IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF NEW JERSEY

NOVO NORDISK INC.

and

NOVO NORDISK PHARMA, INC.,

Plaintiffs,

v.

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

Defendants.

Civil Action No. 3:21-cv-00806
Chief Judge Freda L. Wolfson

Oral argument requested

PLAINTIFFS' COMBINED
CROSS-MOTION FOR SUMMARY JUDGMENT AND OPPOSITION TO DEFENDANTS' MOTION TO DISMISS OR, IN THE ALTERNATIVE, FOR SUMMARY JUDGMENT

NOTICE OF CROSS-MOTION FOR SUMMARY JUDGMENT

PLEASE TAKE NOTICE that Plaintiffs Novo Nordisk Inc. and Novo Nordisk Pharma, Inc. (collectively, "Novo") will move before the Honorable Freda L. Wolfson, Chief Judge of the U.S. District Court for the District of New Jersey, on such date as the Court orders, for summary judgment pursuant to Federal Rule of Civil Procedure 56.

In support of its Motion, Novo relies on the accompanying Memorandum of Law. Novo also submits the accompanying Proposed Order. Novo respectfully requests oral argument on its Motion.

Respectfully submitted,

/s/ Israel Dahan /s/
Israel Dahan (NJ Bar No. 042701997)
KING & SPALDING LLP
1185 Avenue of the Americas, 34th Floor
New York, NY 10036-2601
Telephone: (212) 556-2114
Facsimile: (212) 556-2222
idahan@kslaw.com

Graciela M. Rodriguez (pro hac vice)
Ashley C. Parrish (pro hac vice)
John D. Shakow (pro hac vice)
KING & SPALDING LLP
1700 Pennsylvania Avenue, NW, Suite 200
Washington, D.C. 20006-4707
Telephone: (202) 737-3945
Facsimile: (202) 626-3737
gmrodruiguez@kslaw.com
aparrish@kslaw.com
jshakow@kslaw.com

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

June 1, 2021

CERTIFICATE OF SERVICE

The undersigned hereby certifies that a copy of the foregoing has been filed electronically on the 1st day of June, 2021. Notice of this filing will be sent to counsel of record for the parties by operation of the Court's electronic filing system.

/s/ Israel Dahan
Israel Dahan

IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF NEW JERSEY

NOVO NORDISK INC.

and

NOVO NORDISK PHARMA, INC.,

Plaintiffs,

v.

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

Defendants.

Civil Action No. 3:21-cv-00806
Chief Judge Freda L. Wolfson

Oral argument requested

PLAINTIFFS' COMBINED MEMORANDUM IN SUPPORT OF CROSS-MOTION FOR SUMMARY JUDGMENT AND IN OPPOSITION TO DEFENDANTS' MOTION TO DISMISS OR, IN THE ALTERNATIVE, FOR SUMMARY JUDGMENT

TABLE OF CONTENTS

TABLE OF AUTHORITIES

Cases

Statutes

Rules, Regulations, and Guidance

Other Authorities

INTRODUCTION AND SUMMARY OF ARGUMENT

The issues in this case turn on a straightforward question of statutory interpretation: Does the 340B statute require manufacturers to transfer their drugs at deeply discounted prices to for-profit commercial pharmacies? Because the answer to that question is "no," the government's December 30 decision, as well as its May 17 letter, seeking to impose that obligation exceed its lawful authority and should be struck down. Even if the Court were to conclude that the statute is ambiguous, the government can prevail only if it proves that its position reflects the only permissible reading of what the statute requires. Neither its December 30 decision nor its May 17 letter complies with the Administrative Procedure Act requirements that are mandated before an agency may impose legally binding obligations on regulated parties that are not unambiguously imposed by the statute's plain text. *See Perez v. Mortgage Bankers Ass'n*, 575 U.S. 92 (2015).

All parties agree that the relevant statutory language is as follows:

> The Secretary 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 [the statutorily required 340B ceiling price.] …. Each such 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.

42 U.S.C. § 256b(a)(1) (emphasis added). The government has not claimed that this language is ambiguous. Nor has it attempted to engage in notice-and-comment rulemaking, which is required to impose legal obligations not dictated by the statute's plain text. *But see Phar. Research & Mfrs. of Am. v. HHS*, 43 F. Supp. 3d 28, 41 (D.D.C. 2014) (explaining that Congress limited the agency's rulemaking authority under the 340B program). Instead, in both its December 30 decision and May 17 letter, the government asserts that the statutory language quoted above imposes an *unambiguous* obligation on manufacturers not only to offer their drugs to covered entities for purchase at

discounted prices but also to transfer and deliver the discounted drugs to for-profit commercial pharmacies at locations across the country.

The government is forced to argue that the statute is unambiguous because the financial and policy repercussions of forcing manufacturers to allow commercial pharmacies to participate in and profit off of the 340B program are so significant that there is no reason to think that Congress would have delegated that decision to agency officials. *See Util. Air Regulatory Grp. v. EPA*, 573 U.S. 302, 324 (2014) (Congress must "speak clearly if it wishes to assign to an agency decisions of vast economic and political significance") (quotation marks omitted). Indeed, permitting an unlimited number of for-profit commercial pharmacies to participate in the 340B program has resulted in a vast expansion of the program, with *billions* each year being transferred into the pockets of commercial pharmacies, while also making it much more difficult to police abuses of the statutory requirements. In the government's view, that result is statutorily mandated because the manufacturers' obligation to offer, and the covered entities' right to purchase, the manufacturers' drugs at discounted prices is susceptible to only one interpretation — that manufacturers have no choice but to transfer and deliver their drugs to wherever and whomever a covered entity directs. *See* ADVOP_000003 (contending that covered entities have the right to require that manufacturers deliver drugs to the "lunar surface" or "low-space orbit").

The government's position cannot be reconciled with the statute's plain text. The obligation to "offer" a product at a discounted price to covered entities does not include the much more burdensome obligation to deliver the product to for-profit commercial entities at whatever locations the covered entities demand. Under basic contract law principles, the right to *purchase* at a specified price is not a right to demand *delivery* to wherever and whomever the purchaser requests. The statute is silent on whether manufacturers must transfer discounted drugs to commercial pharmacies at a

covered entity's request. It thus leaves that decision in every instance to the discretion — a voluntary choice — of each manufacturer participating in the 340B program.

That commonsense conclusion is reinforced by other statutory provisions, as well as basic canons of construction. The statute carefully limits which entities qualify as "covered entities" entitled to participate in the 340B program, and expressly prohibits covered entities from transferring drugs to non-patients, thereby strictly restricting which entities are able to profit from the compelled sale of manufacturers' deeply discounted drugs. *See* 42 U.S.C. § 256b(a)(1), (5). Those requirements are necessary to ensure that the 340B statute serves its only legitimate purpose — helping uninsured and underinsured patients gain access to the drugs they need. If Congress had intended to expand the 340B program by billions of dollars for the financial benefit of for-profit commercial pharmacies, it would have said so in a clear and direct fashion. *See Whitman v. Am. Trucking Ass'ns*, 531 U.S. 457, 468 (2001). That is especially true given the serious constitutional concerns that arise from compelling the transfer of manufacturers' drugs for the private benefit of for-profit commercial pharmacies. That type of forced A-to-B taking has long been prohibited. *See Kelo v. City of New London*, 545 U.S. 469, 477 (2005).

Because the government's position cannot be reconciled with the statute's plain text, the Court should strike down the government's December 30 decision and May 17 letter as unlawful and contrary to law. At a minimum, however, the Court should recognize that the December 30 decision and the May 17 letter do not comply with the requirements of reasoned decision-making. *See* 5 U.S.C. § 706(2). Because the government seeks to impose a binding obligation on manufacturers that goes beyond the statute's unambiguous requirements, the government must proceed through notice-and-comment rulemaking and prove that Congress delegated it rulemaking authority to expand the 340B program. *See Kisor v. Wilkie,* 139 S. Ct. 2400, 2420 (2019) (explaining

that rules with "the force and effect of law" must comply with notice-and-comment procedures); *cf. PhRMA*, 43 F. Supp. 3d at 41 (concluding that Congress limited the agency's rulemaking authority under the 340B program). Moreover, the government has not reasonably responded to objections, acknowledged the significant change imposed by its December 30 decision and May 17 letter, or supported its new position with a reasoned explanation and substantial record evidence. *See Motor Vehicle Mfrs. Ass'n v. State Farm Mut. Auto. Ins. Co.*, 463 U.S. 29, 57 (1983).

Fighting against both the statutory text and principles of administrative law, the government wraps its arguments in very aggressive, insistent rhetoric, and claims that its December 30 decision and May 17 letter add nothing to the government's non-binding 1996 and 2010 guidance documents. But guidance documents cannot impose legal obligations that go beyond the plain statutory text, and therefore the government cannot use guidance to obtain regulatory powers that the statute does not grant. *See Christensen v. Harris Cty.*, 529 U.S. 576, 587 (2000). In any event, the agency's earlier guidance did not purport to interpret any specific statutory text or offer any analysis why manufacturers should be forced to transfer their drugs to for-profit commercial pharmacies. Until its December 30 decision, the government publicly stated that its non-binding guidance do not impose obligations on manufacturers. As a result, while the government encouraged manufacturers to voluntarily transfer drugs to for-profit commercial pharmacies, the government recognized it had no legal authority to impose that obligation. The government's new position — that the statute has always unambiguously mandated that manufacturers must transfer their drugs to an unlimited number of contract pharmacies — is flatly contrary to the entire premise of the 1996 guidance and how the 340B program operated for more than 14 years.

The government also raises various jurisdictional arguments, asserting that the December 30 decision is not final and that manufacturers should have challenged its earlier non-binding guidance,

even though the government repeatedly claimed that they had no legal consequences for manufacturers. The government's jurisdictional arguments are meritless because they depend on the conclusion that the December 30 decision merely reiterated what the statute requires. In any event, the government's position is wholly undermined by its recent May 17 letter. Under Supreme Court precedent, because Novo faces a direct threat of enforcement, it is entitled to seek, and the Court has authority to grant, declaratory and injunctive relief. *See U.S. Army Corps of Eng'rs v. Hawkes Co.*, 136 S. Ct. 1807, 1815 (2016); *Sackett v. EPA*, 566 U.S. 120, 127 (2012). The Court should exercise that authority to enforce the statutory requirements.

