

Nos. 21-3128, 21-3405

**In the United States Court of Appeals
for the Seventh Circuit**

ELI LILLY AND COMPANY, ET AL.

Plaintiffs-Appellants, Cross-Appellees,

v.

XAVIER BECERRA, ET AL.,

Defendants-Appellees, Cross-Appellants.

On Appeal from the United States District Court for the
Southern District of Indiana, No. 1-21-cv-00081-SEB-MJD
Hon. Sarah Evans Barker

**BRIEF OF *AMICUS CURIAE* KALDEROS, INC. IN SUPPORT OF
PLAINTIFFS-APPELLANTS/CROSS-APPELLEES AND REVERSAL**

ERIC D. MCARTHUR

Counsel of Record

WILLIAM A. SARRAILLE

PAUL J. ZIDLICKY

JACQUELYN E. FRADETTE

CHRISTOPHER S. ROSS

SIDLEY AUSTIN LLP

1501 K Street, N.W.

Washington, D.C. 20005

Telephone: (202) 736-8000

TREVOR L. WEAR

SIDLEY AUSTIN LLP

One South Dearborn

Chicago, IL 60603

Telephone: (312) 853-7000

June 1, 2022

Counsel for Amicus Curiae

APPEARANCE & CIRCUIT RULE 26.1 DISCLOSURE STATEMENT

Appellate Court No: Nos. 21-3128 & 21-3405

Short Caption: Elil Lilly & Co. & Lilly USA, LLC v. Xavier Becerra, et al.

To enable the judges to determine whether recusal is necessary or appropriate, an attorney for a non-governmental party, amicus curiae, intervenor or a private attorney representing a government party, must furnish a disclosure statement providing the following information in compliance with Circuit Rule 26.1 and Fed. R. App. P. 26.1.

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ii) list any publicly held company that owns 10% or more of the party's, amicus' or intervenor's stock:

None.

(4) Provide information required by FRAP 26.1(b) – Organizational Victims in Criminal Cases:

n/a

(5) Provide Debtor information required by FRAP 26.1 (c) 1 & 2:

n/a

Attorney's Signature: /s/ Eric D. McArthur

Date: June 1, 2022

Attorney's Printed Name: Eric D. McArthur

Please indicate if you are *Counsel of Record* for the above listed parties pursuant to Circuit Rule 3(d).

Yes No

Address: Sidley Austin LLP, 1501 K Street NW, Washington, DC 20005

Phone Number: (202)736-8000

Fax Number: (202)736-8711

E-Mail Address: emcarthur@sidley.com

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Attorney's Signature: /s/ William A. Sarraille Date: June 1, 2022Attorney's Printed Name: William A. SarraillePlease indicate if you are *Counsel of Record* for the above listed parties pursuant to Circuit Rule 3(d).Yes No Address: Sidley Austin LLP, 1501 K Street NW, Washington, DC 20005Phone Number: (202)736-8000Fax Number: (202)736-8711E-Mail Address: wsarraille@sidley.com

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n/a

Attorney's Signature: /s/ Paul J. Zidlicky Date: June 1, 2022

Attorney's Printed Name: Paul J. Zidlicky

Please indicate if you are *Counsel of Record* for the above listed parties pursuant to Circuit Rule 3(d).

Yes No

Address: Sidley Austin LLP, 1501 K Street NW, Washington, DC 20005

Phone Number: (202)736-8000

Fax Number: (202)736-8711

E-Mail Address: pzidlicky@sidley.com

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Attorney's Signature: /s/ Jacquelyn E. Fradette Date: June 1, 2022Attorney's Printed Name: William A. SarraillePlease indicate if you are *Counsel of Record* for the above listed parties pursuant to Circuit Rule 3(d). Yes No Address: Sidley Austin LLP, 1501 K Street NW, Washington, DC 20005Phone Number: (202)736-8000Fax Number: (202)736-8711E-Mail Address: jfradette@sidley.com

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Attorney's Signature: /s/ Christopher S. Ross Date: June 1, 2022

Attorney's Printed Name: Christopher S. Ross

Please indicate if you are *Counsel of Record* for the above listed parties pursuant to Circuit Rule 3(d). Yes No

Address: Sidley Austin LLP, 1501 K Street NW, Washington, DC 20005

Phone Number: (202)736-8000 Fax Number: (202)736-8711

E-Mail Address: christopher.ross@sidley.com

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Attorney's Signature: /s/ Trevor L. Wear Date: June 1, 2022

Attorney's Printed Name: Trevor L. Wear

Please indicate if you are *Counsel of Record* for the above listed parties pursuant to Circuit Rule 3(d). Yes No

Address: Sidley Austin LLP, One South Dearborn, Chicago, IL 60603

Phone Number: (312)853-7000

Fax Number: (312)853-7036

E-Mail Address: twear@sidley.com

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INTEREST OF *AMICUS CURIAE* AND SUMMARY OF ARGUMENT¹

Kalderos, Inc. is a technology company. It has developed an equitable, easy-to-use technology platform designed to implement the 340B program on behalf of covered entities and participating drug manufacturers. Kalderos’s platform (i) ensures 340B covered entities receive the 340B prices to which they are entitled (in a system that is configured to support any number of contract pharmacy relationships) and (ii) helps manufacturers identify duplicate discounts and diversion. Kalderos seeks to be an honest broker assisting both covered entities and manufacturers to secure the statutory benefits and protections Congress provided in Section 340B.

On October 6, 2021, Kalderos filed a challenge under the Administrative Procedure Act (“APA”) in the U.S. District Court for the District of Columbia, *Kalderos, Inc. v. United States*, No. 1:21-cv-02608. Kalderos challenged the new policy of the Health Resources and Services Administration (“HRSA”), contained in violation letters dated May 17, 2021, that all conditions placed by manufacturers on 340B transactions are unlawful—no matter how reasonable they are, and even if they are specifically designed to further the statutory prohibitions against duplicate discounts and diversion. Kalderos’s challenge includes HRSA’s letter to Eli Lilly &

¹ No party’s counsel authored this brief in whole or in part, and no party, its counsel, or any other person—other than Kalderos or its counsel—contributed money intended to fund preparation or submission of this brief. *See* Fed. R. App. P. 29(a)(4)(E). All parties have consented to this filing.

