No. 22-3675

In the United States Court of Appeals for the Eighth Circuit

PHARMACEUTICAL RESEARCH AND MANUFACTURERS OF AMERICA,

Plaintiff-Appellant,

v.

ALAN MCCLAIN, in his official capacity as Commissioner of the Arkansas Insurance Department

Defendant-Appellee,

COMMUNITY HEALTH CENTERS OF ARKANSAS; PIGGOTT COMMUNITY HOSPITAL,

Intervenors-Appellees.

On Appeal from the United States District Court for the Eastern District of Arkansas

Civil Action No.: 4:21-cv-864-BRW

BRIEF OF *AMICUS CURIAE* KALDEROS, INC. IN SUPPORT OF PLAINTIFF-APPELLANT AND REVERSAL

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CORPORATE DISCLOSURE STATEMENT

Pursuant to Federal Rule of Appellate Procedure 26.1 and Local Rule 26.1A of the United States Court of Appeals for the Eighth Circuit, Kalderos, Inc., states that it has no parent corporation and that no publicly held corporation owns 10% or more of any stock in Kalderos, Inc. Kalderos is a technology company that has developed an equitable, easy-to-use technology platform designed to implement the 340B program on behalf of covered entities and participating drug manufacturers.

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GLOSSARY

HHS	U.S. Department of Health and Human Services
HRSA	U.S. Health Resources and Services Administration
Section 340B	Section 340B of the Public Health Service Act, codified at 42 U.S.C. § 256b

INTEREST OF *AMICUS CURIAE*[1]

Kalderos, Inc. is a technology company. It has developed an equitable, easy-to-use technology platform designed to implement the federal 340B program on behalf of covered entities and participating drug manufacturers. Kalderos' platform facilitates both covered entities and pharmaceutical manufacturers receiving benefits and meeting their responsibilities under the 340B statute.

Kalderos is committed to addressing the issues and concerns articulated by covered entities and manufacturers that are impeding the operation of the 340B program. Covered entities express concerns that they do not receive the pricing they are entitled to from manufacturers, and manufacturers express concerns that, because of a lack of transparency into 340B transactions, 340B drugs are being diverted and they are forced to pay duplicate discounts in violation of federal law. Kalderos' platform facilitates the operation of the federal 340B program within the regulatory framework established by Congress. It does so by (1) ensuring that covered entities receive the discounted price required by statute, and (2) helping participants identify and reduce prohibited diversion and duplicate discounts.

[1] No party's counsel authored this brief in whole or in part, and no party, its counsel, or other person—other than Kalderos or its counsel—contributed money to fund preparation or submission of this brief. *See* Fed. R. App. P. 29(a)(4)(E).

Kalderos' platform depends upon its ability to receive 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 claim the discounted 340B price. With these data, the Kalderos platform flags potential diversion and/or duplicate discounts and ensures that the 340B price has been extended to eligible covered entities. The platform is a "win-win" that reflects the statutory balance at the core of the 340B program.

Kalderos submits this brief in support of the petition for rehearing en banc because the decision below upsets the existing regulatory structure of the federal 340B program adopted by Congress. As explained by Plaintiff-Appellant, Act 1103 conflicts with the federal scheme by undercutting HRSA's regulatory authority over the 340B program. PhRMA Petition 1-4 (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) (holding state-law claims preempted because they "would exert an extraneous pull on the scheme established by Congress").

While acknowledging that Act 1103 creates a competing regulatory regime over a federal program enacted by Congress, the panel opinion concludes that Act 1103 is "aimed at activity that falls outside the purview of 340B" but that it simultaneously "fulfill[s] the purpose of 340B." Op. 11. As discussed below, the panel's analysis of the 340B program's scope and how it operates in practice is mistaken in

material respects, including its assertion that the 340B statute governs pricing but does not address the distribution of 340B drugs.