BACKGROUND

The 340B Statute. This case centers on the requirements of section 340B of the Public Health Service Act, which created the "340B program" in 1992. 42 U.S.C. § 256b. The purpose of the program is to ensure that indigent, uninsured, and other vulnerable patients have access to affordable care. Before Congress enacted section 340B, drug manufacturers would help vulnerable patients by voluntarily providing their drugs at reduced prices to institutions that served the needy. Turning this voluntary support into a legal mandate, the 340B statute, as amended in 2010, provides 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. *See id.* § 256b(a)(1); *see also Astra USA, Inc. v. Santa Clara Cty.*, 563 U.S. 110, 113–14 (2011) (explaining that the statute requires manufacturers to sign "Pharmaceutical Pricing Agreements" with provisions that mirror the statutory requirements). The statute defines "covered entities" — and limits manufacturers' "must offer" obligation — to certain hospitals and other safety-net providers that serve predominantly low-income and vulnerable patients. *Id.* § 256b(a)(1), (a)(4).

Congress restricted the scope of the 340B program because of the potential for abuse and the constitutional concerns that arise when government, instead of relying on general tax revenues,

forces the sale of private property to fund a public program. *See Armstrong v. United States*, 364 U.S. 40, 49 (1960) (one purpose of the Takings Clause is "to bar Government from forcing some people alone to bear public burdens which, in all fairness and justice, should be borne by the public as a whole"). Under the 340B program, hospital covered entities that purchase manufacturers' discounted drugs are permitted to provide the drugs to any of their patients — be they rich or poor — and to charge full, non-discounted prices to those patients and their insurance companies. For the vast majority of innovator drugs, the discounts range from 23.1% to more than 99.9% of the average price in the market. *See* 42 U.S.C. § 1396r-8(c); 42 U.S.C. § 256b(a)(1). As a result, the "spread" between the discounted 340B price and the regular market price is often substantial.

The profits generated through the 340B program — from buying low and selling high — are not supposed to enrich the covered entities, let alone third parties. Congress intended that covered entities would use the discounted drugs (and resulting profits) to provide better care and services to the vulnerable patients that visit their facilities. Consistent with that intent, the 340B statute not only limits which healthcare providers qualify as "covered entities," *see id.* § 256b(a)(4), it also 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). In addition, the statute requires that Secretary of the Department of Health and Human Services ("HHS") protect the program's integrity by "provid[ing] for improvements in compliance by covered entities … in order to prevent diversion" and other violations of the statutory requirements. *Id.* § 256b(d)(2)(A). Congress also limited HHS's substantive rulemaking authority, depriving the agency of any authority to expand the program's scope to impose obligations not mandated by the statute itself. *See PhRMA*, 43 F. Supp. 3d at 41.

HHS Non-binding Guidance Documents. Shortly after Congress enacted the 340B statute, certain covered entities sought HHS's permission to enter into contractual relationships with offsite pharmacies, known as "contract pharmacies." Those requests arose because some covered entities were eligible to participate in the program but lacked their own in-house, on-site pharmacies. Instead of establishing in-house pharmacies, covered entities sought HHS's permission to contract with a single outside pharmacy. They sought HHS's guidance because they knew that the statute prohibits diversion and does not grant covered entities any right to contract with outside pharmacies to accept or dispense manufacturers' deeply discounted drugs.

In 1996, HHS issued non-binding guidance addressing this issue. *See* 61 Fed. Reg. 43,549, 43,549 (Aug. 23, 1996) (ADVOP_00370). The agency announced its view that, if a covered entity lacked an in-house pharmacy, it would permit the covered entity to enter a contractual relationship with a *single outside pharmacy* to dispense outpatient drugs to the covered entity's patients. *Id*. The guidance did not identify, or purport to interpret, any provision in the 340B statute. Nor did it purport to interpret the statute to impose obligations on manufacturers to transfer their discounted drugs to contract pharmacies. To the contrary, HHS concluded that the 340B "statute *is silent* as to permissible drug distribution systems," *id*. at 43,549 (emphasis added), and it disclaimed any intent to impose obligations on manufacturers: the guidance "create[d] no new law and create[d] no new rights or duties." *Id.* at 43,550 (ADVOP_000371). HHS's guidance thus represented an exercise of enforcement discretion, a statement that the agency would not enforce the statute's diversion prohibition if a covered entity that lacked an in-house pharmacy entered into a close contractual relationship with a single outside pharmacy subject to its oversight and control. *See id.* at 43,554.

For the next fourteen years, the 340B program operated with the understanding that no covered entity would be permitted to have more than one pharmacy — either an in-house pharmacy

or a single contract pharmacy. In 2010, however, HHS issued new non-binding guidance stating for the first time that the agency would allow covered entities to enter into contractual relationships with an *unlimited* number of contract pharmacies. 74 Fed. Reg. 10,272 (Mar. 5, 2010) (ADVOP-000386). Like the 1996 guidance, the 2010 guidance did not identify or purport to interpret any statutory provision. Nor did it purport to impose any obligation on manufacturers, much less address the legal issues that would arise if the agency attempted to impose such an obligation. The 2010 guidance emphasized that it did not create any new rights or impose new obligations. *See id*. at 10,273 (ADVOP_000387) ("This guidance neither imposes additional burdens upon manufacturers, nor creates any new rights for covered entities under the law").

The Explosion in the Use of Contract Pharmacies. After HHS issued its 2010 guidance, enterprising consultants recognized that contract pharmacies could be used to turn the 340B program from a government-mandated charitable program into a money-making engine for the benefit of covered entities and large commercial pharmacies. Instead of paying pharmacies an appropriate bona fide fee for services rendered, covered entities allowed contract pharmacies to share in the "spread" generated by the forced sale of 340B drugs at discounted prices. *See* GAO, GAO-18-480, Drug Discount Program: Federal Oversight of Compliance at 340B Contract Pharmacies Needs Improvement, at 13 n.27 (2018) ("2018 GAO Report"), https://www.gao.gov/assets/700/692697.pdf (noting that the 340B program "does not impose any requirements or limitations on the fees that covered entities may pay their contract pharmacies or [third-party administrators]"). In addition, instead of serving the patients who visit their facilities and obtain drugs from their in-house pharmacies (or a closely controlled outside pharmacy), covered entities entered into contractual relationships with large commercial pharmacy chains, some with locations thousands of miles away from the covered entities and the vulnerable patients they are supposed to serve. *See id*. at 22.

These recent innovations have allowed commercial pharmacies to become major participants in and beneficiaries of the 340B program, with a recent study reporting *an increase of 4,228%* in the number of contract pharmacies between 2010 and today. *See* Aaron Vandervelde et al., For-Profit Pharmacy Participation in the 340B Program, at 4 (2020); 2018 GAO Report at 10. As the program has expanded, large for-profit commercial pharmacies have pocketed sizeable portions of the profits that Congress intended non-profit covered entities would use to help indigent patients access affordable care. *See* HHS Office of Inspector General, OEI-05-13-00431, Mem. Report: Contract Pharmacy Arrangements in the 340B Program, at 2 (2014) (ADVOP_001403) ("2014 HHS-OIG Report"). A recent study concludes that in 2020 alone, contract pharmacies retained $3.348 billion in profits as a result of 340B discounts. *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).

Studies further show that allowing contract pharmacies to participate in the 340B program has not benefitted patients. *See* PhRMA, Press Release, New Analysis Shows Contract Pharmacies Financially Gain From 340B Program with No Clear Benefit to Patients (Oct. 8, 2020). The windfalls received by commercial pharmacies have not improved services or improved patients' access to low-cost drugs. *See* Adam J. Fein, *The Federal Program That Keeps Insulin Prices High*, Wall. St. J. (Sept. 10, 2020) (explaining that "almost half the U.S. pharmacy industry now profits from the 340B program, which was designed as a narrow support to certain hospitals," while patients "don't benefit," even though manufacturers have "practically given the product away"). In fact, studies show that while the use of contract pharmacies has grown exponentially, the overall level of charitable care provided by covered entities has decreased. *See* Letter from Adam J. Fein to Hon. Lamar Alexander and Hon. Greg Walden in response to request for input on 340B drug pricing

program (Oct. 30, 2020); Adam J. Fein, *340B Program Purchases Reach $24.3 Billion—7%+ of the Pharma Market—As Hospitals' Charity Care Flatlines*, Drug Channels (May 14, 2019).

It bears emphasis that contract pharmacies do not reduce drug prices charged to patients or even make it more convenient for patients to access low-priced drugs. Hospital covered entities and their contract pharmacies are not obliged to extend 340B discounts to indigent patients. From the patient's perspective, a drug dispensed from a commercial pharmacy looks just the same as a drug dispensed from the hospital's in-house pharmacy: same copay, same deductible, same cost. Similarly, a reduction in contract pharmacy usage does not make obtaining medications less convenient for patients, who may continue to have their prescriptions filled at their nearest commercial pharmacy. The only difference — unknown to and unappreciated by the patient — is that the script will not be back-filled by the covered entity at the 340B price (and therefore will not generate the "spread" that the commercial pharmacies and covered entities pocket).

While patients have not benefitted, the extraordinary expansion in the 340B program has resulted in significant waste and abuse. As HHS has acknowledged, contract pharmacy arrangements "create complications in preventing diversion" because contract pharmacies are unable to verify patient eligibility in real-time. 2014 HHS-OIG Report at 1 (ADVOP_001403). The opportunities for unlawful distributions to non-patients and other abuses have increased because commercial pharmacies have been allowed to apply a very loose definition of when a customer is properly deemed a "patient" of a covered entity, and because the government has allowed commercial pharmacies to use what is known as a "replenishment model" for distributing 340B discounted drugs. *See* HHS, Press Release No. 2013-1, Statutory Prohibition on Group Purchasing Organization Participation, at 3 (Feb. 7, 2013); *see also* GAO, GAO-11-836, Drug Pricing:

Manufacturer Discounts in the 340B Program Offer Benefits, but Federal Oversight Needs Improvement, at 28 (2011), https://www.gao.gov/assets/gao-11-836.pdf.

Under the "replenishment" model, instead of shipping discounted drugs to a covered entity to be used with the patients who visit their facilities, the commercial pharmacies dispense 340B drugs from the same inventory as drugs dispensed to all of their other customers (and seek replenishment after the fact). The covered entity never takes title to or possession of the 340B discounted drug. Instead, after a drug is dispensed by the pharmacy to a customer out of its general inventory and the pharmacy later deems the customer to be a covered entity's "patient," the covered entity directs the manufacturer to transfer discounted drugs to the commercial pharmacy (or to facilitate the transfer through a wholesaler) in order to replenish the drugs that have already been dispensed and sold to the patient at the market price.

