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

BRIEF OF *AMICUS CURIAE* KALDEROS, INC. IN SUPPORT OF PETITIONER

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INTEREST OF *AMICUS CURIAE*[1]

Kalderos, Inc. is a technology company. It has developed an equitable, easy-to-use platform designed to implement the federal 340B Drug Pricing Program, 42 U.S.C. § 256b (the "340B program" or "340B statute") on behalf of participating drug manufacturers and covered entities. Kalderos' platform helps both manufacturers and covered entities receive benefits and meet responsibilities under the 340B statute.

Kalderos submits this brief in support of the petition for a writ of certiorari because the decision below upsets the existing regulatory structure of the federal 340B program adopted by Congress. As explained by petitioner, Ark. Code Ann. § 23-92-604(c) ("Act 1103") conflicts with the federal scheme by undercutting the regulatory authority of the Health Resources and Services Administration ("HRSA"), which administers the 340B program on behalf of the Department of Health and Human Services ("HHS"). See Petition ("Pet.") 28–33 (citing *Astra USA, Inc.* v. *Santa Clara Cnty.*, 563 U.S. 110 (2011)); see also *Buckman Co.* v. *Plaintiffs' Legal Comm.*, 531 U.S. 341, 353 (2001) (preempting state law that "would exert an extraneous pull on the scheme established by Congress").

The decision below, if permitted to stand, would upset the careful balance created by Congress by approving a competing enforcement scheme that subjects 340B participants to distinct regulatory requirements

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[1] Pursuant to Rule 37.6, *amicus* affirms that no counsel for a party authored this brief in whole or in part and that no person other than *amicus* or its counsel made any monetary contributions intended to fund the preparation or submission of this brief. All parties were timely notified of the filing of this brief.

and penalties, notwithstanding that Congress has directed that the 340B program should be administered "harmoniously and on a uniform, nationwide basis" solely by HHS. *Astra*, 563 U.S. at 120.

The Eighth Circuit's approval of Act 1103 likewise opens the door to other state laws that contain requirements different from those authorized by Congress (and from those adopted by other states), and thereby undercuts the proper operation of the 340B program. See *Engine Mfrs. Ass'n* v. *S. Coast Air Quality Mgmt. Dist.*, 541 U.S. 246, 255 (2004) ("[I]f one State or political subdivision may enact" standards that alter Congress's program, "then so may any other; and the end result would undo Congress's carefully calibrated regulatory scheme.").[2]

BACKGROUND

Amicus adopts the background set forth in the petition, and highlights additional facts regarding Kalderos' role within the 340B program that are relevant to the Court's decision whether to grant plenary review.

1. Beginning in 2016, Kalderos sought to fix a broken 340B program. Covered entities expressed concerns that they do not receive the 340B pricing they are entitled to from manufacturers, and manufacturers expressed concerns that, because of a lack of transparency, 340B drugs are being diverted and manufacturers are forced to pay duplicate discounts in violation of federal law. See 42 U.S.C. § 256b(a)(5). To address these issues, Kalderos sought to be an honest

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[2] As petitioner has explained, in addition to Arkansas, seven other states (Kansas, Louisiana, Maryland, Minnesota, Mississippi, Missouri, and West Virginia) have enacted similar laws. *See* Pet. 14–15 & n.4, 22–23, 34. Further, twenty-two other states have or are considering similar laws. *Id.* at 15, 23, 34.

broker between covered entities and manufacturers. Kalderos evaluated solutions based on their ability to give covered entities easy access to 340B pricing, while ensuring there are mechanisms to identify violations of the 340B statute's requirements.

Specifically, the 340B statute obligates manufacturers to offer a discounted price for certain drugs to covered entities. 42 U.S.C. § 256b(a)(1). In turn, the 340B statute prohibits covered entities from transferring such drugs "to a person who is not a patient" of the covered entity or from seeking a duplicate discount or rebate. *Id.* § 256b(a)(5)(A), (B). Indeed, the 340B statute defines "covered entity" as an "entity that meets the requirements in paragraph (5)," that is, an entity that is not engaged in diversion and not seeking a duplicate discount. Kalderos' approach of ensuring that the rights of manufacturers and covered entities are respected properly reflects the balance at the core of the 340B statute.

