No. 24-118

IN THE

Supreme Court of the United States

PHARMACEUTICAL RESEARCH AND MANUFACTURERS OF AMERICA,

Petitioner,

v.

ALAN MCCLAIN, IN HIS OFFICIAL CAPACITY AS COMMISSIONER OF THE ARKANSAS INSURANCE DEPARTMENT, ET AL.,

Respondents.

On Petition for a Writ of Certiorari to the United States Court of Appeals for the Eighth Circuit

BRIEF IN OPPOSITION OF RESPONDENT ALAN MCCLAIN

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QUESTION PRESENTED

Section 340B, a federal drug discount statute for drugs purchased by hospitals that serve disadvantaged patients, is silent on where manufacturers must deliver the federally discounted drugs. Manufacturers, exploiting that silence, recently began refusing to deliver discounted drugs to discount-eligible hospitals' outside pharmacies, thus reducing discounted sales to a small fraction of their former amount. Several States responded by enacting laws requiring manufacturers to honor hospitals' requested place of delivery. PhRMA challenged four of those laws as preempted, including Arkansas's law, and lost challenges to all four, with appeals currently pending from those decisions in two circuits besides the court below.

The question presented is:

Whether Section 340B, which is silent on delivery, preempts state laws that regulate delivery terms in contracts between drug manufacturers and purchasers of 340B-discounted drugs.

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STATEMENT

1. This case concerns an Arkansas law that regulates the delivery of drugs under drug sale contracts in Arkansas. In Arkansas, many hospitals participate in the 340B program, a federal program created in 1992 under which drug manufacturers that participate in Medicaid must offer drugs at a discount to so-called "covered entities"—that is, "local facilities that provide medical care for the poor." *Astra USA, Inc. v. Santa Clara Cnty.*, 563 U.S. 110, 115 (2011).

Manufacturers opt into that program by executing a form contract with HHS, which administers the program, under which they agree to abide by the various obligations the 340B statute imposes. *See id.* at 115. Those contracts "simply incorporate statutory obligations." *Id.* at 118. But the contracts manufacturers form with covered entities, or intermediary wholesalers, to sell 340B-discounted drugs are very different. Those contracts are negotiated between the parties, and they are almost entirely unregulated by federal law. As to them, 340B "imposes only a price term," "leaving all other terms blank." *Sanofi Aventis U.S. LLC v. U.S. Dep't of Health & Hum. Servs.*, 58 F.4th 696, 704 (3d Cir. 2023).

As HHS recognized shortly after the 340B program's enactment, "only a very small number" of 340B covered entities "use[] in-house pharmacies"—at that time, less than 10 percent. 61 Fed. Reg. 43,549, 43,550 (Aug. 23, 1996). Instead, most covered entities "rely on outside pharmacies" to dispense 340B-discounted drugs. *Id.* The process is a simple one. "Covered entities using contract pharmacies . . . still order and pay for the drugs," Pet. App. 9a (quoting *Sanofi*, 58 F.4th at 700), but under a so-called "ship to, bill to"

arrangement the drugs are shipped to the covered entity's pharmacy of choice, 61 Fed. Reg. at 43,552. Everything else about the transaction between manufacturer and covered entity remains the same; "[o]nly the delivery of the drug [is] altered." *Id.* When a covered entity uses a contract pharmacy, that pharmacy "act[s] as an agent of the covered entity," not reselling the covered entity's drugs "but rather distribut[ing] the drug on [its] behalf." *Id.* at 43,550.

2. HHS "lacks rulemaking authority over the section 340B program." *Novartis Pharms. Corp. v. Johnson*, 102 F.4th 452, 459 (D.C. Cir. 2024). And the 340B statute says nothing about delivery terms in contracts between manufacturers and covered entities. But recognizing the program would be largely ineffectual without contract pharmacies' involvement, HHS sought to regulate their role for decades through a series of sub-regulatory guidance documents, advisory opinions, and enforcement letters. Those efforts came to a head in the last two years when the Third and D.C. Circuits held that, essential though contract pharmacies might be to the program, HHS lacked authority to require manufacturers to deliver drugs to covered entities' dispensing pharmacies.

When HHS first addressed the involvement of contract pharmacies in the 340B program, in 1996, it acknowledged that "[t]he statute is silent as to permissible drug distribution systems," neither requiring delivery to contract pharmacies nor prohibiting covered entities from using them. 61 Fed. Reg. at 43,549. Moreover, it acknowledged that covered entities' ability to contract with pharmacies to dispense 340B drugs was a matter of "State law"—specifically state contract and agency law—and that under state law "covered entities have

the right to contract with retail pharmacies for the purpose of dispensing 340B drugs." *Id.* at 43,550. And it agreed that because "only a very small number of . . . covered entities used in-house pharmacies," it would "defeat the purpose of the 340B program" if covered entities couldn't use outside pharmacies to dispense 340B drugs. *Id.* Nevertheless, without citing any statutory authority, and lacking any rulemaking authority, HHS purported to impose a "limitation of one pharmacy contractor per [covered] entity" via administrative guidance. *Id.* at 43,555.

