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

IN THE UNITED STATES COURT OF APPEALS
FOR THE THIRD CIRCUIT

NOVO NORDISK INC. AND NOVO NORDISK PHARMA, INC.

Plaintiffs–Appellants–Cross-Appellees,

v.

U.S. DEPARTMENT OF HEALTH AND HUMAN SERVICES, *et al.*,

Defendants–Appellees–Cross-Appellants.

SANOFI-AVENTIS U.S., LLC.

Plaintiff–Appellant–Cross-Appellee,

v.

U.S. DEPARTMENT OF HEALTH AND HUMAN SERVICES, *et al.*,

Defendants–Appellees–Cross-Appellants.

On Appeals from the United States District Court
for the District of New Jersey (Nos. 21-634, 21-806)

PRINCIPAL AND RESPONSE BRIEF FOR THE FEDERAL DEFENDANTS

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INTRODUCTION

Under Section 340B of the Public Health Service Act, as amended by the Patient Protection and Affordable Care Act (ACA or Affordable Care Act), drug manufacturers that choose to be reimbursed under Medicaid or Medicare Part B are subject to an unqualified statutory requirement. They must "offer each covered entity covered outpatient drugs for purchase at or below the applicable ceiling price." 42 U.S.C. § 256b(a)(1). Congress considered but declined to enact a provision that would have confined these price discounts to covered entities that dispense drugs through in-house pharmacies. From the inception of the 340B Program, covered entities have relied on outside pharmacies (known as "contract pharmacies") to dispense the drugs purchased at the 340B price. 61 Fed. Reg. 43549, 43550 (Aug. 23, 1996).

Dissatisfied with the terms of the 340B Program, drug manufacturers recently began adding new conditions of their own. Beginning in 2020, several of the world's largest manufacturers announced that they would no longer offer drugs to covered entities at or below the ceiling price when the covered entity relies on one or more contract pharmacies to dispense the drugs. The stated purpose of the new policies is to prevent duplicative discounts and drug diversion.

The Department of Health and Human Services (HHS) correctly informed plaintiffs and other manufacturers that their new policies violate the 340B statute and are grounds for civil monetary penalties. Contrary to plaintiffs' premise, Congress did not allow drug manufacturers to add provisos to their obligations under the 340B statute. That would be akin to letting the fox guard the henhouse. Congress was aware of the use of outside pharmacies, and chose not to restrict covered entities' use of contract pharmacies or allow drug manufacturers to impose such restrictions unilaterally.

The district court correctly recognized that plaintiffs "may not unilaterally create and establish policies" that "dictate how many contract pharmacies a covered entity may designate to receive delivery of covered drugs." JA105. The court was mistaken, however, in vacating HHS's enforcement letters and remanding for HHS to consider whether to impose such a restriction. HHS has no explicit statutory authority to cap the number of contract pharmacies that a covered entity may use. As plaintiff Sanofi correctly explains (Br. 7), Section 340B gives HHS rulemaking authority in only three limited areas that do not include contract-pharmacy arrangements. The statute alone—rather than HHS's nonbinding guidance—is the source of plaintiffs' obligation to offer discounted prices to

covered entities. And the statute alone provides the basis for the enforcement actions at issue here. Thus, the judgment of the district court should be reversed insofar as it vacated the enforcement letters and remanded to HHS.

STATEMENT OF JURISDICTION

Plaintiffs in these consolidated cases invoked the district court's jurisdiction under 28 U.S.C. § 1331. On November 5, 2021, the district court issued an order granting in part and denying in part the parties' cross-motions for summary judgment. Plaintiffs filed timely notices of appeal on November 19, 2021, and defendants filed timely notices of appeal on December 28, 2021. *See* Fed. R. App. P. 4(a)(1)(B). This Court has appellate jurisdiction under 28 U.S.C. § 1291.

STATEMENT OF THE ISSUES

Under Section 340B of the Public Health Service Act, as amended by the Affordable Care Act, drug manufacturers that participate in Medicaid and Medicare Part B shall "offer each covered entity covered outpatient drugs for purchase at or below the applicable ceiling price." 42 U.S.C. § 256b(a)(1). The questions presented are:

1. Whether the district court correctly held that the statute does not allow drug manufacturers to refuse to offer this price discount to a covered

entity that uses one or more contract pharmacies to dispense the drugs that the covered entity purchases.

2. Whether the district court erred in vacating HHS's enforcement letters and remanding so that HHS—which has no statutory authority to restrict contract-pharmacy arrangements—could consider doing so.

3. Whether the district court correctly rejected Sanofi's procedural challenge to an administrative dispute resolution regulation that Congress required HHS to issue.

STATEMENT OF THE CASE

I. Statutory Background And Agency Guidance

A. The 340B Program

These appeals concern the obligations of drug manufacturers that participate in Medicaid and Medicare Part B, and which accordingly receive reimbursement for their products under those programs. Congress directed that such manufacturers must comply with Section 340B of the Public Health Service Act, which was enacted in 1992 and codified at 42 U.S.C. § 256b. Pub. L. No. 102-585, § 602, 106 Stat. 4943, 4967-71 (1992); *see also* 42 U.S.C. § 1396r-8(a)(1), (5) (cross-referencing 42 U.S.C. § 256b).

Under Section 340B, participating manufacturers "must offer discounted drugs to covered entities, dominantly, local facilities that provide medical care for the poor." *Astra USA, Inc. v. Santa Clara County*,

563 U.S. 110, 115 (2011); *see* 42 U.S.C. § 256b(a)(1), (3), (4). Covered entities include, for example, black lung clinics, federally-qualified health centers, certain children's hospitals and free-standing cancer hospitals, critical access hospitals, rural referral centers, and other federally funded health care entities, 42 U.S.C. § 256b(a)(4), which "generally care for underserved populations," *American Hospital Ass'n v. Azar*, 967 F.3d 818, 822 (D.C. Cir. 2020), *cert. granted*, 141 S. Ct. 2883 (2021). The 340B Program enables covered entities to "stretch scarce Federal resources as far as possible, reaching more eligible patients and providing more comprehensive services." H.R. Rep. No. 102-384, pt. 2, at 12 (1992). Covered entities can use those cost savings "to help subsidize prescriptions for their lower income patients, increase the number of patients whom they can subsidize[,] and expand services and formularies." 61 Fed. Reg. 43549, 43549 (Aug. 23, 1996).

From the outset, Section 340B imposed obligations on both drug manufacturers and covered entities. With respect to manufacturers, the statute specified that the Secretary of Health and Human Services shall "enter into an agreement with each manufacturer of covered outpatient drugs under which the amount required to be paid * * * to the manufacturer for covered outpatient drugs * * * purchased by a covered

entity * * * does not exceed" a specified ceiling price. 42 U.S.C. § 256b(a)(1). The statute thus required manufacturers to sell drugs to covered entities at discounted prices.

With respect to covered entities, the statute prohibited requests for duplicate discounts and the diversion of drugs purchased under the 340B Program. To prevent duplicative discounts, the statute specified that a covered entity shall not request a discount for a drug that is already subject to a separate Medicaid rebate requirement. 42 U.S.C. § 256b(a)(5)(A). To prevent diversion, the statute specified that "a covered entity shall not resell or otherwise transfer the drug to a person who is not a patient of the entity." *Id.* § 256b(a)(5)(B).

To promote transparency, the statute required a covered entity to permit both the Secretary and the manufacturer to audit the covered entity's records. 42 U.S.C. § 256b(a)(5)(C). The statute further provided that, if the Secretary finds that a covered entity is in violation of a requirement, the covered entity shall be liable to the manufacturer for the amount equal to the discount. *Id.* § 256b(a)(5)(D).

B. Covered entities' use of contract pharmacies to dispense drugs purchased under the 340B Program

From the inception of the 340B Program, many covered entities relied on outside pharmacies, which came to be known as "contract pharmacies," to dispense to their patients the drugs purchased at the discounted prices. Indeed, when the program was first implemented, only 5 percent (500 of 11,500) covered entities had in-house pharmacies. *See* 61 Fed. Reg. at 43550.

When Congress was considering the legislation that established the Section 340B Program, it considered a bill that would have limited the discounts to drugs "purchased *and dispensed by, or under a contract entered into for on-site pharmacy services with*," a covered entity. S. Rep. No. 102-259, at 2 (1992) (emphasis added) (considering S. 1729, 102d Cong. (1992)). The emphasized language would have prevented covered entities from using outside pharmacies to dispense the drugs purchased at the discounted prices. Congress did not enact that restriction, however. Instead, Congress broadly required manufacturers to provide discounted prices for "drugs * * * purchased by a covered entity," regardless of whether covered entities used in-house or outside pharmacies to dispense the drugs that the covered entities purchased. 42 U.S.C. § 256b(a)(1).

Congress did not authorize HHS to restrict the use of contract pharmacies by covered entities. Congress gave HHS rulemaking authority with respect to only limited aspects of the 340B Program that do not include contract-pharmacy arrangements. *See* Sanofi Br. 7. However, HHS periodically issued nonbinding guidelines on that topic. *See, e.g.*, 61 Fed. Reg. at 43550 (explaining that "these guidelines create no new law and create no new rights or duties").

HHS's 1996 guidelines explained that a covered entity's use of a contract pharmacy was permissible and did not relieve a manufacturer of its obligation to sell the drugs at the discounted price. 61 Fed. Reg. at 43549-50. HHS noted that "[i]t would defeat the purpose of the 340B Program if these covered entities could not use their affiliated pharmacies in order to participate in the 340B Program," because covered entities "would be faced with the untenable dilemma of having either to expend precious resources to develop their own in-house pharmacies (which for many would be impossible) or forego participation in the program altogether." *Id.*

The 1996 guidelines advised that a covered entity contract with only one pharmacy to provide all pharmacy services for any particular site of the covered entity. 61 Fed. Reg. at 43555. Starting in 2001, however, HHS

began a pilot program under which covered entities used multiple contract pharmacies to increase their patients' access to 340B drugs. 72 Fed. Reg. 1540, 1540 (Jan. 12, 2007). The pilot program's participants were subject to annual, independent audits "for drug diversion and duplicative discounts." *Id.* Based on the results of six years of auditing from the pilot program, HHS proposed new guidelines in 2007 under which covered entities could use multiple contract pharmacies "to provide broader access to 340B discounted drugs to eligible patient[s]." 72 Fed. Reg. at 1540. At the same time, HHS underscored the "particular importance" of the "requirement that appropriate procedures be in place to prevent diversion of 340B drugs or a duplicative 340B drug discount and a Medicaid rebate on the same drug, which are prohibited under the statute." *Id.*

After considering public comments, HHS finalized the proposed guidelines in 2010, shortly before Congress enacted the Affordable Care Act. 75 Fed. Reg. 10272 (Mar. 5, 2010). The 2010 guidelines indicated that covered entities could use multiple contract pharmacies as long as the covered entities complied with guidelines to prevent diversion and duplicate discounts and adhered to policies regarding the definition of a "patient" of a covered entity. *Id.* at 10273.

