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

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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

Exhibit A

IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF DELAWARE

ASTRAZENECA PHARMACEUTICALS LP, Plaintiff, v. XAVIER BECERRA, DANIEL J. BARRY, DIANA ESPINOSA, U.S. DEPARTMENT OF HEALTH AND HUMAN SERVICES, and HEALTH RESOURCES AND SERVICES ADMINISTRATION, Defendants.	C.A. No. 21-27-LPS

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MEMORANDUM OPINION

June 16, 2021
Wilmington, Delaware

STARK, U.S. District Judge:

At the end of 2020, the general counsel of the U.S. Department of Health and Human Services ("HHS," "the agency," or "the government") issued an advisory opinion (the "Opinion") explaining the obligations of pharmaceutical manufacturers who participate in the federal 340B Program..[1] AstraZeneca Pharmaceuticals LP ("AstraZeneca" or "AZ") sued the government, asserting that the issuance of the Opinion violated the Administrative Procedure Act ("APA"), 5 U.S.C. §§ 701-06. AstraZeneca now moves for summary judgment based on the administrative record ("AR"). The government cross-moves to dismiss or for summary judgment in its favor.

This case implicates numerous important issues of public policy, including access to health care, pharmaceutical companies' profit motives, and the wisdom (or not) of shifting some private profits to publicly funded health care facilities. The Court's role, however, is to set aside any personal views it may hold on these matters and to decide only the narrow questions properly before it: do the parties present a dispute over which the Court may exercise jurisdiction and, if so, is the position outlined in the Opinion compelled by the unambiguous text of the 340B statute? For the reasons explained below, the Court concludes that it has jurisdiction and that the Opinion's analysis is not the sole reasonable interpretation of the statute.

Accordingly, the Court will deny the government's motion to dismiss, except with respect to the one claim that AstraZeneca has abandoned. While AstraZeneca has shown that it is

[1] The "340B Program" takes its name from its codification at Section 340B of the Public Health Service Act, 42 U.S.C. § 256b.

entitled to at least some relief, the Court will provide the parties with an opportunity to offer further input on the precise relief to be awarded, the impact of the Court's conclusions on the cross-motions for summary judgment, and how (if at all) this case should now proceed.

BACKGROUND

About thirty years ago, Congress passed the Veterans Health Care Act ("VHCA"), Pub. L. No. 102-585, 106 Stat. 4943 (1992). One part of the VHCA was the establishment of the 340B Program. The Health Resources and Services Administration ("HRSA"), an agency within HHS, administers the 340B Program.

Under the 340B Program, certain hospitals and clinics ("covered entities") may purchase prescription drugs for their patients at or below maximum prices set by statute ("ceiling prices"). In general, covered entities are "public and not-for-profit hospitals that serve large numbers of patients with low income and/or living in rural areas." (D.I. 54 at 2; *see also* 42 U.S.C. § 256b(a)(4) (defining covered entities to include variety of organizations receiving federal funds, such as federally qualified health centers, sole community hospitals, and rural referral centers))

Congress created a powerful incentive to induce drug manufacturers' participation in the 340B Program: if drug manufacturers wish to receive reimbursements for their drugs under the Medicare Part B and Medicaid programs, the manufacturers must permit covered entities to buy those drugs at the 340B Program's discounted rates. *See* 42 U.S.C. § 1396r-8.

The 340B statute is not especially long nor detailed. The provisions most pertinent to the issues before the Court are reproduced below:

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

Id. § 256b(a)(1) (emphasis added). As discussed below, the government relies heavily on the first of these highlighted terms (the "purchased by" provision), while AstraZeneca emphasizes the latter (the "must offer" requirement). (*Compare, e.g.*, D.I. 56 at 23 & n.6 *with* D.I. 65 at 13; *see also* D.I. 43 at 3)

The dispute in this case relates to covered entities' use of third-party pharmacies, referred to by the parties (and the Court) as "contract pharmacies." Neither the "purchased by" provision nor the "must offer" requirement – nor any other part of the 340B statute – addresses whether a covered entity must have an in-house pharmacy for purchasing discounted drugs from manufacturers, or whether the covered entity may or must use an outside, third-party pharmacy to make purchases. The statute is silent on this matter.