In 2010, belatedly recognizing that its single-pharmacy cap had imposed "transportation barriers [and] other obstacles" to many patients' "fill[ing] their prescriptions," HHS lifted that cap, allowing covered entities to contract with pharmacies of their choice. 75 Fed. Reg. 10,272, 10,273 (Mar. 5, 2010). HHS explained that although covered entities could contract with outside pharmacies to dispense the drugs they purchased under 340B, covered entities must purchase and maintain title to those drugs, only arranging for their shipment to contract pharmacies. *Id.* at 10,277.

By lifting its unlawful cap and allowing covered entities to dispense 340B drugs through the pharmacies where their patients filled their prescriptions, HHS made it possible for many patients of covered entities who couldn't previously access 340B-discounted drugs to access them. Whereas under HHS's former guidance hospitals were forced to select a single pharmacy close to the majority of its patients, by 2017 a quarter of covered entities' contract pharmacies were over 20 miles away from the entity, and over 70 percent of disproportionate share hospitals had at least one contract pharmacy over 30 miles away. U.S. Gov't

Accountability Off., GAO-18-480, *Drug Discount Program: Federal Oversight of Compliance at 340B Contract Pharmacies Needs Improvement* 23-24 (June 2018), https://www.gao.gov/assets/gao-18-480.pdf. That allowed those often rural hospitals to "serve patients who live far away." *Id.* at 23 n.38.

The pharmaceutical industry never challenged HHS's 2010 guidance, and for ten years it abided by it, shipping 340B drugs to covered entities' contract pharmacy of choice. But in 2020 drug manufacturers, in an attempt to reduce the amount of discounted drugs they sold, unilaterally cracked down, adopting distribution policies that attempted to recreate HHS's former unlawful one-pharmacy cap by refusing to ship to more than one pharmacy per covered entity. *See Sanofi*, 58 F.4th at 701 (summarizing three of the leading policies).

As the Eighth Circuit found below, "[t]his caused covered entities dependent on contract pharmacies to become unable to serve patients in need." Pet. App. 3a. It also caused a third of rural community access hospitals, which relied on 340B savings to fund their operations, to cut programs and services for low-income and rural patients.[1] The pinch was especially acute in Arkansas, where virtually all covered entities—non-profit, tax-exempt, and governmentally funded hospitals—cannot operate their own in-house pharmacies. Ark. Code Ann. 17-92-607(a).

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[1] *See* 340B Health, *Restrictions on 340B Contract Pharmacy Increase Drug Company Profits but Lead to Lost Savings, Patient Harm, and Substantial Burden for Safety-Net Hospitals* 8 (March 2023), https://www.340bhealth.org/files/Contract_Pharmacy_Survey_Report_March_2023.pdf.

HHS attempted to fix the problem, claiming in an advisory opinion and a series of enforcement letters that 340B required manufacturers to deliver 340B drugs to covered entities' preferred contract pharmacies. *See Novartis*, 102 F.4th at 458-59. Though well-intended, HHS's efforts were doomed to fail. For as it candidly acknowledged decades prior when it attempted to impose its own one-pharmacy cap, state law—not 340B—regulates agency relationships between covered entities and pharmacies. Consequently, when manufacturers challenged HHS's enforcement actions, court after court, including ultimately the Third and D.C. Circuits, held them unlawful. As those courts explained, 340B is "silent about delivery conditions," *Novartis*, 102 F.4th at 460, and indeed "silent about delivery" altogether, *Sanofi*, 58 F.4th at 703. So though the manufacturers' restrictions might well "thwart Congress's purpose in enacting Section 340B," *id.* at 706, HHS was powerless to act.

3. In 2021, the State of Arkansas—where the 340B drug-access crisis caused by manufacturers' delivery restrictions was especially acute, given the restrictions on operating in-house pharmacies—responded by enacting Act 1103. That law voided restrictions on delivery to covered entities' contract pharmacies that manufacturers might impose in their contracts with covered entities or intermediary drug wholesalers. *See* Ark. Code Ann. 23-92-604(c).

Two months after Act 1103 went into effect, PhRMA filed suit in the Eastern District of Arkansas, claiming that it was preempted by both 340B and the Food, Drug and Cosmetic Act, and that it violated the dormant Commerce Clause. Pet. App. 19a-20a. One year later, never having sought injunctive relief,

PhRMA moved for summary judgment on preemption alone. Pet. App. 20a.

The district court rejected PhRMA's various preemption theories and granted the state summary judgment. Rejecting PhRMA's field-preemption theory, the district court explained that 340B didn't occupy the field of how 340B drugs are distributed, because—as HHS had once acknowledged—340B "is silent as to permissible drug distribution systems." Pet. App. 30a (quoting 61 Fed. Reg. at 43,549). Rejecting PhRMA's impossibility-preemption theory, which PhRMA has since abandoned, it explained that contrary to PhRMA's claims 340B doesn't forbid covered entities from dispensing drugs through contract pharmacies. Pet. App. 32a. And rejecting PhRMA's obstacle-preemption theory, it explained that Act 1103 doesn't interfere with federal enforcement of 340B because Arkansas's law didn't enforce 340B; Act 1103 only regulates distribution, not the 340B drug prices regulated by HHS. Pet. App. 34a. The district court also rejected PhRMA's FDCA preemption claim. Pet. App. 34a-36a.

