Nos. 21-3168, 21-3380

UNITED STATES COURT OF APPEALS
FOR THE THIRD CIRCUIT

NOVO NORDISK INC. AND NOVO NORDISK PHARMA, INC.,

Appellants,

v.

UNITED STATES DEPARTMENT OF HEALTH AND HUMAN SERVICES; SECRETARY, UNITED STATES DEPARTMENT OF HEALTH AND HUMAN SERVICES; GENERAL COUNSEL; UNITED STATES DEPARTMENT OF HEALTH AND HUMAN SERVICES; HEALTH RESOURCES SERVICES ADMINISTRATION; ADMINISTRATOR OF THE HEALTH RESOURCES SERVICES ADMINISTRATION,

Appellees.

On Appeal from the United States District Court for the District of New Jersey, No. 3:21-cv-00806, Hon. Freda L. Wolfson, U.S. District Judge

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OPENING BRIEF OF APPELLANTS NOVO NORDISK INC. AND NOVO NORDISK PHARMA, INC.

Nicole Bronnimann
KING & SPALDING LLP
1100 Louisiana Street
Suite 4100
Houston, TX 77002
(713) 751-3200

Ashley C. Parrish
Graciela M. Rodriguez
John D. Shakow
KING & SPALDING LLP
1700 Pennsylvania Avenue NW
Washington, DC 20006
(202) 737-0500
aparrish@kslaw.com

Counsel for Appellants Novo Nordisk Inc. and Novo Nordisk Pharma, Inc.

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CORPORATE DISCLOSURE

In accordance with Rule 26.1 of the Federal Rules of Appellate Procedure and the Third Circuit Local Appellate Rules, appellants Novo Nordisk Inc. and Novo Nordisk Pharma, Inc. certify that their parent company is Novo Nordisk U.S. Commercial Holdings, Inc. No publicly held corporation has a ten percent or greater ownership interest in either Novo Nordisk Inc. or Novo Nordisk Pharma, Inc.

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INTRODUCTION

This case is about the government's attempt to rewrite a federal health care statute to impose onerous obligations on pharmaceutical manufacturers. Section 340B of the Public Health Service Act (the "340B statute") requires manufacturers to "offer" their drugs for "purchase" at discounted prices to certain health clinics, non-profit hospitals, and other "covered entities" that disproportionately care for poor and uninsured patients. 42 U.S.C. § 256b. Congress intended the covered entities to use the deeply discounted drugs for the benefit of the patients who come to their facilities for medical services and care. To protect against abuses, the statute limits which entities may participate in the program, *id.* § 256b(a)(4), and prohibits covered entities from transferring manufacturers' drugs to anyone who is not a patient, *id.* § 256b(a)(5).

No one can reasonably dispute that Novo Nordisk Inc. and Novo Nordisk Pharma, Inc. (collectively, "Novo") comply with the statute's express requirements. Covered entities are able to purchase as much of Novo's drugs as they desire at the discounted price, Novo ensures that its discounted drugs are delivered to the covered entities, and no patient is denied access to Novo's life-saving medications. But the government seeks to impose an additional obligation on Novo and other drug manufacturers that appears nowhere in the 340B statute, threatening manufacturers with civil monetary penalties if they do not comply. Specifically, the government

seeks to require manufacturers to transfer their drugs at deeply discounted prices to for-profit commercial pharmacies for their own private benefit, a requirement never articulated by Congress or promulgated in any substantive rule or regulation.

Allowing for-profit commercial pharmacies to participate in and profit from the 340B program has undermined the program's integrity and dramatically expanded the financial burden on manufacturers. Covered entities have entered into contractual relationships with numerous commercial pharmacies to dispense manufacturers' drugs to the pharmacies' customers, many of whom have only an attenuated connection to the covered entity. Through this arrangement, the pharmacies reap *billions* in profits by selling manufacturers' drugs at regular prices and then replenishing their inventories with discounted drugs that covered entities direct manufacturers to deliver directly to the pharmacies. The profits captured by the commercial pharmacies are not being used for the benefit of needy patients; indeed, commercial pharmacies have no incentive or legal obligation to do anything with the profits they receive other than keep them for themselves.

The district court correctly recognized that the 340B statute is "silent" on the issue of contract pharmacies. Nothing in the statute authorizes the government to force manufacturers to transfer their discounted drugs to contract pharmacies. That is consistent with conclusions reached by two district courts in carefully reasoned decisions. *See Novartis Pharms. Corp. v. Espinosa*, No. 21-CV-1479, 2021 WL

5161783 (D.D.C. Nov. 5, 2021); *AstraZeneca Pharms. LP v. Becerra,* No. 21-27-LPS, 2022 WL 484587 (D. Del. Feb. 16, 2022). It is also consistent with how the statute operated for more than 14 years. *See* 61 Fed. Reg. 43,549 (Aug. 23, 1996). That should have been the end of this case.

The government's position — advanced for the first time in an "Advisory Opinion" issued in December 2020 (the "December decision") and then in a "violation" letter issued in May 2021 (the "May letter") — relies on the unfounded view that the statute's requirement that manufacturers "offer" their drugs to covered entities for "purchase" at discounted prices also encompasses a separate obligation that manufacturers deliver their drugs to whomever, and ship the drugs to wherever, covered entities request. According to the government, the statute's plain text mandates that manufacturers deliver their drugs to commercial pharmacies on the "lunar surface," if that is what covered entities demand. R.40-1 at 3 (JA__).

The district court should have rejected the government's meritless interpretation. Because the statute is "silent" on the issue of contract pharmacies, it cannot be read to impose an obligation on manufacturers to transfer discounted drugs to them. The obligation to sell products at a specified price to a specified purchaser does not include an unwritten obligation to deliver the products to third parties at whatever locations the purchaser may desire. Congress has not granted the government general rulemaking authority to administer the 340B statute and, in any

event, the government has not even attempted to follow necessary procedures to impose new substantive obligations on manufacturers. As a result, except as otherwise expressly mandated by the statute, manufacturers retain their common law rights, including the right to choose not to transfer their drugs at discounted prices to for-profit commercial pharmacies.

Instead of reaching that straightforward conclusion, the district court committed serious errors. Departing from settled principles of administrative and constitutional law, the court concluded that the statute's silence means that manufacturers have no right to restrict the delivery of their own drugs to third parties, never mind manufacturers' common law property rights. Departing from settled principles of statutory interpretation, the court equated the 340B statute's silence with ambiguity — and then rewrote the statute to suit its own policy preferences — even though the court did not identify any relevant statutory terms susceptible to more than one interpretation. Departing from settled principles of judicial review, the court reached beyond the government's articulated basis for its interpretation to make its own (uninformed) findings about the 340B program and the effect of manufacturers' policies on patients.

None of these errors should be left uncorrected. Nothing in the 340B statute establishes that Congress intended to force manufacturers to transfer their drugs to for-profit contract pharmacies for the financial benefit of the pharmacies themselves.

The district court's decision should be reversed, and the government's unlawful actions should be vacated.[1]

SUBJECT MATTER & APPELLATE JURISDICTION

The district court had jurisdiction under 28 U.S.C. § 1331. Novo's claims arise under the Public Health Service Act, 42 U.S.C. § 256b, the Administrative Procedure Act, 5 U.S.C. §§ 701–706, the Declaratory Judgment Act, 28 U.S.C. §§ 2201-2202, and the U.S. Constitution. This Court has jurisdiction because the district court entered final judgment on November 5, 2021, and Novo filed a timely notice of appeal on November 19, 2021. *See* 28 U.S.C. § 1291; Fed. R. App. P. 4(a)(1)(B).

ISSUES

1. Did the district court err in failing to declare unlawful and strike down the agency's May 17, 2021 letter?

a. Having recognized that the 340B statute is silent on the issue of contract pharmacies, did the district court err in permitting the government to impose a new obligation on manufacturers to transfer their drugs at discounted prices to contract pharmacies?

b. Given that manufacturers have common law rights to control when and how their drugs are distributed to third parties, did the district court err in

[1] Novo incorporates Sanofi's brief filed in case numbers 21-3167 and 21-3379.

concluding that manufacturers have no right to impose conditions on the transfer of their drugs merely because Congress did not address the issue in the 340B statute?

c. Did the district court err in developing purported rationales for the government's letter that were never articulated by the government itself or supported by any reasoned explanation?

2. Did the district court err in dismissing Novo's legal challenges to the December 30, 2020 decision as moot and, if so, does that decision violate the 340B statute and exceed the agency's lawful authority, and is it arbitrary and capricious under the Administrative Procedure Act?

RELATED CASES AND PROCEEDINGS

1. *Sanofi-Aventis U.S., LLC v. HHS*, No. 21-3167 (3d Cir.).

2. *Eli Lilly & Co. v. HHS*, No. 21-3128 (7th Cir.).

3. *Novartis Pharms. Corp. v. Johnson*, No. 21-5299 (D.C. Cir.).

4. *United Therapeutics Corp. v. Espinosa*, No. 21-5304 (D.C. Cir.).

5. *AstraZeneca Pharms. LP v. Becerra*, No. 21-cv-27 (D. Del.).

6. *Kalderos, Inc. v. United States*, No. 21-cv-02608 (D.D.C.).

7. *Boehringer Ingelheim Pharms., Inc. v. Becerra*, No. 21-cv-2826 (D.D.C.).

8. *Ryan White Clinics for 340B Access v. Azar*, No. 20-cv-02906 (D.D.C.).

9. *Nat'l Ass'n of Community Health Ctrs. v. Azar*, No. 20-cv-03032 (D.D.C.)

10. *Pharm. Rsch. & Mfrs. of Am. v. Cochran*, No. 8:21-cv-198 (D. Md.).

11. *Mosaic Health, Inc. v. Sanofi-Aventis U.S., LLC*, No. 6:21-cv-6507 (W.D.N.Y.).