Company (“Eli Lilly” or “Lilly”).² Kalderos filed suit because the claims data it collects from covered entities under the 340B program are essential to Kalderos’s platform and to addressing the pervasive, government-acknowledged threats plaguing the 340B program. These data are customarily provided by customers seeking price concessions, are routinely provided by contract pharmacies to secure payment, and, as 20 years of industry experience have shown, are the minimum necessary to assess duplicate discounts and diversion in any meaningful way.

Although the district court did not consider whether manufacturers may condition their 340B offers on the provision of claims data, it ruled broadly that the 340B statute does not “permit drug manufacturers to impose extra-statutory conditions on covered entities’ access to discounted medications.” *Eli Lilly & Co. v. HHS*, No. 1:21-cv-00081-SEB-MJD, 2021 WL 5039566, at *20 (S.D. Ind. Oct. 29, 2021). That sweeping ruling would preclude manufacturers from requesting basic claims data.³ If manufacturers cannot require basic claims data, they will not enter into or continue with contracts with Kalderos for its service. Kalderos thus has a substantial

² The *Kalderos* lawsuit was filed as a related case to the *United Therapeutic* and *Novartis* cases. On November 5, 2021, Judge Friedrich granted summary judgment in favor of the manufacturers in those cases. The government appealed the summary judgment order, and the court stayed *Kalderos*’s case pending the appeal.

³ *Kalderos* notes that, in December of 2021, Lilly added an additional exception to its Bill To/Ship To policy that permits an unlimited number of contract pharmacy transactions where claims data are provided. *See Lilly Br. 24 n.7.*

interest in this matter. The district court's erroneous holding, which implicates a conflict among the lower courts on this issue, is a fundamental threat to Kalderos's business and the role it seeks to play as an honest broker to both covered entities and manufacturers.

HRSA's new policy prohibiting **all** manufacturer conditions is unlawful and must be set aside for two reasons. *First*, requiring covered entities to provide basic claims data is consistent with the text and purpose of the 340B statute. Nothing in the statutory text prohibits manufacturers from imposing reasonable terms and conditions on 340B sales. Moreover, requiring claims data serves Section 340B's purpose to prevent duplicate discounts and diversion and does not discriminate against covered entities or undermine their access to 340B pricing. *Second*, HRSA's new policy is arbitrary and capricious. The May 17 letters announcing the new policy are a clear, unacknowledged, and unexplained departure from past agency positions and practice. Accordingly, the Court should reverse the decision below to the extent it holds that all "extra-statutory" manufacturer conditions are unlawful, and make clear that nothing in Section 340B precludes manufacturers from requiring covered entities that wish to receive 340B discounted pricing to provide basic claims data.

BACKGROUND

A. The History of the 340B Statute

The 340B program, enacted in 1992, “was designed to fix a snafu created by the 1990 Medicaid Drug Rebate Program” (“MDRP”). W. Winegarten, Pac. Res. Inst., *Addressing the Problems of Abuse in the 340B Drug Pricing Program*, at 4 (Dec. 2017).⁴ Before the MDRP, manufacturers had long “offer[ed] safety-net providers ... large discounts on their purchases of medicines.” *Id.*; see also Fisher, *supra*, at 29 (“Prior to the MDRP, drug manufacturers regularly offered discounts to ... hospitals and other safety-net providers”). Because the MDRP included these voluntary “large discounts” in the calculation of “best price” for purposes of determining Medicaid rebates, the “unintended consequence” of this pricing “snafu” was that manufacturers were forced to “discontinu[e]” these discounts. Winegarten, *supra*, at 4; see also Fisher, *supra*, at 30. The problem created by Congress concerned only the pricing on these sales. No other terms associated with historical sales, such as their data requirements, were at issue.

⁴ See also N.C. Fisher, *The 340B Program: A Federal Program in Desperate Need of Revision*, 22 J. Health Care L. & Pol’y 25, 30 (2019) (“drug manufacturers were disincentivized to continue giving discounts on drugs” as an “unintended consequence from the MDRP”); D. Holtz-Eakin, *Oversight and Reform of the 340B Program*, Daily Dish (Oct. 10, 2017) (the 340B program is the “offspring of price controls in the Medicaid program”).

Having inadvertently cut off the large discounts that had historically been provided to safety-net providers, Congress enacted a “fix” that narrowly addressed the specific price issue that it had itself created. Under the 340B program, Congress required drug manufacturers to sell outpatient drugs at reduced prices to “covered entities”—the entities that had historically received the discounted prices. These 340B prices were made a condition for drugs to be covered by Medicaid, with a corresponding exemption of these prices from “best price” under the MDRP. *See* H.R. Rep. No. 102-384, pt. 2, at 12 (1992).

As the House Report to the 340B statute stated:

The Committee bill ... provides protection from drug price increases to specified Federally-funded clinics and public hospitals that provide direct clinical care to large numbers of uninsured Americans...[;] prices charged to these “covered entities” would be exempt from the calculation of the Medicaid “best price” for purposes of determining the Medicaid rebate. *The Committee expects that this exemption will remove any disincentive that the Medicaid rebate program creates to discourage manufacturers from providing substantial voluntary or negotiated discounts to these clinics, programs, and hospitals....*

Id. (emphasis added).

Recognizing that the original “snafu” had focused on how “unsustainable” it would be to require manufacturers to provide *both* a 340B price *and* a Medicaid rebate on the same drugs, Winegarden, *supra*, at 4, Congress prohibited such “duplicate discounts,” 42 U.S.C. §§ 256b(a)(5)(A)(i), 1396r-8(j)(1), as well as covered entity diversion, *id.* § 256b(a)(5)(B) (prohibiting reselling or otherwise transferring

340B drugs to any person not a patient of the covered entity). Further, having dealt with the specific pricing issue that its earlier legislation created, Congress did not risk creating any additional disruptions and left most aspects of the sales between manufacturers and covered entities to the parties. *See id.* § 256b(a)(1)–(2) (setting out manufacturer requirements narrowly addressing the “maximum price” covered entities may be required to pay and related pricing issues).