Transferring 340B drugs to contract pharmacies has also dramatically increased the risk of duplicate Medicaid rebate discounts, which the 340B statute also prohibits. *See* 42 U.S.C. § 256b(a)(5)(A). Under the replenishment model, requests for Medicaid reimbursement are made by the pharmacy that fills the prescription, not by the covered entity. As a result, there is no effective or comprehensive (much less timely) way to know based on publicly available information when a contract pharmacy's prescriptions are being submitted for *both* a 340B discount and a Medicaid rebate (the duplicate discounting § 256b(a)(5)(A) expressly prohibits). Even HHS has recognized that these arrangements "create complications in preventing … duplicate discounts." 2014 HHS-OIG Report at 1–2 (ADVOP_001403–04). HHS's audits have uncovered numerous violations linked to the use of contract pharmacies. *See* HRSA, *Program Integrity: FY19 Audit Results* (updated May 19, 2021).

Manufacturers' Policies. As these abuses of the 340B program multiplied, manufacturers repeatedly urged HHS to enforce the statutory requirements. HHS refused — even in the face of reports and mounting concerns raised by other government entities. *See* 2018 GAO Report; H. Comm. on Energy & Commerce, 114th Cong., Review of the 340B Drug Pricing Program, at 38 (2018); 2014 HHS-OIG Report at 2 (ADVOP_001403–04).

Because HHS abandoned its oversight role, manufacturers were forced to exercise their rights to control the sale of their drugs consistent with the statutory requirements. In 2020, certain manufacturers, including Novo, implemented policies that limit when they will honor requests that 340B-discounted drugs be transferred to for-profit commercial pharmacies. *See* Am. Compl. ¶¶ 5, 60–65 (ECF No. 40). Novo's contract pharmacy policy — which took effect January 2021 — makes clear that it will no longer indiscriminately accept hospital covered entity requests that it facilitate the transfer of 340B-covered outpatient drugs to commercial pharmacies. *See id.* ¶ 61.

In implementing its policy, Novo emphasized that it will continue to offer each and every covered entity the ability to purchase its covered outpatient drugs at or below the applicable ceiling price set by statute. 42 U.S.C. § 256b(a)(1); *see also* Am. Compl. ¶¶ 62–63. Its policy thus ensures that, as the statute requires, each covered entity is offered and able to purchase Novo's 340B drugs at deeply discounted prices. If a covered entity does not have an in-house pharmacy, Novo will allow the covered entity to designate a single outside pharmacy to dispense the drug to the covered entity's patients, and Novo will facilitate shipment to that single contract pharmacy. But Novo is no longer willing to facilitate the transfer of its drugs to an unlimited number of commercial pharmacies; nor is it willing to facilitate their extra-statutory participation in the program.

Novo's policy returns to the approach that applied for the 14 years between 1996 and 2010. Because restrictions on the use of contract pharmacies between 1996 and 2010 were lawful and

consistent with the 340B statute then, they also must be lawful now. The only change that the government has ever identified is HHS's 2010 guidance, but that non-binding guidance has no legal consequence beyond reflecting HHS's enforcement position vis-à-vis covered entities. The 2010 guidance expressly did not (and could not) create new rights or impose new obligations.

HHS's December 30, 2020 decision. If the statute unambiguously mandates that manufacturers must transfer their drugs to commercial contract pharmacies, as the government now contends, HHS would have responded to manufacturer concerns — raised repeatedly over many years — by directing them to the relevant statutory provision. But the statute does not impose any such obligation. As a result, in response to manufacturer initiatives limiting distribution to contract pharmacies, HHS initially recognized that, while it encouraged manufacturers to transfer drugs to contract pharmacies, its "current 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). In fact, the agency repeatedly took the position that it lacked authority to compel manufacturers to transfer drugs to contract pharmacies. *See* Tom Mirga, *HRSA Says Its 340B Contract Pharmacy Guidance Is Not Legally Enforceable*, 340B Report (July 9, 2020) (ADVOP_001592–93) (noting government's statement that "[t]he 2010 guidance … is not legally enforceable" against manufacturers and that HHS could not "compel[]" manufacturers "to provide 340B discounts on drugs dispensed by contract pharmacies.").

Under intense political pressure, however, HHS reversed its position and attempted to impose a new obligation on manufacturers through two final agency actions — first, establishing an administrative dispute resolution ("ADR") process and purporting to authorize ADR panels to resolve disputes over the use of contract pharmacies, and, second, issuing a decision that is

effectively binding on the ADR panels and requires manufacturers to transfer their drugs to contract pharmacies.

On December 14, 2020, after a delay of more than ten years, HHS hastily promulgated a new administrative process for adjudicating disputes between manufacturers and covered entities. *See* 42 C.F.R. § 10.20 (the "ADR rule") (ADVOP_000083). Although the statute dictates that the ADR process may be used only when manufacturers are accused of charging a covered entity too much for a discounted 340B drug, *see* 42 U.S.C. § 256b(d)(3)(A), (d)(3)(B)(iii), HHS asserted that it would use the ADR process to require manufacturers to transfer their drugs to contract pharmacies at discounted prices. The ADR process is deeply biased in favor of covered entities and raises serious constitutional concerns, as HHS purported to authorize agency officials serving on the ADR panels to resolve important policy issues outside the scope articulated in the statute and sought to insulate their decisions from de novo judicial review. A court has already preliminarily enjoined enforcement of the ADR rule, finding that HHS's actions in promulgating the ADR rule were "ambiguous, confusing, duplicitous, and misleading — the antithesis of fair notice under the" Administrative Procedure Act. Order Granting Plaintiffs' Motion for Preliminary Injunction at 23, *Eli Lilly & Co. v. Cochran*, 1:21-cv-00081 (S.D. Ind. Mar. 16, 2021), ECF No. 81.

On December 30, 2020, HHS issued a decision — labeled an "Advisory Opinion" — that for the first time ever purports to require manufacturers to facilitate the transfer of their products to for-profit commercial pharmacies. *See* HHS, Advisory Opinion No. 20-06, *Contract Pharmacies Under the 340B Program* (Dec. 30, 2020) (ADVOP_000001). The December 30 decision reflects the agency's definitive position on the use of contract pharmacies and is effectively binding on the ADR panels, ensuring that the outcome of any administrative proceeding on the use of contract pharmacies is a forgone conclusion. In its December 30 decision, HHS assumes without analysis that large

commercial pharmacy chains are acting as "agents" of covered entities, even though it cites no evidence suggesting that covered entities control the actions of or impose fiduciary obligations on commercial pharmacies. It then announces 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." ADVOP_000001.

HHS's December 30 decision concludes that because the statute requires manufacturers to "offer" their discounted drugs for "purchase" by covered entities, manufacturers also must transfer their drugs to wherever and whoever the covered entities direct. The December 30 decision offers no support for its view that a contractual right to purchase a product at a certain price also includes the right to dictate shipping directions. According to HHS, however, the "situs of delivery, be it the lunar surface, low-earth orbit, or a neighborhood pharmacy, is irrelevant." ADVOP_000003. HHS's decision does not acknowledge that commercial pharmacies are reaping billions at the expense of patients and manufacturers. Instead, the December 30 decision asserts that manufacturers concerned with abuses have no ability to control who receives their drugs or to impose any conditions on transferring their drugs to third parties; manufacturers must do whatever covered entities tell them. *See* ADVOP_000005. The December 30 decision also threatens that if manufacturers do not comply with the agency's new position, they will be subject to civil monetary penalties. *Id.*

HHS's May 17 Letter. On May 17, 2021, HHS sent a letter to Novo that threatens to impose massive penalties on Novo unless it accedes to HHS's position on the ultimate legal issue this litigation seeks to resolve. Reiterating the position adopted in its December 30 decision, the letter states that Novo has violated the 340B statute by not agreeing to transfer its discounted drugs to commercial contract pharmacies. The letter threatens that if Novo does not "immediately" capitulate

and begin transferring "its covered outpatient drugs at the 340B ceiling price" to commercial pharmacies, then HHS may seek to impose substantial civil monetary penalties. The government contends that the May 17 letter is separate action from its December 30 decision, but it cannot deny that the letter threatens to enforce against Novo the same legal obligation that the December 30 decision seeks to impose on manufacturers in general.

LEGAL STANDARD

Under the Administrative Procedure Act ("APA"), a "reviewing court shall … hold unlawful and set aside agency action, findings, and conclusions found to be" either (1) "arbitrary, capricious, an abuse of discretion, or otherwise not in accordance with law"; (2) "contrary to constitutional right, power, privilege, or immunity;" (3) "in excess of statutory jurisdiction, authority, or limitations, or short of statutory right;" or (4) "without observance of procedure required by law." 5 U.S.C. § 706(2). Summary judgment is appropriate if the party challenging government action shows that the action is inconsistent with these requirements of reasoned decision-making. *Fla. Power & Light Co. v. Lorion*, 470 U.S. 729, 744–45 (1985). The government's motion to dismiss is governed by Rule 12(b)(6). *Ashcroft v. Iqbal*, 556 U.S. 662, 678 (2009).

ARGUMENT

I. The December 30 Decision and May 17 Letter Exceed HHS's Lawful Authority Because They Seek to Impose Obligations Beyond the Statutory Requirements.

HHS can prevail in this case only if can show that the statute unambiguously imposes an affirmative obligation on manufacturers to transfer their drugs to for-profit commercial pharmacies. HHS has not met and cannot meet that burden. The statute requires only that manufacturers "offer" their drugs at discounted prices for "purchase" by covered entities. The obligation to offer a drug for sale at a discounted price does not encompass an additional obligation to transfer and deliver the

drug to wherever and whomever the covered entity demands. That conclusion is reinforced by the statute's structure and purpose, basic canons of construction, and principles of constitutional law.

A. The 340B Statute Does Not Require Manufacturers to Transfer Their Discounted Drugs to Commercial Pharmacies.

When asked to resolve a question of statutory interpretation, the court must begin "with the text of the statute." *Hawaii v. Office of Hawaiian Affairs*, 556 U.S. 163, 173 (2009). The court applies "traditional tools of statutory construction," considering the statute's text, structure, and purpose. *Nat. Res. Def. Council, Inc. v. Daley*, 209 F.3d 747, 752 (D.C. Cir. 2000). Where, as here, the text is clear, the inquiry "ends there as well." *Nat'l Ass'n of Mfrs. v. Dep't of Def.*, 138 S. Ct. 617, 631 (2018).

