Nos. 21-3167, 21-3379 (cross-appeal)

IN THE UNITED STATES COURT OF APPEALS
FOR THE THIRD CIRCUIT

SANOFI-AVENTIS U.S., LLC,
Plaintiff-Appellant,

v.

U.S. DEPARTMENT OF HEALTH AND HUMAN SERVICES; SECRETARY, U.S. DEPARTMENT OF HEALTH AND HUMAN SERVICES; GENERAL COUNSEL, U.S. DEPARTMENT OF HEALTH HUMAN SERVICES; HEALTH RESOURCES SERVICES ADMINISTRATION; ADMINISTRATOR OF THE HEALTH RESOURCES SERVICES ADMINISTRATION,
Defendants-Appellees.

On Appeal from the United States District Court for the District of New Jersey (No. 3:21-cv-00634)

OPENING BRIEF FOR APPELLANT SANOFI-AVENTIS U.S., LLC

Toni-Ann Citera
Rajeev Muttreja
JONES DAY
250 Vesey Street
New York, New York 10281
(212) 326-3939
tcitera@jonesday.com
rmuttreja@jonesday.com

Noel J. Francisco
Brett A. Shumate
JONES DAY
51 Louisiana Ave. NW
Washington, DC 20001
(202) 879-3939
njfrancisco@jonesday.com
bshumate@jonesday.com

Counsel for Appellant Sanofi-Aventis U.S., LLC

CORPORATE DISCLOSURE STATEMENT

Pursuant to Federal Rule of Appellate Procedure 26.1 and Third Circuit Local Appellate Rule 26.1.1, Appellant Sanofi-Aventis U.S., LLC states that its parent corporation is Sanofi, that no publicly held corporation owns 10% or more of any stock in Sanofi-Aventis U.S., LLC, and that Sanofi is the only non-party publicly held corporation with a financial interest in the outcome of this proceeding.

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INTRODUCTION

Sanofi-Aventis U.S., LLC ("Sanofi"), one of the world's largest drug manufacturers, is committed to making its medicines accessible to patients in need, including through a drug-discounting program known as the 340B Program. When creating this manufacturer-funded program in Section 340B of the Public Health Service Act, Congress restricted eligibility for steeply discounted 340B prices to certain categories of non-profit and governmental healthcare providers (known as "covered entities") that may dispense these drugs only to their patients. But in the last decade, for-profit "contract pharmacies" (such as Walgreens and CVS) have exploded within the now-$38 billion 340B Program, despite never being mentioned in the statute.

These pharmacies, which frequently profit from 340B discounts at the expense of covered entities and patients, are responsible for skyrocketing rates of waste and abuse within the 340B Program. These problems escalated after 2010, when the U.S. Department of Health and Human Services ("HHS")—which administers the 340B Program—allowed covered entities to enter into unlimited arrangements with contract pharmacies, causing the program to quadruple in size in less

than a decade. Instead of addressing widespread waste and abuse at contract pharmacies, HHS has instructed that manufacturers like Sanofi are often best positioned to catch these problems.

To that end, in 2020, Sanofi (like some other manufacturers) took steps to address the explosive growth of contract pharmacies. Sanofi in particular adopted an integrity initiative under which it continues to offer 340B-priced drugs to all covered entities (as Section 340B requires) and will even provide these drugs to a single contract pharmacy (which Section 340B does not address) if a covered entity has no in-house pharmacy. Sanofi will also provide 340B-priced drugs to an *unlimited* number of contract pharmacies, if the covered entity submits minimal claims data that is just a subset of what insurance companies require. Sanofi uses this data to detect waste and abuse at contract pharmacies, precisely as HHS has suggested. And to further minimize the impact on covered entities, Sanofi exempted from its integrity initiative many categories of covered entities at which waste and abuse are less prevalent. To date, hundreds of covered entities have participated in Sanofi's integrity initiative.

But in 2021, HHS declared Sanofi's integrity initiative unlawful and threatened Sanofi with massive financial penalties. Abandoning its longstanding recognition of not only the statute's silence on contract pharmacies but also the agency's lack of authority to enforce any such rule, HHS claimed that Section 340B unambiguously requires Sanofi to provide 340B-priced drugs to an unlimited number of contract pharmacies without imposing any conditions. And the District Court largely upheld HHS's violation letter—despite acknowledging, like the agency had previously, that "§ 340B is silent on what role (if any) contract pharmacies play in Congress' discount drug scheme"—by relying on the statute's "legislative history," "purpose," and "post-enactment history."

This Court should reverse the District Court because HHS exceeded its statutory authority—and acted arbitrarily and capriciously—by penalizing Sanofi for violating a statutory requirement that does not exist. Court after court—including the District Court—has recognized that the statute says nothing about whether manufacturers must provide 340B-priced drugs to contract pharmacies. That means Congress did not require Sanofi to provide discounted drugs to contract pharmacies, much less require that Sanofi do so unconditionally. Instead, the text of Section

340B simply requires Sanofi to "offer" 340B-priced drugs to covered entities, which Sanofi does by making these drugs available in multiple ways, including through an unlimited number of contract pharmacies with minimal conditions. Accordingly, this Court should vacate HHS's violation letter to Sanofi and, also, the agency's similar, now-withdrawn Advisory Opinion regarding contract pharmacies.

HHS acted unlawfully in another way, too. Congress set a 2010 deadline for HHS to establish an administrative dispute resolution ("ADR") process for the 340B Program. But when HHS finally rushed out a decade-late ADR rule in December 2020, it did so on the basis of a notice of proposed rulemaking that the agency had *withdrawn* years earlier—and despite having just announced that it had no plans to issue a rule. This violated the Administrative Procedure Act ("APA") and requires the ADR rule to be vacated.

STATEMENT OF JURISDICTION

The District Court had federal-question jurisdiction under 28 U.S.C. § 1331 and, on November 5, 2021, issued final judgment. JA8-10 (D.Ct.ECF.111 ("Order")); JA11-132 (D.Ct.ECF.110 ("Op.")). On

November 19, 2021, Sanofi filed a timely notice of appeal. JA1-2; *see also* JA6 (cross-appeal). This Court has jurisdiction under 28 U.S.C. § 1291.

STATEMENT OF THE ISSUES

1. Whether HHS exceeded its statutory authority under Section 340B, or otherwise violated the APA, by requiring Sanofi to unconditionally provide discounted drugs to an unlimited number of contract pharmacies, even though contract pharmacies are not mentioned in Section 340B.

2. Whether HHS exceeded its authority under Section 340B, or otherwise violated the APA, by determining that Sanofi's integrity initiative violates Section 340B, even though Sanofi continues to offer 340B-priced drugs to all covered entities and makes those drugs available in multiple ways—including by providing the drugs to an unlimited number of contract pharmacies if covered entities submit minimal claims data that can help identify unlawful duplicate discounts.

3. Whether Sanofi's challenge to HHS's Advisory Opinion regarding contract pharmacies presents a live controversy—when HHS withdrew that Opinion, and two courts vacated it, but HHS threatens to

enforce the same legal interpretation against Sanofi—and, if so, whether the Opinion violates the APA.

4. Whether HHS violated the APA by promulgating the ADR rule on the basis of a notice of proposed rulemaking that was withdrawn, with the agency further announcing that no rule was forthcoming.

STATEMENT OF RELATED CASES AND PROCEEDINGS

In addition to the related actions identified in Novo Nordisk's brief filed in Nos. 21-3168 and 21-3380, which are consolidated with this appeal, Sanofi identifies *National Association of Community Health Centers v. Sanofi-Aventis U.S., LLC*, No. 210112-2 (HHS ADR Board).*

STATEMENT OF THE CASE

A. The 340B Program

This case concerns the government's authority to take enforcement action against participants in the 340B Program, which is administered by HHS and its agency the Health Resources and Services Administration ("HRSA," and together, "HHS"). Established in 1992, the 340B Program requires drug manufacturers like Sanofi to offer drugs at

* Sanofi incorporates Novo Nordisk's brief filed in Nos. 21-3168 and 21-3380.

steeply discounted prices to specific categories of health care providers—termed "covered entities"—as a condition of participating in Medicaid and Medicare Part B. 42 U.S.C. § 256b. The statute enumerates 15 such categories, which include black lung clinics, hemophilia diagnostic treatment centers, and other non-profit or governmental entities. *See id.* § 256b(a)(1), (4)(A)-(O). In recent years, covered entities have purchased more than $38 billion in 340B-priced drugs. JA17-18 (Op.7-8). But the 340B Program was just a small fraction of this size as recently as 2014. *See id.*

HHS does not have the authority to expand the list of covered entities; only Congress may do that, by amending the statute. JA14 (Op.4). Section 340B gives HHS rulemaking authority only in three "limited contexts"—a dispute resolution process, pricing, and civil monetary penalties. JA86 (Op.76); *see Pharm. Rsch. & Mfrs. of Am. v. HHS*, 43 F. Supp. 3d 28, 41-45 (D.D.C. 2014).

Section 340B(a)(1) requires HHS to ensure, through contracts that "simply incorporate statutory obligations," *Astra USA, Inc. v. Santa Clara Cnty.*, 563 U.S. 110, 118 (2011), that "the amount required to be paid … to the manufacturer for covered outpatient drugs … purchased

by a covered entity" does not exceed a ceiling price determined through a prescribed formula. 42 U.S.C. § 256b(a)(1). The ceiling price for Sanofi's drugs is typically "much lower" than the market price—approximately 20–50% lower according to HHS, and sometimes "as little as one penny per pill." JA15 (Op.5); *see* JA579 (GAO, HHS Uses Multiple Mechanisms to Help Ensure Compliance with 340B Requirements, GAO-21-107, at 1 (Dec. 2020), https://tinyurl.com/5ee9pm8n).

In 2010, Congress amended Section 340B(a)(1) to further direct "that the manufacturer *offer* each covered entity covered [outpatient] drugs for purchase at or below" the ceiling price. Pub. L. No. 111-148, § 7102(b), 124 Stat. 119, 827 (2010), *codified at* 42 U.S.C. § 256b(a)(1) (emphasis added). This provision—commonly known as the "must offer" or "shall offer" provision—does not specify any terms of the mandatory offer except for the price. Nor does the statute restrict what covered entities may charge their patients for these discounted drugs or limit their ability to seek standard reimbursement from third-party payors (*e.g.*, health insurers) for filled prescriptions.

Reflecting that its steep discounts could be easily exploited, Section 340B explicitly aims to combat waste and abuse in the 340B Program.

