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' REPLY IN SUPPORT OF CROSS-MOTION FOR SUMMARY JUDGMENT

TABLE OF CONTENTS

TABLE OF AUTHORITIES

Cases

Statutes

Rules and Regulations

Other Authorities

INTRODUCTION AND SUMMARY OF ARGUMENT

This case turns on a question of statutory construction. The 340B statute imposes only one relevant obligation on manufacturers: they must "offer" their drugs to "covered entities" for "purchase" at deeply discounted prices. *See* 42 U.S.C. § 256b(a)(1). It does not impose the additional obligation to *transfer* and *deliver* drugs to commercial pharmacies across the country at the request of covered entities. To the contrary, precisely because of the potential for abuse — an ever-present concern when government forces the sale of private property — the statute's provisions prohibit third parties from participating in the 340B program and profiting from the sale of manufacturers' drugs. *See* 42 U.S.C. § 256b(a)(4), (a)(5)(B).

Because the 340B statute does not impose any affirmative obligation on manufacturers to transfer their drugs to commercial pharmacies, the government has no authority to impose that obligation through administrative fiat. The statute is silent on the question of contract pharmacies. Congressional silence cannot be construed to authorize the Health Resources & Services Administration ("HRSA") to go beyond the statutory requirements and further intrude on manufacturers' constitutional and common law rights to control their own property. *See Arangue v. Whitaker*, 911 F.3d 333, 339–43 (6th Cir. 2018) (discussing presumption that general statutory language incorporates and does not override common-law principles). That principle applies with particular force given the enormous financial consequences of forcing manufacturers to transfer their drugs to commercial pharmacies. There is no indication that Congress intended, through mere silence, to permit such a massive revision to the 340B program, which does not benefit the vulnerable patients that the 340B program was designed to serve.

If there were any lingering questions about the merits of the government's position, they are resolved by Judge Leonard Stark's opinion in *AstraZeneca Pharmaceuticals LP v. Becerra*, No. 21-27-LPS (D. Del. June 16, 2021), ECF No. 78 (Ex. A) ("*Astra* Op."). Judge Stark's decision

dismantles the foundation for the government's December 30 decision and the arguments it has advanced before this Court. Judge Stark's decision rejects the government's suggestion that its interpretation of the 340B statute has been consistent for the past 25 years, recognizing that the government's new position is "materially different" from the positions taken in its 1996 and 2010 guidance. *See Astra* Op. 10–12. Judge Stark's decision finds that the government's new interpretation — that the statute requires manufacturers to transfer 340B drugs to multiple contract pharmacies — was announced for the first time in its December 30 decision. *See id.* at 12. It also concludes that the December 30 decision is "final agency action" subject to judicial review because it reflects the agency's definitive position and has legal consequences for manufacturers. *See id*. at 14–15. And it rejects the government's contention that challenges to its new interpretation of the statute are time barred. *See id.* at 16. Most importantly, Judge Stark's decision holds that the government's December 30 decision "wrongly determines" that the government's new interpretation is compelled by the statute. *See id*. at 17. Instead, Judge Stark finds that the statute is "silent" on the contract pharmacy question, and that requiring manufacturers to deliver their deeply discounted drugs to an unlimited number of contract pharmacies is the "kind of policymaking" that "is for Congress, not this Court." *Id*. at 18, 24.

In response to Judge Stark's order, the government has withdrawn its December 30 decision but nonetheless argues that it is entitled to enforce the same interpretation of the statute through another vehicle, its May 17 letter. (Judge Stark has recently entered a separate order rejecting the government's meritless suggestion that by withdrawing its December 30 decision, it mooted the pending litigation. *See AstraZeneca Pharm. LP v. Becerra*, No. 21-27-LPS (D. Del. June 30, 2021), ECF No. 83 (Ex. B)). The May 17 letter was not before Judge Stark at the time of his June 16 ruling, but the May 17 letter is equally flawed as the government's December 30 decision. The letter — a

two-page document that offers only conclusory assertions — relies on the same mistaken understanding of the 340B statute as the December 30 decision. It is therefore invalid for all the reasons the December 30 decision is invalid. *See* Novo Resp. to May 17 Letter (Ex. C).

In addition, the May 17 letter fails to comply with the requirements of reasoned decision-making. The government's counsel touts the 8,000+ page administrative record and urges the Court to consider materials in the record as factual support for the government's decision. But it is well settled that an agency's decision can be upheld only on the grounds articulated by the agency itself. A court may not rely on post hoc rationalizations of counsel or permit counsel to put forward policy justifications or factual findings not set out in the agency's decision. *Motor Vehicle Mfrs. Ass'n of U.S., Inc. v. State Farm Mut. Auto. Ins. Co.*, 463 U.S. 29, 50 (1983). Nor would it be appropriate for this Court to credit the one-sided materials cited in the record, where manufacturers have not been given an opportunity to comment or respond, and the government has failed to address objections and evidence counter to its position. Agencies are required to make a balanced assessment of the issues, drawing a rational connection between the facts found by the agency and its ultimate decision. *See id*. They are also required to acknowledge and explain when they change their position. *See Am. Wild Horse Preservation Campaign v. Perdue*, 873 F.3d 914, 923 (D.C. Cir. 2017). The government's May 17 letter fails all of these basic requirements.

Consistent with Judge Stark's ruling, this Court should strike down the government's May 17 letter as well as its withdrawn December 30 decision. The Court should declare that the 340B statute does not require manufacturers to transfer their 340B drugs to contract pharmacies. In addition, the Court should enjoin the government from enforcing either its May 17 letter or the withdrawn December 30 decision or taking any other administrative action that seeks to impose an extra-statutory obligation on manufacturers to transfer their drugs to commercial pharmacies.

