[ORAL ARGUMENT NOT YET SCHEDULED]

Nos. 21-5299, 21-5304

In the United States Court of Appeals for the District of Columbia Circuit

NOVARTIS PHARMACEUTICALS CORP.
Plaintiff-Appellee,
v.
CAROLE JOHNSON, in her capacity as Administrator, U.S. Health Resources and Services Administration, *et al.*, *Defendants-Appellants*.

UNITED THERAPEUTICS CORP., *Plaintiff-Appellee*,
v.
CAROLE JOHNSON, in her capacity as Administrator, U.S. Health Resources and Services Administration, *et al.*, *Defendants-Appellants*.

On Appeal from the United States District Court for the District of Columbia (Hon. Dabney L. Friedrich)

BRIEF OF *AMICUS CURIAE* KALDEROS, INC. IN SUPPORT OF PLAINTIFFS-APPELLEES AND AFFIRMANCE

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CERTIFICATE AS TO PARTIES, RULINGS, AND RELATED CASES

Amicus curiae Kalderos, Inc. certifies the following information regarding the parties, rulings and related cases in this appeal. *See* D.C. Cir. R. 28(a)(1).

Parties and *Amici*. All parties and *amici* appearing before the district court are as stated in the Opening Brief of the Federal Defendants-Appellants.

In this Court, all parties are as stated in the Opening Brief of the Federal Defendants-Appellents. The *amici curiae* in this Court thus far are as identified in the brief filed by Plaintiff-Appellee United Therapeutics Corporation, except that Kalderos, Inc. is seeking leave to participate as *amicus curiae* in support of Plaintiffs-Appellees.

Ruling Under Review. The ruling under review appears in the Opening Brief of the Federal Defendants-Appellants.

Related Cases. The Federal Defendants-Appellants and Plaintiff-Appellee United Therapeutics Corporation identify the related cases, including the lawsuit filed by Kalderos, Inc. *See Kalderos, Inc. v. United States*, No. 21-cv-2608 (D.D.C.).

CORPORATE DISCLOSURE STATEMENT

Pursuant to Federal Rule of Appellate Procedure 26.1 and D.C. Circuit Rule 26.1(a), 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. Pursuant to D.C. Circuit Rule 26.1(b), Kalderos is a technology company that has developed an equitable, easy-to-use technology platform designed to implement the 340B program on behalf of covered entities and participating drug manufacturers.

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GLOSSARY

ACA	Patient Protection and Affordable Care Act
GAO	Government Accountability Office
HHS	U.S. Department of Health and Human Services
HRSA	U.S. Health Resources and Services Administration
Section 340B	Section 340B of the Public Health Service Act, codified at 42 U.S.C. § 256b

INTEREST OF *AMICUS CURIAE* 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 configured to support an unlimited number of contract pharmacies) 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 suit 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 may be. Kalderos's challenge includes HRSA's letters to United Therapeutics ("UT") and Novartis Pharmaceuticals ("Novartis").

[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).

The *Kalderos* lawsuit was filed as a related case to the *UT* and *Novartis* cases. Kalderos filed suit because the claims data it collects from covered entities are essential to Kalderos's platform and to addressing the pervasive, government-acknowledged duplicate discount and diversion problems plaguing the 340B program. These data are customarily provided by customers seeking price concessions, routinely provided by contract pharmacies to secure payment, and the minimum necessary to assess duplicate discounts and diversion in any meaningful way. If manufacturers cannot require basic claims data, they will not contract with Kalderos. Kalderos thus has a substantial interest in this matter.

On November 5, 2021, Judge Friedrich granted summary judgment in favor of UT and Novartis. After the government appealed, the trial court stayed Kalderos's litigation pending resolution of this appeal. The district court's holding, which implicates a conflict among the lower courts, is critically important to Kalderos 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 statute prohibits manufacturers from imposing reasonable terms on 340B sales. Moreover, requiring claims data serves Section 340B's purpose to prevent duplicate

discounts and diversion, does not discriminate against covered entities, and preserves access to 340B pricing. *Second*, HRSA's May 17 letters are arbitrary and capricious because the new policy they announce is a clear, unacknowledged, and unexplained departure from established agency positions. This Court should affirm the decision below and make clear that nothing in Section 340B precludes manufacturers from insisting that covered entities 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." W. Winegarden, Pac. Res. Inst., *Addressing the Problems of Abuse in the 340B Drug Pricing Program*, at 4 (Dec. 2017).[2] Before the Medicaid Drug Rebate Program, 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 [Medicaid Drug Rebate Program], drug manufacturers regularly offered discounts to … hospitals and other safety-net providers"). Because the Medicaid Drug Rebate Program included these voluntary "large