2. With these principles in mind, Kalderos has worked with stakeholders to address duplicate discounts and diversion. Kalderos has estimated that there are Medicaid duplicate discounts of up to $1.6 billion annually—and this estimate does not include additional duplicate discounts or instances of diversion that would be identified using claims data.[3] Kalderos has endeavored to address 340B program compliance concerns, including those created by contract pharmacies, through "good faith" inquiries to covered entities.

Consistent with federal guidance from HRSA, Kalderos looked to identify "customary business practices"

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[3] *See* Kalderos, *2021 Annual Report* (2021), at 17, https://www.kalderos.com/2021-annual-report.

involving "request[s] for standard information" that are part of "contract provisions," *Final Notice Regarding Section 602 of the Veterans Health Care Act of 1992 Entity Guidelines*, 59 Fed. Reg. 25,110, 25,114 (May 13, 1994), in agreements between manufacturers and health plans, pharmacy benefit managers, hospitals, pharmacies, and state Medicaid agencies. Based on these customary practices, Kalderos developed an electronic platform to administer 340B transactions. Covered entities use Kalderos' platform to share a limited number of data elements when they request a 340B price. The covered entities provide to Kalderos the drug's prescription number, the prescriber identification number, and other limited information, similar to the standard information used by covered entities to purchase drugs and submit claims for reimbursement. This information allows Kalderos to identify and prevent duplicate discounts and diversion.[4]

3. Kalderos' platform facilitates the operation of the federal 340B program within the regulatory framework established by Congress. Kalderos' platform depends upon the receipt of data from both sets of stakeholders, including sales and pricing information from manufacturers and standard data sets from covered entities relating to the products covered entities have purchased and for which they request the discounted 340B price. With these data, the Kalderos platform flags potential diversion and/or duplicate discounts

[4] An example illustrates how Kalderos' platform averts duplicate discounts. A covered entity submits a request for the 340B discount price, provides the requested claims data and receives payment. Several months later, a state Medicaid agency submits an invoice for a Medicaid rebate. Kalderos matches the earlier paid 340B discount to the Medicaid rebate request and informs the manufacturer that it can deny the Medicaid rebate because it would be a duplicate discount.

and ensures that the 340B price is extended to eligible covered entities. The platform is a "win-win" that reflects the statutory balance at the core of the 340B program.[5] Kalderos' system achieves the balance reflected in the statute—in a manner that is fair to manufacturers and covered entities alike.

SUMMARY OF ARGUMENT

Review should be granted to decide whether Arkansas and other states are free to add restrictions and impose a parallel enforcement mechanism over the operation of the federal 340B program.

First, the Eighth Circuit's decision holding that Arkansas Act 1103 is not preempted by federal law cannot be reconciled with decisions of the D.C. Circuit and Third Circuit. The Eighth Circuit held that Arkansas is free to impose restrictions on the 340B program, but both the D.C. Circuit and the Third Circuit ruled that the imposition of such conditions on the 340B program is not in keeping with the statute enacted by Congress. See *Novartis Pharms. Corp.* v. *Johnson*, 102 F.4th 452, 460 (D.C. 2024) (ruling that Congress intended to allow "private parties" to "act freely" with respect to delivery conditions); *Sanofi Aventis U.S., LLC* v. *HHS*, 58 F.4th 696, 707 (3d Cir. 2023) (striking down agency's imposition of conditions that "overstepped the statute's bounds"). State law that limits discretion that Congress intended private parties to exercise

[5] The data that Kalderos utilizes are routinely secured in determining price concessions for managed care, pharmacy benefit manager, pharmacy, hospital, physician, and group purchasing organization customers, and to seek reimbursement from payors, including Medicare and Medicaid. Contract pharmacies, in fact, must submit this (and additional) information to all third-party payors to secure payment for the 340B drugs they dispense.

within the 340B program conflicts with federal law under this Court's precedent. Moreover, that result cannot be avoided through a presumption against preemption as that canon is inapplicable to efforts by states to regulate the elements of a federal program.

