private enforcement, but the county argued it could still enforce manufacturers' PPAs, supposedly helping HRSA by "spreading the enforcement burden." *Id.* at 119. The Supreme Court rejected that position, concluding Congress intended the opposite: "centralized enforcement in the [federal] government." *Id.* (quotation omitted).

31. An amicus brief the Solicitor General filed on behalf of the United States in *Astra* highlights the interactions between Medicaid and the 340B Program.[12] Given "[t]he interdependent nature" of the 340B Program and MDRP, he explained, "an adjudication of rights under one program must proceed with an eye towards any implications for the other." *Astra* Amicus Brief, *supra* n.12, at 34. A single, centralized federal administrator is therefore "best positioned to determine manufacturers' obligations in the first instance." *Id.* at 33.

32. The Supreme Court expressly adopted the Solicitor General's view. *Astra*, 563 U.S. at 119-120. Congress intended HRSA to "administer both Medicaid and § 340B harmoniously and on a uniform, nationwide basis." *Id.* at 120. The county's lawsuit could not proceed because it would flout Congress's "unitary administrative and enforcement scheme" in favor of "a multitude of dispersed and uncoordinated lawsuits by 340B entities." *Id.*

33. Under both the 340B statute and the Supreme Court's holding in *Astra*, HRSA's exclusive administrative scheme contains only two pathways. First, the agency has direct enforcement power. If a manufacturer fails to provide 340B pricing when due, it may incur "civil monetary penalties." 42 U.S.C. § 256b(d)(1)(B)(vi). But these penalties are carefully circumscribed: They apply only to "knowing[ ] and intentional[ ]" violations, and fines "shall not exceed $5,000" per violation, *id.* §§ 256b(d)(1)(B)(vi)(II)-(III).[13] When HRSA determines that a violation has occurred, it refers the matter to the HHS Office of Inspector General (OIG) to determine "on a case-by-case basis" whether monetary penalties are warranted. 82 Fed. Reg. 1,210, 1,221 (Jan. 5, 2017).

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[12] *See generally* Brief for the United States as Amicus Curiae Supporting Petitioners at 4-5, 29-35, *Astra USA, Inc. v. Santa Clara County*, 563 U.S. 110 (2011) (No. 09-1273) (*Astra* Amicus Brief), https://tinyurl.com/bdeah9c4.

[13] HHS adjusts this amount annually for inflation. 45 C.F.R. § 102.3.

34. Second, HRSA maintains an Administrative Dispute Resolution (ADR) process for disputes between manufacturers and covered entities. 42 U.S.C. § 256b(d)(3). Manufacturers may bring ADR claims alleging that a covered entity has illegally diverted 340B-priced drugs to non-patients or claimed discounts that duplicate MDRP rebates. *Id.*; *see also id.* §§ 256b(a)(5)(A)-(B) (prohibiting these practices). Before bringing an ADR claim, though, manufacturers must complete a statutory audit process. *Id.* § 256b(d)(3)(B)(iv).

35. Covered entities may bring ADR claims alleging that a manufacturer has overcharged the entity or unduly "limited [its] ability to purchase covered outpatient drugs at" the 340B price. 42 C.F.R. § 10.21(a)(1). An overcharge occurs whenever an order for a 340B-eligible unit of a drug "results in [the] covered entity paying more" than the 340B price. *See id.* § 10.11(b).

C. Contract Pharmacies

36. A covered entity's profits from the 340B Program are driven by the number of drug units the covered entity can claim were dispensed to people it can try to claim as its patients. Each time this occurs, it creates an opportunity for the covered entity to buy a unit at the 340B price and demand reimbursement at a much higher commercial rate. Long et al., *supra* n.4, § IV.

37. Originally, the only way to trigger 340B discounts was for a patient to purchase a drug from a covered entity's in-house pharmacy. *See* 61 Fed. Reg. 43,549, 43,550 (Aug. 23, 1996). That is consistent with the 340B statute, which "suggests that [Congress] had in mind one-to-one transactions between a covered entity and a drug maker." *Sanofi*, 58 F.4th at 704-706.

38. Not all covered entities have an in-house pharmacy, however. 61 Fed. Reg. at 43,550. And even a covered entity with an in-house pharmacy can make more money from the 340B Program when more units of drugs dispensed at more pharmacies are claimed by the covered entity to trigger the 340B discount. That's where "contract pharmacies" came in. Covered entities started entering into contracts with for-profit, third-party pharmacies (like CVS and Walgreens).

These contracts are not designed to allow covered entities to dispense more drugs to their patients. No special arrangement with third-party pharmacies is needed to get drugs into patients' hands because a covered entity's patient can always purchase a drug at any pharmacy that has access to it.

39. That is why a 340B contract pharmacy arrangement has no analogue in the world of commercially-priced drug transactions. As HRSA has explained, the purpose of a contract pharmacy arrangement "is *only* providing . . . covered entities . . . a process for accessing 340B pricing." 61 Fed. Reg. at 43,550. To that end, a contract pharmacy arrangement enables an accounting trick so that covered entities can claim (rightly or wrongly) 340B discounts on drug units that were previously dispensed to pharmacy customers. These dispenses to pharmacy customers would occur whether or not the covered entity uses the dispenses as a basis for claiming 340B pricing. Absent the discounted pricing made available by the 340B Program, pharmacies would directly purchase drugs themselves like they do with all other drugs, with no involvement by any covered entity.

40. Contract pharmacy arrangements work like this: The contract pharmacy dispenses drugs to any customer with a prescription. Some of these pharmacy customers will inevitably have visited one or more covered entities for medical care at one time or another. The covered entity purports to match pharmacy customers to the names of people who have previously visited the covered entity—even if the visit was for an unrelated condition, or occurred many years earlier, or both—so that the covered entity can try to claim the pharmacy customer is also its "patient." To do that, the parties often employ a for-profit third-party administrator, whose job is to sift oceans of data, looking for these purported matches.

41. By the time a purported match is found, the customer has long since left the pharmacy with her drug, for which she has paid a non-discounted price—usually the price set by her insurer as a co-pay. The covered entity therefore needs a *retroactive* method of claiming 340B pricing for that unit. Multiple retroactive pricing mechanisms exist, and they have become the dominant way for covered entities to claim 340B pricing.

42. The most common retroactive pricing method is called the replenishment model. HELP Comm. Report, *supra* n.3, at 31. Here are the finer points:

a. The pharmacy first purchases units of a drug at the commercial price. The pharmacy places these units in its common inventory—that is, the pharmacy maintains no distinction between "340B" drugs and other drugs.

b. Over time, the pharmacy dispenses these units from its common inventory whenever a customer arrives at the pharmacy counter with a prescription. The pharmacy does so without regard to whether the customer is a patient of the covered entity or whether the prescription is 340B-eligible.

c. A third-party administrator gathers claims data from both covered entities and contract pharmacies to analyze prior dispenses to assess which of them it thinks *could* have been 340B-eligible. That call is made through an opaque algorithm that drug manufacturers never see. And the third-party administrator is incentivized to "find" 340B eligibility as often as possible because it (like contract pharmacies) gets paid based on the number of "matches" it reports.

d. When the third-party administrator purports to identify a certain number of 340B-eligible transactions, the covered entity (or sometimes the contract pharmacy or

third-party administrator) orders "replenishment" units of the drug at the discounted 340B price.

e. The pharmacy places the replenishment drug purchased at the 340B price in its common inventory, to be dispensed to the next customer who walks in the door with that prescription—whether the new customer is a supposed patient of the covered entity or not. And the cycle begins all over again.

43. The replenishment model (like all retroactive pricing models) is based on an accounting trick. The upshot is that 340B drugs are dispensed without regard to 340B eligibility. A unit may receive 340B pricing based on the identification of a previously dispensed drug—often one dispensed long ago—as ostensibly 340B-eligible. But a pharmacy that receives 340B-priced drugs does not treat that inventory as belonging to the 340B Program, and it acquires the same drugs at commercial prices irrespective of the 340B Program.

44. Pharmacy customers, for their part, almost always pay whatever price their insurance ordinarily requires, without regard to whether their prescription was the trigger for 340B eligibility. Indeed, pharmacy customers "are often unaware that they have participated in the 340B Program at all."[14] Thus, contract pharmacy arrangements are not about getting discounted drugs to patients any more than they are about physical delivery of drugs to patients. Their sole function is to facilitate a subsidy to the *covered entity*.

45. Because the replenishment model is based on a retroactive price adjustment implemented through a separate purchase of a different unit of drug, in federal-law terms there is no such thing as a singular "340B drug." The discounted nature of a single unit of drug shifts over

[14] Neal Masia, Alliance for Integrity & Reform, *340B Drug Pricing Program: Analysis Reveals $40 Billion in Profits in 2019* 2 (May 2021), https://tinyurl.com/7cc3dw2t.

time, because drugs bought at the commercial price are later deemed to be eligible for 340B pricing, and drugs purchased at 340B pricing are dispensed in transactions that are not eligible for the discount.

D. HRSA's Contract Pharmacy Guidance

46. In 1996, HRSA issued guidance allowing covered entities to use *one* contract pharmacy as a way of permitting covered entities without an in-house pharmacy to access 340B pricing. 61 Fed. Reg. at 43,555. This system persisted until 2010, when "HRSA swerved" by opining that covered entities could instead "contract with an *unlimited* number of outside pharmacies . . . regardless of whether the entities have in-house pharmacies." *Novartis*, 102 F.4th at 457 (citing 75 Fed. Reg. 10,272, 10,272-73 (Mar. 5, 2010)) (emphasis added).[15]

47. HRSA's 2010 guidance had dramatic consequences for the 340B Program. When this guidance was issued, total 340B spending was about $6.6 billion.[16] By 2024 (the last year for which data is available) that spending had multiplied more than *twelvefold*, reaching over

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[15] HRSA's 1996 guidance still requires that contract pharmacies act as a covered entity's agent in dispensing 340B-priced drugs, with the covered entity maintaining title until the drug is dispensed. 61 Fed. Reg. at 43,553-54. But the replenishment model may make it impossible for covered entities to abide by these strictures. A covered entity cannot necessarily maintain title to a "replenishment" unit of a drug, for example, because the unit may later be dispensed to a non-patient of that covered entity, *supra* ¶ 41(e)—and if that unit were deemed to still belong to the covered entity, this sale would be illegal diversion, *see* 42 U.S.C. § 256b(a)(5)(B). Accordingly, the few public examples of contract pharmacy agreements appear to disclaim compliance with these agency-and-title requirements. *E.g.*, 340B Contract Pharmacy Services Agreement – ReCept Pharmacy for the DCHHS Sexual Health Clinic, 340B Drug Pricing Program § 3.2 (Oct. 1, 2019) ("[The covered entity] shall purchase 340B Drugs . . . and shall hold title to such drugs from the time the Supplier fills the order from [the contract pharmacy] made on behalf of the [covered entity] *until the time that* [*the contract pharmacy*] *takes delivery of the drugs*." (emphasis added)), https://tinyurl.com/4x2hssf4; Pharmacy Services Agreement Between the County of Monterey & CVS Pharmacy, Inc. § 26 (Oct. 4, 2019) (denying that the contract creates an "agency . . . relationship among or between the parties"), https://tinyurl.com/crzwcvyw.