[2] *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 [Medicaid Drug Rebate Program]").

discounts" in determining "best price" and Medicaid rebates, the "unintended consequence" of this pricing "snafu" was that manufacturers were forced to "discontinu[e]" these discounts. Winegarden, *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.

Having inadvertently cut off the large discounts that had historically been provided to certain providers, Congress enacted a "fix" that narrowly addressed that specific pricing issue. Under the 340B program, Congress required drug manufacturers to sell drugs at reduced prices to "covered entities"—the entities that had historically received the discounted prices. These 340B prices were made a condition for Medicaid drug coverage, with a corresponding exemption of these prices from "best price." *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" …. *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 pricing "snafu" that its earlier legislation created, Congress did not risk creating additional disruptions and left the other aspects of the sales to the parties to negotiate. *See id.* § 256b(a)(1)–(2) (narrowly addressing the "maximum price" covered entities may be required to pay).

In keeping with the statute's narrow focus on addressing the "price" issue, but not 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) (Congress did not authorize HRSA to make rules regarding the terms 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,"[3] Congress has repeatedly declined to expand HRSA's authority. Despite the clearly limited nature of its authority, HRSA nevertheless maintains—without citing any provision of law—that it can limit some manufacturer non-price conditions. HRSA takes this position even though the government has conceded that "HHS has no rulemaking authority with respect to contract-pharmacy arrangements." Gov't Br. 38.

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

[3] 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.[4] Further, 340B pricing is provided through "chargebacks or rebates," both of which require the covered entity to provide a variety of data to validate the 340B price. *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"). 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 that limit customers to securing product through even 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.

[4] Indeed, without data to identify these transactions, it would be impossible to calculate a 340B price, which requires that the 340B transactions be 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).

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, the 340B program is fundamentally broken. Covered entities are concerned that they are sometimes not receiving 340B prices, and manufacturers 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. As documented in a series of government reports and by Kalderos,[5] the 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 failed to address these concerns.

[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"); Kalderos Inc., *Making Health Policy Work for Patients: How Platform Solutions Enable More Affordable Drugs*, at 15, 25 (2021), https://www.kalderos.com/2021-annual-report ("Our research shows that misapplied discounts and rebates are rampant").

The prevalence of duplicate discounts and diversion in contract pharmacy transactions is no surprise. As Kalderos 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 separate third-party administrator, which has no contact with the patient, is made through algorithms weeks or months after the fact. There is no transparency into the algorithms' "matching" rules.

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

Beginning in 2016, Kalderos sought to fix a broken 340B program. Its philosophy was to be an honest broker between covered entities and manufacturers. Kalderos evaluated solutions based on their ability to give covered entities easy access to 340B pricing, while ensuring there are 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 exceed $1.6 billion annually—and this estimate does not account for additional duplicate discounts that would be identified using 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 or will not make refunds when a violation is established, which HRSA permits. Kalderos 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, 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 affect a balance between ensuring access to 340B prices by covered entities using contract pharmacies 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 health plans, pharmacy benefit managers, hospitals, pharmacies, and state Medicaid agencies.

[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. Audits cannot address the lack of transparency in contract pharmacy transactions because a manufacturer cannot initiate an audit unless it already has "evidence in support" of a violation. 61 Fed. Reg. 65,406, 65,409–10 (Dec. 12, 1996).

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 a 340B price. The covered entities provide to Kalderos the drug's prescription 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 the 340B price. The covered entity provides the requested data and receives payment. Several months later, a state Medicaid agency submits an invoice for a Medicaid rebate. Kalderos matches the earlier paid 340B discount to the Medicaid rebate request and informs the manufacturer that it can deny the Medicaid rebate. There is no impact to the covered entity or contract pharmacy. Importantly, at a May 18, 2022 webinar, it was reported that more than 30,000 contract pharmacy locations already are registered to provide claims data. *See* 340B Report, *Implementing Drug Manufacturers' New 340B Contract Pharmacy Rules* (May 18, 2022) (sub. req.), https://340breport.com/webinars.