In keeping with the statute’s narrow focus on addressing the “price” associated with sales to 340B covered entities, but not most other aspects or conditions of those sales, the 340B statute only provides HRSA limited regulatory authority. Congress did not provide broad regulatory or “gap-filling” authority to HRSA to promulgate additional requirements for 340B sales, precisely because the statute had a limited scope and purpose. *See Sanofi-Aventis U.S., LLC v. HHS*, No. 21-634, 2021 WL 5150464, at *34 (D.N.J. Nov. 5, 2021) (recognizing that Congress did not authorize HRSA to make rules regarding the terms and conditions of 340B sales), *appeal docketed*, No. 21-3168 (3d Cir. Nov. 26, 2021); *see also PhRMA v. HHS*, 43 F. Supp. 3d 28, 45 (D.D.C. 2014) (discussing HRSA’s limited rulemaking authority). HRSA has acknowledged the limited nature of its regulatory authority. *See, e.g., T. Mirga, HRSA Says its Contract Pharmacy Guidance Is Not Legally Enforceable*, 340B Report (July 9, 2020), <https://340breport.com/hrsa-says-its-340b-contract-pharmacy/> (sub. req.) (HRSA conceding its “guidance is not legally enforceable”).

Although HRSA has asked Congress for “regulatory authority in the President’s Budget each year since FY 2017,”⁵ Congress has repeatedly declined to expand HRSA’s authority. Although HRSA has nevertheless historically asserted—without citing any authority—that it can limit some manufacturer non-price conditions on 340B sales, the Department of Justice has recently conceded that HRSA has no rule-making authority over contract pharmacy questions. *See, e.g.*, Federal Defendants’ Br. at 38, *Novartis Pharms. Corp. v. Johnson*, Nos. 21-5299 & 21-5304 (D.C. Cir. May 9, 2022) (“HHS has no rulemaking authority with respect to contract-pharmacy arrangements”).

Despite HSRA’s new position that no conditions can be asserted by manufacturers under any circumstances, HRSA has previously allowed manufacturers to employ a wide variety of conditions, including many data conditions. For instance, to be able to order any 340B product, a covered entity must provide data in connection

⁵ HRSA, HHS, *Fiscal Year 2021: Justification of Estimates for Appropriations Committees*, at 296 (2020), <https://www.hrsa.gov/sites/default/files/hrsa/about/budget/budget-justification-fy2021.pdf>.

with its order, including its unique 340B identifier. These data requirements are nowhere mentioned in the statute, but apply universally.⁶ Further, 340B pricing is provided through “chargebacks or rebates,” both of which require the covered entity to make available a variety of data to support their 340B price concessions. *See* 42 U.S.C. § 256b(a)(1)–(2) (referencing “rebate or discount” mechanisms); Model N, *Best Practices for Managing PHS 340B Chargebacks*, at 6 (2013), http://pages.modeln.com/rs/modeln/images/WP_340B.pdf (industry data controller discussing the various data elements required “for chargeback processing among the Big Three Drug Wholesalers,” the distribution contractors used by many manufacturers); HRSA, Notice Regarding Section 602 of the Veterans Health Care Act of 1992—Rebate Option, 63 Fed. Reg. 35,239, 35,241 (June 29, 1998) (stating that “[s]tandard business practices should be utilized” for “claim data reporting” to request rebates from manufacturers).

Such conditions have been recognized by HRSA because it has long acknowledged that manufacturers can apply conditions that reflect “customary business practice[s],” that include “request[s for] standard information,” or that involve “appropriate contract provisions.” 59 Fed. Reg. 25,110, 25,114 (May 13, 1994). Indeed,

⁶ Indeed without these 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).

HRSA approves conditions far more restrictive than a request for “standard information,” such as the imposition of limited distribution systems, which can limit customers to securing product through a single distribution point. *See, e.g.,* Origin Biosciences, *340B Distribution Notice for Nulibry™* (Feb. 26, 2021), <https://www.hrsa.gov/sites/default/files/hrsa/opa/pdf/notice-nulibry.pdf>. The HRSA website contains more than forty such examples of manufacturer-imposed conditions. HRSA, HHS, *Manufacturer Notices to Covered Entities*, <https://www.hrsa.gov/opa/manufacturer-notices> (last updated Dec. 2021).

Despite the statute’s balanced design, intended to provide 340B prices to covered entities and to prevent duplicate discounts and diversion, the 340B program is fundamentally broken. Covered entities are concerned that they are not receiving properly calculated 340B prices, and manufacturers assert that they are being forced to provide 340B prices where duplicate discounts and diversion violations are occurring. Duplicate discounts and diversion of 340B drugs represent significant, ongoing problems, particularly in connection with the use of contract pharmacies. As documented in a series of government reports and in Kalderos’s own analyses,⁷ the

⁷ *See, e.g.,* GAO, *Manufacturer Discounts in the 340B Program Offer Benefits, but Federal Oversight Needs Improvement*, GAO 11-836, at 28 (Sept. 23, 2011) <https://www.gao.gov/assets/gao-11-836.pdf> (“Operating the 340B program in contract pharmacies creates more opportunities for drug diversion compared to in-house pharmacies.”); GAO, *Federal Oversight of Compliance at 340B Contract Pharmacies Needs Improvement*, GAO-18-480, at 44 (June 2018), <https://www.gao.gov/assets/700/692697.pdf> (concluding that “[t]he identified noncompliance at contract

explosion of contract pharmacies and the absence of federal oversight have caused these problems to grow unchecked, undermining the integrity of the program. HRSA has proven either unwilling or unable to address these concerns.