For example, the statute prohibits "duplicate discounts or rebates," which occur when the same prescription receives both a 340B discount and a Medicaid rebate (both of which are funded by the manufacturer). 42 U.S.C. § 256b(a)(5)(A). This is a common risk, because covered entities' patients are often insured by Medicaid. JA568 (CMS, Best Practices for Avoiding 340B Duplicate Discounts in Medicaid 1 (Jan. 8, 2020) ("Best Practices"), https://tinyurl.com/59ufxx49). Section 340B also prohibits "diversion," which occurs when covered entities resell or transfer discounted drugs to persons other than their patients. 42 U.S.C. § 256b(d)(2)(A). Manufacturers can audit a covered entity in certain circumstances if they suspect duplicate discounting or diversion. *See id.* § 256b(a)(5)(C).

Section 340B creates no private rights of action. *See Astra*, 563 U.S. at 113-14. However, Congress required HHS to establish an administrative dispute resolution ("ADR") process for resolving claims by program participants by September 20, 2010. *See* 42 U.S.C. § 256b(d)(3). As discussed below, HHS missed this deadline by more than a decade.

B. HHS's Longstanding Interpretation of Section 340B

For decades, HHS has recognized that Section 340B has "many gaps" and—importantly for this case—"is silent as to permissible drug distribution systems." JA171-72, 177 (61 Fed. Reg. 43,549, 43,549-50, 43,555 (Aug. 23, 1996) (VLTR.88-89, 94)). The agency has also acknowledged that its "enforcement authority" under Section 340B is "quite limited" and, moreover, that it cannot issue any "binding, enforceable document[s]" that "dictate specific 340B Program requirements." JA523 (GAO, Federal Oversight of Compliance at 340B Contract Pharmacies Needs Improvement, GAO-18-480, at 57 (June 2018), https://tinyurl.com/yckwyecd). HHS has long complained about this to Congress.

As recently as 2017 and 2018, the longtime Director of the HRSA Office of Pharmacy Affairs, which leads the 340B Program, testified that Section 340B is "silent" about many issues in the 340B Program, including "how these covered entities dispense and get these drugs to their patients." JA353-54, 357, 359, 375, 377 (Examining HRSA's Oversight of the 340B Drug Pricing Program: Hearing Before the Subcomm. on Oversight and Investigations of the H. Comm. on Energy

and Commerce, 115th Cong. (2017) ("Director 2017 Testimony"), https://tinyurl.com/e9ccpdrv); *see* JA534 (Statement of Krista M. Pedley, at 4 (2018) ("Director 2018 Testimony"), https://tinyurl.com/2p92njh7) (Section 340B "does not specify how a covered entity may provide or dispense such drugs to its patients").

Director Pedley has also emphasized to Congress the need for "comprehensive regulatory authority" under Section 340B to clarify "the requirements of the program." JA366, 379 (Director 2017 Testimony). For the last four years, HHS has requested that Congress broaden its regulatory authority under Section 340B. *See* JA736, 755 (HHS, FY2022 Budget at 13, 32, https://tinyurl.com/mr47xfcj); JA532 (Director 2018 Testimony at 2). Just last year, the HHS Secretary testified that the agency needs "more authority to actually give clear guidance on what can be done and can't be done on 340B." JA695 (Hearing on Fiscal Year 2022 Budget Request for HHS Before the Subcomm. on Lab., Health, and Human Servs., Educ., and Related Agencies of the S. Appropriations Comm., 117th Cong. (June 9, 2021) ("Secretary 2021 Testimony")). But Congress has declined to act.

C. The Explosion of Contract Pharmacy Arrangements—and Abuses—in the 340B Program

Congress did not include contract pharmacies—for-profit third-party pharmacies that fill prescriptions written by other healthcare providers—in the statutory list of covered entities entitled to 340B discounts. Nor did Congress define any other role for contract pharmacies in Section 340B, despite explicitly addressing the roles of other third parties that can work with covered entities. *See* 42 U.S.C. § 256b(d)(1)(B)(v), (d)(2)(B)(iv), (d)(3)(B)(b)(i). Nonetheless, HHS has advised via nonbinding guidance that covered entities may sometimes use contract pharmacies.

In 1996, recognizing that Section 340B is "silent" as to contract pharmacies, HHS allowed any covered entity without its own in-house pharmacy to contract with one third party to provide pharmacy services for 340B-priced drugs. *See* JA171-72, 177 (61 Fed. Reg. at 43,549-50, 43,555 (VLTR.88-89, 94)). Then, in 2010, the agency advised in new guidance that *all* covered entities (even those with in-house pharmacies) could contract with an *unlimited* number of outside pharmacies. *See* JA180 (75 Fed. Reg. 10,272, 10,273 (Mar. 5, 2010) (VLTR.101)). Both the 1996 guidance and the 2010 guidance gave the agency's position on what

covered entities were *permitted* to do, not what manufacturers were *required* to do.

Indeed, neither guidance document purported to be binding or to impose legal obligations on manufacturers, *see id.*, and HHS officials have acknowledged that the guidance "is not legally enforceable," JA800 (Tom Mirga, HRSA Says Its 340B Contract Pharmacy Guidance Is Not Legally Enforceable, 340B Report (July 9, 2020)). As HHS recently told a covered-entity organization, "the agency strongly encourages all manufacturers to sell 340B priced drugs to covered entities through contract pharmacy arrangements, [but] HRSA's current authority … is limited because Congress has not granted it comprehensive regulatory authority to develop enforceable policy that ensures clarity in program requirements." *Am. Hosp. Ass'n v. HHS*, No. 20-cv-8806, 2021 WL 616323, at *3 (N.D. Cal. Feb. 17, 2021).

Following the 2010 guidance, covered entities' use of contract pharmacies exploded. The number of for-profit contract pharmacies participating in the 340B Program increased more than twenty-fold, from 1,300 in 2010 to 28,000 in 2020, with nearly a third of those pharmacies getting involved after 2017. JA20 (Op.10); JA803-05 (Adam Fein,

Walgreens and CVS Top the 28,000 Pharmacies Profiting from the 340B Program. Will the Unregulated Party End?, Drug Channels (July 14, 2020), https://tinyurl.com/6umbwxkx). By 2020, there were more than 100,000 arrangements between covered entities and contract pharmacies, with some covered entities contracting with pharmacies thousands of miles away. JA833-84 (PhRMA, Petition for Rulemaking (Nov. 24, 2020) ("Petition") (ADVOP.1383-84)); JA488-89 (GAO-18-480 at 22-23). 340B-priced sales saw a corresponding spike, rising from approximately $9 billion in 2014 to more than $38 billion in 2020. *See* JA17-18 (Op.7-8). And the "dramatic[]" expansion of contract-pharmacy arrangements has been accompanied by significant problems. *See* JA107 (Op.97).

For one thing, contract pharmacies regularly "use the 340B Program for profit" by keeping portions of the discounts that Congress intended for covered entities. JA108 & nn.61-62 (Op.98 & nn.61-62); *see* JA488-89 (GAO-18-480 at 22-23). Contract pharmacies seek standard payment from insurance or the patient for 340B-priced drugs, yielding a large profit margin over the 340B price, some of which may be shared with the covered entity, but much of which the pharmacy often pockets.

See JA108 & n.61 (Op.98 & n.61); JA496 (GAO-18-480 at 30); JA835-37 (Petition (ADVOP.1385-87)); JA825 (PhRMA, New Analysis Shows Contract Pharmacies Financially Gain From 340B Program With No Clear Benefit to Patients (Oct. 8, 2020), https://tinyurl.com/bddaupw5).

Also, "contract pharmacy arrangements increase the rate of fraud in the 340B Program." JA106 & n.55 (Op.96 & n.55). In particular, as HHS has acknowledged, the use of contract pharmacies "creates more opportunities for drug diversion compared to in-house pharmacies." JA288 (GAO, Manufacturer Discounts in the 340B Program Offer Benefits, But Federal Oversight Needs Improvement, GAO-11-836, at 28 (Sept. 2011), https://tinyurl.com/4ke28sr3); *see* JA106 n.55 (Op.96 n.55). Under the prevailing "replenishment" model, contract pharmacies determine a patient's 340B status only *after* a drug is dispensed—and initially treat covered entities' patients like the general public, using the same supply of full-price drugs. Later, contract pharmacies "replenish [those drugs] with 340B drugs [at 340B prices]." JA314-15 (HRSA, 340B Drug Pricing Program Release No. 2013-1, at 2-3 (Feb. 7, 2013), https://tinyurl.com/yz3dp9bh); *see* JA108 & n.62 (Op.98 & n.62). In part because of this commingling of 340B and non-340B patients, the

expansion of contract-pharmacy arrangements also has led to widespread duplicate discounting, through prescriptions that receive both a 340B discount and a Medicaid rebate. *See* JA106 n.55 (Op.96 n.55); JA611-48 (HRSA, Program Integrity: FY19 Audit Results, https://tinyurl.com/yc2xhjak); JA808-10 (Adam Fein, The Federal Program That Keeps Insulin Prices High, WSJ (Sept. 10, 2020)).

HHS itself has recognized that contract-pharmacy arrangements "create complications in preventing duplicate discounts." JA316-17 (HHS OIG, Contract Pharmacy Arrangements in the 340B Program, OEI-15-13-00431, at 1-2 (Feb. 4, 2014) (ADVOP.1403-04)); *see* JA106 n.55 (Op.96 n.55). These problems stem in part from information gaps—as Medicaid payments are tied to the pharmacy that *fills* the prescription, but 340B discounts are linked to the underlying covered entity that *prescribes* the drug, and neither HHS nor manufacturers have complete insight into which covered entities use which contract pharmacies. Because of this, as HHS has stated, "duplicate discounts can often best be identified from a review of claims level data by the manufacturers," which can help "facilitate compliance," reduce disputes, and "ensure there are no duplicate discounts." JA573 (Best Practices at 6).

Although the problems at contract pharmacies have been severe, according to a 2014 HRSA report, the "overwhelming majority (82 percent) of covered entities do not contract with pharmacies." JA334 (HRSA, Contract Pharmacy Oversight (Feb. 6, 2014) ("HRSA Oversight"), https://tinyurl.com/323ynmx7). Moreover, for the limited covered entities using contract pharmacies, "75 percent have fewer than 5 contract pharmacy arrangements," *id.*—and some "may not actually use the [contract] pharmacy to dispense 340B drugs," and instead rely on their own in-house pharmacies instead of "pay[ing] [others] to dispense drugs on their behalf." JA585 (GAO-21-107 at 7); JA484 (GAO-18-480 at 18).

