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, COMMUNITY HEALTH CENTERS OF ARKANSAS, AND PIGGOTT COMMUNITY HOSPITAL,

Respondents.

ON PETITION FOR A WRIT OF CERTIORARI TO THE UNITED STATES COURT OF APPEALS FOR THE EIGHTH CIRCUIT

REPLY BRIEF FOR PETITIONER

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INTRODUCTION

Respondents do not contest that the federal 340B program is of vital national importance. Nor do they identify any issue with this case as a vehicle for review. Instead, Arkansas contends merely that the issue presented "doesn't merit *immediate* review." McClain BIO 23 (emphasis added). But the circuits are already split on the touchstone question of whether 340B preserves manufacturers' authority to impose reasonable conditions on the delivery of their drugs at federally discounted 340B prices. Pet. 24-28; Kalderos Amicus Br. 6-13. Arkansas's attempt to strip manufacturers of that authority—along with similar efforts by a growing number of other States—already "upsets" the balance struck by Congress, strips HHS of the "control reins" over 340B, and has "a significant adverse impact on the 340B program, across the country." Kalderos Amicus Br. 1, 13-14. Certiorari is needed now, before the problem worsens.

ARGUMENT

I. The Question Presented Is Undeniably Important

Respondents do not dispute that the proper functioning of 340B is critically important to the nation's healthcare safety net, or that the unfettered use of contract pharmacies has ballooned the size of and increased the attendant threat of abuse of the federal program. Nevertheless, Respondents contend that review is not warranted—now. That contention ignores the grave threat that appending up to 50 different sets of state rules and enforcement schemes governing 340B presents to the program.

As the Federal Government has touted, 340B is "a carefully calibrated drug-purchasing program with

limitations." Defs.' Opp'n to Pl.'s Mot. Summ. J. and Cross-Mot. Summ. J. 27, *Genesis Health Care Inc. v. Xavier Becerra*, No. 4:19-cv-01531 (D.S.C. July 28, 2023), ECF No. 101. Those limitations set the terms by which manufacturers agree to participate in the federal 340B program and ensure manufacturers are not disincentivized from participating in 340B and, thus, Medicare Part B and the federal portion of Medicaid. The Federal Government has stressed the importance of maintaining this balance, emphasizing that courts should reject a characterization of 340B that maximizes the number of 340B-discounted drugs manufacturers are required to provide to covered entities. *See id.*

As amicus Kalderos explains (at 13-14), the Eighth Circuit's decision "tramples on" this balance, threatening the program. Yet, Respondents suggest that because "the program didn't crumble" previously, it "won't crumble now." McClain BIO 23. That ignores reality. From 2010-2022, contract pharmacy arrangements exploded—by a "twentyfold" increase. *Sanofi Aventis U.S. LLC v. U.S. Dep't of Health & Human Servs.*, 58 F.4th 696, 700 (3d Cir. 2023). And that drastic increase led to similar explosive growth in the amount of 340B discounts. In 2022, discounted purchases under 340B reached $53.7 billion, which represented a $9.8 billion growth (+22.3%) in a single year.[1] The explosion of contract pharmacies invited abuse and ballooned the size of the program. Pet. 8-9. And this unsustainable growth prompted

[1] Adam J. Fein, *The 340 B Program Reached $54 Billion in 2022—up 22% vs. 2021*, Drug Channels (Sept. 24, 2023), https://www.drugchannels.net/2023/09/exclusive-340b-program-reached-54.html.

manufacturers to institute policies to protect against that abuse. Absent the Court's intervention, that type of dramatic growth, and the abuse that comes with it, will continue to destabilize and threaten this critically important healthcare program.

Nor are the harms solely financial; they go to the heart of the federal program. At bottom, the question is whether 340B will be administered by one federal agency or 50 different state agencies—creating "a dizzying array of compliance and enforcement remedies." Kalderos Amicus Br. 15. In addition to delivery requirements, some States have even attempted to restrict manufacturers' ability to obtain basic information from covered entities regarding 340B claims, information needed to access the federal enforcement scheme. *See, e.g.*, W. Va. Code § 60A-8-6a(b)(2). These state laws drive a stake through the centralized enforcement mechanism Congress created for 340B. *Astra USA, Inc. v. Santa Clara County*, 563 U.S. 110, 120 (2011). And this case vividly illustrates the conflict. While Congress gave HHS the "control rein" over 340B, the Eighth Circuit held that Arkansas could impose requirements on manufacturers that two Circuits have held HHS itself *cannot* impose. This radical Balkanization of the program will fundamentally alter the scheme Congress intended and take away HHS's control rein.