12. *Dickinson Cnty. Healthcare Sys. v. Novo Nordisk*, No. 210916-9 (HHS ADR proceeding).

STATEMENT OF THE CASE

A. Relevant Facts

1. The 340B statute

This case turns on the requirements of section 340B of the Public Health Service Act. 42 U.S.C. § 256b. Before Congress enacted section 340B, drug manufacturers voluntarily provided their drugs at reduced prices to organizations that served poor and uninsured patients. In 1992, Congress turned those charitable commitments into a legal mandate, creating the "340B program."

Section 340B requires that any manufacturer that participates in the Medicaid Drug Rebate Program must "offer" to "covered entities" its covered outpatient drugs "for purchase" at deeply discounted prices. *Id*. § 256b(a)(1). The statute defines "covered entities" as 15 categories of clinics, non-profit hospitals, and other safety-net providers that provide medical services to predominantly low-income and uninsured patients. *Id.* § 256b(a)(1), (a)(4)(A)–(O). Congress thus limited which entities are entitled to participate in — and benefit from — the 340B program.

When Congress enacted section 340B, it also limited HHS's substantive rulemaking authority, denying the agency power to expand the program's reach. *See Pharm. Research & Mfrs. of Am. v. U.S. Dep't of Health & Hum. Servs*., 43 F. Supp. 3d 28, 41 (D.D.C. 2014). Limiting the program's expansion is important because, under the statute, covered entities are not required to use manufacturers' discounted drugs to treat needy patients (and in many instances they do not). Indeed, 340B

"patients" need not be poor or uninsured: 340B covered entities regularly treat wealthy and fully insured patients. Nor are covered entities required to extend the discounts to patients, even indigent patients. *See Eli Lilly & Co. v. U.S. Dep't of Health & Hum. Servs*., No. 21-cv-0008, 2021 WL 5039566, at *2 (S.D. Ind. Oct. 29, 2021). Instead, covered entities are permitted to sell the discounted drugs to any of their patients and charge full, non-discounted prices to those patients and their insurers. For most innovator drugs, the discounts range from 23.1% to 99.9% of the average price (many drugs are available under the 340B program at a penny per pill). *See* 42 U.S.C. § 1396r-8(c), *id.* § 256b(a)(1).

The profits generated by the sale of manufacturers' drugs — from allowing covered entities to buy low and sell high — are not intended to enrich for-profit, commercial pharmacies. To the contrary, Congress structured the statute to prevent others from participating in the program. The statute prohibits what is known as "diversion," mandating that covered entities "shall not resell or otherwise transfer" manufacturers' discounted drugs "to a person who is not a patient of the entity." *Id.* § 256b(a)(5)(B). In addition, the statute prohibits duplicate discounts, *see id.* § 256b(a)(5)(A), forbidding a covered entity from generating *both* a 340B discount and a Medicaid rebate on purchased drugs. These restrictions are essential to ensuring that the 340B statute serves its only lawful purpose — helping vulnerable

patients that receive services from covered entities gain better access to medications and care.

2. HHS's non-binding guidance documents

Shortly after the 340B statute took effect, covered entities that lacked their own in-house pharmacies sought HHS's permission to enter into contractual relationships with offsite pharmacies, known as "contract pharmacies," to dispense manufacturers' drugs to their patients.

In 1996, HHS issued non-binding guidance addressing this issue. *See* 61 Fed. Reg. at 43,549. HHS admitted that the 340B "statute is silent as to permissible drug distribution systems." *Id*. The agency announced that if a covered entity lacked an in-house pharmacy, it would permit the covered entity to contract with a *single outside pharmacy* to dispense drugs to the covered entity's patients. *Id*. HHS treated the single outside pharmacy as operating in the shoes of an in-house pharmacy. In taking that position, HHS disclaimed any intent to impose obligations on manufacturers, emphasizing that its guidance "create[d] no new law and create[d] no new rights or duties." *Id.* at 43,550.

For the next 14 years, the 340B program operated with the understanding that the government would permit covered entities to have either an in-house pharmacy or a single outside contract pharmacy, but not both. No one argued (and HHS obviously did not believe) that the 1996 guidance was unlawful because the statute

already granted covered entities an open-ended right to use as many contract pharmacies as they desired. It was understood that the 340B statute limited which entities could participate in and profit from the program, and the 1996 guidance was tailored to effectuate the program's intent.

In 2010, HHS issued new non-binding guidance stating that it would then allow covered entities to contract with an *unlimited* number of contract pharmacies. 75 Fed. Reg. 10,272 (Mar. 5, 2010). Like the 1996 guidance, the 2010 guidance did not create new rights or impose new obligations on manufacturers. *See id*. at 10,273. But this change in non-binding guidance eventually resulted in an unprecedented increase in program growth, expense, and abuse.

3. The explosion in 340B program abuses

In recent years, the 340B program has grown to become the country's second largest prescription drug program, larger than even the Medicaid Drug Rebate Program from which it was created. *See* Aaron Vandervelde & Andrew Brownlee et al., Revisiting the Pharmaceutical Supply Chain: 2013-2018, at 8 (2020). The explosive growth was not caused by an increase in the number of indigent patients; it has resulted almost entirely from allowing multiple contract pharmacies to participate in and profit from the 340B program. One recent study reported *an increase of 4,228%* in the number of contract pharmacies between 2010 and 2020.

See R.40-3 at 4, Aaron Vandervelde et al., For-Profit Pharmacy Participation in the 340B Program (2020) (JA__).

The program's expansion has taken advantage of a recent innovation known as the "replenishment model." *See* R.40-5 at 28, GAO, GAO-11-836, Drug Pricing: Manufacturer Discounts in the 340B Program Offer Benefits, but Federal Oversight Needs Improvement (2011) ("2011 GAO Report") (JA__). Under the traditional model in place when Congress enacted the 340B statute, hospital covered entities purchased drugs directly from manufacturers (or their wholesalers), took title and possession of the drugs, and then used the drugs to provide services and care to their patients. In contrast, the "replenishment model" severs the link between the hospital and the medical services that the hospital provides to patients. Instead of a hospital dispensing drugs to the patients that come to its facilities for medical services and care, commercial pharmacies sell manufacturers' drugs to the pharmacies' customers at the full market price — in some cases at locations thousands of miles from the hospital and the vulnerable patients it serves. *See* R.40-9 at 22, GAO, GAO-18-480, Drug Discount Program: Federal Oversight of Compliance at 340B Contract Pharmacies Needs Improvement (2018) ("2018 GAO Report") (JA__). After a drug is dispensed to a pharmacy customer out of the pharmacy's general inventory (and sold at full price to the customer or her insurer), if the pharmacy later deems the customer to be a "patient" of the covered entity, the pharmacy seeks

"replenishment." In particular, the pharmacy instructs the covered entity to direct the manufacturer to replenish the pharmacy's supply by facilitating the delivery of discounted drugs to the pharmacy, while billing the covered entity at discounted 340B prices. Under the replenishment model, covered entities never take possession or title to the discounted drugs.

Because the commercial pharmacy does not segregate 340B-priced drugs from its general inventory, and because it sells the drugs to all of its customers regardless of whether the drugs are prescribed in connection with medical services provided by the covered entity, it is difficult to protect against misuse, fraud, and abuse. As the government itself has recognized, the use of contract pharmacies makes it difficult to ensure that manufacturers' discounted drugs are being sold only to "patients" of the covered entity, increasing the prevalence of diversion. Covered entities and their pharmacies often apply an expansive definition of "patient" that sweeps in pharmacy customers with only the most attenuated connections to the hospital. *See* R.40-4 at 1, 16, HHS-OIG Memorandum Report: Contract Pharmacy Arrangements in the 340B Program (2014) ("2014 HHS-OIG Report") (JA__); 2011 GAO Report at 28 (JA__). Similarly, the replenishment model makes it difficult to police duplicate discounts. *See* 2014 HHS-OIG Report at 1-2 (JA__). Moreover, because manufacturers do not have access to adequate records of pharmacy sales,

manufacturers are unable to detect abuses and institute meaningful audits of improper activity, as Congress intended. *See* 42 U.S.C. § 256b(a)(5)(C).

Significantly, instead of receiving bona fide fees for services rendered, contract pharmacies often share in the "spread" generated by the sale of manufacturers' drugs at discounted prices. The resulting opportunity for profit has caused an explosion in the use of contract pharmacies, while also reducing the incentives to protect against fraud and abuses.

The amount of money involved is staggering. Commercial pharmacies (including the largest chain-store pharmacies in the country) have pocketed *billions* (on top of the profits received by hospital covered entities). *See* Eric Percher et al., Nephron Research LLC, The 340B Program Reaches a Tipping Point: Sizing Profit Flows and Potential Disruption, at 31 fig. 43 (2020) (concluding that $3.348 billion in 340B discounts were retained as profit by contract pharmacies in 2020 alone). But the profits that go to the for-profit commercial pharmacies are not used to benefit patients and the medical services they receive. *See* Press Release, PhRMA, *New Analysis Shows Contract Pharmacies Financially Gain From 340B Program with No Clear Benefit to Patients* (Oct. 8, 2020); R.40-6, Adam J. Fein, *The Federal Program That Keeps Insulin Prices High*, Wall St. J. (Sept. 10, 2020) (JA__) (explaining that "almost half the U.S. pharmacy industry now profits from the 340B program," while patients "don't benefit"). Moreover, studies show that while the

use of contract pharmacies has grown exponentially, the overall level of charitable care provided by hospital covered entities has not. *See* Wayne Winegarden, PRI Ctr. for Med. Econ. & Innovation, Profiting From 340B: A Review of Charity Care and Financial Performance at 340B Hospitals, at 7 (2021); R.40-8 at 1, Adam J. Fein, *Exclusive: 340B Program Purchases Reach $24.3 Billion—7%+ of the Pharma Market—As Hospitals' Charity Care Flatlines*, Drug Channels (May 14, 2019) (JA__).