1. The 340B Statute's Text, Structure, and Purpose Confirm That Congress Limited the Obligations Imposed on Manufacturers.

The 340B statute's plain text requires manufacturers to enter into pharmaceutical pricing agreements with HHS and, under the terms of those agreements, 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). The 340B statute in turn grants covered entities a right that mirrors manufacturers' obligation, stating that the "amount required to be paid" for covered outpatient drugs "purchased by a covered entity" shall not "exceed" the ceiling price. *Id.* That is the sum total of the statute's language regarding manufacturers' obligation to offer drugs at discounted prices and covered entities' right to purchase manufacturers' drugs at those prices. Neither the statute nor the pharmaceutical pricing agreement says anything about contract pharmacies. Neither the statute nor the agreement imposes any third-party delivery obligation on manufacturers. And neither the statute nor the agreement prohibits manufacturers from refusing requests by covered entities to transfer their drugs to for-profit commercial pharmacies.

The statute's plain text is reinforced by other statutory provisions, its structure, and express purpose. Perhaps most importantly, the statute strictly limits which entities are eligible to participate in the 340B program and obtain access to manufacturers' drugs. *See* 42 U.S.C. § 256b(a)(4). The statute enumerates 17 particular kinds of "covered entities" and conspicuously omits any catchall provision that would allow this list to be expanded. *See 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" (quoting *United States v. Vonn*, 535 U.S. 55, 65 (2002)). The statute's exhaustive list of "covered entities" includes only those hospitals, clinics, and health care providers that predominantly serve low-income and uninsured patients. *See id.*; *see Robinson v. Napolitano*, 554 F.3d 358, 365 (3d Cir. 2009) (applying *expressio unius* canon). No one has ever suggested that for-profit commercial pharmacies qualify as "covered entities." And for good reason: Congress designed the 340B program to include only certain "providers of safety net services to the poor," *PhRMA*, 138 F. Supp. 3d at 34 (quoting *Astra*, 563 U.S. at 113), not commercial pharmacies that serve their shareholders and profit from manufacturers' discounts.

The statute also prohibits the sale or transfer of drugs to anyone who is not a patient of a covered entity. The statute states that "a covered entity shall not resell or otherwise transfer" 340B drugs to any "person who is not a patient of the entity." 42 U.S.C. § 256b(a)(5)(B). Because covered entities are prohibited from transferring manufacturers' discounted drugs to non-patients, they cannot circumvent that restriction by forcing manufacturers to transfer the drugs for them. *See Altamont Gas Transmission Co. v. FERC*, 92 F.3d 1239, 1248 (D.C. Cir. 1996) (recognizing that an agency may not "attempt[] to do indirectly what it could not do directly"). Although HHS has not enforced this prohibition against covered entities when they use contract pharmacies, that exercise

of enforcement discretion does not change the statutory text or allow it to be rewritten to impose an extra-statutory obligation on manufacturers. *See Util. Air Regulatory Grp.*, 573 U.S. at 328 (reaffirming "core administrative-law principle that an agency may not rewrite clear statutory terms to suit its own sense of how the statute should operate"). Congress prohibited the transfer of drugs to ensure (1) that covered entities used the drugs for the benefit of needy patients that visit their facilities, and (2) that third parties cannot participate in the 340B program and benefit at the expense of patients and manufacturers.

These statutory provisions are further reinforced by an important canon of construction: Requiring manufacturers to transfer their discounted drugs to for-profit commercial pharmacies is such a massive expansion of the 340B program — a transfer of billions of dollars each year — that it would be improper to infer that Congress intended that result absent clear statutory language. *See id.* at 324; *Gonzales v. Oregon*, 546 U.S. 243, 267 (2006). As noted above, the statute requires only that manufacturers "offer" their drugs to covered entities for "purchase" at a discounted price. 42 U.S.C. § 256b(a). That would be an uncommonly cryptic and obscure way for Congress to require manufacturers to transfer their drugs to for-profit 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*, 531 U.S. at 468.

2. The Government's Textual Arguments Cannot Be Reconciled with the Statute's Plain Text.

The government has not identified — and cannot identify — any statutory provision that requires manufacturers to transfer their deeply discounted drugs to commercial pharmacies. The government's position depends on an extraordinary exercise of textual contortionism: According to the government, the requirement that HHS enter into agreements with drug manufacturers "under

which the amount required to be paid" for certain drugs "*purchased by a covered entity*" does not exceed the ceiling price, 42 U.S.C. § 256b(a)(1) (emphasis added), necessarily requires that manufacturers transfer their drugs to wherever and whomever a covered entity dictates. That argument is meritless.

First, as a matter of linguistics and basic contract law, no one would reasonably conclude that an obligation to "offer" a product at a discounted price (and the buyer's right to "purchase" at that price) also imposes an obligation to deliver the product to wherever and whoever the buyer demands. Under well settled contract law, the price of a product and the requirements for delivering it are separate and distinct. *See* U.C.C. § 2-308 (explaining that "[u]nless otherwise agreed," the "place for delivery of goods is the seller's place of business"); *see also In re Valley Media, Inc.*, 226 F. App'x 120, 122–23 (3d Cir. 2007) (rejecting argument that the terms "sale" and "delivery" are equivalent, and recognizing that "delivery" has a well-defined meaning). Where, as here, the costs of delivery are so significant, it is particularly unreasonable to graft an unlimited delivery obligation onto the statutory obligation to "offer" for "purchase" at a specified price.

The December 30 decision contends that the "situs of delivery, be it the lunar surface, low-earth orbit, or a neighborhood pharmacy is irrelevant." ADVOP_000003. Given the costs involved, HHS's analogy to the space program may be apt. But that attempt at rhetorical flourish only highlights how far HHS has departed from the statutory text. In common parlance, no one would argue that an obligation to offer a product at a discounted price also imposes a requirement to deliver the product to the moon or wherever else the purchaser may request. When a supermarket offers a discounted price on a product to anyone who cuts a coupon from their local paper, the coupon holder does not gain a right to demand delivery to their preferred location, much less a right to demand that the product be shipped to someone else.

Second, contrary to the government's unsupported assertions, Novo's refusal to transfer its drugs to an unlimited number of commercial pharmacies does not prevent covered entities from acquiring and dispensing 340B discounted drugs to their patients. *See* HHS Br. 7–8 (ECF 37). Under Novo's policy, covered entities are able to purchase Novo's drugs at the 340B discounted price in whatever quantities they need. No covered entity is denied its statutory right to purchase as much of Novo's drugs at the discounted price as it desires. Consistent with 14 years of practice between 1996 and 2010, Novo will ship its drugs to either the covered entity's in-house pharmacy or, if it lacks an in-house pharmacy, to one outside pharmacy of the covered entity's choosing. In addition, Novo will continue — as it has under the 2010 guidance — voluntarily shipping drugs to contract pharmacies in its discretion in situations where the risks of abuse are less significant.

The government draws an inapt analogy to using a courier service. *See* HHS Br. 32–33. Unlike a hypothetical courier, commercial pharmacies are not receiving a commercially reasonable, bona fide fee for the dispensing services they provide. Instead, they are sharing in the profits (the "spread") that results from purchasing manufacturers' drugs at deeply discounted prices and then selling them at much higher, non-discounted prices. The outsized profits they pocket do not benefit the patients the 340B program is designed to serve. Moreover, as noted above, the use of contract pharmacies has dramatically increased the problems of prohibited duplicate discounts and sales to non-patients. If couriers were to raise the same problems, manufacturers would be well within their rights to refuse to allow couriers to profit from the 340B program.

The government's misplaced courier analogy also does not capture how commercial pharmacies operate. Contract pharmacies keep no 340B product in stock, but instead dispense drugs from their own supply, assert that a customer qualifies as a patient of a covered entity, and then request that their supply be "replenish[ed]" *post hoc* at 340B prices. *See* 2014 HHS-OIG Report at

5. That acknowledged replenishment practice means that, although contract pharmacies may not formally make the purchases, they drive the transactions. Indeed, under the replenishment model, covered entities never take title to or possession of the discounted drugs. That is inconsistent with Congress' intent that only covered entities should participate in the 340B program. Congress gave no indication that by granting covered entities the right to "purchase" drugs at discounted prices, it also intended to impose a far more burdensome obligation on manufacturers to transfer their drugs to for-profit commercial pharmacies.

Third, the government suggests that because the statute is silent on how a covered entity may distribute discounted drugs to its patients, manufacturers are not permitted to impose conditions that are not expressed in the statute. *See* ADVOP_000002. That ignores who owns the drugs and the constitutional limits on the executive branch when regulating private rights. The discounted drugs belong to manufacturers, which may sell or distribute them however they desire unless otherwise restricted by law. Similarly, the only rights that covered entities have with respect to manufacturers' drugs are those granted by statute. If the statute is silent, manufacturers' rights to control the sale and distribution of their own property prevail over any interests covered entities might have in requesting that 340B drugs be delivered to commercial pharmacies. In other words, while the government is correct that neither the agency or a private actor can impose obligations "beyond what is specifically set forth by Congress" in the law, *Radovich v. Nat'l Football League*, 352 U.S. 445, 454 (1957), that principle does not help the government. *See* ADVOP_000002. It is the government, not manufacturers, that is trying to impose new obligations that go beyond what Congress intended.

Fourth, reports show that the recent growth in contract pharmacies has resulted in billions being taken for the benefit of for-profit, commercial pharmacies. There is no evidence — and certainly no record evidence — that any of this growth benefits patients. In fact, the evidence is just

the opposite. *See* Sunita Desai & J. Michael McWilliams, *Consequences of the 340B Drug Pricing Program*, 378 New Eng. J. Med. 539, 539 (2018) (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"). An interpretation that so drastically undermines the purposes of the statute "provides strong indication that something in [that] interpretation is amiss." *Freeman v. Quicken Loans, Inc*., 566 U.S. 624, 632 (2012); Antonin Scalia & Bryan A. Garner, Reading Law: The Interpretation of Legal Texts 167 (2012) (noting that courts should "consider the entire text, in view of its structure and the physical and logical relation of its many parts").

B. The Government's Extratextual Arguments Are Meritless and Provide No Basis for Rewriting the Statute's Plain Text.

Because the statute does not support the government's position, it relies heavily on extratextual arguments. It insists that it has interpreted the statute for 25 years — in both its 1996 and 2010 non-binding guidance — to impose an obligation on manufacturers to transfer discounted drugs to commercial pharmacies. It also suggests that imposing a new transfer obligation on manufacturers is insignificant because the for-profit commercial pharmacies serve as "agents" of the covered entities. Both arguments are meritless.