Second, allowing Arkansas and other states to alter the metes and bounds of the 340B program conflicts with this Court's decision holding that Congress intended that the 340B program be administered solely by HHS, thus ensuring that the program is implemented "harmoniously and uniformly." *Astra*, 563 U.S. at 120. The restrictions adopted by Arkansas and other states would deny HHS centralized authority over the 340B program, would create a patchwork of differing compliance standards throughout the country, and would prevent efforts by regulated parties to implement solutions to the manifest problems that have plagued the 340B program.

ARGUMENT

I. THE DECISION BELOW CANNOT BE RECONCILED WITH THE DECISIONS OF THE D.C. CIRCUIT AND THE THIRD CIRCUIT.

The Eighth Circuit's conclusion that Act 1103 is not preempted by the 340B statute is fundamentally at odds with the interpretation of the 340B statute by the D.C. Circuit and Third Circuit. Under the Eighth Circuit's construction, Arkansas and other states across the country would be free to impose restrictions and additions to the federal 340B program that the D.C. and Third Circuits have held cannot be imposed by the federal agency chosen by Congress to administer the 340B program "harmoniously and on a uniform, nationwide basis." *Astra*, 563 U.S. at 120.

In *Novartis Pharmaceuticals Corp.* v. *Johnson*, the D.C. Circuit rejected HRSA's position that the 340B

statute categorically prohibits drug manufacturers from imposing any conditions on their offers to covered entities under the 340B program. See 102 F.4th at 463. According to HRSA, "[n]othing in the 340B statute grants a manufacturer the right to place conditions on its fulfillment of its statutory obligation to offer 340B pricing on covered outpatient drugs purchased by covered entities." *Id.* at 459. The D.C. Circuit rejected that position both because it would "produce absurd consequences" and because the 340B statute cannot be read "to subject manufacturers to whatever delivery conditions any covered entity might find most convenient." *Id.* at 461. Specifically, the D.C. Circuit rejected HRSA's position that it could prohibit a drug manufacturer from requiring a covered entity to provide "claims data," which the record reflected imposed only a "minimal" burden on the covered entity and which was supported by HRSA's earlier interpretations of the 340B statute. *Id.* at 463.

Analyzing the text of the 340B statute, the court held that Congress's "silen[ce] about delivery conditions" "preserves—rather than abrogates—the ability of sellers to impose at least some delivery conditions" because "statutory silence implies that private parties may act freely." *Id.* at 460. The D.C. Circuit relied on this Court's decision in *Christensen* v. *Harris County*, 529 U.S. 576 (2000), where the Court rejected the argument that the Fair Labor Standards Act prohibits employers from imposing certain contractual conditions on employees because the statute does not expressly permit such conditions. In *Christensen*, this Court explained that such an argument has it "exactly backwards" because statutory silence does not prohibit otherwise lawful conduct. *Id.* at 588. Applying *Christensen* to the 340B statute, the D.C. Circuit held that

Congress's "[s]tatutory silence implies that manufacturers *may* impose distribution conditions by contract." *Novartis*, 102 F.4th at 460 (emphasis in original).

Adopting the same construction of the 340B statute, the Third Circuit likewise rejected HRSA's attempt to restrict the ability of manufacturers to impose any conditions on their offer to provide covered outpatient drugs to covered entities under the 340B program. *Sanofi*, 58 F.4th 696. The Third Circuit observed that the text of the 340B statute is "silent about delivery," *id.* at 703, and, relying on *Christensen*, it too concluded that this statutory silence—the fact that Congress did not prohibit delivery conditions by manufacturers—means that "the drug makers' policies" that impose such conditions "are lawful," *id.* at 704; see also *id.* at 699, 704 (recognizing that Congress "impose[d] only a price term for drug sales to covered entities, leaving all other terms blank," and that "when Congress's words run out," courts "must resist the urge to fill in words"). The Third Circuit held that HRSA "overstepped the statute's bounds" by interpreting it to prevent manufacturers from imposing any conditions on their offer of outpatient drugs to covered entities under the 340B program. *Id.* at 707.