4. Manufacturers' contract pharmacy policies

Manufacturers repeatedly urged HHS to address abuses and prevent pharmacies from profiting from the 340B program. But HHS refused — even in the face of multiple reports and mounting concerns raised by other government entities. *See* 2018 GAO Report at 37 (JA__); R.40-10 at 38, H. Comm. on Energy & Commerce, 114th Cong., Review of the 340B Drug Pricing Program (2018) (JA__); 2014 HHS-OIG Report at 2 (JA__).

With HHS abandoning its oversight role, manufacturers individually took steps to address abuses. At different times in 2020 and 2021, certain manufacturers implemented policies that in different ways limit when they will facilitate the transfer of their 340B-priced drugs to contract pharmacies. Novo's policy — which took effect in January 2021 — makes clear that the company will not facilitate the transfer of its 340B drugs to unlimited numbers of contract pharmacies. *See* VLTR

at 7754-7758 (JA__). (Novo's policy does not apply to non-hospital covered entities, such as rural community health centers and clinics, where the risks of abuse are less.)

At no time has Novo's policy prevented covered entities from purchasing its drugs at discounted prices. 42 U.S.C. § 256b(a)(1). Nor is there any risk that patients will be denied access to Novo's drugs (which are carried by every pharmacy whether or not they serve as 340B contract pharmacies). If a covered entity does not have an in-house pharmacy, Novo allows the covered entity to designate a single outside pharmacy to dispense drugs to the covered entity's patients, and Novo facilitates shipment to that pharmacy (and to any pharmacies that are owned by the covered entity). Novo's policy is thus consistent with the approach that was in place — which the government deemed to comply with the statute — for 14 years between 1996 and 2010. (Novo recently revised its policy to allow hospital covered entities to designate up to a total of two contract pharmacy locations.)

5. The government's final agency actions

In response to manufacturer initiatives, HHS initially recognized that its "authority to enforce certain 340B policies … [was] limited." *Am. Hosp. Ass'n v. HHS*, No. 4:20-8806, 2021 WL 616323, at *3 (N.D. Cal. Feb 17, 2021) (quoting correspondence from HRSA Communications Director). The agency confirmed as recently as 2020 that it lacked authority to compel manufacturers to transfer drugs

to contract pharmacies. *See* R.40-11 at 3, Tom Mirga, *HRSA Says Its 340B Contract Pharmacy Guidance Is Not Legally Enforceable*, 340B Report (July 9, 2020) (JA__) (noting government's statement that "[t]he 2010 guidance … is not legally enforceable" and HHS could not "compel[]" manufacturers "to provide 340B discounts on drugs dispensed by contract pharmacies").

In late 2020, however, HHS reversed position. Through three separate final agency actions, HHS sought to impose a third-party delivery obligation on manufacturers that appears nowhere in the 340B statute.

First, on December 14, 2020, after a delay of more than ten years, HHS hastily promulgated an administrative dispute resolution ("ADR") process for adjudicating disputes between manufacturers and covered entities. *See* 42 C.F.R. § 10.20 (the "ADR rule"). The ADR process is biased in favor of covered entities, and the ADR rule improperly purported to authorize agency officials serving on ADR panels to resolve important policy issues, including the use of contract pharmacies.

Second, on December 30, 2020, HHS's Office of the General Counsel issued a decision — an "Advisory Opinion" — that *for the first time* interpreted the 340B statute as *requiring* manufacturers to facilitate the transfer of their products to an unlimited number of for-profit commercial pharmacies. *See* December decision (JA__). In its decision, HHS assumed without analysis that commercial pharmacies are "agents" of covered entities, even though it cited no evidence establishing that

covered entities control the actions of, or impose fiduciary obligations on, commercial pharmacies. It then announced that "to the extent that contract pharmacies are acting as agents of a covered entity, a drug manufacturer in the 340B Program is obligated [1] to deliver its covered outpatient drugs to those contract pharmacies and [2] to charge the covered entity no more than the 340B ceiling price for those drugs." *Id.* at 1 (JA__).

HHS's December decision concluded that because the statute requires manufacturers to "offer" their discounted drugs for "purchase" by covered entities, the statute also obligates manufacturers to transfer the drugs to whomever and at whatever locations the covered entities direct. *Id.* at 8 (JA__). The December decision offered no support for the view that a contractual right to purchase a product at a specified price includes the right to dictate shipping directions to someone else. According to HHS, however, covered entities can force manufacturers to deliver their drugs to third parties and the "situs of delivery, be it the lunar surface, low-earth orbit, or a neighborhood pharmacy, is irrelevant." *Id.* at 3 (JA__).

Third, on May 17, 2021, the government sent Novo (and other manufacturers) a letter purporting to enforce the 340B statute. *See* R.38-2 (JA__). The letter provided almost no reasoning to support the agency's position and did not address manufacturers' objections. Nor did it attempt to reconcile its position with the reality that Novo has continued to offer its drugs at the statutory price to all covered entities

and delivers them to the covered entities (either directly or through at least one contract pharmacy of the covered entity's choosing). The letter nonetheless stated that Novo had violated the 340B statute by not agreeing to transfer its discounted drugs to an unlimited number of commercial contract pharmacies.

B. Procedural history

Novo filed this lawsuit on January 15, 2021, challenging the December decision and seeking declaratory and injunctive relief. In early May, consistent with an agreed-on briefing schedule, the government filed a motion to dismiss or, in the alternative, for summary judgment. The government argued that its December decision was an "interpretive rule" that did not impose any obligations on manufacturers that were not already imposed by the text of the 340B statute. *See* R.37-1 at 22 (JA__).

Less than a week later — with no notice to Novo or the district court — the government issued its May letter, threatening to impose civil monetary penalties on Novo unless it acceded to HHS's position. The May letter contended that Novo was "in direct violation of the 340B statute," claiming that "the 340B statute requires manufacturers to honor … purchases" made through contract pharmacies. May letter at 1 (JA__).

Novo objected to the government's attempt to interfere with ongoing litigation by threatening civil monetary penalties if Novo did not capitulate. In response, the

district court directed Novo to file an amended complaint challenging the May letter. Novo complied and the parties continued briefing dispositive motions.

On June 18, 2021, the government filed a notice indicating that it had withdrawn its December decision. *See* R.52 at 1 (JA__). The government took that action in response to a ruling by the district court for the district of Delaware. *See AstraZeneca Pharms. LP v. Becerra*, 543 F. Supp. 3d 47 (D. Del. 2021). That court recognized that the government's position had changed over time without reasoned explanation, and it held that the 340B statute is "silent" on the use of contract pharmacies. It then struck down the December decision because the government had improperly concluded that the 340B statute requires manufacturers to transfer drugs to contract pharmacies. *See id.* at 60. The court explained that imposing that obligation on manufacturers was the "kind of policymaking" reserved for Congress. *Id*. at 62.

In the wake of that ruling, the government should have also withdrawn its May letter. Instead, it continued to argue that the text of the 340B statute requires manufacturers to transfer their drugs to contract pharmacies. In September, the agency referred the matter to the HHS Office of Inspector General to consider imposing civil monetary penalties, claiming that Novo had failed "to comply with its 340B statutory obligations." *See* R.66-1 at 1 (JA__).

On November 5, 2021, without holding argument, the district court issued a decision resolving Novo's claims and the claims filed by Sanofi in a related case. *See* R.69, *Sanofi-Aventis U.S., LLC v. HHS*, Nos. 21-634, 21-806, 2021 WL 5150464 (D.N.J. Nov. 5, 2021) (JA__).

Rejecting Sanofi's arguments, the court upheld the ADR rule. Departing from other courts to have considered the issue, it held that the government did not violate notice-and-comment rulemaking requirements when it resurrected a proposed rule it had previously withdrawn. *Cf. Eli Lilly & Co. v. Cochran*, 526 F. Supp. 3d 393, 407 (S.D. Ind. 2021) ("conclu[ding] that "the agency's message regarding the ongoing rulemaking related to the ADR Rule was ambiguous, confusing, duplicitous, and misleading—the antithesis of fair notice under the APA"). According to the district court, manufacturers had sufficient notice merely because the statute "mandated" an ADR rule "at some point, sooner or later." R.69 at 32 (JA__).

The court held that Novo's and Sanofi's challenges to the December decision were moot because the agency might "substantial[ly] revis[e]" its position going forward. *Id.* at 21 n.31 (JA__). The court did not explain how the government could carry its burden to demonstrate mootness while continuing to seek to enforce its interpretation against manufacturers.

The court then turned to the two-page May letter. Although judicial review of administrative action is limited to the grounds articulated by the agency for its

decision, the court devoted more than 50 pages to making its own findings. *See id.* at 71-122 (JA__). The court recognized that the 340B statute is silent on the use of contract pharmacies and concluded that the withdrawn December decision was improper. *Id.* at 78 (JA__). But it claimed the May letter was substantially different from the December decision merely because the government had issued it after assembling an administrative record. *Id.* at 74 (JA__). Although the court could not identify any statutory language requiring manufacturers to transfer their drugs to contract pharmacies, the court relied on disputed legislative history and its own conclusions about Congress's purposes to conclude that forcing manufacturers to transfer their drugs to contract pharmacies is "consistent" with the statute. *See id.* at 81-91 (JA__). The court then concluded that manufacturers have no rights over their own drugs except those bestowed by Congress. In the court's view, because the statute is silent on the issue of contract pharmacies, manufacturers cannot control the distribution of their own products. *See id.* at 101-06 (JA__).

Despite ruling for the government, the district court vacated the May letter's determination that Novo owed credits, refunds, or penalties "to the extent that such determinations may depend on the number of permissible contract pharmacy arrangements under the 340B statute." *Id.* at 122 (JA__). Finding that the government had not adequately addressed "how many contract pharmacies the 340B statute permits," the court remanded for the government to determine "whether the

[340B] statute permits multiple or unlimited contract pharmacies." *Id.* at 73, 95 (JA__). The court did not explain how the government could undertake that task without exercising rulemaking authority, which Congress has not granted to the agency.