C. The Affordable Care Act's amendments to the 340B Program

As part of the Affordable Care Act, Congress amended the 340B statute in a subtitle designed to provide "More Affordable Medicines for Children and Underserved Communities." Pub. L. No. 111-148, Title VII, subtitle B, 124 Stat. 119, 821 (2010).

Section 7101 of the Affordable Care Act, entitled "Expanded Participation In 340B Program," expanded the list of "covered entities" eligible to participate in the 340B Program. 124 Stat. at 821-22 (amending 42 U.S.C. § 256b(a)(4)). It added certain children's hospitals, critical access hospitals, rural referral centers, and sole community hospitals to the list of facilities that may purchase drugs from manufacturers at discounted prices.

Section 7102, entitled "Improvements To 340B Program Integrity," added a series of new provisions designed to improve compliance with 340B Program requirements by both drug manufacturers and covered entities. 124 Stat. at 823-27 (amending 42 U.S.C. § 256b(d)).

First, Congress directed the Secretary to improve oversight of manufacturers in various specified ways and authorized the Secretary to impose sanctions against manufacturers in the form of civil monetary

penalties, not to exceed $5,000 for each instance of overcharging a covered entity. 42 U.S.C. § 256b(d)(1).[1]

Second, Congress directed the Secretary to improve covered entities' compliance with the statute's prohibitions on diversion and duplicate discounts in various specified ways, such as by requiring covered entities to regularly update information on an HHS website. 42 U.S.C. § 256b(d)(2)(B). In addition, Congress significantly increased the penalties if covered entities violate program requirements. Congress authorized the Secretary to impose sanctions against covered entities—including monetary penalties, removal from the 340B Program, and referral to other federal agencies for appropriate action—for diversion, duplicate discounts, or other violations of program requirements. *Id.* § 256b(d)(2)(B)(v).

Third, Congress directed the Secretary to promulgate regulations to establish an administrative process for HHS to resolve (subject to judicial review) covered entities' claims that they have been overcharged and manufacturers' claims that covered entities violated the statute's prohibitions on duplicative discounts and diversion. 42 U.S.C. § 256b(d)(3). *See also infra* pp.21-22.

[1] *See also* 87 Fed. Reg. 15100, 15105 (Mar. 17, 2022) (adjusting penalty for inflation to $6,323).

The ACA's amendments to Section 340B did not restrict covered entities' use of contract pharmacies, nor did Congress authorize drug manufacturers or HHS to impose such a restriction. On the contrary, the ACA's amendments specified, without qualification, that the Secretary's agreement with a drug manufacturer "shall require that the manufacturer offer each covered entity covered outpatient drugs for purchase at or below the applicable ceiling price if such drug is made available to any other purchaser at any price." 42 U.S.C. § 256b(a)(1). *Accord* 59 Fed. Reg. 25110, 25111-12 (May 13, 1994) ("Manufacturers may not single out covered entities from their other customers for restrictive conditions that would undermine the statutory objective.").

Section 7103 directed the Government Accountability Office (GAO) to report to Congress with recommendations for further improvements to the 340B Program. 124 Stat. at 827-28.

II. Factual Background

A. GAO reports on the growth of the 340B Program

In the decade since the Affordable Care Act's amendments, the GAO has submitted a series of reports to Congress on the 340B Program. These reports describe significant growth in the 340B Program and attribute that growth to a combination of factors, including the Affordable Care Act's expansion of the list of covered entities that can participate in the 340B

Program, the enrollment of more facilities in the 340B Program, and covered entities' increased use of contract pharmacies to distribute the drugs they purchase.

The GAO reported that participation in the 340B Program grew from nearly 9,700 covered entities in 2010 to 12,700 covered entities in 2020. *See* GAO-21-107, *Drug Pricing Program: HHS Uses Multiple Mechanisms to Help Ensure Compliance with 340B Requirements* 2 (2020).[2] The GAO reported that, between 2010 and 2017, the number of contract pharmacies increased from about 1,300 to about 20,000. *See* GAO-18-480, *Drug Discount Program: Federal Oversight of Compliance at 340B Contract Pharmacies Needs Improvement* 2 (2018).[3] Elaborating on the use of contract pharmacies, the GAO reported that, as of 2017, about one-third of the covered entities in the 340B Program used contract pharmacies, but the extent varied by type of entity. *See id.* at 16. For example, a higher percentage of hospitals (69.3%) used at least one contract pharmacy compared to federal grantees (22.8%). *See id.* And among the six types of hospitals eligible to participate in the 340B Program, the percentage that used at least one contract pharmacy ranged from 39.2% of children's

[2] https://www.gao.gov/products/gao-21-107
[3] https://www.gao.gov/products/gao-18-480

hospitals to 74.1% of critical access hospitals. *See id.* Among the 10 types of federal grantees, the percentage with at least one contract pharmacy ranged from 3.9% of family planning clinics to 75.2% of federally qualified health centers. *See id.*

The GAO made a number of recommendations to improve HHS's oversight of contract-pharmacy arrangements, while at the same time recognizing that HHS has limited authority to issue regulations governing the 340B Program. *See* GAO-18-480, at 47. For example, the GAO recommended that HHS require covered entities to register contract pharmacies for each site of the entity for which a contract exists. *See id.* at 46. The GAO did not recommend that HHS limit the number of contract pharmacies that a covered entity may use, however, nor did the GAO suggest that drug manufacturers themselves may impose restrictions on covered entities' use of contract pharmacies.

B. Drug manufacturers' new policies restricting covered entities' use of contract pharmacies

Beginning in 2020, a number of the country's largest drug manufacturers, including plaintiffs, announced that they would cease shipping discounted drugs to contract pharmacies used by covered entities, unless various conditions were met. The claimed objective of these new policies is to prevent duplicative discounting and drug diversion.

The details of these policies differ by manufacturer. For example, plaintiff Novo will not provide the 340B discounted price unless the covered hospital designates a single contract pharmacy, or if Novo determines "in its discretion" that the contract pharmacy poses a lesser risk of abuse to the 340B Program. JA21-22; JA1042-44. Plaintiff Sanofi will not provide discounted prices unless a covered entity uses an in-house pharmacy, has no in-house pharmacy and uses only a single contract pharmacy, or registers with and provides claims-level data to a third-party data-sharing platform designated by Sanofi. JA21; JA904-05. Eli Lilly will not provide discounted prices unless the covered entity owns the outside pharmacy or has no in-house pharmacy. *Eli Lilly & Co. v. U.S. Department of Health and Human Services*, 2021 WL 5039566, at *5 (S.D. Ind. Oct. 29, 2021), *appeals pending*, Nos. 21-3128, 21-3405 (7th Cir.). Novartis Pharmaceuticals will not provide discounted prices unless the covered entity is a federal grantee (as distinct from a hospital) or if the contract pharmacy is within 40 miles of the covered entity. *Novartis Pharm. Corp. v. Espinosa*, 2021 WL 5161783, at *3 (D.D.C. Nov. 5, 2021), *appeals pending*, Nos. 21-5299, 21-5304 (D.C. Cir.). United Therapeutics, AstraZeneca, and other manufacturers have adopted similar policies. *See*

id. at *4; *see also AstraZeneca Pharms. LP v. Becerra*, 2022 WL 484587, at *1 (D. Del. Feb. 16, 2022), *appeal pending*, No. 22-1676 (3d Cir.).

As a consequence of these policies, numerous covered entities complained to HHS that they could no longer obtain eligible drugs at the 340B discounted prices to dispense to their patients through contract pharmacies. For example, the organization AIDS Response Effort notified HHS that it could no longer obtain cancer medications manufactured by plaintiff Sanofi at the 340B price. JA1147-50; *see also* JA1095-1162 (documenting the medications that AIDS Response Effort was unable to obtain under these policies). HHS received a similar complaint from Presence St. Francis Hospital, which informed HHS that it could no longer obtain insulin from plaintiff Novo at the 340B price. JA1198-1205.

Covered entities informed HHS that the manufacturers' new policies impair the covered entities' ability to serve their patients. For example, one federally funded health center, Medical Associates Plus, explained that its in-house pharmacies could only serve a minority of its 25,000 patients, who are a "medically underserved population." JA1179-80. It explained that most of its clinical locations do not have an in-house pharmacy, and those that do are only open during work-hours, making it difficult for many patients to access them. *Id.* The center explained that it "depends on its

340B Program savings and revenue to help support approximately 41% of" its expenses not covered by federal grants, and that the new policies will cause a "significant financial loss" that "will also result in reduction in other clinical and/or patient services." JA1182. *See also* JA1174-78 (covered entity that serves thousands of patients across a 10,000 square mile area, including Michigan's upper peninsula, explains that manufacturers' policies will "significantly and irreparably harm[]" its patients).

Another federally funded health center, North Country HealthCare, informed HHS that it uses dozens of contract pharmacy locations to dispense needed medications to tens of thousands of its patients across northern Arizona. JA1167-69. Without contract pharmacies, many of the center's patients would have to travel over a hundred miles each way to reach one of the center's locations that operates an in-house pharmacy. JA1170. Illustrating its concern, the center noted that this travel was not realistically feasible for one of its uninsured diabetic patients, who was located "approximately 280 miles from our closest in-house pharmacy." JA1172. Starting in October 2020, that patient could no longer access Sanofi's insulin medication at his contract pharmacy. *Id.* Other insulin options, manufactured by Novartis and Eli Lilly—which had adopted similar policies—were "also not available at 340B pricing." *Id.* The center

described the consequences in stark terms: "This patient's body is unable to make insulin. Without it he will die." *Id.* The center emphasized that many of its other patients "are being denied access to evidence-based, guideline-driven, best practice quality care because of their inability to access affordable medications." *Id.*

In all, HHS received thousands of pages from covered entities documenting their inability to receive and dispense medications at the 340B price after the manufacturers implemented their new policies. *See generally* Dkt. 60 at 110-6,806, *Novo Nordisk Inc. v. U.S. Department of Health and Human Servs.*, No. 21-806 (D.N.J. July 2, 2021). The new policies caused a precipitous decline in drug sales at the 340B prices. For example, in the month before announcing its new policy, plaintiff Novo had sold 3.32 million units of drugs at the 340B prices; the month after it adopted the new policy, that number dropped by more than 2 million units—a decline of 64%. JA901. Plaintiff Sanofi had sold 2.04 million units at 340B prices in the month before its new policy; that figure dropped to 0.37 million units the month after—a drop of 82%. *Id.* Based on such data, HHS calculated that covered entities had lost hundreds of millions in savings over just the few months after the new policies took effect, and would lose over $3.2 billion over the course of a full year. JA900. That

included almost $100 million in lost savings from Novo and $47 million in lost savings from Sanofi—both in just a single month. JA903.