The prevalence of duplicate discounts and diversion in connection with contract pharmacy transactions is no surprise. As Kalderos's work has demonstrated, contract pharmacies, often located dozens or hundreds of miles from the covered entity, typically do not identify the patient as having any connection to the covered entity at the time of service. The identification (or misidentification) of the patient by a third-party administrator (separate from both the covered entity and the contract pharmacy), which has had no contact with the patient, is made through algorithms weeks or months after the fact. There is no transparency into the algorithms' specific "matching" rules. Significantly, the data provided to these third-party administrators include the subset of more limited data elements Kalderos's model seeks to obtain.

B. Kalderos and Its Efforts to Solve the Program's Problems

Beginning in 2016, Kalderos sought to develop solutions to fix a broken 340B program. Its philosophy was to act as an honest broker between covered entities and manufacturers. Kalderos evaluated solutions based on their ability to give covered

pharmacies raises questions about the effectiveness of covered entities' current oversight practices"); Kalderos Inc., *Making Health Policy Work for Patients: How Platform Solutions Enable More Affordable Drugs*, at 17, 25 (2021), <https://www.kalderos.com/2021-annual-report>.

entities, including those using contract pharmacies, easy access to 340B pricing, while simultaneously ensuring there are systems to identify duplicate discounts and diversion. Kalderos’s principles reflect the balance at the core of the 340B statute.

With these principles in mind, Kalderos has worked with stakeholders to address duplicate discounts and diversion. Kalderos estimates Medicaid duplicate discounts are as high as \$1.6 billion annually—and this estimate does not account for additional duplicate discounts that would be identified using more complete claims data. Kalderos has tried to address issues created by contract pharmacies through “good faith” inquiries to covered entities. Unfortunately, many covered entities fail to respond to those requests and will not make refunds when a violation is established, which HRSA permits. Kalderos also examined the possibility of undertaking audits of covered entities under 42 U.S.C. § 256b(a)(5)(C), but HRSA’s audit requirements, which exceed those that apply to non-340B commercial customers of manufacturers, have rendered those audits useless, as a practical matter.⁸ Kalderos has repeatedly urged HRSA to address its audit requirements, without any success.

⁸ As the Government Accounting Office has documented, “although manufacturers have the authority to audit covered entities, they have only conducted them in egregious circumstances, because agency requirements for these audits—such as a requirement to hire an independent third party to conduct the audits—are costly and administratively burdensome.” GAO, *Manufacturer Discounts*, *supra*, at 22. The inability of audits to address the lack of transparency in contract pharmacy transactions is underscored by the fact that a manufacturer cannot initiate an audit until and unless it already has “evidence in support” of a violation. 61 Fed. Reg. 65,406, 65,409–10 (Dec. 12, 1996).

Unable to use these mechanisms to effect a balance between ensuring access by covered entities using contract pharmacies to 340B prices and reducing duplicate discounts and diversion, Kalderos considered how similar risks are addressed for non-340B customers that receive price reductions. Specifically, Kalderos identified the “customary business practices” involving “request[s] for standard information” that are part of “contract provisions,” 59 Fed. Reg. at 25,114, in agreements between manufacturers and commercial health plans, pharmacy benefit managers, hospitals, specialty pharmacies, retail pharmacies, and state Medicaid agencies.

Based on these customary practices, Kalderos developed an electronic platform to administer 340B transactions. Covered entities use Kalderos’s platform to share a limited number of data elements when they request the statutory ceiling price. When requesting the 340B price, covered entities provide to Kalderos the drug’s prescription or Rx number, the prescriber identification number, and other limited information. This information allows Kalderos to identify and prevent duplicate discounts and diversion. The system is configured to facilitate **an unlimited number of transactions with an unlimited number of contract pharmacies.**

An example may be helpful. A covered entity using a contract pharmacy submits a request for payment. The covered entity references the underlying Rx number 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. There is no impact to the covered entity or contract pharmacy.

The data that Kalderos utilizes are routinely secured in determining price concessions for managed care, pharmacy benefit manager, retail pharmacy, hospital, physician, and group purchasing organization customers. Contract pharmacies, in fact, must submit this (and additional) information to all third-party payors, like Medicaid, to secure payment for the 340B drugs they dispense. In Kalderos's review, this system achieves the balance reflected in the statute—in a manner that is fair to both sides.⁹

C. HRSA's Recent Change in Position and Subsequent Litigation

On May 17, 2021, HRSA issued violation letters to multiple manufacturers concerning their 340B policies. For instance, HRSA stated that Eli Lilly's program is in "direct violation of the 340B statute." Letter to D.L. Asay, Eli Lilly, from D. Espinosa, HRSA, at 1 (May 17, 2021), <https://www.hrsa.gov/sites/default/files/hrsa/opa/pdf/hrsa-letter-eli-lilly-covered-entities.pdf>. Without acknowledging its prior acceptance of many manufacturer conditions, HRSA concluded:

Nothing in the 340B statute grants a manufacturer the right to place conditions on its fulfillment of its statutory obligation to offer 340B

⁹ The government and *amici* in other cases argue that 340B covered entities will be decimated if any condition is asserted in connection with 340B discounts. But that contention is utterly baseless with respect to a claims data program like Kalderos's, which, as noted above, would permit an unlimited number of transactions with an unlimited number of contract pharmacies.

pricing on covered outpatient drugs purchased by covered entities. Section 340B(a)(1) of the PHS Act also requires manufacturers that have signed a Pharmaceutical Pricing Agreement (PPA) and PPA addendum to comply with these requirements.

Id. (emphasis added). The letter further states “manufacturers are expected to provide the same opportunity for 340B covered entities and non-340B purchasers to purchase covered outpatient drugs.” *Id.* The letter does not address what data manufacturers secure from non-340B customers, from whom the same or comparable data are often secured.

HRSA’s violation letters have resulted in multiple APA lawsuits concerning the legality of conditions imposed by manufacturers on their 340B offers. In this case, Judge Barker ruled that “[c]onstruing the 340B statute not to permit drug manufacturers to impose extra-statutory conditions on covered entities’ access to discounted medications is not only a permissible construction, but, in our view, the construction that best aligns with congressional intent.” 2021 WL 5039566, at *20. Accordingly, she held that Section 340B, “correctly construed, does not permit drug manufacturers, such as Lilly, to impose unilateral extra-statutory restrictions on its offer to sell 340B drugs to covered entities.” *Id.* at *24. Although the court specifically addressed conditions preventing covered entities from “utilizing multiple contract pharmacy arrangements,” *id.*, both the court’s statement of its holding and the

logic of its decision would preclude manufacturers from imposing other offer conditions, including the production of claims data—even when the manufacturer supports an unlimited number of contract pharmacy arrangements and transactions.