Novo and Sanofi each filed appeals on November 19, 2021, and the government filed notices of cross-appeals on December 28, 2021.

C. Rulings presented for review

Opinion, *Novo Nordisk Inc. v. HHS,* No. 21-00806, 2021 WL 5150464 (D.N.J. Nov. 5, 2021) (Hon. Freda Wolfson), R.69.

Order, *Novo Nordisk Inc. v. HHS*, No. 21-00806 (D.N.J. Nov. 5, 2021) (Hon. Freda Wolfson), R.70.

SUMMARY OF ARGUMENT

1. The government's December decision and May letter are unlawful because they rely on an impermissible interpretation of the 340B statute. The statute does not impose any obligation on manufacturers to transfer their 340B discounted drugs to commercial pharmacies. Because the statute is silent on shipments to third parties, it cannot be interpreted to eliminate manufacturer's common law rights to control the distribution of their own drugs. *See Coffelt v. Fawkes*, 765 F.3d 197, 202-04 (3d Cir. 2014); *see also Kirtsaeng v. John Wiley & Sons, Inc.*, 568 U.S. 519, 538 (2013) (noting that Congress is presumed to retain common law rights). That conclusion is confirmed by the statute's text, structure, and stated purpose, which all underscore that Congress limited which parties could participate in the 340B program and profit from the resale of manufacturers' drugs. Commercial pharmacies are not one of those entities.

Interpreting the 340B statute to require manufacturers to transfer their drugs to commercial pharmacies violates principles of statutory construction, including the principle that Congress would not have *sub silentio* imposed such a significant obligation on manufacturers. It also raises serious constitutional concerns. Forcing manufacturers to transfer their drugs to commercial pharmacies for the pharmacies' own private benefit has no essential nexus to any valid government objective. *Cf.*

Nollan v. Cal. Coastal Comm'n, 483 U.S. 825, 837 (1987). Yet neither the December decision nor the May letter respond to these and other serious concerns.

2. The district court's decision upholding the government's position is infected with numerous errors. Although the district court properly recognized that the statute is silent on the issue of contract pharmacies, it violated precedent in assuming that silence is equivalent to ambiguity (while never identifying any relevant statutory language susceptible to more than one meaning). It then rewrote the 340B statute to impose an obligation that appears nowhere in the text, based on unreliable legislative history and its own views of Congress's purposes. It also attempted to buttress its decision with lengthy (and factually incorrect) findings about the 340B program, even though judicial review of administrative action is supposed to be limited to the grounds articulated by the agency itself. *See SEC v. Chenery Corp.*, 318 U.S. 80, 87 (1943).

3. Because the government's December decision and May letter are both not supported by the statute's plain text, they cannot be upheld as valid interpretive rules. Nor can they be upheld as valid legislative rules. The government has not followed notice-and-comment procedures, which are necessary when an agency seeks to impose substantive obligations not imposed by a statute's plain text. *See Kisor v. Wilkie*, 139 S. Ct. 2400, 2420 (2019). Even though the government has withdrawn its December decision, Novo's challenge to that decision is not moot

because the government is still trying to enforce its statutory interpretation and has not satisfied its heavy burden to establish mootness. *Hartnett v. Pa. State Educ. Ass'n*, 963 F.3d 301, 306-07 (3d Cir. 2020).

STANDARD OF REVIEW

This Court reviews the district court's decision *de novo* and reviews the government's actions under the standards set forth in the Administrative Procedure Act. *See Eid v. Thompson*, 740 F.3d 118, 122 (3d Cir. 2014); 5 U.S.C. § 706(2). The government is not entitled to *Chevron* deference because it has not proceeded through notice-and-comment rulemaking; indeed, as the district court acknowledged, the government lacks general rulemaking authority under the 340B statute. *See United States v. Mead Corp.*, 533 U.S. 218, 226-27 (2001); *Christensen v. Harris County*, 529 U.S. 576, 587 (2000). Nor is the government entitled to *Skidmore* deference, as the government "wrongly believes" its interpretation is "compelled by Congress." *Peter Pan Bus Lines, inc. v. Fed. Motor Carrier Safety Admin.*, 471 F.3d 1350, 1354 (D.C. Cir. 2006).

ARGUMENT

I. The 340B Statute Imposes No Obligation on Manufacturers to Transfer Their Drugs to Commercial Pharmacies.

The government argues that its December decision is an interpretive rule that imposes no obligations on manufacturers beyond what the statute already requires. The government similarly contends that its May letter is merely enforcing the statute. Accordingly, the government can prevail only if it proves that the 340B statute's plain text imposes a third-party delivery obligation on manufacturers. Because it cannot carry that burden, the government's actions are unlawful.

A. The 340B Statute Is Silent on the Issue of Delivering Drugs to Contract Pharmacies.

The obligations imposed by the 340B statute on manufacturers, and the rights granted to covered entities, are appropriately limited and carefully defined. The statute requires each manufacturer to "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); *see also Astra USA, Inc. v. Santa Clara County*, 563 U.S. 110, 113 (2011) (explaining that the Pharmaceutical Pricing Agreements between manufacturers and covered entities are "uniform agreements that recite the responsibilities § 340B imposes"). The statute further states that the amount paid for each manufacturer's drugs "purchased by" a covered entity" shall not exceed a mandated ceiling price. 563 U.S. at 113.

As the district court acknowledged, these provisions "contain[] the sum total of the statute's language regarding manufacturers' obligations[.]" R.69 at 78 (JA__) (quotation marks omitted). Issues not addressed by the statute are left to the discretion of the manufacturers who own the drugs and owe no obligations beyond what the statute mandates. *See W. Va. Univ. Hosps., Inc. v. Casey*, 499 U.S. 83, 98-99 (1991) ("The purpose of a statute includes not only what it sets out to change, but also what it resolves to leave alone.").

The government asserts that the 340B statute requires manufacturers to deliver their drugs to an unlimited number of contract pharmacies at the request of covered entities. *See* December decision at 2-3 (JA__); May letter at 1 (JA__). But no one has ever identified any statutory language that imposes that obligation. None exists. Indeed, every court to have considered the issue, including the court below, has recognized that the statute is *silent* on the issue of contract pharmacies. *See* R.69 at 78 (JA__) ("By its terms, § 340B is silent on what role (if any) contract pharmacies play in Congress' discount drug scheme."); *AstraZeneca*, 543 F. Supp. 3d at 59; *AstraZeneca*, 2022 WL 484587, at *9; *Novartis*, 2021 WL 5161783, at *6; *Eli Lilly*, 2021 WL 5039566, at *17.

That should be the end of this case. A statute that is silent on an issue cannot be said to impose an affirmative obligation. *See Christensen*, 529 U.S. at 585-88; *see also Prestol Espinal v. Att'y Gen.*, 653 F.3d 213, 220-21 (3d Cir. 2011) (a court

cannot create ambiguity from silence). Nor does silence confer any authority on the government to impose an obligation by fiat. A federal agency "literally has no power to act … unless and until Congress confers power upon it." *City of Philadelphia v. Att'y Gen.*, 916 F.3d 276, 284 (3d Cir. 2019) (quoting *La. Pub. Serv. Comm'n v. FCC*, 476 U.S. 355, 357 (1986)). Because "[a]dministrative agencies are creatures of statute," they "possess only the authority that Congress has provided." *NFIB v. Dep't of Labor*, 142 S. Ct. 661, 665 (2022) (per curiam). Here, Congress has not granted the government any rulemaking authority that would be necessary to impose obligations not contained in the statute's plain text. *See Pharm. Research*, 43 F. Supp. 3d at 41; *see also Kisor*, 139 S. Ct. at 2420.

With no answer to these basic principles, the government contends that the statutory obligation to "offer" drugs to covered entities at the statutory price encompasses a much broader obligation to deliver the drugs to whomever, and ship the drugs to wherever, covered entities demand, including to an unlimited number of commercial pharmacies. May letter at 1 (JA__); December decision at 2-3 (JA__). But that interpretation is inconsistent with the ordinary meaning of the statutory terms. *See Wis. Cent. Ltd. v. United States*, 138 S. Ct. 2067, 2070 (2018) ("Our job is to interpret the words consistent with their ordinary meaning ... at the time Congress enacted the statute.") (quotation marks omitted).

Contract law has long distinguished between the "price term" in a requirements contract and the place and manner of delivery. Contract law also distinguishes between an "offer" — the "manifestation of willingness to enter into a bargain," Restatement Second of Contracts § 24 (1981) — and other contractual requirements. *See Noble v. Samsung Elecs. Am., Inc.*, 682 F. App'x 113, 116 (3d Cir. 2017). An express obligation to "offer" products to a specified party for "purchase" at a specified "price" is markedly different from an unwritten obligation to deliver the products to an unlimited number of third parties at other locations.

That conclusion is consistent with commonsense understandings. *See Carachuri-Rosendo v. Holder*, 560 U.S. 563, 573-74 (2010) (when "interpreting the statutory provisions," courts "begin by looking at the terms of the provisions and the 'commonsense conception' of those terms"). When a shopper has a coupon for 50% off a product at a local store, no one would suggest that the right to purchase the product at the discounted price includes a separate right to extend his discount to others and force the store to deliver the discounted product to them at whatever locations the purchaser demands.