The Eighth Circuit's construction of the 340B statute is fundamentally at odds with the decisions of these other circuits. In analyzing the preemption issue before it, the Eighth Circuit failed to recognize that Congress intended to allow conditions on the offer of outpatient drugs under the 340B program. The divergence in statutory interpretation is evident in two aspects of the Eighth Circuit's decision.

First, the D.C. Circuit and Third Circuit decisions underscore the Eighth Circuit's erroneous holding that

Act 1103 is not preempted by federal law. The Supremacy Clause provides that federal law "shall be the supreme Law of the Land," U.S. Const. art. VI, cl. 2, and state law that conflicts with federal law is "without effect," *Mut. Pharm. Co.* v. *Bartlett*, 570 U.S. 472, 475 (2013); see also *PLIVA, Inc.* v. *Mensing*, 564 U.S. 604, 617 (2011) ("[w]here state and federal law directly conflict, state law must give way"). A conflict exists where state law "stands as an obstacle to the accomplishment and execution of the full purposes and objectives of Congress." *Hines* v. *Davidowitz*, 312 U.S. 52, 67 (1941). The "ultimate touchstone" of preemption analysis is Congressional intent. *Cipollone* v. *Liggett Grp., Inc.*, 505 U.S. 504, 516 (1992).

Under the interpretation of the 340B statute adopted by the D.C. and Third Circuits, there is a clear conflict between the 340B statute and Act 1103. These circuits held that HRSA's effort to prevent manufacturers from imposing any and all conditions on 340B purchases was contrary to Congress's intent under the 340B statute, namely, that stakeholders "*may* impose distribution conditions by contract." *Novartis*, 102 F.4th at 460 (emphasis in original). Act 1103, which directly regulates the actions of pharmaceutical manufacturers under the 340B program, provides that manufacturers *may not* impose certain conditions on 340B transactions.[6] In other words, Act 1103 prohibits

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[6] Act 1103, codified at Ark. Code Ann. § 23-92-604(c), provides:

> A pharmaceutical manufacturer shall not:
>
> (1) Prohibit a pharmacy from contracting or participating with an entity authorized to participate in 340B drug pricing by denying access to drugs that are manufactured by the pharmaceutical manufacturer; or
>
> (2) Deny or prohibit 340B drug pricing for an Arkansas-based community pharmacy that receives drugs purchased under a

actions by drug makers that Congress intended to allow. That is a direct and incontestable conflict under this Court's federal preemption decisions.

This Court has applied conflict preemption to strike down state laws that similarly bar conduct or choices that federal law intended to preserve. For example, in *Fidelity Fed. Sav. & Loan Assn.* v. *De la Cuesta*, 458 U.S. 141, 156 (1982), this Court held that a federal regulation that permitted, but did not require, national banks to include certain debt accelerating clauses preempted a state law that prohibited the exercise of such clauses at the lender's option because it limited "the availability of an option" deemed "essential" under federal law. Similarly, in *Lawrence County* v. *Lead-Deadwood School District*, 469 U.S. 256, 263 (1985), this Court held that a federal law providing that local government units "may" expend federal funds for any purpose preempted a state law that restricted the expenditure of those funds because Congress intended that local governments (i) "receive adequate amounts of money" and (ii) have "the freedom and flexibility to spend the federal money as they saw fit." Finally, in *Geier* v. *American Honda Motor Co.*, 529 U.S. 861 (2000), this Court held that federal law preempted a state law that required installation of airbags in all cars because it "stood 'as an obstacle to the accomplishment and execution of' . . . important means-related federal objectives," namely, a more flexible approach to safety requirements that allowed manufacturers to utilize a "variety and mix of [safety] devices" including passive restraints. *Id.* at 881 (quoting *Hines*, 312 U.S. at 67).