LEGAL STANDARD

The government's brief misunderstands the requirements that apply when an agency seeks to enforce generally applicable rules that affect private rights. Four points bear emphasis.

First, the government's enforcement efforts, whether based on its May 17 letter or its December 30 decision, squarely rest on its assumption that the 340B statute imposes an obligation on manufacturers to transfer their drugs to for-profit commercial pharmacies. Because that assumption is wrong and the statute is "silent" on the issue (as Judge Stark has held), the May 17 letter and the December 30 decision exceed the government's lawful authority. *See* 5 U.S.C. § 706(2). Manufacturers are entitled to control the distribution of their own property unless and until Congress directs otherwise. *See United States v. Texas*, 507 U.S. 529, 534 (1993) (federal statute must "speak directly" to question when invading common law rights).

Second, to the extent the government belatedly asserts that it is resolving ambiguities, rather than reading into the text requirements that do not exist, the May 17 letter and the December 30 decision are invalid for not complying with the procedural and substantive requirements of the Administrative Procedure Act ("APA"). When a government agency seeks "to impose legally binding obligations … on regulated parties … that would be the basis for an enforcement action," it must proceed through notice-and-comment rulemaking. *Nat'l Mining Ass'n v. McCarthy,* 758 F.3d 243, 251 (D.C. Cir. 2014).[1] Before promulgating a rule that carries the force of law, the agency must first show that Congress delegated to it the "power to promulgate binding regulations in the

[1] Agencies often have discretion to proceed by case-by-base adjudication instead of by rulemaking, but the May 17 letter has none of the hallmarks of a lawful adjudication. Novo was never given an opportunity to be heard before HRSA issued its May 17 letter, and interested parties were not given an opportunity to submit facts and arguments. *See* 5 U.S.C. § 554(c). Nor was the letter adopted pursuant to "a relatively formal administrative procedure tending to foster the fairness and deliberation" required to impose a legal obligation on regulated parties. *United States v. Mead Corp.*, 533 U.S. 218, 230 (2001). The two-page letter is nothing more than a threatened enforcement of the legislative rule first announced by the government in its December 30 decision.

relevant area." *Batterton v. Marshall*, 648 F.2d 694, 701–02 (D.C. Cir. 1980). Congress has not done so here. *See Pharm. Research & Mfrs. of Am. v. HHS*, 43 F. Supp. 3d 28, 41 (D.D.C. 2014). The agency also must allow for public comment, support its position with findings backed up by substantial evidence, and reasonably respond to the objections and evidence that contradict its position. *See Home Box Office, Inc. v. FCC*, 567 F.2d 9, 35–36 (D.C. Cir. 1977) (per curiam) ("the opportunity to comment is meaningless unless the agency responds to significant points raised by the public"); *Hoctor v. U.S. Dep't of Agric.*, 82 F.3d 165, 171 (7th Cir. 1996) (interested parties must be given an opportunity to "communicate their concerns in a comprehensive and systematic fashion"). The government cannot escape these essential constraints by imposing new obligations on manufacturers through guidance, advisory opinions, or unreasoned "violation" letters.

Third, the May 17 letter can be "upheld, if at all, [only] on the basis articulated by the agency itself." *State Farm*, 463 U.S. at 50. An agency is required to "examine the relevant data and articulate a satisfactory explanation for its action including a 'rational connection between the facts found and the choice made.'" *Id.* at 43. Because the agency must "make findings that support its decision, and those findings must be supported by substantial evidence," *Burlington Truck Lines, Inc. v. United States*, 371 U.S. 156, 168 (1962), courts should not accept "counsel's *post hoc* rationalizations," *State Farm*, 463 U.S. at 50. Materials that were not relied on by the agency as an articulated basis for its decision cannot justify the agency's action. Indeed, the government's May 17 letter is not entitled even to the weakest form of deference under *Skidmore v. Swift & Co.*, 323 U.S. 134 (1944), because the letter is "neither adequately explained … nor supported by agency precedent." *Fox v. Clinton*, 684 F.3d 67, 80 (D.C. Cir. 2012). As Judge Stark found, the agency's rationale and interpretation "has not remained constant but has, instead, evolved over time." *Astra*

Op. 6. That unacknowledged inconsistency "defeats any claim to *Skidmore* deference." *Hornbeck Offshore Transp. LLC v. U.S. Coast Guard*, 424 F. Supp. 2d 37, 50 (D.D.C. 2006).

Fourth, while judicial review is generally limited to the administrative record, that does not prevent the Court from considering extra-record materials. Extra-record materials are appropriately considered both as background and to determine whether the agency has failed to consider factors relevant to its decision or improperly excluded adverse materials from the record. *Esch v. Yeutter*, 876 F.2d 976, 991–92 (D.C. Cir. 1989); *Public Citizen v. Heckler*, 653 F. Supp. 1229, 1237 (D.D.C. 1987) (considering materials known to the agency that were "directly related to the decision made" and "adverse to the agency's position"). That is especially important in circumstances where, as here, the agency record was not developed after a hearing or through a public notice-and-comment process and, therefore, interested parties were not afforded an opportunity to provide input. Indeed, the record shows that HRSA held multiple meetings with covered entities and even pharmacies, but none with manufacturers. *See* VLTR_007884–VLTR_007934. Because the government's cherry-picked record reflects only a one-sided presentation, considering extra-record materials is appropriate to putting the agency's decision in context and understanding whether it has complied with the requirements of reasoned decision-making.[2] *Cf. Esch*, 876 F.2d at 993 ("Consideration of all relevant factors includes at least an effort to get both sides of the story"); *Camp v. Pitts*, 411 U.S. 138, 141 (1973) (per curiam) ("de novo review is appropriate" when agency decision is adjudicatory in nature and "there are inadequate factfinding procedures").

