Nos. 22-1676

In the United States Court of Appeals for the Third Circuit

ASTRAZENECA PHARMACEUTICALS LP,

Plaintiff-Appellee,

v.

SECRETARY, UNITED STATES DEPARTMENT OF HEALTH & HUMAN SERVICES, *et al*.,

Defendants-Appellants.

On Appeal from the United States District Court for the District of Delaware, No. 1:21-cv-00027 (Hon. Leonard P. Stark)

BRIEF OF *AMICUS CURIAE* KALDEROS, INC. IN SUPPORT OF PLAINTIFF ASTRAZENECA PHARMACEUTICALS LP

PAUL J. ZIDLICKY
ERIC D. MCARTHUR
SIDLEY AUSTIN LLP
1501 K Street, N.W.
Washington, D.C. 20005
Telephone: (202) 736-8000

TREVOR L. WEAR
SIDLEY AUSTIN LLP
One South Dearborn
Chicago, IL 60603
Telephone: (312) 853-7000

July 28, 2022

Counsel for Amicus Curiae

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.

TABLE OF CONTENTS

TABLE OF AUTHORITIES

Page(s)

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

The issues presented in this appeal overlap substantially with the issues presented in the consolidated appeals pending before this Court in *Sanofi Aventis U.S., LLC v. U.S. Department of Health & Human Services*, Nos. 21-3167, 21-3379, and *Novo Nordisk Inc. v. U.S. Department of Health & Human Services*, Nos. 21-3168, 21-3380. Pursuant to this Court's order dated April 28, 2022, *amicus curiae* Kalderos, Inc., which filed an *amicus* brief in the *Sanofi/Novo Nordisk* appeals, has sought to avoid repetition and thus incorporates by reference relevant portions of its *amicus* brief in the *Sanofi/Novo Nordisk* appeals. *See* Brief of *Amicus Curiae* Kalderos, Inc. (Mar. 15, 2022) ("Kalderos Br. (*Sanofi/Novo Nordisk*)").

Kalderos adopts, by incorporation, its prior discussion of (i) the history of the 340B statute, (ii) Kalderos's role in attempting to address the problems of duplicate discounts and diversion within the 340B Program, and (iii) HRSA's recent change in policy culminating with multiple Violation Letters sent to pharmaceutical manufacturers, including AstraZeneca Pharmaceuticals LP ("AstraZeneca"), and this litigation. *See* Kalderos Br. (*Sanofi/Novo Nordisk*) at 3–14.

[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 to this appeal have consented to this filing.

As relevant to this appeal, in a Memorandum Opinion ("Op.") dated February 16, 2022, Judge Leonard P. Stark set aside the May 17, 2021 "Violation Letter" sent to AstraZeneca by the Acting Administrator of the Health Resources and Services Administration ("HRSA") within the U.S. Department of Health and Human Services ("HHS"). In the Violation Letter, HRSA concluded that (i) "[n]othing in the 340B statute grants a manufacturer the right to place conditions on its fulfillment of its statutory obligation to offer 340B pricing on covered outpatient drugs purchased by covered entities," and (ii) AstraZeneca's actions in placing restrictions on 340B pricing with respect to contract pharmacies "are in direct violation of the 340B statute." Violation Letter at 1.

In the judgment under review, Judge Stark set aside the Violation Letter. Op. at 1. Judge Stark held that the Violation Letter reflected the same legally flawed reading of the 340B statute that had earlier caused him to set aside HHS's earlier Advisory Opinion. As relevant to Kalderos's interests, Judge Stark explained that the Violation Letter (and the earlier Advisory Opinion) both reflect the view "that drug manufacturers may not place conditions on their offers of 340B drugs." *Id.* at 9. Judge Stark ruled that HRSA's determination that drug manufacturers may not "place conditions on their offers of 340B drugs" "evinces an understanding that [the agency's] conclusion is driven by a clear statutory command with respect to drug

manufacturers' obligations," *id.* at 9, 12, but that interpretation is "not compelled by the unambiguous text of the statute." *Id.* at 3.

In its brief, the government repeats its position that the 340B "statute does not 'gran[t] 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,'" Gov't Br. 6, and argues that "HHS's guidance consistently interpreted the statute as prohibiting drug manufacturers from creating extra-textual barriers to a covered entity's ability to obtain drugs at the 340B price," *id.* at 11. As discussed below, the government's position is flatly incorrect and should be rejected.

ARGUMENT

The lower court's decision setting aside the Violation Letter should be affirmed. In the Violation Letter, "[a]ccording to HRSA, '[n]othing in the 340B statute grants a [drug] 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.'" Op. 5 (second alteration by Judge Stark). As reflected in Kalderos's *amicus* brief filed in the *Sanofi/Novo Nordisk* appeals, the government's interpretation is (i) unsupported by the 340B statute, and (ii) arbitrary and capricious because it is an unexplained and unacknowledged departure from prior agency guidance that authorized manufacturers to impose conditions on 340B sales.

First, the language and purpose of the 340B statute do not prohibit manufacturers from requiring covered entities to provide basic claims data when seeking 340B pricing. *See* Kalderos Br. (*Sanofi/Novo Nordisk*) at 14–24. The government points to its earlier brief to argue that "tools of statutory interpretation" Gov't Br. 10, support its current view that Section 340B prohibits "drug manufacturers from creating extra-textual barriers to a covered entity's ability to obtain drugs at the 340B price," *id.* at 11. But, as Kalderos has shown, (i) nothing in the statutory text of 340B prohibits manufacturers from imposing reasonable terms and conditions on 340B sales, Kalderos Br. (*Sanofi/Novo Nordisk*) at 14–19, (ii) requiring covered entities to provide basic claims data is consistent with the 340B statute and its purposes, *id.* at 19–20, and (iii) a requirement to provide claims data will not diminish access to 340B pricing for covered entities as compared to other purchasers, *id.* at 22–24.