C. HHS's enforcement actions

In December 2020, HHS's general counsel issued an advisory opinion stating that manufacturers are "obligated to deliver [their] outpatient drugs to those contract pharmacies" used by covered entities "and to charge the covered entity no more than the 340B ceiling price for those drugs." JA211. However, HHS voluntarily withdrew that advisory opinion "in the interests of avoiding confusion and unnecessary litigation" after a district court declared that it rested on a statutory interpretation that was permissible but not compelled by the statute's text. JA24; *see AstraZeneca Pharms. LP v. Becerra*, 543 F. Supp. 3d 61-62 (D. Del. 2021).

In May 2021, HHS took the enforcement actions at issue here. HHS sent plaintiffs and other manufacturers similarly worded letters notifying them that their new policies were in violation of 42 U.S.C. § 256b and resulted in prices above the ceiling price of the 340B Program. For example, HHS's letter to Novo explained 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." JA221. The letter recognized that the

manufacturer's claimed rationale for its new restrictions is to prevent diversion and duplicate discounts, and the letter explained that "[t]he 340B statute provides a mechanism by which a manufacturer can address these concerns." JA222. "Specifically, the manufacturer must (1) conduct an audit and (2) submit a claim through the Administrative Dispute Resolution process as described in section 340B(d)(3)(A)" of the Public Health Service Act. *Id.* The letter directed the manufacturer to immediately resume offering its drugs at discounted prices to covered entities through their contract pharmacy arrangements, and to credit or refund covered entities for all overcharges. *Id.* The letter warned that, if the manufacturer continued its policy, HHS may seek civil monetary penalties of up to $5,000 for each instance of overcharging. *Id.* (citing 42 U.S.C. § 256b(d)(1)(B)(ii)). HHS's letter to Sanofi was materially similar. *See* JA219-20.

D. HHS's administrative dispute resolution regulation

As noted above, the ACA's amendments to Section 340B directed HHS to "promulgate regulations to establish and implement an administrative process for the resolution of" covered entities' claims that they have been overcharged and manufacturers' claims that covered entities violated certain statutory requirements. 124 Stat. at 826-27 (enacting 42

U.S.C. § 256b(d)(3)). Congress specified that the regulations should: (1) designate an HHS official or HHS decision-making body to be responsible for reviewing such claims; (2) establish deadlines and procedures as necessary to ensure that claims shall be resolved fairly, efficiently, and expeditiously; (3) establish procedures for covered entities to obtain relevant information from the manufacturer or third parties; (4) require that a manufacturer conduct an audit of a covered entity pursuant to 42 U.S.C. § 256b(a)(5)(C) as a prerequisite to initiating administrative dispute resolution proceedings against a covered entity; and (5) permit the consolidation or joinder of claims by multiple manufacturers against the same covered entity and by multiple covered entities against the same manufacturer. 42 U.S.C. § 256b(d)(3)(B)(i)-(vi). Congress provided that the administrative resolution of a claim or claims under the regulations shall be a final agency decision that is binding upon the parties involved, unless invalidated by an order of a court of competent jurisdiction. *Id.* § 256b(d)(3)(C).

HHS issued an advance notice of proposed rulemaking and a request for comments in 2010. 75 Fed. Reg. 57233, 57233-35 (Sept. 20, 2010). In 2016, HHS issued a notice of proposed rulemaking for a model of how the dispute resolution mechanism would operate and requested comments on

that proposal. 81 Fed. Reg. 53381, 53381-88 (Aug. 12, 2016). In 2017, after the change in presidential administration, HHS "paus[ed] action on the proposed rule" pending an Executive Branch review of pending regulatory proposals. 85 Fed. Reg. 80632, 80633 (Dec. 14, 2020).[4] After that review, HHS issued the final rule in 2020. *Id.* at 80632-46.

III. The District Court's Rulings

In these consolidated district court actions, all plaintiffs challenged HHS's enforcement letters and advisory opinion, and plaintiff Sanofi challenged the administrative dispute resolution regulation. JA1080-81; JA981-82. The district court granted in part and denied in part the parties' cross-motions for summary judgment.

A. The district court's interpretation of the 340B statute

Addressing the central legal issue, the district court rejected plaintiffs' contention that the 340B statute allows drug manufacturers to "unilaterally create and establish policies" that "dictate how many contract pharmacies a covered entity may designate to receive delivery of covered drugs." JA105. The court reasoned that Congress's explicit direction that drug

[4] Other agencies similarly paused their regulatory proposals pending that government-wide review process. *See Organization for Competitive Markets v. U.S. Department of Agriculture*, 912 F.3d 455, 458 (8th Cir. 2018).

manufacturers "shall offer" their products to covered entities at discounted prices "does not permit Plaintiffs to take specific actions, like their policies, just because those actions are not expressly prohibited by the broad text." JA104. On the contrary, the court explained, "there is no 'such thing as a "canon of donut holes," in which Congress's failure to speak directly to a specific case * * * that falls within a more general statutory rule * * * creates a tacit exception.'" JA103-04 (quoting *Bostock v. Clayton County*, 140 S. Ct. 1731, 1747 (2020)). "Instead, when Congress chooses not to include any exceptions to a broad rule, courts apply the broad rule." *Id.* (quoting *Bostock*, 140 S. Ct. at 1747).

The district court concluded that this interpretation is supported by "the statutory context, structure, history, and purpose." JA101. The court explained that when Congress originally enacted Section 340B, Congress considered a bill that would have limited the discounts to "drugs 'purchased by and *dispensed by, or under a contract entered into for on-site pharmacy services with*,' a covered entity.'" JA91 (district court's emphasis) (quoting S. Rep. No. 102-259, at 2 (1992)). But Congress did not enact that limit on dispensing drugs, and instead made the discounts available to any "drugs 'purchased by' covered entities, without limiting (or remarking on) the dispensing mechanism." *Id.* Thus, because "Congress

eliminated a clear limitation on contract pharmacy arrangements * * * it likely did not intend *to prohibit* them altogether." JA91-92 (collecting cases).

The district court explained that plaintiffs' interpretation would undermine the statute's purpose to benefit "small, often remote, and almost always resource-limited providers who are receiving federal assistance for serving disadvantaged populations." JA93-94. The court noted that few covered entities "maintained in-house pharmacies when Congress passed § 340B in 1992." JA96. It was "unrealistic to assume that Congress enacted a comprehensive legislative scheme to aid safety-net providers and vulnerable patients—but intentionally and implicitly structured it in such a way that only 5% of the providers" could actually participate. JA96-97 (quotation marks omitted). The court emphasized that, for many covered entities, contract pharmacies "are not just commonplace * * * they are a necessary—perhaps even indispensable—means of attaining § 340B's ends." JA94. Contract pharmacies "enable safety net providers to expand their distribution networks for 340B drugs, fill more prescriptions, and generate additional savings and revenue to fund both higher discounts and more comprehensive healthcare services." *Id.* "Absent contract pharmacy arrangements, § 340B may be a dead letter in many of its applications * * *

given the number of covered entities which cannot afford to create or maintain in-house pharmacies." *Id.* (quotation marks omitted). The court concluded that plaintiffs' policies would undermine the statute's objective, which is a "strong indication" that something in their interpretation "is amiss." JA93 (quoting *Freeman v. Quicken Loans, Inc.*, 566 U.S. 624, 632 (2012)).

The district court further explained that Congress amended the statute after HHS published guidance regarding the use of contract pharmacies. JA95. The court found it reasonable "to presume that Congress knew about" and "seemingly ratified contract pharmacy arrangements." *Id.* The court rejected plaintiffs' contention that the ACA's amendments implicitly delegated to manufacturers the power to restrict covered entities' use of contract pharmacies, rejecting plaintiffs' attempt to "locate a unilateral power to impose offer conditions in a provision Congress added to § 340B eighteen years after enacting the Program, and which Congress passed largely to ensure equal treatment between covered entities and commercial purchasers." JA103. The court emphasized that plaintiffs identified nothing in the statute to indicate that Congress "*intended* to delegate discretion to manufacturers to impose" conditions on the availability of discounted drugs. *Id.* And the court concluded that

Congress did not "alter the fundamental details of [a] regulatory scheme[] in vague terms or ancillary provisions." *Id.* (quoting *Whitman v. American Trucking Ass'ns*, 531 U.S. 457, 468 (2001)).

B. The district court's partial vacatur of the enforcement letters and remand to HHS

The district court recognized that "HHS has not been granted broad rulemaking authority to carry out all the provisions of the 340B Program," and, specifically, that HHS lacks authority to regulate contract-pharmacy arrangements. JA86. Accordingly, the court concluded that the *Chevron* framework does not govern the statutory-interpretation question presented here, observing that "HHS does not contend otherwise." *Id.*

Nonetheless, the district court determined that it was appropriate to partially vacate HHS's enforcement letters and remand to HHS to address what the court described as an "unresolved" question of statutory interpretation: "how many contract pharmacies the 340B statute permits, if there is a ceiling at all." JA105. "Rather than decide this issue," the court decided *sua sponte* to "remand to the agency for 'additional investigation or explanation.'" *Id.* (quoting *Negusie v. Holder*, 555 U.S. 511, 523 (2009)).

The district court directed HHS to determine on remand "whether HHS has the statutory authority to require Plaintiffs to ship their drugs to multiple or unlimited contract pharmacies." JA105. The court identified

several concerns that, in its view, could arise from permitting covered entities to contract with multiple pharmacies: increased risk of diversion, weaker compliance mechanisms, greater failure to pass discounts to patients, and failure of covered entities to possess 340B drugs under certain distribution systems. JA107-08. The court declared that HHS should assess these concerns on remand to determine "whether it is permissible under the 340B statute to enforce a one-size-fits-all contract pharmacy policy, or whether more specific and holistic guidance is necessary." JA108.