According to the administrative record the government has put before the Court,[2] HRSA has issued two relevant guidance documents relating to covered entities' use of contract pharmacy services.

HRSA issued the first relevant guidance document in 1996. *See* Notice Regarding Section 602 of the Veterans Health Care Act of 1992; Contract Pharmacy Services, 61 Fed. Reg. 43,549 (Aug. 23, 1996) ("1996 Guidance"). In the 1996 Guidance, HRSA acknowledged that "[t]he statute is silent as to permissible drug distribution systems." *Id.* at 43,549. At the time, "only a very small number of the 11,500 covered entities used in-house pharmacies (approximately 500)." *Id.* at 43,550. For covered entities that did not have in-house pharmacies, establishing them would likely have been prohibitively expensive. *See id.* Under the 1996 Guidance, each covered entity was permitted to contract with one (and only one) outside pharmacy to dispense 340B drugs. *Id.* at 43,555 ("Each covered entity [that] purchases its covered outpatients drugs has the option of individually contracting for pharmacy services with the pharmacy of its choice. The ***limitation of one pharmacy contractor per entity*** does not preclude the selection of a pharmacy contractor with multiple pharmacy sites, ***as long as only one site is used for the contracted services***.") (emphasis added).

HRSA issued the second relevant guidance document 14 years later. *See* Notice Regarding 340B Drug Pricing Program – Contract Pharmacy Services, 75 Fed. Reg. 10,272 (Mar. 5, 2010) ("2010 Guidance"). The 2010 Guidance was similar to the 1996 Guidance in

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[2] The parties agree that the government is solely responsible for preparing the administrative record and providing it to the Court (*see* D.I. 76 at 28, 105), as it has done. (*See generally* D.I. 40, 40-1, 40-2, 40-3, 40-4, 40-5, 40-6, 40-7) The parties further agree that the Court's decision must be based on the administrative record. (*See* D.I. 76 at 21-22, 38, 59)

many respects, but with at least one crucial difference: the 2010 Guidance allowed covered entities to use an unlimited number of contract pharmacies to dispense 340B drugs. *See id.* at 10,277 ("In addition to contracting with a single pharmacy for each clinical site, ***covered entities may pursue more complex arrangements that include multiple pharmacies*** . . . .") (emphasis added).[3]

Since the issuance of the 2010 Guidance, the number of contract pharmacies dispensing 340B drugs has increased dramatically. (*See* D.I. 43 at 4) (citing U.S. Gov't Accountability Off., *Drug Discount Program: Federal Oversight of Compliance at 340B Contract Pharmacies Needs Improvement* 2 (June 2018), https://www.gao.gov/assets/700/692697.pdf (noting increase from about 1,300 contract pharmacies in 2010 to about 20,000 contract pharmacies in 2017)) The five largest U.S. pharmacy chains – CVS, Walgreens, Walmart, Rite-Aid, and Kroger – constitute 60% of all contract pharmacies under the 340B Program. (*Id.*) Some drug manufacturers have suggested that the widespread use of contract pharmacies has increased pharmacies' profits without providing significant benefits for patients. (*See id.* at 4-5; *see also* D.I. 46 at 19-20)

Evidently in response to the proliferation of contract pharmacies, AstraZeneca announced in August 2020 that, effective October 1, 2020, it would begin limiting distribution of 340B drugs to: (i) covered entities with in-house pharmacies, as long as they do not use any contract pharmacy; and (ii) covered entities without in-house pharmacies, as long as they use only a

[3] The 2010 Guidance explicitly states that a covered entity having an in-house pharmacy may also use an unlimited number of contract pharmacies to "supplement" its services. 75 Fed. Reg. at 10,277.

single contract pharmacy. (*See* AR 1107; *see also id.* at 1075-78).[4] AstraZeneca asked HRSA to post a notice about AstraZeneca's policy change on HRSA's website. (*See id.* at 1110-11) HRSA declined that request. (*Id.*)

