Nos. 21-3167, 21-3168, 21-3379, 21-3380

In the United States Court of Appeals for the Third Circuit

SANOFI-AVENTIS U.S., LLC,
Appellants/Cross-Appellee,

v.

U.S. DEPARTMENT OF HEALTH AND HUMAN SERVICES, ET AL.,
Appellees/Cross-Appellants.

NOVO NORDISK INC. AND NOVO NORDISK PHARMA, INC.,
Appellants/Cross-Appellees,

v.

U.S. DEPARTMENT OF HEALTH AND HUMAN SERVICES, ET AL.
Appellees/Cross-Appellants.

On Appeal from the United States District Court for the District of New Jersey, Nos. 3-21-cv-00634 & 3-21-cv-00806, Hon. Freda L. Wolfson

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BRIEF OF *AMICUS CURIAE* KALDEROS, INC.

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CORPORATE DISCLOSURE STATEMENT

Pursuant to Federal Rule of Appellate Procedure 26.1 and Third Circuit Local Appellate Rule 26.1.1, 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.

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INTEREST OF *AMICUS CURIAE* AND SUMMARY OF ARGUMENT[1]

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 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 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 Sanofi-Aventis

[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.

("Sanofi").[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 limited, customarily provided by non-340B customers seeking price concessions, and entirely consistent with the purpose of the 340B program.

If manufacturers cannot require basic claims data, manufacturers will not enter into or continue with contracts with Kalderos for its service. Kalderos thus has a substantial interest in this matter. Because the district court's opinion below misconstrued the purpose and importance of claims data in supporting the 340B program, 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.

HRSA's new policy prohibiting all manufacturer conditions, including the production of claims data, 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 340B's purpose to prevent duplicate discounts and diversion and

[2] The *Kalderos* lawsuit was filed as a related case to the *United Therapeutic* and *Novartis* cases, which also challenge the May 17 letters. On November 5, 2021, Judge Friedrich granted summary judgment in favor of the manufacturers in the *United Therapeutic* and *Novartis* cases. The government has appealed the summary judgment order, and the court stayed Kalderos's case pending the appeal.

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 an unacknowledged and clear departure from past agency positions and practice that fails to address significant aspects of the problem.

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. Winegarden, Pac. Res. Inst., *Addressing the Problems of Abuse in the 340B Drug Pricing Program*, at 4 (Dec. 2017).[3] Before the MDRP, manufacturers had long "offer[ed] safety-net providers … large discounts on their purchase 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." Winegarden, *supra*,

[3] *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 & Reform of 340B Program*, Daily Dish (Oct. 10, 2017) (the 340B program is the "offspring of price controls in the Medicaid program").

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.

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) (district court recognizing that Congress did not authorize HRSA to make rules regarding the terms and conditions of 340B sales); *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,"[4] Congress has repeatedly declined to expand HRSA's authority.

HRSA has nevertheless historically asserted—without citing any regulatory authority—that it can limit some manufacturer non-price conditions on 340B sales. At the same time, it has repeatedly allowed manufacturers to impose a wide variety of conditions. For instance, 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 and defining the "[r]ebate percentage"); Model N, *Best Practices for Managing PHS 340B Chargebacks*, at 6 (2013), http://pages.modeln.com/rs/modeln/images/WP_340B.pdf (leading industry data controller discussing the various data elements required "for chargeback processing among the Big Three Drug Wholesalers," the agents used by many manufacturers); HRSA, Notice Regarding Section 602 of the Veterans Health Care Act of 1992—Rebate Option,

[4] 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.

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, 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. 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/ops/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,[5] developments over the last decade 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

[5] *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 pharmacies raises questions about the effectiveness of covered entities' current oversight practices").

"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 340B covered entities and manufacturers. Kalderos evaluated and developed solutions based on their ability to give 340B covered entities, including those using contract pharmacies, easy access to 340B pricing, while simultaneously ensuring that there are systems in place 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 try to address duplicate discounts and diversion. Kalderos estimates Medicaid duplicate discounts are as high as $1.6 billion annually, even without the ability to identify additional duplicate discounts using limited claims data. Kalderos has tried to address issues created by contract pharmacies through "good faith" inquiries to covered entities, for instance. Unfortunately, more and more covered entities fail to respond to those requests and will not make refunds when a violation is established, in part because HRSA has not supported these efforts. Kalderos also examined the possibility of undertaking audits of covered entities using contract pharmacies 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.[6] Kalderos has repeatedly urged HRSA to address its audit requirements, without any success.