As a result, the panel decision, 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 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 panel's approval of Act 1103 likewise opens the door to other State laws, reflecting requirements different from those authorized by Congress, 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]

[2] In addition to Arkansas, three other states have enacted similar laws. La. Stat. Ann. §§ 2881–2886 (2024); H.B. 728, 139th Leg., 2024 Reg. Sess. (Miss. 2024) (enacted); S.B. 325, 2024 Leg., Reg. Sess. (W. Va. 2024) (enacted). Bills are awaiting governors' decisions in Kansas and Maryland. S.B. 28, 90th Leg., 2024 Reg. Sess. (Kan. 2024); H.B. 1056, 446th Sess. Gen. Assemb. (Md. 2024). In Virginia, the governor returned a proposed bill to the legislature. S.B. 119, 2024 Reg. Sess. (Va. 2024). One legislative chamber has passed such restrictions in Kentucky and Massachusetts. S.B. 27, 2024 Reg. Sess. (Ky. 2024); S.B. 2520, 193d Gen. Court (Mass. 2024). Finally, similar bills have been introduced in sixteen other states. *See* S.B. 1251, 56th Leg., 2d Reg. Sess. (Ariz. 2024); S.B. 8, Gen. Assemb., 2024 Feb. Sess. (Conn. 2024); S.B. 1608, 126th Reg. Sess. (Fla. 2024); H.B. 671, 67th Leg., 2d Reg.

ARGUMENT

I. THE PANEL DECISION IS BASED UPON A MISTAKEN VIEW OF THE OPERATION OF THE 340B PROGRAM.

Kalderos is concerned that the panel decision misunderstands the operation of the 340B Program. Kalderos' extensive experience as a data technology company operating in the 340B program environment for over 8 years has given it unique insights into the program's operations.

First, the panel stated that "the 340B Program 'is silent about delivery' and distribution of pharmaceuticals *to patients*." Op. 7 (quoting *Sanofi-Aventis US, LLC v. US Dep't HHS*, 58 F.4th 696, 703 (3d Cir. 2023)) (emphasis added). That statement misreads the 340B statute and the Third Circuit's decision in *Sanofi*. The 340B statute plainly imposes requirements concerning delivery and distribution of drugs "***to patients***." 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). As explained in *Sanofi*, "[Section 340B] bans diversion: covered entities can sell 340B drugs to only their own patients." 58 F.4th at 700. Thus, the

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Sess. (Idaho 2024); S.B. 3727, 103d Gen. Assemb., 2d Reg. Sess. (Ill. 2024); H.S.B. 590, 90th Gen. Assemb., 2024 Sess. (Iowa 2024); H.B. 5350, 102d Leg., 2024 Reg. Sess. (Mich. 2023); H.F. 4991, 93d Leg., 2d Reg. Sess. (Minn. 2024); S.B. 751, 102d Gen. Assemb., 2d Reg. Sess. (Mo. 2024); L.B. 984, 108th Leg., 2nd Sess. (Neb. 2024); A.B. 7789, 246th Leg. Sess. (N.Y. 2024); S.B. 1628, 59th Leg., Reg. Sess. (Okla. 2024); H.B. 4010, 82d Leg. Assemb., 2024 Reg. Sess. (Or. 2024); H. 7879, 2024 Leg. Sess. (R.I. 2024); S. 1239, 125th Gen. Assemb., 2d Reg. Sess. (S.C. 2024); S.B. 256, 65th Leg., 2024 Gen. Sess. (Utah 2024).

340B statute does address distribution of 340B drugs "to patients" and imposes a significant limitation on distribution.[3]

Second, according to the panel, under the 340B program, "[p]harmacies do not purchase 340B drugs," Op. 10, and "[c]overed entities maintain legal title to the 340B drugs." Op. 7. That too is mistaken. As a number of federal courts have explained, under the "now-prevalent 'replenishment model,' pharmaceutical manufacturers ship prescription drugs to pharmacies for dispensing to all patients," and "[a]t the time of dispensing, the pharmacies do not know whether the prescriptions were written by medical providers at covered entities and qualify for 340B discounts." *AstraZeneca Pharms. LP v. Becerra*, 543 F. Supp. 3d 47, 61 n.19 (D. Del. 2021); *see Sanofi-Aventis US, LLC v. US Dep't HHS*, 570 F. Supp. 3d 129, 206 & n.63 (D.N.J. 2021) (describing replenishment model). Under this model, only "***[a]fter*** 340B eligibility is later determined (typically using an algorithm), the manufacturers process chargebacks to account for the 340B drugs' discounted prices." *AstraZeneca*, 543 F. Supp. 3d at 61 n.19 (emphasis added); *id.* ("The covered entities never physically possess the drugs.").[4]

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[3] The panel quoted *Sanofi*, but that court's statement that the 340B statute was "silent about delivery" addressed a separate issue, *i.e.*, whether 340B "requires drug makers to deliver drugs to an unlimited number of contract pharmacies." *Id.* at 703.