After the district court entered a final judgment on PhRMA's preemption claims under Rule 54(b), PhRMA appealed to the Eighth Circuit, which unanimously affirmed the district court. Pet. App. 15a. By the time that court decided PhRMA's appeal, the Third Circuit had held in *Sanofi* that 340B doesn't regulate drug delivery, and that decision played a large role in the Eighth Circuit's analysis.

First, agreeing with the Third Circuit that "340B 'is silent about delivery' of drugs," Pet. App. 11a (quoting *Sanofi*, 58 F.4th at 703), the Eighth Circuit held that logically meant 340B doesn't occupy the field of drug delivery. Likewise, HHS's lack of authority to regulate

drug delivery meant Act 1103 doesn't entrench on HHS's jurisdiction to enforce 340B; its power is limited to regulating pricing and diversion, while Act 1103 regulates where 340B-priced drugs are shipped. Pet. App. 12a-13a. And Act 1103 didn't pose any obstacle to achieving 340B's purposes because it's aimed at different activity than 340B regulates. Pet. App. 14a. Indeed, if anything, the Eighth Circuit reasoned, by allowing "covered entities dependent on contract pharmacies" to continue to receive 340B discounts, Pet. App. 3a, "Act 1103 assists in fulfilling the purpose of 340B." Pet. App. 14a. The Eighth Circuit also rejected PhRMA's FDCA preemption claim. Pet. App. 15a-16a.

PhRMA then petitioned for panel rehearing or rehearing en banc. The Eighth Circuit denied its petition; no judge dissented. Pet. App. 37a.

REASONS FOR DENYING THE PETITION

I. The Eighth Circuit's decision doesn't conflict with decisions of other circuits.

This petition presents a question on which there's complete unanimity. When HHS attempted to mandate manufacturers to deliver 340B drugs to contract pharmacies, the Third and D.C. Circuits held it couldn't do so because Section 340B doesn't regulate drug delivery. Since then, four courts—the Eighth Circuit below and three district courts in two other circuits—have addressed the question presented here: whether Section 340B preempts States from requiring delivery to contract pharmacies. Agreeing with the Third and D.C. Circuits that Section 340B doesn't regulate delivery, each of those courts has held that means Section 340B doesn't preempt States from regulating it. There is no conflict.

PhRMA, however, claims there's a hidden one. Even though the Eighth Circuit expressly relied on the decisions that Section 340B doesn't regulate delivery, PhRMA claims it unknowingly created a conflict with them, because those decisions supposedly held that Section 340B "specifically preserved manufacturers' ability" to deny delivery to contract pharmacies. Pet. 25. But those decisions didn't hold that. Instead, they merely held that 340B, by its silence, preserved from *federal* interference whatever rights manufacturers otherwise have to limit delivery—not that it rendered delivery a law-free zone on which no sovereign may speak. So not only is there no conflict with those decisions, but those decisions actually suggest—as every court to consider the question has held—that 340B doesn't preempt laws like Arkansas's.

A. Two courts of appeals have addressed whether HHS may mandate drug manufacturers to deliver 340B drugs to contract pharmacies—and held it can't. But the court of appeals and district court below were the first courts to decide whether Section 340B preempts *States* from requiring delivery to a covered entity's agents. Far from disagreeing with the Third and D.C. Circuits' holdings that 340B doesn't authorize Health Res. & Servs. Admin. to regulate delivery, the Eighth Circuit relied on the Third Circuit's conclusion that 340B is silent on delivery to hold that 340B doesn't preempt state regulation on the subject. And since its decision, three district courts have unanimously agreed that under the Third and D.C. Circuits' reading of 340B, delivery terms in contracts between manufacturers and covered entities were left for States to regulate. There is no conflict on

preemption, and no conflict on whether 340B regulates delivery.

Below, PhRMA claimed Arkansas's law was field- and conflict-preempted. The Eighth Circuit (which issued its decision before the D.C. Circuit's in *Novartis*) explained that under the Third Circuit's reading of 340B, which it followed, that was incorrect. Section 340B did not occupy the relevant field because, as the Third Circuit held, it did not even regulate the field; "the text of 340B 'is silent about delivery' of drugs to patients." Pet. App. 11a (quoting *Sanofi*, 58 F.4th at 703). Likewise, Arkansas's law did not conflict with 340B because it was "aimed at activity that falls outside the purview of 340B," Pet. App. 14a, as the Third Circuit had held.