The data that Kalderos utilizes are routinely secured in determining price concessions for managed care, pharmacy benefit manager, pharmacy, hospital, physician, and group purchasing organization customers. 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. Kalderos's system achieves the balance reflected in the statute—in a manner that is fair to both sides.[7]

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 UT's and Novartis's programs are in "direct violation of the 340B statute."[8] Without acknowledging its prior acceptance of 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

[7] 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 in a claims data program like Kalderos's, which, as noted above, would permit an unlimited number of transactions and contract pharmacies.

[8] Letter to L. Robson, UT, from D. Espinosa, HRSA, at 1 (May 17, 2021), https://www.hrsa.gov/sites/default/files/hrsa/opa/pdf/hrsa-letter-united-therapeutics-covered-entities.pdf; Letter to D. Lopuch, Novartis, from D. Espinosa, HRSA, at 1 (May 17, 2021), https://www.hrsa.gov/sites/default/files/hrsa/opa/pdf/hrsa-letter-novartis-pharmaceuticals-covered-entities.pdf.

> conditions on covered entities' access to 340B pricing, *including the production of claims data*.

Id. (emphases added). Although 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*., it does not address the data manufacturers secure from non-340B customers, which routinely provide required data.

HRSA's violation letters have resulted in multiple APA lawsuits. In this case, 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). 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, 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 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.

In contrast, in the Eli Lilly & Company lawsuit, 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 [her] view, the construction that best aligns with congressional intent." *Eli Lilly & Co. v. HHS*, No. 1:21-cv-00081-SEB-MJD, 2021 WL 5039566 at *20 (S.D. Ind. Oct. 29, 2021), *appeal docketed*, No. 21-3128 (7th Cir. Nov. 15, 2021). In addition, in the New Jersey litigation, Judge Wolfson partially vacated HRSA's letters, but upheld HRSA's conclusion that a manufacturer cannot require the production of claims data. *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 claims data, *id*. at *43. The court held that private parties could be prohibited from attaching conditions to 340B transactions unless those conditions are affirmatively authorized by statute. *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*.

ARGUMENT

I. REQUIRING BASIC CLAIMS DATA TO PREVENT DUPLICATE DISCOUNTS AND DIVERSION IS ENTIRELY CONSISTENT WITH THE STATUTE.

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 government's contrary position improperly imposes requirements that do not appear in the statutory text, rests on the mistaken view that allowing manufacturers to impose conditions would render 340B a dead-letter, and undermines Congress's purpose, as part of a balanced approach, to prevent duplicate discounts and diversion. Section 340B allows manufactures to impose reasonable terms on 340B sales, especially where they facilitate compliance with the statute's prohibitions and do not disadvantage covered entities as compared to non-340B customers.

A. The Statutory Text Does Not Prohibit Manufacturers from Imposing Reasonable Terms.

"As with all questions of statutory interpretation, [this Court] start[s] with the text." *PhRMA v. FDA*, 957 F.3d 254, 260 (D.C. Cir. 2020) (citing *Ross v. Blake*, 578 U.S. 632, 638 (2016)). 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 … 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 … if such drug is made available to any other purchaser." 42 U.S.C. § 256b(a)(1).

The statutory text thus imposes only two requirements. *First*, if a manufacturer makes a covered outpatient drug available to any other purchaser, it must offer

that 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 Medicaid Drug Rebate Program "snafu" that gave rise to the 340B program, the statute does not address the other terms of 340B transactions. The statute leaves those terms to be negotiated by the parties, just as they were in the days before the Medicaid "snafu."