[4] Kalderos is aware that covered entities and contract pharmacies are utilizing a new claims purchasing model in which there is no shipment of a 340B drug. Instead, a distributor merely adds a credit to the contract pharmacy account and a debit to the covered entity account. The covered entity never has or maintains title.

Third, the panel tries to distinguish 340B pricing from the distribution of 340B drugs. It asserts that "[contract] pharmacies do not become beneficiaries of the 340B Program," Op. 7, and "do not receive the 340B price discounts," *id.* at 10, but instead merely provide covered entities "'a process for accessing 340B pricing' ***for patients***," *id.* at 7 (emphasis added). That, too, is not accurate. As noted by several courts, contract pharmacies "use the 340B program for profit, in particular *by declining to pass along drug discounts . . . to covered patients*." *Sanofi-Aventis*, 570 F. Supp. 3d at 205 & n.61 (emphasis added).

Finally, the panel opinion fails to consider the essential role of uniform, federal regulatory oversight required to ensure that (i) covered entities receive 340B discount pricing where appropriate and (ii) the prohibitions on duplicate discounts and diversion are followed. One critical aspect of the 340B program administered by HHS is its oversight of conditions through which participants implement the 340B program. Under that regulatory regime, HRSA has acknowledged and approved reasonable restrictions on delivery that reflect "customary business practice[s]," including "request[s for] standard information," or otherwise "appropriate contract provisions." 59 Fed. Reg. 25,110, 25,114 (May 13, 1994). Indeed, before it can order a 340B product, a covered entity must provide data in connection with

its order, including its unique 340B identifier.[5] 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.[6]

In fact, a number of courts have recognized that conditions, including data submission requirements, may be deployed to achieve legitimate objectives consistent with the 340B program. As the Third Circuit has held, the 340B statute permits stakeholders to introduce conditions, such as requiring standard information necessary to facilitate a 340B transaction, that are consistent with the text, structure, and purpose of the statute. *See Sanofi Aventis*, 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 Pharms. Corp. v. Espinosa*, No. 21-cv-1479, 2021 WL 5161783, at *7 (D.D.C. Nov. 5, 2021) (holding that Section 340B does not "*prohibit* manufacturers from placing *any* conditions on covered entities").

[5] Without data to identify these transactions, it would be impossible for manufacturers to calculate a 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).

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

II. THE PANEL DECISION CONFLICTS WITH CONTROLLING PRECEDENT ON AN ISSUE OF SURPASSING IMPORTANCE.

A. Arkansas Act 1103 Is 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," *Mutual Pharm. Co. v. Bartlett*, 570 U.S. 472, 475 (2013). State law is preempted where it "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). For the reasons set forth by Plaintiff, rehearing en banc should be granted because the panel decision conflicts with controlling precedent concerning the proper interplay between the 340B program adopted by Congress and Arkansas' adoption of a separate enforcement mechanism. *See* PhRMA Petition 1-4, 8-15.

Act 1103 also is preempted because it purports to regulate the scope of a federal program by imposing restrictions and authorizing penalties and equitable relief over and above what Congress has dictated for the 340B program. On this issue, the Supreme Court's decision in *Buckman Co. v. Plaintiffs' Legal Committee*, is instructive. There, the Supreme Court held that a state law that would have required a private party to provide additional information to a federal agency was preempted because "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." 531 U.S. at 347. The *Buckman* Court

explained that the state law impermissibly (i) "would exert an extraneous pull on the scheme established by Congress," *id.* at 353, (ii) would "conflict with [the agency's] responsibility" to administer federal law "consistently with the [agency's] judgment and objectives," *id.* at 350, and (iii) would "dramatically increase the burdens facing [regulated parties]" who must comply with "the [agency's] detailed regulatory regime in the shadow of 50 states'" laws. *Id.*

Here, too, Arkansas Act 1103 likewise upsets the balance struck by Congress when it enacted the 340B statute. Act 1103 would infringe on HHS's authority over the 340B program by imposing additional obligations on participants to the 340B program that would be policed by Arkansas. It would radically complicate compliance with the 340B program and destabilize the program to the extent it calls into question conditions that already have been approved by HHS based upon an argument that they might "***interfer[e]*** in a covered entity's agreement with a contract pharmacy." Op. 8.