Based on that reasoning, the district court indicated that it would "uphold HHS' assessment that Plaintiffs cannot impose restrictions on offers to covered entities and that their policies must cease," but "vacate HHS' determination that Plaintiffs owe credits or refunds to covered entities, and face" civil monetary penalties, "to the extent that such determinations may depend on the number of permissible contract pharmacy arrangements under the 340B statute." JA105-06. The court rejected plaintiffs' other challenges to the enforcement letters, including their contentions that the enforcement letters were arbitrary and capricious, procedurally unsound, or a Fifth Amendment taking. JA110-

32.[5]

C. The district court's rejection of Sanofi's challenges to the administrative dispute resolution regulation

The district court rejected Sanofi's various statutory and constitutional challenges to the HHS regulation that established an administrative process for resolving disputes. JA36-81. Sanofi has abandoned all but one of those challenges on appeal; thus, we describe only the relevant part of the district court's reasoning.

As relevant here, the district court rejected Sanofi's argument that "HHS needed to initiate a new notice and comment period" before promulgating the final rule because—although HHS never withdrew the proposed rule—HHS removed the item from "the Unified Agenda in 2017." JA37. The court rejected the suggestion that the industry lacked fair notice that the final rule could be promulgated. JA38. The court explained that the "public and industry were well aware" that "HHS had to issue a final Rule at some point," because "Congress mandated the [administrative dispute resolution] Rule through legislation." JA42 (citing 42 U.S.C. § 256b(d)(3)(A)). Therefore, Sanofi "could not have been reasonably

[5] The district court concluded that plaintiffs' challenge to the advisory opinion issued by HHS's general counsel (but which was later withdrawn) was moot. JA31 n.31, JA132.

caught off guard when the final Rule—on the horizon since 2010—issued." *Id.* Moreover, the court explained that Sanofi had failed to identify "*relevant* changes in the regulated market or 340B landscape in the interim that might make the prior notice and comment period stale." JA43.

SUMMARY OF ARGUMENT

Drug manufacturers that wish to be reimbursed under the federally funded Medicaid and Medicare Part B programs are subject to a separate statutory requirement. Pursuant to Section 340B of the Public Health Service Act, such manufacturers must offer their drugs at discounted prices to specified "covered entities." When Congress enacted the Section 340B Program, it considered a bill that would have confined these price discounts to covered entities that dispense drugs through in-house pharmacies. Congress declined to enact that bill, however, and covered entities have since the inception of the 340B Program relied on outside pharmacies (known as "contract pharmacies") to dispense the discounted drugs.

In 2020, drug manufacturers including plaintiffs announced policies that dramatically curtailed the manufacturers' obligations under the 340B Program. Although the details of these policies vary, the manufacturers generally refuse to ship discounted drugs to covered entities' contract pharmacies unless specified conditions are met. For example, plaintiff

Novo will not provide discounted prices unless the covered entity designates only a single contract pharmacy, or if Novo determines "in its discretion" that the contract pharmacy poses a lesser risk of abuse to the 340B Program. JA22. As a consequence of the manufacturers' new policies, drug sales at the discounted prices plummeted. HHS correctly informed plaintiffs and other manufacturers that their new policies violate the 340B statute and are grounds for civil monetary penalties.

I. The district court correctly held that drug manufacturers "may not unilaterally create and establish policies" that "dictate how many contract pharmacies a covered entity may designate to receive delivery of covered drugs." JA105. As the court explained in its comprehensive opinion, that conclusion flows from the text, structure, history, and purpose of the 340B statute. Plaintiffs claim that their new policies are meant only to prevent duplicative discounts and drug diversion. But Congress specifically addressed those concerns through calibrated program-integrity provisions. Congress did not, however, restrict covered entities' use of contract pharmacies or allow drug manufacturers to impose such restrictions.

II. Although the district court correctly held that drug manufacturers cannot restrict covered entities' use of contract pharmacies, the court erred in partially vacating HHS's enforcement actions and remanding for HHS to

consider whether to impose such a restriction. All parties agree that HHS lacks rulemaking authority with respect to contract-pharmacy arrangements. Indeed, the district court recognized as much and acknowledged that HHS does not claim and is not entitled to *Chevron* deference with respect to the question of statutory interpretation presented in this case. Even assuming arguendo that the statutory text is ambiguous, it was the court's responsibility to resolve the ambiguity by reference to the statutory context, history, and purpose—which is precisely what the district court did in its opinion. Having correctly concluded that the statute prohibits plaintiffs' policies, the court should have entered final judgment for the federal government.

III. Equally meritless is Sanofi's separate procedural challenge to an HHS regulation that established an administrative process for resolving disputes between manufacturers and covered entities. The district court correctly held that HHS complied with the notice-and-comment requirements of 5 U.S.C. § 553 when it promulgated that regulation. HHS issued a notice of proposed rulemaking, considered and responded to comments it received, and then promulgated a final rule. Nothing more was required. Sanofi argues that HHS was required to go through a second round of notice-and-comment, but Sanofi's arguments are premised on

misunderstandings of how agencies promulgate regulations and what the Administrative Procedure Act requires.

STANDARD OF REVIEW

This Court reviews the district court's summary judgment ruling de novo. *Bruni v. City of Pittsburgh*, 941 F.3d 73, 82 (3d Cir. 2019). Agency action is reviewed to determine if it is "arbitrary, capricious, an abuse of discretion, or otherwise not in accordance with law." 5 U.S.C. § 706.

ARGUMENT

I. The 340B Statute Requires Manufacturers To Sell Drugs To Covered Entities At The Discounted Price, Regardless Of Whether Covered Entities Use Contract Pharmacies To Dispense The Drugs Purchased

A. Drug Manufacturers Cannot Unilaterally Add Provisos To Their Statutory Obligations

Under Section 340B of the Public Health Service Act (42 U.S.C. § 256b), "manufacturers participating in Medicaid must offer discounted drugs to covered entities, dominantly, local facilities that provide medical care for the poor." *Astra USA, Inc. v. Santa Clara County*, 563 U.S. 110, 115 (2011). Since the inception of the program, the statute has set forth the manufacturer's obligation in broad terms, requiring the Secretary to enter into an agreement with the manufacturer "under which the amount required to be paid * * * to the manufacturer for covered outpatient drugs * * * purchased by a covered entity * * * does not exceed" the ceiling price.

42 U.S.C. § 256b(a)(1). Likewise, when Congress expanded the 340B Program as part of the Affordable Care Act, it specified—without qualification—that the Secretary's agreement "shall require that the manufacturer offer each covered entity covered outpatient drugs for purchase at or below the applicable ceiling price if such drug is made available to any other purchaser at any price." *Id.* The bottom line requirement is straightforward: if drug manufacturers want to be reimbursed for their drugs by the federally funded Medicaid and Medicare Part B programs, they also must sell their drugs to covered entities at a discounted price.

Contrary to plaintiffs' premise, drug manufacturers cannot add provisos to that straightforward statutory requirement. The statutory directives do "not permit Plaintiffs to take specific actions, like their policies, just because those actions are not expressly prohibited by the broad text." JA104. There is "'no such thing as a "canon of donut holes," in which Congress's failure to speak directly to a specific case * * * that falls within a more general statutory rule * * * creates a tacit exception.'" JA103-04 (quoting *Bostock v. Clayton County*, 140 S. Ct. 1731, 1747 (2020)). Instead, when "Congress chooses not to include any exceptions to a broad

rule, courts apply the broad rule." *White v. United Airlines, Inc.*, 987 F.3d 616, 621 (7th Cir. 2021).

Put another way, Congress created the 340B Program to ensure that covered entities could obtain discounted drugs under the conditions that *Congress* established. Accordingly, the statutory scheme must be construed to ensure that "everything necessary to making it effectual, or requisite to attaining the end, is implied." Antonin Scalia & Bryan A. Garner, *Reading Law: The Interpretation of Legal Texts* 193 (2012) (*Reading Law*). That necessarily precludes manufacturers from imposing their own conditions that would prohibit covered entities from otherwise obtaining drugs at a discounted price. Accordingly, "Congress's use of broad language in enacting this statute" while omitting specific prohibitions "does not leave room for drug manufacturers to unilaterally condition or control the availability of their 340B pricing." *Eli Lilly & Co v. U.S. Department of Health and Human Services*, 2021 WL 5039566, at *19 (S.D. Ind. Oct. 29, 2021).

"Practical considerations strongly support [this] reading" of the statute, whereas plaintiffs' interpretation "would frustrate Congress' manifest purpose." *United States v. Hayes*, 555 U.S. 415, 426-27 (2009). Congress established the 340B Program to provide covered entities with

drugs at a discounted price, at a time when the vast majority of covered entities dispensed their drugs to patients through outside pharmacies. Yet under plaintiffs' reading, drug manufacturers could have refused to provide the discounted price to all of the covered entities that relied on those pharmacies to distribute the drugs purchased. Under plaintiffs' interpretation, Section 340B "would have been 'a dead letter' * * * from the very moment of its enactment," *id.* at 427, because manufacturers could have eliminated their obligation to sell discounted drugs to 95% of covered entities, *see* 61 Fed. Reg. 43549, 43550 (Aug. 23, 1996) (explaining that only 500 of 11,500 covered entities had in-house pharmacies when the 340B Program was first implemented).

Such an interpretation is incompatible with basic tenets of statutory construction. The Supreme Court has repeatedly emphasized that it is a court's "job to avoid rendering what Congress has plainly done * * * devoid of reason and effect." *Great-West Life & Annuity Ins. Co. v. Knudson*, 534 U.S. 204, 217-18 (2002). Accordingly, courts construe statutes to ensure that "a text's manifest purpose is furthered, not hindered." *Reading Law* 63 (collecting cases).

Congress knew of these pharmacy arrangements when it enacted the 340B statute. Contemporaneously with Congress's original consideration

of the statute, Congress considered a bill that would have limited the discounts to drugs "purchased and *dispensed by, or under a contract entered into for on-site pharmacy services with*," a covered entity. S. 1729, at 9, 102d Cong. (Mar. 3, 1992) (emphasis added). But Congress did not enact that limit on the mechanism for dispensing drugs. Instead, Congress made the discounts available to "drugs 'purchased by' covered entities"—regardless of whether drugs are dispensed by in-house or contract pharmacies. JA91.