Since that decision, three district courts in two different Circuits have followed suit in challenges brought by PhRMA itself, with appeals from those decisions pending in both Circuits. First, PhRMA was denied an injunction in a suit challenging a similar law in the Southern District of Mississippi. *See Pharm. Rsrch. & Mfrs. of Am. v. Fitch*, No. 24-cv-160, 2024 WL 3227365 (S.D. Miss. July 1, 2024), *appeal filed*, No. 24-60340 (5th Cir. July 5, 2024). That court agreed with the Third and D.C. Circuits that 340B does "not *require*" delivery to contract pharmacies. *Id.* at *9 (discussing *Sanofi* and *Novartis*). But it rejected the argument that 340B therefore preempted state regulation that did, explaining that "the same 'statutory silence' that does not *implicitly mandate* that manufacturers deliver to any contract pharmacy does not . . . show that Congress clearly intended to *preclude states*" from requiring delivery to contract pharmacies. *Id.* (alteration omitted) (quoting *Sanofi*,

58 F.4th at 699). That decision is on appeal to the Fifth Circuit, with only PhRMA's opening brief filed.

Next, PhRMA was denied an injunction in a suit challenging a similar law in the District of Maryland. *Pharm. Rsrch. & Mfrs. of Am. v. Brown*, No. 24-cv-1557 (D. Md. Sept. 5, 2024), *appeal docketed*, No. 24-1978 (4th Cir. Oct. 8, 2024). That court agreed with the Third and D.C. Circuits that "340B does not speak to or regulate delivery or distribution of drugs." *Brown*, Tr. at 114 (D.M.D. Sept. 4, 2024). But it disagreed with PhRMA that "Congress' silence . . . is somehow evidence of its intent to preempt state regulation of delivery to contract pharmacies," *id.* at 116, or that it "confers a right on drug manufacturers to restrict delivery to contract pharmacies," *id.* at 117, noting that "neither the Third Circuit in *Sanofi*, [nor] the D.C. Circuit in *Novartis* said anything of that sort," *id.* at 116. That decision was appealed last month to the Fourth Circuit; no briefs have been filed.

Finally, one month ago, the Western District of Louisiana entered judgment against PhRMA in its challenge to a similar Louisiana law. *Pharm. Rsrch. & Mfrs. of Am. v. Murrill*, No. 23-cv-997, 2024 WL 4361597 (W.D. La. Sept. 30, 2024), *appeal docketed*, No. 24-30673 (5th Cir. Oct. 21, 2024). That court too agreed with the Third and D.C. Circuits that "340B is silent with respect to contract pharmacies." *Id.* at *8. But it explained that "holding is fatal" to PhRMA's preemption claims, *id.*; if 340B says nothing about delivery to contract pharmacies, it couldn't occupy the field of delivery, *see id.* at *7, or conflict with "a state statute that specifically addresses" the subject, *id.* at *8. That decision was just appealed to the Fifth Circuit.

B. Every court that has decided the preemption issue has concluded that under the Third and D.C. Circuit's reading of 340B, there is no preemption. Yet PhRMA insists the opposite must be true because those circuits read 340B to "preserve" manufacturers' ability to restrict delivery and thus state laws prohibiting such restrictions must conflict with 340B. But that isn't how preemption works. When federal law leaves an activity unregulated, the default rule is that it *doesn't* preempt state regulation. That rule can only be overcome where courts conclude that maintaining private parties' autonomy was a significant purpose of federal law—not just that Congress left some activity unregulated, or even that it did so intentionally. Neither the Third nor D.C. Circuit ascribed any anti-regulatory purpose to 340B, instead holding only that 340B is textually silent on delivery, and what little they said on purpose suggests Congress had no anti-regulatory purpose. So their decisions don't necessitate a finding of preemption, and if anything undercut PhRMA's arguments for it.

1. When Congress chooses not to regulate something, its inaction sometimes "may imply an authoritative federal determination that the area is best left *un*regulated," to the exclusion of contrary state law. *Ark. Elec. Coop. Corp. v. Ark. Pub. Serv. Comm'n*, 461 U.S. 375, 384 (1983). Yet far more often, a federal decision not to regulate is just a decision that *federal law* shouldn't regulate, and doesn't preempt state law that does. *See, e.g.*, *Chamber of Com. of U.S. v. Whiting*, 563 U.S. 582, 608-09 (2011) (holding States could mandate participation in a voluntary federal program); *Williamson v. Mazda Motor of Am., Inc.*, 562 U.S. 323 (2011) (holding a federal regulation that gave carmakers

a choice between two kinds of seat belts didn't preempt state tort suits that would require one); *Sprietsma v. Mercury Marine*, 537 U.S. 51, 65-68 (2002) (holding the Coast Guard's decision to not require propeller guards on motorboats didn't preempt States from requiring propeller guards); *Cal. Div. of Lab. Standards Enf't v. Dillingham Const., N.A., Inc.*, 519 U.S. 316, 330 (1995) (rejecting as "unsettling" a reading of ERISA to preempt state law in "areas where ERISA has nothing to say").

Accordingly, to find preemption of state law it never suffices just to find that federal law doesn't regulate the same conduct, or even that Congress purposefully left that conduct unregulated. Instead, to infer preemption from non-regulation courts must find that "giving [regulated entities] a choice" between different permissible courses of conduct "was a *significant objective*" of federal law. *Williamson*, 562 U.S. at 330 (emphasis in original).