[2] The arbitrariness of the government's position is highlighted by its suggestion that the expert analyses undertaken by Mr. Vandervelde and others are entitled to no consideration because they support manufacturers and have a "*financial* stake" in the issues. HHS SJ Br. 13 n.8. The government relies indiscriminately on statements made by covered entities, without acknowledging that they too have a "financial stake." The government's failure to reconcile these positions is further evidence that it has not engaged in reasoned decision-making.

ARGUMENT

I. The May 17 Letter Exceeds HHS's Lawful Authority Because It Seeks to Impose Obligations Beyond the Statutory Requirements.

The government's May 17 letter is unlawful for the same reasons its December 30 decision is unlawful. Both documents contend that the 340B statute compels manufacturers to transfer their drugs at discounted prices to an unlimited number of commercial pharmacies. That reading of the statute is wrong as a matter of law. The obligation to offer a drug to a covered entity for purchase at a discounted price does not include the separate obligation to transfer the drug to wherever and whomever the covered entity demands.

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

The government does not dispute that the only obligation that the statute imposes on manufacturers is the obligation 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). As Judge Stark concluded, the statute is "silent as to the role that contract pharmacies may play in connection with covered entities' purchases of 340B drugs." *Astra* Op. 18 (explaining that the statute's provisions "say[] nothing about the permissible role (if any) of contract pharmacies"). That silence means that, contrary to the government's position, the statute does not require manufacturers to transfer or facilitate the transfer of their drugs to contract pharmacies. In fact, Congress carefully structured the 340B statute to limit its scope. The statute restricts which entities are entitled to participate in the 340B program, *see* 42 U.S.C. § 256b(a)(4), and it forbids covered entities from transferring 340B drugs to non-patients, *see id.* § 246b(a)(5)(B).

The government cites *no authority* supporting its position that the right to purchase at a price includes the right to demand delivery to wherever and to whomever the purchaser demands. The

law is just the opposite. There is a well-settled distinction — both as a matter of linguistics and basic contract principles — between the price at which a product is sold and any delivery requirement. *See* Novo SJ Br. 20; *see also In re Valley Media, Inc.*, 226 F. App'x 120, 122–23 (3d Cir. 2007) (noting that terms "sale[]" and "delivery" are not equivalent). When Congress directed manufacturers to sell their drugs to covered entities at discounted prices, it did not impose the additional obligation to facilitate delivery to contract pharmacies across the country. *See Astra* Op. 20 (noting that Congress "could have explicitly stated that drug manufacturers are required to deliver 340B drugs to an unlimited number of contract pharmacies," but it instead was "silent on the issue").

In a footnote, the government brushes aside this plain text distinction, contending in *ipse dixit* fashion that "contract-law principles have no bearing on this dispute" because the agreement with the Secretary under the 340B statute is "not a bargained-for contract." HHS SJ Br. 17 n.12 (citing *Astra USA, Inc. v. Santa Clara Cty.*, 563 U.S. 110, 113 (2011)). But the mere fact that the agreement's terms are dictated by statute does not alter the fundamental principle that when Congress has not defined statutory terms, they should be given their "ordinary meaning." *Schindler Elevator Corp. v. United States*, 563 U.S. 401, 407 (2012). Under the terms' ordinary meaning, the obligation to sell at a discounted price does not encompass an obligation to deliver to wherever and whomever the purchaser demands.

The government's reply brief asserts for the first time that Novo's policy violates the statute's "*additional* non-discrimination requirement" because it "treat[s] commercial purchases far more favorably than 340B purchases, as evidenced by it placing no delivery-location and dispensing-mechanism restrictions on full-priced sales." HHS SJ Br. 10 (emphasis in original). But that conclusion is not supported by any factual findings in the May 17 letter. It also relies on an articulation of a non-discrimination requirement that appears nowhere in the statute. The 340B

statute provides that manufacturers must "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 statute is focused on price and purchaser. It says nothing about delivery obligations, which makes sense given that the 340B program, unlike sales in the commercial context, is designed to ensure that only covered entities and their patients benefit from the program. *See* 42 C.F.R. § 10.11(b)(2) (noting that each manufacturer has "an obligation to ensure that the 340B discount is provided through distribution arrangements made by the manufacturer"). Refusing to deliver discounted drugs to commercial pharmacies is consistent with the statute's objectives, as it ensures that the drugs are used for the benefit of vulnerable patients and do not result in a windfall for commercial contract pharmacies.

Tellingly, the government has no response to the fact that Novo's policy complies with HRSA's 1996 guidance or that the government's new interpretation of the statute contradicts the entire premise of that guidance, which governed the 340B program for more than 14 years. *See* Novo SJ Br. 25; *see also Astra* Op. 12 (recognizing this point). The government's non-response is devastating to its position. If the 340B statute has always required manufacturers to transfer their drugs to an unlimited number of contract pharmacies — as the government now contends — the 1996 guidance, which permitted covered entities to use no more than a single contract pharmacy, was both unnecessary and contrary to the statute's plain text. *Cf.* HHS SJ Br. 7 (arguing that HRSA has consistently interpreted the statute since 1996) *with Astra* Op. 12 n.10 (noting that the government "now suggests" that the 1996 guidance "was wrong"). The government cannot retroactively disavow its own guidance, in place for almost a decade and a half, merely because the guidance undermines its current litigation position.