[16] Rebecca Sachs & Joshua Varcie, Congressional Budget Off., *Spending in the 340B Drug Pricing Program, 2010 to 2021* 2 (June 17, 2024), https://tinyurl.com/ykt2d4v9.

$81.4 billion.[17] In the last seven years of data, the 340B Program grew by over 174 percent—far outpacing the growth rate for drug sales in general.[18] The 340B Program is now significantly larger than Medicaid and Medicare Part B, even though access to those programs is supposed to be the incentive for manufacturers to participate in the 340B Program.[19] Thus, "[w]hat was once a modest payday became a jackpot for covered entities" following the 2010 guidance, resulting in "more revenues for covered entities, to be split with their contract pharmacies, and reduced revenues for manufacturers." *McCuskey*, 171 F.4th at 685.

48. HRSA's 2010 guidance triggered much of this growth. The number of contract pharmacy arrangements exploded during the same period. In 2010, covered entities collectively had about 1,300 contract pharmacy locations;[20] now, that figure is about 35,000.[21] Multiple independent analyses—including from a Senate committee and the Congressional Budget Office—have also confirmed that the increase in contract pharmacy arrangements "fueled rapid program growth."[22]

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[17] Adam Fein, *340B Hit $81 Billion in 2024 (+23%): Why CMS and the IRA Are Poised to Cool the Program's Runaway Growth* (Dec. 15, 2025), https://tinyurl.com/bdhd6rh2.

[18] Rory Martin & Harish Karne, *The Size & Growth of the 340B Program in 2024* 2 (May 2025), https://tinyurl.com/22hsx4sj.

[19] *See* 42 U.S.C. §§ 1396r-8(a)(1), (5)(A); Long et al., *supra* n.4, § II.

[20] Government Accountability Off. (GAO), *340B Discount Program: Oversight of the Intersection with the Medicaid Drug Rebate Program Needs Improvement*, GAO-20-212 at 2 (Jan. 2020) (GAO 2020 Report), https://www.gao.gov/assets/gao-20-212.pdf

[21] *See* Milena Sullivan et al., *Contract Pharmacy Trends May Help Inform 340B Reform Debate*, Avalere Health (June 10, 2024), https://tinyurl.com/3umyyrvc.

[22] Long et al., *supra* n.4, § II; *see also, e.g.*, HELP Comm. Report, *supra* n.3, at 32-33 (finding "significant increases in 340B sales to contract pharmacies compared to direct sales to [covered entities]"); Congressional Budget Off., *Growth in the 340B Drug Pricing Program* 19 (Sep. 2025) ("The expanded use of contract pharmacies increased the proportion of prescriptions for which 340B facilities received a 340B discount."), https://tinyurl.com/4j45ybvn; *see also McCuskey*, 171 F.4th at 685 n.3.

49. This connection between unlimited contract pharmacy arrangements and 340B Program growth is also unsurprising. Each party that facilitates retroactive 340B pricing has a strong incentive to claim as many 340B-eligible transactions as possible: As the D.C. Circuit has explained, "[t]he covered entity, the pharmacy, and the third-party administrator often divvy up the spread between the discounted price and the higher insurance reimbursement rate." *Novartis*, 102 F.4th at 457-458. More contract pharmacies and third-party administrators participating in the 340B Program means more middlemen seeking their cut of these profits.

50. This incentive structure has made big business out of purporting to identify 340B-eligible transactions. A handful of massive for-profit pharmacy chains and pharmacy benefit managers now dominates the contract pharmacy industry.[23] These corporate interests siphon about 16 percent of *all* 340B revenue—a share so large that some covered entities have reported a "net loss" on 340B transactions "as a result of their high external operational costs."[24] Meanwhile, major pharmacy chains CVS and Walgreens have warned investors that changes to contract pharmacy arrangements would materially hurt their bottom lines.[25]

51. These intermediaries largely work in secret. Under retroactive pricing models, covered entities typically do not tell manufacturers which specific transactions they have identified as 340B-eligible or why—either before or after demanding 340B pricing for a past purchase. In

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[23] Adam Fein, *EXCLUSIVE: For 2023, Five For-Profit Retailers & PBMs Dominate an Evolving 340B Contract Pharmacy Market*, Drug Channels (July 11, 2023), https://tinyurl.com/5n6hfmtd.

[24] Minnesota Dep't of Health, *340B Covered Entity Report* 9, 25 (Nov. 25, 2024), https://www.health.state.mn.us/data/340b/docs/2024report.pdf.

[25] CVS Health, *2025 Annual Report* 22 (Feb. 10, 2026) ("A reduction in Covered Entities' participation in contract pharmacy arrangements, a reduction in the use of the Company's administrative services by Covered Entities . . . could materially and adversely affect the Company."), https://tinyurl.com/ynrvt7vn; Walgreens Boots Alliance, *2024 Annual Report* 35 (Oct. 15, 2024) (similar), https://tinyurl.com/32nssxjm.

other words, the covered entities and their for-profit partners demand that manufacturers offer massive discounts without providing basic documentation showing the sale's eligibility.

52. Predictably, the increase in contract pharmacy arrangements has also spawned increasing compliance failures in the 340B Program, as the federal government has repeatedly recognized. HHS OIG, for example, found that the proliferation of contract pharmacies "create[s] complications in preventing" both unlawful "diversion" and "duplicate discounts."[26] GAO, too, has noted that drug dispenses at contract pharmacies often do not produce data that allows manufacturers "to detect potential duplicate discounts." GAO 2020 Report, *supra* n.20, at 32-33. In short, 340B "discount errors" have become "likely" and "duplicate discounts" are now "quite common."[27] And these "transparency and oversight concerns . . . prevent 340B discounts from translating to better access or lower costs for patients." HELP Comm. Report, *supra* n.3, at 38.

E. The Importance of Claims Data

53. The retroactive nature of the replenishment model means that manufacturers have little information about covered entities' purported bases for claiming 340B pricing on any particular units. Manufacturers typically are unable to tell which unit of drug nominally triggered the need for a retroactive discount, let alone which pharmacy customer purchased that unit. Manufacturers therefore lack basic insight into which covered entities are stretching the bounds of federal 340B requirements to claim discounts to which they are not entitled.

54. Claims data also facilitate manufacturers' access to the federal ADR process. Before a manufacturer can bring an ADR claim, it must first complete an audit. 42 U.S.C.

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[26] HHS OIG, *Contract Pharmacy Arrangements in the 340B Program*, OEI-05-13-00431 at 5 (Feb. 4, 2014), https://tinyurl.com/2nmdrcey.

[27] House Energy & Com. Comm., *Review of the 340B Drug Pricing Program*36 (Jan. 10, 2018), https://tinyurl.com/58rpjkfv.

§ 256b(d)(3)(A). The 340B statute gives manufacturers the right "to audit . . . the records of [a covered] entity that directly pertain to the entity's compliance" with the statute's prohibitions on duplication and diversion. *Id.* § 256b(a)(5)(C). But to do that, a manufacturer must first become aware of the need to audit a particular covered entity. Given how little information manufacturers receive under the replenishment model, they often need claims data to identify circumstances in which they should "ask [HRSA] for an audit." *Drummond*, 808 F. Supp. 3d at 1278.

55. Once a manufacturer has identified the need for an audit, claims data also help manufacturers clear the regulatory audit threshold. To receive permission for an audit, HRSA requires manufacturers to first show "reasonable cause" to believe a covered entity has violated a 340B compliance requirement. 61 Fed. Reg. 65,406, 65,410 (Dec. 12, 1996). To do so, a manufacturer must adduce "sufficient facts and evidence in support" of its suspicion. *Id.* Claims data and other forms of data help enable manufacturers to satisfy this standard. *PhRMA v. Morrisey*, 760 F. Supp. 3d 439, 453 (S.D. W. Va. 2024) (describing collection of claims data as "the initial steps necessary to start" the federal audit process); *see also* 61 Fed. Reg. at 65,406 (explaining that manufacturers may need data showing "[s]ignificant changes in quantities of specific drugs ordered by a covered entity").

56. Finally, if HRSA finds sufficient cause to initiate an audit, the covered entity may sue to challenge HRSA's finding of "reasonable cause."[28] Possessing robust claims data that illuminate the covered entity's 340B activities can help the agency—or the manufacturer as an

[28] *See*, *e.g.*, *Oregon Health & Sci. Univ. v. Engels*, 24-CV-2184 (D.D.C. filed July 24, 2024); *Maine General Med. Ctr. v. Engels*, 24-CV-2187 (D.D.C. filed July 24, 2024); *University of Rochester v. Engels*, 24-CV-2268 (D.D.C. filed Aug. 1, 2024); *Children's Nat'l Med. Ctr. v. Engels*, 24-CV-2563 (D.D.C. filed Sept. 6, 2024); *University of Wash. Med. Ctr. v. Kennedy*, No. 24-CV-2998 (D.D.C. filed Oct. 22, 2024); *University of Kan. Hosp. Auth. v. Kennedy*, No. 25-CV-549 (D.D.C. filed Feb. 24, 2025).

intervenor—defend this decision, ensuring that manufacturers may access statutory remedial processes as Congress intended.

57. Historically, this system has proven difficult for manufacturers to navigate. According to HRSA's Director of the Office of Pharmacy Affairs, the agency approved just 37 audit plans in *over a decade*—and only 18 of those audits were successfully completed.[29] HRSA's recent rulemaking thus noted the "infrequency of finalized manufacturer audit reports," identifying only *two* between November 2022 and April 2024. 89 Fed. Reg. 28,643, 28,644 (Apr. 19, 2024).