Manufacturers can thus comply with the 340B statute by doing what it says — offering their drugs to covered entities at the discounted statutory price. 42 U.S.C. § 256b(a)(1). Indeed, where, as here, Novo arranges for discounted drugs to be delivered to the hospital covered entity's doorstep (or, if the hospital lacks its own

in-house pharmacy, to at least one contract pharmacy of the hospital's choosing), no one can reasonably dispute that it has complied with its statutory obligation to "offer" its drugs to the covered entity for purchase at the discounted price. *See* 18 Williston on Contracts § 52:1 (4th ed.) (noting that "the seller must be ready and willing to give possession of the goods to the buyer"). Because the statute specifies no separate, third-party delivery obligation, manufacturers are free to limit when they will transfer their drugs to commercial pharmacies to protect against misuse, fraud, and abuse. *Novartis*, 2021 WL 5161783, at *6.

B. A Multi-Billion-Dollar Obligation That Displaces Common Law Property Rights Cannot Be Inferred From Statutory Silence.

The government has argued that because the 340B statute is silent with respect to contract pharmacies, manufacturers lack any "unilateral power" to impose conditions on the delivery of their drugs. R.69 at 93 (JA__). In the district court's words, the manufacturers' policies are "*ultra vires*" because the statute "does not permit [them] to take specific actions, like their policies, just because those actions are not expressly prohibited [by the statute's] broad text." *Id.* at 94 (JA__).

That conclusion is at odds with basic principles of constitutional government. *See United States v. Morrison*, 529 U.S. 598, 618 (2000) (noting that Congress lacks any "plenary police power"). Government agencies can act "ultra vires" because they need an affirmative statutory basis for what they do; private parties do not. Private parties retain their common law rights unless Congress enacts a statute that

restricts those rights. Indeed, when Congress intends to interfere with common law rights, a statute must "speak directly" to the question. *United States v. Texas*, 507 U.S. 529, 534 (1993); *U.S. Forest Serv. v. Cowpasture River Pres. Ass'n*, 140 S. Ct. 1837, 1849-50 (2020) (rejecting view that agency has authority, "without a word from Congress," to alter "the power of the Government over private property").

One important common law right is the right to control one's own property. *See Shaw v. R.R.*, 101 U.S. 557, 565-66 (1879) (noting that the "law has most carefully protected the ownership of personal property"). The Supreme Court has held that, even in times of crisis, Congress must "enact *exceedingly clear language*" if it wishes to authorize agency officials to intrude on "fundamental elements of property ownership." *Ala. Ass'n of Realtors v. HHS*, 141 S. Ct. 2485, 2489 (2021) (per curiam) (emphasis added). Those elements include the right to exclude, preventing others from benefiting from the use of property. *See Cedar Point Nursery v. Hassid*, 141 S. Ct. 2063, 2072 (2021) ("The right to exclude is 'one of the most treasured' rights of property ownership."). Accordingly, because the drugs are created by and belong to the manufacturers, they retain their rights to exclude others from using them except to the extent that a statute restricts those rights in "exceedingly clear language."

In suggesting that manufacturers' property rights were extinguished when Congress enacted section 340B, the government's position has it "exactly

backwards." *Christensen*, 529 U.S. at 588; *see also Novartis*, 2021 WL 5161783, at *7 (nothing in the 340B statute "*prohibit[s]* manufacturers from placing *any* conditions on covered entities"). In *Christensen*, the Supreme Court rejected precisely that argument. The Department of Labor issued an opinion letter interpreting a statute to prohibit employers from compelling employees to use their accrued time off (instead of receiving monetary compensation). 529 U.S. at 578. The government argued that because "neither the statute nor the regulations *permit* an employer to require an employee to use accrued compensatory time," employers were prohibited from doing so. *Id.* at 588. The Supreme Court rejected that extreme position as "exactly backwards." *Id*. An agency may not infer from a statute's silence an "implicit[]" prohibition on an otherwise lawful practice. *Id.* at 582; *see also Coffelt*, 765 F.3d at 202-04.

C. Traditional Tools of Construction Confirm Manufacturers Are Not Required to Transfer Their Drugs to Contract Pharmacies.

Because the 340B statute does not require manufacturers to transfer their drugs to commercial pharmacies, the government's attempts to impose that obligation are both unreasonable and contrary to law. That conclusion is reinforced by the 340B statute's text and structure, the agency's own guidance documents, and traditional canons of statutory construction.

1. Text and structure confirm that manufacturers have no obligation to transfer their drugs to contract pharmacies.

The 340B statute as a whole confirms that Congress did not *sub silentio* impose an unwritten obligation on manufacturers to deliver their drugs to contract pharmacies. Congress carefully cabined the program's scope to protect its integrity, recognizing that allowing others to profit from the sale of manufacturer's drugs would invite abuse. *See* 42 U.S.C. § 256b(d)(2)(A).

The statute expressly limits which entities are permitted to participate in the program. 42 U.S.C. § 256b(a)(4). The statute is surgically precise in defining covered entities, enumerating 15 kinds of safety-net entities and omitting any catchall provision that would allow this list to be expanded. *See AstraZeneca*, 2022 WL 484587, at *6; *Barnhart v. Peabody Coal Co.*, 537 U.S. 149, 168 (2003) (emphasizing that when "items expressed are members of an 'associated group or series,'" courts should infer that "items not mentioned were excluded by deliberate choice, not inadvertence"). For-profit commercial pharmacies are not covered entities.

The 340B statute also precisely specifies when agency-like relationships are permitted, restricting when covered entities may have others act on their behalf. *See* 42 U.S.C. § 256b(d)(3)(B)(vi) (referring separately to "associations or organizations representing the interests of [] covered entities"). If Congress had wanted to allow for-profit pharmacies to act broadly as "agents" of covered entities, it knew how to

say so. Indeed, in the same statute that created the 340B program, Congress elsewhere dealt *specifically* with contract arrangements, prescribing special treatment for drugs purchased by a federal agency and "delivered through … a commercial entity operating under contract with such agency." Veterans Health Care Act of 1992, Pub. L. No. 102-585, § 603(a)(1), 106 Stat. 4943, 4974 (codified at 38 U.S.C. § 8126(h)(3)(A)). As another district court has concluded, this provision shows that "Congress knows how to write statutes that cover agents and contractors, but did not do so in the 340B statute." *AstraZeneca*, 543 F. Supp. 3d at 60.

In addition, Congress structured the statute to prevent third parties from profiting from the sale of manufacturers' drugs. Most critically, the statute prohibits "diversion," mandating that covered entities "shall not resell or otherwise transfer" manufacturers' discounted drugs "to a person who is not a patient of the entity." 42 U.S.C. § 256b(a)(5), (d)(2). The government argues that this provision does not apply to contract pharmacies, because Congress did not intend to limit how covered entities dispense drugs to patients. But that misses the point. Novo has not restricted how the covered entities themselves dispense the drugs they purchase. Novo is merely refusing to transfer the drugs to an unlimited number of contract pharmacies that are profiting from selling the drugs to patients who often have no meaningful connection to the hospital and any medical services received there. Even the

government has determined that "contract pharmacy arrangements increase the rate of fraud" in the 340B program. R.69 at 96 (JA__) (describing 2018 GAO report). There is no indication that Congress intended to disarm manufacturers from addressing that fraud.

2. The government's new interpretation is contrary to how the 340B program operated for more than 14 years.

The government admitted in its 1996 guidance that the "statute is silent as to permissible drug distribution systems." 61 Fed. Reg. at 43,549. The 1996 guidance stated that the government would allow each covered entity to use a single contract pharmacy if it lacked an in-house pharmacy (implicitly recognizing that delivery to the covered entity is the norm). Even as an exercise of enforcement discretion, the 1996 guidance's limit to one contract pharmacy would have been unlawful if the statute already mandated that manufacturers must transfer their drugs to as many contract pharmacies as covered entities demand. Indeed, accepting the government's current position requires assuming that the 1996 guidance — which governed the 340B program for more than 14 years — imposed restrictions that violated what the government now contends is a clear statutory requirement. *Cf. Yi v. Sterling Collision Ctrs., Inc.*, 480 F.3d 505, 510-11 (7th Cir. 2007) (implausible to conclude that an entire industry operated illegally without anyone noticing).

That makes no sense. Until its December decision, HHS repeatedly recognized that it had no authority to force manufacturers to transfer their drugs to contract pharmacies:

- On July 8, 2020, HHS told a covered entity membership organization "that although the agency strongly encourages all manufacturers to sell 340B priced drugs to covered entities through contract pharmacy arrangements, HRSA's current authority … is limited because Congress has not granted it comprehensive regulatory authority to develop enforceable policy that ensures clarity in program requirements." *Am. Hosp. Ass'n*, 2021 WL 616323, at *3 (email from HRSA Communications Director M. Kramer to 340B Health) (quotation marks omitted).

- On July 9, 2020, HHS publicly stated that "[t]he 2010 guidance … is not legally enforceable" against manufacturers and that it could not "compel[]" manufacturers "to provide 340B discounts on drugs dispensed by contract pharmacies." R.40-11 at 3 (JA__).

- In June and August 2020, the government explained that its "contract pharmacy advice" was not set out in "binding regulations." R.45-1 at 24; ADVOP_001053-54, 1057, 1098 (JA__).

- In December 2020, the Government Accounting Office reported that HHS had stopped auditing contract pharmacies for diversion violations "because the 340B statute does not address contract pharmacy use." R.40-12 at 15-16, GAO, GAO-21-107, HHS Uses Multiple Mechanisms to Help Ensure Compliance With 340B Requirements (2020) (JA__).

This history is powerful evidence that the government's new interpretation is wrong.

3. Canons of construction further confirm that the statute does not impose a delivery obligation on manufacturers.

The conclusion that Congress did not impose an unwritten obligation on manufacturers to transfer their drugs to commercial pharmacies is further confirmed

by traditional canons of construction. *See United States v. Cooper*, 396 F.3d 308, 310-11 (3d Cir. 2005), *as amended* (Feb. 15, 2005) (courts apply canons of construction before considering whether government's interpretation is reasonable).