The government likewise fails to address other important principles of statutory construction. As Novo's opening brief explains, requiring manufacturers to transfer discounted drugs to commercial pharmacies works a massive expansion of the 340B program — a transfer of several billions of dollars each year for the benefit of pharmacies and not for the benefit of patients — and it would be improper to infer that Congress intended that result absent particularly clear statutory language. *See* Novo SJ Br. 19 (citing *Util. Air Regulatory Grp. v. EPA*, 573 U.S. 302, 324 (2014); *Gonzales v. Oregon*, 546 U.S. 243, 267 (2006)). Forcing that affirmative obligation on manufacturers and depriving them of any choice in the matter is a dramatic imposition. The government identifies no reason to assume that Congress intended HRSA to have such expansive authority (and there is none). As Judge Stark recognized, if Congress had intended to include commercial pharmacies within the definition of "covered entities" or had otherwise intended them to participate in the 340B program, it certainly knew how to do so. *Astra* Op. 20–21; *see also Jama v. ICE*, 543 U.S. 335, 341 (2005) ("We do not lightly assume that Congress has omitted from its adopted text requirements that it nonetheless intends to apply, and our reluctance is even greater when Congress has shown elsewhere in the same statute that it knows how to make such a requirement manifest.").

The government also has no meaningful response to the statute's prohibition on transferring drugs to non-patients. *See* 42 U.S.C § 246b(a)(5)(B). It reads the statute as requiring only that covered entities institute safeguards to prevent drugs from being distributed to *ineligible patients*. But it provides no textual basis for that unduly narrow construction. The statute's language sweeps broadly to prohibit transfers to *any* non-patients, including commercial entities, that might attempt to profit from the sale of manufacturers' drugs.

In this vein, the government repeatedly downplays the dramatic consequences of allowing an unlimited number of commercial pharmacies to participate in the 340B program. The government's 1996 guidance allowed a covered entity to contract with a single outside pharmacy if it lacked an in-house pharmacy, meaning that the outside pharmacy served the same function as the in-house pharmacy. That simply is not true for the thousands of commercial pharmacies that receive outsized profits from the sale of manufacturers' drugs and have no meaningful connection to the fundamental purpose of the 340B program. *See* Adam J. Fein, *Walgreens and CVS Top the 28,000 Pharmacies Profiting from the 340B Program. Will the Unregulated Party End?*, Drug Channels (July 14, 2020); Aaron Vandervelde et al., Berkeley Research Grp., For-Profit Pharmacy Participation in the 340B Program (2020) (noting that, as of today, "half of the twenty largest for-profit corporations in the United States . . . are active participants in the 340B program through contract pharmacy arrangements").

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

With no foothold in the statutory text, the government relies on extra-textual arguments. *But cf. Astra* Op. 24 (noting that "policymaking is for Congress, not this Court"). None have merit.

First, the government asserts that it has always interpreted the statute to require manufacturers to transfer their drugs to an unlimited number of contract pharmacies. *See* HHS SJ Br. 9. It insists that its 1996 and 2010 guidance "were unequivocal" and it refers to other "historic evidence" suggesting that HRSA "always has understood the statute … to prohibit drug makers from placing restrictive conditions on covered entities' access to 340B discounts." *Id.*; *see also id.* at 12.

These arguments are the same arguments that Judge Stark properly rejected. The statute has long required manufacturers to provide discounts to covered entities, and Novo's policy fully complies with that requirement. But the government has never before concluded that the statute

imposes an affirmative obligation on manufacturers to transfer their drugs to contract pharmacies at the request of covered entities. *Astra* Op. 13. The government has never even attempted to promulgate regulations addressing the use of contract pharmacies. Moreover, as Judge Stark found, the government's December 30 decision is the "first document in which HHS explicitly concluded that *drug manufacturers* are required *by statute* to provide 340B drugs to *multiple* contract pharmacies." *Id*. at 12 (emphasis in original). "[T]he government's interpretation of manufacturers' obligations under the 340B program has not remained constant but has, instead, evolved over time." *Id*. at 12–13 (government's position has "materially shifted"); *see also* Novo SJ Br. 23–26 (explaining why the government's earlier non-binding guidance to covered entities are not reasonably interpreted to require manufacturers to transfer their drugs to contract pharmacies).

Judge Stark's conclusions are borne out by the administrative record and statements made by the government. *See* Novo SJ Br. 24. If the statute imposed an affirmative obligation on manufacturers, as the government now contends, the government would have responded to manufacturers' initiatives by pointing to the statutory text and its earlier interpretations. Instead, in letter after letter, the government stated that it was merely "considering" the issue and "encouraged" manufacturers to reconsider declining requests to deliver their drugs to contract pharmacies. *See* VLTR_007668; VLTR007721; VLTR007723. Those statements show that the government's new statutory position is not a long-standing interpretation, but a new position taken in response to pressures from covered entities. *See* VLTR_000110–VLTR_006807; HHS SJ Br. 3 (record "chiefly contains *thousands of pages* of complaints from covered entities") (emphasis in original).

Second, the government relies unconvincingly on legislative history. It argues that because unenacted draft legislation would have limited covered entities to using an on-site pharmacy, the court should assume that, by not including that limitation in the final law, Congress intended to grant

covered entities an unfettered right to demand delivery to wherever and whomever they choose. As the government admits, Judge Stark has rejected this reading, concluding that the legislative history points in the opposite direction. *See* HHS SJ Br. 11 n.7. As Judge Stark explains, evidence that Congress considered but did not include language "referring to drugs 'purchased and dispensed by, or *under a contract entered into for on-site pharmacy services* with'" covered entities suggests that Congress did not "clearly intend to require manufacturers to deliver 340B drugs to an unlimited number of contract pharmacies." *Astra* Op. 21; *see also Motion Pictures Ass'n of Am., Inc. v. FCC*, 309 F.3d 796, 806 (D.C. Cir. 2002) (explaining that Congress's "silence," after considering and rejecting legislative change, "cannot be read as ambiguity resulting in delegated authority" for agency "to promulgate disputed regulations").