The explosive growth of contract pharmacies in recent years, and the corresponding problem of duplicate discounting, is thus attributable to the small fraction of covered entities that make extraordinary use of contract pharmacies. *See* JA580 (GAO-21-107 at 2). Indeed, the government has identified a few types of covered entities as being the heaviest users of contract pharmacies, "with disproportionate share hospitals having the most on average (25 contract pharmacies)," while other types of covered entities barely use contract pharmacies at all.

JA482-84 (GAO-18-480 at 16-18). The District Court similarly found that only "approximately one-third of all covered entities currently use contract pharmacy arrangements, ranging from 1 to 439 per covered entity, with an average of 12." JA20; *see also* JA534 (Director 2018 Testimony at 4) ("The majority (73 percent) of covered entities do not contract with pharmacies.").

D. Sanofi's 340B Integrity Initiative

In recent years, Sanofi has discovered significant duplicate discounting for its own drugs. In response, Sanofi announced an integrity initiative in July 2020 that aims to prevent duplicate discounts and other problems in the 340B Program. Other manufacturers have also taken actions in response to the contract-pharmacy problems, but those actions have differed from Sanofi's integrity initiative.

Under the integrity initiative, which took effect on October 1, 2020, Sanofi continues to offer discounted pricing to all covered entities. Sanofi merely requests that, subject to limited exceptions, covered entities submit minimal claims data in order to have 340B-priced drugs dispensed to their patients by contract pharmacies. *See* JA21 (Op.11); JA904-05, 910-11, 912-14 (Sanofi Program Updates in July 2020

(D.Ct.ECF.68-3), August 2020, (D.Ct.ECF.68-5), and September 2020 (D.Ct.ECF.68-6)). In addition, as of early 2021, Sanofi allows any covered entity without an in-house pharmacy to designate a contract pharmacy at which its patients can receive 340B-priced drugs—regardless of whether the covered entity provides any claims data. *See* JA21 (Op.11); JA921 (Sanofi Program Update (Feb. 1. 2021) (D.Ct.ECF.68-10)).

Sanofi's integrity initiative narrowly focuses on the categories of covered entities (*e.g.*, certain hospitals) that are the heaviest users of contract pharmacies and thus connected to the recent spike in duplicate discounting. Sanofi's program exempts the many categories of covered entities that do *not* make extensive use of contract pharmacies, such as children's hospitals, Ryan White HIV/AIDS clinics, and family planning clinics. *Id.*; JA482-84 (GAO-18-480 at 16-18).

Overall, then, for those covered entities that fall under the integrity initiative, Sanofi offers 340B-priced drugs in three ways: (i) through the covered entity's own in-house pharmacy; (ii) through a single, designated contract pharmacy, if the covered entity has no in-house pharmacy; and (iii) through multiple contract pharmacies, if the covered entity submits the requested claims data. JA21 (Op.11).

Providing this data imposes little (if any) burden on covered entities. The initial setup requires only 15 minutes, and biweekly submissions take approximately 5 minutes. JA994-95 (Declaration of Scott Bray ("Bray Declaration") (D.Ct.ECF.94-2 at 10-11)); JA125 (Op.115). Further, the data is anonymized, and an independent third-party expert has certified the process as HIPAA-compliant. JA996-97 (Bray Declaration (D.Ct.ECF.94-2 at 12-13)). And the data requested by Sanofi is just a subset of what covered entities already submit to third-party payors for reimbursement. JA993-94 (Bray Declaration (D.Ct.ECF.94-2 at 9-10)).

In other words, Sanofi is not asking these covered entities to do anything more than they already do to get reimbursed—indeed it is less. By comparing the requested claims data to Medicaid payor data, Sanofi can identify impermissible duplicate discounts that would otherwise go undetected—as HHS itself has previously recognized. *See* JA573 (Best Practices at 6).

To date, hundreds of covered entities have participated in Sanofi's integrity initiative, by either providing claims data or registering a single contract pharmacy. But other covered entities have refused to

participate—and have instead clamored for HHS to shut down Sanofi's integrity initiative as well as other manufacturers' different contract-pharmacy policies. *See, e.g.*, JA1084, 1183. These complaints culminated in several lawsuits, filed in late 2020, seeking to compel HHS both to enforce Section 340B against Sanofi and other manufacturers, and to create the statutorily required ADR process—which at that point was a decade late.

E. The Challenged HHS Actions

In response to these suits, HHS promptly issued the ADR rule, the Advisory Opinion, and the Violation Letter, all of which are at issue here.

1. Administrative Dispute Resolution Rule

On December 14, 2020, HHS promulgated the long-overdue ADR rule, establishing an administrative process for resolving, among other things, covered entities' claims that they have been overcharged for drugs. JA196-210 (85 Fed. Reg. 80,632 (Dec. 14, 2020) (ADR.12-26) (codified at 42 C.F.R. pt. 10)) (the "ADR rule"). Although Congress required HHS to establish an ADR process by 2010, *see supra* at 9, HHS took until 2016 to issue a notice of proposed rulemaking ("NPRM") for a potential ADR rule. *See* JA187-94 (81 Fed. Reg. 53,381 (Aug. 12, 2016)

(ADR.4-11)). But after that proposed rule drew comments, HHS withdrew the NPRM without explanation on August 1, 2017. *See* JA195 (OIRA, RIN 0906-AA90 (2017), https://tinyurl.com/5y66nkjp ("Unified Agenda")).

In the years that followed, HHS took no public action regarding an ADR process. And in March 2020, an HHS official explained that the agency "d[id] not plan to move forward on issuing a regulation," because "many of the issues that would arise for dispute are only outlined in guidance" that was not itself enforceable. *Eli Lilly & Co. v. Cochran*, 526 F. Supp. 3d 393, 402, 406 (S.D. Ind. 2021) ("*Lilly I*") (quoting JA788 (Tom Mirga, HRSA: 340B Dispute Resolution Will Stay on Hold Until We Get Broader Regulatory Authority, 340B Report (Mar. 12, 2020))). "Without comprehensive regulatory authority," the official continued, HHS lacks "appropriate enforcement capability" and "is unable to develop enforceable policy that ensures program requirements across all the interdependent aspects of the Program are met." JA788 (Mirga, *supra*).

When HHS nonetheless promulgated the ADR rule in December 2020, it surprised Sanofi and other manufacturers, because the agency had not issued a new NPRM or otherwise solicited new comments.

Instead, the agency chose to rely on the withdrawn 2016 NPRM and the comments received years earlier. JA197 (85 Fed. Reg. at 80,633 (ADR.13)). But much had changed in the interim, including the explosion in the use of contract pharmacies. JA17-18 (Op.7-8); *see supra* at 13-17.

In March 2021, a federal court preliminarily enjoined the ADR rule for violating the APA's notice-and-comment requirement. *See Lilly I*, 526 F. Supp. 3d at 407-08. Although HHS continues to defend the ADR rule in litigation, it announced in November 2021 that it intends to replace the rule to "correct procedural deficiencies." JA237 (OIRA, RIN 0906-AB28 (2021), https://tinyurl.com/2mcsaxur). As of the filing of this brief, HHS has not yet disclosed its replacement ADR rule, and the December 2020 version of the rule remains effective. After that version took effect in January 2021, an association of 328 covered entities filed an ADR petition against Sanofi regarding the integrity initiative. JA1183. That petition remains pending.

2. Advisory Opinion

On December 30, 2020, about two weeks before the ADR rule took effect, the HHS General Counsel issued Advisory Opinion 20-06,

determining that manufacturers must provide 340B-priced drugs unconditionally to contract pharmacies. JA211-18.

The Advisory Opinion departed sharply from the agency's longstanding view that Section 340B is silent regarding contract pharmacies. *See supra* at 10-11. Whereas the agency's earlier non-binding guidance found, at most, that Section 340B's silence on contract pharmacies *permits* covered entities to use contract pharmacies, the Advisory Opinion concluded that Section 340B unambiguously *requires* manufacturers to provide discounted drugs anywhere covered entities wish—whether that be to contract pharmacies, "low-earth orbit," or the "lunar surface"—so long as the recipient is "acting as [an] agent[] of a covered entity." JA211-13. The Opinion also determined that Section 340B prohibits manufacturers from placing conditions on the provision of 340B-priced drugs to contract pharmacies based on concerns about duplicate discounting and diversion. JA211, 215.

Shortly thereafter, a federal court held that the Advisory Opinion is "legally flawed" because it "wrongly determines" that Section 340B unambiguously requires manufacturers to provide discounted drugs to contract pharmacies. *AstraZeneca Pharms. LP v. Becerra*, 543 F. Supp.

3d 47, 58-59, 61-62 (D. Del. 2021) (Stark, J.) ("*AstraZeneca I*"). On the contrary, the court explained, Section 340B is "simply silent" on the "permissible role (if any) of contract pharmacies" in the 340B Program. *Id.* at 51, 59; *see also Eli Lilly & Co. v. HHS*, No. 21-cv-0081, 2021 WL 5039566, at *14, *25 (S.D. Ind. Oct. 29, 2021) ("*Lilly II*").

Within days of *AstraZeneca I*, HHS withdrew the Advisory Opinion. JA231; *see* JA24 (Op.14). But the *AstraZeneca I* court later vacated the Advisory Opinion, finding that HHS's withdrawal did not moot the case because it was not "absolutely clear" that HHS would not resume the challenged conduct. ECF No. 83, at 2-3, *AstraZeneca Pharms. LP*, No. 21-cv-0027 (D. Del. June 30, 2021) (JA233-34); *see also Lilly II*, 2021 WL 5039566, at *12, *25 (same).

3. Violation Letter

On May 17, 2021, before the Advisory Opinion had been vacated or withdrawn, HHS sent the Violation Letter to Sanofi and similar letters to other manufacturers. JA219-20; *see* JA221-30. The Violation Letter determined that Sanofi's integrity initiative is "in direct violation of the 340B statute" because—as the Advisory Opinion stated—the statute "requires" manufacturers to provide discounted drugs to contract

pharmacies and prohibits manufacturers from imposing conditions on 340B offers. JA219. Discarding one aspect of the Advisory Opinion, however, the Violation Letter determined that manufacturers must provide discounted drugs to *all* contract pharmacies that have arrangements with covered entities, not just those acting as covered entities' agents. *See* JA219-20. The Violation Letter also stated that Sanofi's program "ha[s] resulted in overcharges," ordered Sanofi to refund or credit these overcharges, and threatened Sanofi with additional penalties. *Id.* HHS subsequently referred Sanofi to HHS's Inspector General for potential civil monetary penalties. JA235.