1. The Government's Guidance Documents Do Not and Cannot Change the Statutory Requirements.

The government asserts that HHS has "long understood the 340B statute to direct drug makers to sell discounted drugs to *covered entities* regardless [of] whether they use contract pharmacies for distributing those drugs." HHS Br. 31. Pointing to isolated statements made in its 1996 and 2010 guidance, and a complaint filed by an industry association in 1996, the government argues that its purported long-standing position on what the statute requires should carry weight. *See* HHS Br. 16 n.4 (arguing that "the agency's position on the statutory question has not changed

since the 1996 guidance was issued"). That is wrong as a matter of law, and contrary to what the guidance documents actually say, as well as other statements made by the government.

Until its December 30 decision, HHS repeatedly emphasized that it had no authority to force manufacturers to honor contract pharmacy arrangements. For example:

- On July 8, 2020, HHS told 340B Health "that although the agency strongly encourages all manufacturers to sell 340B priced drugs to covered entities through contract pharmacy arrangements, HRSA's current authority to enforce certain 340B policies … 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 Commn'cns Director M. Kramer to 340B Health (quotation marks omitted)).

- On July 9, 2020, HHS publicly stated in a 340B-focused publication 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." ADVOP_001592–93.

- In June and August, 2020, in response to contract pharmacy initiatives adopted by manufacturers Eli Lilly and AstraZeneca, the government explained that its "contract pharmacy advice" was not set out in "binding regulations" and stated that it was "considering" whether there was a violation of the 340B statute, while "encourag[ing]" the manufacturers to "reconsider [their] position." ADVOP_001053–54, 001057, 001098, _001110–1111.

- In December 2020, the Government Accounting Office issued a report noting that HHS had stopped auditing contract pharmacies for diversion violations "because the 340B statute does not address contract pharmacy use." GAO, GAO-21-107, HHS Uses Multiple Mechanisms to Help Ensure Compliance With 340B Requirements, at 15–16 (2020), https://www.gao.gov/assets/gao-21-107.pdf.

None of these statements are consistent with the government's revisionist history. To the contrary, the statements are inexplicable if HHS had for 25 years interpreted the statute to impose a binding obligation on manufacturers to transfer discounted drugs to commercial pharmacies.

In any event, it is axiomatic that an agency cannot change statutory requirements through non-binding guidance documents. *See* 5 U.S.C. § 553(b)(3)(A) (exempting non-binding "interpretive rules [and] general statements of policy" from rulemaking requirements). By definition, a guidance document "lack[s] the force of law" and cannot create or change substantive

rights and obligations. *Christensen*, 529 U.S. at 587. Because a guidance document cannot compel a regulated entity to do anything, it has "no legal impact" and regulated parties are "free to ignore it" or, if they prefer, to "voluntarily conform." *Nat'l Mining Ass'n v. McCarthy*, 758 F.3d 243, 253 (D.C. Cir. 2014) (quotation marks omitted).

An agency cannot gain extra-statutory powers through a form of adverse possession after issuing guidance. To the contrary, as the Department of Justice's own Justice Manual makes clear, enforcement actions "brought by the Department must be based on violations of applicable legal requirements, not mere noncompliance with guidance documents issued by federal agencies, because *guidance documents cannot by themselves create binding requirements that do not already exist by statute or regulation*." Justice Manual, Limitation on Use of Guidance Documents in Litigation, ¶ 1-20.100 (2018) (emphasis added) (explaining that the Department "should not treat a party's noncompliance with a guidance document as itself a violation of applicable statutes or regulations"). Accordingly, even if the government were correct in its description of the 1996 and 2010 guidance, it would make no difference. The statute is controlling.

But the government is not correct. Its position is flatly inconsistent with the entire premise of its 1996 guidance. As HHS admitted in that document, "[the 340B] statute *is silent as to permissible drug distribution systems*." 61 Fed. Reg. at 43,549 (emphasis added). Because the statute is silent, HHS permitted covered entities without in-house pharmacies to use a *single* contract pharmacy. That position would have been blatantly unlawful if the government's position now were correct. If the statute unambiguously imposed an affirmative obligation on manufacturers to accept covered entity requests to transfer drugs to an *unlimited* number of contract pharmacies, the government would have had no business limiting covered entities to *only one* contract pharmacy. To accept the government's current position, the Court must conclude that the 1996

guidance — which governed the 340B program for more than fourteen years — imposed restrictions on covered entities that contravened what the government now contends is an unambiguous statutory requirement. There is no reason to embrace such a far-fetched conclusion.

The government's description of its guidance is simply not accurate. If the government were correct that the 1996 and 2010 guidance recognized a mandatory obligation for manufacturers to serve unlimited contract pharmacies, there would have been no need for its December 30 decision (or its May 17 letter). HHS would have simply referred manufacturers and covered entities to the statute and its earlier guidance. But reading the guidance documents shows that the government is not fairly describing their content. Both the 1996 and 2010 guidance are focused on *covered entities* and whether they would be permitted to use contract pharmacies. Neither guidance purports to interpret a statutory provision or meaningfully addresses manufacturers' obligations. Both guidance documents were issued before Congress enacted the statutory language — the "must offer" obligation — that is the focus of this case. And neither guidance contains any of the analysis that appears in the December 30 decision or its May 17 letter. While the December 30 decision and the May 17 letter both read like "a ukase" — they "command[], … require[], … order[], … dictate[]" — the earlier guidance documents are much different in both tone and focus. *Nat'l Mining*, 758 F.3d at 252.

To be sure, the government highlights language in the 1996 guidance that it says supports its position. *See* HHS Br. 3. But the language merely states that a manufacturer must "sell [its] drug at the discounted price" even if a covered entity "directs the drug shipment to its contract pharmacy." 61 Fed. Reg. at 43,549–50. That ambiguous language — written in the passive voice — confirms that manufacturers must offer their drugs at discounted prices. It is unaccompanied by any analysis of the statute's provision to suggest that the agency has authority to force manufacturers to do

anything beyond selling their drugs to covered entities at the discounted price. The only plausible interpretation of the earlier guidance is that they are what they purport to be — *non-binding* guidance that reflect the government's views on how it intended to exercise its enforcement discretion in response to covered entity requests to use contract pharmacies.

Nothing in the 1996 lawsuit brought by an industry association changes that analysis. The document, which was filed before HHS issued its 1996 guidance, is not part of the administrative record and therefore cannot be relied on by the government to support its decision. *See Christ the King Manor, Inc. v. Sec'y HHS*, 730 F.3d 291, 305 (3d Cir. 2013) (court's review is limited to the "administrative record already in existence before the agency, not some new record made initially in the reviewing court or post-hoc rationalizations" made by counsel) (quotation marks and alterations omitted). The allegation quoted from the complaint was made on "information and belief" and, notably, the government has failed to produce the answer it filed in response, which presumably disputed the allegations on which the government now seeks to rely (because of pandemic restrictions and the age of the litigation, Novo has been unable to obtain a copy). Moreover, the complaint was dismissed by stipulation without prejudice.

It is therefore inappropriate to draw inferences from allegations that cannot be put in context. But, in all events, the allegations in a complaint cannot change the statutory requirements. The burden is still on the government to identify an unambiguous statutory provision that requires manufacturers to transfer their drugs to an unlimited number of commercial pharmacies. The materials cited by the government do not help its position, because the statements made in the complaint and attached letter occurred in the context of HHS permitting covered entities that lacked an in-house pharmacy to use a single contract pharmacy. HHS Br., Exs. 1, A–D. The letter says nothing about the circumstances of this case, the massive growth in the use of contract pharmacies,

the evidence of program abuse that occurs in the commercial contract pharmacy system, or the fact that contract pharmacies are sharing in the profits generated by the 340B program. There is no dispute that, under both the 1996 guidance and Novo's policy, every covered entity that desires to purchase drugs at the 340B price can do so (even those lacking an in-house pharmacy).

2. The Government's Agency Theory Is Contrary to the Statute.

HHS's agency argument is also unavailing. Even if contract pharmacies act as agents for covered entities (which they do not), their status as agents is irrelevant to whether manufacturers are statutorily obligated to transfer their drugs to wherever the covered entities dictate.

HHS's "agency" theory is inconsistent with the statutory text. As with its careful definition of covered entities, the 340B statute precisely specifies when agency-like relationships are permitted. *See* 42 U.S.C. § 256b(d)(3)(B)(vi) (referring separately to "associations or organizations representing the interests of [] covered entities," rather than simply calling them "covered entities"); *id.* § 256b(d)(1)(B)(v) (same for "wholesalers"); *id.* § 256b(d)(2)(B)(iv) (same for "distributors"). If Congress had wanted to allow for-profit pharmacies to act broadly as "agents" of covered entities, it knew how to say so. The statute's precise language confirms that contract pharmacies are not among the statute's contemplated "agents." Contract pharmacies are retailers, not "wholesalers" or "distributors." Nor are they organizations "of which the covered entities are members" that represent the interests of covered entities. Contract pharmacies are private, for-profit businesses that represent their own interests and have no membership-style affiliation with covered entities.

The government contends that "the relationship between" contract pharmacies and covered entities "generally functions like a principal-agent relationship," HHS Br. 32, but it cites no record evidence to support that sweeping conclusion. It certainly makes no showing that covered entities exercise control over commercial pharmacies or that commercial entities are acting in a fiduciary capacity, fundamental criteria of a principal-agent relationship. *See* Restatement (Third) of Agency

§ 1.01, cmt. f (2006) ("essential element" of an agency relationship is "the principal's right to control the agent's actions"); *see also Appollo Techs. Corp v. Centrosphere Indus. Corp.*, 805 F. Supp. 1157, 1195 (D.N.J. 1992) (noting principle that an "agency is a fiduciary relationship" where the agent acts on the principal's behalf, subject to its control, and only for its benefit).

Under the 1996 guidance, it may have been reasonable to assume that a single outside pharmacy would serve as an agent because it would be closely controlled by the covered entity and was intended to function the same as an in-house pharmacy. But that assumption does not apply in the "multiple contract pharmacy" situation. Forcing manufacturers without limitation to transfer their drugs to an unlimited number of commercial pharmacies undermines the 340B statute's basic structure. It is a fundamental principle of statutory interpretation that statutes must not be interpreted in ways that are "inconsisten[t] with the design and structure of the statute as a whole," *Univ. of Tex. Sw. Med. Ctr. v. Nassar*, 570 U.S. 338, 353 (2013). Under the government's "agency" approach, however, the covered entity does nothing more than lend its name to the prescription, which means that a covered entity could claim entire institutions that are not covered entities are acting as their purported "agents," undermining the statutory limits on covered entities and diversion.