The Court's car-safety preemption cases illustrate what's required. In *Geier v. American Honda Motor Co.*, the Court held that a regulation that gave carmakers a choice between airbags and other passive restraint systems preempted state tort suits that would require airbags. 529 U.S. 861 (2000). Yet the choice alone wasn't enough. Rather, the Court found preemption only because it concluded the regulation "sought"—not just permitted—a "mix of devices" on the view that "safety would best be promoted" by a mix. *Id.* at 881. In *Williamson*, the Court again confronted a regulation that gave carmakers a choice, there between two different types of seat belts. But there the Court didn't find preemption. The Court explained that the agency hadn't affirmatively "sought to maintain manufacturer choice," *id.* at 336; it merely declined to require

the safer belt because it concluded requiring it wouldn't "be cost effective." *Id.* at 335. That judgment that the marginal safety benefits weren't worth the cost a federal mandate would impose didn't forbid States from "reach[ing] a different conclusion." *Id.*

2. For the Eighth Circuit's decision to conflict with the Third and D.C. Circuits', then, it wouldn't suffice that those courts held Section 340B doesn't regulate delivery, or even that the omission was intentional. Instead, there would only be a conflict had those courts held that Congress left delivery unregulated *with the purpose* of giving manufacturers free rein to condition sales of 340B drugs on delivery terms of their choosing. Unsurprisingly, as those courts weren't addressing preemption, they didn't even engage in the relevant inquiry. Instead, they held only that, intentionally or otherwise, Section 340B didn't regulate delivery. That holding doesn't conflict with the Eighth Circuit's holding that States may regulate delivery, but rather supports it.

The Third Circuit was the first court of appeals to reject HHS's attempts to regulate 340B delivery. Though PhRMA claims only the Eighth Circuit relied on 340B's "supposed 'silence'" on delivery, Pet. 26, almost the entirety of the Third Circuit's reasoning was that 340B's "text is silent about delivery." *Sanofi*, 58 F.4th at 703. Section 340B, that court declared, "[n]owhere . . . mention[s] contract pharmacies," *id.*, "says nothing about delivery," *id.* at 704, and regulates only the "price term for drug sales to covered entities, leaving all other terms blank," *id.* The Third Circuit didn't surmise, much less decide, what the reason for that blank was. PhRMA points out (Pet. 25) that the Third Circuit noted a neighboring provision "contemplate[d] drug makers selling discounted drugs through contract

pharmacies," and "presume[d]" that Congress didn't include similar language in 340B "intentionally." 58 F.4th at 705. But that at most suggests the Third Circuit deemed 340B's silence intentional, not that giving manufacturers freedom to choose where to deliver 340B drugs was an objective of 340B. And the Third Circuit didn't even decide that much, acknowledging later in its opinion that a rejected version of 340B would have prohibited using contract pharmacies, and ultimately declining to "draw[] inferences" about Congress's intentions beyond its textual silence. *Id.*

The D.C. Circuit's rationale for rejecting HHS's delivery mandate was no different. "[A]gree[ing] entirely" with the Third Circuit, *Novartis*, 102 F.4th at 461, it concluded that 340B is "silent about delivery conditions," *id.* at 460. And "statutory silence implies that"—so far as the statute in question is concerned—"private parties may act freely." *Id.* So the D.C. Circuit didn't hold that Congress sought to give manufacturers autonomy over delivery, but only that it said nothing about delivery.

To be sure, PhRMA emphasizes different language in *Novartis*. It suggests the D.C. Circuit glossed 340B's use of the term "offer" to "specifically preserve[] manufacturers' ability to limit" delivery. Pet. 25. Yet in reality, that court only rejected HHS's argument that 340B's mandate to "offer" drugs to covered entities *prohibits* imposing delivery conditions, because offers to contract "often" include terms about delivery. *Novartis*, 102 F.4th at 460 ("[I]ncluding such terms is fully consistent with making an 'offer.'"). And the D.C. Circuit's statement that 340B's "silence preserves . . . the ability of sellers to impose at least some delivery conditions," *id.*, merely indicates that 340B left

manufacturers' freedom to contract about delivery under "background contract principles" of state law untouched, *id.*, not that 340B created a novel freedom to contract about delivery untouched by state law.

Ultimately, then, PhRMA's claim that *Sanofi* and *Novartis* conflict with the decision below rests solely on its ipse dixit that "[a]llowing the States to impose requirements on [businesses] participating in a federal program that the administering federal agency cannot turns the Supremacy Clause on its head." Pet. 27. Yet in *Chamber of Commerce of U.S. v. Whiting* this Court held the Supremacy Clause allows just that. There, the Court held States could mandate participation in the federal E-Verify program even though the statute creating the program said the "Secretary of Homeland Security may not require any person . . . to participate," simply reasoning that "the State of Arizona is not the Secretary of Homeland Security." 563 U.S. at 608. And if the Supremacy Clause allows States to mandate participation in a federal program "that the administering federal agency cannot," Pet. 27, it certainly allows States to regulate matters that a federal program doesn't even regulate.