Plaintiffs nonetheless contend that because Section 340B has no *explicit* prohibition on adding conditions to the discounted price, Congress has implicitly permitted them to add on those conditions. But that "inference drawn from congressional silence certainly cannot be credited when it is contrary to all other textual and contextual evidence of congressional intent." *Burns v. United States*, 501 U.S. 129, 136 (1991) (holding that district court was required by the Federal Rules of Criminal Procedure to provide notice to criminal defendant of an upward departure from the sentence guidelines, even though that requirement was not made explicit in the rules) (abrogated on other grounds). Moreover, "the mere possibility of clearer phrasing cannot defeat the most natural reading of a statute; if it could (with all due respect to Congress), we would interpret a

great many statutes differently than we do." *Caraco Pharm. Laboratories, Ltd. v. Novo Nordisk A/S*, 566 U.S. 399, 416 (2012).

On plaintiffs' logic, a drug manufacturer could offer their drugs to covered entities at the discounted price—but only if the covered entity agreed to purchase the manufacturer's drugs whenever possible, and never a competitor's. There is nothing in the 340B statute that explicitly prohibits such a unilateral condition. But the fact that Congress did not directly bar such a self-serving business practice does not mean that Congress *permitted* it. A contrary conclusion "not only would defy common sense, but also would defeat Congress' stated objective" of ensuring that covered entities could consistently—and without hindrance—obtain drugs at a discounted price. *See Quarles v. United States*, 139 S. Ct. 1872, 1879 (2019) ("We should not lightly conclude that Congress enacted a self-defeating statute."). Likewise, the district court correctly held that drug manufacturers "may not unilaterally create and establish policies" that "dictate how many contract pharmacies a covered entity may designate to receive delivery of covered drugs." JA105; *accord Eli Lilly*, 2021 WL 5039566, at *20 (drug manufacturers "may not usurp" Congress's directive in the 340B statute "through unilateral extra-statutory restrictions").

B. Drug Manufacturers Cannot Supplement The Statute's Mechanisms For Preventing Diversion And Duplicative Discounts

Plaintiffs claim that their new policies are intended only to prevent the diversion of drugs and duplicative discounts that the 340B statute itself prohibits. Sanofi Br. 1-2; Novo Br. 15-16. Even assuming that this is so, the policies are impermissible. Congress specified in the statute the means to be used to prevent diversion and duplicative discounts.

From the inception of the 340B Program, Congress provided that covered entities "shall not request payment" that would result in a duplicate discount in the form of a Medicaid rebate, and Congress provided that covered entities "shall not resell or otherwise transfer" the discounted drug to non-patients. 42 U.S.C. § 256b(a)(5)(A)-(B). Congress also mandated that covered entities must permit both HHS and drug manufacturers to conduct audits of the entity's records "that directly pertain to" these requirements. *Id.* § 256b(a)(5)(C). And Congress provided that a covered entity "shall be liable to the manufacturer" for the discount if HHS determined, after notice and a hearing, that a covered entity had committed a statutory violation. *Id.* § 256b(a)(5)(D).

Congress expanded these measures when it amended the statute as part of the Affordable Care Act. Congress enacted a series of provisions

explicitly designed to enhance program integrity, including provisions that guard against diversion and duplicative discounts and authorize substantial penalties for noncompliance by covered entities.

For example, Congress directed HHS to develop procedures by which the agency would obtain and verify information from covered entities on a regular basis to ensure their compliance with the 340B Program. 42 U.S.C. § 256b(d)(2)(B)(i)-(ii). Congress also required HHS to develop "more detailed guidance describing methodologies and options" to avoid duplicate Medicaid discounts, and to establish a "single, universal, and standardized" system for identifying covered entities so that HHS, manufacturers, and others could confirm it and "facilitate the ordering, purchasing, and delivery of covered outpatient drugs * * * including the processing of chargebacks for such drugs." *Id.* § 256b(d)(2)(B)(iii)-(iv). And Congress further provided that covered entities would face significant sanctions for intentional violations of the 340B Program, including monetary payments to affected manufacturers, disqualification from the 340B Program for "systematic and egregious" violations, and potential referral to various federal agencies for additional measures. *Id.* § 256b(d)(2)(B)(v).

Congress thus addressed the risks of diversion and duplicative discounts through a calibrated statutory scheme. Congress did not, as

plaintiffs contend, implicitly authorize manufacturers to augment these carefully crafted provisions with policies that undermine the ability of covered entities to provide patients with 340B drugs through their contract pharmacies. *See supra* pp.18-19 (describing the precipitous drop in discounted sales that the manufacturers' new policies caused). To the contrary, Congress enacted numerous measures to ensure that manufacturers sold their drugs to covered entities at the ceiling price, that manufacturers would provide refunds when they overcharged, that HHS would audit manufacturers "to ensure the integrity of the drug discount program," and that HHS would impose money penalties of up to $5,000 "for each instance of overcharging a covered entity." 42 U.S.C. § 256b(d)(1)(B). Congress thus recognized that *both* manufacturers and covered entities must be well regulated in order to ensure compliance with the 340B Program. And if there is a dispute about compliance, Congress provided for an administrative dispute resolution process to address those concerns, *see id.* § 256b(d)(3), but did not permit manufacturers to make such determinations on their own and impose whatever consequences they saw fit.

Nothing in this statutory scheme allows manufacturers to engage in self-help, impose the cost of proving compliance on the covered entities, or

otherwise deny them the statutory discount. *Cf.* 42 U.S.C. § 256b(a)(5)(D) (penalty for a covered entity's noncompliance is an after-the-fact refund of the discounted amount to the manufacturer). Thus, even if plaintiffs' policies "share the same goals" as the statute, "[t]he fact of a common end hardly neutralizes conflicting means." *Crosby v. National Foreign Trade Council*, 530 U.S. 363, 379 (2000).

For similar reasons, manufacturers cannot unilaterally make the 340B discounts contingent on covered entities' agreement to produce claims data on a given manufacturer's preferred platform or in a given manufacturer's preferred format. *See* Sanofi Br. 18. Instead, the 340B statute authorizes manufacturers to audit covered entities as the means to uncover duplicative discounts or diversion. 42 U.S.C. § 256b(a)(5)(C). Notably, Congress required manufacturers to bear the expense of such audits, rather than impose those costs on the covered entities. *Id.* Moreover, Congress has made an audit conducted pursuant to that statutory provision a prerequisite for a manufacturer's administrative claim against a covered entity. *Id.* § 256b(d)(3)(B)(iv).

Contrary to Sanofi's assertion, it cannot ignore this reticulated scheme for auditing and adjudicating potential violations by demanding that covered entities instead collect and submit claims data on a biweekly

basis to the manufacturer's preferred platform (with unknown privacy protections). As HHS explained at the inception of the 340B Program, a "manufacturer may not condition the offer of statutory discounts upon an entity's assurance of compliance with section 340B provisions" because the program's enforcement "is a Federal responsibility." 58 Fed. Reg. 68922, 68925 (Dec. 29, 1993). Accordingly, manufacturers may not require covered entities to "submit[] information related to drug acquisition, purchase, and inventory systems" as a condition of obtaining discounted drugs. *Id.* at 68925. So while a manufacturer can appropriately ask a covered entity for "routine information necessary to set up and maintain an account" as part of its "normal business policies," the manufacturer "may not enforce" its own *sui generis* requirements that a covered entity prove its "compliance with section 340B." 59 Fed. Reg. 25110, 25112 (May 13, 1994).

Moreover, it is not just Sanofi and Novo's policies that are at issue here. Many drug manufacturers have recently imposed their own new policies and restrictions on covered entities' ability to access drugs under the 340B Program. *See Eli Lilly & Co. v. U.S. Department of Health and Human Services*, 2021 WL 5039566, (S.D. Ind. Oct. 29, 2021); *Novartis Pharm. Corp. v. Espinosa*, 2021 WL 5161783 (D.D.C. Nov. 5, 2021); *AstraZeneca Pharms. LP v. Becerra*, 2022 WL 484587 (D. Del. Feb. 16,

2022). Under plaintiffs' logic, there is no reason for these manufacturer policies to follow the same criteria—and indeed these policies impose different substantive limitations and requirements on covered entities simply to obtain the same 340B price that was previously available. Thus while Sanofi requires the regular submission of claims data, Eli Lilly requires covered entities to own the contract pharmacy, have no in-house pharmacy, or designate a single contract pharmacy that Eli Lilly alone determines is "eligible,", *Eli Lilly*, 2021 WL 5039566, at *5, while Novartis Pharmaceuticals only provides the 340B price if the covered entities are federal grantees or if the contract pharmacy is within a 40-mile radius, *Novartis Pharm. Corp.*, 2021 WL 5161783, at *3. Covered entities thus must seek to accommodate a web of restrictive manufacturer conditions simply to obtain the discounted drug price that Congress enacted the 340B Program to provide them.

That manufacturer-imposed burden increases costs for covered entities, diverts their time away from medical care, and seriously harms their patients. As the administrative record demonstrates, even in the limited time these new policies have been in place, covered entities have been unable to purchase drugs at the discounted price and patients have struggled to obtain their needed medications from their pharmacies. *Supra*

pp.16-18. The result is billions' worth of savings lost, and people's health put in jeopardy. Accordingly, HHS properly informed the manufacturers that their new policies violate the statutory scheme and must end.

C. Novo's Constitutional Arguments Lack Merit

Novo suggests that if it is not allowed to place conditions on its sale of drugs in the 340B Program, then its sale of drugs at the discounted price through the program might constitute a Fifth Amendment Taking. *See* Novo Br. 38-41, 52-54. The district court rightly rejected this assertion as a "last-ditch attempt to invalidate the Violation Letters." JA111. The 340B Program does not qualify as a physical taking because "HHS does not acquire title to [Novo's] drugs, obtain them for a third party, or compel Novo to surrender them." JA112 (citations omitted). Nor does it qualify as a regulatory taking. The only reason that Novo is subject to the 340B Program is because Novo has willingly chosen to participate in (and profit from) the federally funded Medicaid and Medicare Part B programs. 42 U.S.C. §§ 256b(a)(1), 1396r-8(a)(1), (5). Thus, although the statute requires Novo to sell some of its drugs at a discounted price, that is a voluntary choice Novo has made in order to "receive[] a 'valuable Government benefit' in exchange," and does "not subject[] [Novo] to a taking." *Horne v. Department of Agriculture*, 576 U.S. 350, 366 (2015); *accord Ruckelshaus*

v. Monsanto Co., 467 U.S. 986, 1007 (1984) (the "voluntary" relinquishment of property "in exchange for economic advantages * * * can hardly be called a taking"). Because "Novo voluntarily joined the 340B Program with full knowledge of the discount scheme it effected," and benefited from that choice, it cannot seriously claim that the discount drug program is unconstitutional. JA115.