In short, the undenied importance of the question presented warrants intervention now, not later.

II. The Eighth Circuit's Decision Conflicts With Decisions Of Other Circuits And This Court

A. The Circuits Are Split Regarding The Authority Preserved To Manufacturers

As amicus Kalderos explains (at 13), the Eighth Circuit's decision "squarely conflict[s]" with the decisions of the Third Circuit and D.C. Circuit on the central question of whether Congress preserved manufacturers' authority to place reasonable delivery conditions on 340B offers. The Eighth Circuit has answered that question in the negative, whereas the Third Circuit and D.C. Circuit have held the opposite.

1. Respondents incorrectly suggest that the Third Circuit and D.C. Circuit opinions did not "ascribe[] any regulatory purpose to 340B" and held only that "340B is textually silent on delivery." McClain BIO 11. The D.C. Circuit held that 340B "preserves—rather than abrogates—the ability of sellers to impose at least some delivery conditions." *Novartis Pharms. Corp. v. Johnson*, 102 F.4th 452, 460 (D.C. Cir. 2024). Specifically, 340B requires that manufacturers make a bona fide "offer" to sell their covered outpatient drugs to covered entities at a specific ceiling price. *Id.* As non-price terms, like delivery terms, are typical in contracts for sale, the court reasoned, manufacturers are permitted to include them in their 340B offers. *Id.*

The Third Circuit reached the same conclusion in *Sanofi*. It determined that Congress "had in mind one-to-one transactions between a covered entity and a drug maker without mixing in a plethora of pharmacies." *Sanofi*, 58 F.4th at 704. It drew that conclusion, in part, from the fact that Congress allowed contract pharmacy use in a neighboring provision, but "intentionally" did not do so in 340B.

Id. at 704-05. Thus, both the Third Circuit and D.C. Circuit held that Congress affirmatively preserved manufacturers' authority to impose reasonable conditions related to contract pharmacy use on their 340B offers. *Id.* at 706; *Novartis*, 102 F.4th at 462-64.

Respondents, like the Eighth Circuit, claim that statutory "silence" on the obligation to deliver to an unlimited number of contract pharmacies is the beginning and end of the inquiry. But as Judge Katsas explained, after carefully reviewing the statutory scheme, "[s]tatutory silence implies that manufacturers *may* impose distribution conditions by contract, not that they are prohibited from doing so." *Novartis*, 102 F.4th at 460; *see also Sanofi*, 58 F.4th at 703 (a manufacturer "still present[s] . . . drugs for covered entities' acceptance" when it "limit[s] where [it] will deliver drugs"). Moreover, as Judge Katsas recognized, the statute requires that manufacturers make a "bona fide offer," meaning an offer with reasonable delivery conditions. *Novartis*, 102 F.4th 462; *see also Sanofi*, 58 F.4th at 703-04 (manufacturers can impose conditions so long as the offer still amounts to "'present[ing]' discounted drugs 'for acceptance'"). A state law—like Act 1103—that makes it illegal to impose such conditions does not fill any intended regulatory "gap[]," but rather runs headlong into the authority that Congress actually "preserve[d]" to manufacturers. *See Novartis*, 102 F.4th at 456-57, 460 (citation omitted).

The Eighth Circuit decision conflicts with the D.C. Circuit's and Third Circuit's decisions in *Novartis* and *Sanofi* by rejecting the very authority that those cases held Congress preserved to manufacturers. Pet. 26-27. Worse, the Eighth Circuit held that a State can restrict a manufacturer's offer in a manner that the

federal administrator—HHS—cannot. That upside-down conception of the relationship between the Federal Government and the States when it comes to administering a carefully calibrated federal program—which Respondents ignore—highlights the need for this Court's review.

2. Respondents posit that the Third Circuit and D.C. Circuit decisions only conflict with the Eighth Circuit's decision if those courts had "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." McClain BIO 13. But the text is the best evidence of Congress's intent. And the D.C. Circuit, analyzing that text, held that Congress's "silence implies that private parties *may* impose distribution conditions by contract, not that they are prohibited from doing so." *Novartis,* 102 F.4th at 460; *see also Sanofi*, 58 F.4th at 704 (Congress "had in mind one-to-one transactions between a covered entity and a drug maker without mixing in a plethora of pharmacies."). In other words, the text affirmatively *preserves* manufacturers' authority to impose reasonable conditions on delivery to contract pharmacies. *See Novartis,* 102 F.4th at 460. Under the Supremacy Clause, a State simply cannot override that federal decision.