The government's argument to the contrary is simply wrong. As Judge Friedrich recognized, the government reads into the statute a prohibition that it does not contain. *See Novartis*, 2021 WL 5161783, at *7 ("Neither the 'Shall Offer' provision nor any other in Section 340B contains such clear language that forbids drug manufactures from imposing *any* additional conditions—no matter how minor—on covered entities that purchase drugs at 340B discount prices."). The government's position 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 of 340B

sales, it would have done so explicitly.[9] Having once inadvertently disrupted normal discounting practices, Congress, understandably, did not risk doing so again. Courts may not add text that Congress omitted, because that 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 government argues that statute's silence on non-price terms "necessarily precludes manufacturers from imposing their own conditions," Gov't Br. 27, including a requirement that covered entities "produce claims data," *id.* at 34. That is backwards. Sales by manufacturers to covered entities are private transactions. They do not require statutory authority from Congress. Like any commercial actors, manufacturers and covered entities are free to negotiate reasonable terms absent a specific government prohibition. In Section 340B, Congress restricted the *price* of 340B sales, but left other terms to the parties. As the district court recognized, the "statute's silence on these questions suggests 'that the statute does not compel any particular outcome.'" *Novartis*, 2021 WL 5161783, at *6 (quoting *AstraZeneca Pharms., LP v. Becerra*, No. 21-27, 2021 WL 2458063, at *9 (D. Del. June 16, 2021)).

[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.

The government's position 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 them 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. *See infra*, § II.

Nor, as the government contends, is the authority to impose conditions on 340B sales predicated on reading into the statutory text a "tacit exception" to the "'shall … offer'" provision. Gov't Br. 26. Rather, it rests on the absence of any statutory text—at any point in time—prohibiting non-price conditions. *See Novartis*, 2021 WL 5161783, at *7. The 2010 amendment only imposed a requirement prohibiting manufacturers from refusing to deal with covered entities when drugs are

[10] For example, in a chargeback, as long accepted by HRSA, a wholesaler that is specified by the manufacturer, using a specified electronic system, requires a covered entity to submit data required by the manufacturer. Those data are then provided to the manufacturer to authorize the discount. *See supra*, at 7.

made available to others. 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 *Full Committee Open Markup Session (Part I)*, YouTube (July 21, 2011), 1:24:23, https://youtu.be/La-CUslC6Lm8?t=5063.

As Judge Friedrich explained, "Congress knows full well how to" impose a "broad anti-discrimination rule," but it did not do so here. *Novartis*, 2021 WL 5161783, at *7. Congress did not alter the substantive scope of what Section 340B required in 2010 or the non-price terms left 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 because the statute's silence on non-price conditions is a "gap" for the agency to fill. Congress did not leave a "gap." *See Ry. Labor Execs.' Ass'n v. Nat'l Mediation Bd.*, 29 F.3d 655, 671 (D.C. Cir. 1994) (en banc) ("[T]here is no gap for the agency to fill" where Congress did not delegate "authority to the agency"). Rather, it left the non-price terms of 340B sales, including data requirements, to the parties. *See id.* ("Were courts to *presume* a delegation of power absent an express *withholding* of such power, agencies would enjoy virtually limitless hegemony."). 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 government next argues that allowing drug manufacturers to adopt conditions "would frustrate Congress' manifest purpose." Gov't Br. 27–28 (quoting *United States v. Hayes*, 555 U.S. 415, 426–27 (2009)). Not so. Far from "frustrat[ing] Congress' manifest purpose," *id.*, the provision of claims data *furthers* the statute's purpose by facilitating statutory compliance and ensuring the integrity of the 340B program.

The government's analysis of the statutory purpose is incomplete and flawed. Although the 340B program is designed to support access to discounts, "[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 government considers only one side of the statutory balance.

As Judge Friedrich concluded, 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. 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 an ADR nor an ADR can be initiated, as a practical matter.[11] It is HRSA's refusal to permit claims data that frustrates the purposes of the statute.

[11] *See* 61 Fed Reg. at 65,409–10 (requiring "evidence in support" as a condition of starting an audit). More fundamentally, the statute's text and structure do not provide that the ADR process—which was first added in 2010—is the exclusive means to combat duplicate discounts and diversion—which were prohibited when Congress first enacted the statute 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 reflects a Congressional determination that manufacturer concerns are legitimate; Congress did not *sub silentio* prohibit manufacturers from insisting on reasonable conditions to prevent statutory violations. *See Novartis*, 2021 WL 5161783, at *8.