Notably, the Violation Letter—unlike the previous HHS guidance on contract pharmacies—did not acknowledge that Section 340B is silent about contract pharmacies. Instead, the Violation Letter indicated that Section 340B unambiguously prohibited Sanofi's integrity initiative, and that HHS had always understood the statute to require manufacturers to provide discounted drugs to an unlimited number of contract pharmacies. JA219-20. Like the Advisory Opinion, the Violation Letter took this position without addressing HHS's prior, inconsistent guidance.

F. Procedural History

Sanofi filed this lawsuit in 2021 challenging all three final agency actions under the APA. The District Court largely upheld these actions in an opinion that also resolved a similar lawsuit filed by the manufacturer Novo Nordisk, which has a different contract-pharmacy policy, JA21 (Op.11).

First, the District Court rejected Sanofi's challenges to the ADR rule. As relevant here—and in direct conflict with *Lilly I*—the court held that HHS did not violate the APA's notice-and-comment requirement when promulgating the ADR rule, because the agency did not actually withdraw the rule's 2016 NPRM "in the sense of the APA." JA40, 45. As the court saw it, even though HHS had explained that an ADR rule was not forthcoming, Section 340B still "mandated" that the agency issue an ADR regulation "at some point, sooner or later," and thus gave manufacturers fair notice. JA42, 44.

Second, in a footnote, the District Court denied as moot Sanofi's challenge to the Advisory Opinion. JA31 n.31; *see* JA9 (Order). With little explanation, the court observed that HHS had withdrawn the Advisory Opinion, that *AstraZeneca I* and *Lilly II* both vacated the

Opinion, and that the agency might "substantial[ly] revis[e]" its position going forward. JA31 n.31. The District Court did not address the reasoning of *AstraZeneca I* and *Lilly II*, which both held that similar challenges to the Advisory Opinion were not moot. *Id.*; *see supra* at 24-25.

Third, the District Court largely upheld the Violation Letter's determination that Section 340B requires manufacturers to unconditionally provide discounted drugs to contract pharmacies and thus prohibits Sanofi's integrity initiative. But the court first held that HHS's interpretation "is not entitled to any agency deference." JA90. Deference under *Chevron, U.S.A., Inc. v. NRDC, Inc.*, 467 U.S. 837 (1984), was unavailable because HHS lacks general rulemaking authority under Section 340B. JA85-86. And deference under *Skidmore v. Swift & Co.*, 323 U.S. 134 (1944), was unwarranted because HHS wrongly treated Section 340B as unambiguous. JA90.

The District Court then found that Section 340B is "silent" regarding "what role (if any) contract pharmacies play" in the 340B Program and, further, does not "expressly prohibit[]" Sanofi's initiative. JA88, 104. Nevertheless, relying on legislative history and statutory purpose, the court held that "HHS has the statutory authority to require

manufacturers to ship 340B drugs to at least one contract pharmacy site each." JA91-94, 101. In addition, the court held that the "best reading" of Section 340B "forecloses" Sanofi's integrity initiative. JA91, 104; *see* JA9 (Order at 2). In the District Court's view, these issues hinged on whether Section 340B grants manufacturers the "authority" or "power" to place conditions on their offers—not whether Section 340B authorizes HHS to prohibit such conditions. JA103-04.

Although the District Court largely upheld the Violation Letter, the court declined to resolve whether a covered entity could force a manufacturer to provide 340B-priced drugs to multiple contract pharmacies and, instead, vacated the Letter's determination that Sanofi owed credits, refunds, or penalties "to the extent that such determinations may depend on the number of permissible contract pharmacy arrangements under the 340B statute." JA105-06, 116. Recognizing that large numbers of contract-pharmacy arrangements threaten to render the 340B Program "unworkable," the District Court found that HHS had not adequately addressed "how many contract pharmacies the 340B statute permits." JA105-06. The court vacated the

Violation Letter in part and remanded for HHS to further consider that question. JA10 (Order at 3).

Notably, the District Court's decision departs from other decisions that vacated materially identical violation letters HHS sent to other manufacturers. In *Lilly II*, despite agreeing with HHS's interpretation of Section 340B, the court found that HHS impermissibly failed to explain its "dramatic[]" departure from the agency's past guidance. 2021 WL 5039566, at *22-23, *25. In *AstraZeneca II*, the court held that the agency's violation letter suffered from the same "legally flawed" interpretation of Section 340B as the Advisory Opinion and rested on the same "faulty assumption that HRSA's position has not shifted over time." ECF 112, at 8, 13, *AstraZeneca Pharms. LP*, No. 21-cv-0027 (D. Del. Feb. 16, 2022) ("*AstraZeneca II*") (capitalization altered). And in *Novartis Pharmaceuticals Corp. v Espinosa*, the court held that HHS "rest[ed] upon an erroneous reading of Section 340B," because "[t]he statute's plain language, purpose, and structure do not *prohibit* drug manufacturers from attaching any conditions to the sales of covered drugs through contract pharmacies." No. 21-cv-1479, 2021 WL 5161783, at *9 (D.D.C. Nov. 5, 2021). Echoing the District Court here, the *Novartis*

court explained that Section 340B is "silent" as to "what distribution requests manufacturers must accept"—but, unlike the court here, the *Novartis* court then held that the statute's silence required vacatur. *Id.* at *6, *9. *Lilly II* and *Novartis* have been appealed to the Seventh and D.C. Circuits, respectively.

SUMMARY OF THE ARGUMENT

1.a. HHS exceeded its authority by requiring Sanofi to provide discounted drugs to contract pharmacies without any conditions. All agree—the government, the District Court, and every other court to address the issue—that Section 340B is silent as to contract pharmacies. This silence alone demonstrates that the statute does not require Sanofi to provide discounted drugs to any contract pharmacies, nor does it authorize HHS to adopt such a rule. The text, context, structure, and purpose of Section 340B instead confirm that Sanofi is required only to "offer" discounted drugs at a specified price to the covered entities listed in the statute—which Sanofi indisputably does. As a result, both the Violation Letter and the Advisory Opinion should be vacated, and the District Court's judgment should be reversed.

b. Even if Section 340B required Sanofi to provide 340B-priced drugs to contract pharmacies, that would not resolve the legality of Sanofi's integrity initiative. Nothing in the statute prohibits Sanofi from including conditions on its offer to provide these drugs to contract pharmacies. Sanofi must, of course, make a bona fide offer, and cannot adopt conditions that effectively nullify the offer that Section 340B requires. But under its unique integrity initiative, Sanofi indisputably satisfies this obligation by offering to provide 340B-priced drugs to covered entities in multiple ways—even to an unlimited number of contract pharmacies, if the covered entity submits minimal claims data that can be used to identify duplicate discounts prohibited by Section 340B. Sanofi's integrity initiative thus serves the statute's purposes of making 340B-priced drugs available to covered entities while also identifying unlawful duplicate discounting. By nonetheless penalizing Sanofi, HHS exceeded its authority and acted arbitrarily and capriciously.

2. This Court should also vacate the ADR rule for violating the APA's notice-and-comment requirement. HHS promulgated the ADR rule in 2020 on the basis of an NPRM that was withdrawn in 2017 and,

moreover, after announcing in 2020 that no ADR rule would be issued. This denied the fair notice that the APA guarantees.

STANDARD OF REVIEW

This Court reviews the District Court's decision *de novo*, while reviewing the underlying agency actions under the APA. *See Eid v. Thompson*, 740 F.3d 118, 122 (3d Cir. 2014); 5 U.S.C. § 706(2).

ARGUMENT

I. HHS Exceeded Its Authority, and Acted Arbitrarily and Capriciously, by Requiring Sanofi to Unconditionally Provide Discounted Drugs to Contract Pharmacies.

Through the Violation Letter, HHS claimed statutory authority to penalize Sanofi for its integrity initiative. JA219-20. But, as HHS has previously recognized, Section 340B is silent as to contract pharmacies—which demonstrates that Sanofi is neither (1) required to provide discounted drugs to contract pharmacies, nor (2) prohibited from placing conditions on its offer to provide these drugs to contract pharmacies. HHS thus exceeded its authority and, regardless, acted arbitrarily and capriciously by issuing the Violation Letter.

A. HHS Must Have Statutory Authority to Enforce Section 340B Against Sanofi.

A bedrock precept of administrative law is that a federal agency "literally has no power to act … unless and until Congress confers power upon it." *City of Philadelphia v. Att'y Gen.*, 916 F.3d 276, 284 (3d Cir. 2019). "Administrative agencies are creatures of statute," and "[t]hey accordingly possess only the authority that Congress has provided." *NFIB v. OSHA*, 142 S. Ct. 661, 665 (2022).

To issue a regulation or take enforcement action, an agency thus must have a "congressional delegation of administrative authority." *N.Y. Stock Exch. LLC v. SEC*, 962 F.3d 541, 552-53, 554 (D.C. Cir. 2020). Courts cannot "presume a delegation of power." *Ry. Lab. Execs.' Ass'n v. Nat'l Mediation Bd.*, 29 F.3d 655, 671 (D C. Cir. 1994) (en banc). "If no statute confers authority to a federal agency, it has none." *Judge Rotenberg Educ. Ctr., Inc. v. FDA*, 3 F.4th 390, 399 (D.C. Cir. 2021). Any agency action taken without such authority "cannot stand." *Atl. City Elec. Co. v. FERC*, 295 F.3d 1, 8 (D.C. Cir. 2002). And "when authorizing an agency to exercise powers of vast economic and political significance," courts expect Congress not only to speak, but "to speak clearly." *NFIB*, 142 S. Ct. at 665.

To determine "whether the agency has stayed within the bounds of its statutory authority," *City of Arlington v. FCC*, 569 U.S. 290, 297, 301 (2013), courts must interpret the statute underlying the agency's action using standard principles of statutory construction. *City of Philadelphia*, 916 F.3d at 284. And when a statute carries a plain, non-absurd meaning, "the sole function of the courts … is to enforce it according to its terms." *Riccio v. Sentry Credit, Inc.*, 954 F.3d 582, 588, 592 (3d Cir. 2020) (en banc).

To that end, when a statute *does not* address an issue—*i.e.*, when the statute is *silent* on a matter—courts must enforce that congressional choice. "It is a fundamental principle of statutory interpretation that absent provision[s] cannot be supplied by the courts," because doing so "is not a construction of a statute, but, in effect, an enlargement of it by the court." *Rotkiske v. Klemm*, 140 S. Ct. 355, 360-61 (2019). In other words, courts (like agencies) may not "add" to the words chosen by Congress, *United States v. Lovett*, 467 F.3d 374, 377 (3d Cir. 2006), or inject language that is "absent" from the statute, *Riccio*, 954 F.3d at 587-89. Nor may courts permit an agency to do this. *See SAS Inst., Inc. v. Iancu*, 138 S. Ct. 1348, 1355 (2018).