Second, the Violation Letter also is arbitrary and capricious. As Kalderos has shown previously, the Violation Letter did "not acknowledge that HRSA's new policy differs markedly from past agency positions and practice or provide a reasoned explanation for the change." *Id.* at 26; *see also* AstraZeneca Brief 59–62. On appeal, the government asserts that (i) "the consistency of an agency's interpretation bear[s] on the question whether the agency's interpretation is due *Chevron* deference," Gov't Br. 9, and (ii) "HHS's guidance consistently interpreted

the statute as prohibiting drug manufacturers from creating extra-textual barriers to a covered entity's ability to obtain drugs at the 340B price," *id.* at 11. Neither argument withstands scrutiny.

An assessment whether an agency has changed its approach is relevant not only on the issue of deference, but also to whether agency action is arbitrary and capricious. Specifically, "[a]lthough 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." Kalderos Br. (*Sanofi/Novo Nordisk*) at 24 (quoting *Johnson v. Ashcroft*, 286 F.3d 696, 700 (3d Cir. 2002) (quoting *Fertilizer Inst. v. Browner*, 163 F.3d 774, 778 (3d Cir. 1998))); *see Motor Vehicle Mfrs. Ass'n of U.S., Inc. v. State Farm Mut. Auto. Ins. Co*., 463 U. S. 29, 56 (1983) ("While the agency is entitled to change its view . . . , it is obligated to explain its reasons for doing so"). Thus, an agency may not "depart from a prior policy *sub silentio*," *FCC v. Fox Television Stations, Inc.*, 556 U.S. 502, 515 (2009), and, at a minimum, it "must at least 'display awareness that it is changing its position,'" *Encino Motorcars, LLC v. Navarro*, 579 U.S. 211, 221 (2016) (quoting *Fox Television*, 556 U.S. at 515); *see Nat'l Cable & Telecomms. Ass'n v. Brand X Internet Servs.*, 545 U.S. 967, 981 (2005) ("Unexplained inconsistency is . . . a reason for holding an interpretation to be an arbitrary and capricious change from agency practice under the Administrative Procedure Act").

Here, the Violation Letter states that "'[n]othing in the 340B statute grants a manufacturer the right to place conditions on its fulfillment of its statutory obligation to offer 340B pricing on covered outpatient drugs purchased by covered entities.'" Op. 9 (quoting AR1). That is an unacknowledged change in policy. The government argues that "HHS's guidance *consistently* interpreted the statute as prohibiting drug manufacturers from creating extra-textual barriers to a covered entity's ability to obtain drugs at the 340B price." Gov't Br. 11 (emphasis added). But that is wrong.

Indeed, the same 1994 HHS guidance cited in the government's brief reflects the government's earlier position that (i) "[i]f a manufacturer asks a covered entity whether the entity is in fact participating in the section 340B discount program, *the entity must supply the manufacturer with this information*," and (ii) manufacturers may "include provisions that address customary business practice, request standard information, or include other appropriate contract provisions." 59 Fed. Reg. 25,110, 25,114 (May 13, 1994) (emphasis added). Thus, as far back as 1994, HHS acknowledged that manufacturers could impose "conditions" associated with 340B sales and that doing so was perfectly appropriate under the 340B statute. HRSA offered no acknowledgement of its change in policy.

Finally, the government suggests that "the evolution of HHS's guidance regarding the number of contract pharmacies" was not "left unexplained." Gov't Br. 12. That, too, is wrong. The agency's position with respect to contract pharmacies

is predicated on the agency's adoption of a blanket prohibition on *any* conditions imposed by manufacturers. The Violation Letter nowhere acknowledges the inconsistency between the agency's current policy and the long-standing view adopted by HHS in 1994 that certain "conditions" were permissible under the 340B statute. That unacknowledged departure from the agency's prior interpretation is arbitrary and capricious, and therefore, the Violation Letter properly was set aside.

CONCLUSION

For these reasons, and those stated by Plaintiff-Appellee AstraZeneca, the judgment of the district court should be affirmed.

Date: July 28, 2022

Respectfully submitted,

/s/ Paul J. Zidlicky

PAUL J. ZIDLICKY
ERIC D. MCARTHUR
SIDLEY AUSTIN LLP
1501 K Street, N.W.
Washington, D.C. 20005
Telephone: (202) 736-8000

TREVOR L. WEAR
SIDLEY AUSTIN LLP
One South Dearborn
Chicago, IL 60603
Telephone: (312) 853-7000

Counsel for Kalderos LLC

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 1,513 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: July 28, 2022

/s/ Paul J. Zidlicky
PAUL J. ZIDLICKY

CERTIFICATE OF VIRUS SCAN

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

Date: July 28, 2022

/s/ Paul J. Zidlicky
PAUL J. ZIDLICKY

CERTIFICATE OF BAR MEMBERSHIP

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

Date: July 28, 2022

/s/ Paul J. Zidlicky
PAUL J. ZIDLICKY

CERTIFICATE OF SERVICE

I hereby certify that on July 28, 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.

Date: July 28, 2022

/s/ Paul J. Zidlicky
PAUL J. ZIDLICKY