II. Novartis's Contract Pharmacy Policies and Related Litigation

58. Following HRSA's 2010 contract pharmacy guidance, Novartis became concerned about the seemingly endless growth of contract pharmacy arrangements and their abuses of the 340B Program. As that growth rapidly accelerated in recent years, Novartis implemented policies placing reasonable limitations on contract pharmacy arrangements, aiming to mitigate their harms and to restore contract pharmacies to the place they historically occupied in the 340B Program.

59. Novartis implemented its first contract pharmacy policy in late 2020. Under that policy, Novartis honored contract pharmacy arrangements only if the third-party pharmacy was within 40 miles of the covered entity. But Novartis exempted federal grantees[30] and permitted other covered entities to request exemptions if justified by a specific need. Novartis also requested—but did not require—that covered entities give Novartis basic claims data.

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[29] Declaration of Chantelle Britton, *University of Wash. Med. Ctr. v. Kennedy*, No. 24-CV-2998 (D.D.C. Dec. 20, 2024), ECF No. 22-1 ¶ 15.

[30] Federal grantees are specific types of covered entities, most notably federally qualified health centers (FQHCs) and FQHC lookalikes. *See generally* 42 U.S.C. § 1396d(*l*)(2)(B); Janet Weiner, *Community Health Centers & Value-Based Payment* 2 (April 2024), https://tinyurl.com/bdd5zb78. Novartis exempts grantees because—unlike other covered entities—they often *do* pass on 340B discounts to their patients. HELP Committee Report, *supra* n.3, at 2.

60. Covered entities complained to HRSA. Letter from HRSA to Novartis at 1 (May 17, 2021), https://tinyurl.com/d34r9ajp. In response, HRSA initially took the position that Novartis's policy violated the federal 340B statute. *Id.* HRSA claimed that "[n]othing in the 340B statute grants a manufacturer the right to place conditions" on offers to provide drugs at 340B prices. *Id.* So HRSA threatened Novartis with civil monetary penalties and ordered Novartis to "plan to restart selling, without restriction, 340B covered outpatient drugs at the 340B price to covered entities with contract pharmacy arrangements." *Id.* at 2.

A. Federal Litigation

61. Novartis challenged HRSA's 2021 letter as inconsistent with the federal 340B statute. *Novartis Pharms. Corp. v. Espinosa*, No. 1:21-CV-1479 (D.D.C. filed May 31, 2021). The U.S. District Court for the District of Columbia set aside HRSA's letter. *Id.*, 2021 WL 5161783 (D.D.C. Nov. 5, 2021). It rejected HRSA's position that the federal 340B statute "prohibit[s] . . . manufacturers from imposing any conditions on their offers of 340B-priced drugs to covered entities." *Id.* at *9 (emphasis omitted).

62. Novartis updated its contract pharmacy policy in 2023. Under that policy, Novartis provided 340B-priced drugs directly to covered entities with an in-house pharmacy. Covered entities without an in-house pharmacy could select one contract pharmacy where Novartis would provide 340B pricing. Novartis also again requested that covered entities provide claims data.

63. About a year later, the U.S. Court of Appeals for the D.C. Circuit affirmed the district court's decision setting aside HRSA's 2021 letter. *Novartis*, 102 F.4th 452. The court "reject[ed] HRSA's position that section 340B prohibits drug manufacturers from imposing any conditions" on the use of contract pharmacies. *Id.* at 459. HRSA had argued that the statute does not expressly tell manufacturers they may impose such conditions. But the D.C. Circuit concluded that Congress acted deliberately, and "this silence preserves—rather than abrogates"—

manufacturers' discretion to impose reasonable conditions. *Id.* at 460. Among other problems, HRSA's contrary reading would have "categorically requir[ed] manufacturers to deal with an unlimited number of contract pharmacies"—an obligation not found in the federal statute. *See id.* at 462.

64. Despite referring to statutory "silence," the D.C. Circuit did not suggest that the federal 340B statute leaves manufacturers' ability to condition 340B pricing unregulated. Rather, the federal 340B statute requires manufacturers to "offer each covered entity covered outpatient drugs for purchase" at or below the "ceiling price." 42 U.S.C. § 256b(a)(1). That requirement prevents manufacturers from imposing conditions so onerous that they amount to a failure to make a "bona fide offer"—for example, if the conditions "effectively increase the contract 'price,' thus perhaps nudging it above the statutory ceiling." *Novartis*, 102 F.4th at 462. But within the range of bona fide offers, Congress affirmatively and intentionally granted "private parties" the right to "act freely" in agreeing to contractual terms. *See id.* at 460.

65. The D.C. Circuit expressly held Novartis's updated contract pharmacy policy lawful. It reasoned that limiting covered entities to in-house pharmacies or to "a single contract pharmacy . . . neither precludes Novartis from making a bona fide 'offer' nor increases its contract 'price.' " *Novartis*, 102 F.4th at 463-464. That condition on 340B sales is "consistent with historic practices under the section 340B Program." *Id.* at 464.

66. The Third Circuit reached a similar conclusion regarding other manufacturers' policies. Surveying the text, context, and history of the 340B statute, it concluded that federal law does not "requir[e] delivery of discounted drugs to an unlimited number of contract pharmacies." *Sanofi*, 58 F.4th at 704-706. The court pointed out, for example, that Congress had rejected a bill

that would have required manufacturers to provide discounts at contract pharmacies, and that "Section 340B's statutory neighbor" contains a similar requirement. *Id.* at 704-705.

B. Novartis's Current Policy

67. Novartis has since updated its contract pharmacy policy to reflect these decisions. (Novartis Contract Pharmacy Policy, a copy of which is attached as Exhibit 1.) Three aspects of this policy are most relevant here.

68. First, consistent with the D.C. Circuit's decision, Novartis recognizes that a covered entity without an in-house pharmacy may use one contract pharmacy, but Novartis otherwise provides 340B pricing only on covered entities' direct purchases.

69. Second, and also consistent with the D.C. Circuit's decision, a covered entity must provide basic claims data—such as the specific transaction for which the discount is claimed, the drug dispensed, the pharmacy name, and the prescriber name—showing that the pharmacy customer actually was a patient of the covered entity.

70. Third, federal grantees are still exempted from Novartis's policy.

III. Illinois Enacts Its Own 340B Legislation

71. The Illinois legislature recently enacted H.B. 2371.

A. Contract Pharmacy Requirements

72. H.B. 2371 is expressly and solely directed at "the program established under Section 340B of the federal Public Health Service Act." H.B. 2371 § 10. The Illinois statute defines the term "340B covered entity" as any "entity in Illinois that qualifies as a covered entity under Section 340B of the federal Public Health Service Act, 42 U.S.C. 256b(a)(4)." *Id.* When a covered entity contracts with a "340B contract pharmacy," whether that pharmacy is located in Illinois or any other "state, commonwealth, or territory of the United States," *id.*, manufacturers are forbidden to "deny, restrict, prohibit, condition, or otherwise interfere with" the contract

pharmacies' ability to acquire 340B-priced drugs, *id.* § 15(a), or to "impose any restriction on the ability of a 340B covered entity to contract with or designate a 340B contract pharmacy, including restrictions relating to the number, location, ownership, or type of 340B contract pharmacy," *id.* § 15(b). H.B. 2371 also prohibits manufacturers from "compel[ling] a 340B covered entity or 340B contract pharmacy to (1) submit or otherwise provide ingredient cost or pricing data pertinent to 340B drugs"; "(2) institute requirements in any way relating to how a 340B covered entity manages its inventory of 340B drugs"; or "(3) submit data or information that is not required by a State or federal law as a condition for a 340B covered entity, its 340B contract pharmacy, or a location otherwise authorized by a 340B covered entity to receive 340B drugs." *Id.* § 15(c).

73. In short, under Illinois law, manufacturers cannot impose reasonable conditions on covered entities' use of contract pharmacies—even though they can do so under federal law, as approved by the courts in *Novartis* and *Sanofi*. The practical effect of this state-law restriction is to require manufacturers to provide a 340B-discounted drug in situations where they would otherwise provide a commercially priced drug. Put differently, H.B. 2371 regulates drug pricing.

74. H.B. 2371 exempts manufacturer conditions that are "*required* by a State or federal law." H.B. 2371 §§ 15(c)(1), (3) (emphasis added). But this exemption does not, by its terms, apply to manufacturer conditions that are implicitly authorized by the federal 340B statute or recognized under federal case law interpreting those statutes—including the *Novartis* and *Sanofi* decisions. Federal law permits manufacturers to limit the use of contract pharmacies because of what it does *not* explicitly say: Congress chose not to require manufacturers to provide 340B-priced drugs to unlimited numbers of contract pharmacies, *Novartis*, 102 F.4th at 460; *Sanofi*, 58 F.4th at 704-706, and so this burden is not part of the bargain Congress struck with drug manufacturers when creating the 340B Program, *McCuskey*, 171 F.4th at 692. By demanding that

manufacturers identify federal statutory text explicitly adopting a particular limitation on the use of contract pharmacies, H.B. 2371 ignores the nature of this federal spending-power bargain.

75. To put this in concrete terms: Novartis maintains a contract pharmacy policy limiting covered entities without an in-house pharmacy to a single contract pharmacy. (Ex. 1 at 1.) That policy has repeatedly been found consistent with federal law. *Novartis*, 102 F.4th at 463-464; (Nov. 2025 ADR Ruling, a copy of which is attached as Exhibit 2, at 2) (finding no violation under "court rulings with respect to Novartis's policy"); (June 2025 ADR Ruling, a copy of which is attached as Exhibit 3, at 2) (similar). But under H.B. 2371, Novartis's policy would be forbidden by state law as an additional "condition" or "restriction" on Novartis's offers to sell 340B-priced drugs to Illinois covered entities. H.B. 2371 §§ 15(a)–(b). As a result, Novartis would be forced to provide a much larger volume of 340B-discounted drugs in Illinois.

76. To be clear, Novartis's contract pharmacy policy does not restrict the physical delivery of drugs to contract pharmacies—just the ability to claim 340B pricing for drugs delivered to contract pharmacies. Under its policy, Novartis is already selling the same drugs to the same pharmacies at commercial prices. By prohibiting Novartis from imposing any conditions on contract pharmacy arrangements, H.B. 2371 would force Novartis to charge 340B prices on those transactions instead.