Elsewhere, in related litigation filed in New Jersey, Judge Wolfson partially vacated two of HRSA’s letters, but upheld HRSA’s conclusion that a manufacturer cannot require the production of claims data as a condition under the 340B program. *See Sanofi*, 2021 WL 5150464, at *42–43. Although the court correctly determined that HRSA has authority to issue rules under 340B in only “three limited contexts,” *id.* at *34, it failed to apply those limits in incorrectly concluding that HRSA has plenary authority to prohibit private parties from requesting claims data, *id.* at *43. It thus held that private parties could be prohibited from attaching conditions to 340B transactions unless those conditions are affirmatively authorized by the statutory text of Section 340B. *Id.* The court implicitly acknowledged the problem created by its holding, highlighting the “seriousness of drug diversion and duplicate discounting, which § 340B prohibits and which are increasingly serious problems.” *Id.*

Finally, in marked contrast to the decision below and Judge Wolfson’s decision, Judge Friedrich concluded that Section 340B does not “*prohibit* manufacturers from placing *any* conditions on covered entities.” *Novartis Pharms. Corp. v. Espinosa*, No. 21-1479, 2021 WL 5161783, at *7 (D.D.C. Nov. 5, 2021) (emphases in original), *appeal docketed*, No. 21-5299 (D.C. Cir. Dec. 30, 2021). Judge Friedrich

reasoned that “HRSA itself has long recognized that manufacturers are allowed to ‘include provisions’ in their contracts with covered entities ‘that address customary business practice, request standard information, or include other appropriate contract provisions.’” *Id.* (quoting 59 Fed. Reg. at 25,114). Given that history (which neither the district court here nor Judge Wolfson addressed), Judge Friedrich concluded that “HRSA d[id] not adequately explain why the plain language of the statute allows manufacturers to impose only the conditions they previously imposed.” *Id.* The *No-vartis* court ruled that Section 340B’s “plain language, purpose, and structure do not *prohibit* drug manufacturers from attaching any conditions to the sales of covered drugs.” *Id.* at *9.¹⁰

ARGUMENT

I. REQUIRING BASIC CLAIMS DATA TO PREVENT DUPLICATE DISCOUNTS AND DIVERSION IS ENTIRELY CONSISTENT WITH THE 340B STATUTE’S TEXT AND PURPOSE.

Section 340B does not prohibit manufacturers from requiring covered entities to meet conditions, like providing basic claims data, that are not specifically found in the statute. The district court’s contrary ruling improperly imposes requirements that do not appear in the statutory text, undermines Congress’s purpose, as part of its balanced approach, to prevent duplicate discounts and diversion, and rests on the

¹⁰ Judge Friedrich declined to resolve whether Section 340B permits the specific conditions at issue there because “the parties ha[d] not adequately argued their respective positions on Section 340B’s structure.” *Id.* at *8.

mistaken view that allowing manufacturers to impose offer conditions would render their 340B offers “hollow.” Section 340B allows manufactures to impose reasonable terms and conditions on 340B sales, especially where those conditions are designed to facilitate compliance with the statute’s prohibitions on duplicate discounts and diversion and do not disadvantage covered entities as compared to similarly situated non-340B customers.

A. The Statutory Text Does Not Prohibit Manufacturers from Imposing Reasonable Terms and Conditions on 340B Sales.

“As with all issues of statutory interpretation, the appropriate place to begin [the] analysis is with the text itself.” *Bass v. Stolper, Koritzinsky, Brewster & Neider*, 111 F.3d 1322, 1324 (7th Cir. 1997); *see also Sobitan v. Glud*, 589 F.3d 379, 382 (7th Cir. 2009). The statutory text provides that (i) the Secretary must enter into an agreement with each participating manufacturer “under which the amount required to be paid ... to the manufacturer for covered outpatient drugs ... purchased by a covered entity ... does not exceed” the applicable ceiling price, and (ii) the agreement must “require that the manufacturer offer each covered entity covered outpatient drugs for purchase at or below the applicable ceiling price if such drug is available to any other purchaser at any price.” 42 U.S.C. § 256b(a)(1).

The statutory text thus imposes only two requirements on manufacturers. *First*, if a manufacturer makes a covered outpatient drug available to any other purchaser, it must offer that drug to covered entities (*i.e.*, the manufacturer may not

refuse to sell the drug to covered entities). *Second*, the manufacturer must offer the drug to covered entities at or below the ceiling price. That is it. The statutory text does not impose any other obligations on manufacturers. Apart from the price, the issue that was at the heart of the MDRP “snafu” that gave rise to the 340B program, the statute does not address the other terms and conditions of 340B transactions. The statute leaves those terms and conditions to be negotiated by the parties, just as they were in the days before the MDRP “snafu.”

The district court’s holding to the contrary reflects a series of related errors. Most importantly, the court read into the statute a prohibition that it does not contain. This contravenes the “fundamental principle of statutory interpretation that absent provisions cannot be supplied by the courts.” *Little Sisters of the Poor Saints Peter & Paul Home v. Pennsylvania*, 140 S. Ct. 2367, 2381 (2020) (cleaned up); *accord Rotkiske v. Klemm*, 140 S. Ct. 355, 361 (2019) (rejecting “[a]textual judicial supplementation” of statutes). If Congress had intended to restrict the other terms and conditions of 340B sales, it would have done so in text.¹¹ Having once inadvertently disrupted normal discounting practices, Congress, quite understandably, did not risk doing so again. Courts may not add terms that Congress omitted, because this is “not

¹¹ Nor, despite being asked *five* times by HRSA, has Congress given the agency the regulatory authority to create such a prohibition. *See HRSA, Fiscal Year 2021: Justification, supra*, at 296 (“HRSA has requested regulatory authority in the President’s Budget *each year* since FY 2017”) (emphasis added).

a construction of a statute, but, in effect, an enlargement of it.” *Nichols v. United States*, 578 U.S. 104, 110 (2016).