II. The District Court Erred In Partially Vacating The Enforcement Letters And Remanding To HHS

Having held that "Plaintiffs cannot impose restrictions on offers to covered entities and that their policies must cease," JA105, the district court should have entered judgment in HHS's favor. Instead, the court partially vacated the enforcement letters and remanded to HHS to address what the court described as an "unresolved" question of statutory interpretation: "how many contract pharmacies the 340B statute permits, if there is a ceiling at all." *Id.* "Rather than decide this issue," the court decided *sua sponte* to "remand to the agency for 'additional investigation or explanation.'" *Id.* (quoting *Negusie v. Holder*, 555 U.S. 511, 523 (2009)). The court reasoned that "[t]he proper course, except in rare circumstances, is to remand," *id.* (quoting *Gonzales v. Thomas*, 547 U.S. 183, 186 (2006) (per curiam)), and instructed HHS to consider on remand issues such as whether use of multiple contract pharmacies creates an increased risk of

diversion, weaker compliance mechanisms, lower likelihood of passing on discounts to patients, and failure of covered entities to possess 340B drugs under certain distribution systems. JA107-08.

The partial vacatur and remand rested on a misunderstanding of the administrative-law principles on which the district court relied. In the cases that the district court cited—*Negusie* and *Gonzales*—Congress had delegated to the agency the authority to resolve ambiguities and fill gaps in the statutory scheme. For example, *Negusie* involved authority delegated to the Bureau of Immigration Affairs under the Immigration and Nationality Act. The Supreme Court explained that it was "well settled that principles of *Chevron* deference are applicable to this statutory scheme." *Negusie*, 555 U.S. at 516 (quotation marks omitted). The Supreme Court remanded because the Bureau of Immigration Affairs had "not yet exercised its *Chevron* discretion to interpret the statute in question." *Id.* at 523. The Court noted that "'the proper course, except in rare circumstances, is to remand to the agency for additional investigation or explanation.'" *Id.* (quoting *Gonzales*, 547 U.S. at 186). The Court explained that "[t]his remand rule exists, in part, because ambiguities in statutes within an agency's jurisdiction to administer are delegations of authority to the agency to fill the statutory gap in reasonable fashion." *Id.*

(quotation marks omitted). "Filling these gaps * * * involves difficult policy choices that agencies are better equipped to make than courts." *Id.* (quotation marks omitted).

The remand rule does not apply here, however, because Congress did not delegate general authority to HHS to make substantive rules regarding the 340B Program. As Sanofi explains, "Section 340B gives HHS rulemaking authority only in three 'limited contexts'—a dispute resolution process, pricing, and civil monetary penalties." Br. 7. Indeed, the district court likewise recognized that "HHS has not been granted broad rulemaking authority to carry out all the provisions of the 340B Program," and, specifically, that HHS lacks authority to regulate contract-pharmacy arrangements. JA86. The district court thus recognized that HHS is not entitled to *Chevron* deference on matters pertaining to contract pharmacies and that "HHS does not contend otherwise." *Id.*

Under these circumstances, there was no basis for a remand. For the reasons set out at length in the district court's opinion, the 340B statute does not cap the number of contract pharmacies that a covered entity may use, nor does the statute allow manufacturers to impose such restrictions unilaterally. If Congress determines that allowing multiple contract pharmacies presents policy concerns, Congress can amend the statute as it

sees fit. But that legislative judgment is not for a court—or HHS—to make. HHS has no statutory authority to restrict covered entities' use of contract pharmacies.

It likewise makes no difference whether the 340B statute *unambiguously* prohibits plaintiffs' policies. Ambiguity would matter only if HHS were entitled to *Chevron* deference, which it is not. Thus, Sanofi's argument on that issue (Br. 59-61) is beside the point. The statutory scheme, correctly construed, prohibits plaintiffs' policies. Even if the text is initially regarded as ambiguous, the court's role is to resolve the ambiguity by looking to "text, structure, history, and purpose of" the statute. *Kisor v. Wilkie*, 139 S. Ct. 2400, 2415 (2019) ("[A] court cannot wave the ambiguity flag just because" the text is "impenetrable on first read," because such issues "can often be solved"). The district court did exactly that and correctly held that the statute prohibits plaintiffs' policies. That should have been the end of the case.

Plaintiffs' various objections to the reasoning in HHS's enforcement letters are irrelevant for the same reason. HHS agrees with plaintiffs that the statute alone dictates the manufacturers' substantive obligations with respect to covered entities' use of contract pharmacies. Likewise, the enforcement actions at issue here are based on the statute's requirements

alone. Indeed, HHS emphasized at the outset of the 340B Program that its guidelines regarding contract-pharmacy arrangements are nonbinding. *See, e.g.*, 61 Fed. Reg. at 43550 (explaining that "these guidelines create no new law and create no new rights or duties"). Thus, Novo correctly notes that HHS generally lacks authority to promulgate binding legislative rules for the 340B Program (Br. 37). But Novo is clearly wrong to suggest that HHS lacks enforcement authority. Congress expressly granted HHS the authority to enforce the statutory scheme and to stop manufacturers from violating it. 42 U.S.C. § 256b(d)(1)(B)(vi). The enforcement letters are an exercise of that authority.

Plaintiffs quarrel with an earlier advisory opinion issued by HHS's general counsel (Sanofi Br. 63-66; Novo Br. 55-57), but that dispute is academic. It is unclear what relief plaintiffs actually seek, as HHS has already withdrawn that advisory opinion. JA24. The district court thus appropriately declined to address the opinion. JA31 n.31. In any event, for all the reasons discussed above, the statutory scheme does not permit plaintiffs' unilateral policies. Regardless of the advisory opinion, the enforcement actions at issue here must be sustained on the basis of the statute alone.

III. HHS Promulgated The Administrative Dispute Resolution Rule Consistent With Notice-And-Comment Requirements

The Administrative Procedure Act (APA) requires that when federal agencies promulgate a legislative rule, they must comply with certain procedures for notice and comment. 5 U.S.C. § 553. As relevant here, when HHS promulgated the alternative dispute resolution rule, it was required to publish a "[g]eneral notice of proposed rulemaking" in the Federal Register and to "give interested persons an opportunity to participate in the rule making through submission of written data, views, or arguments." *Id.* § 553(b)-(c). Thereafter, HHS must consider those comments and determine how to proceed with a final rule, as Congress had already mandated that HHS must promulgate the rule and largely defined its substance. *See* 42 U.S.C. § 256b(d)(3) HHS fulfilled those requirements here—it promulgated an advance notice of proposed rulemaking, a notice of proposed rulemaking, and after receiving comments responded to them in the final rule. 75 Fed. Reg. 57233 (Sept. 20, 2010) (advance notice); 81 Fed. Reg. 53381 (Aug. 12, 2016) (notice of proposed rulemaking); 85 Fed. Reg. 80632, 80633-642 (Dec. 14, 2020) (final rule responding to comments). Accordingly, the district court concluded that HHS had complied with the

APA's notice-and-comment requirements in promulgating the final rule. JA36-45.

The district court's holding is sound. HHS complied with all portions of 5 U.S.C. § 553, and those are the "maximum procedural requirements" that HHS was required to follow. *Perez v. Mortgage Bankers Ass'n*, 575 U.S. 92, 100 (2015) (quoting *Vermont Yankee Nuclear Power Corp. v. Natural Resources Defense Council*, 435 U.S. 519, 524 (1978)).

Sanofi resists this conclusion, but notably does not raise any substantive challenge to the final rule. Instead, Sanofi contends (at 66-69) that HHS was required to go through *another* round of notice and comment because at one point the proposed rule was removed from the Unified Agenda. Sanofi cites no authority from this Court or the Supreme Court for that novel proposition, which misunderstands how agencies promulgate regulations. The Unified Agenda is a collection of documents that "provides information about regulations that the Government is considering or reviewing." 86 Fed. Reg. 41166, 41166 (July 30, 2021) (*Introduction to the Unified Agenda of Federal Regulatory and Deregulatory Actions*). The Unified Agenda was not created by Congress as part of the APA, but rather and "helps agencies comply with their obligations under the Regulatory Flexibility Act and various Executive

orders and other statutes." *Id.* at 41167 (citing the Unfunded Mandates Reform Act of 1995, the Small Business Regulatory Enforcement Fairness Act, and Executive Orders 12866, 13132, and 13211). As the district court recognized, the Unified Agenda "does not create a legal obligation on agencies to adhere to schedules" of anticipated rulemaking, but "merely represents what agencies have tried to predict as their activities over the next 12 months." JA40 (quotation marks omitted).

In 2017, after the change in presidential administration, HHS "paus[ed] action on the proposed rule" as part of an Executive Branch review of pending regulatory proposals. 85 Fed. Reg. at 80633.[6] During that review, the notice of proposed rulemaking was removed from the Unified Agenda, but HHS never issued a withdrawal of proposed rulemaking in the Federal Register. After HHS completed its review, HHS promulgated the final rule in 2020. *Id.* at 80632.

Sanofi incorrectly contends that because the proposed rule was not on the Unified Agenda, it had been withdrawn and HHS was required to restart the rulemaking from scratch. But that misconceives how agencies

[6] Other agencies similarly paused their regulatory proposals pending that government-wide review process. *See Organization for Competitive Markets v. U.S. Department of Agriculture*, 912 F.3d 455, 458 (8th Cir. 2018).

withdraw proposed rules, which is ordinarily through a Federal Register notice, often accompanied by an explanation. *E.g.*, *International Union, United Mine Workers of America v. U.S. Dep't of Labor*, 358 F.3d 40, 42 (D.C. Cir. 2004) (acknowledging withdrawal of proposed rule published in the Federal Register); *Center for Auto Safety v. National Highway Traffic Safety Admin.*, 710 F.2d 842, 844 (D.C. Cir. 1983) (same); 78 Fed. Reg. 12702 (Feb. 25, 2013) (HHS withdrawal of proposed rule); 79 Fed. Reg. 19848 (Apr. 10, 2014) (same); 83 Fed. Reg. 60804 (Nov. 27, 2018) (same); 84 Fed. Reg. 37821 (Aug. 2, 2019) (same). This is the standard manner by which HHS communicates to the public whether a rule has been proposed, withdrawn, or finalized. Indeed, it would be odd if HHS could terminate a proposed rule simply by omitting it from the Unified Agenda without further explanation, since such a withdrawal might be challenged as final agency action under the APA. *See Center for Auto Safety*, 710 F.2d at 846-47 (holding that "an agency decision to terminate its rulemaking proceedings usually is ripe for review").