77. For those reasons, H.B. 2371 does not affect Illinois patients' access to drugs. The same units of the same drugs are already being delivered to the same pharmacies at commercial prices, where they will be dispensed to the same customers at the prices normally paid. Recall that under retroactive pricing models, contract pharmacy arrangements are based on an accounting fiction. Pharmacies do not try to identify 340B-eligible drugs until long after a drug has been dispensed. A third-party administrator culls through data after the fact and tries to match up *prior*

dispenses to pharmacy customers with the names of covered entities' patients. And when the covered entity claims the discount based on that prior dispense, it is not shared or passed on to the pharmacy customer.

78. An example of H.B. 2371's operation might look like this:

a. Suppose a person visits an Illinois clinic for a routine checkup. Later, the same person fills an unrelated prescription for a Novartis product at a CVS pharmacy—but not the clinic's one designated contract pharmacy.

b. Under federal law alone, the transaction remains simple: The pharmacy pays the commercial price for the drug; the customer pays the co-pay set by her insurer; and the clinic pays nothing—because it plays no role in the transaction.

c. But under H.B. 2371, Novartis is prohibited from imposing restrictions on the number of contract pharmacies it will recognize. As a result, the clinic can claim entitlement to 340B pricing on dispenses by the pharmacy, by using the replenishment model to retroactively anoint the same transaction as a fictional 340B-priced sale. The clinic can demand that a 340B-priced "replenishment" unit be shipped to the pharmacy instead of a commercially-priced drug, and the pharmacy would then pay the clinic for the drug (minus a finder's fee).

d. The pharmacy customer would have paid the same co-pay. But the manufacturer would have been forced to give a 340B discount that was not owed under federal law, and the clinic and its middlemen could then "divvy up the spread between the discounted price and the higher insurance reimbursement rate." *Novartis*, 102 F.4th at 457.

79. The purpose and effect of the Illinois law are to provide a greater subsidy to covered entities in the state. When a covered entity is empowered to leverage an unlimited number of

contract pharmacy arrangements, it may engage in more of these buy-low-sell-high transactions that earn revenue for the covered entity (and its for-profit, middleman partners). Long *et al.*, *supra* n.4, at §§ III-V(A); *supra* ¶¶ 35-43.

80. In this way, H.B. 2371 seeks to expand the subsidy manufacturers are required to provide under the federal 340B Program—using Medicaid and Medicare Part B as leverage.

B. Restrictions on Data Collection

81. H.B. 2371's prohibition on additional 340B conditions also extends to manufacturer policies relating to "audits" or claims "data or information." H.B. 2371 §§ 15(c)(2)-(3). These statutory provisions target the requirement in Novartis's contract pharmacy policy "that all non-grantee covered entities upload their claims data" to an electronic platform." (Ex. 1 at 1.)

82. H.B. 2371's prohibition on requiring claims data would frustrate efforts to make the federal 340B Program more transparent in Illinois. This would effectively create, as one court put it, "a system where the fox guards the hen house." *Morrisey*, 760 F. Supp. 3d at 453.

C. Enforcement Mechanisms and Penalties

83. H.B. 2371 backs up these changes to the 340B Program with severe penalties.

a. The Illinois Attorney General has authority to bring an action for a civil penalty of up to $1,000 for each violation of H.B. 2371 § 15. *See* H.B. 2371 §§ 40(a), (b)(3); 15 Ill. Comp. Stat. 205/4. And "[e]ach individual transaction . . . that is subject to a prohibited act in subsections (a) and (b) shall constitute a separate violation of th[e] Act," subject to a separate civil penalty. H.B. 2371 § 15(d).

b. The Attorney General may also seek money damages from a manufacturer deemed to have violated the statute, which would then be paid to a 340B covered entity. H.B. 2371 § 40(b)(2).

84. H.B. 2371 further authorizes Defendant to bring an action enjoining "any act, policy, or practice that violates th[e] Act." H.B. 2371 § 40(b)(1). This amounts to allowing the Illinois Attorney General to *compel* manufacturers to offer 340B discounts on their drugs—a power not even HRSA possesses.

85. Given the huge volume of drug transactions that could be deemed to fall within the 340B Program, *see supra* ¶¶ 46-48, these penalties could stack up quickly.

86. Thus, these penalties create a compliance dilemma that supports injunctive relief. Novartis must either abandon policies federal law permits or maintain them and risk substantial per-transaction penalties, damages, and injunctive enforcement by the Illinois Attorney General.

H.B. 2371 VIOLATES THE SUPREMACY CLAUSE

87. "The Supremacy Clause provides a clear rule that federal law 'shall be the supreme law of the land . . . anything in the . . . [l]aws of any State to the contrary notwithstanding.'" *Arizona v. United States*, 567 U.S. 387, 399 (2012) (quoting U.S. Const. art. VI, cl. 2).

88. As relevant here, Congress may implicitly preempt state law by occupying a legislative field so thoroughly "as to make reasonable the inference that Congress left no room for the States to supplement it." *Fidelity Fed. Sav. & Loan Ass'n v. de la Cuesta*, 458 U.S. 141, 153 (1982) (quotation omitted). State laws are also "preempted when they conflict with federal law," including by posing "an obstacle to the accomplishment and execution of the full purposes and objectives of Congress." *Arizona*, 567 U.S. at 399 (quotation omitted). And states may not "discriminate against the Federal Government or those with whom it deals" by "regulat[ing] them unfavorably on some basis related to their governmental status." *United States v. Washington*, 596 U.S. 832, 838-839 (2022) (quotations omitted and alteration adopted).

89. H.B. 2371 is unconstitutional under all of these principles. The federal government agrees: It has filed multiple amicus briefs explaining that laws like H.B. 2371 "interfere[ ] with

Congress's design for the 340B Program." Brief for the United States as Amicus Curiae in Support of Appellees and Affirmance at 14, *Novartis Pharms. Corp. v. Drummond*, No. 25-6182 (10th Cir. filed Mar. 30, 2026), Dkt. No. 67 (U.S. Br.). A Fourth Circuit panel also has agreed that laws like Illinois's impermissibly remake the terms of Congress's "spending-power bargain," intruding on the federal field of 340B Program requirements and conflicting with other aspects of the 340B Program. *McCuskey*, 171 F.4th at 687–695.[31] Another district court adopted the same reasoning when it found that federal law preempts a similar state statute, concluding that this sort of state-law "interference constitutes an impermissible insertion into a federal program that Congress did not invite" and "inhibit[s] the ability of the government to exercise its spending power." *Wrigley*, 2026 WL 1133457, at *10.

IV. H.B. 2371 Is Preempted by Federal Law.

A. Federal Law Occupies the Field.

90. State laws are field preempted in either of two scenarios: (a) where a "federal interest [is] so dominant that the federal system will be assumed to preclude enforcement of state laws on the same subject," *Arizona*, 567 U.S. at 399 (quotation omitted), and (b) where federal law creates "a framework of regulation so pervasive . . . that Congress left no room for the States to supplement it," *Id.* (quotation omitted). Both of those things are true here.

91. The first step is to define the relevant field. To do so, courts look "to the effects of the [state] law" and assess its actual "impact . . . on the federal scheme." *See Gade v. National Solid Wastes Mgmt. Ass'n*, 505 U.S. 88, 105 (1992); *see also Kurns v. Railroad Friction Prods.*

[31] Although the panel decision in *McCuskey* has been vacated automatically by the Fourth Circuit's decision to grant rehearing en banc, *PhRMA v. McCuskey*, 176 F.4th 830 (4th Cir. 2026), the panel majority's analysis remains persuasive. This Court is "free to give statements in a vacated opinion persuasive value." *Friends of Everglades v. South Fla. Water Mgmt. Dist.*, 570 F.3d 1210, 1218 (11th Cir. 2009).

Corp., 565 U.S. 625, 636 (2012) (defining the field "on the basis of the physical elements regulated"). Because this inquiry is focused on how state and federal law interact, "the scope of a field deemed preempted by federal law may be narrowly defined." *Abdullah v. American Airlines, Inc.*, 181 F.3d 363, 367 (3d Cir. 1999); *see also, e.g.*, *Arizona*, 567 U.S. at 401 (defining the field as "alien registration"—not immigration more broadly).

92. H.B. 2371 regulates participants' obligations under the federal 340B Program. It does not apply generally to all drug sales or to all transactions at Illinois pharmacies. H.B. 2371 §§ 15(a)-(c). Participants' 340B obligations are, of course, a subject already covered by federal law: If a manufacturer wishes to have its drugs reimbursed by Medicaid and Medicare Part B, it must accept the conditions imposed by the federal 340B statute—conditions that Congress was required to spell out in advance. *Supra* ¶ 27. That is, the manufacturer must "offer each covered entity covered outpatient drugs for purchase at or below the [340B] price," 42 U.S.C. § 256b(a)(1), subject to reasonable conditions the manufacturer may place on that offer, *Novartis*, 102 F.4th at 462-463.

93. Under H.B. 2371's regime, however, manufacturers must accept additional 340B burdens. In Illinois, manufacturers must now recognize an unlimited number of contract pharmacy arrangements, H.B. 2371§§ 15(a)-(b), and cannot require claims data, *id.* § 15(c)(3), which increases the cost of participating in the federal 340B Program, *supra* ¶¶ 26, 46-51. The effect of H.B. 2371, in other words, is to "raise[] a manufacturer's price of admission to participate in Medicaid and Medicare Part B." *Drummond*, 808 F. Supp. 3d at 1273.

94. H.B. 2371 also imposes new obligations on covered entities in areas directly regulated by federal law. It purports to create bespoke limitations governing when a person is a covered entity's patient, H.B. 2371 § 30, and requires covered entities to adopt policies related to

duplicate discounting between Medicaid and 340B, H.B. 2371 § 35. Both of these subjects are expressly covered by the federal 340B statute and regulations. *E.g.*, 42 U.S.C. § 256b(a)(5)(A)(ii) (requiring HHS to "establish a mechanism" for policing duplicate discounting); 61 Fed. Reg. 55,156, 55,157-58 (defining the statutory term "patient").

95. Thus, the relevant field is the scope of participants' obligations under the federal 340B Program. *See McCuskey*, 171 F.4th at 691 (defining the federal field as "the 340B program requirements" for a similar state law).