There is no reason to conclude that Congress, through silence, intended to dramatically expand the 340B program's scope. *See MCI Telecomms. Corp. v. AT&T Co.*, 512 U.S. 218, 231 (1994) (rejecting suggestion that Congress would allow agency to change regulation of entire industry through modification of basic rate-filing requirements). As noted above, the 340B statute requires only that manufacturers "offer" their drugs to covered entities for "purchase" at a discounted price, while prohibiting covered entities from transferring the drugs to non-patients. 42 U.S.C. § 256b(a). That would be an uncommonly cryptic way for Congress to express an intent that manufacturers must transfer their drugs to commercial pharmacies. *See FDA v. Brown & Williamson Tobacco Corp.*, 529 U.S. 120, 160 (2000). Because Congress does not "alter the fundamental details of a regulatory scheme in vague terms or ancillary provisions," the statute should not be interpreted to impose such a sweeping obligation. *Whitman v. Am. Trucking Ass'ns*, 531 U.S. 457, 468 (2001).

The government's position also raises serious constitutional concerns. *See Edward J. DeBartolo Corp. v. Fla. Gulf Coast Bldg. & Constr. Trades Council*, 485 U.S. 568, 575 (1988) (statutes should be interpreted to avoid constitutional doubt).

Congress has no authority to effectuate "a naked transfer of property from private party *A* to *B* solely for *B*'s private use and benefit." *Carole Media LLC v. N.J. Transit Corp*., 550 F.3d 302, 311 (3d Cir. 2008). But that is precisely what occurs under the government's interpretation — manufacturers are forced to transfer discounted drugs to commercial pharmacies for their own private benefit.

The government has argued that Congress may impose conditions on manufacturers in return for participating in federal healthcare programs. But there are important limits on that authority, especially where, as here, the government is not exercising procurement power as a market participant. *See Am. Trucking Ass'ns v. City of Los Angeles*, 569 U.S. 641, 646 (2013) (distinguishing between procurement and regulatory powers). The government cannot leverage its purchasing power as a market participant to avoid the constitutional constraints on its exercise of regulatory power. *Cf. S.-Cent. Timber Dev., Inc. v. Wunnicke*, 467 U.S. 82, 97-98 (1984) (concluding that while a State acting as a market participant may impose burdens on commerce that would otherwise be unconstitutional, it "may not impose conditions … that have substantial regulatory effect outside of that particular market"). That principle applies with particular force here because the government is not purchasing manufacturers' drugs for itself; it is trying to impose an obligation on manufacturers to transfer them to third parties for those parties' own private benefit.

In any event, the "government may require property owners to cede a right of access as a condition of receiving certain benefits" *only if* the condition bears an "essential nexus" and "rough proportionality" to a legitimate government interest. *Cedar Point*, 141 S. Ct. at 2079 (quoting *Dolan v. City of Tigard*, 512 U.S. 374, 386, 391 (1994)). In *Nollan*, the Supreme Court held that, while the government could prevent a landowner from constructing a house on beachfront property to protect the public's ability "to see the beach," it could not condition a permit on requiring the landowner to grant a public easement across its land. Because the condition did not "further the end advanced as the justification" for the permit, it amounted to "an out-and-out plan of extortion." *Nollan*, 483 U.S. at 837 (quotation marks omitted).

The same analysis applies here. The required "nexus" and "proportionality" is missing with respect to forcing manufacturers to transfer their drugs to commercial pharmacies. The 340B statute is a charitable program that grants covered entities access to discounted drugs for the benefit of patients that receive medical services at their facilities. There is no "essential nexus" between the 340B program's justification and the requirement that manufacturers transfer their drugs to for-profit commercial pharmacies so the pharmacies can profit from the sale of manufacturers' drugs and increase the rate of fraud in the program. Patients see no benefit, even in terms of convenience, as the pharmacies will carry the drugs regardless of whether they are able to profit from the 340B program. In these circumstances, the

government's attempt to read an unwritten obligation into the 340B statute is nothing more than "an out-and-out plan of extortion." *Nollan*, 483 U.S. at 837 (quotation marks omitted). Nor is there any "rough proportionality." The 340B program was created out of the Medicaid drug program, but because the government has allowed commercial pharmacies to profit from the sale of manufacturers' drugs, the 340B program has grown to be even larger than the Medicaid drug program itself. *See* Adam J. Fein, *Exclusive: The 340B Program Soared to $38 Billion in 2020—Up 27% vs. 2019*, Drug Channels (June 16, 2021) ("The 340B program's size now exceeds the Medicaid program's outpatient drug sales").

These constitutional concerns are especially significant because the government has such a dominant position in the healthcare markets. *Cf. NFIB v. Sebelius*, 567 U.S. 519, 582 (2012) (noting concern when government engages in "economic dragooning" of regulated parties). The government should not be permitted to hold participation in Medicaid "hostage, to be ransomed by the waiver of constitutional protection." *Horne v. Dep't of Agric.*, 576 U.S. 350, 366 (2015). Instead, the 340B statute should be interpreted consistent with its plain terms and, where possible, away from constitutional doubt. *See DeBartolo*, 485 U.S. at 575.

D. The Government's Actions Are Arbitrary and Capricious.

The government's December decision and May letter should also be declared unlawful because the government failed to engage in reasoned decision-making.

Despite the seriousness of the issues, it has not adequately explained its position. *See Stovic v. R.R. Ret. Bd.*, 826 F.3d 500, 506 (D.C. Cir. 2016) (an agency's decision must be "reasonable and reasonably explained"); *see also Prometheus Radio Project v. FCC*, 373 F.3d 372, 390 (3d Cir. 2004), *as amended* (June 3, 2016) (noting that courts "may not supply a reasoned basis for the agency's action that the agency itself has not given"). Both the December decision and the May letter are devoid of meaningful findings that respond to serious objections. They also fail to address the serious "takings issues" raised by the forced transfer of manufacturers' drugs to for-profit commercial pharmacies, another reason the agency's actions cannot stand. *See Nat'l Wildlife Fed'n v. ICC*, 850 F.2d 694, 708 (D.C. Cir. 1988).

The government also failed to "display awareness that it is changing position," "show that there are good reasons for the new policy," or consider that longstanding policies may have "engendered serious reliance interests that must be taken into account." *FCC v. Fox Television Stations,* 556 U.S. 502, 515 (2009); *see also Encino Motorcars, LLC v. Navarro*, 579 U.S. 211, 221-22 (2016). The government avoided any explanation because it contends that the third-party delivery "obligation" it seeks to impose is not new. But that contention is wrong for all the reasons explained above, including because it is counter to the agency's historical interpretation of the statute reflected in its 1996 guidance. *See AstraZeneca*, 2022

WL 484587, at *5-6 (providing a table demonstrating that agency's interpretation has changed over time).

Similarly, the government refused to consider how the use of contract pharmacies has increased diversion and duplicate discounts, even though it is bedrock law that an agency must "examine the relevant data," *Fox Television Stations*, 556 U.S. at 513, and consider important factors bearing on its decision, *Motor Vehicle Mfrs. Ass'n of U.S., Inc. v. State Farm Mut. Auto. Ins. Co.*, 463 U.S. 29, 43 (1983). The government also failed to address evidence that patients do not meaningfully benefit from contract pharmacy participation in the 340B program. *See* 2018 GAO Report at 45 (multiple "weaknesses … impede [HHSs'] ability to ensure compliance with 340B Program requirements at contract pharmacies"); Sunita Desai & J. Michael McWilliams, *Consequences of the 340B Drug Pricing Program*, 378 N. Eng. J. Med. 539, 539 (2018).

These problems have been flagged repeatedly — and not just by manufacturers. Nonetheless, the government's December decision and May letter pay only lip service to these serious concerns. *Cf. Panhandle E. Pipe Line Co. v. FERC*, 890 F.2d 435, 439-41 (D.C. Cir. 1989) (agency must take a "'hard look at the salient problems' before it").

II. The District Court's Decision Exceeds the Proper Judicial Role.

The district court should have declared both the December decision and May letter unlawful and unenforceable. In stretching to apply its own sense of what the statute should require, the district court exceeded its proper judicial role.

A. The District Court Exceeded Its Lawful Authority.

When reviewing agency action, a court is limited to the findings made and justifications provided in the agency's underlying decision. A court may not make its own findings or offer reasons for the agency's decision not articulated by the agency in its administrative decision. *Chenery*, 318 U.S. at 87; *State Farm*, 463 U.S. at 50 ("an agency's action must be upheld, if at all, on the basis articulated by the agency itself"). A court may not "search the record to find support for the agency's decision," *W.R. Grace & Co. v. EPA*, 261 F.3d 330, 338 (3d Cir. 2001), nor may it give any weight to "*post hoc* rationale of counsel." *La. Ass'n of Indep. Producers & Royalty Owners v. FERC,* 958 F.2d 1101, 1123 n.12 (D.C. Cir. 1992) (per curiam). As the Supreme Court has emphasized, "reviewing courts … must assess the lawfulness of an agency's action in light of the explanations the agency offered for it rather than any *ex post* rationales a court can devise." *Garland v. Ming Dai*, 141 S. Ct. 1669, 1679 (2021); *DHS v. Regents of Univ. of Cal.*, 140 S. Ct. 1891, 1909 (2020).

The district court violated these requirements. *First*, it wrongly upheld the government's interpretation on grounds that the statute is "ambiguous," even though the government never advanced that claim in either its December decision or its May letter. *See* R.37-1 at 26, Mot. to Dismiss ("the statute is unambiguous"). If the statute were ambiguous, the Secretary would not be able to resolve the ambiguity — and impose a new obligation on manufacturers — without first undertaking notice-and-comment rulemaking (a power the Secretary lacks). *See Chao v. Rothermel*, 327 F.3d 223, 227 (3d Cir. 2003) (explaining that rules imposing "new duties" with the "force and effect of law" must comply with procedural rulemaking requirements).