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 conditions" 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 minimal number of data elements when they request the statutory ceiling price from manufacturers working with Kalderos. When requesting the 340B price, covered entities provide to Kalderos the drug's

[6] 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 untenability of audits as a practical means 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).

prescription or Rx number, the prescriber identification number, and other basic information. This information allows Kalderos to identify and prevent duplicate discounts and diversion in violation of the statute, where the product is observed being dispensed by an unauthorized entity.[7] The system is configured to facilitate transactions with any number of contract pharmacies.

The prescription and prescriber identification that Kalderos utilizes is routinely secured in determining the appropriateness of price concessions in managed care, pharmacy benefit manager, retail pharmacy, hospital, physician, and group purchasing organization contracts. Contract pharmacies, in fact, must submit this (and additional) information to all third-party payors to secure payment for the 340B drugs they dispense. Use of the Kalderos platform would be a condition required by manufacturers choosing to work with Kalderos for transactions involving contract pharmacies. In Kalderos's review, this system achieves the balance reflected in the statute—in a manner that is fair to both sides.

[7] 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.

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 Sanofi's program—which requires covered entities to provide claims data to a third-party platform—is in "direct violation of the 340B statute." Letter to G. Gleeson, Sanofi, from D. Espinosa, HRSA at 1 (May 17, 2021), https://www.hrsa.gov/sites/default/files/hrsa/opa/pdf/hrsa-letter-sanofi-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 pricing on covered outpatient drugs purchased by covered entities. Furthermore, the 340B statute does not permit manufacturers to impose conditions on covered entities' access to 340B pricing, including the production of claims data.

Id. 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.

HRSA's violation letters have resulted in multiple APA lawsuits. In the opinion below, Judge Wolfson partially vacated two of the 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 ignored those limits by 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 nevertheless acknowledged the "seriousness of drug diversion and duplicate discounting, which § 340B prohibits and which are increasingly serious problems." *Id*.

In marked contrast to the decision below, Judge Friedrich in the District of Columbia 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 Judge Wolfson did not address), 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 *Novartis* 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.[8]

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 provide basic claims data when seeking 340B pricing. 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 mistaken view that requiring covered entities to provide claims data would render manufacturers' 340B offers "hollow." Section 340B allows manufactures to impose reasonable terms and conditions on 340B sales, especially where, as here, those terms and 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 purchasers seeking price concessions.

[8] 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.

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

"As with any question of statutory interpretation," the analysis "must begin with the statutory text." *Khan v. Att'y Gen.*, 979 F.3d 193, 197 (3d Cir. 2020). The text provides that 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 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 at any price, 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 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 inadvertently forced discounts to be cut off.

The district court's holding below 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 addressing those terms and conditions.[9] Having once inadvertently disrupted normal discounting practices, it, quite understandably, did not risk doing so again. Courts may not add terms that Congress omitted, because this is "not 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 not identifying any affirmative statutory "authority for [their] policies" or any statutory text "indicating that Congress *omitted* language on offer conditions because it *actually intended* to delegate discretion to manufacturers to impose them." *Sanofi*, 2021 WL 5150464, at

[9] 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).

*42–43. That is backwards. Sales by drug manufacturers to covered entities are inherently private commercial transactions. They do not require statutory authority or a delegation 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 it 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.[10] That is why HRSA itself has long recognized that manufacturers may impose conditions on 340B sales. *See infra*, § II.

[10] All of these conditions currently apply, for instance, to 340B chargebacks. 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 a payment in the amount of the discount.

The district court also misapprehended the import of the "shall offer" provision added to the statute in 2010. *See Sanofi*, 2021 WL 5150464, at *42. Contrary to the district court's analysis, manufacturers' "power to impose offer conditions" is not "locate[d]" in the language added in 2010. *Id.* at *43. 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 with regard to covered outpatient drugs made available to others.[11] But it did not alter the

[11] 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 to continue working on this language to make sure that our intent is clear….

Statement of Chairman Waxman, House Energy and Commerce Committee Mark-Up 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, and it did not do so in Section 340B. *Novartis*, 2021 WL 5161783, at *7.

substantial scope of what the statute leaves to the 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 would or would not apply, to the parties. *See Coffelt v. Fawkes*, 765 F.3d 197, 202 (3d Cir. 2014) ("Even where a statute is 'silent' on the question at issue, such silence does not confer gap-filling power on an agency unless the question is in fact a gap—an ambiguity tied up with the provisions of the statute." (internal quotation marks omitted; quoting *Lin–Zheng v. Att'y Gen.*, 557 F.3d 147, 156 (3d Cir. 2009) (en banc))). 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 requiring covered entities to provide basic claims data would undermine the purpose of Section 340B. *See Sanofi*, 2021 WL 5150464, at *43. Not so. Far from "threaten[ing] to undo the statutory scheme," *id.*, the provision of claims

data *furthers* 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.