1. Manufacturers' 340B Obligations Implicate Dominant Federal Interests.

96. That field implicates two dominant federal interests.

97. First, as established by *Astra*, the federal government has a dominant interest in maintaining the nationwide uniformity of the 340B Program. When Congress intends federal law to operate the same way nationwide, state law must yield. In *Arizona*, for instance, the Supreme Court pointed to the "comprehensive and unified" nature of federal alien-registration requirements in finding the field "occupied by federal law." 567 U.S. at 401-402. Likewise, in *Hughes v. United Van Lines, Inc.*, the Seventh Circuit reasoned that where "[t]he purpose of th[e] statute is to establish uniform federal guidelines," Congress "intended to take possession of the subject and supersede all state regulation with reference to it." 829 F.2d 1407, 1413, 1415 (7th Cir. 1987) (quoting *Adams v. Croninger*, 226 U.S. 491, 505 (1913)).

98. The Supreme Court's holding in *Astra* makes clear that Congress intended the 340B Program to operate uniformly nationwide. The Court rejected any effort to enforce purported 340B obligations outside of Congress's "unitary administrative and enforcement scheme," *Astra*, 563 U.S. at 120. Congress intended "centralized enforcement in the government," allowing HHS

to "administer both Medicaid and § 340B harmoniously and on a uniform, nationwide basis." *Id.* at 119-120 (quoting *Astra* Amicus Brief, *supra* n.12, at 32).

99. H.B. 2371 intrudes on this field by both creating *and* enforcing 340B obligations outside of the centralized system Congress designed. This effect is underscored by the fact that H.B. 2371 has no force or meaning outside of the federal 340B Program. If Congress were to repeal the federal 340B statute, H.B. 2371 would cease to have any effect. *See, e.g.*, H.B. 2371 § 10 (citing 42 U.S.C. § 256b). This state law, in other words, "is inherently federal in character" because it regulates relationships that "originate[ ] from, [are] governed by, and terminate[ ] according to federal law." *Buckman Co. v. Plaintiffs' Legal Comm.*, 531 U.S. 341, 347 (2001).

100. The federal government also has a dominant interest in the functioning of Medicaid and Medicare Part B. H.B. 2371 would harm that interest in at least two ways. On the unit-by-unit level, this would occur as more drug sales are swept into the 340B Program's discounting requirement. That means fewer transactions that would be eligible for Medicaid rebates, 42 U.S.C. § 256b(a)(5)(A)(i), which in turn means significantly less revenue to the federal government. *Supra* ¶¶ 23-24. This direct financial impact on the federal government would harm a "uniquely federal interest." *See Boyle v. United Techs. Corp.*, 487 U.S. 500, 507, 512 (1988) (state law preempted even where there was *no* federal statute on point because state law could "raise [the] price" of equipment purchased by the government).

101. At the macro level, H.B. 2371 risks disincentivizing manufacturers from participating in these federal healthcare programs altogether. By making 340B costlier for manufacturers, this state law "distorts the attractiveness of the spending-power bargain," *McCuskey*, 171 F.4th at 693, and risks "the deleterious effect of causing drug manufacturers to opt out of Medicaid and Medicare Part B," *Drummond*, 808 F. Supp. 3d at 1277. The federal

government is concerned that this is already happening. U.S. Br. at 16 (noting that a manufacturer attributed its withdrawal to "recent legislative changes" (quotation omitted)). As a result, the federal "interest in determining the costliness of Medicare and Medicaid participation could hardly be stronger." *Id.* at 28.

2. Federal Law Pervasively Regulates Manufacturers' 340B Obligations.

102. As a separate basis for field preemption, federal law also already regulates manufacturers' 340B obligations pervasively.

103. Federal law governs the 340B Program from soup to nuts. The statute starts by defining the prices of drugs purchased under the program, 42 U.S.C. §§ 256b(a)(1)-(2), the drugs eligible for that pricing, *id.* § 256b(a)(3), the entities entitled to receive that pricing, *id.* § 256b(a)(4), and the compliance obligations those entities accept, *id.* § 256b(a)(5).

104. From there, the statute directs HHS to create a program to effectuate "distribution" of 340B-priced drugs, 42 U.S.C. § 256b(a)(8), and a "single, universal, and standardized" system for "facilitating the ordering, purchasing, and delivery" of 340B-priced drugs, *id.* § 256b(d)(2)(B)(iv). HHS has done so via the Prime Vendor Program, intended to be a "central source overseeing distribution" under HRSA's ultimate oversight.[32]

105. On the back end, federal law creates a comprehensive enforcement system, including direct enforcement by HHS, 42 U.S.C. § 256b(d)(2)(B)(v), and adjudications of both "claims by covered entities" and "claims by manufacturers" in the ADR process, *id.* § 256b(d)(3)(A).

106. HHS has expanded on these requirements by regulation. 42 C.F.R. §§ 10.1-10.25.

[32] Apexus, *About Apexus* (last visited August 7, 2026), https://tinyurl.com/yck4v9aj.

107. This regulatory suite "provide[s] a full set of standards . . . , including the punishment for noncompliance." *Arizona*, 567 U.S. at 401. Through these comprehensive tools, Congress has already equipped HHS "adequately to address the precise concerns" H.B. 2371 "purports to manage." *Schneidewind v. ANR Pipeline Co.*, 485 U.S. 293, 309 (1988). Field preemption follows directly from that conclusion. *E.g.*, *id.*; *Wisconsin Cent., Ltd. v. Shannon*, 539 F.3d 751, 763-764 (7th Cir. 2008) ("Congress's comprehensive federal regulation" "manifested its intent that states be precluded from enacting and enforcing" state laws in that field).

108. The federal statute's comprehensiveness is not undercut by the fact that H.B. 2371 purports to create novel obligations not found in federal law. A comprehensive federal scheme often reflects not only affirmative requirements, but also "considered decisions to refrain from mandating certain actions or protections." *National Fed'n of the Blind v. United Airlines Inc.*, 813 F.3d 718, 733 (9th Cir. 2016) (emphasis added); *Wisconsin Cent., Ltd.*, 539 F.3d at 764–765 (explaining that the "mere absence of federal legislation" on a particular subtopic is consistent with field preemption where Congress "intentionally leaves a portion of the regulated field without controls" (quotation omitted)).

109. That is especially true of the 340B Program because of its Spending Clause nature. Federal 340B law "did not merely set a floor to which States may add additional obligations." *McCuskey*, 171 F.4th at 692. Instead, "Congress struck a careful bargain" that manufacturers accepted after determining "that the upside of Medicaid market access outweighed the downside of selling drugs for a lower price than they otherwise would." *Id.* Although Illinois may be "unsatisfied with [Congress's] bargain," it cannot constitutionally enact a law like H.B. 2371 that "singles out 340B manufacturers" while also "explicitly add[ing] requirements" that "distort[ ] the attractiveness" of participating in the federal program. *Id.* at 692-693.

110. Regulated parties also need clear, advance notice of what they are agreeing to do by joining the program. That is precisely why manufacturers who elect to participate in 340B sign a PPA spelling out the terms of the bargain. In this bargain, the things the 340B statute and PPA do *not* require are just as important as the things they *do* require: Both equally determine the sum total of Congress's conditions for accessing Medicaid and Medicare Part B. Any requirement not imposed by federal law reflects Congress's judgment that such "regulation simply should not be employed." *Schneidewind*, 485 U.S. at 306; *see* U.S. Br. at 11 ("Congress left no role for States in determining manufacturers' 340B obligations.").[33]

B. H.B. 2371 Obstructs Federal Law.

111. H.B. 2371 is also invalid under obstacle-preemption principles. The Illinois law impedes "the full purposes and objectives of Congress" and "interferes with the methods by which the federal statute was designed to reach [its] goal[s]." *International Paper Co. v. Ouellette*, 479 U.S. 481, 492, 494 (1987) (quotation omitted).

112. H.B. 2371 obstructs Congress's purposes and objectives in three main ways: (1) forbidding what federal law allows; (2) altering Congress's balance of benefits and burdens among 340B, Medicaid, and Medicare Part B; and (3) inviting inconsistent adjudications regarding 340B obligations.

[33] Two circuits have rejected challenges to similar state laws, *see AbbVie, Inc. v. Murrill*, 166 F.4th 528 (5th Cir. 2026); *PhRMA v. McClain*, 95 F.4th 1136 (8th Cir. 2024), but those courts "neglect[ed] to consider" this point, *McCuskey*, 171 F.4th at 695 n.12; *see also Novartis Pharms. Corp. v. Fitch*, No. 24-60342, 2026 WL 963504 (5th Cir. Apr. 9, 2026) (applying the Fifth Circuit's prior decisions to a Novartis appeal). The Fifth and Eighth Circuits erred by "rest[ing] entirely on statutory silence" without considering the special significance of that silence in the spending-power context. U.S. Br. at 21; *see also Wrigley*, 2026 WL 1133457, at *9 (district court within the Eighth Circuit finding that "*McClain* is not controlling in the present case" because *McClain* "did not address field preemption regarding Congress's spending power").

1. H.B. 2371 Outlaws Conduct That Federal Law Intentionally Permits.

113. Federal law purposely gives manufacturers discretion to set reasonable limits on the use of contract pharmacies to claim 340B pricing. Novartis has done just that. (Ex. 1 at 1.)

114. H.B. 2371 attempts to restrict that discretion by prohibiting manufacturers from limiting the number of contract pharmacies that they will recognize, and by forbidding manufacturers to condition access to 340B pricing on submission of claims data. H.B. 2371 §§ 15(a)-(c).

115. There can be no dispute that federal law allows Novartis to maintain its contract pharmacy policy. Two circuit courts have already held as much. In *Novartis*, the D.C. Circuit explained that manufacturers may restrict 340B pricing to drugs dispensed at "a covered entity's in-house pharmacy or [at] a single contract pharmacy designated by the covered entity." 102 F.4th at 463-464. And the court confirmed that manufacturers may condition 340B pricing at contract pharmacies on the receipt of claims data, consistent with longstanding record-retention policies governing the 340B Program. *Id.* at 463. The Third Circuit approved the same requirements. *See Sanofi*, 58 F.4th at 701 (summarizing the contested policies).

116. HRSA is now applying the same understanding of federal law, and it has therefore recently rejected two ADR claims submitted by covered entities challenging Novartis's contract pharmacy policy as unlawful. (Ex. 2 at 2 (finding "no overcharge violation"); Ex. 3 at 2 (same)); *see also* HRSA, 340B ADR Decision Summaries (last updated July 16, 2026) (HRSA uniformly finding "no overcharge violation" in ADR petitions brought against Novartis and other manufacturers), https://tinyurl.com/5dht28c9.