In any event, Congress's unexplained decision to remove words from draft legislation is the type of "'mute intermediate legislative maneuver[]' [that is] not [a] reliable indicator[] of congressional intent." *Mead Corp. v. Tilley*, 490 U.S. 714, 723 (1989). More fundamentally, courts should "not resort to legislative history to cloud a statutory text that is clear." *Ratzlaf v. United States*, 510 U.S. 135, 147–48 (1994). Here, because the statute is silent on the issue of contract pharmacies, there is only one permissible conclusion: Congress did not impose a transfer and delivery obligation on manufacturers. Legislative silence cannot be converted, through administrative alchemy, into enforceable obligations that intrude on manufacturers' property rights.

Third, the government contends that by refusing to accept covered entity requests that manufacturers deliver their drugs to commercial pharmacies, manufacturers are erecting "practical barriers restricting covered entities' access" to their drugs at discounted prices. HHS SJ Br. 8. That is simply inaccurate. Novo's policy does not prevent any covered entity from accessing its drugs at the discounted price. *See* Ltr. to Rear Admiral Pedley (explaining Novo's policy) (VLTR_007757).

Nor is Novo preventing covered entities from choosing how to dispense drugs to patients. All covered entities are able to purchase Novo's drugs in whatever quantities they desire at the 340B price, as long as they take possession of the drugs at their registered location (or at the location of one designated contract pharmacy). Novo is merely refusing to transfer or facilitate the transfer of its drugs to an unlimited number of commercial contract pharmacies at the covered entity's request.

While that arrangement may be less convenient for covered entities, it does not "restrict" access in an impermissible manner under the statute. Indeed, because covered entities are able to profit from the "spread" — purchasing the manufacturers' drugs at deeply discounted prices and selling at full list prices to insured patients — the 340B statute expressly prohibits covered entities from transferring the drugs to third parties, such as for-profit commercial pharmacies. *See* 42 U.S.C. § 246b(a)(5)(B). That restriction is designed to ensure a close nexus between the covered entity itself and the uninsured and underinsured patients that visit and are treated at its facilities. Without that nexus, the covered entity can generate massive amounts of "spread" by using pharmacies to sell the drugs to "patients" with only the loosest connection to the covered entity. Indeed, in recent years, while charity care has decreased under the 340B program, covered entities and contract pharmacies have reaped windfalls. *See* HHS Office of Inspector General, OEI-05-13-00431, Mem. Report: Contract Pharmacy Arrangements in the 340B Program, at 2 (2014) (ADVOP_001404) ("2014 HHS-OIG Report"); *see also* 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) ("Nephron Report") (concluding that $3.348 billion in 340B discounts were retained as profit by contract pharmacies in 2020 alone); Press Release, PhRMA, New Analysis Shows Contract Pharmacies Financially Gain From 340B Program With No Clear Benefit to Patients (Oct. 8, 2020).

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

Any doubt over the meaning of the 340B statute should be resolved in favor of avoiding the serious constitutional concerns raised by the government's statutory interpretation. Constitutional concerns loom large here because, instead of funding the 340B program through general tax revenues, the government is forcing an A-to-B transfer of private property. The government's arguments are foreclosed by both Judge Stark's ruling and recent Supreme Court precedent.[3]

The government first contends that the Court should not apply the canon of constitutional avoidance because the "340B statute offers but 'one plausible construction.'" As explained above, that patently unpersuasive argument has been rejected by Judge Stark. As his decision recognizes, the statute is silent on the question of contract pharmacies. *See Astra* Op. 19.

The government next asserts that the forced transfer of drugs from manufacturers to contract pharmacies must be analyzed as a "regulatory taking" under *Penn Central Transportation Co. v. City of New York*, 438 U.S. 104 (1978). The Supreme Court recently rejected that argument in *Cedar Point Nursery v. Hassid*, 141 S. Ct. 2063 (2021), where it distinguished between physical takings and regulatory takings. A regulatory taking occurs when government "imposes regulations that restrict an owner's ability to use his own property," *id*. at 2071; in contrast, when government "physically appropriates property" for itself or the benefit of someone else, "by whatever means," it is engaged in a *per se* physical taking. *See id*. at 2072; *see also Horne v. Dep't of Agric.*, 576 U.S. 350, 361 (2015) (holding that compelling raisin growers to set aside a percentage of their crop for the government constituted a physical taking). When the government engages in a *per se* taking, the government "must pay for what it takes." *Cedar Point*, 141 S. Ct. at 2071.

[3] Judge Stark did not address the constitutional concerns raised by the government's new statutory interpretation because the constitutional issues were not presented in that case. The significant takings concerns provide an additional reason the government's May 17 letter is invalid and why any ambiguities should be resolved away from constitutional doubt.

Here, under the government's interpretation, the 340B program operates as a *per se* physical taking because the government is appropriating manufacturers' drugs at confiscatory prices and requiring them to be transferred to commercial pharmacies. That is a direct intrusion on manufacturers' rights to control their own property. As the Supreme Court has recognized, "[p]roperty rights in a physical thing" include the rights "'to possess, use and dispose of it.'" *Loretto v. Teleprompter Manhattan CATV Corp.*, 458 U.S. 419, 435 (1982). It also includes the right to exclude, preventing others from benefiting from the use of the property. *Cedar Point*, 141 S. Ct. at 2072. All of these rights are violated by a government program that forces manufacturers to transfer their drugs to commercial pharmacies at deep discounts.

The government contends that no unauthorized taking has occurred because Novo voluntarily participates in the 340B program. But Novo has already shown that manufacturers are effectively compelled to participate. Novo SJ Br. 32; *Nat'l Fed. of Indep. Bus. v. Sebelius*, 567 U.S. 519, 581 (2012). In any event, the government's argument depends on its mistaken assertion that the statute has always imposed an obligation on manufacturers to transfer their drugs to contract pharmacies. As Novo's opening brief explains, Novo has never agreed to transfer its drugs to commercial pharmacies. The statute does not impose that obligation and, as Judge Stark recognized, the first time the government interpreted the statute to impose that obligation was in its December 30 decision. *Astra* Op. 12; *Cf. Pennhurst State Sch. & Hosp. v. Halderman*, 451 U.S. 1, 25 (1981) (noting that while Congress may impose conditions on States receiving federal funds, those powers do "not include surprising participating States with post acceptance or 'retroactive' conditions").