Further, the district court wrongly faulted plaintiffs for relying upon the 340B “statute’s silence ... to unilaterally impose a wide variety of restrictions on their offers.” 2021 WL 5039566, at *19. That is backwards. Sales by drug manufacturers to covered entities are private commercial transactions. They do not require statutory authority from Congress. Like any commercial actors, manufacturers and covered entities are free to negotiate reasonable terms and conditions absent a specific government prohibition. In Section 340B, Congress restricted the *price* of 340B sales, but left most other terms and conditions of such sales to the parties.

The district court’s contrary conclusion reflects a fundamental misconception about the scope of the statute. The 340B statute was a targeted attempt to restore discounts that had previously been provided to certain providers. It did not purport to prohibit the range of conditions that the parties, through negotiation, had historically applied to such sales. The statutory language does not, for example, preclude the parties from specifying required wholesalers for distribution, requiring entities to satisfy a credit check, requiring covered entities to use certain financial systems to request discounts, or negotiating other conditions that are not “authorized” by

statute, but are unquestionably permitted.¹² That is why HRSA itself has long recognized that manufacturers may impose conditions. *See infra*, § II.

The district court also misapprehended the import of the “shall ... offer” provision added to the statute in 2010. *See* 2021 WL 5039566, at *19. Contrary to the district court’s analysis, the authority to impose conditions on 340B sales is not predicated on “reading into the statutory text an exception to the ‘shall ... offer’ and ‘purchased by’ provisions.” *Id.* Rather, it rests on the absence of any statutory text—at any point in time—prohibiting conditions. *See Novartis*, 2021 WL 5161783, at *7. The 2010 amendment imposed an additional requirement prohibiting manufacturers from refusing to deal with covered entities when drugs are made available to others.¹³ But it did not alter the substantial scope of what the statute leaves to the

¹² All of these conditions currently apply, for instance, to 340B chargebacks, a mechanism that HRSA has long endorsed. In a chargeback, a wholesaler specified by the manufacturer, using a specified electronic system, requires a covered entity to submit certain data, as directed by the manufacturer. Those data are then provided to the manufacturer to authorize the discount. *See infra*, at 8.

¹³ More specifically, Congress was responding to some 340B covered entities’ concerns that some manufacturers, in periods of drug shortages, would not sell to them, but only to non-340B customers. Like the original statute, the “shall offer” language was a targeted response to a defined issue. As Chairman Waxman explained:

I want to clarify our intent here in cases where there may be a drug shortage. We’re not saying that 340B entities automatically go to the front of the line, but we are saying that manufacturers cannot send them to the back of the line either. With regard to supply shortages and drug availability manufacturers must treat 340B entities the same way they treat all other customers. As the legislation moves forward, I’m happy

parties' negotiation. The 2010 amendment shows that when Congress believes that a prohibition is needed, it imposes it expressly.

Finally, HRSA's interpretation cannot be upheld on the theory that the statute's silence on non-price conditions is a "gap" for the agency to fill. Congress did not leave a "gap." Rather, it left the non-price terms and conditions of 340B sales, including what data requirements apply, to the parties. *See Bob Evans Farms, Inc. v. NLRB*, 163 F.3d 1012, 1019 (7th Cir. 1998) ("This is not an instance where Congress has left a gap for the [agency] to fill."). This is why Congress did not provide "gap-filling" authority to HRSA. *See Sanofi*, 2021 WL 5150464, at *34; *see also PhRMA*, 43 F. Supp. 3d at 45.

B. Requiring that Covered Entities Provide Basic Claims Data Is Consistent with the 340B Statute and Its Purposes.

Having misread the statutory text, the district court compounded its error by concluding that allowing drug manufacturers "to impose unilateral restrictions on the distribution of the drugs" would frustrate the purpose of Section 340B. *See* 2021

to continue working on this language to make sure that our intent is clear....

Statement of Chairman Waxman, House Energy and Commerce Committee Markup of H.R. 3200, Sept. 23, 2009, Video Stream available at H.R. Energy and Commerce Committee, *Sept. 23, 2009 – Full Committee Open Markup Session (Part I)*, YouTube (July 21, 2011), 1:24:23, <https://youtu.be/LaCUslC6Lm8?t=5063>. Further, as Judge Friedrich explained, "Congress knows full well how to" impose a "broad anti-discrimination rule" when that is its intent, but it did not do so in Section 340B. *Novartis*, 2021 WL 5161783, at *7.

WL 5039566, at *19. Not so. Far from “frustrat[ing] Congress’ manifest purpose,” *id.*, the provision of claims data *further*s the statute’s purpose by facilitating statutory compliance and ensuring the integrity of the 340B program for all participants.

The district court’s analysis of the statutory purpose is incomplete and flawed. While the 340B program is designed to support access to discounts by covered entities, “[n]o legislation pursues its purposes at all costs.” *Am. Express Co. v. Italian Colors Rest.*, 570 U.S. 228, 234 (2013) (quoting *Rodriguez v. United States*, 480 U.S. 522, 525–26 (1987) (per curiam)). Congress carefully balanced the goal of assisting covered entities *and* protecting manufacturers from duplicate discounts and diversion. To that end, Congress expressly prohibited duplicate discounts, 42 U.S.C. § 256b(a)(5)(A)(i), and diversion, *id.* § 256b(a)(5)(B). The district court erred by considering only one side of the statutory balance.

Here, providing claims data *further*s the statute’s purpose by enabling manufacturers “to better utilize the anti-fraud audit and ADR procedures that Congress established for manufacturers in Section 340B.” *Novartis*, 2021 WL 5161783, at *8. Specifically, Kalderos and its clients, if they cannot resolve an issue, would use the claims data in an ADR proceeding. Without those claims data, neither the audit precursor to the ADR proceeding nor an ADR proceeding can be initiated, as a practical

matter.¹⁴ It is HRSA’s refusal to permit claims data that frustrates the purposes of the statute.