340B drug pricing contract pharmacy arrangement with an entity authorized to participate in 340B drug pricing.

The Eighth Circuit ruled that there was no conflict because it concluded that Act "1103 assists in fulfilling the purpose of 340B." Pet. App. 14a. That conclusion is irreconcilable with the other circuits' construction of the 340B statute. The D.C. and Third Circuits concluded, based on the statute's text, that one of Congress's purposes is to allow stakeholders to make their own choices about conditions relating to the offer of covered drugs under 340B. These other circuits therefore held that HRSA, the implementing federal agency, "overstepped" its bounds and acted unlawfully when it barred certain contract conditions. *Sanofi*, 58 F.4th at 707. Under that view, Arkansas's attempt in Act 1103 to prohibit certain conditions likewise stands as an obstacle to—and does not "fulfill[ ]"—Congress's purpose and is therefore preempted.

Second, the divergent views of the circuits are confirmed by the Eighth Circuit's improper reliance on the presumption against preemption. This Court has held that when "Congress legislate[s] . . . in a field which the States have traditionally occupied," courts must "start with the assumption that the historic police powers of the States were not to be superseded by the Federal Act unless that was the clear and manifest purpose of Congress." *Rice* v. *Santa Fe Elevator Corp.*, 331 U.S. 218, 230 (1947) (citations omitted). The Eighth Circuit reasoned that "[p]harmacy has traditionally been regulated at the state level, and [it] must assume that absent a strong showing that Congress intended preemption, state statutes that impact health and welfare are not preempted." Pet. App. 13a.

The presumption against preemption does not apply here, however. Act 1103 is not a generally applicable regulation of pharmacy that Arkansas adopted pursuant to its traditional police powers. Instead, Act

1103—tellingly entitled the "340B Drug Pricing Nondiscrimination Act," see Pet. 13—directly regulates the conduct of drug makers under, and only under, the 340B program. See Ark. Code Ann. § 23-92-604(c) (providing that "[a] pharmaceutical manufacturer shall not" take certain actions with respect to "340B drug pricing" or "a 340B drug pricing contract pharmacy arrangement").

The presumption against preemption does not allow states to interfere with the operation of a federal program, which is precisely what Act 1103 is designed to do. See, *e.g.*, *United States* v. *Locke*, 529 U.S. 89, 108 (2000) ("an assumption of nonpreemption is not triggered when the State regulates in an area where there has been a history of significant federal presence") (internal quotation omitted); *Buckman*, 531 U.S. at 347 (rejecting a presumption against preemption for state-law fraud-on-the-FDA claims on the ground that "the relationship between a federal agency and the entity it regulates is inherently federal in character because the relationship originates from, is governed by, and terminates according to federal law"). Under these precedents, the Eighth Circuit should not have applied a presumption against preemption. The relationship between HHS and the drug manufacturers it regulates is "inherently federal in character" because it originates in and is governed by the 340B program, which is wholly a product of federal law.

The Eighth Circuit's invocation of the presumption against preemption also underscores the conflict in the circuits' interpretation of the 340B statute. After discussing pharmacy as an area of traditional state regulation, the Eighth Circuit concluded that "Congressional silence on pharmacies in the context of 340B reflects that Congress did not intend to preempt the field." Pet. App. 12a. This indicates that the Eighth

Circuit viewed Congress's silence on delivery conditions in the 340B statute as a gap or void that states are at liberty to fill by prohibiting manufacturers from imposing certain delivery conditions. That is not the view of the other circuits. As shown, their view is that Congress created certain express obligations on drug manufacturers under the 340B program, but that its "silence" on other issues such as delivery conditions leaves manufacturers to "act freely" and thereby "preserves . . . the ability of sellers to impose at least some delivery conditions." *Novartis*, 102 F.4th at 460. Under the other circuits' view, therefore, Congress left no gap to fill because it wrote a statute providing that "manufacturers *may* impose distribution conditions by contract." *Id.* (emphasis in original).