Reasonable efforts to identify duplicate discounts and diversion do not in any way undermine access to 340B 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 government's position 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.

Finally, the government argues that allowing manufacturers to impose *any* conditions would render Section 340B "a dead letter." Gov't Br. 28 (quoting *Hayes*, 555 U.S. at 427). That hyperbolic argument is baseless. Requiring covered entities to provide basic claims data will not render Section 340B a "dead letter" because it will in no way prohibit 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 entirely consistent with the statute.

Moreover, the limited data that Kalderos seeks reflects "customary practice" of both the covered entities and others. 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 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. Again, over 30,000 contract pharmacies have registered to provide claims data. *See, supra,* at 11.

Nor does requiring covered entities to provide data disadvantage them compared to other customers. Indeed, manufacturers require non-340B customers, in-

cluding health plans, hospitals, physicians, pharmacies, group purchasing organizations, and States participating in the Medicaid programs to submit data.[12] In other words, not only is the government's position not necessary to prevent discrimination against 340B entities, it would actually mandate a *preference* in their favor—one not enjoyed by non-340B customers. Section 340B mandates no such preference.

II. HRSA'S NEW POLICY THAT PROHIBITS ALL CONDITIONS IS ARBITRARY AND CAPRICIOUS.

HRSA's new policy prohibiting *all* conditions also 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*

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[12] *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' provision of record ID, labeler code, units reimbursed, package size, number of prescriptions, and other data in 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/ (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 a wide array of stakeholders to seek drug price concessions includes such standard data elements as "Claim Number," "Prescriber ID," "Prescription/Service Reference Number").

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"). 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 Am. Wild Horse Pres. Campaign v. Perdue,* 873 F.3d 914, 923 (D.C. Cir. 2017) ("[A]n agency may not … depart from a prior policy *sub silentio*"). 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 Dist. Hosp. Partners, LP v. Burwell*, 786 F.3d 46, 57 (D.C. Cir. 2015). The May 17 letters' categorical prohibition on conditions fails these requirements.

A. HRSA Has Previously Permitted Manufacturers to Impose Conditions on 340B Transactions.

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

Indeed, 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's current position barring all conditions cannot be reconciled with that guidance or the agency's existing practice of permitting multiple conditions. As discussed earlier, a wide variety of conditions have been routinely permitted and even approved by HRSA. *See, supra*, 6-8, 23 (chargeback and rebate data, data for patient "matches," credit checks, limited distribution systems, use of unique 340B identifiers, and mandated financial systems).

Kalderos has relied on HRSA's guidance permitting conditions. It was not given notice or an opportunity to comment on HRSA's recent unilateral change in its position.

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 an explanation for the change. The letters announced a new, unqualified policy: no condition may be imposed, regardless of how reasonable. Although this policy conflicts directly with HRSA's prior

positions, HRSA failed even to *acknowledge* its departure from its 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).

Second, HRSA failed to address significant aspects of the problem. An agency must provide an affirmative showing supporting 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 if manufacturers cannot impose *any* conditions. It did not explain why claims data conditions would "undermine the statutory objective" or "have the effect of discouraging entities from participating in the discount program." 59 Fed. Reg. at 25,113. It did not grapple with the rampant problems of duplicate discounts and diversion that undermine the program's integrity.[13]

[13] 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 ignores the limitations of that process that make it ineffective in preventing duplicate discounts and diversion.

CONCLUSION

For these reasons, the judgment of the district court should be affirmed.

Date: June 15, 2022

Respectfully submitted,

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CERTIFICATE OF COUNSEL

Pursuant to D.C. Circuit Rule 29(d), I certify that a separate *amicus* brief is necessary because of the unique perspective offered by Kalderos as a technology company seeking to serve as an "honest broker" between drug manufacturers and covered entities to ensure that both sides receive the statutory benefits and protections Congress provided in Section 340B.

Date: June 15, 2022

/s/ Paul J. Zidlicky
PAUL J. ZIDLICKY

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 6205 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 15, 2022

/s/ Paul J. Zidlicky
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CERTIFICATE OF SERVICE

I hereby certify that on June 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.

/s/ Paul J. Zidlicky
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