117. These rulings reflect Congress's purposeful decision to give manufacturers discretion to implement policies like Novartis's. After observing that federal law does not require delivery of 340B-priced drugs to unlimited contract pharmacies, the D.C. Circuit concluded "that

this silence preserves—rather than abrogates—the ability of sellers to impose at least some delivery conditions." *Novartis*, 102 F.4th at 460. The Third Circuit likewise held that Congress "chose not to" require what H.B. 2371 requires, explaining that federal law "leav[es] drug makers discretion on delivery" of 340B-priced drugs. *Sanofi*, 58 F.4th at 704-705. As the federal government has explained, states cannot "achieve a contrary result" by passing their own laws. U.S. Br. at 11.

118. Permitting manufacturers to require basic claims data about the unit of drug on which the discount is claimed also serves vital federal objectives. These data help ensure manufacturers' access to the statutory audit and ADR procedures Congress created. *Supra* ¶¶ 55-57. As other courts have concluded in finding similar laws preempted, requiring claims data is "*the* way to detect possible [compliance violations]." *Drummond*, 808 F. Supp. 3d at 1278; *see also Morrisey*, 760 F. Supp. 3d at 453. Federal law therefore allows manufacturers to require covered entities to submit basic claims data demonstrating that transactions at contract pharmacies are eligible for 340B pricing. *Novartis*, 102 F.4th at 463-464.

119. When federal law intentionally gives regulated parties a choice, state law cannot take away that choice. *See*, *e.g.*, *Geier v. American Honda Motor Co.*, 529 U.S. 861, 881 (2000) (state could not mandate airbags where federal law permitted a "variety and mix of [passive-restraint] devices"); *de la Cuesta*, 458 U.S. at 156 (state law "limit[ed] the availability of an option the [federal regulator] considers essential").

2. H.B. 2371 Upsets Congress's Careful Balance of Interests.

120. H.B. 2371 also expands the universe of transactions for which manufacturers must provide 340B discounts, disrupting the delicate balance Congress created between burdens and benefits of participating in the 340B Program. *Supra* ¶¶ 72-80.

121. The primary purpose and effect of this state law is to expand the subsidy manufacturers must provide to Illinois covered entities through the 340B Program. The problem with this purpose is that Congress "struck a delicate balance with the federal 340B Program." *Drummond*, 808 F. Supp. 3d at 1277; *see also McCuskey*, 171 F.4th at 684 ("Congress struck a balance between supporting covered entities and encouraging manufacturer participation."); U.S. Br. at 22 ("When Congress set out the terms of the 340B Program, it made a series of policy choices concerning how much of a burden to impose on manufacturers and what benefits to offer covered entities.").

122. The extent to which federal law requires manufacturers to offer 340B discounts is part of that balance. "The Program is a bargain between drug manufacturers and the federal government whereby" manufacturers agree to this subsidy "in exchange for access to . . . Medicaid and Medicare Part B." *Drummond*, 808 F. Supp. 3d at 1277; *McCuskey*, 171 F.4th at 682 (explaining Congress's "spending-power bargain" in the 340B Program). Thus, Congress "limited the scope of the 340B Program to ensure that the price of admission wasn't too high." *Drummond*, 808 F. Supp. 3d at 1277.

123. H.B. 2371 not only disturbs the policy tradeoffs Congress made, but also jeopardizes the entire interrelated scheme of federal healthcare programs. *Drummond*, 808 F. Supp. 3d at 1277. As the federal government has noted in voicing its view that state 340B laws violate the Supremacy Clause: When the costs of 340B participation increase, "rational manufacturers can be expected to withdraw"—as at least one manufacturer appears to have done already. U.S. Br. at 16. Only the federal government can determine the extent to which it will tolerate [the] risk" to program stability caused by "manufacturer withdrawal." *Id.* "Patchwork state regulation" is no substitute for the "wide-angle study" HHS can employ, and the

government's "interest in determining the costliness of Medicare and Medicaid participation could hardly be stronger." *Id.* at 18, 22. This is precisely why Congress gave HHS exclusive 340B enforcement power. *Astra*, 563 U.S. at 119-120.

124. State law "must yield to the extent that it clashes with the balance struck by Congress." *Bonito Boats, Inc. v. Thunder Craft Boats, Inc.*, 489 U.S. 141, 152 (1989); *see also, e.g.*, *MITE Corp. v. Dixon*, 633 F.2d 486, 496-498 (7th Cir. 1980) (state law preempted where it would "second-guess Congress's judgment" that "maintenance of an equitable balance between the contending sides" is a "principal means of investor protection"), *aff'd on other grounds*, *Edgar v. MITE Corp.*, 457 U.S. 624 (1982).

3. H.B. 2371 Creates Conflicting Enforcement Procedures.

125. H.B. 2371's parallel state-level enforcement scheme independently obstructs federal law.

126. When a manufacturer's 340B compliance is questioned, federal law channels the claim down one of two paths: HHS may assess the appropriateness of sanctions, or a covered entity may bring an ADR claim. 42 U.S.C. §§ 256b(d)(1)(B)(vi), (d)(3)(A). Those two paths are exclusive. *Astra*, 563 U.S. at 121-122.

127. Illinois now purports to create a *third* enforcement path: The Illinois Attorney General can surmise that a manufacturer should have provided 340B pricing on a particular drug and seek to enforce that view with fines, damages to be paid to the 340B covered entity, and injunctive relief, as well as "any other relief" a court considers appropriate. H.B. 2371 §§ 40(a), (b)(1)-(4); 15 Ill. Comp. Stat. 205/4.

128. This outcome is exactly the kind of "dispersed and uncoordinated" 340B enforcement effort *Astra* rejected for fear of producing "conflicting adjudications." 563 U.S. at 120.

129. The overlap between state and federal law arises primarily from H.B. 2371's definitions of a "340B drug" and a "340B covered entity." A 340B drug is defined under state law to mean "a drug that has been subject to any offer for reduced prices by a manufacturer pursuant to 42 U.S.C. 256b and is purchased by a 340B covered entity." H.B. 2371 § 10. A 340B covered entity is defined under state law to mean "an entity in Illinois that qualifies as a covered entity under Section 340B of the federal Public Health Service Act, 42 U.S.C. 256b(a)(4)." *Id.* Both state-law terms are thus defined solely by incorporating federal 340B requirements.

130. In turn, these terms are incorporated into the Illinois statute's principal mandates to manufacturers. H.B. 2371 § 15(a)-(c). For *every* alleged violation of these requirements, the state must prove that *every* federal 340B condition was satisfied, plus the additional conditions of state law. Federal law imposes fact-intensive conditions that determine whether a covered entity is entitled to the 340B price on a particular purchase. For example, was the relevant unit dispensed to a "patient" of the covered entity? 42 U.S.C. § 256b(a)(5)(B). Did the manufacturer pay a Medicaid rebate for that unit? *Id.* § 256b(a)(5)(A)(i). The list goes on.

131. These questions are far from straightforward. As just one example, consider that the federal statute does not define a "patient" of the covered entity. 42 U.S.C. § 256b(a)(5)(B). HRSA deems a person an entity's patient if:

> [1] the covered entity has established a relationship with the individual, such that the covered entity maintains records of the individual's health care; and
>
> [2] the individual receives health care services from a health care professional who is either employed by the covered entity or provides health care under contractual or other arrangements . . . such that responsibility for the care provided remains with the covered entity; and
>
> [3] [for federal grantees,] the individual receives a health care service or range of services from the covered entity which is consistent with the . . . range of services for which . . . funding . . . has been provided to the entity.

61 Fed. Reg. 55,156, 55,157-58 (Oct. 24, 1996).

132. Needless to say, two decisionmakers could apply that fact-driven standard differently to the same transaction. Yet to enforce H.B. 2371, the state must prove—transaction by transaction—that a commercially-priced drug was dispensed by a contract pharmacy to a person who qualifies as a patient of the covered entity. If the standard is not met, the drug is not a 340B drug because it cannot be "subject to any offer for reduced prices" under the 340B Program. H.B. 2371 § 10. And this singular eligibility condition is just the tip of the iceberg.

133. H.B. 2371 therefore puts the Illinois Attorney General on a collision course with nuanced federal questions that only HRSA can answer. For example, how will Illinois handle a pharmacy customer who had an appendectomy at a covered entity hospital over a year ago, and who is now filling an antibiotic prescription for a sinus infection? What if that customer also recently gave birth at a different covered entity hospital? And what if *both* covered entities claim the discount on that same sale? There is no telling what position Defendant will take on patient-definition questions like these—but take a position he must.

134. Moreover, H.B. 2371 provides no guidance about how to handle practical problems arising from these overlapping enforcement procedures. What will the Attorney General do if he is attempting to enforce H.B. 2371 against an alleged violation, but an ADR claim is already pending before HRSA regarding exactly the same units of a drug? Will the State await the outcome of the federal process before imposing sanctions? And what will Illinois do if it punishes a violation, but HRSA later finds the manufacturer was *not* required to offer 340B pricing on the same unit? *See Morrisey*, 760 F. Supp. 3d at 458 (risk of conflicting adjudications was substantial because there can be no "assurances" that "state actors would adopt a 'wait and see' approach" and defer state enforcement until after federal ADR proceedings had concluded).

135. Only one thing is certain: Contrary to Congress's design, HRSA will no longer "hold the control rein" if H.B. 2371 is permitted to take effect. *Astra*, 563 U.S. at 120. Congress intended to leave HRSA—not any state—"in control of § 340B's drug-price prescriptions." *Id.* at 114. Thus, as the federal government has explained, *Astra* "is particularly applicable in this context" because laws like H.B. 2371 "arrogat[e] to the State enforcement authority that properly belongs to the federal government alone." U.S. Br. at 15; *see also McCuskey*, 171 F.4th at 693 (holding that a similar state law "intrudes on HHS's enforcement authority").

136. State law is preempted when it detracts from exclusive enforcement authority Congress gave to a federal agency. *See*, *e.g.*, *Buckman*, 531 U.S. at 350 (state attempts to enforce federal law "inevitably conflict with [the agency's] responsibility to police [the same subject matter] consistently with the [agency's] judgment and objectives"); *Effex Capital v. National Futures Assoc.*, 933 F.3d 882, 894-895 (7th Cir. 2019) (state claims preempted where they would "effectively" permit states to "supervise" self-regulatory association's "discipline and disciplinary process" and "impede its federally mandated role in the [statute]'s overall scheme"); *Boomer v. AT&T Corp.*, 309 F.3d 404, 418 (7th Cir. 2002) (state claims preempted where Congress intended "federal law [to] govern" the "uniform terms and conditions of service" and assigned enforcement of compliance to federal agency).