Reasonable efforts to identify duplicate discounts and diversion do not in any way undermine the access to statutory ceiling prices. The statute’s plain language provides that a covered entity is *not entitled* to 340B pricing where the prohibitions on duplicate discounts or diversion apply. To be entitled to 340B pricing in the first place, a covered entity must “mee[t] the requirements described in paragraph (5),” 42 U.S.C. § 256b(a)(4), which contains the prohibitions on duplicate discounts and diversion, *id.* § 256b(a)(5)(A)&(B). Accordingly, the district court’s ruling would effectively mandate discounts that are actually prohibited by the statute.

C. Requiring Claims Data Will Not Diminish Access to 340B Pricing or Disadvantage Covered Entities.

At bottom, the district court’s decision appears to have been driven by the concern that imposition of conditions would render “hollow” section 340B’s “‘offer’

¹⁴ See 61 Fed Reg. at 65,409–10 (requiring “evidence in support” as a condition of starting an audit). More fundamentally, nothing in the statute’s text or structure suggests that the ADR process—which was first added to the statute in 2010—is the exclusive means to combat duplicate discounts and diversion, which were prohibited when 340B was first enacted by Congress in 1992. The ADR process does not even apply to many claims, which will be under the monetary threshold for ADR. The addition of the ADR provisions in 2010, which reflect a Congressional determination that manufacturer concerns are legitimate, did not *sub silentio* prohibit manufacturers from insisting on reasonable conditions to prevent statutory violations. See *Novartis*, 2021 WL 5161783, at *8.

to sell” obligation. 2021 WL 5039566, at *19 n.13. That concern is misplaced. Requiring basic claims data does not render 340B offers “hollow,” and requiring covered entities to provide data will not impede their access to 340B pricing whenever they are entitled to it.

If a covered entity’s request for 340B pricing is appropriate, claims data systems like Kalderos’s will facilitate the 340B transaction and ensure that the appropriate 340B price is, in fact, paid. But if the request violates the prohibition on duplicate discounts or diversion, then the covered entity is not entitled to 340B pricing and the manufacturer is not obligated to offer it. This is the essence of Kalderos’s honest-broker approach—to be fair to both sides—and it is wholly consistent with manufacturers’ obligations under the statute.

Moreover, the limited data that Kalderos seeks reflects “customary practice,” both of the covered entities themselves and other stakeholders. The information requested by Kalderos is readily available and tracks what covered entities and their contract pharmacies use when they attempt to “match” a drug dispensed by the contract pharmacy back to the covered entity’s 340B patient. It is even *less* than the information that HRSA *itself* has recommended that covered entities *require* contract pharmacies to identify before dispensing a 340B drug. *See* 61 Fed. Reg. 43,549, 43,556 (Aug. 23, 1996) (recommending that contract pharmacies dispense only “[u]pon presentation of a prescription bearing the covered entity’s name, the eligible

patient’s name, a designation that the patient is an eligible patient, and the signature of a legally qualified health care provider affiliated with the covered entity”). It is also less than the information provided in the pharmacy claim submitted by the contract pharmacy to secure reimbursement from a third-party payor.

Nor does requiring covered entities to provide data disadvantage them compared to other customers. To the contrary, it is consistent with what manufacturers require of non-340B customers seeking price concessions, including managed care entities, hospitals, physicians, retail pharmacies, group purchasing organizations, and States participating in the Medicaid programs.¹⁵ In other words, not only is the

¹⁵ See, e.g., CMS, *MDRP Electronic State Invoice Form CMS-R-144; Data Definitions effective July 1, 2021* (2020), <https://www.medicaid.gov/medicaid/prescription-drugs/downloads/cms-r-144-state-invoice-data-definitions-jul-2021.pdf> (addressing state Medicaid programs’ practice of providing record ID, labeler code, units reimbursed, package size, number of prescriptions, and other data in their invoices to manufacturers); HHS Office for Civil Rights, *HIPAA FAQ 455* (June 8, 2020), <https://www.hhs.gov/guidance/document/faq-455-does-privacy-rule-permit-health-plans-disclose-protected-health-information> (addressing “health plan ... disclos[ing] protected health information, such as prescription numbers, to a pharmaceutical manufacturer” for purposes of “adjudicating claims submitted under a drug rebate contract”); Mark Campbell, RxBenefits, *What Employers Need to Know About Drug Rebates* (June 24, 2021), <https://www.rxbenefits.com/blogs/understanding-the-role-of-drug-rebates/> (drug price concessions “are paid on a per-claim basis”); Nat’l Council for Prescription Drug Plans, *Manufacturer Rebate Utilization, Plan, Formulary, Market Basket, and Reconciliation Flat File Standard; Implementation Guide, Version 07.02*, at 15, 20–22 (Jan. 2019) (standard setting organization “flat file” used by “State Medicaid Agencies, Health Maintenance Organizations ..., Pharmacy Benefit Managers ..., Long Term Care Facilities, Mail Order Providers, Insurance Carriers, Employer Groups, etc.” to seek drug price concessions includes such standard data elements as “Claim Number,” “Prescriber ID,” “Prescription/Service Reference Number”).

district court's holding not necessary to prevent discrimination against 340B entities, it would actually mandate a *preference* in their favor—one not enjoyed by non-340B customers. Nothing in Section 340B mandates such a preference.