The district court further erred in concluding that "concerns regarding duplicate discounting or diversion must be resolved through the ADR rule." *Sanofi*, 2021 WL 5150464, at *43 (citing 42 U.S.C. § 256b(d)(3)(B)(iv)). Here too, providing claims data *furthers* 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. Indeed, Kalderos and its clients, if they cannot resolve an issue, would use the claims data in an ADR pro-

ceeding. Without those claims data, neither the audit precursor to the ADR proceeding (which requires "evidence in support" of a violation before an audit can even be initiated[12]) nor an ADR proceeding can be initiated, as a practical matter.[13]

Reasonable efforts to identify duplicate discounts and diversion do not in any way undermine the access to applicable ceiling prices called for by the statute. 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.

[12] 61 Fed Reg. at 65,409–10.

[13] 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. It does not even apply to many claims, which will be under the monetary threshold for ADR. The addition of the ADR provisions in 2010 did not *sub silentio* prohibit manufacturers from insisting on reasonable conditions to prevent statutory violations. *See Novartis*, 2021 WL 5161783, at *8.

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

At bottom, the district court's decision appears to have been driven by the concern that allowing manufacturers to impose conditions "would threaten to undo the statutory scheme by rendering 340B offers hollow." *Sanofi*, 2021 WL 5150464, at *43. 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' obligation to offer covered entities 340B drugs at the ceiling price.

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 matches 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, like Medicaid.

Nor does requiring covered entities to provide claims data disadvantage them compared to other purchasers. 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.[14] In other words, not only

[14] *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,*

will the district court's holding not prevent discrimination against 340B entities, it would actually mandate a *preference* being made in their favor—one not enjoyed by non-340B customers. Such a preference would be contrary to even the district court's understanding of the statute's purpose. *See Sanofi*, 2021 WL 5150464, at *43 ("to ensure *equal treatment* between covered entities and commercial purchasers") (emphasis added).

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 any and all conditions in connection with 340B transactions is arbitrary and capricious. "Although an agency can change or adapt its policies, it acts arbitrarily if it departs from its established precedents without 'announcing a principled reason' for the departure." *Johnson v. Ashcroft*, 286 F.3d 696, 700 (3d Cir. 2002) (quoting *Fertilizer Inst. v. Browner,* 163 F.3d 774, 778 (3d Cir. 1998)). Further, an agency "must support its conclusion with demonstrable reasoning based on the facts

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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").

in the record"; an agency's action is arbitrary and capricious when it fails "to consider an important aspect of the problem." *Sierra Club v. EPA*, 972 F.3d 290, 298 (3d Cir. 2020) (quoting *Motor Vehicle Mrs. Ass'n v. State Farm Mut. Auto. Ins. Co.*, 463 U.S. 29, 43 (1983)). 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 for 340B transactions.

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, including requests for standard claims data, cannot be reconciled with the 1994 guidance or the agency's current 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 and practice 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 that condition may be. This policy conflicts directly with HRSA's long-held positions described above. Yet, HRSA failed even to *acknowledge* that the May 17 letters' ban on all conditions was a departure from the agency's prior policies and practice, let alone to provide a reasoned explanation for the change. That was arbitrary and capricious. *See CBS Corp. v.*

FCC, 663 F.3d 122, 147 (3d Cir. 2011) (an agency's failure "to even acknowledge its departure from its former policy" is "arbitrary and capricious").

Second, HRSA failed to address significant aspects of the problem. An agency's "obligation to supply a reasoned analysis for a policy departure requires an affirmative showing on record," including an examination of "the relevant data" and an articulation of "a satisfactory explanation for its action.'" *Id.* at 145 (quoting *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 and participants' confidence in it.[15]

CONCLUSION

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

[15] 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.

Date: March 15, 2022

Respectfully submitted,

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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 6,471 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.

Pursuant to Local Rule 31.1(c), the undersigned also certifies that the text of the electronic brief is identical to the text in the paper copies.

Date: March 15, 2022

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I hereby certify, pursuant to Local Rule 31.1(c), that virus scan detection programs have been run on the file of the electronic version of this brief and that no virus was detected. The virus detection programs are: Cisco threat Grid: v. 3.5.27; Crowdstrike: v. 6.25.13909.0.

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/s/ Paul J. Zidlicky
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Pursuant to Local Rule 28.3(d), I hereby certify that I am a member of the Bar of this Court.

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I hereby certify that on March 15, 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.

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