137. Harsh penalties also exacerbate H.B. 2371's overlapping-enforcement problem.

138. Congress carefully calibrated the consequences of 340B noncompliance: Penalties for violations of 340B "shall not exceed $5,000"—and only for a manufacturer that "knowingly and intentionally" overcharges a covered entity. 42 U.S.C. § 256b(d)(1)(B)(vi).

139. H.B. 2371 now raises the stakes: steep fines, damages, and injunctions mandating discounts on drugs—and all with no indication of any scienter requirement. *See* H.B. 2371 § 40(b)(1)-(3).

140. When Congress selects a penalty, it has necessarily determined that a higher penalty "would be inappropriate." *Arizona*, 567 U.S. at 406.

141. Yet again, H.B. 2371 second-guesses Congress's judgment. This creates another basis for preemption: H.B. 2371's additional penalties add further disincentives to 340B participation, putting Medicaid and Medicare Part B at greater risk. *See Drummond*, 808 F. Supp. 3d at 1277; U.S. Br. at 15-18.

142. State law is preempted where it brings "separate remedies . . . to bear on the same activity" for which federal law already specifies a penalty. *Wisconsin Dep't of Indus., Lab. & Hum. Rels. v. Gould Inc.*, 475 U.S. 282, 286 (1986) (quotation omitted); *see also Crosby v. National Foreign Trade Council*, 530 U.S. 363, 380 (2000); *Arizona*, 567 U.S. at 406.

B. H.B. 2371 Discriminates Against Participants in a Federal Program.

143. H.B. 2371 also violates the Supremacy Clause by singling out manufacturers that participate in the 340B Program for "less favorable treatment" than manufacturers that do not participate in the federal program. *Washington*, 596 U.S. at 839 (quotation omitted).

144. The oldest Supremacy Clause principle is the one Chief Justice Marshall set forth over 200 years ago in *McCulloch v. Maryland*: States cannot "impede, burden, or in any manner control the operations of the constitutional laws enacted by congress to carry into execution the powers vested in the general government." 17 U.S. (4 Wheat.) 316, 436 (1819). This principle covers states' treatment of "those who deal with the federal government"—thus helping carry out federal legislative initiatives. *Dawson v. Steager*, 586 U.S. 171, 177 (2019) (quotation omitted);

see also Phillips Chem. Co. v. Dumas Indep. Sch. Dist., 361 U.S. 376, 387 (1960) (states cannot "discriminate against the Government or those with whom it deals").

145. Manufacturers that agree to participate in 340B deal directly with the federal government. To "effectuate[ ] the statutory scheme" Congress created, manufacturers sign a PPA with the HHS Secretary. *Example PPA*, *supra* ¶ 29, § VII(g). Pursuant to the PPAs, HHS exercises direct control over manufacturers' 340B conduct. *See Astra*, 563 U.S. at 115-116. And for certain covered entities that receive federal grants, the subsidy manufacturers provide through the 340B Program also helps serve a federal function by helping to "stretch scarce federal resources." *See* H.R. Rep. No. 102-384(II), *12 (1992).

146. H.B. 2371 treats drug manufacturers that have signed a PPA differently from those that have not. The state law's mandates apply only to entities that participate in the 340B program. *See* H.B. 2371 §§ 10, 15(a)-(c). But drug sales within the 340B Program represent just one part of overall drug spending. *See* HRSA, 2024 340B Covered Entity Purchases (last updated Dec. 2025), https://tinyurl.com/yuavb733. H.B. 2371 therefore leaves a large swath of drug sales, healthcare providers, and pharmacy transactions untouched.

147. H.B. 2371's requirements are also very costly for manufacturers. *Supra* ¶¶ 46-48, 78. By imposing these additional burdens on manufacturers that participate in the federal 340B Program—but no other manufacturers—this Illinois law "regulates [340B participants] unfavorably on some basis related to their governmental 'status.'" *Washington*, 596 U.S. at 839 (quoting *North Dakota v. United States*, 495 U.S. 423, 438 (1990) (plurality op.)).

148. This differential treatment of participants in a federal program might be permissible if Congress had clearly authorized it. *Goodyear Atomic Corp. v. Miller*, 486 U.S. 174, 180 (1988). But the opposite is true here: "Congress left no role for States in determining manufacturers' 340B

obligations." U.S. Br. at 11. And the federal government has explained that laws like H.B. 2371 are unconstitutional because they "impermissibly target[ ] and discriminate[ ] against" "manufacturers with 340B agreements," treating them "worse than manufacturers who do not participate in the 340B Program." *Id.* at 12-14. That is the core of what the Supremacy Clause forbids.

H.B. 2371 VIOLATES THE DORMANT COMMERCE CLAUSE

149. H.B. 2371 is also an unlawful extraterritorial regulation in violation of the dormant Commerce Clause.

150. The Commerce Clause grants Congress the power to regulate interstate commerce. U.S. Const. art. I, § 8, cl. 3. That power carries with it a "negative" or "dormant" restriction: Even where Congress has not exercised its commerce power, states are prohibited from unduly burdening or interfering with interstate commerce. *See generally Comptroller of the Treasury of Md. v. Wynne*, 575 U.S. 542, 549-550 (2015) (quotation omitted).

151. This principle "precludes the application of a state statute to commerce that takes place wholly outside of the State's borders, whether or not the commerce has effects within the State." *Edgar*, 457 U.S. at 642-643. States must respect "the territorial limits of [their] authority under the Constitution's horizontal separation of powers." *National Pork Producers Council v. Ross*, 598 U.S. 356, 376 n.1 (2023).

152. H.B. 2371 attempts to regulate wholly out-of-state conduct by capping the prices of transactions between manufacturers and wholesalers. To see how, it is necessary to carefully trace each step in the series of transactions that effectuate 340B pricing:

a. Rather than attempt to deal directly with many thousands of pharmacies, manufacturers sell their drugs to a handful of national wholesale distributors. These sales

occur at commercial prices, and at this point, no one can know which units of a drug may ultimately be subject to 340B pricing.

b. Wholesalers then resell those drugs to pharmacies. As explained above, pharmacies place these drugs in their common inventories and do not attempt to segregate units that will ultimately be dispensed to alleged patients of a covered entity.

c. Pharmacies then dispense units of the drugs to their customers as they arrive at the pharmacy counter with a prescription—regardless of potential 340B eligibility.

d. Some time after the pharmacy dispenses the drug, the covered entity—or maybe its contract pharmacy or third-party administrator—claims a prior dispense was 340B eligible. When that occurs, it is the wholesaler who provides the 340B discount, often by shipping the pharmacy a new, discounted "replenishment" drug. Under H.B. 2371, these pharmacies may be located anywhere in any "state, commonwealth, or territory of the United States." H.B. 2371 § 10.

e. The wholesaler then requests a refund from the manufacturer so the wholesaler can profit by selling the replenishment unit at the 340B price.

153. H.B. 2371 regulates the actions of manufacturers. Like most manufacturers, Novartis is located outside of Illinois, and upon information and belief, so are all of its wholesalers. All transactions between Novartis and its wholesalers therefore occur outside of Illinois. By ordering manufacturers to charge no more than a certain price in their transactions with wholesalers, H.B. 2371 seeks to "directly control[ ] commerce occurring wholly outside the boundaries of [the] State." *Healy v. Beer Inst., Inc.*, 491 U.S. 324, 336 (1989).

154. Two federal courts of appeals have recently invalidated state laws that regulate the conduct of drug manufacturers taking place outside of the state. In *Association for Accessible*

Meds. v. Ellison, the court enjoined enforcement of a law insisting "that out-of-state manufacturers sell their drugs to wholesalers for a certain price." 140 F.4th 957, 960-961 (8th Cir. 2025). Likewise, in *Association for Accessible Medicines v. Frosh*—a decision cited favorably by the Supreme Court in *Pork Producers*, 598 U.S. at 374—the Fourth Circuit held that a state price-control statute violated the dormant Commerce Clause because it targeted the "price the manufacturer or wholesaler charge[d] *in the initial sale of the drug*," rather than the "the price the . . . consumer ultimately pays." 887 F.3d 664, 671 (4th Cir. 2018).

155. H.B. 2371 is invalid for the same reasons as the laws in *Ellison* and *Frosh*.

V. H.B. 2371 Will Cause Novartis Imminent, Irreparable Harm.

156. Novartis will be irreparably harmed if H.B. 2371 is enforced.

157. H.B. 2371 puts Novartis in a lose-lose situation: If the law's enforcement is not enjoined, Novartis must decide whether to comply. If Novartis does so, it will be forced to expend significant resources to achieve the law's mandates. If it does not comply, it will risk significant penalties, including up to $1,000 for each transaction deemed in violation of the act. H.B. 2371 §§ 15(d), 40(b)(2-3). Being put to that choice by an unconstitutional law is an irreparable harm that warrants injunctive relief. *See Morales v. Trans World Airlines, Inc.*, 504 U.S. 374, 381 (1992); *City of Chicago v. Sessions*, 264 F. Supp. 3d 933, 950 (N.D. Ill. 2017) (irreparable harm where plaintiff faced a "Hobson's choice" between declining to comply with federal conditions it "believe[d] to be unconstitutional" or complying with the conditions).

158. Being subject to an unconstitutional law is itself a significant irreparable harm. *See, e.g.*, *Preston v. Thompson*, 589 F.2d 300, 303 n.3 (7th Cir. 1978) ("The existence of a continuing constitutional violation constitutes proof of an irreparable harm."); *City of Chicago v. Sessions*, 321 F. Supp. 3d 855, 878 (N.D. Ill. 2018); *NA Main St. LLC v. Cook*, 508 F. Supp. 3d 320, 332-333 (S.D. Ind. 2020) (irreparable harm, in part, where plaintiff was subject to a law likely

unconstitutional under the dormant Commerce Clause). That is especially so here, where H.B. 2371 undermines Novartis's ability to rely on rights conferred by federal law to structure its conduct. *See Novartis*, 102 F.4th at 463-464; *Sanofi*, 58 F.4th at 703-706.