II. HRSA'S NEW POLICY THAT THE STATUTE PROHIBITS ALL CONDITIONS ON 340B SALES IS ARBITRARY AND CAPRICIOUS.

In addition to contravening the statute's text and purpose, HRSA's new policy prohibiting *all* conditions is arbitrary and capricious. An “unexplained inconsistency” in agency policy is ‘a reason for holding an interpretation to be an arbitrary and capricious change from agency practice.’ *Encino Motorcars, LLC v. Navarro*, 579 U.S. 211, 222 (2016) (quoting *Nat'l Cable & Telecomms. Ass'n v. Brand X Internet Servs.*, 545 U.S. 967, 981 (2005)); *see Brand X*, 545 U.S. at 1001 (an agency must “adequately justif[y] the change”). Thus, an agency “must at least ‘display awareness that it is changing position,’ and ‘show that there are good reasons for the new policy.’” *Encino Motorcars*, 579 U.S. at 221 (quoting *FCC v. Fox Television Stations, Inc.*, 556 U.S. 502, 515 (2009)); *see also Cook County v. Wolf*, 962 F.3d 208, 229 (7th Cir. 2020) (similar), *cert. dismissed*, 141 S. Ct. 1292 (2022). Further, an agency's action is arbitrary and capricious when it (i) fails “to consider an important aspect of the problem” or (ii) “offer[s] an explanation for its decision that runs counter to the evidence before the agency.” *Motor Vehicle Mfrs. Ass'n v. State Farm Mut. Auto. Ins. Co.*, 463 U.S. 29, 43 (1983); *accord Zero Zone, Inc. v. U.S.*

Dep't of Energy, 832 F.3d 654, 668 (7th Cir. 2016). The May 17 letters' categorical prohibition on the use of any conditions fails these requirements.

A. HRSA Has Previously Construed the Statute to Permit Manufacturers to Impose Conditions on 340B Transactions.

For decades, HRSA has allowed manufacturers to impose terms and conditions on 340B transactions. Until the May 17 letters, HRSA had never interpreted the statute to prohibit all terms and conditions.

As noted above, HRSA's 1994 guidance—issued shortly after the 340B program's launch—explained that manufacturers could employ “customary business practice[s],” “request standard information,” and adopt “appropriate contract provisions.” 59 Fed. Reg. at 25,114. HRSA did not impose any blanket prohibition on conditions. *Id.* HRSA's current position barring manufacturers from imposing *any* conditions cannot be reconciled with the 1994 guidance or the agency's existing practice of permitting multiple conditions.

For example, HRSA has allowed manufacturers “to develop alternate allocation procedures” for “situations when the available supply of a covered drug is not adequate to meet market demands.” HRSA, HHS, *340B Drug Pricing Program Notice, Release No. 2011-1.1* (May 23, 2012) (citing 59 Fed. Reg. at 25,110). Under this policy, HRSA allows manufacturers to impose a condition that covered entities

must purchase certain covered drugs through limited distribution points. The guidance notes that this condition, which is much more restrictive than requesting claims data, “is consistent with” the 340B statute’s “offer” requirement. *Id.*

Kalderos has relied on HRSA’s guidance permitting conditions. It was not given notice or an opportunity to comment on HRSA’s unilateral change in its position reflected in the May 17 letters.

B. The May 17 Letters Are Arbitrary and Capricious.

HRSA’s new policy prohibiting any conditions, including customary business practices such as requiring the provision of standard claims information, is arbitrary and capricious for two reasons.

First, the May 17 letters do not acknowledge that HRSA’s new policy differs markedly from past agency positions or provide a reasoned explanation for the change. The May 17 letters announced a new, unqualified policy: no condition may be imposed, regardless of how reasonable it is. Although this policy conflicts directly with HRSA’s long-held positions described above, HRSA failed even to *acknowledge* its departure from the agency’s prior policies, let alone to provide a reasoned explanation for the change. That was arbitrary and capricious. *See Encino Motorcars*, 579 U.S. at 221 (an agency “must at least ‘display awareness that it is changing position,’ and “show that there are good reasons for the new policy” (quoting *Fox Television*, 556 U.S. at 515); *accord Wolf*, 962 F.3d at 229.

Second, HRSA failed to address significant aspects of the problem. An agency has an obligation to provide an affirmative showing in support of its decision, including an examination of “the relevant data” and an articulation of “a satisfactory explanation for its action.” *State Farm*, 463 U.S. at 42–43. Here, HRSA did not explain how the 340B program can function properly if manufacturers cannot impose *any* conditions. It did not explain why claims data conditions like Kalderos’s would “undermine the statutory objective” or “have the effect of discouraging entities from participating in the discount program.” 59 Fed. Reg. at 25,113. And it did not meaningfully grapple with the rampant problems of duplicate discounts and diversion that undermine the program’s integrity.¹⁶

¹⁶ The *only* response HRSA offered was that duplicate discounts and diversion must be addressed exclusively through the ADR process, which is wrong for the reasons discussed above, and further ignores the limitations of the ADR process that have made it ineffective in preventing duplicate discounts and diversion.

CONCLUSION

For these reasons, and those stated by Plaintiffs-Appellants, the judgment of the district court should be reversed.

Date: June 1, 2022

Respectfully submitted,

/s/ Eric D. McArthur

ERIC D. MCARTHUR

Counsel of Record

WILLIAM A. SARRAILLE

PAUL J. ZIDLICKY

JACQUELYN E. FRADETTE

CHRISTOPHER S. ROSS

SIDLEY AUSTIN LLP

1501 K Street, N.W.

Washington, D.C. 20005

Telephone: (202) 736-8000

TREVOR L. WEAR

SIDLEY AUSTIN LLP

One South Dearborn

Chicago, IL 60603

Telephone: (312) 853-7000

Counsel for Kalderos, Inc.

CERTIFICATE OF COMPLIANCE

This brief complies with the type-volume limitations of Federal Rules of Appellate Procedure 29(a)(5) and 32(a)(7)(B) and the rules of this Court, because it contains 6,926 words (as determined by the Microsoft Word 2016 word-processing system used to prepare the brief), excluding the parts of the brief exempted by Federal Rule of Appellate Procedure 32(a)(7)(B)(iii).

This brief complies with the typeface and type style requirements of Federal Rule of Appellate Procedure 32(a)(5)–(6). The brief was prepared in a proportionally spaced typeface using Microsoft Word 2016 in 14-point Times New Roman font.

Date: June 1, 2022

/s/ Eric D. McArthur

ERIC D. MCARTHUR

CERTIFICATE OF SERVICE

I hereby certify that on June 1, 2022, 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.

/s/ Eric D. McArthur

ERIC D. MCARTHUR