Finally, there is no presumption against preemption where, as here, "'considerable federal interests' are at stake." *Bell v. Blue Cross & Blue Shield of Okla.*, 823 F.3d 1198, 1201 (8th Cir. 2016). Specifically, in *Bell*, this Court acknowledged that "health care in general is an area of traditional state regulation," but rejected any presumption against preemption because "th[e] dispute concerns benefits from a federal health insurance plan . . . that arise from a federal law." *Id.* at 1201–02. In the

same vein, Act 1103 grants Arkansas regulatory authority not over the "practice of pharmacy" as a general matter, but regulatory authority over participants in the federal 340B program, including state-law authority over conditions designed to ensure that 340B participants comply with the federal requirement to provide discounts to covered entities for eligible transactions, including the prohibitions against duplicate discounts and the diversion of 340B drugs.

B. The Panel Incorrectly Decided An Issue Of National Significance.

With respect to the items described in the 340B statutory balance—price and protection against duplicate discounts and diversion—Congress intended a national, uniform program. That national, uniform program is—without question—threatened by Act 1103. As discussed, the Arkansas statute fundamentally alters the balance of stakeholders' defined rights and responsibilities. *See Heckler v. Ringer*, 466 U.S. 602, 627 (1984) ("If the balance is to be struck anew, the decision must come from Congress and not from this court"). The threat to the national, uniform program enacted by Congress, moreover, is not limited to Arkansas. *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."). Other states, following Arkansas' lead, have enacted or proposed their own state-law amendments to the 340B statute. *See* note 2, *supra*.

Accordingly, the panel decision, if permitted to stand, could encourage states across the country to add their own addenda to the federal program adopted by Congress. Those revisions and amendments would exert an extraneous pull on the scheme established by Congress. Such a patchwork system would do what the Supremacy Clause says state law cannot: cast aside the Congress' statutory scheme and thwart its purposes and objectives.

CONCLUSION

For these reasons, and those stated by Plaintiff-Appellant, the petition for rehearing en banc should be granted.

Date: April 16, 2024

Respectfully submitted,

/s/ Paul J. Zidlicky

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CERTIFICATE OF COMPLIANCE WITH FEDERAL RULE OF APPELLATE PROCEDURE 32(a) AND LOCAL RULE 28A(h)

I hereby certify that this brief complies with the type-volume limitations of Federal Rules of Appellate Procedure 32(a)(7)(B) and 29(a)(5) because the brief contains 2,581 words, excluding the parts of the brief exempted by Federal Rule of Appellate Procedure 32(a)(7)(B)(iii).

I also certify that this brief complies with the typeface requirements of Federal Rule of Appellate Procedure 32(a)(5) and (6) because this brief was prepared using Microsoft Word 2016 in 14-point Times New Roman font.

Pursuant to Eighth Circuit Rule 28(A)(h), I further certify that Appellant's Brief and Addendum have been converted to Adobe PDF format by printing to Adobe PDF from the original word processing file, and has been provided to the Court and counsel for Appellees. The brief and Addendum have been scanned for viruses using a commercial virus scanning program, which reports the brief and Addendum to be virus free.

s/ Paul J. Zidlicky
Paul J. Zidlicky

Dated: April 16, 2024

CERTIFICATE OF SERVICE

I hereby certify that on April 16, 2024, a true and correct copy of the foregoing was timely filed with the Clerk of the Court using the appellate CM/ECF system, which will send notifications to all counsel registered to receive electronic notices.

Within five days of receipt of notice that the foregoing document has been filed, Kalderos will serve each party separately represented with a paper copy of its amicus brief.

I further certify that ten paper copies of Kalderos' Brief as amicus curiae will be provided to the Court within five days after receipt of notice that the foregoing document has been filed pursuant to Rule 28A(d).

/s/ Paul J. Zidlicky
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