More fundamentally, the unconstitutional conditions doctrine prevents the government from imposing that type of forced-transfer requirement as a condition of participation. *See* Novo SJ Br. 31–33. The government argues that the unconstitutional conditions doctrine is limited to "the special

context of exactions" in land-use permitting decisions. HHS SJ Br. 22. But that narrow view is contrary to Supreme Court precedent. In *Cedar Point*, the Court explained that "government may require property owners to cede a right of access as a condition of receiving certain benefits," but only if the condition bears an "'essential nexus'" and "'rough proportionality'" to the impact of the proposed use of the property. 141 S. Ct. at 2079. Even the case the government relies on — *Ruckelshaus v. Monsanto Co.*, 467 U.S. 986 (1984), which does not involve a land-use exaction — makes plain that when the government imposes conditions they must be "rationally related to a legitimate government interest." *Id*. at 1007.

Contrary to the government's assertions, Novo is not contending that "*all* conditions on government benefits that affect constitutionally protected interests are *per se* invalid." HHS SJ Br. 22. Instead, it is arguing that there must be an "essential nexus" between the imposed condition and a valid public purpose. That nexus is lacking if the statute is interpreted to require manufacturers to transfer their drugs to an unlimited number of contract pharmacies. Transferring drugs to contract pharmacies does not help vulnerable patients gain access to drugs at discounted prices. Instead, it does just the opposite: it enriches commercial pharmacies at the expense of manufacturers and the vulnerable patients the program is designed to serve. Because there is no essential nexus between the 340B program's only legitimate objective and the government's attempt to force manufacturers to transfer their drugs to contract pharmacies, the statute should be interpreted away from constitutional doubt. In the face of Congressional silence, the government should not be allowed to force this massive expansion of the 340B program.

II. The May 17 Letter Violates the Requirements of Reasoned Decision-Making.

The government does not dispute that its May 17 letter qualifies as final agency action that is subject to judicial review. It nonetheless contends that there is no basis to set aside the May 17 letter. That is wrong. For the reasons explained above, and for the same reasons Judge Stark struck

down the government's December 30 decision, the May 17 letter is contrary to the statute's plain text. The May 17 letter also does not satisfy the requirements of reasoned agency decision-making.

A. The May 17 Letter Is Contrary to the Statute and Procedurally Invalid.

Although the 340B statute is "silent" on the issue of contract pharmacies, *Astra* Op. 18, that silence does not mean that Congress delegated HRSA authority to impose new obligations on manufacturers. Congress is expected to speak clearly when it intrudes on common law and constitutional rights — in this case, manufacturers' rights to control their own property. *See Shaw v. R.R.*, 101 U.S. 557, 565–66 (1879) (noting that the "law has most carefully protected the ownership of personal property … against misappropriation" and that "[n]o statute is to be construed as altering the common law, farther than its words import"). It is also expected to speak clearly before it delegates to an agency the authority to make fundamental changes in a statutory scheme with consequences amounting to billions of dollars each year. *See* Novo SJ Br. 19.

The government nonetheless contends that, if the Court finds the 340B statute to be ambiguous, it should defer to the government's interpretation under *Skidmore*. HHS SJ Br. 18. But the government has not identified any word or phrase in the 340B statute that it contends is ambiguous. Instead, the government's position is driven by its mistaken view that its reading of the statute is the only permissible one. As courts have recognized, "deference to an agency's interpretation of a statute is not appropriate when the agency wrongly believes that interpretation is compelled by Congress." *Peter Pan Bus Lines, Inc. v. Fed. Motor Carrier Safety Admin.*, 471 F.3d 1350, 1354 (D.C. Cir. 2006) (internal quotation marks omitted). Moreover, even if the government were to identify an ambiguity, when an agency seeks to impose "new law, rights, or duties," it must comply with the APA's notice-and-comment rulemaking procedures. *See Perez v. Mortg. Bankers Ass'n*, 575 U.S. 92, 104 (2015); *Kisor v. Wilkie*, 139 S. Ct. 2400, 2420 (2019). That mandate is especially significant here because Congress did not grant HRSA general rulemaking authority under

the 340B statute. *Pharm. Research*, 43 F. Supp. 3d at 41. Congress's decision to limit HRSA's rulemaking authority underscores Congress's intent that, except as specifically provided by statute, manufacturers would retain control over their own drugs and the ability to decide for themselves whether and when to honor requests to transfer them to commercial pharmacies.

Even if Congress had granted HRSA general rulemaking authority (which it has not), notice-and-comment rulemaking is essential to ensure that manufacturers "are treated with fairness and transparency after due consideration and industry participation." *Iowa League of Cities v. EPA*, 711 F.3d 844, 871 (8th Cir. 2013). Rulemaking procedures ensure that the "public" has "an opportunity to participate" and requires the agency "to educate itself before establishing rules and procedures which have a substantial impact on those regulated." *Texaco, Inc. v. FPC*, 412 F.2d 740, 744 (3d Cir. 1969); *see also Am. Hosp. Ass'n v. Bowen*, 834 F.2d 1037, 1044 (D.C. Cir. 1987).