To be sure, courts may sometimes defer to an agency interpretation that fills a statutory "gap" created by "an ambiguity tied up with the provisions of the statute," *Prestol Espinal v. Att'y Gen.*, 653 F.3d 213, 221 (3d Cir. 2011) (quoting *Lin-Zheng v. Att'y Gen.*, 557 F.3d 147, 156 (3d Cir. 2009) (en banc)), if the agency has "received congressional authority to" fill that gap, *City of Arlington*, 569 U.S. at 306. But *ambiguity* is not the same as *silence*: When a statute is "*silen[t]* on a given issue," the agency has no "gap-filling power." *Prestol Espinal*, 653 F.3d at 221 (emphasis added) (quoting *Lin-Zheng*, 557 F.3d at 156); *see De Leon-Ochoa v. Att'y Gen.*, 622 F.3d 341, 355 (3d Cir. 2010) (same).

Christensen v. Harris County, 529 U.S. 576 (2000), illustrates the point. There, the Supreme Court held that a "silent" labor statute did not empower a federal agency to "prohibit" an employer's policy because the statute "sa[id] nothing about" the issue in question. *Id.* at 585, 588. Nor did the employer need to prove that the statute "permit[ted]" its policy—which would get things "exactly backwards." *Id.* at 588. This Court has held similarly. *See, e.g.*, *Coffelt v. Fawkes*, 765 F.3d 197, 202-04 (3d Cir. 2014); *Lin-Zheng*, 557 F.3d at 156.

B. HHS Exceeded Its Authority Because Section 340B Does Not Require Sanofi to Provide Discounted Drugs to Contract Pharmacies.

These principles should have been dispositive in this case. Because every court to address the issue—and even the government—has agreed that Section 340B is silent as to contract pharmacies, the statute does not (and HHS thus cannot) require Sanofi to provide discounted drugs to any contract pharmacies.

1. Section 340B does not require Sanofi to provide discounted drugs to contract pharmacies, because the statute is silent as to contract pharmacies.

As the government admitted below, Section 340B "is *silent* as to the role that contract pharmacies may play in connection with covered entities' purchases of 340B drugs." D.Ct.ECF.93 at 22 (quoting *AstraZeneca I*, 543 F. Supp. 3d at 59) (emphasis added). Consistent with HHS's longstanding view, *see supra* at 10-11, the District Court—like every other court to address the issue—recognized that Section 340B is "*silent*" on "what role (*if any*) contract pharmacies play in Congress' discount drug scheme." JA88 (emphasis added); *see also AstraZeneca I*, 543 F. Supp. 3d at 59; *Novartis*, 2021 WL 5161783, at *6, *8; *AstraZeneca II*, *supra*, at 11; *Lilly II*, 2021 WL 5039566, at *14.

Due to Section 340B's widely acknowledged "silence," JA103, 116 (Op.93, 106), HHS "literally has no power" to require manufacturers to provide discounted drugs to contract pharmacies. *City of Philadelphia*, 916 F.3d at 284. As discussed above, statutory *silence* does not impose a statutory *requirement*, much less authorize HHS to create such a requirement. *See, e.g.*, *Riccio*, 954 F.3d at 587-88; *Lovett*, 467 F.3d at 377. Nor does HHS have the rulemaking authority necessary "to fill a gap in this statute." *Novartis*, 2021 WL 5161783, at *8; *see also* JA85-86 (Op.75-76). Even HHS has acknowledged that Section 340B's silence on many topics means that the agency "doesn't have authority" to impose extra-statutory requirements. JA353 (Director 2017 Testimony); *see* JA695 (Secretary 2021 Testimony); ECF No. 103, at 51, *AstraZeneca Pharms. LP*, No. 21-cv-0027 (D. Del. Oct. 22, 2021) (HHS concession that "HRSA can't add to the statutory obligation[s]" contained in Section 340B); *supra* at 10-11.

Indeed, Section 340B's text, context, structure, and purpose all confirm that "the statute does not compel any particular outcome with respect to covered entities' use of pharmacies." *Novartis*, 2021 WL 5161783, at *4 (quoting *AstraZeneca I*, 543 F. Supp. 3d at 59).

To begin, the text defines "covered entity" to "mean[]" a specific list of 15 types of covered entities. 42 U.S.C. § 256b(a)(4); *see supra* at 7. By using "means" rather than a more open-ended verb like "includes," Congress "cabin[ed]" the covered-entity definition to the "specific list" and excluded contract pharmacies and all other entities. *Christopher v. SmithKline Beecham Corp.*, 567 U.S. 142, 162 (2012); *see also Robinson v. Napolitano*, 554 F.3d 358, 365 (3d Cir. 2009) (an "express[]" statutory "list" excludes any unlisted items); *Lin-Zheng*, 557 F.3d at 156 (similar). As *AstraZeneca I* put it, "[i]t is hard to believe that Congress enumerated 15 types of covered entities with a high degree of precision and intended to include contract pharmacies as a 16th option by implication." 543 F. Supp. 3d at 60; *see also AstraZeneca II*, *supra*, at 11. The statute's prohibition on "diversion" confirms that Congress intended the list to be exclusive. 42 U.S.C. § 256b(a)(5)(B), (d)(2)(A).

Statutory context and structure reinforce that Section 340B does not require Sanofi to provide 340B-priced drugs to contract pharmacies. "Congress knows how to write statutes that cover agents and contractors, but it did not do so in the 340B statute" with respect to contract pharmacies. *AstraZeneca I*, 543 F. Supp. 3d at 60; *AstraZeneca II*, *supra*,

at 11; *see* 42 U.S.C. § 256b(d)(1)(B)(v) (wholesalers), (d)(2)(B)(iv) (distributors), (d)(3)(B)(iii) ("third parties" with information relevant to overcharge claims), (d)(3)(B)(vi) (associations and organizations representing covered entities).

Moreover, in the same law that created Section 340B, Congress established requirements for discounted drugs purchased by federal agencies but "delivered through … a commercial entity" (*i.e.*, a contract pharmacy)—yet included no similar provision in Section 340B. Veteran's Health Care Act of 1992, Pub. L. No. 102-585, § 603(a)(1), 106 Stat. 4943, 4974, *codified at* 38 U.S.C. § 8126(h)(3)(A). By remaining silent about contract pharmacies in Section 340B, Congress thus made a deliberate choice that HHS must respect. *See Salinas v. U.S. R.R. Ret. Bd.*, 141 S. Ct. 691, 698 (2021) ("Where Congress includes particular language in one section of a statute but omits it in another section of the same Act, it is generally presumed that Congress acts intentionally and purposely in the disparate inclusion or exclusion."); *see, e.g.*, *Coffelt*, 765 F.3d at 203 (statutory silence is "intentional" when legislature elsewhere imposed the rule at issue); *City Select Auto Sales Inc. v. David Randall Assocs., Inc.*, 885 F.3d 154, 161 (3d Cir. 2018) (similar).

Reading this statutory silence to nevertheless compel the provision of drugs to contract pharmacies conflicts with the principle that Congress "does not alter the fundamental details of a regulatory scheme in vague terms or ancillary provisions—it does not, one might say, hide elephants in mouseholes." *Whitman v. Am. Trucking Ass'ns*, 531 U.S. 457, 468 (2001). Had Congress wanted to mandate the provision of 340B-priced drugs to contract pharmacies, it would have done so "clearly"—not through silence. *NFIB*, 142 S. Ct. at 665.

This interpretation of Section 340B also advances the statute's purpose of ensuring that covered entities "obtain lower prices on the drugs that they provide to their patients." H.R. Rep. No. 102-384, pt. 2, at 7 (1992); *see also* S. Rep. No. 102-259, at 6 (1992) (JA243). Congress had good reason to remain silent as to contract pharmacies, because they siphon revenue away from covered entities with high fees. *See* JA490-93 (GAO-18-480 at 24-27). Congress had no intention of having steep 340B discounts function as a windfall for contract pharmacies—which HHS did not even deem to be permissible until four years after the 340B Program started. *See* JA172 (61 Fed. Reg. at 43,550 (VLTR.89)). Recognizing that contract pharmacy arrangements go beyond what Section 340B requires

would hold true to Congress's original design for the 340B Program—to benefit covered entities, not for-profit third-party pharmacies.

All of these tools of statutory interpretation—text, structure, context, and purpose—thus confirm that Section 340B is silent about contract pharmacies. By nonetheless attempting to enforce an extra-statutory requirement regarding contract pharmacies that it "prefer[s]," HHS exceeded its authority. *SAS Inst.*, 138 S. Ct. at 1355. This requires the District Court to be reversed, and the Violation Letter to be vacated in full.

2. The District Court erred in finding that Section 340B authorizes the Violation Letter.

Despite recognizing that Section 340B is "silent" as to contract pharmacies, JA88, the District Court interpreted Section 340B as authorizing HHS to penalize Sanofi for not providing discounted drugs to contract pharmacies. This was erroneous in multiple ways.

(a) The District Court erroneously held that statutory silence authorizes HHS to penalize Sanofi.

Most fundamentally, the District Court misunderstood the consequence of Section 340B's silence about contract pharmacies, *see*

supra Part I.A, by requiring *Sanofi* to show its statutory "authority" or "permi[ssion]" to adopt the integrity initiative. JA103-04.

This approach was "exactly backwards." *Christensen*, 529 U.S. at 588. Only *HHS*—not Sanofi—needs statutory authority to act. *See id.* Private parties like Sanofi can do whatever they wish unless it conflicts with a lawful "prohibition." *Id.*; *see City of Philadelphia*, 916 F.3d at 284. Thus, as the *Novartis* court explained, manufacturers' policies are not "prohibit[ed]" merely because Section 340B does not grant "authority" for them. 2021 WL 5161783, at *7.

Attempting to support its conclusion, the District Court asserted that "HHS has the statutory authority to require manufacturers to ship 340B drugs" to contract pharmacies because "the 340B statute does not wholly foreclose contract pharmacy arrangements"—*i.e.*, because such arrangements are "permissible" under the statute. JA91, 101. But that does not follow. Section 340B's silence does not *prohibit* contract-pharmacy arrangements—and manufacturers thus *may*, if they wish, provide discounted drugs to contract pharmacies. But that does not establish that manufacturers "*must*" provide these drugs to contract

pharmacies, nor does it empower HHS to impose such a requirement. *Novartis*, 2021 WL 5161783, at *6-7.