159. H.B. 2371 will also cause Novartis unrecoverable financial harms. If Novartis is forced to comply with the law, it will lose millions of dollars annually by providing additional 340B discounts not required by federal law, as well as the administrative costs of compliance. If Novartis does not comply—or even if the State ever takes the position that Novartis has not fully complied—Novartis must expend significant resources defending itself or its employees, on top of financial penalties that may be imposed. *See* H.B. 2371 §§ 40(b)(1)-(4). Even if H.B. 2371 is later deemed unlawful, Illinois cannot be held directly liable for these damages because of its sovereign immunity.

160. These unrecoverable financial losses constitute irreparable harm that supports an injunction. *Whitaker ex rel. Whitaker v. Kenosha Unified Sch. Dist. No. 1 Bd. of Educ.*, 858 F.3d 1034, 1045 (7th Cir. 2017), *abrogated on other grounds by Nken v. Holder*, 556 U.S. 418, 434 (2009), *as recognized by Illinois Republican Party v. Pritzker*, 973 F.3d 760, 762 (7th Cir. 2020).

161. For the same reasons, Novartis must divert substantial resources from research and development of new drug therapies whether or not it complies with H.B. 2371. These opportunity costs can never be regained. Because these losses are impossible to measure, they constitute irreparable harm that supports an injunction. *See*, *e.g.*, *BrightStar Franchising, LLC v. Foreside Mgmt. Co.*, 808 F. Supp. 3d 870, 888 (N.D. Ill. 2025) ("The degree of damage to [Plaintiff's] business flowing from Defendants' conduct is difficult to determine, and as a result '[i]njunctive relief is therefore the best, and probably the only, adequate remedy.'"); *GemShares LLC v. Lipton*, No. 17-CV-6221, 2019 WL 3287838, at *4 (N.D. Ill. July 21, 2019).

162. Finally, H.B. 2371 would cause irreparable harm to Novartis's reputation and goodwill. Notwithstanding the lawfulness of Novartis's policy under federal law, H.B. 2371 seeks to stigmatize Novartis and label it a wrongdoer. This damage, too, is irreparable and supports an injunction. *Stuller, Inc. v. Steak N Shake Enters., Inc*., 695 F.3d 676, 680 (7th Cir. 2012); *see also SMC Corp. v. Lockjaw, LLC*, 481 F. Supp. 2d 918, 928 (N.D. Ill. 2007).

163. Injunctive relief will preserve the status quo and cause Defendant no harm. Illinois has no interest in enforcing an unconstitutional law, and the public interest is harmed by enforcement of unconstitutional laws. *See*, *e.g.*, *City of Chicago v. DHS*, 815 F. Supp. 3d 727, 763 (N.D. Ill. 2025); *Baskin v. Bogan*, 983 F. Supp. 2d 1021, 1029 (S.D. Ind. 2014).

164. Injunctive relief will also serve the public interest by maintaining the integrity of a carefully planned federal program. *See*, *e.g.*, *United States v. Alabama*, 691 F.3d 1269, 1301 (11th Cir. 2012) ("Frustration of federal statutes and prerogatives are not in the public interest.").

165. Finally, the public will benefit from an injunction ensuring Novartis can direct its resources where they are most needed: researching and developing new drug therapies for patients. And patients will suffer no harm; they "do not directly enjoy the benefits of the 340B program" and thus "should not find their access to the underlying drugs impeded." *McCuskey*, 171 F.4th at 696; *see also Wrigley*, 2026 WL 1133457, at *13 (finding the public interest would not be harmed by enjoining a similar state law that "has no effect on the price patients pay for their medication," particularly because there is "no requirement that the revenue going to the [covered entities] is spent on patients").

COUNT I
(Federal Field Preemption—U.S. Const. art. VI, cl. 2)

166. Novartis realleges, reasserts, and incorporates by reference each of the foregoing allegations as though set forth fully herein.

167. Federal law is "the supreme Law of the Land; . . . any Thing in the . . . Laws of any State to the Contrary notwithstanding." U.S. Const. art. VI, cl. 2.

168. Congress created the federal 340B Drug Pricing Program under its spending power, which required Congress to clearly spell out the conditions of participation in advance. Manufacturers' obligations under the 340B Program must therefore be determined entirely by the requirements of federal law—the requirements manufacturers accepted when joining the program.

169. H.B. 2371 expressly targets manufacturers' obligations under "the program established under Section 340B of the federal Public Health Service Act," H.B. 2371 § 10, adding new conditions of participating in the 340B Program—and, by extension, Medicaid and Medicare Part B.

170. The field that H.B. 2371 seeks to regulate is the scope of participants' 340B obligations.

171. Congress intended the scope of participants' 340B obligations to be regulated exclusively by federal law. As evidence of that intent, participants' 340B obligations—and especially manufacturers' 340B obligations—implicate dominant federal interests, including national uniformity in the 340B Program and the operations of Medicaid and Medicare Part B. As further evidence, participants' 340B obligations are already regulated pervasively by federal law, leaving no room for state supplementation.

172. H.B. 2371 therefore violates the Supremacy Clause of the U.S. Constitution.

COUNT II
(Federal Obstacle Preemption—U.S. Const. art. VI, cl. 2)

173. Novartis realleges, reasserts, and incorporates by reference each of the foregoing allegations of paragraphs 1 through 172 as though set forth fully herein.

174. H.B. 2371 repeatedly frustrates Congress's full purposes and objectives, as well as the means by which Congress designed the federal 340B Program to achieve its goals.

175. Under federal law, manufacturers may impose reasonable conditions on access to 340B-priced drugs, including limitations on the number of contract pharmacy arrangements a manufacturer will recognize and a requirement that covered entities provide claims data. Congress intentionally left this discretion to manufacturers.

176. H.B. 2371 nevertheless seeks to abrogate that discretion by outlawing the same contract pharmacy policies that have been deemed compliant with federal law.

177. H.B. 2371 also requires that manufacturers subsidize covered entities in Illinois beyond the level required by federal law. This interferes with the careful balance Congress struck in setting the appropriate subsidy for the 340B Program—large enough to serve the program's purposes, but not so large as to discourage participation in Medicaid and Medicare Part B.

178. H.B. 2371 further frustrates Congress's uniform, nationwide design for the 340B Program by inviting inconsistent rulings regarding manufacturers' 340B obligations. H.B. 2371 incorporates federal law to determine whether a manufacturer was required to provide a discount on a particular unit of its drug. That incorporation carries with it numerous difficult questions of federal law, such that H.B. 2371 can never be enforced without resolving nuanced and subjective federal issues already committed to HRSA's exclusive jurisdiction. This guarantees conflicting adjudications concerning manufacturers' 340B obligations—exactly what Congress intended to prevent, as the Supreme Court explained in *Astra*.

179. Further, H.B. 2371 increases the potential penalties associated with 340B noncompliance beyond what Congress provided for in the federal 340B statute.

180. H.B. 2371 therefore violates the Supremacy Clause of the U.S. Constitution.

COUNT III
(Federal Discrimination—U.S. Const. art. VI, cl. 2)

181. Novartis realleges, reasserts, and incorporates by reference each of the allegations of paragraphs 1 through 180 as though set forth fully herein.

182. In its capacity as a 340B participant, Novartis deals directly with the federal government. Novartis has signed a PPA with the Secretary of Health and Human Services, which lays out Novartis's and the federal government's respective obligations under the 340B statute. Novartis's participation also helps the federal government carry out its statutory obligations under 42 U.S.C. § 256b(a)(1) and, for certain covered entities that receive federal grants, the subsidies Novartis provides under the 340B Program help stretch scarce federal resources further.

183. H.B. 2371 discriminates against Novartis because of Novartis's dealings with the federal government. The state law expressly targets manufacturers like Novartis that participate in the 340B Program and subjects them to costly compliance requirements, such as requiring the participating manufacturers to provide steep discounts not mandated by federal law.

184. H.B. 2371 does not apply to manufacturers that abstain from the 340B Program. The law does not regulate otherwise-identical drug sales that occur between manufacturers, wholesalers, healthcare providers, and pharmacies outside the 340B Program. In this way, H.B. 2371 singles out Novartis and other 340B Program participants for unfavorable treatment.

185. Congress has not authorized Illinois to discriminate against manufacturers that participate in the 340B Program. In fact, the federal government has argued that laws like H.B. 2371 are unconstitutional for precisely this reason.

186. H.B. 2371 therefore violates the Supremacy Clause of the U.S. Constitution.

COUNT IV
(Extraterritorial Regulation—U.S. Const. art. I, § 8, cl. 3)

187. Novartis realleges, reasserts, and incorporates by reference each of the foregoing allegations of paragraphs 1 through 186 as though set forth fully herein.

188. Under the Commerce Clause, Congress has the power to regulate commerce among the several states. U.S. Const. art. I, § 8, cl. 3. The corresponding "dormant" Commerce Clause prevents states from regulating conduct that occurs wholly outside their borders.

189. H.B. 2371 violates this principle by capping the prices of sales between manufacturers like Novartis and their wholesalers.

190. Novartis is not located in Illinois and, upon information and belief, neither are any of its wholesalers. As a result, these transactions occur wholly outside of Illinois.

191. H.B. 2371 therefore violates the Commerce Clause of the U.S. Constitution.

PRAYER FOR RELIEF

For the foregoing reasons, Novartis prays for the following relief:

A. A declaration under 28 U.S.C. § 2201 that H.B. 2371 violates the Supremacy Clause and is thus null, void, and unenforceable;

B. A declaration under 28 U.S.C. § 2201 and Fed. R. Civ. P. 57 that H.B. 2371 violates the dormant Commerce Clause and is thus null, void, and unenforceable;

C. Preliminary and permanent injunctive relief preventing Defendant from implementing or enforcing H.B. 2371 against Novartis or any of its affiliates, officers, agents, representatives, wholesalers, distributors, or contractors;

D. Preliminary and permanent injunctive relief preventing Defendant from seeking any remedy arising from an alleged violation of H.B. 2371 by Novartis or any of its affiliates, officers, agents, representatives, wholesalers, distributors, or contractors;

E. An order awarding Novartis its costs, expenses, and attorney's fees incurred in these proceedings; and

F. Such other and further relief as the Court deems proper.

Dated: August 7, 2026

Respectfully submitted,

/s/ *Stephen J. Siegel*

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**Motion for admission pro hac vice forthcoming*

VERIFICATION

I declare under penalty of perjury that the foregoing is true and correct. Executed on August 7, 2026.

Shannon McCrudden
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Novartis Pharmaceuticals Corporation