The May 17 letter fails these requirements. The letter rests on the mistaken view that the statute compels manufacturers to transfer their drugs to contract pharmacies. *See* VLTR_000007. It provides no other detail or rationale for the agency's decision. In its brief, the government goes far beyond the rationale articulated in the May 17 letter, repeatedly citing to purported "facts" cherry-picked from the record. The government contends, for instance, that "HRSA relied on clear evidence of harm to covered entities" when it issued its May 17 letter. HHS SJ Br. 24. It cites self-interested statements by covered entities about the harms that might result from enforcing the statute as written by Congress. *See id*. at 5. And it relies on supposed harms to covered entities, such as Indian Health Centers, that are not even subject to Novo's contract pharmacy policy (under Novo's policy, "grantee" covered entity types are not restricted in their use of contract pharmacies). *See id*. at 6.

These post hoc rationalizations only underscore the seriousness of the government's rule-of-law violations. The Court should not credit these assertions by government's counsel. Nor can it

uphold the government's action based on "findings" that were never made by the agency itself. *See CBS Corp. v. FCC*, 663 F.3d 122, 137 (3d Cir. 2011) (a "reviewing court should not attempt" to address "deficiencies" by supplying a "reasoned basis for the agency's action that the agency itself has not given"). The whole point of rulemaking is to ensure procedural and substantive fairness. The government cannot dodge those requirements by issuing a "violation" letter in the middle of litigation challenging the new legislative rule issued by the agency in its December 30 decision, and then directing its counsel to assemble a one-sided record, when the agency itself has never followed the procedures necessary for allowing public comment.

B. The May 17 Letter is Arbitrary and Capricious

The government's position is also not entitled to deference because the government's May 17 letter did not "examine the relevant data," *FCC v. Fox Television Stations, Inc.*, 556 U.S. 502, 513 (2009), "articulate a satisfactory explanation for its action," *State Farm*, 463 U.S. at 43, or draw a rational connection between the facts found and the government's regulatory judgment, *see CBS Corp.*, 663 F.3d at 137 (citing cases). The government's May 17 letter is not entitled even to *Skidmore* deference because there is no "thoroughness evident" in its consideration of the issues and its letter is not consistent with its earlier guidance. *Mercy Catholic Med. Ctr. v. Thompson*, 380 F.3d 142, 155 (3d Cir. 2004); *see also Astra* Op. 13 (explaining that the government's position has "evolved over time"). The 2-page letter also contains "no reasoning or analysis that a court could properly find persuasive." *Packard v. Pittsburgh Transp. Co.*, 418 F.3d 246, 253 (3d Cir. 2005). The May 17 letter neither justifies its interpretation of the statute nor reasonably explains its conclusion that Novo has violated the statutory requirements.

First, the government's May 17 letter is arbitrary and capricious because it refuses to acknowledge that the government's position has changed. *See FCC v. Fox*, 556 U.S. at 515; *Encino Motocars, LLC v. Navarro*, 136 S. Ct. 2117, 2126 (2016). Even though Judge Stark found that the

government's position has "evolved" and "materially" changed, *Astra* Op. 10–13, the government continues to insist that its position has remained constant for the past 25 years. *See* HHS SJ Br. 23.

Second, the government has not explained significant differences between its May 17 letter and its December 30 decision. For instance, while the December 30 decision focuses on the statute's "purchased by" language, *see* VLTR_008049, the May 17 letter does not even mention that part of the statutory text, *see* VLTR_000007. Similarly, the government has not addressed its December 30 decision's "agency" theory, which was a crucial part of that decision. *See* VLTR_008048. The May 17 letter walks away from the "agency" theory and the government no longer seeks to defend it, presumably because it now recognizes that large commercial pharmacies are not in an agency relationship with covered entities. But the government has not explained or acknowledged its change in position. That itself is grounds for striking down the May 17 letter. *See State Farm*, 463 U.S. at 48–49; *Bauer v. DeVos,* 325 F. Supp. 3d 74, 109 (D.D.C. 2018) ("an unacknowledged and unexplained inconsistency is the hallmark of arbitrary and capricious decision-making").

Third, the government asserts that requiring manufacturers to transfer their drugs to contract pharmacies is essential to serving the statute's goal of assisting vulnerable patients. The government also takes the remarkable position that contract pharmacies are not able to profit from the 340B program, arguing that HRSA has not "allowed commercial pharmacies to become major participants in and beneficiaries of the 340B program." HHS SJ Br. 8. But the May 17 letter contains no findings to support those baseless assertions. The government's brief cites to self-interested statements made by certain covered entities, with no findings that their experience is even representative of covered entities in general. *See id*. at 5 n.4. The letter identifies no evidence concerning how much revenue covered entities receive (versus how much contract pharmacies keep for themselves). Nor does it explain how much of the revenues are used by covered entities to benefit patients.

The suggestion that contract pharmacies are not beneficiaries of the 340B program is factually incorrect. Extensive evidence shows that commercial pharmacies are profiting enormously from the sale of manufacturers discounted 340B drugs, and that the growth of the 340B program far outpaces any charitable services provided to uninsured and underinsured patients. *See* 2014 HHS-OIG Report; Nephron Report. As a recent report explains, information obtained from HRSA shows that the 340B program reached $38 billion in 2020 alone, an "astonishing" 27% increase over 2019. Adam J. Fein, *Exclusive: The 340B Program Soared to $38 Billion in 2020—Up 27% vs. 2019*, Drug Channels (Jun 16, 2021). Over the past 12 months, the number of pharmacies in the 340B program has grown by more than 2,000 locations. *See* Adam J. Fein, *Exclusive: 340B Continues its Unbridled Takeover of Pharmacies and PBMs*, Drug Channels (June 15, 2021). And this massive growth has not resulted in any meaningful improvements for the vulnerable patients that Congress designed the 340B program to serve. *See* Press Release, PhRMA, New Analysis Shows Contract Pharmacies Financially Gain From 340B Program with No Clear Benefit to Patients (Oct. 8, 2020); Cmty. Oncology All., The 340B Drug Discount Program in Review: How Abuse of the 340B Program Is Hurting Patients (2017). At a minimum, the government was required to address this evidence.