On December 30, 2020, in light of the policy change by AstraZeneca (and similar changes by other drug manufacturers), and in response to expressions of concern from other stakeholders, including covered entities and contract pharmacies (*see, e.g.*, *id.* at 1065-70, 1084-85, 1090-92), the HHS general counsel issued the Opinion (*see id.* at 1-8). The Opinion concluded: "covered entities under the 340B Program are entitled to purchase covered outpatient drugs at no more than the 340B ceiling price – and manufacturers are required to offer covered outpatient drugs at no more than the 340B ceiling price – even if those covered entities use contract pharmacies to aid in distributing those drugs to their patients." (*Id.* at 8) The Opinion added that, "to the extent contract pharmacies are acting as agents of a covered entity, a drug manufacturer in the 340B Program is obligated to deliver its covered outpatient drugs to those contract pharmacies and to charge the covered entity no more than the 340B ceiling price for those drugs." (*Id.* at 1) According to the Opinion, "manufacturers may not refuse to offer the ceiling price to covered entities, even where the latter use distribution systems involving contract pharmacies." (*Id.* at 8) Therefore, the view expressed in the Opinion is that all covered entities – and, implicitly, not just those lacking in-house pharmacies – may use contract pharmacy services without any limit on the number of contract pharmacies per covered entity.

[4] The Court cites the administrative record using the pagination provided in the bottom righthand corner. For example, "AR 1107" refers to the page marked "ADVOP_001107."

The Opinion asserts that its conclusions are compelled by the "plain meaning" of the 340B statute. (*Id.* at 2-3) Moreover, the Opinion declares that the government's interpretation of the statute has been consistent throughout the past 25 years. (*See id.* at 4-5)

Two weeks after HHS issued the Opinion, AstraZeneca sued the government in this Court. (D.I. 1).[5] AstraZeneca subsequently amended its complaint. (D.I. 13) ("Am. Compl.") The amended complaint contains four claims for declaratory and/or injunctive relief: (i) in promulgating and enforcing the Opinion, the government failed to observe notice-and-comment procedures, in violation of 5 U.S.C. § 706(2)(D); (ii) the Opinion exceeds the government's authority under the 340B statute, in violation of § 706(2)(A) & (C); (iii) the Opinion is arbitrary and capricious, in violation of § 706(2)(A); and (iv) in failing to post AstraZeneca's notice to covered entities on HRSA's website, the government exceeded its authority under the 340B statute and unlawfully withheld agency action, in violation of § 706(1). (Am. Compl. ¶¶ 141-65)

AstraZeneca moved for a preliminary injunction and sought to expedite the proceedings. (D.I. 14, 17) After negotiations with the government, the parties agreed to an accelerated briefing schedule for dispositive motions, and AstraZeneca dropped its motion for a preliminary injunction. (D.I. 23, 31)

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[5] Three other drug manufacturers brought similar suits against the government. *See Eli Lilly & Co. v. Cochran*, No. 1:21-cv-00081-SEB-MJD (S.D. Ind.) (filed Jan. 12, 2021); *Sanofi-Aventis U.S., LLC v. U.S. Dep't of Health & Human Servs.*, No. 3:21-cv-00634-FLW-LHG (D.N.J.) (filed Jan. 12, 2021); *Novo Nordisk Inc. v. U.S. Dep't of Health & Human Servs.*, No. 3:21-cv-00806-FLW-LHG (D.N.J.) (filed Jan. 15, 2021). A trade association representing various brand-name pharmaceutical companies also sued HHS. *See Pharm. Research & Mfrs. of Am. v. Cochran*, No. 8:21-cv-99198-PWG (D. Md.) (filed Jan. 22, 2021).

On May 17, 2021, while briefing was ongoing, HRSA sent AstraZeneca a letter stating that AstraZeneca is "in direct violation of the 340B statute." (D.I. 66-1 at 1) ("Violation Letter") HRSA told AstraZeneca that it "must immediately begin offering its covered outpatient drugs at the 340B ceiling price to covered entities through their contract pharmacy arrangements." (*Id.* at 2) The Violation Letter warned AstraZeneca that it faces civil monetary penalties if it does not comply with its statutory obligations. (*Id.*) HRSA initially requested a response from AstraZeneca by June 1, 2021 (*see id.*), though it subsequently extended that deadline to June 10 (*see* D.I. 77).