C. The Government's Position Raises Serious Constitutional Concerns.

The government's new position should also be rejected because it would render the statute unconstitutional. *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). As noted above, commercial pharmacies are pocketing the profits resulting from the sale of manufacturers' drugs. 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); *Reagan v. Farmers' Loan & Tr. Co.*, 154 U.S. 362, 399, 410 (1894); *Calder v. Bull,* 3 U.S. (3 Dall.) 386, 388 (1798) (op. of Chase, J.). Indeed, private use takings

are always unconstitutional, since "[n]o amount of compensation can authorize such action." *Lingle v. Chevron U.S.A. Inc*., 544 U.S. 528, 543 (2005). Yet that is exactly what the December 30 decision and May 17 letter require: They force Novo to give the outpatient drugs it manufacturers to for-profit retail chains at sub-market prices. And they do so for the pharmacies' *private use — i.e.*, they get to keep the money — not for one of the public uses that the Constitution recognizes.

The 340B program raises concerns under the Takings Clause because, instead of relying on general tax revenues, the program is funded entirely by drug manufacturers. *See Armstrong*, 364 U.S. at 49 (one purpose of the Takings Clause is "to bar Government from forcing some people alone to bear public burdens which, in all fairness and justice, should be borne by the public as a whole"). It operates as a classic take-and-transfer scheme, requiring manufacturers to provide their drugs to covered entities at confiscatory prices, and then permitting covered entities to sell the drugs or seek reimbursement at market prices. *See Calder*, 3 U.S. at 388 ("It is against all reason and justice" to presume that the legislature has been entrusted with the power to enact "a law that takes property from A and gives it to B"); *Horne v. Dep't of Agric*., 576 U.S. 350, 352 (2015).

The government asserts that these constitutional concerns do not apply because (1) any taking under the 340B program purportedly satisfies the Fifth Amendment's "public use" requirement because it helps patients afford costly medications, and (2) the manufacturers voluntarily participate in the 340B program. HHS Br. 34–37. Neither argument is persuasive, let alone supported by the administrative record.

First, the government offers no explanation why forcing manufacturers to transfer drugs to commercial pharmacies furthers any justifiable public purpose. The government simply assumes that it does, despite evidence showing that contract pharmacies are receiving a windfall in private benefits. The government nonetheless argues that the forced transfer serves a public use because it

"benefit[s] both [uninsured and under-insured] patients." HHS Br. 38. Putting to one side the evidence demonstrating that patients do not benefit from contract pharmacy participation in the 340B program, the government's position stretches the term "public use" far beyond what the Constitution permits. Even in *Kelo v. City of New London*, 545 U.S. 469 (2005), the most expansive interpretation of the Takings Clause, the Court not only reaffirmed that "the sovereign may not take the property of *A* for the sole purpose of transferring it to another private party *B*, even though *A* is paid just compensation," *id*. at 477, but also made clear that it would not have upheld the taking under the Fifth Amendment had the taking benefitted "a particular class of identifiable individuals" rather than the public at large, *id*. at 478 (quotation marks omitted). That dooms the government's position. Giving contract pharmacies Novo's property does not abate some public nuisance; HHS is indifferent about whether the contract pharmacies keep a substantial portion of the money. It follows that the Court should not read the statute to authorize unconstitutional private wealth transfers of the kind the December 30 decision and May 17 letter require, since "[n]o amount of compensation can authorize such action." *Lingle*, 544 U.S. at 543. As "[a] purely private taking," the December 30 decision and May 17 letter "serve no legitimate purpose of government" and are "void." *Haw. Hous. Auth. v. Midkiff*, 467 U.S. 229, 245 (1984). They should therefore be set aside as "contrary to constitutional right." 5 U.S.C. § 706(2)(B).

The serious constitutional concerns raised by the 340B program explain why the 340B statute requires a close nexus between its only legitimate public purpose — helping vulnerable patients — and the enumerated entities entitled to gain access to manufacturers' drugs at deeply discounted prices. *See Nollan v. Cal. Coastal Comm'n*, 483 U.S. 825, 837 (1987) (noting that when government imposes a regulatory exaction as a condition of receiving a government benefit, the exaction must have a sufficient nexus to a legitimate public purpose). The statute's careful limits

on which entities may participate in the program, and the restriction on transfers to non-patients, are essential to keeping the statute within constitutional bounds. In contrast, forcing manufacturers as a condition of participating in the program to transfer their drugs at confiscatory prices to commercial pharmacies is a bridge too far.

Second, there is no merit to the government's argument that the constitutional concerns should be overlooked because Novo has "voluntarily" participated in the 340B program. The agreement Novo signed with HHS makes clear that "[n]othing in the Agreement shall be construed as a waiver or relinquishment of any legal rights of the Manufacturer or the Secretary under the Constitution." Pharm. Pricing Agreement § VII(f) (2019) (ADVOP_000052). It makes no sense to say that Novo assented to HHS's current (flawed) position on the statute's requirements when it joined the 340B program; after all, Novo has never "voluntarily" participated in the program with an unconstitutional requirement to transfer its drugs to commercial contract pharmacies.

The government argues that if Novo does not like the new extra-statutory requirements, Novo should simply cease participating in the 340B program. *See* HHS Br. 36. The unconstitutional conditions doctrine forecloses that argument. That doctrine "vindicates the Constitution's enumerated rights by preventing the government from coercing people into giving them up" to obtain a benefit, including the right to retain one's own property unless properly taken by the government (*i.e.*, taken for a public purpose and reimbursed). *Koontz v. St. Johns River Water Mgmt. Dist.*, 570 U.S. 595, 604 (2013). That a party could simply reject the government's offer is irrelevant. *Dolan v. City of Tigard*, 512 U.S. 374, 385–86 (1994) (purported "voluntariness" made no difference to the Court where it "forced her to choose between the building permit and her right under the Fifth Amendment to just compensation for the public easements.").

The "choice" the government has put to Novo has all the hallmarks of an "[e]xtortionate demand[]," in clear violation of the unconstitutional-conditions doctrine. *Koontz,* 570 U.S. at 605. The December 30 decision and May 17 letter purport to require, as a condition of continued participation in the 340B program, that manufacturers charge below-market (and often below-cost) prices for their drugs that are re-sold at market, non-discounted prices by for-profit retailers. *See* ADVOP_000001. If manufacturers will not agree to provide discounts to for-profit retailers, they will lose access to coverage and reimbursement under Medicare and Medicaid, trillion-dollar programs that provide a huge share of all drug manufacturers' revenues. Such a "financial 'inducement' … is much more than 'relatively mild encouragement' — it is a gun to the head." *Nat'l Fed. of Indep. Bus. v. Sebelius*, 567 U.S. 519, 581 (2012). And whether applied to states seeking to protect their constitutional federalism interests or to private entities seeking to protect their constitutional property interests, the Constitution forbids the government from "using financial inducements to exert a 'power akin to undue influence.'" *Id*. at 577 (quoting *Steward Mach. Co. v. Davis*, 301 U.S. 548, 590 (1937)).

In short, the government cannot condition pharmaceutical manufacturers' participation in Medicaid on allowing for-profit pharmacy chains to take hundreds of millions of dollars straight out of their pockets, with no regard for public use. If Congress wants to levy taxes and then appropriate funds to subsidize CVS and Walgreens, it can do so — subject to the constraints of the Constitution and re-election. But in the absence of such taxing and spending legislation, a federal agency cannot force massive private wealth transfers, with no reasonable nexus to the only legitimate public purpose (here, helping needy patients) as a condition of participation in public programs.

II. The December 30 Decision and May 17 Letter Violate the Requirements of Reasoned Decision-making.

Because the government is unable to cite any statutory provision that imposes an unambiguous obligation on manufacturers to transfer their drugs to commercial pharmacies, the Court can and should strike down both the December 30 decision and May 17 letter as exceeding HHS's lawful authority. Because HHS is a "creature of statute," *Michigan v. EPA*, 268 F.3d 1075, 1081 (D.C. Cir. 2001), it has no valid power to act "unless and until Congress confers power upon it," *Wabash Valley Power Ass'n v. Rural Electrification Admin.*, 988 F.2d 1480, 1486 (7th Cir. 1993). "In the absence of statutory authorization for its act, an agency's '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*, 268 F.3d at 1081).

Even if the Court were to conclude that the government's position is not contrary to the statute's plain text, it would still have to strike down the December 30 decision and the May 17 letter. HHS has not complied with the APA's procedural mandates or the requirements of reasoned decision-making.

A. The December 30 Decision and May 17 Letter Are Procedurally Invalid.

It is well-established that agencies must comply with the APA's notice-and-comment procedure before issuing a "legislative rule." *Kisor,* 139 S. Ct. at 2420; *Perez*, 575 U.S. at 96, 101. "[L]egislative rules" are those that "'create new law, rights, or duties,'" *Metro. Sch. Dist. v. Davila*, 969 F.2d 485, 489 (7th Cir. 1992) (quoting *United Techs. Corp. v. EPA*, 821 F.2d 714, 718 (D.C. Cir. 1987)), and are subject to judicial review in federal court, *Nat. Res. Def. Council v. EPA*, 643 F.3d 311, 320–21 (D.C. Cir. 2011). To issue a valid rule, an agency "shall … publish[]" "[g]eneral notice of proposed rulemaking" "in the Federal Register," and "give interested persons an opportunity to participate in the rule making through submission of written data, views, or

arguments." 5 U.S.C. § 553(b)(3), (c). As the Supreme Court made clear in *Azar v. Allina Health Services*, "the agency overseeing Medicare can't evade its notice-and-comment obligations for new rules that bear the force and effect of law by the simple expedient of call[ing] them mere statements of policy." 139 S. Ct. 1804, 1811 (2019) (quotation marks omitted). Just as the agency could not evade the APA in *Allina* by denying the legal consequences of the challenged rule, the agency cannot evade the APA by pretending that the December 30 decision and May 17 letter do not seek to impose new obligations on manufacturers.