The District Court read this Court's decision in *Sun Wen Chen v. Attorney General*, 491 F.3d 100 (3d Cir. 2007), to call for a different result, on the basis that "[s]ilence on a particular matter germane to the provisions of a statute suggests a gap of the sort that the administering agency may fill." JA89 (quoting 491 F.3d at 107). But *Sun Wen Chen* was expressly "overrule[d]" by this Court, sitting *en banc*, in *Lin-Zheng*, which clarified that an agency does not have gap-filling power just because a statute is silent on "germane" matters; instead, there must be an actual ambiguity tied up with the provisions of the statute. *See* 557 F.3d at 156-57. Even if *Sun Wen Chen* were still good law, HHS has only limited rulemaking authority under Section 340B, and thus cannot fill any gap regarding contract pharmacies. *Supra* at 7, 10-11, 37-38. Nor did HHS even purport to fill a gap or identify any ambiguous statutory term—and the District Court never identified such a gap either. Instead, HHS asserted (incorrectly) that Section 340B *unambiguously* compels manufacturers to provide discounted drugs to contract pharmacies. JA89-90 (Op.79-80); *see* JA219 (Violation Letter (VLTR.9)).

(b) The District Court misapplied basic principles of statutory construction when interpreting Section 340B.

The District Court also ignored the principles of statutory interpretation discussed above—which demonstrate that HHS exceeded its authority—and instead relied on three atextual considerations that are not only disfavored but actually support Sanofi.

First, the District Court "start[ed]" its interpretation of Section 340B with legislative history. JA91. But statutory interpretation must always "begin[] with the text," *Ross v. Blake*, 578 U.S. 632, 638 (2016), and courts should consider legislative history only "as a last resort," if at all, *In re Trump Ent. Resorts*, 810 F.3d 161, 168 (3d Cir. 2016).

In any event, the legislative history cited by the District Court favors *Sanofi*. When crafting Section 340B in 1992, Congress considered requiring manufacturers to provide discounts for drugs "purchased and dispensed by, *or under a* <u>*contract*</u> *entered into for* <u>*on-site*</u> *pharmacy services with*," a covered entity. S. Rep. No. 102-259, at 2 (JA239) (quoting S. 1729, 102d Cong. (1992)) (emphasis added). Had Congress enacted this language, Section 340B would have required providing discounted drugs to certain contract pharmacies—but Congress instead

omitted it, which confirms that the statute does *not* require providing discounted drugs to contract pharmacies. *See AstraZeneca I*, 543 F. Supp. 3d at 60; *AstraZeneca II*, *supra*, at 11-12 & n.9.

The District Court read this legislative history to instead show that Congress intended to eliminate any "limitation" on contract-pharmacy arrangements. JA91. But that ignores what Congress actually did: remove a *requirement* that manufacturers provide drugs to on-site contract pharmacies, not a *limitation* prohibiting off-site contract pharmacies. *AstraZeneca II*, *supra*, at 12 n.9. And even if Congress had struck such a limitation, that hardly "shows that the statute *requires* manufacturers to accept *all* outside pharmacy arrangements." *Novartis*, 2021 WL 5161783, at *8 n.7 (emphasis added); *see also AstraZeneca I*, 543 F. Supp. 3d at 60-61. The only other piece of legislative history cited by the District Court was a 1992 report that said nothing about restrictions on manufacturers, and instead merely stated that the *government* could not limit discount-drug purchases by covered entities. JA92-93 (citing H.R. Rep. No. 102-384, pt. 2, at 16).

Second, the District Court turned to how it understood Section 340B's "purpose" and "policy," opining that contract-pharmacy

arrangements seem "necessary" because they help providers without in-house pharmacies "meaningfully participate" in the 340B Program. JA93-94. But the District Court admitted that "none" of Section 340B's purposes "has anything to say about the precise question at issue—the use of contract pharmacies as a dispensing mechanism." JA93 (alterations omitted). The District Court nonetheless adopted the "long[-]rejected … notion that *whatever* furthers the statute's primary objective must be the law." *Cyan, Inc. v. Beaver Cnty. Emps. Ret. Fund*, 138 S. Ct. 1061, 1073 (2018). But no law pursues a single purpose to the exclusion of all others. Thus, "[r]egardless of the purported intent of the legislature," a court is "not free to ignore the plain and unambiguous language of the statute." *In re Pro. Ins. Mgmt.*, 130 F.3d 1122, 1127 (3d Cir. 1997); *see also, e.g.*, *Henson v. Santander Consumer USA Inc.*, 137 S. Ct. 1718, 1725 (2017).

In any event, the District Court was wrong to conclude (without record support) that omitting contract pharmacies would render Section 340B a "dead letter in many of its applications." JA94. The government's own data shows that the "overwhelming majority" of covered entities do not even *use* contract pharmacies—and instead use their in-house

pharmacies to dispense 340B drugs to patients. *See supra* at 17-18. Even for the small minority of covered entities that currently use contract pharmacies, the District Court cited nothing in the record to support the conclusion that contract pharmacies are truly "necessary" or "perhaps even indispensable." JA94. Instead, there is ample reason to doubt that conclusion, when most covered entities have decided—perhaps because of the high fees charged by contract pharmacies—to set up their own in-house pharmacies to dispense 340B drugs. *See* JA491-93 (GAO-18-480 at 25-27 (contract pharmacies generally charge covered entities $6 to $15, but up to $1,750, per 340B prescription)). And while the District Court remarked that "covered entities without in-house pharmacies cannot easily set them up," JA94 n.53, it cited no record support for this point, nor did HHS make such a finding in the Violation Letter.

To be sure, the statutory requirement to "offer" 340B-priced drugs does mean that manufacturers must offer *some* method of providing the drugs to a covered entity. 42 U.S.C. § 256b(a)(1). But the statute says nothing about *where* the drugs must be provided. Manufacturers comply with their statutory obligation by providing the drugs directly to covered entities, which accept the drugs through an in-house pharmacy in most

cases. *Cf.* 18 Williston on Contracts §§ 52:1, 52:6 (4th ed.). It would twist the statute's text and purpose if Sanofi had to "offer" to provide 340B-priced drugs to contract pharmacies that are not eligible to "purchase" those drugs.

Third, the District Court invoked Section 340B's "post-enactment history," asserting that Congress "seemingly ratified" contract-pharmacy arrangements by amending the statute in 2010 without disturbing the agency's 1996 non-binding guidance that such arrangements are "permitt[ed]." JA95. But post-enactment history is a "hazardous basis for inferring the intent of an earlier Congress"—especially when it depends on "[c]ongressional inaction," which "is generally entitled to minimal weight in the interpretive process." *In re Visteon Corp.*, 612 F.3d 210, 231 (3d Cir. 2010). If anything, by not granting HHS's repeated requests for more authority under Section 340B, Congress ratified HHS's longstanding view—stated as recently as 2020—that Section 340B is "silent" as to contract pharmacies and does not authorize the agency to regulate in this area. JA171 (61 Fed. Reg. at 43,549 (VLTR.88)); JA366, 377 (Director 2017 Testimony); *see also supra* at 10-11. Further, even if Congress had "ratified" the aspect of the 1996 guidance invoked by the

District Court, that could at most suggest that Section 340B "permit[s]" one contract pharmacy per covered entity without an in-house pharmacy (which Sanofi's program allows)—*not* that providing the drugs to unlimited contract pharmacies is *required*. JA95 (Op.85).

C. Even If Sanofi Must Provide Discounted Drugs to Contract Pharmacies, Section 340B Does Not Prohibit Sanofi from Including Conditions with Its Offer.

Even if HHS correctly interpreted Section 340B as requiring Sanofi to provide discounted drugs to contract pharmacies, that would not determine the legality of Sanofi's integrity initiative. Under its unique integrity initiative, Sanofi offers to provide 340B-priced drugs in three ways: (1) directly to the covered entity without any conditions if it has an in-house pharmacy; (2) to a single contract pharmacy if the covered entity lacks its own pharmacy; or (3) to an unlimited number of contract pharmacies, so long as the covered entity submits minimal claims data. *Supra* at 19. Nothing in Section 340B prohibits Sanofi from attaching these conditions to its "offer" of 340B-priced drugs, particularly when these conditions further the statute's purposes, are not unduly burdensome, and provide multiple ways for covered entities to "purchase" 340B drugs at the "ceiling price." 42 U.S.C. § 256b(a)(1). HHS thus

exceeded its statutory authority by determining that these conditions violate Section 340B.

1. Section 340B does not prohibit all conditions on the provision of discounted drugs.

Section 340B's "silence" as to contract-pharmacy arrangements is strong—if not dispositive—evidence that the statute does not prohibit conditions on contract-pharmacy use. *Novartis*, 2021 WL 5161783, at *6. HHS nonetheless asserted that the statutory obligation to "offer" discounted drugs to covered entities implicitly requires Sanofi to provide those drugs to contract pharmacies without any "qualifi[cations]." JA219 (Violation Letter (VLTR.9)). But neither the "must offer" provision nor "any other language in Section 340B" requires that offers must be *unconditional*. *Novartis*, 2021 WL 5161783, at *6-7, *9. Sanofi's "one core statutory obligation … is to offer a price not to exceed the 340B ceiling price to covered entities," JA534 (Director 2018 Testimony at 4), but the statute does not specify where the drugs must be delivered. And because an "offer" is merely "[t]he act or instance of presenting something for acceptance," *Novartis*, 2021 WL 5161783, at *6 (quoting Black's Law Dictionary (11th ed. 2019)), Section 340B "do[es] not prohibit … manufacturers from imposing *any* conditions on their offers of 340B-

priced drugs." *Id.* at *9. Instead, as the *Novartis* court held, manufacturers may permissibly attach conditions to their offers of 340B pricing—particularly if those conditions apply only to the provision of drugs to contract pharmacies. *Id.* at *6-7, *9.

Of course, Sanofi does not have carte blanche to impose conditions that might render the offer worthless. But the statutory requirement that Sanofi must "offer each covered entity covered outpatient drugs for purchase at or below the applicable ceiling price" simply means that its "offer" must be made in good faith. 42 U.S.C. § 256b(a)(1). In other words, the statute requires "meaningful, *bona fide* offers." *Novartis*, 2021 WL 5161783, at *6; *see also* Scalia & Garner, *Reading Law* 35, 63 (2012) (noting "[a] textually permissible interpretation that furthers rather than obstructs the document's purpose should be favored" provided it does not "expand [the text] beyond its permissible meaning"); *In re Pro. Ins. Mgmt.*, 130 F.3d at 1127 ("Although a statute should be interpreted in a fashion that does not defeat the congressional purpose ... a court may not rewrite an unambiguous law.").