The circuits' interpretations of the 340B statute squarely conflict and will produce inconsistent results based on the vagary of where litigants bring their suits. This Court can and should restore uniformity.

II. REVIEW IS WARRANTED BECAUSE THE DECISION BELOW THREATENS TO RENDER THE 340B PROGRAM UNWORKABLE.

The issue presented by the petition is important and merits review because the Eighth Circuit's ruling, if permitted to stand, would have a significant adverse impact on the 340B program across the country. Under the Eighth Circuit's ruling, states would have free rein to reset the balance adopted by Congress by imposing restrictions on the operation of the 340B program that both the D.C. Circuit and Third Circuit have concluded that Congress did not authorize. Congress intended a national, uniform program overseen by HHS that provides covered entities with the 340B price, while protecting manufacturers from duplicate discounts and diversion. The Eighth Circuit's decision tramples on

Congress's balanced approach by allowing states to restrict the ability of stakeholders to adopt conditions necessary to implement the core requirements of the 340B program.

1. The 340B program is the second largest federal prescription drug program.[7] As reported in congressional oversight hearings, the 340B program accounts for almost $54 billion in annual discounted sales. Moreover, the 340B program is intertwined with the federal Medicaid Drug Rebate Program, and therefore "adjudication of rights under one program must proceed with an eye towards any implications for the other." *Astra*, 563 U.S. at 120. For this reason, Congress intended that the 340B program and Medicaid both be overseen solely by HHS. *Id.* at 117 (explaining that, apart from HHS, Congress "assigned no auxiliary enforcement role to covered entities"). As this Court recognized, "centralized enforcement in [HHS]" is critically important because if HHS were "unable to hold the control rein, the risk of conflicting adjudications would be substantial." *Id.* at 120. This interconnection between the 340B program and other federal programs is even greater today with the new Medicare drug price negotiation program, the Medicare inflation rebates, and the Medicare discarded drug refund program, all of which must consider whether a drug dispense is a potential 340B drug.[8]

The Eighth Circuit's decision gives a green light to states to impose conditions and exercise enforcement

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[7] *See Subcommittee Chair Griffith Opening Remarks at Oversight Hearing on the 340B Program* (June 4, 2024), https://tinyurl.com/ytx3s8xr.

[8] *See*, *e.g.*, 42 U.S.C. § 1320f-2(d) (Inflation Reduction Act); CMS, *Medicare Drug Price Negotiation Program Draft Guidance* at 1, 49 (May 3, 2024), https://tinyurl.com/yc4s8txy.

authority over the 340B program, contrary to what Congress has authorized in the 340B statute. A growing number of states have enacted statutes that regulate and impose restrictions on the operation of the 340B program that are distinct from limitations actually intended by Congress. The statutes include vague language prohibiting conduct that "interfere[s] with" or "limit[s]" the "acquisition of a 340B drug." See Ark. Code Ann. § 23-92-604(c); Md. Code Ann., Health Occ. § 12-6C-09.1(c)(1). Some of these state laws targeting the 340B program impose restrictions solely on manufacturers. *E.g.*, Ark. Code Ann. § 23-92-604(c); S.B. 28, 90th Leg., 2024 Reg. Sess. (Kan. 2024); Md. Code Ann., Health Occ. § 12-6C-09.1(c)(1); H.F. 4991, 93d Leg., 2d Reg. Sess. (Minn. 2024). Other states also impose such restrictions on (1) distributors, La. Rev. Stat. § 40:2884 (2024); H.B. 728, 139th Leg., 2024 Reg. Sess. (Miss. 2024); (2) agents or affiliates of a manufacturer, S.B. 325, 2024 Leg., Reg. Sess. (W. Va. 2024); S.B. 751, 102d Gen. Assemb., 2d Reg. Sess. (Mo. 2024), or (3) third-party logistics providers, *id.*