Second, the district court tried to buttress its policy conclusions by making assumptions about the 340B program that are disputed. For instance, the court made its own findings about legislative history, the costs of setting up an in-house pharmacy, and speculation that 340B sales "dropped so precipitously" because of manufacturers' contract pharmacy policies. R.69 at 84 & n.53 (JA__). The district court also appeared to suggest that if manufacturers did not deliver their drugs to contract pharmacies, patients would be denied access to manufacturers' drugs. *See id*. at 110 (JA__). Not only are these conclusions incorrect, they were never articulated as bases for the government's decision.

Judicial review of administrative action is not supposed to result in judicial fact-finding based on cherry-picked evidence taken from an "administrative record" assembled without input from all interested parties; instead, it is limited to reviewing the justifications provided by the agency itself. *See Bhd. of Locomotive Eng'rs & Trainmen v. Fed. R.R. Admin.*, 972 F.3d 83, 117 (D.C. Cir. 2020) ("[I]t is a foundational principle of administrative law that judicial review of agency action is limited to the grounds that the agency invoked when it took the action.") (quoting *Regents*, 140 S. Ct. at 1907). Judicial review of agency action is not an opportunity for parties to conduct discovery, present witnesses, and make arguments for preferred policy outcomes. None of the district court's "findings" are permissible or a proper basis for upholding the government's statutory interpretation. "Vacatur" — not remedial judicial factfinding — "'is the normal remedy' when [courts] are faced with unsustainable agency action." *Bhd. of Locomotive Eng'rs*, 972 F.3d at 117 (quoting *Allina Health Servs. v. Sebelius*, 746 F.3d 1102, 1110 (D.C. Cir. 2014)).

B. The District Court's Decision Violates Principles of Statutory Interpretation.

The district court brushed aside the statute's text and structure, relying on disputed legislative history and sweeping assumptions about Congress's purposes. The court also concluded, based on its own policy considerations, that at least one,

but maybe not all, contract pharmacy arrangements should be permitted. R.69 at 120-21 (JA__). These errors violate precedent and should be corrected.

1. The district court never identified any textual ambiguity.

Although the district court asserted that the 340B statute is ambiguous, it never identified any statutory word or phrase susceptible to more than one interpretation. *See Arobelidze v. Holder*, 653 F.3d 513, 518-19 (7th Cir. 2011) ("When … 'there are two plausible but different interpretations of statutory language, there is ambiguity.'"). The court instead transformed Congress's utter silence on contract pharmacies into an extra-textual, unwritten delivery obligation on manufacturers. That violates principles of statutory interpretation.

When a statute is "silent" on a question, that silence "'does not confer gap-filling power on an agency unless the question is in fact a gap — an ambiguity tied up with the provisions of the statute.'" *Lin-Zheng v. Att'y Gen.*, 557 F.3d 147, 155-56 (3d Cir. 2009) (en banc); *see also Coffelt*, 765 F.3d at 202; *Prestol*, 653 F.3d at 220-21. Neither courts nor agencies have authority to infer ambiguity from statutory silence based on their own general sense of Congress's intent. *Prestol*, 653 F.3d at 221; *cf. Ry. Lab. Execs.' Ass'n v. Nat'l Mediation Bd.*, 29 F.3d 655, 671 (D.C. Cir.), *amended*, 38 F.3d 1224 (D.C. Cir. 1994) (noting that "[w]ere courts to *presume* a delegation of power absent an express *withholding* of such power, agencies would enjoy virtually limitless hegemony").

Indeed, it is a "fundamental principle of statutory interpretation that absent 'provision[s] cannot be supplied by the courts,'" because doing so "'is not a construction of a statute, but, in effect, an enlargement of it by the court.'" *Rotkiske v. Klemm*, 140 S. Ct. 355, 360-61 (2019) (citations omitted). Courts may not "add" to the statutory requirements imposed by Congress. *United States v. Lovett*, 467 F.3d 374, 377 (3d Cir. 2006). A court has "no license to disregard clear language based on an intuition that Congress must have intended something broader." *Cyan v. Beaver Cnty. Emps. Ret. Fund*, 138 S. Ct. 1061, 1078 (2018) (quotation marks omitted); *cf. State of New Jersey v. New York*, 523 U.S. 767, 783 n.6 (1998) (noting that it is impermissible to "convert an agreement's utter silence on an issue into contractual ambiguity").

The cases cited by the district court are inapposite. *See* R. 69 at 80-81 (JA__). None address a situation, such as this one, where (1) the agency argues that the statute's text unambiguously authorizes the agency to impose a requirement, (2) the district court correctly determines that the statute's text *does not* say anything about the issue, but (3) the district court nonetheless proceeds to allow the agency to impose the requirement anyway.

2. The district court improperly relied on legislative history.

The district court also erred in relying on legislative history. Because "legislative history can never defeat unambiguous statutory text," *Bostock v. Clayton*

County, 140 S. Ct. 1731, 1750 (2020), a court should not "resort to legislative history to cloud a statutory text that is clear," *Estate of Arrington v. Michael*, 738 F.3d 599, 605 (3d Cir. 2013) (quoting *Ratzlaf v. United States,* 510 U.S. 135, 147-48 (1994)). Here, every court to consider the matter has agreed that the text of the 340B statute says nothing about an obligation to deliver to contract pharmacies. Because the statutory text is unambiguously silent — in that it does not impose any third-party delivery obligation on manufacturers — the district court had no license to refer to legislative history.

Moreover, the legislative history on which it did rely is unreliable. Congress's unexplained removal of words from draft legislation is the type of "'mute intermediate legislative maneuver[]' [that is] not [a] reliable indicator[] of congressional intent." *Mead Corp. v. Tilley*, 490 U.S. 714, 723 (1989) (quoting *Trailmobile Co. v. Whirls*, 331 U.S. 40, 61 (1947)). It does not logically follow from the Senate's removal of a provision that would have required covered entities to use in-house pharmacies that Congress intended to require manufacturers to deliver their drugs to an unlimited number of outside pharmacies. *Cf. Bridgestone/Firestone, Inc. v. Pension Benefit Guar. Corp.*, 892 F.2d 105, 110 (D.C. Cir. 1989) (finding that the absence of specific language that Congress considered in the final statute did not speak to whether Congress rejected that scheme); *see also Novartis*, 2021 WL 5161783, at *8 n.7 (explaining that "there is insufficient evidence" that the 340B

statute's legislative history supports an obligation to honor all contract pharmacy arrangements).

Indeed, another court has held that the very same legislative history "cuts against the government's position because Congress specifically did not enact statutory language referring to contract pharmacies." *AstraZeneca,* 2022 WL 484587, at *2; *see also AstraZeneca*, 543 F. Supp. 3d at 60-61. When it enacted section 340B in 1992, Congress considered requiring manufacturers to provide discounts for 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). Because it omitted that language, the legislative history confirms that the statute does not require manufacturers to deliver their discounted drugs to contract pharmacies.

3. The district court improperly relied on assumptions about Congress's purposes.

In the district court's view, any condition imposed by manufacturers that results in a "large-scale reduction in 340B sales" is contrary to congressional intent, which is to "maximize" the number of low-income individuals served. R.69 at 82-83 (JA__). That overly simplistic conclusion ignores what the statute says. As noted above, section 256b(a)(4) provides an exhaustive list of 15 categories of covered entities allowed to participate in 340B program. Similarly, section 256b(a)(5) is designed to prevent non-patients from benefitting from the 340B program, which is

precisely what certain contract pharmacy arrangements are enabling. *See Freeman v. Quicken Loans, Inc.*, 566 U.S. 624, 632 (2012) (determining that an interpretation that drastically undermines a statute's purposes "provides strong indication that something in [that] interpretation is amiss").

In any event, "'no legislation pursues its purposes at all costs' .... [a]nd Section 340B is no exception." *Novartis*, 2021 WL 5161783, at *7 (quoting *CTS Corp. v. Waldburger*, 573 U.S. 1, 12 (2014)). It is never a court's "role ... to 'correct' the text so that it better serves the statute's purposes, for it is the function of the political branches not only to define the goals but also to choose the means for reaching them." *Engine Mfrs. Ass'n v. EPA*, 88 F.3d 1075, 1089 (D.C. Cir. 1996). As this Court has recognized, "freewheeling statutory construction, even though embarked upon to vindicate corrected perceived underlying purposes, has little place in the context of a carefully balanced and reticulated statute." *Hozier v. Midwest Fasteners, Inc.*, 908 F.2d 1155, 1169-70 (3d Cir. 1990).

The district court forgot that legislation is "the art of compromise, the limitations expressed in statutory terms often the price of passage." *Henson v. Santander Consumer USA Inc.,* 137 S. Ct. 1718, 1725 (2017) (citing *Rodriguez v. United States*, 480 U.S. 522, 526 (1987) (per curiam)). To suggest that Congress wanted to "maximize" the number of low-income patients served is to disregard that Congress was also concerned about protecting the program's integrity, shielding

manufacturers from unrestrained financial obligation, and evidence showing that contract pharmacies are not improving care for needy patients. *See* Desai & McWilliams, 378 New Eng. J. Med. at 539 (for-profit pharmacies' "[f]inancial gains" under the program post- 2010 "have not been associated with clear evidence of expanded care or lower mortality among low-income patients"). A court should never "rewrite" statutory text "under the banner of speculation about what Congress might have done" had it chosen to address an issue on which it instead remained silent. *Henson,* 137 S. Ct. at 1725.

C. The District Court Improperly Brushed Aside the Constitutional Concerns Raised by the Government's Interpretation.

Disregarding concerns that Congress would not have imposed a multi-billion-dollar obligation on manufacturers in such a cryptic fashion, the district court emphasized that "Congress intended [the agency] (by statute) to effectuate § 340B." R.69 at 90 (JA__). But that ignores that, as noted above, Congress did not grant the agency general rulemaking authority, *Pharm. Research*, 43 F. Supp. 3d at 41, and that HHS did not purport to exercise any such authority in this case. The issue is not whether Congress delegated HHS *some* authority to administer the 340B statute, but whether it is permissible for the agency to write into the statute a new obligation that radically changes the very nature, scope, and scale of the program.