Sanofi appears to suggest that the mere passage of time between a proposed rule and a final rule could violate the APA. Br. 67 (citing *Mobil Oil Corp. v. EPA*, 35 F.3d 579, 584 (D.C. Cir. 1994)). But the APA contains no such limitation, and there are many cases in which it may take an agency

a comparable amount of time to promulgate a final rule. *See, e.g.*, 85 Fed. Reg. 49240, 49244 (Aug. 13, 2020) (final rule addressing food labeling issued nearly five years after notice of proposed rulemaking); 85 Fed. Reg. 13312, 13314 (Mar. 6, 2020) (final rule addressing medical devices issued nearly four years after notice of proposed rulemaking). And Sanofi's citation to *Mobil Oil* is misplaced. *Mobil Oil* concerned a "Bevill mixture rule" that the D.C. Circuit had vacated and remanded to the agency, which was summarily re-promulgated as a final rule without notice and comment. 35 F.3d at 582, 584. The D.C. Circuit explained that the rule had been vacated and set aside, the agency "must comply with the applicable provisions of the APA" to re-promulgate it, including a period for notice and comment. *Id.* at 584. That requirement has already been met here, and the D.C. Circuit nowhere suggested that an agency must engage in multiple rounds of notice and comment merely because time has passed.

Consistent with these principles, the district court concluded that "agencies are not required to promulgate proposed rules immediately or within a certain timeframe," but rather "are free—indeed, they are encouraged—to modify [them]." JA44 (quotation marks omitted). And to the extent Sanofi's compliant is that it lacked the fair notice required by the APA, the district court rightly rejected that argument, explaining that HHS

did not "promulgate[] the final Rule out of the blue," but rather "had to issue a final Rule at some point, sooner or later, to comply with Congress' directive." JA42 (citing 42 U.S.C. § 256b(d)(3)(A)). And tellingly, "Sanofi has not pointed to *relevant* changes in the regulated market or 340B landscape in the interim" that might have affected the notice and comment period, "or render[ed] the agency's information in 2016 particularly out of date now." JA43. Accordingly, the final rule complies with the requirements of 5 U.S.C. § 553.

CONCLUSION

For the foregoing reasons, the judgment of the district court should be reversed insofar as it vacated the enforcement letters and remanded to HHS. The judgment should otherwise be affirmed.

Respectfully submitted,

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COMBINED CERTIFICATIONS

1. Government counsel are not required to be members of the bar of this Court.

2. This brief complies with the type-volume limit of Federal Rule of Appellate Procedure 32(a)(7)(B) because it contains 11,196 words. This brief also complies with the typeface and type-style requirements of Federal Rule of Appellate Procedure 32(a)(5)-(6) because it was prepared using Microsoft Word 2016 in Georgia 14-point font, a proportionally spaced typeface.

3. On July 7, 2022, I electronically filed the foregoing brief with the Clerk of the Court for the United States Court of Appeals for the Third Circuit by using the appellate CM/ECF system.

4. The text of the electronic version of this document is identical to the text of the hard copies that will be provided.

5. This document was scanned for viruses using Symantec Endpoint Protection version 14, and no virus was detected.

/s/ Daniel Aguilar
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ADDENDUM

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42 U.S.C. § 256b. Limitation on prices of drugs purchased by covered entities.

(a) Requirements for agreement with Secretary

(1) In general

The Secretary shall enter into an agreement with each manufacturer of covered outpatient drugs under which the amount required to be paid (taking into account any rebate or discount, as provided by the Secretary) to the manufacturer for covered outpatient drugs (other than drugs described in paragraph (3)) purchased by a covered entity on or after the first day of the first month that begins after November 4, 1992, does not exceed an amount equal to the average manufacturer price for the drug under title XIX of the Social Security Act in the preceding calendar quarter, reduced by the rebate percentage described in paragraph (2). Each such agreement shall require that the manufacturer furnish the Secretary with reports, on a quarterly basis, of the price for each covered outpatient drug subject to the agreement that, according to the manufacturer, represents the maximum price that covered entities may permissibly be required to pay for the drug (referred to in this section as the "ceiling price"), and shall require that the manufacturer offer each covered entity covered outpatient drugs for purchase at or below the applicable ceiling price if such drug is made available to any other purchaser at any price.

(2) "Rebate percentage" defined

(A) In general

For a covered outpatient drug purchased in a calendar quarter, the "rebate percentage" is the amount (expressed as a percentage) equal to--

(i) the average total rebate required under section 1927(c) of the Social Security Act with respect to the drug (for a unit of the dosage form and strength involved) during the preceding calendar quarter; divided by

(ii) the average manufacturer price for such a unit of the drug during such quarter.

(B) Over the counter drugs

(i) In general

For purposes of subparagraph (A), in the case of over the counter drugs, the "rebate percentage" shall be determined as if the rebate required under section 1927(c) of the Social Security Act is based on the applicable percentage provided under section 1927(c)(3) of such Act.

(ii) "Over the counter drug" defined

The term "over the counter drug" means a drug that may be sold without a prescription and which is prescribed by a physician (or other persons authorized to prescribe such drug under State law).

(3) Drugs provided under State Medicaid plans

Drugs described in this paragraph are drugs purchased by the entity for which payment is made by the State under the State plan for medical assistance under title XIX of the Social Security Act.

(4) "Covered entity" defined

In this section, the term "covered entity" means an entity that meets the requirements described in paragraph (5) and is one of the following:

(A) A Federally-qualified health center (as defined in section 1905(l)(2)(B) of the Social Security Act).

(B) An entity receiving a grant under section 256a of this title.

(C) A family planning project receiving a grant or contract under section 300 of this title.

(D) An entity receiving a grant under subpart II of part C of subchapter XXIV (relating to categorical grants for outpatient early intervention services for HIV disease).

(E) A State-operated AIDS drug purchasing assistance program receiving financial assistance under subchapter XXIV.

(F) A black lung clinic receiving funds under section 937(a) of title 30.

(G) A comprehensive hemophilia diagnostic treatment center receiving a grant under section 501(a)(2) of the Social Security Act.

(H) A Native Hawaiian Health Center receiving funds under the Native Hawaiian Health Care Act of 1988.

(I) An urban Indian organization receiving funds under title V of the Indian Health Care Improvement Act.

(J) Any entity receiving assistance under subchapter XXIV (other than a State or unit of local government or an entity described in subparagraph (D)), but only if the entity is certified by the Secretary pursuant to paragraph (7).

(K) An entity receiving funds under section 247c of this title (relating to treatment of sexually transmitted diseases) or section 247b(j)(2) of this title (relating to treatment of tuberculosis) through a State or unit of local government, but only if the entity is certified by the Secretary pursuant to paragraph (7).

(L) A subsection (d) hospital (as defined in section 1886(d)(1)(B) of the Social Security Act) that--

(i) is owned or operated by a unit of State or local government, is a public or private non-profit corporation which is formally granted governmental powers by a unit of State or local government, or is a private non-profit hospital which has a contract with a State or local government to provide health care services to low income individuals who are not entitled to benefits under title XVIII of the Social Security Act or eligible for assistance under the State plan under this subchapter;

(ii) for the most recent cost reporting period that ended before the calendar quarter involved, had a disproportionate share adjustment percentage (as determined under section 1886(d)(5)(F) of the Social Security Act) greater than 11.75 percent or was described in section 1886(d)(5)(F)(i)(II) of such Act; and

(iii) does not obtain covered outpatient drugs through a group purchasing organization or other group purchasing arrangement.

(M) A children's hospital excluded from the Medicare prospective payment system pursuant to section 1886(d)(1)(B)(iii) of the Social Security Act, or a free-standing cancer hospital excluded from the Medicare prospective payment system pursuant to section 1886(d)(1)(B)(v) of the Social Security Act, that would meet the requirements of subparagraph (L), including the disproportionate share adjustment percentage requirement under clause (ii) of such subparagraph, if the hospital were a subsection (d) hospital as defined by section 1886(d)(1)(B) of the Social Security Act.

(N) An entity that is a critical access hospital (as determined under section 1820(c)(2) of the Social Security Act), and that meets the requirements of subparagraph (L)(i).

(O) An entity that is a rural referral center, as defined by section 1886(d)(5)(C)(i) of the Social Security Act, or a sole community hospital, as defined by section 1886(d)(5)(C)(iii) of such Act, and that both meets the requirements of subparagraph (L)(i) and has a disproportionate share adjustment percentage equal to or greater than 8 percent.

(5) Requirements for covered entities

(A) Prohibiting duplicate discounts or rebates

(i) In general

A covered entity shall not request payment under title XIX of the Social Security Act for medical assistance described in section 1905(a)(12) of such Act with respect to a drug that is subject to an agreement under this section if the drug is subject to the payment of a rebate to the State under section 1927 of such Act.

(ii) Establishment of mechanism

The Secretary shall establish a mechanism to ensure that covered entities comply with clause (i). If the Secretary does not establish a mechanism within 12 months under the previous sentence, the requirements of section 1927(a)(5)(C) of the Social Security Act shall apply.

(B) Prohibiting resale of drugs

With respect to any covered outpatient drug that is subject to an agreement under this subsection, a covered entity shall not resell or otherwise transfer the drug to a person who is not a patient of the entity.

(C) Auditing

A covered entity shall permit the Secretary and the manufacturer of a covered outpatient drug that is subject to an agreement under this subsection with the entity (acting in accordance with procedures established by the Secretary relating to the number, duration, and scope of audits) to audit at the Secretary's or the manufacturer's expense the records of the entity that directly pertain to the entity's compliance with the requirements described in subparagraphs[1] (A) or (B) with respect to drugs of the manufacturer.

(D) Additional sanction for noncompliance

If the Secretary finds, after audit as described in subparagraph (C) and after notice and hearing, that a covered entity is in violation of a requirement described in subparagraphs[1] (A) or (B), the covered entity shall be liable to the manufacturer of the covered outpatient drug that is the subject of the violation in an amount equal to the reduction in the price of the drug (as described in subparagraph (A)) provided under the agreement between the entity and the manufacturer under this paragraph.

(6) Treatment of distinct units of hospitals

In the case of a covered entity that is a distinct part of a hospital, the hospital shall not be considered a covered entity under this paragraph unless the hospital is otherwise a covered entity under this subsection.