In response to the Violation Letter, AstraZeneca filed an emergency motion seeking an "administrative stay" and, in the alternative, expedition of the proceedings. (D.I. 66) The Court declined to enter an administrative stay but agreed to further expedite the already-expedited proceedings, moving up the motions hearing by about two weeks. (D.I. 71)

The Court has carefully considered the administrative record, the parties' briefing, and related materials. (*See generally* D.I. 40, 43, 56, 65, 74).[6] It has also considered the views of several *amici curiae*. (*See generally* D.I. 46, 54, 59, 72) The Court heard extensive oral argument by videoconference on May 27, 2021. (*See* D.I. 76) ("Tr.").[7]

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[6] The government's surreply brief is laden with unfair characterizations of AstraZeneca's positions. (*See, e.g.*, D.I. 74 at 1 (accusing AstraZeneca of making "blatant misstatements" and "spurious" contentions), *id.* at 4 ("preposterous," "nonsensical," "gallingly"), *id.* at 5 ("lengthy diatribe," "invective"), *id.* at 7 ("disingenuous," "bizarrely contends")) While these attacks have not affected the Court's decision, litigants should understand that this type of rhetoric is rarely justified and, more commonly, undermines confidence in the position of the party employing such language.

[7] During the hearing, the government lodged an objection to AstraZeneca's slide

LEGAL STANDARDS

I. Motion To Dismiss

"To survive a motion to dismiss, a civil plaintiff must allege facts that 'raise a right to relief above the speculative level on the assumption that the allegations in the complaint are true . . . .'" *Victaulic Co. v. Tieman*, 499 F.3d 227, 234 (3d Cir. 2007) (quoting *Bell Atl. Corp. v. Twombly*, 550 U.S. 544, 555 (2007)). A claim is facially plausible "when the plaintiff pleads factual content that allows the court to draw the reasonable inference that the defendant . . . has acted unlawfully." *Ashcroft v. Iqbal*, 556 U.S. 662, 678 (2009). The Court is not obligated to accept "bald assertions" as true. *Morse v. Lower Merion Sch. Dist.*, 132 F.3d 902, 906 (3d Cir. 1997) (internal quotation marks omitted). Nor is it obligated to credit "unsupported conclusions and unwarranted inferences." *Schuylkill Energy Res., Inc. v. Pa. Power & Light Co.*, 113 F.3d 405, 417 (3d Cir. 1997).

II. Administrative Procedure Act

"[W]hen a party seeks review of agency action under the APA, the district judge sits as an appellate tribunal." *Am. Bioscience, Inc. v. Thompson*, 269 F.3d 1077, 1083 (D.C. Cir. 2001). In that posture, "[t]he entire case on review is a question of law." *Marshall Cnty. Health Care Auth. v. Shalala*, 988 F.2d 1221, 1226 (D.C. Cir. 1993). Accordingly, the "customary summary judgment standard" under Federal Rule of Civil Procedure 56 "does not apply." *Bintz v. Fed. Emergency Mgmt. Agency*, 413 F. Supp. 3d 349, 360 (D. Del. 2019) (citing *Am. Bioscience*, 269 F.3d at 1083). Rather, the APA provides the applicable standard for the reviewing court. *See*

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presentation for purportedly containing evidence outside the administrative record. (*See* Tr. 21-22) Because the Court's decision does not depend on any information that is contained only in the slide presentation, that objection is overruled.

id. According to the APA, the Court shall "hold unlawful and set aside agency action" that is "arbitrary, capricious, an abuse of discretion, or otherwise not in accordance with law," "in excess of statutory jurisdiction, authority, or limitations," or "without observance of procedure required by law." 5 U.S.C. § 706(2)(A), (C) & (D).

DISCUSSION

I. The Court May Review The Opinion

The parties dispute whether the Opinion is final and reviewable, as well as whether AstraZeneca's challenge to the Opinion is timely. The Court concludes that the Opinion is final and reviewable and that AstraZeneca promptly challenged it.

A. The Opinion Is Materially Different From The 1996 And 2010 Guidance

The government's arguments regarding unreviewability and untimeliness largely rest on its repeated contention that the Opinion merely restates a position that the government has held throughout the entirety of the 340B Program. (*See. e.g.*, D.I. 56 at 1, 16, 18, 24, 28; D.I. 74 at 1-2, 6-8, 10) The Court rejects this contention.