3. Finally, if anything, *Novartis* and *Sanofi* strongly suggest that 340B's silence on delivery isn't the kind of non-regulation that preempts state regulation. To start, *Novartis* expressly acknowledged the role state contract law plays—and must play—in regulating delivery. When explaining how "background contract principles" show that offers to contract "typically include" delivery terms, it cited a series of provisions of the U.C.C. 102 F.4th at 460. Yet the U.C.C. is not a brooding omnipresence, but positive state law, and the provisions the D.C. Circuit cited are a mix of gap-filling

terms that address delivery if a contract is silent, *see* U.C.C. 2-307, and provisions that regulate delivery even when a contract addresses it, *see, e.g.*, U.C.C. 2-503 (restricting the permissible manner of delivery). Nor could it be otherwise. With 340B "silent about delivery conditions," *Novartis*, 102 F.4th at 460, state law is left to address those conditions' enforcement, interpretation, and validity.

Besides expressly acknowledging state law's role, both *Novartis* and *Sanofi* suggest in many ways that 340B's silence on delivery was just that—silence—not a purposeful policy of promoting unfettered contracting on delivery. First, as both decisions emphasize, 340B is merely silent on delivery. It doesn't contain language affirmatively conferring choice on manufacturers, unlike the regulation in *Geier*, or even the language that didn't suffice for preemption in *Whiting*. Second, as both decisions acknowledge, the one alternate proposal Congress considered—and rejected—on the subject "would have categorically prohibited the use of any contract pharmacies," *Novartis*, 102 F.4th at 462; *see also Sanofi*, 58 F.4th at 705, which hardly suggests allowing manufacturers to decline to deliver to contract pharmacies was a "significant objective," *Williamson*, 562 U.S. at 330. Third, both decisions didn't seriously dispute the government's argument that "letting drug makers limit the use of contract pharmacies would thwart Congress's purpose in enacting Section 340B," *Sanofi*, 58 F.4th at 706, but instead reasoned only that the government's "appeal to statutory purpose" could not defeat "the most natural reading of [340B's] terms," *Novartis*, 102 F.4th at 462. That is a sound basis for not reading 340B to restrict limitations on delivery. But the acknowledgement that such limita-

tions tend to frustrate 340B's purposes forecloses PhRMA's claim that *restrictions* on those limitations conflict with 340B's purposes.[2]

II. The Eighth Circuit's decision doesn't conflict with this Court's precedents.

PhRMA also claims the decision below conflicts with two of this Court's precedents. But the decisions it relies on are either too narrow or too broad. It first looks to *Astra USA, Inc. v. Santa Clara County*, which held that only HHS, not courts in private suits, can enforce the statutory price terms of manufacturers' agreements with HHS. 563 U.S. 110 (2011). But unfortunately for PhRMA, that's all *Astra* held, and *Astra* disclaimed any holding on the enforcement of terms in private 340B contracts that don't merely parrot the statute. The venue to enforce those terms, which 340B and HHS don't regulate, is state courts and agencies.

PhRMA next claims the decision below conflicts with *Arizona v. United States*, 567 U.S. 387 (2012), an immigration preemption case that it reads as holding States may not impose sanctions for violations of federal law that differ from federal sanctions, or "layer [their] own requirements" over a federal program. Pet.

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[2] Previewing its arguments on appeal in the Fifth Circuit, PhRMA claims in a footnote that the decision below conflicts with that court's decision that a federal law banning harmful phone "spoofing" preempts by omission state laws that ban non-harmful "spoofing." Pet. 32 n.8 (citing *Teltech Sys., Inc. v. Bryant*, 702 F.3d 232 (5th Cir. 2012)). That decision only illustrates that whether federal non-regulation preempts state regulation is a statute-by-statute inquiry; there the Fifth Circuit, "resorting to legislative history to clarify congressional intent," divined an "intent to protect non-harmful spoofing." 702 F.3d at 238.

32. As to the first rule, whether *Arizona* announced it or not it isn't violated here, because the sanctions Arkansas's law imposes are for conduct 340B doesn't regulate at all. The second rule simply cannot be found in *Arizona*. What *Arizona*, like *Geier*, held is that where federal law has an affirmative policy of non-regulation, state law that conflicts with that policy is preempted—not that state law can never "layer" over a federal program. Indeed, *Whiting* held just the opposite.

A. PhRMA claims that the decision below conflicts with this Court's decision in *Astra*. That's wrong. *Astra* held that only HHS can "enforce the [340B] statute itself," 563 U.S. at 118; it didn't hold that HHS is the enforcer or regulator of terms in 340B-related contracts on which 340B is silent. More specifically, *Astra* held that covered entities could not bring third-party beneficiary suits in federal court to enforce ceiling-price terms of manufacturers' contracts with HHS that "simply incorporate[d] statutory obligations" under 340B. *Id.* The Court reasoned that such a suit was "in essence a suit to enforce the statute itself," *id.*, not "any independent substantive obligation arising only from" the contracts, *id.* at 119, and that covered entities lacked "a private right to enforce the statut[e]" and therefore couldn't sue under the statute-parroting contracts, *id.* at 118.