Likewise, the state laws green-lighted by the Eighth Circuit's decision offer a dizzying array of compliance and enforcement remedies. Thus, a violation of these state laws targeting the 340B program exposes a regulated party to a civil fine of up to (1) one thousand dollars in Missouri, see S.B. 751, 102d Gen. Assemb., 2d Reg. Sess. (Mo. 2024), (2) five thousand dollars in Arkansas, Louisiana and Maryland, see Ark. Code Ann. §§ 23-92-604(c), 23-66-210(a)(1); La. Rev. Stat. Stat. Ann. §§ 40:2885, 51:1406 (2024); Md. Code, Health Occ. § 12-6C-09.1(d)(2)(i), (3) ten thousand dollars in Mississippi, H.B. 728, 139th Leg., 2024 Reg. Sess. (Miss. 2024), and (4) fifty thousand dollars in West Virginia, S.B. 325, 2024 Leg., Reg. Sess. (W. Va. 2024). Regulated parties also run the risk of license

suspension and revocation, and, in Kansas and Missouri, the state laws create a private right of action to enforce each of their restrictions on the 340B program, S.B. 28, 90th Leg., 2024 Reg. Sess. (Kan. 2024); S.B. 751, 102d Gen. Assemb., 2d Reg. Sess. (Mo. 2024). Finally, in Maryland, Mississippi and Missouri, the state statutes directed at the federal 340B program call for criminal penalties. Md. Code Ann., Health Occ. § 12-6C-09.1(d)(1)(i)(1) (referencing Title 13 of Commercial Law Article, which includes Md. Comm. Law § 13-411(a) (criminal penalties)); H.B. 728, 139th Leg., 2024 Reg. Sess. (Miss. 2024); S.B. 751, 102d Gen. Assemb., 2d Reg. Sess. (Mo. 2024). This patchwork of differing legal requirements is the antithesis of the centralized enforcement structure envisioned by Congress.

2. Any state law that restricts the collection of claims data is of particular concern. For example, one recently-enacted statute provides that "[a] manufacturer, agent, or affiliate of such manufacturer shall not, either directly or indirectly, require a 340B entity to submit any claims or utilization data as a condition for allowing the acquisition of a 340B drug by, or delivery of a 340B drug to, a 340B entity unless the claims or utilization data sharing is required by the United States Department of Health and Human Services." See W. Va. Code § 60A-8-6a(b)(2).

That state-law requirement conflicts with federal agency guidance. In 1994, soon after the 340B statute was enacted, HRSA itself interpreted the 340B statute to allow "customary business practice[s]," including "request[s for] standard information," or otherwise "appropriate contract provisions." 59 Fed. Reg. at 25,114. Under the Eighth Circuit's ruling, however, a state could prohibit such standard business practices by characterizing them as a restriction on "delivery" and "distribution." Pet. App. 8a ("[T]he 340B Program

'is silent about delivery' and distribution of pharmaceuticals to patients." (quoting *Sanofi*, 58 F.4th at 703)).

Moreover, state-imposed restrictions on the collection of claims data would critically undermine the operation of the 340B program. Under the 340B statute, a covered entity may not resell or transfer 340B drugs "to a person who is not a patient of the entity." See 42 U.S.C. § 256b(a)(5)(B). Thus, as explained in *Sanofi*, "[Section 340B] bans diversion: covered entities can sell 340B drugs to only their own patients." 58 F.4th at 700. Likewise, the 340B statute prohibits "duplicate discounts or rebates." 42 U.S.C. § 256b(a)(5)(A). Compliance with these restrictions is fundamental to the 340B statute, which (i) requires manufactures to "offer" the "ceiling price" for "covered outpatient drugs" to "each covered entity," *id.* § 256b(a)(1), but (ii) defines "covered entity" to exclude those entities that are violating the prohibition against duplicate discounts or engaged in drug diversion "to a person who is not a patient of the entity," *id.* § 256b(a)(4), (5)(B). A state-law restriction preventing the collection of claims data would prevent stakeholders from implementing these structural limits.