Fourth, the government has failed to respond to serious objections about how the use of contract pharmacies has resulted in massive, unchecked, and unprincipled growth in the 340B program. The government contends that these concerns are not relevant because the only issue before it was whether "Novo's specific policy violated the 340B statute." HHS SJ Br. 23. But that makes no sense. Before imposing new substantive requirements on regulated parties, the government is required to justify its decision — which is why an agency cannot enforce new requirements through an unreasoned enforcement letter. At a minimum, those requirements must be set forth in advance in a published rule so parties have reasonable notice of what the law requires.

Reeve Aleutian Airways, Inc. v. United States, 982 F.2d 594, 599 (D.C. Cir. 1993), *as amended* (Mar. 26, 1993) ("[d]ue process requires 'notice reasonably calculated … to apprise interested parties of the pendency of the action and afford them an opportunity to present their objections'").

The government also contends that concerns about abuses must be addressed through the ADR process. HHS SJ Br. 23–24. But that too is incorrect. As Judge Stark recognized, the ADR process is not designed to resolve challenges to agency action. *Astra* Op. 15. Instead, the ADR process is limited to addressing three types of disputes between covered entities and manufacturers — situations where (1) drugs are sold to non-patients, (2) covered entities improperly generate duplicate discounts, and (3) manufacturers overcharge covered entities. 42 U.S.C. § 256b(d)(3)(A). It was never intended to allow the government to force programmatic changes in the statute, which intrude on well-established constitutional and common-law rights, and then hide behind the ADR process. *See Astra* Op. 15–16 (recognizing that manufacturers have the right to challenge the government's new interpretation in court). Indeed, the May 17 letter rests on its unexplained assumption that the failure to transfer drugs to contract pharmacies results in an "overcharge," but there is no reasoned basis for that conclusion. *See* Novo Resp. to May 17 Letter (Ex. C).

In short, the May 17 letter, just like the government's withdrawn December 30 decision, satisfies none of the hallmarks of reasoned decision-making. The government is not entitled to impose new binding requirements on regulated parties without following proper procedures and providing the type of reasoned justification that is required.

III. The Court Should Vacate Both the December 30 Decision and the May 17 Letter.

Judge Stark's recent ruling grants summary judgment against the government, holding that the government's December 30 decision is invalid. *See* Ex. B, *Astra* Op. 2 (granting relief on AstraZeneca's first claim in its amended complaint); *see* First Amended Compl. ¶¶ 141–47, *AstraZeneca Pharm., LP v. Becerra*, No. 21-27-LPS (D. Del. Feb. 12, 2021), ECF No. 13 (First

Claim for Relief: seeking declaratory and injunctive relief that in promulgating and enforcing the December 30 decision, the government failed to observe notice and comment procedures required by law). In granting this relief, Judge Stark has rejected the government's suggestion that withdrawing its December 30 decision moots the litigation. *See* Ex. B, *Astra* Op. 2 (citing *Buckhannon Bd. & Care Home, Inc. v. W. Va. Dep't of Health & Human Res.*, 532 U.S. 598, 609 (2001); *Solar Turbines Inc. v. Seif*, 879 F.2d 1073, 1078–79 (3d Cir. 1989)).

Judge Stark has denied without prejudice the other claims for relief and directed the parties to submit a proposed schedule for the parties to brief the legality of the government's May 17 letter, which Judge Stark has not yet considered. In short, Judge Stark has now directed the parties to address all of the issues that have been briefed before this Court.

For the reasons set forth above, this Court should grant summary judgment in Novo's favor and reject the government's attempt to rewrite the statutory requirements. The statute does not impose any affirmative obligation on manufacturers to transfer their drugs to commercial pharmacies. As a result, manufacturers are free to decide for themselves whether to accept covered entity requests that such transfers be made. Because the statute is silent on the issue of contract pharmacies, the government may not impose additional obligations on manufacturers and the use of their property that have not been imposed by Congress.

This Court should therefore declare that the government's May 17 letter, like its December 30 decision, is unlawful. The government has no authority to subject manufacturers to extra-statutory requirements that Congress has not imposed. The Court should also enjoin the government from enforcing its May 17 letter or taking any other action to force manufacturers to transfer 340B drugs to commercial pharmacies.

* * * *

Manufacturers have repeatedly urged HRSA to address pervasive abuses that are distorting the 340B program, but to no avail. One of the most significant abuses has involved allowing covered entities to use unlimited commercial pharmacies, which has dramatically expanded the program beyond its essential charitable purpose and allowed pharmacies to obtain windfall profits from the sale of manufacturers' drugs, without any benefit for the uninsured and underinsured patients that the program is intended to serve. Manufacturers have reasonably responded to the government's failures by standing on their rights. While they continue to offer their drugs to covered entities for purchase at the 340B discounted price, as the statute requires, they are no longer willing to voluntarily transfer their drugs to for-profit commercial pharmacies at the request of covered entities. Because the drugs belong to the manufacturers and nothing in the statute requires manufacturers to transfer their drugs to contract pharmacies, that should be the end of the matter. The government has no authority to impose obligations that go beyond the statutory requirements. The government's attempts to circumvent that limit on its authority through an unreasoned enforcement letter supported by nothing more than post hoc rationalizations of counsel only confirms that the agency has exceeded its lawful authority and has not complied with the requirements of reasoned decision-making.

CONCLUSION

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

Respectfully submitted,

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Dated: July 6, 2021

CERTIFICATE OF SERVICE

The undersigned hereby certifies that a copy of the foregoing has been filed electronically on the 6th day of July, 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