The government asserts that its Decision 30 decision is not a legislative rule because it purportedly does not "alter legal rights" and merely explains the agency's interpretation of the statutory phrase "purchased by." HHS Br. 22–23. But that assertion cannot withstand even minimal scrutiny. "A key feature of [interpretive] rules is that … they are not supposed to … bind private parties." *Kisor*, 139 S. Ct. at 2420. Here, however, December 30 decision itself "evinces the agency's intent to speak with the force of law." *Nat. Res. Def. Council v. Wheeler*, 955 F.3d 68, 83 (D.C. Cir. 2020). The December 30 decision unequivocally changed the agency's position that requiring manufacturers to provide contract pharmacies with 340B prices was legally unenforceable — its position until December 20, 2020 — and converted it into a mandate that manufacturers must follow or else face binding judgments from ADR panels (or even HHS itself) commanding them to do so. There can be no doubt that the December 30 decision was intended to "bind private parties" in an immediate and immediately consequential way. *See Hoctor v. U.S. Dep't of Agric.*, 82 F.3d 165, 171 (7th Cir. 1996) (noting the substantial public interest in notice-and-comment rulemaking). Indeed, that conclusion is only reinforced by the May 17 letter, which directly threatens Novo to comply "immediately" with the government's position or face potentially massive civil penalties.

Contrary to the government's assertions, the new obligation that the December 30 decision and May 17 letter seek to impose is a classic example of a legislative rule. The December 30 decision requires for the first time that manufacturers transfer 340B discounted drugs to contract pharmacies; it can be the basis of an action brought by covered entities in the ADR process; and it is viewed as binding by the agency itself. *See Am. Mining Cong. v. Mine Safety & Health Admin.*, 995 F.2d 1106, 1112 (D.C. Cir. 1993) (rule is "legislative" if the absence of the rule there would not be an adequate basis for enforcement action); *see also NRDC*, 643 F.2d at 321. Indeed, both the December 30 decision and May 17 letter are replete with language to that effect. The government has proclaimed that "a drug manufacturer in the 340B Program is *obligated* to deliver its covered outpatient drugs to those contract pharmacies," and it makes plain that "manufacturers *may not refuse* to offer the ceiling price" for contract pharmacy sales (so long as the tenuous "agency" condition is met). ADVOP_000008 (emphases added); *see also* Press Release, HHS, HHS Releases Advisory Opinion Clarifying that 340B Discounts Apply to Contract Pharmacies (Dec. 30, 2020) ("Through the new advisory opinion, HHS has clarified that drug manufacturers *must provide* 340B discounts when a contract pharmacy is acting as an agent of a covered entity[.]" (emphasis added)).

B. The December 30 Decision and May 17 Letter Are Arbitrary and Capricious.

The test for determining whether an agency's action is arbitrary and capricious is well-settled. The APA requires an agency to "examine the relevant data," *FCC v. Fox Television Stations, Inc.*, 556 U.S. 502, 513 (2009), consider important aspects of the problem its regulations implicate or create, and "articulate a satisfactory explanation for its action," *Motor Vehicle Mfrs.*, 463 U.S. at 43. Both the December 30 decision and the May 17 letter fail these requirements in every respect.

First, the government has not adequately explained how the "agency" theory that serves as the foundation of its decision is consistent with the 340B statute's text, structure, and purposes. On that basis alone, the court should vacate the decision. *See Brown & Williamson*, 529 U.S. at 139–

143 (rejecting agency interpretation of statute that was at odds with the text and structure of the statutory and regulatory scheme); *Ill. Cent. Gulf R.R. v. ICC*, 702 F.2d 111, 115 (7th Cir. 1983) (rejecting agency action where it was based on an interpretation "contrary to the command" of other applicable statutory provisions). In addition, the "agency" theory must be rejected because it is not "'reasonable and reasonably explained.'" *Stovic v. R.R. Ret. Bd.*, 826 F.3d 500, 506 (D.C. Cir. 2016) (Kavanaugh, J.). The December 30 decision is devoid of any findings, let alone any substantial evidence to support them, that the contracts between covered entities and commercial pharmacies meet any of the required elements of agency, particularly the "essential element[,] … the principal's right to control the agent's actions." Restatement (Third) of Agency § 1.01, cmt. f. That is because such control likely does not exist — and, certainly, such control is not required under HHS's December 30 decision and May 17 letter for manufacturers' new obligations to be triggered. Instead, HHS's approach compels manufacturers to send drugs to commercial pharmacies at covered entity requests, without the need for the covered entities to have any involvement in, let alone control over, what happens to those drugs.

Second, the government contends that generating revenue for covered entities is one of the 340B statute's goals and that, because many covered entities lack in-house pharmacies, Congress must have intended for multiple contract pharmacies to be included. The government does not cite a single case or study to support this atextual interpretation. Aside from reiterating this alleged "purpose," the December 30 decision does not support that contention with any evidence concerning how much revenue covered entities receive (versus how much contract pharmacies keep) or how it is used. ADVOP_000003–04. The government cannot rest a decision with such far-reaching consequences on conclusory statements unsupported by any evidence. *See Amerijet Int'l, Inc. v.*

Pistole, 753 F.3d 1343, 1350 (D.C. Cir. 2014) ("[C]onclusory statements will not do; an 'agency's statement must be one of *reasoning*.'").

Third, the December 30 decision and the May 17 letter cannot stand because the agency failed to "display awareness that it *is* changing position" from its previous interpretation of the statute, "show that there are good reasons for the new policy," and consider that longstanding policies may have "engendered serious reliance interests that must be taken into account." *FCC v. Fox,* 556 U.S. at 515; *Encino Motorcars, LLC v. Navarro*, 136 S. Ct. 2117, 2126 (2016). Even now, the government refuses to do so, claiming that the "obligation" imposed by the December 30 decision and the May 17 letter is not new. For the many reasons explained above, the government's contention is baseless. Even assuming HHS had statutory authority to require manufacturers to transfer drugs to commercial pharmacies (which it does not), HHS has not adequately responded to objections or explained how its position can be reconciled with its earlier pronouncements about what the statute requires.

Fourth, HHS failed to consider and respond to serious objections and concerns about how the use of contract pharmacies has resulted in massive, unchecked, and unprincipled growth of the 340B program. The contract pharmacy model has been linked to a host of program integrity concerns, including increased diversion and duplicate discounts. These concerns were flagged repeatedly — and not just by the manufacturers. In fact, HHS itself has recognized that the 340B program needs to be reined in due to abuses that do not benefit the program's intended recipients; in part because of concerns that 340B hospitals were overprescribing 340B drugs to receive revenue through reimbursement, HHS cut the reimbursement rate to hospitals by 28.5%. *See Am. Hosp. Ass'n v. Azar*, 967 F.3d 818, 821 (D.C. Cir. 2020).

In its December 30 decision and May 17 letter, HHS paid lip service to these grave concerns, placing the burden on manufacturers to conduct covered-entity-by-covered-entity audits; and submit claims to the ADR process. *See* ADVOP_000005. That is a significant — indeed, insurmountable — burden when HHS issued an ADR rule, knowing that its December 30 decision would be binding on the ADR panels. Far from providing a reasonable explanation, one cursory sentence instructing manufacturers to conduct audits and submit claims to the ADR process serves only to compound the arbitrary and capricious nature of the agency's action. Faced with evidence that the agency's chosen path may lead to prohibited activity, the agency cannot throw up its hands and offload the problems it has created onto manufacturers. *Cf. Panhandle E. Pipe Line Co. v. FERC*, 890 F.2d 435, 439–41 (D.C. Cir. 1989) (finding it arbitrary and capricious for an agency not to take a "hard look at the salient problems before it" and to merely "assum[e] away the problem").

Diversion and duplicate discounts are hardly the only program integrity concerns at play. The government has also found that "large numbers of low-income patients" do not receive any discounts when they acquire drugs through contract pharmacies, H.R. Rep. No. 102-384, at 10 (1992), and that "uninsured patients" instead "pay the full non-340B price for their prescription drugs at contract pharmacies," even when they are eligible for 340B discounts and even when the contract pharmacy is purporting to act as a covered entity's common-law agent, 2014 HHS-OIG Report at 2;H *see also* H. Comm. on Energy & Commerce, 114th Cong., *Review of the 340B Drug Pricing Program*, at 75 (Jan. 11, 2018) (raising "concerns about whether the money" the 340B program exacts from manufacturers "is truly devoted to improving patient care"). HHS made no mention of these issues in its December 30 decision and May 17 letter; nor did it try to reconcile its approach with these well-documented abuses. That too is another reason the December 30 decision and May 17 letter should not be allowed to stand.

III. The Government's Jurisdictional Arguments Cannot Be Reconciled With the Statute or Basic Principles of Administrative Law.

The government contends that its December 30 decision does not qualify as final agency action and that Novo's challenge is untimely. Both arguments depend on the government's improper attempt to rewrite the statutory requirements. Both arguments should be rejected.

A. The December 30 Decision and May 17 Letter Qualify as Final Agency Action.

The government contends that the Court should not decide the important statutory issues presented because its December 30 decision is not final agency action. *See* HHS Br. 22. But that fails for the same reasons the government's position has no basis in the statute. The December 30 decision meets the two conditions for final agency action because it (1) "mark[s] the consummation of the agency's decisionmaking process" and (2) is an agency action "by which rights or obligations have been determined, or from which legal consequences will flow." *Hawkes*, 136 S. Ct. at 1813 (quoting *Bennett v. Spear*, 520 U.S. 154, 177–78 (1997)); *see also Tomasi v. Twp. of Long Beach*, 364 F. Supp. 3d 376, 390 (D.N.J. 2019) (citing *Ocean Cty. Landfill Corp. v. EPA*, 631 F.3d 652, 655 (3d Cir. 2011)). That conclusion is only reinforced by the May 17 letter.

First, the December 30 decision and May 17 letter mark the consummation of the agency's decision-making process about manufacturers' obligation to deliver discounted drugs to contract pharmacies. *See* 5 U.S.C. § 551(4) (defining a "rule" as "an agency statement of general or particular applicability and future effect designed to implement, interpret, or prescribe law or policy"). In a stark departure from its earlier statements to the contrary, the agency now says that manufacturers, including Novo, are obligated to deliver drugs to wherever covered entities demand. That represents "a definitive pronouncement of [agency] policy," *Home Builders Ass'n of Greater Chi. v. U.S. Army Corps of Eng'rs*, 335 F.3d 607, 615 (7th Cir. 2003), and it provides the interpretation the agency

"believes is the *only permissible* interpretation of the statute," *Cal. Cmties. Against Toxics v. EPA*, 934 F.3d 627, 636 (D.C. Cir. 2019).