Importantly, the Opinion's analysis is based (at least in part) on the "must offer" requirement. (*See* AR 2) ("[T]he core requirement of the 340B statute . . . is that manufacturers must 'offer' covered outpatient drugs at or below the ceiling price for 'purchase by' covered entities.") Congress did not codify the "must offer" requirement until March 23, 2010, ***after*** HRSA issued the 2010 Guidance on March 5. It was impossible, therefore, for either the 1996 or 2010 Guidance to have addressed the then-nonexistent provision. To the extent that the Opinion interprets manufacturers' obligations in accordance with the "must offer" requirement, it treads "new ground." *Indep. Equip. Dealers Ass'n v. EPA*, 372 F.3d 420, 428 (D.C. Cir. 2004).

Furthermore, the focus of the Opinion is different from the focus of the 1996 and 2010 Guidance. Both guidance documents were directed toward covered entities, explaining how they could take full advantage of the 340B Program. *See, e.g.*, 1996 Guidance, 61 Fed. Reg. at 43,555 ("Covered entities that wish to utilize contract pharmacy services to dispense section 340B outpatient drugs are encouraged to sign and have in effect a contract pharmacy service agreement between the covered entity and the pharmacy."); 2010 Guidance, 75 Fed. Reg. at 10,277 ("This mechanism is designed to facilitate program participation for those covered entities that do not have access to available or appropriate 'in-house' pharmacy services . . . ."). On the other hand, the Opinion is directed toward drug manufacturers. (*See, e.g.*, AR 1) ("[W]e conclude that . . . a drug manufacturer in the 340B Program is obligated to deliver its covered outpatient drugs to those contract pharmacies . . . .")

AstraZeneca also persuasively argues that the mode of analysis in the Opinion is different from the mode of analysis employed in the 1996 and 2010 Guidance. (*See, e.g.*, D.I. 65 at 6-7) The 1996 Guidance acknowledged there were "many gaps" in the 340B statute. *See* 61 Fed. Reg. at 43,550.[8] The 2010 Guidance similarly recognized that HRSA sought to "create a working framework" to fill in statutory gaps. *See* 75 Fed. Reg. at 10,273. Neither guidance document cited specific provisions in the 340B statute. (*See* Tr. 71-72) That is, neither the

[8] The government tries to explain away the 1996 Guidance's reference to "gaps" by insisting that it was referring solely to the "approximately 11,500 eligible entities, 500 participating manufacturers, numerous wholesalers and many Federal Programs affected by this legislation," all of whom were "seeking guidance on how the Department intend[ed] to administer the 340B Program." (D.I. 56 at 27 n.9) (citing 61 Fed. Reg. at 43,550; internal quotation marks omitted) This explanation is unpersuasive. In context, HRSA was acknowledging a statutory "gap" as to the proper treatment of pharmacies.

1996 Guidance nor the 2010 Guidance cites § 256b nor discusses its particular provisions. The Opinion, by contrast, is explicitly an exercise in statutory interpretation. (*See* AR 2) ("[O]ur inquiry begins with the statutory text, and ends there as well if the text is unambiguous.") (quoting *BedRoc Ltd., LLC v. United States*, 541 U.S. 176, 183 (2004)) Statutory interpretation is a fundamentally different approach from programmatic gap-filling. (*See generally* Tr. 71) (government conceding that, in guidance documents, "the agency didn't engage in this sort of longer form of statutory interpretation that it did in the advisory opinion")

Based on the administrative record, the Court concludes that the Opinion is the first document in which HHS explicitly concluded that ***drug manufacturers*** are required ***by statute*** to provide 340B drugs to ***multiple*** contract pharmacies.[9] Indeed, as noted above, the 1996 Guidance limited covered entities to using no more than a single contract pharmacy. *See* 61 Fed. Reg. at 43,555 (acknowledging "limitation of one pharmacy contractor per entity"). Strikingly, AstraZeneca's new policy, as announced in August 2020, would not have run afoul of the 1996 Guidance – yet it directly contradicts the Opinion.[10] This reality demonstrates that the

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[9] During the hearing, the government insisted that HHS had articulated this position before 2020, but it could not cite anything in the administrative record to support this assertion. (*See* Tr. 72-73)

[10] The government now suggests that the 1996 Guidance was wrong in limiting covered entities to a single contract pharmacy. (*See* Tr. 67; *see also id.* at 94 (same for *amici*)) Regardless of whether the 1996 Guidance was correct, the important point is that the government's interpretation of the statute has not been consistent.