The district court also rejected any need to interpret the statute to avoid takings concerns. But its analysis violates Supreme Court precedent at every step. The court

first suggested that the government is not compelling manufacturers to surrender their drugs to a third party. *See* R.69 at 101-02 (JA__). That is wrong. The government's May letter directly seeks to compel manufacturers to transfer their discounted drugs to contract pharmacies.

The district court also suggested that it is unclear that a per se takings analysis applies when personal property (instead of real property) is at stake. *Id.* (JA__). That likewise ignores precedent. *See Horne*, 576 U.S. at 358 (the Takings Clause "protects 'private property' without any distinction between different types"). The 340B statute, as interpreted by the government, is not restricting manufacturers' "ability to use [their] own property," *Cedar Point*, 141 S. Ct. at 2071; it is "physically appropriat[ing] property" for the benefit of for-profit pharmacies. *Id*. at 2072. By trying to grant contract pharmacies a "right to take access" to manufacturers' drugs, the government's interpretation effects a per se taking. *Id.* at 2075.

The district court also accepted the government's suggestion that takings concerns do not exist because manufacturers have not lost the entire value of their property. R.69 at 102-03 (JA__). That too runs counter to Supreme Court precedent, which holds that when the government "physically takes possession of an interest in property for some public purpose, it has a categorical duty to compensate the former owner, regardless of whether the interest that is taken constitutes an entire parcel or merely a part thereof." *Horne*, 576 U.S. at 363 (quoting *Tahoe-Sierra Pres. Council,*

Inc. v. Tahoe Reg'l Planning Agency, 535 U.S. 302, 324 (2002)); *see also Loretto v. Teleprompter Manhattan CATV Corp.*, 458 U.S. 419, 436 (1982) (installing a cable box on a small corner of a rooftop was still a per se taking even if property owner could still sell and economically benefit from the property).

The district court's takings analysis misses the larger point. It may be permissible for Congress to require manufacturers to sell their drugs to non-profit hospitals at below cost prices as a condition of participating in the Medicaid Drug Rebate Program, as long as the 340B program serves its intended charitable purposes and the discounted drugs are integral to improving the medical services that the hospitals provide to their patients. But forcing manufacturers to transfer their drugs at discounted prices to for-profit commercial pharmacies for the benefit of the pharmacies themselves is a bridge too far. The commercial pharmacies have no obligation to use the profits from selling manufacturers' drugs to benefit needy patients. Moreover, forcing manufacturers to facilitate their participation in the 340B program dramatically increases the financial burden — leading to unchecked growth — and the opportunities for fraud. That expansion in the program is not supported by the statute's plain text, and reading a new obligation into the statute that raises constitutional concerns should be avoided.

III. The Court Should Vacate the Government's Actions.

For all the reasons explained above, the government's actions should be struck down as in excess of the government's statutory authority and contrary to the requirements of reasoned decision-making. *See* 5 U.S.C. § 706(2). The government's December decision and May letter cannot be sustained as "interpretive rules" because they do not rely on proper interpretations of the statute's plain text. *See SBC Inc. v. FCC*, 414 F.3d 486, 498 (3d Cir. 2005) (noting that an "interpretive rule simply states what the administrative agency thinks the statute means, and only reminds affected parties of existing duties"). They also cannot be upheld as "legislative rules" because the government has not followed necessary procedures to impose new substantive obligations on manufacturers. *See id.* at 497-98; *see also Kisor*, 139 S. Ct. at 2420 (an agency must "use notice-and-comment procedures before issuing legislative rules").

A. The December Decision Should Be Declared Unlawful.

The district court correctly recognized that the government's withdrawn December decision is legally flawed. *See* R.69 at 21 n.31 (JA__). It nonetheless held that, because it expects the government to make "substantial revisions" on remand, *id.* (JA__), Novo's legal challenge is moot. That is contrary to the well-reasoned decision of another district court in this Circuit. *See AstraZeneca Pharms.*

LP v. Becerra, No. 21-27-LPS (D. Del. June 30, 2021), ECF No. 83. It is also contrary to settled precedent.

A defendant's voluntary cessation of challenged conduct does not automatically moot a case. *See City of Mesquite v. Aladdin's Castle, Inc*., 455 U.S. 283, 289 (1982). This Court has explained that it "will understandably be skeptical of a claim of mootness when a defendant yields in the face of a court order and assures us that the case is moot because the injury will not recur, yet maintains that its conduct was lawful all along." *Hartnett*, 963 F.3d at 306-07. A case becomes moot only if events make it "absolutely clear that the allegedly wrongful behavior could not reasonably be expected to recur." *Id.* (quoting *Fields v. Speaker of Pa. House of Representatives*, 936 F.3d 142, 161 (3d Cir. 2019)). Moreover, the party asserting mootness bears the "heavy burden" of proof on this "stringent" standard. *Friends of the Earth, Inc. v. Laidlaw Env't Servs. (TOC), Inc*., 528 U.S. 167, 189 (2000) (quotation marks omitted).

The government has not met its heavy burden. The December decision places Novo at a heightened risk of enforcement action and potential civil monetary penalties. *See Sackett v. EPA*, 566 U.S. 120, 127 (2012). Far from demonstrating that its "allegedly wrongful behavior could not reasonably be expected to recur," the government has continued to pursue enforcement proceedings in lockstep with the arguments articulated in its December decision. *AstraZeneca*, ECF No. 83, at 2

(because the government "intend[s] to act in accordance with the withdrawn [decision], this litigation is not moot").

B. The May Letter Should Be Declared Unlawful and Vacated.

The Court should also strike down the May letter without remand, and grant the declaratory and injunctive relief that Novo seeks, because the letter relies on an impermissible interpretation of the statute. The May letter was not promulgated through notice-and-comment procedures, which are necessary to impose an enforceable obligation not imposed by the statute's plain text. *See Chao*, 327 F.3d at 227; *see also Nat'l Min. Ass'n v. McCarthy*, 758 F.3d 243, 251 (D.C. Cir. 2014). As another district court considering this matter recognized, "the agency's shifting guidance illustrates that [it is] attempting to fill a gap in this statute, and this the agency cannot do. Any such gap-filling must be accomplished by a legislative rather than an interpretive rule. But HRSA lacks the authority to issue a legislative rule." *Novartis,* 2021 WL 5161783, at *8 (citations omitted); *see also Ry. Lab. Execs.' Ass'n*, 29 F.3d at 670 ("[I]t is beyond cavil that an agency's power is no greater than that delegated to it by Congress.").

Acknowledging the problems caused by allowing covered entities to contract with an unlimited number of contract pharmacies, the district court remanded for the agency to determine an appropriate number. R.69 at 96-97 (JA__). But determining what number of commercial pharmacies should be allowed to participate in the 340B

program is an exercise of legislative authority that can be accomplished only by the statute itself or through proper rulemaking procedures. *See SBC Inc.*, 414 F.3d at 497-98; *see also Hoctor v. U.S. Dep't of Agric.*, 82 F.3d 165, 171 (7th Cir. 1996) ("an interpretive rule can never have a numerical component"). Because HHS has no authority to complete that task, its "action is plainly contrary to law and cannot stand." *Atl. City Elec. Co. v. FERC*, 295 F.3d 1, 8 (D.C. Cir. 2002) (quoting *Michigan v. EPA*, 268 F.3d 1075, 1081 (D.C. Cir. 2001)).

CONCLUSION

The Court should reverse the district court, strike down and declare unlawful the December decision and May letter, and enjoin the government from taking enforcement action against Novo.

Respectfully submitted,

/s/ Ashley C. Parrish

Nicole Bronnimann
(TX Bar No. 24109661)
KING & SPALDING LLP
1100 Louisiana Street
Suite 4100
Houston, TX 77002
(713) 751-3200

Ashley C. Parrish
(DC Bar No. 464683)
Graciela M. Rodriguez
(DC Bar No. 438955)
John D. Shakow
(DC Bar No. 451429)
KING & SPALDING LLP
1700 Pennsylvania Avenue NW
Washington, DC 20006
(202) 737-0500
aparrish@kslaw.com

Counsel for Appellants Novo Nordisk Inc. and Novo Nordisk Pharma, Inc.

March 8, 2022

CERTIFICATE OF COMPLIANCE

1. Pursuant to Local Rule 28.3(d), I hereby certify that the attorneys whose names appear on this brief are members of the bar of this court.

2. This brief complies with the type-volume requirements of Federal Rule of Appellate Procedure 32(a)(7)(B) because it contains 12,990 words, excluding the parts of the brief exempted by Federal Rule of Appellate Procedure 32(f).

3. The brief complies with the typeface requirements of Federal Rule of Appellate Procedure 32(a)(5) and the type style requirements of Federal Rule of Appellate Procedure 32(a)(6) and 3d Cir. L.A.R. 32.1(c) because it has been prepared in a proportionally spaced typeface using Microsoft Word 365 ProPlus in Times New Roman 14-point font.

4. Pursuant to Local Rule 31.1(c), I hereby certify that the text of the electronic brief is identical to the text in the paper copies, and that it has been scanned for viruses using McAfee Endpoint Security, Version 10.7.1, and no virus was detected.

Date: March 8, 2022

/s/ Ashley C. Parrish
Ashley C. Parrish

CERTIFICATE OF SERVICE

I hereby certify that on March 8, 2022, I electronically filed the foregoing with the Clerk of the Court for the United States Court of Appeals for the Third Circuit by using the CM/ECF system. I certify that all participants in the case are registered CM/ECF users and that service will be accomplished by the CM/ECF system.

/s/ Ashley C. Parrish
Ashley C. Parrish