(7) Certification of certain covered entities

(A) Development of process

Not later than 60 days after November 4, 1992, the Secretary shall develop and implement a process for the certification of entities described in subparagraphs (J) and (K) of paragraph (4).

(B) Inclusion of purchase information

The process developed under subparagraph (A) shall include a requirement that an entity applying for certification under this paragraph submit information to the Secretary concerning the amount such entity expended for covered outpatient drugs in the preceding year so as to assist the Secretary in evaluating the validity of the entity's subsequent purchases of covered outpatient drugs at discounted prices.

(C) Criteria

The Secretary shall make available to all manufacturers of covered outpatient drugs a description of the criteria for certification under this paragraph.

(D) List of purchasers and dispensers

The certification process developed by the Secretary under subparagraph (A) shall include procedures under which each State shall, not later than 30 days after the submission of the descriptions under subparagraph (C), prepare and submit a report to the Secretary that contains a list of entities described in subparagraphs (J) and (K) of paragraph (4) that are located in the State.

(E) Recertification

The Secretary shall require the recertification of entities certified pursuant to this paragraph on a not more frequent than annual basis, and shall require that such entities submit information to the Secretary to permit the Secretary to evaluate the validity of subsequent purchases by such entities in the same manner as that required under subparagraph (B).

(8) Development of prime vendor program

The Secretary shall establish a prime vendor program under which covered entities may enter into contracts with prime vendors for the distribution of covered outpatient drugs. If a covered entity obtains drugs directly from a manufacturer, the manufacturer shall be responsible for the costs of distribution.

(9) Notice to manufacturers

The Secretary shall notify manufacturers of covered outpatient drugs and single State agencies under section 1902(a)(5) of the Social Security Act of the identities of covered entities under this paragraph, and of entities that no longer meet the requirements of paragraph (5) or that are no longer certified pursuant to paragraph (7).

(10) No prohibition on larger discount

Nothing in this subsection shall prohibit a manufacturer from charging a price for a drug that is lower than the maximum price that may be charged under paragraph (1).

(b) Other definitions--

(1) In general

In this section, the terms “average manufacturer price”, “covered outpatient drug”, and “manufacturer” have the meaning given such terms in section 1927(k) of the Social Security Act.

(2) Covered drug

In this section, the term “covered drug”--

(A) means a covered outpatient drug (as defined in section 1927(k)(2) of the Social Security Act); and

(B) includes, notwithstanding paragraph (3)(A) of section 1927(k) of such Act, a drug used in connection with an inpatient or outpatient service provided by a hospital described in subparagraph (L), (M), (N), or (O) of subsection (a)(4) that is enrolled to participate in the drug discount program under this section.

(c) Repealed. Pub.L. 111-152, Title II, § 2302(2), Mar. 30, 2010, 124 Stat. 1083

(d) Improvements in program integrity

(1) Manufacturer compliance

(A) In general

From amounts appropriated under paragraph (4), the Secretary shall provide for improvements in compliance by manufacturers with the requirements of this section in order to prevent overcharges and other violations of the discounted pricing requirements specified in this section.

(B) Improvements

The improvements described in subparagraph (A) shall include the following:

(i) The development of a system to enable the Secretary to verify the accuracy of ceiling prices calculated by manufacturers under subsection (a)(1) and charged to covered entities, which shall include the following:

(I) Developing and publishing through an appropriate policy or regulatory issuance, precisely defined standards and methodology for the calculation of ceiling prices under such subsection.

(II) Comparing regularly the ceiling prices calculated by the Secretary with the quarterly pricing data that is reported by manufacturers to the Secretary.

(III) Performing spot checks of sales transactions by covered entities.

(IV) Inquiring into the cause of any pricing discrepancies that may be identified and either taking, or requiring manufacturers to take, such corrective action as is appropriate in response to such price discrepancies.

(ii) The establishment of procedures for manufacturers to issue refunds to covered entities in the event that there is an overcharge by the manufacturers, including the following:

(I) Providing the Secretary with an explanation of why and how the overcharge occurred, how the refunds will be calculated, and to whom the refunds will be issued.

(II) Oversight by the Secretary to ensure that the refunds are issued accurately and within a reasonable period of time, both in routine instances of retroactive adjustment to relevant pricing data and exceptional circumstances such as erroneous or intentional overcharging for covered outpatient drugs.

(iii) The provision of access through the Internet website of the Department of Health and Human Services to the applicable ceiling prices for covered outpatient drugs as calculated and verified by the Secretary in accordance with this section, in a manner (such as through the use of password protection) that limits such access to covered entities and adequately assures security and protection of privileged pricing data from unauthorized re-disclosure.

(iv) The development of a mechanism by which--

(I) rebates and other discounts provided by manufacturers to other purchasers subsequent to the sale of covered outpatient drugs to covered entities are reported to the Secretary; and

(II) appropriate credits and refunds are issued to covered entities if such discounts or rebates have the effect of lowering the applicable ceiling price for the relevant quarter for the drugs involved.

(v) Selective auditing of manufacturers and wholesalers to ensure the integrity of the drug discount program under this section.

(vi) The imposition of sanctions in the form of civil monetary penalties, which--

(I) shall be assessed according to standards established in regulations to be promulgated by the Secretary not later than 180 days after March 23, 2010;

(II) shall not exceed $5,000 for each instance of overcharging a covered entity that may have occurred; and

(III) shall apply to any manufacturer with an agreement under this section that knowingly and intentionally charges a covered entity a price for purchase of a drug that exceeds the maximum applicable price under subsection (a)(1).

(2) Covered entity compliance

(A) In general

From amounts appropriated under paragraph (4), the Secretary shall provide for improvements in compliance by covered entities with the requirements of this section in order to prevent diversion and violations of the duplicate discount provision and other requirements specified under subsection (a)(5).

(B) Improvements

The improvements described in subparagraph (A) shall include the following:

(i) The development of procedures to enable and require covered entities to regularly update (at least annually) the information on the Internet website of the Department of Health and Human Services relating to this section.

(ii) The development of a system for the Secretary to verify the accuracy of information regarding covered entities that is listed on the website described in clause (i).

(iii) The development of more detailed guidance describing methodologies and options available to covered entities for billing covered outpatient drugs to State Medicaid agencies in a manner that avoids duplicate discounts pursuant to subsection (a)(5)(A).

(iv) The establishment of a single, universal, and standardized identification system by which each covered entity site can be identified by manufacturers, distributors, covered entities, and the Secretary for purposes of facilitating the ordering, purchasing, and delivery of covered outpatient drugs under this section, including the processing of chargebacks for such drugs.

(v) The imposition of sanctions, in appropriate cases as determined by the Secretary, additional to those to which covered

entities are subject under subsection (a)(5)(D), through one or more of the following actions:

(I) Where a covered entity knowingly and intentionally violates subsection (a)(5)(B), the covered entity shall be required to pay a monetary penalty to a manufacturer or manufacturers in the form of interest on sums for which the covered entity is found liable under subsection (a)(5)(D), such interest to be compounded monthly and equal to the current short term interest rate as determined by the Federal Reserve for the time period for which the covered entity is liable.

(II) Where the Secretary determines a violation of subsection (a)(5)(B) was systematic and egregious as well as knowing and intentional, removing the covered entity from the drug discount program under this section and disqualifying the entity from re-entry into such program for a reasonable period of time to be determined by the Secretary.

(III) Referring matters to appropriate Federal authorities within the Food and Drug Administration, the Office of Inspector General of Department of Health and Human Services, or other Federal agencies for consideration of appropriate action under other Federal statutes, such as the Prescription Drug Marketing Act (21 U.S.C. 353).

(3) Administrative dispute resolution process

(A) In general

Not later than 180 days after March 23, 2010, the Secretary shall promulgate regulations to establish and implement an administrative process for the resolution of claims by covered entities that they have been overcharged for drugs purchased under this section, and claims by manufacturers, after the conduct of audits as authorized by subsection (a)(5)(C), of violations of subsections[2] (a)(5)(A) or (a)(5)(B), including appropriate procedures for the provision of remedies and enforcement of determinations made pursuant to such process through mechanisms and sanctions described in paragraphs (1)(B) and (2)(B).

(B) Deadlines and procedures

Regulations promulgated by the Secretary under subparagraph (A) shall--

(i) designate or establish a decision-making official or decision-making body within the Department of Health and Human Services to be responsible for reviewing and finally resolving claims by covered entities that they have been charged prices for covered outpatient drugs in excess of the ceiling price described in subsection (a)(1), and claims by manufacturers that violations of subsection (a)(5)(A) or (a)(5)(B) have occurred;

(ii) establish such deadlines and procedures as may be necessary to ensure that claims shall be resolved fairly, efficiently, and expeditiously;

(iii) establish procedures by which a covered entity may discover and obtain such information and documents from manufacturers and third parties as may be relevant to demonstrate the merits of a claim that charges for a manufacturer's product have exceeded the applicable ceiling price under this section, and may submit such documents and information to the administrative official or body responsible for adjudicating such claim;

(iv) require that a manufacturer conduct an audit of a covered entity pursuant to subsection (a)(5)(C) as a prerequisite to initiating administrative dispute resolution proceedings against a covered entity;

(v) permit the official or body designated under clause (i), at the request of a manufacturer or manufacturers, to consolidate claims brought by more than one manufacturer against the same covered entity where, in the judgment of such official or body, consolidation is appropriate and consistent with the goals of fairness and economy of resources; and

(vi) include provisions and procedures to permit multiple covered entities to jointly assert claims of overcharges by the same manufacturer for the same drug or drugs in one administrative proceeding, and permit such claims to be asserted on behalf of covered entities by associations or organizations representing the

interests of such covered entities and of which the covered entities are members.

(C) Finality of administrative resolution

The administrative resolution of a claim or claims under the regulations promulgated under subparagraph (A) shall be a final agency decision and shall be binding upon the parties involved, unless invalidated by an order of a court of competent jurisdiction.

(4) Authorization of appropriations

There are authorized to be appropriated to carry out this subsection, such sums as may be necessary for fiscal year 2010 and each succeeding fiscal year.

(e) Exclusion of orphan drugs for certain covered entities

For covered entities described in subparagraph (M) (other than a children's hospital described in subparagraph (M)), (N), or (O) of subsection (a)(4), the term “covered outpatient drug” shall not include a drug designated by the Secretary under section 360bb of Title 21 for a rare disease or condition.