As that distinction of purely contractual obligations suggests, *Astra* did not even touch on, much less resolve, the proper venue for covered entities to enforce non-statutory terms of their own contracts with manufacturers or their wholesalers. But under *Astra*'s rationale, the answer is state courts or agencies as mediated by state law. For while Congress provided

an administrative remedy for "claims by covered entities that they have been charged prices . . . in excess" of the statutory price, 42 U.S.C. 256b(d)(3)(B)(i)—which *Astra* relied on, *see* 563 U.S. at 121-22—it unsurprisingly provided no remedy for covered entities who claim a breach of contract on matters about which 340B is silent, or who challenge the terms that manufacturers seek to impose on those matters. Yet those terms must be enforceable and subject to challenge somewhere. For that reason, when Astra was specifically asked at oral argument whether covered entities could sue to enforce "delivery" or other "terms beyond those in the statute," Astra readily conceded they could—even if those terms were contained in *the government*'s contracts with manufacturers. Tr. of Oral Arg. 17, *Astra* (No. 09-1273). The same is true, *a fortiori*, for covered entities' own contracts.

Nevertheless, PhRMA claims that Arkansas's law conflicts with *Astra* because it applies only to 340B-covered entities. That in turn, PhRMA claims, could require the State to collaterally adjudicate whether a hospital *is* a covered entity, thus risking conflicting adjudications with HHS or other States. Pet. 30. That argument fails for multiple reasons. In the first place, HHS maintains a "full list" of covered entities on its website, which the State would simply follow. Health Res. & Servs. Admin., *340B Drug Pricing Program*, https://www.hrsa.gov/opa. And in the unlikely event a hospital's eligibility were somehow disputed, the State Insurance Department wouldn't adjudicate that issue itself, but stay its adjudication of the entity's delivery dispute pending HHS's determination of eligibility. Yet even if that weren't true, the State's adjudication of those questions would not pose the sort of "risk of

conflicting adjudications," *Astra*, 563 U.S. at 120, *Astra* was concerned about. In *Astra*, permitting third-party-beneficiary suits would have allowed different courts to reach different conclusions about what a drug's 340B price was, vitiating 340B's uniformity. Here, if Arkansas collaterally adjudicated an entity's 340B eligibility and HHS later found it ineligible, the entity would be out of the program, whatever Arkansas had to say about it.

B. Nor does the decision below conflict with *Arizona*. *Arizona* contains two holdings that PhRMA claims are relevant. Pet. 30-31. First, it held that federal immigration law preempted more severe state sanctions for a violation of immigration law than federal law imposed. 567 U.S. at 403. Second, it held federal immigration law preempted a state law that criminalized aliens' engaging in unauthorized work, because "Congress made a deliberate choice not to impose criminal penalties on aliens," but only on their employers. *Id.* at 405.

Neither of these holdings supports preemption here. PhRMA says that Arkansas's law imposes different penalties than those HHS imposes for "a violation of 340B." Pet. 32. But Arkansas's penalties aren't penalties for violations of 340B; they're penalties for conduct that 340B doesn't address. Indeed, 340B's silence on delivery is the whole basis for PhRMA's preemption claim. So Arkansas hasn't "impose[d] its own penalties for . . . federal offenses." *Arizona*, 567 U.S. at 402.

Nor does the decision below conflict with *Arizona*'s holding that States could not penalize immigration conduct that "Congress made a deliberate choice" not to penalize. *Arizona*, 567 U.S. at 405. PhRMA doesn't

even attempt to argue that Congress made a deliberate choice or "considered judgment," *id.*, to allow manufacturers to refuse to deliver 340B drugs to contract pharmacies. Nor could it where the only deliberate choice Congress made on the subject was to reject a proposal that would have prohibited the use of contract pharmacies, as PhRMA's members would.

Instead, PhRMA suggests that a State is always preempted from "layer[ing] its own requirements . . . on top of [a] federal program." Pet. 32. But *Whiting* held just the opposite in a case of far more acute "layering"; there a State mandated participation in a federal program that under federal law was purely voluntary. The Court held the State could do so because mandating participation, even though contrary to federal policy, wouldn't "obstruct[] achieving th[e] aims" of the program. *Whiting*, 563 U.S. at 609 (plurality opinion). As the Eighth Circuit explained, the same is true here. Pet. App. 14a.

III. The decision below is correct.

For many of the same reasons that the decision below doesn't conflict with other circuits' or this Court's precedent, the decision below is correct.

PhRMA says Arkansas's law conflicts with 340B's supposed preservation of PhRMA's members' ability to limit delivery. Pet. 33. But under this Court's precedent, state regulation only conflicts with federal non-regulation where Congress affirmatively sought to carve out regulatory space. Here, Congress was merely silent on delivery, and the only evidence of its intentions beyond that silence is its rejection of proposals to prohibit using contract pharmacies. PhRMA next says there's a categorical rule against a State's

"layering its own enforcement scheme on top of a centralized federal enforcement scheme," citing *Astra* and *Arizona*. Pet. 33. But that rule only applies where a State is enforcing federal law, not imposing its own strictures on matters federal law doesn't address. Finally, PhRMA asserts in a sentence that Arkansas's law intrudes on an area where Congress occupied the field. Pet. 33-34. To the contrary, Congress left the field of drug delivery and pharmacies' role in dispensing 340B drugs wide open. Indeed, Congress's studied silence on that issue is the very basis for PhRMA's conflict-preemption claim.