Nonetheless, Arkansas, somewhat strangely, claims the authority to augment the federal program in an effort to evade the conflict. It attempts to separate its delivery requirement from the federal pricing requirement, contending that its delivery requirement attaches only after 340B sets the pricing obligation. CA8 Def.-Appellee's Br. 22 (filed Apr. 10, 2023); App.14a. But that artificial distinction

between pricing and delivery makes no sense. Pet. 27. In any event, the federal pricing obligation is not set until a covered entity accepts the federal offer, and *Sanofi* and *Novartis* have already held that manufacturers are only required to make a reasonable 340B offer. That reasonable offer may include reasonable conditions on contract pharmacy use. The Eighth Circuit ignored that, requiring manufacturers to offer the federal 340B discount even where, as under the Arkansas law, they are prohibited from imposing reasonable conditions on the offer. The Supremacy Clause does not allow Arkansas to rewrite the terms of the federal program.

Respondents' cited cases are not to the contrary. None involves a state law that changes the requirements of participating in an exclusively federal program. For example, in *Chamber of Commerce of the United States v. Whiting*, the state law required employers to check employment eligibility status using the federal E-Verify system—something the Secretary of Homeland Security was prevented from doing. 563 U.S. 582, 608 (2011). The Court found that law was not preempted. *Id.* But forcing an employer to use a federal tool is far from stripping a regulated party of the authority preserved to it under a federal protection.

Respondents' other cases involve instances where States imposed free-standing requirements that did not rely on (or defeat) a preexisting federal obligation. *Williamson v. Mazda Motor of Am., Inc.*, 562 U.S. 323, 327-28 (2011) (state tort claim not preempted where federal agency imposed only minimum safety regulatory standards); *Sprietsma v. Mercury Marine*, 537 U.S. 51, 65-68 (2002) (State could regulate propellers despite federal decision not to regulate).

Here, by contrast, the state law strips manufacturers of authority preserved by the federal program.

The direct conflict between the Eighth Circuit and the D.C. Circuit and Third Circuit on the central question of whether 340B preserves to manufacturers the authority to impose reasonable conditions on 340B alone offers warrants certiorari.

B. The Eighth Circuit's Decision Conflicts With This Court's Precedent

Respondents' attempts to distinguish this Court's cases are unpersuasive.

1. Respondents contend that *Astra* was narrowly focused only on determining federal 340B pricing. McClain BIO 18-19. But this Court unanimously made clear in *Astra* that Congress "centralized enforcement" in the Federal Government over 340B. 563 U.S. at 119 (citation omitted). The alternative, "a multitude of dispersed and uncoordinated lawsuits by 340B entities," created a substantial "risk of conflicting adjudications," and frustrated HHS's ability to maintain the "control rein" of 340B—"undermin[ing] the agency's efforts to administer both Medicaid and § 340B harmoniously and on a uniform, nationwide basis." *Id.* at 120; *see also Buckman Co. v. Plaintiffs' Legal Comm.,* 531 U.S. 341, 350-51 (2001). That reasoning in *Astra* is binding. *See, e.g.*, *Seminole Tribe of Fla. v. Florida*, 517 U.S. 44, 67 (1996) ("[P]ortions of the opinion necessary" to the result are binding.). By creating its own enforcement mechanism, the Arkansas law will disrupt HHS's ability "to administer" 340B "on a uniform, nationwide basis." *Astra*, 563 U.S. at 120. As a result, the Eighth Circuit's decision upholding

that alternative enforcement mechanism conflicts with *Astra*.

In any event, the Arkansas law *does* impact pricing. Arkansas itself has repeatedly contended that its requirements build on manufacturers' federal pricing obligations. *See* Ark. Code Ann. § 23-92-604(c)(2) (manufacturers cannot "[d]eny or prohibit 340B drug *pricing*" for Arkansas pharmacies that receive drugs pursuant to a "340B drug pricing contract pharmacy arrangement" (emphasis added)). Accordingly, in any adjudication of a purported violation of Act 1103, a state decisionmaker will be required to first decide whether a covered entity had a right to obtain drugs at the 340B ceiling price and whether that price was provided. *See id.* But *Astra* establishes that such questions are subject to *exclusive* federal resolution. *See* 563 U.S. at 117 ("Congress vested authority to oversee compliance with the 340B Program in HHS.").