All this means is that Sanofi cannot nullify its offer by effectively refusing to provide the drugs. The statutory requirement to "offer" the

ceiling price does *not* allow the covered entity to demand that Sanofi provide its drugs to anyone and anywhere, including (in HHS's words) the "lunar surface." JA212-13 (Advisory Opinion (ADVOP.2-3)). In short, so long as 340B-priced drugs are meaningfully available to covered entities, a condition on the provision of such drugs is permissible—particularly if the condition is tethered to one of the statute's purposes, such as preventing duplicate discounting, stopping diversion, or auditing covered entities. 42 U.S.C. § 256b(a)(5)(A)-(C).

Even HHS has recognized this. *See Novartis*, 2021 WL 5161783, at *7. For example, HHS has long advised that manufacturers may condition an offer of discounted drugs on a covered entity's provision of "standard information." JA170 (59 Fed. Reg. 25,110, 25,114 (May 13, 1994) (VLTR.85)). HHS has also opined that manufacturers may require that covered entities agree to "the manufacturer's normal business policies" as part of a 340B offer. JA168-170 (59 Fed. Reg. at 25,112-14 (VLTR.83-85)). And HHS has approved of manufacturers limiting the quantity of drugs offered at the 340B price during shortages. JA311 (HRSA, 340B Drug Pricing Program Release No. 2011-1.1 (May 23, 2012) (VLTR.108)). Section 340B does not prohibit these—or any other—

conditions that are part of "*bona fide* offers" of 340B-priced drugs. *Novartis*, 2021 WL 5161783, at *6-7.

2. Sanofi imposes a permissible condition on the provision of discounted drugs to contract pharmacies.

Sanofi's integrity initiative is another example of a permissible condition on the provision of discounted drugs. Requiring minimal, anonymized claims data for prescriptions filled at contract pharmacies is wholly consistent with Section 340B, particularly because that data can be used both to prevent duplicate discounting and to inform whether to audit a covered entity. Similar to a program considered in *Novartis* that required claims data for the use of one contract pharmacy, Sanofi "continue[s] to present [its] drugs to covered entities," *id.* at *6, offering them discounted drugs in three ways. *See supra* at 19. Although Sanofi's offers are "subject to more conditions than they previously were, they are still meaningful, *bona fide* offers." *Novartis*, 2021 WL 5161783, at *6. And, for several reasons, the provision of minimal claims data in order to use unlimited contract pharmacies is hardly something that might make the offer meaningless or "hollow." JA104 (Op.94).

First, Sanofi's integrity initiative is *more generous* than HHS's 1996 guidance, which permitted covered entities to use only *one* contract pharmacy if they lacked an in-house pharmacy. Sanofi not only does that but provides "far more opportunities to purchase drugs at 340B prices," by also allowing covered entities to use unlimited contract pharmacies under certain conditions. *Novartis*, 2021 WL 5161783, at *6; *see AstraZeneca I*, 543 F. Supp. 3d at 55-56. When even HHS's past guidance was less permissive, it is difficult to see how Sanofi's integrity initiative could somehow violate the statute.

Second, providing the requested claims data imposes little (if any) logistical or financial burden on covered entities. JA994 (Bray Declaration (D.Ct.ECF 94-2 at 10)); *see supra* at 20. The District Court suggested otherwise—even though there was no dispute that covered entities already provide this information to insurance companies—on the basis of purported "practical realities" faced by "resource-strapped covered entities." JA126. But this overstepped this District Court's role, because the Violation Letter did not conclude that Sanofi's program is burdensome (instead announcing that all conditions are illegal, regardless of burden). *DHS v. Regents of Univ. of Cal.*, 140 S. Ct. 1891,

1907 (2020). Nor is the District Court's conclusion entitled to any "deference" on appeal. *Crooks v. Mabus*, 845 F.3d 412, 416 (D.C. Cir. 2016); *see Eid*, 740 F.3d at 122.

In any event, the District Court's conclusion about burden was unfounded. The court cited merely a handful of complaints from covered entities that did not even *claim* to have tried participating in Sanofi's integrity initiative. *See* JA126 (Op.116) (citing JA1090-91, 1093-94, 1165-66). This ignored the real-world experience of the many covered entities that actually *have* participated in Sanofi's program. Nor did the District Court explain why Sanofi's integrity initiative imposed a condition more burdensome than the conditions HHS has previously permitted—much less burdens so steep as to effectively nullify Sanofi's offer. *See Novartis*, 2021 WL 5161783, at *8.

The District Court also held that it was "impermissible" for Sanofi to have "the sole authority to determine whether covered entities have complied [with the data request]—or to change the requirements of its policy." JA125. But this again goes well beyond anything found in Section 340B or the Violation Letter. Nor is there any evidence of Sanofi abusing this so-called "sole authority." Indeed, the only changes made by

Sanofi have made it *easier* for covered entities to use contract pharmacies—by allowing certain covered entities to designate a single contract pharmacy, and by exempting many categories of covered entities from the integrity initiative. *See supra* at 19.

Third, Sanofi's program furthers the purposes of Section 340B. By collecting claims data for prescriptions filled at contract pharmacies, Sanofi can help address the fast-growing problem of duplicate discounting—which Section 340B expressly prohibits—without materially limiting the legitimate availability of 340B-priced drugs. *See* 42 U.S.C. § 256b(a)(5), (d)(2)(A), (d)(3)(A). Reflecting its narrow focus, Sanofi's integrity initiative applies to only the few categories of covered entities that most heavily use contract-pharmacy arrangements—and thus have the most duplicate discounting. *See supra* at 16-19. With claims data and improved insight into duplicate discounting, Sanofi can also "better utilize the anti-fraud audit and ADR procedures … in Section 340B." *Novartis*, 2021 WL 5161783, at *8; *see also* JA573 (Best Practices at 6) ("duplicate discounts can often best be identified from a review of claims level data by the manufacturers").

The District Court nonetheless opined that Sanofi's integrity initiative "frustrate[s]" Section 340B's "purpose" because it renders the statute a "dead letter." JA94, 104. That too is wrong. Sanofi's program is narrowly tailored to ensure the ready availability of 340B-priced drugs while *also* furthering the statutory purpose of preventing waste and abuse. *Novartis*, 2021 WL 5161783, at *7. And when covered entities—the "overwhelming majority" of which do not even use contract pharmacies—now have "far more opportunities" to purchase discounted drugs under Sanofi's program than they did under HRSA's guidance in 1996, *Novartis*, 2021 WL 5161783, at *6, Section 340B is not close to becoming a "dead letter," JA94 (Op.84). Indeed, the District Court appeared to misunderstand Sanofi's program, which—unlike other manufacturers' policies—does *not* "dictate how many contract pharmacies a covered entity may [use]," so long as the covered entity submits claims data that can help identify unlawful duplicate discounting. JA105 (Op.95).

In short, even if HHS were correct that manufacturers must provide 340B-priced drugs to contract pharmacies, Section 340B does not require that these offers be unconditional—and Sanofi makes such offers

on a bona fide basis. *Novartis* held that Section 340B did not prohibit requiring claims data in order to use a *single* contract pharmacy. 2021 WL 5161783, at *6, *9. The same conclusion is warranted here, where Sanofi's program is less restrictive and requires claims data only for the use of *unlimited* contract pharmacies. And because Sanofi's program does not violate Section 340B, Sanofi does not "overcharge" any covered entities that choose to pay higher prices for Sanofi's drugs after rejecting Sanofi's conditions. JA109-10 (Op.99-100). This provides further, independent reason why the District Court's decision should be reversed and the Violation Letter should be vacated.

D. HHS Acted Arbitrarily and Capriciously By Requiring Sanofi to Unconditionally Provide Discounted Drugs to Contract Pharmacies.

Even if HHS acted within its statutory authority, the Violation Letter should be vacated as arbitrary and capricious on multiple grounds.

1. HHS erred in concluding that Section 340B is unambiguous.

First, "it is black letter law that where an agency purports to act solely on the basis that a certain result is legally required, and that legal premise turns out to be incorrect, the action must be set aside, regardless of whether the action could have been justified as an exercise of

discretion." *Regents of Univ. of Cal. v. DHS*, 908 F.3d 476, 505 (9th Cir. 2018) (citing *SEC v. Chenery Corp.*, 318 U.S. 80, 94 (1943)), *rev'd in part, vacated in part sub nom. Regents*, 140 S. Ct. 1891; *Peter Pan Bus Lines, Inc. v. Fed. Motor Carrier Safety Admin.*, 471 F.3d 1350, 1354 (D.C. Cir. 2006); *PDK Lab'ys Inc. v. DEA*, 362 F.3d 786, 798 (D.C. Cir. 2004).

As every court has found, including the District Court, HHS erroneously concluded that Section 340B *unambiguously* requires manufacturers to provide discounted drugs to contract pharmacies without any conditions. JA89-90 (Op.79-80); *see* JA219-20 (Violation Letter (VLTR.9-10)). For this reason, the *AstraZeneca* court vacated a materially identical violation letter, and the *AstraZeneca* and *Lilly* courts vacated the Advisory Opinion. *AstraZeneca II*, *supra*, at 12; *see AstraZeneca I*, 543 F. Supp. 3d at 61-62; ECF No. 83, at 3, *AstraZeneca*, *supra* (JA234); *Lilly II*, 2021 WL 5039566, at *14, *25. The District Court erred in denying the same relief to Sanofi.

Moreover, it is well-settled that a court cannot "sustain" agency action on "some other" theory of statutory authority that the agency "did not mention" when taking that action. *PDK Lab'ys Inc.*, 362 F.3d at 797-98; *see also Bus. Roundtable v. SEC*, 905 F.2d 406, 417 (D.C. Cir. 1990);

Conn. Dep't of Pub. Util. Control v. FERC, 484 F.3d 558, 560 (D.C. Cir. 2007). Accordingly, the Violation Letter can be sustained only on those grounds stated by the Letter itself—namely, that Section 340B *unambiguously* prohibits Sanofi's integrity initiative. *See Regents*, 140 S. Ct. at 1907; *SEC v. Chenery Corp.*, 332 U.S. 194, 196 (1947). After recognizing that the Violation Letter rested on a "mistaken legal interpretation," JA89, the District Court ignored this hornbook principle by sustaining the Violation Letter on a new theory that Section 340B is "ambiguous on contract pharmacies" and requires Sanofi to deliver discounted drugs to "at least one contract pharmacy site each." JA90-91.