Yet there is a more fundamental reason that Arkansas's law isn't preempted. While the form contracts between manufacturers and the government addressed in *Astra* are entirely creatures of federal law, the contracts manufacturers make with covered entities or intermediary wholesalers to sell 340B drugs are creatures of state law. As to those contracts federal law "imposes only a price term," *Sanofi*, 58 F.4th at 704—"leaving all other terms blank," *id.*—and provides only a remedy for pricing disputes, *see* 42 U.S.C. 256b(d)(3)(A)—leaving all other terms unenforced. Everything else, from contract formation to enforcement, interpretation and validity, is a question of state law. For Congress's imposition of a maximum price no more federalizes 340B drug sale contracts than its imposition of a minimum wage federalizes the ordinary employment contract. And just as States uncontroversially may regulate the manner in which 340B drugs are delivered, *see Novartis*, 102 F.4th at 460 (citing U.C.C. 2-503), States may render void against public policy terms that would deny delivery to a hospital's agent pharmacies, thus practically denying it the

benefit of its bargain. Indeed, as HHS once recognized, covered entities' right to request delivery to agent pharmacies is a "right that covered entities enjoy under *State* law," not 340B. 61 Fed. Reg. at 43,550 (emphasis added).

IV. The split-less question presented doesn't merit immediate review.

Ultimately, PhRMA's argument for review is that the question presented is so important that the Court must intervene now—even though the court below is the only court of appeals to address the question, and PhRMA itself has pending appeals presenting it in two other circuits. Such hasty intervention isn't warranted. PhRMA claims to fear that laws like Arkansas's will threaten the viability of the 340B program. Yet Arkansas's law merely recreates in Arkansas what reigned nationally under HHS guidance for a decade: covered entities' freedom to use contract pharmacies of their choice. The program didn't crumble then, and it won't crumble now if the Court follows its normal course of waiting to see whether PhRMA's attempts to create a split succeed.

For 10 years, from 2010 to 2020, covered entities nationwide were free to use contract pharmacies of their choice, per HHS guidance. *See* 75 Fed. Reg. at 10,273 (authorizing the use of multiple contract pharmacies). Manufacturers didn't challenge that guidance, or resist it, for a decade, only adopting policies to deny delivery to contract pharmacies in 2020. *See Sanofi*, 58 F.4th at 700-01. PhRMA vaguely speculates that if individual States are allowed to return to the 2010s status quo ante, manufacturers might leave the program, raise drug prices outside the

program, or "forego critical research." Pet. 35. But it cites no evidence that any of those things occurred during the decade when Arkansas's policy was effectively the law of the land.

Lacking any evidence of programmatic collapse or even strain under HHS's former regime, PhRMA attempts to at least show that regime was unduly costly for its members. But it doesn't even show that. PhRMA first notes that in the decade after HHS lifted the one-contract-pharmacy cap, the number of 340B contract pharmacies grew many times over. Pet. 8-9. But that isn't surprising or troubling; it merely illustrates the obvious fact that a single hospital's patients buy drugs from many pharmacies, not just one. By permitting covered entities to contract with all the pharmacies where their patients bought drugs, HHS simply made it possible for covered entities to receive the full discounts they were entitled to instead of a small fraction of them. Nor was the number of contract pharmacies inordinately large in proportion to the program's size: 20,000 contract pharmacies for over 12,000 covered entities. GAO 18-480 at 1, 10.

PhRMA next notes that two thirds of the instances of 340B drug diversion found in HHS audits took place at contract pharmacies. Pet. 9-10, 21. That too isn't surprising, as outside pharmacies, not in-house pharmacies that many hospitals lack, are where most drugs are dispensed. The more salient question is how much diversion occurs at contract pharmacies, and the answer is very little; of the over 1,000 audits of covered entities HHS conducted between 2019 and 2024, almost 95 percent found no diversion of any amount at *any* of a covered entity's contract pharmacies—which as PhRMA notes, often number in the dozens or even

hundreds.[3] *See* Health Res. & Servs. Admin., *Program Integrity*, https://www.hrsa.gov/opa/program-integrity. PhRMA's members' access restrictions may have caused a crisis for the 340B program; Arkansas's invalidation of those restrictions within its borders will not.

CONCLUSION

The petition for a writ of certiorari should be denied.

Respectfully submitted,

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[3] In a footnote PhRMA says that contract pharmacies "also contribute to duplicate discounting," the practice of illicitly seeking 340B discounts and Medicaid rebates on the same drugs. Pet. 21 n.6. But the GAO found that, of the duplicate discounts found in HHS audits, only 7 percent took place at contract pharmacies, a disproportionately low number that suggests contract pharmacies' involvement *reduces* duplicate discounting. GAO-18-480 at 38.