Respondents assert this is not a problem because HHS maintains a list of covered entities and, if covered entity status were disputed, Arkansas "wouldn't adjudicate that issue itself, but stay its adjudication . . . pending HHS's determination of eligibility." McClain BIO 19; *see also* Intervenors' BIO 35 (contending that such issues should "be addressed in a federal ADR proceeding"). But that is just one of several federal issues and manufacturer defenses that Arkansas would need to resolve—others include whether the prescriptions and drugs themselves are actually eligible for 340B pricing and whether there has been diversion or duplicate

discounting.[2] Referring such issues to HHS is no answer: Covered entities in *Astra* argued that if any "difficult issues arise, they [could] be dealt with through primary jurisdiction referrals" to the federal agency. *Astra* Resp't's Merits Br. 51-52 (No. 09-1273). The Court rejected that argument in *Astra*, and it likewise fails here.[3]

2. The Eighth Circuit's decision also conflicts with *Arizona*, which underscores that state laws—like Act 1103—that interfere with a centralized federal enforcement scheme are preempted. Pet. 31-32.

Respondents contend that *Arizona* does not apply because Arkansas's law penalizes conduct that 340B simply "doesn't address." McClain BIO 20. Again, that is incorrect. 340B directly addresses manufacturers' obligations to provide 340B-priced drugs, including in the very *same* scenario implicated by Arkansas's law. *See supra* at 4-6. And, to be clear, instead of attempting to enact its own drug pricing program (which would present its own issues), Arkansas dictates what conditions a manufacturer may impose on the 340B offer, thereby changing the

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[2] Only manufacturers, authorized covered entities, and HHS have access to the 340B ceiling price for a particular drug. 42 U.S.C. §§ 256b(d)(1)(B)(iii), 1396r-8(b)(3)(D). *Astra* explained this limited access demonstrated "the incompatibility of private suits with the statute Congress enacted." 563 U.S. at 121. States similarly cannot access 340B ceiling price data, underscoring why State involvement is incompatible with 340B and *Astra*.

[3] Arkansas considered an regulation implementing such a deferral approach and removed it from the final version. *Compare* App.69a-70a, *with* App.65a; *see also* App.67a (explaining the removal of the deferral provision).

requirements of 340B participation. *See Arizona v. United States*, 567 U.S. 387, 400-01 (2012).

Even if Arkansas were correct that Act 1103 is penalizing different conduct, *Arizona* addresses that too. *See id.* at 403. There, Arizona "enact[ed] a state criminal prohibition where no federal counterpart exist[ed]," criminalizing an unauthorized alien applying for work. *Id.* Yet this Court held that the state statute was preempted. *Id.* at 406.

So too here. In crafting 340B, Congress provided when manufacturers were required to offer the 340B price and what that offer must include. *See supra* at 4-6. Congress also provided what was to be done with those drugs once purchased, barring each covered entity from "transfer[ring]" 340B-priced drugs to anyone but the entity's patients. 42 U.S.C. § 256b(a)(5)(B). And Congress did not include contract pharmacies in its lists of who could receive 340B-priced drugs or to whom covered entities were permitted to transfer such drugs. Arkansas's attempt to penalize manufacturers for conduct that Congress permitted under 340B runs afoul of *Arizona*.

Against that text, Arkansas suggests that Congress "reject[ed] a proposal that would have prohibited the use of contract pharmacies." McClain BIO 21. But as the Third Circuit explained in *Sanofi*, "Congress could have omitted the language [Arkansas references] because it did not want *any* contract pharmacy involved in the 340B program," which supports the exact opposite inference. 58 F.4th at 705. The best resource here is the statutory text and structure, which indicate that Congress did not intend for the unlimited use of contract pharmacies, much less mandate that manufacturers permit the use of an unlimited number. *Id.* at 704 ("Congress's

use of the singular 'covered entity' . . . suggests that it had in mind one-to-one transactions between a covered entity and a drug maker without mixing in a plethora of pharmacies.").

* * *

Act 1103—and the growing number of similar state laws—pose a clear threat to the viability of a vitally important federal program. At a minimum, they will subject the participants in that program to an unworkable enforcement regime in which up to 50 States may append 50 different enforcement schemes to the federal program. Even Respondents seem to recognize the question is *when,* not whether, this Court should intervene. Waiting will only needlessly heighten the risk to this critical federal program.

CONCLUSION

The petition for certiorari should be granted.

Respectfully submitted,

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