2. HHS failed to address its change in positions.

Second, the Violation Letter is also arbitrary and capricious because HHS changed its longstanding interpretation of Section 340B in several ways without "at least 'display[ing] awareness that it is changing position'" and providing a "'reasoned explanation'" for the changes. *Encino Motorcars, LLC v. Navarro*, 579 U.S. 211, 221-22 (2016) (quoting *FCC v. Fox Television Stations, Inc.*, 556 U.S. 502, 515-16 (2009)).

Even a cursory examination of HHS's actions shows that, as multiple courts have held, the agency's positions on contract pharmacies

have "not remained constant" but instead have repeatedly "shifted." *Novartis*, 2021 WL 5161783, at *4, *8 (quoting *AstraZeneca I*, 543 F. Supp. 3d at 56); *see Lilly II*, 2021 WL 5039566, at *22-23; *AstraZeneca II*, *supra*, at 13-18; *supra* at 10-11, 24, 30. Despite this significant "inconsistency," the Violation Letter ignored the agency's change in positions. *Encino Motorcars*, 579 U.S. at 221-22; *see also Novartis*, 2021 WL 5161783, at *7-8. Thus, the Violation Letter is arbitrary and capricious—just like the similar letters vacated by other courts. *See Lilly II*, 2021 WL 5039566, at *22-23, *25; *AstraZeneca II*, *supra*, at 13-18.

The District Court agreed that HHS's position has "evolved," JA127, but nonetheless held that the Violation Letter is not arbitrary and capricious. The District Court's reasoning cannot withstand scrutiny.

First, the District Court held that HHS *has* been consistent, because the agency has maintained since 1996 that contract-pharmacy arrangements are "permissible." JA121-23. But no one disputes that contract-pharmacy arrangements are *permissible*. The critical question is whether Section 340B *requires* manufacturers to provide discounted drugs to contract pharmacies. And it was not until 2020 that HHS first answered that question affirmatively, after previously stating that it was

powerless to enforce any such rule. *AstraZeneca I*, 543 F. Supp. 3d at -54-56; *AstraZeneca II*, *supra*, at 13.

Second, the District Court concluded that HHS's positions have been based on a consistent "underlying" "rationale": "expanding patient access … while saving covered entities money." JA122-23. But even if true, different agency actions supported by the same rationale are still different agency actions. Each must comply with the APA, which requires that changes be acknowledged and explained. *See Fox Television Stations, Inc.*, 556 U.S. at 515.

Third, the District Court suggested that any changes in position have been adequately explained by HHS in this litigation. JA127. *But see AstraZeneca II*, *supra*, at 14 n.11. But agency action may be upheld only on "the grounds that the agency invoked when it took the action." *Regents*, 140 S. Ct. at 1907. Here, when issuing the Violation Letter, HHS only *denied* that any changes had occurred. JA219.

II. The Advisory Opinion Suffers from the Same Legal Flaws as the Violation Letter.

The Advisory Opinion—which announced "essentially the same statutory interpretation" that HHS later enforced against Sanofi—is

unlawful for the same reasons as the Violation Letter. *AstraZeneca II*, *supra*, at 10; *see also supra* Parts I.B-D; *AstraZeneca I*, 543 F. Supp. 3d at 58-61; *Lilly II*, 2021 WL 5039566, at *14. Despite withdrawing the Advisory Opinion, HHS still threatens to enforce that same interpretation of Section 340B against Sanofi in other contexts. *See, e.g.*, JA219, 235, 1183. Enjoining HHS from enforcing the Advisory Opinion's interpretation against Sanofi is necessary to provide "complete relief," *City of Philadelphia*, 916 F.3d at 292, and to make clear that the agency has *never* permissibly announced any such rule.

The District Court nonetheless concluded that Sanofi's challenge was moot. JA31 n.31. But HHS failed to carry its "heavy burden" to establish mootness by showing that it is "absolutely clear" that the challenged conduct "cannot reasonably be expected to start up again." *Friends of the Earth, Inc. v. Laidlaw Env't Servs. (TOC), Inc.*, 528 U.S. 167, 189 (2000). To the contrary, HHS withdrew the Advisory Opinion without "alter[ing] its position on the merits." *Solar Turbines, Inc. v. Seif*, 879 F.2d 1073, 1079 (3d Cir. 1989). And HHS continues to enforce that position—as two other courts recognized when rejecting the government's mootness arguments in other challenges to the Advisory

Opinion. *See* ECF No. 83, at 2, *AstraZeneca*, *supra* (JA233); *Lilly II*, 2021 WL 5039566, at *12.

Nor was Sanofi's challenge mooted when those two courts vacated the Advisory Opinion, because it was still "possible" for the District Court to grant "effectual relief" to Sanofi. *Del. Riverkeeper Network v. Sec'y Pa. Dep't of Env't Prot.*, 833 F.3d 360, 374 (3d Cir. 2016). For example, the District Court still could have enjoined enforcement actions or declared Sanofi's statutory obligations. *See* JA981-82 (Sanofi Compl. at 60-61).

The dispute is also capable of repetition yet evading review, *Turner v. Rogers*, 564 U.S. 431, 440 (2011), because the Advisory Opinion's effective period was "too short" to be "fully litigated" prior to its vacatur, and HHS's ongoing enforcement position raises at least a "reasonable expectation" that Sanofi "[will] be subjected to the same action again." *Id.*; *see United States v. A.D.*, 28 F.3d 1353, 1355 n.1 (3d Cir. 1994); *cf. City & Cnty. of San Francisco v. USCIS*, 944 F.3d 773, 788 (9th Cir. 2019) (holding that a challenge to agency action was not mooted by nationwide injunctions against the action in different cases).

The District Court likewise had no basis to "decline" to resolve the dispute because of the hypothetical possibility that HHS might

"substantial[ly] revis[e]" its position. JA31 n.31. Federal courts "have no more right to decline the exercise of jurisdiction which is given, than to usurp that which is not given." *Sprint Commc'ns, Inc. v. Jacobs*, 571 U.S. 69, 77 (2013).

III. HHS Violated the APA When Promulgating the ADR Rule.

Finally, HHS also issued the ADR rule in violation of the APA's notice-and-comment requirement. *See Lilly I*, 526 F. Supp. 3d at 407-08.

Under that requirement, an agency must announce any proposed rule in an NPRM and receive comments on the rule. 5 U.S.C. § 553(b)(1)-(3), (c); *Council Tree Commc'ns, Inc. v. FCC*, 619 F.3d 235, 250 (3d Cir. 2010). Although the ADR rule purports to be based on a 2016 NPRM, *see* JA197 (85 Fed. Reg. at 80,633 (ADR.13)), HHS *withdrew* that NPRM in 2017. *See* JA195 (Unified Agenda). Even the District Court acknowledged that the Executive Branch publicly described the 2016 NPRM as "Withdrawn" as of 2017. JA28 (quoting OIRA website). In the years that followed, HHS took no public action regarding an ADR process, and an agency official even announced in March 2020 that HHS "d[id] not plan to move forward on issuing a regulation." *Lilly I*, 526 F. Supp. 3d at 402, 406 (quoting JA788 (Mirga, *supra* at 22)).

Through its words and conduct, HHS thus gave no indication that the 2016 NPRM might still yield a final rule—and instead affirmatively stated that such a rule would *not* be forthcoming. The District Court even recognized that the "four-year delay" between the NPRM and the ADR rule had (at best for the government) "approache[d] the limit for taking action," because the "'useful life'" of an NPRM and its comment period "'is not infinite.'" JA39, 42 (quoting *Mobil Oil Corp. v. EPA*, 35 F.3d 579, 584 (D.C. Cir. 1994)). Accordingly, when the agency suddenly issued the ADR rule in late 2020, it violated the APA. *Lilly I*, 526 F. Supp. 3d at 407-08.

The District Court's holding that HHS nonetheless complied with the APA does not withstand scrutiny. *First*, the District Court suggested that the NPRM was not withdrawn but instead merely "de-list[ed]" or "remove[d]" from the Unified Agenda. JA40. But the Executive Branch *explicitly stated* otherwise, announcing that the NPRM was "Withdrawn" and later assigning the final ADR rule a different regulatory identification number. JA195 (Unified Agenda); *see Lilly I*, 526 F. Supp. 3d at 406-07.

Second, the District Court suggested that "the nature of the ADR Rule" lessened the "degree of notice" required. JA42. But the APA's

requirements do not change based on the type of rule. *See* 5 U.S.C. § 553(b).

Third, the District Court claimed that Section 340B itself provided adequate notice of the rulemaking, even if HHS did not. JA42-44. But the APA requires not just notice but also an opportunity to comment. Moreover, the APA requires the notice to be published in the Federal Register, 5 U.S.C. § 553(b), which "must come—if at all—from the Agency," *Horsehead Res. Dev. Co. v. Browner*, 16 F.3d 1246, 1268 (D.C. Cir. 1994). And, in any event, Section 340B describes the contemplated rule too vaguely to provide sufficient notice, *see* 42 U.S.C. § 256b(d)(3); 42 C.F.R. §§ 10.20 to 10.24.

Finally, the District Court claimed nothing happened to the 340B Program "that might make the prior notice and comment period stale." JA43. But the District Court itself recognized the seismic impact that contract pharmacies have recently had on the 340B Program. *See* JA17-18, 107; *supra* at 13-17. Manufacturers even sought to "supplement the [agency's] record" with this "significant new evidence" before the ADR rule issued. JA829, 838 (Petition (ADVOP.1379, 1388)).

CONCLUSION

This Court should reverse the judgment below and (1) set aside the Violation Letter, the Advisory Opinion, and the ADR Rule; (2) declare that Section 340B does not require Sanofi to provide discounted drugs to contract pharmacies; (3) declare that the conditions included as part of Sanofi's integrity initiative comply with Section 340B; and (4) enjoin HHS from taking further enforcement action against Sanofi for operating its integrity initiative.

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Respectfully submitted,

s/ Brett A. Shumate

Noel J. Francisco
Brett A. Shumate
JONES DAY
51 Louisiana Ave. NW
Washington, DC 20001
(202) 879-3939
njfrancisco@jonesday.com
bshumate@jonesday.com

Toni-Ann Citera
Rajeev Muttreja
JONES DAY
250 Vesey Street
New York, New York 10281
(212) 326-3939
tcitera@jonesday.com
rmuttreja@jonesday.com

Counsel for Appellant Sanofi-Aventis U.S., LLC

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s/ Brett A. Shumate

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I hereby certify that, on July 14, 2022, I filed the foregoing brief using this Court's CM/ECF system, which effected service on all parties.

s/ Brett A. Shumate