Moreover, because the December 30 decision exposes manufacturers, including Novo, to potential money damages and substantial civil monetary penalties, there is no requirement that Novo wait for agency proceedings to conclude before seeking judicial relief. *See Hawkes*, 136 S. Ct. at 1815–16; *Sackett*, 566 U.S. at 126–27; *D.E. v. Cent. Dauphin Sch. Dist.*,765 F.3d 260, 275 (3d Cir. 2014) (recognizing that exhaustion of administrative process is not required when it would be futile). That is especially true because the agency's December 30 decision is binding on the government employees appointed to the ADR panels, which means that the outcome of any ADR proceeding is preordained and biased against manufacturers.

Any doubt that the December 30 decision is properly subject to judicial review is dispelled by the government's recent May 17 letter. That letter threatens to enforce the legal obligations first addressed in the December 30 decision and threatens Novo with civil monetary penalties if it does not "immediately" comply. The letter thus confirms that this Court has jurisdiction to review both the December 30 decision and the May 17 letter. *See Barrick Goldstrike Mines Inc. v. Browner,* 215 F.3d 45, 48 (D.C. Cir. 2000) (making regulated entities "subject to an enforcement action and fines … constitute[s] final agency action").

Second, the December 30 decision and May 17 letter both "determined" "rights or obligations," and it is inarguable that real "legal consequences will flow" from them. *Hawkes*, 136 S. Ct. at 1813 (quoting *Bennett*, 520 U.S. at 178). The "core question" is whether the agency's decision will "directly affect the parties" and have a "direct effect on … day-to-day business." *W. Ill. Home Health Care, Inc. v. Herman*, 150 F.3d 659, 662 (7th Cir. 1998) (quotation marks omitted). The answer to that question is self-evidently "yes," as the December 30 decision and May 17 letter

command Novo either to transfer its property to commercial pharmacies or risk severe penalty and possible expulsion from the program (and with it, from Medicaid). Courts have not hesitated to conclude that even changes in internal business practices to maintain compliance with an announced rule constitute final agency action. *See Reckitt Benckiser Inc. v. EPA*, 613 F.3d 1131, 1138 (D.C. Cir. 2010) (agency action that "forced" a company to offer products in a particular way was final because it had a "direct effect on [the company's] day-to-day business").

The December 30 decision and May 17 letter also have "direct and appreciable legal consequences," as "fail[ure] to heed the determination" carries "the risk of significant criminal and civil penalties." *Cal. Cmties*., 934 F.3d at 637. The government glosses over the fact that, a mere ten days before issuing the December 30 decision, HHS issued an ADR rule that was ten years overdue. That history undermines the government's suggestion that the December 30 decision has no legal consequences. *See Ipsen Biopharm., Inc. v. Azar*, 943 F.3d 953, 956–57 (D.C. Cir. 2019) (holding that "'legal consequences will flow'" from an agency's statement of position if it "increase[s] the probability that in the future [the plaintiff] could be found to have 'knowingly'" violated the law (quotation marks omitted)). In an expansion of the rights granted to the process by statute, the ADR rule states that ADR panels will be able to resolve "legal questions," including "whether a pharmacy is part of a 'covered entity.'" 85 Fed. Reg. 80,632, 80,633, 80,640 (Dec. 14, 2020). For the first time, and in conjunction with the ADR rule, covered entities can hale Novo into an (unconstitutional) forum and forced by an (unlawfully constituted) ADR panel to relinquish its property to contract pharmacies at 340B prices, or else face sanctions and other penalties. *See* 42 C.F.R. § 10.24(e) (allowing ADR panel to make referrals for monetary penalties).

The government contends that "[w]here, as here, Novo 'continue[s] to operate' its illegal policy until some further action is taken, it cannot claim that the finality test is satisfied." HHS Br.

16. But the only case cited by the government does not support its position and is readily distinguished. In *Ocean County Landfill v. EPA,* 631 F.3d 652, the Environmental Protection Agency had issued a "final" letter in connection with a permitting process relating to the Clean Air Act. The court found that the letter did not constitute final agency action because, among other things, "the letter was only one, intermediate, step in the permitting process" and permit holders such as plaintiff would continue to operate under the terms of existing permits until a new permit issued. *Ocean Cty. Landfill Corp*., 631 F.3d at 655–57. The court's finding of no final agency action was also based on the fact that there was an administrative process that had to be followed before a new permit issued. The parties and the EPA would receive from the New Jersey Department of Environmental Protection notice and an opportunity to comment on any draft permit. EPA's "decision" therefore did "not contemplate immediate compliance." *Id.* at 655–56. Here, the exact opposite is true. The government declined to go through any sort of notice-and-comment process and is, instead, trying to end run the APA by asserting that *the statute itself* imposes an obligation on manufacturers to transfer their drugs to any contract pharmacy that the covered entities demand.

B. This Lawsuit Has Been Timely Filed.

Similar reasoning dispels the government's made up statute of limitations defense. The six-year limitations period set forth in 28 U.S.C. § 2401(a) applies to challenges to agency action brought pursuant to the APA. *See Preminger v. Sec'y of Veterans Affairs*, 517 F.3d 1299, 1307 (Fed. Cir. 2008). Under section 2401(a), Novo's claim asking the court to declare the December 30 decision invalid would accrue — at the earliest — when HHS issued the decision. A party's "right of action first accrues" as soon as he or she has suffered a legally cognizable injury and is entitled to seek legal relief. John Kendrick, *(Un)limiting Administrative Review: Wind River, Section 2401(A), and the Right to Challenge Federal Agencies*, 103 Va. L. Rev. 157, 158 (2017).

Although the statute of limitations does not run until December 30, 2026, or later, the government insists that "Novo's challenge is time-barred because the General Counsel's analysis [in the December 30 decision] broke no new ground and simply reiterated the agency's twenty-five-year, consistent position." HHS Br. 2. That is wrong for all the reasons set forth above. The December 30 decision for the very first time imposed a requirement on manufacturers to transfer their 340B discounted drugs to contract pharmacies. HHS implemented this new rule within two weeks of implementing its ADR rule, and recently HHS sent Novo its May 17 letter threatening massive civil monetary penalties if Novo does not immediately comply.

The government cites no case to support its novel theory that manufacturers have waited too long to file their challenge. There are no such cases. The government's entire position relies on the misguided notion that non-binding guidance documents can impose requirements that are not imposed by statute or regulation. Of course, that ignores the reality of what has happened. Manufacturers accepted requests to ship to contract pharmacies as a voluntary matter and as a courtesy to covered entities. But the growth of contract pharmacies has exploded in recent years. Abuses are rampant. And 340B revenues are accruing to commercial pharmacies to which they have no right. Moreover, the government repeatedly rejected manufacturer requests to address these well-documented abuses. That left Novo and other manufacturers with no choice but to adopt initiatives that were within their right to do. These are, after all, their drugs. Manufacturers are exercising private rights that they hold as owners of the drugs they produce. They are entitled to challenge HHS's attempt to restrict those rights through its December 30 decision and later May 17 decision.

* * * *

The government's position in this case is extraordinary. It is attempting to impose extra-statutory requirements on manufacturers that Congress has never authorized. It has no answer to the

statute's plain language, and its main defense relies on an obvious misreading of non-binding guidance documents that cannot impose new obligations beyond what the statute requires. And yet, the government has threatened Novo that if it does not immediately accede to HHS's position, it could impose massive civil monetary penalties on Novo for exercising its rights. There is no reason Novo should be put in that impossible position. Because the statutory text is plain, there is no reason not to decide the important statutory question at the heart of this case. The court can preserve judicial economy and the parties' resources by resolving the merits and striking down HHS's unlawful attempt to rewrite the statutory requirements.

CONCLUSION

The Court should strike down the unlawful December 30 decision and May 17 letter, and grant declaratory and injunctive relief in Novo's favor.

Respectfully submitted,

/s/ Israel Dahan
Israel Dahan (NJ Bar No. 042701997)
KING & SPALDING LLP
1185 Avenue of the Americas, 34th Floor
New York, NY 10036-2601
Telephone: (212) 556-2114
Facsimile: (212) 556-2222
idahan@kslaw.com

Graciela M. Rodriguez (pro hac vice)
Ashley C. Parrish (pro hac vice)
John D. Shakow (pro hac vice)
KING & SPALDING LLP
1700 Pennsylvania Avenue, NW, Suite 200
Washington, D.C. 20006-4707
Telephone: (202) 737-3945
Facsimile: (202) 626-3737
gmrodruiguez@kslaw.com
aparrish@kslaw.com
jshakow@kslaw.com

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

June 1, 2020

IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF NEW JERSEY

NOVO NORDISK INC.

and

NOVO NORDISK PHARMA, INC.,

Plaintiffs,

v.

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

Defendants.

Civil Action No. 3:21-cv-00806
Chief Judge Freda L. Wolfson

[PROPOSED] ORDER

Upon consideration of Defendants' Motion to Dismiss or, in the Alternative, for Summary Judgment and Plaintiffs' Cross-Motion for Summary Judgment, it is **ORDERED** that the Defendants' Motion is **DENIED** and Plaintiffs' Motion for Summary Judgment is **GRANTED**.

It is further **ORDERED**, pursuant to 5 U.S.C. § 706, that the U.S. Department of Health and Human Services Office of General Counsel Advisory Opinion 20-06, On Contract Pharmacies Under the 340B Program (Dec. 30, 2020) (its "December 30 decision") is **VACATED**.

It is further **ORDERED**, pursuant to 5 U.S.C. § 706, that the letter from the U.S. Department of Health and Human Services officials dated May 17, 2020, seeking to enforce the obligations sought to be imposed by the December 30 decision is also **VACATED**.

The Court enters a **DECLARATORY JUDGMENT** that Section 340B of the Public Health Service Act ("Section 340B"), 42 U.S.C. § 256b, does not require drug manufacturers to

provide discounted covered outpatient drugs to contract pharmacies; that Section 340B does not prohibit drug manufacturers from imposing conditions on the provision of discounted covered outpatient drugs to contract pharmacies; and that it is lawful for Plaintiffs not to transfer or cause their outpatient drugs at 340B discounted prices to be transferred to contract pharmacies.

It is further **ORDERED** that Defendants are permanently enjoined from enforcing the December 30 decision or the May 17 letter in any administrative proceeding or other enforcement action.

SO ORDERED.

Date: _____

_____
Hon. Freda L. Wolfson
Chief United States District Judge