Kalderos has developed a platform to ensure that stakeholders properly can determine whether discounts on 340B drugs are owed. Kalderos' platform depends on the receipt of limited claims data, which are essential for all phases of the Section 340B program. They are essential on the front end of 340B transactions because 340B identifiers and other data make it possible for manufacturers to determine eligibility and calculate the 340B price, which requires that the 340B transactions be identified and excluded from the underlying component prices of Average Manufacturer

Price and best price. 42 C.F.R. § 447.504(c)(1); *id.* § 447.505(c)(2).

Claims data requirements are also essential on the back end. Without claims data, manufacturers cannot comply with Section 340B's quarterly price reporting requirements and HHS cannot conduct the statutory audits. See 42 U.S.C. § 256b(a)(1), (a)(5)(C). Further, claims data requirements do not impose additional costs on covered entities because payors, pharmacy benefit managers, third-party administrators, and others already require covered entities to maintain and supply the relevant information. See *Novartis*, 102 F.4th at 463 (recognizing that "the 1994 Guidance itself" opined that manufacturers may require "claims data" from covered entities). Indeed, HRSA requires that covered entities maintain these same records to ensure that they are in compliance with the 340B statute's requirements. HRSA, *Notice Regarding 340B Pricing Program–Contract Pharmacy Services*, 75 Fed. Reg. 10,272, 10,274 (Mar. 5, 2010) ("Covered entities are required to maintain auditable records sufficient to demonstrate continued compliance with 340B requirements").

Consistent with their view that Section 340B allows manufacturers to act freely in imposing delivery conditions, the D.C. and Third Circuits have held that the statute permits stakeholders to impose conditions, including a requirement to provide standard information necessary to facilitate a 340B transaction, that are consistent with the text, structure, and purpose of the statute. See *Sanofi*, 58 F.4th at 704 (explaining that drug makers' policies, including requirement to provide claims data, are "lawful" because 340B "imposes only a price term for drug sales to covered entities"); *Novartis*, 102 F.4th at 459 (holding that a manufacturer's requirement that contract pharmacies provide

claims data for their orders did "not violate section 340B"). In contrast, under the Eighth Circuit's view, any state could impose added restrictions on the 340B statute that Congress did not intend. Because claims data are essential to the operation of the 340B program, the decision below therefore could cripple the proper operation of the program. And, as petitioners explained, a patchwork of potentially conflicting rules on claims data and other conditions would pose a compliance nightmare for all participating entities. See Pet. at 30.

3. This patchwork of state-law restrictions would interfere with federal regulatory oversight designed to ensure that (i) covered entities receive 340B discount pricing where appropriate and (ii) the prohibitions on duplicate discounts and diversion are followed. For example, before a covered entity can order a 340B product, it must provide data in connection with its order, including its unique 340B identifier. HRSA has approved and posts on its website scores of examples of conditions on 340B transactions, including the distribution of 340B drugs, that have been approved by the agency.[9]

Allowing states to impose their own restrictions on the 340B program would undermine HHS's ability to maintain the "control rein" over the federal 340B program and administer it "on a uniform, nationwide basis." *Astra*, 563 U.S. at 120; see *Engine Mfrs. Ass'n*, 541 U.S. at 255 ("[I]f one State or political subdivision may enact" rules that frustrate Congress's goals, "then so may any other; and the end result would undo Congress's carefully calibrated regulatory scheme.").

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[9] *See* HRSA, HHS, *Manufacturer Notices to Covered Entities*, https://www.hrsa.gov/opa/manufacturer-notices (last updated Aug. 2024).

CONCLUSION

For these reasons, and those stated by petitioner, the petition for a writ of certiorari should be granted.

Respectfully submitted,

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