government's interpretation of manufacturers' obligations under the 340B Program has not remained constant but has, instead, evolved over time..[11]

The following table summarizes some of the key differences between the guidance documents and the Opinion:

Document	**Directed to:**	**Number of Contract Pharmacies Permitted**	**Mode of Analysis**	**Interprets "Must Offer" Requirement?**	**Does AZ's 2020 Policy Comply?**
1996 Guidance	Covered entities	One	Programmatic Gap Filling	No (did not exist)	Yes
2010 Guidance	Covered entities	Unlimited	Programmatic Gap Filling	No (did not exist)	No
2020 Opinion	Drug manufacturers	Unlimited	Statutory Interpretation	Yes	No

For at least the reasons already explained, and especially in combination, these differences establish that the government's position on drug manufacturers' obligations with respect to participation in the 340B Program has ***not*** remained constant but has, instead, materially shifted.

To be sure, since 1996, the government has maintained that the 340B statute broadly requires pharmaceutical manufacturers to provide discounts to covered entities. *See, e.g.*, 1996 Guidance, 61 Fed. Reg. at 43,549 ("It has been the Department's position that if a covered entity using contract pharmacy services requests to purchase a covered drug from a participating manufacturer, the statute directs the manufacturer to sell the drug at the discounted price."); *id.* at

[11] As AstraZeneca points out, "the Opinion does not acknowledge (much less explain) a change in approach from prior agency guidance." (D.I. 65 at 1) The failure to accept this reality does not, of course, change the fact that the government's interpretation of the statutory obligations of drug manufacturers has actually changed. *See generally Encino Motorcars, LLC v. Navarro*, 136 S. Ct. 2117, 2126 (2016) ("[T]he agency must at least display awareness that it is changing position and show that there are good reasons for the new policy.") (internal quotation marks omitted).

43,555 ("Under section 340B, we believe that if a covered entity using contract pharmacy services requests to purchase a covered drug from a participating manufacturer, the statute directs the manufacturer to sell the drug at the discounted price."); 2010 Guidance, 75 Fed. Reg. at 10,278 (similar). But the government's position overlooks that, throughout the past 25 years, the government has dramatically expanded how covered entities may purchase 340B drugs. The agency's interpretation of manufacturers' obligations with respect to covered entities necessarily shifts every time that HHS changes its guidance with respect to covered entities' rights. In this context, it is inaccurate to insist that manufacturers' duties have never changed, solely on the grounds that the government has always required manufacturers to accommodate all contract pharmacy arrangements that the government has permitted. Again, because the government has changed what covered entities ***may*** do, it has consequently changed what drug manufacturers ***must*** do.

B. The Opinion Constitutes Final Agency Action

There are two requirements for agency action to be final. First, "the action must mark the consummation of the agency's decisionmaking process." *Bennett v. Spear*, 520 U.S. 154, 177-78 (1997) (internal quotation marks omitted). That is, the action cannot be "merely tentative or interlocutory." *Id.* at 178. Second, "the action must be one by which rights or obligations have been determined, or from which legal consequences will flow." *Id.* (internal quotation marks omitted). Both requirements are satisfied here.

The Opinion is the "consummation" of HHS's decisionmaking process. The Court agrees with AstraZeneca that the Opinion is not "tentative": it "was issued by the agency's General Counsel," "announces unqualified conclusions," and "anticipates no further

reconsideration of the issue." (D.I. 65 at 2) The government's only argument to the contrary, raised in a footnote, rests on the premise that the Opinion merely restates the position that HHS has held since 1996. (*See* D.I. 56 at 13 n.4) For the reasons explained above, that premise is faulty.

The Opinion also has legal consequences for AstraZeneca. It repeatedly states that pharmaceutical manufacturers are "obligated" and cannot "refuse" to provide 340B drugs to multiple pharmacies who contract with covered entities. (AR 1, 8) That language is mandatory and conveys at least the impression that HHS expects "immediate compliance." *Univ. of Med. & Dentistry of N.J. v. Corrigan*, 347 F.3d 57, 69 (3d Cir. 2003) (internal quotation marks omitted). The Opinion, then, is fairly characterized as "the agency's definitive position." *Id.* (internal quotation marks omitted). HHS has not offered only preliminary thoughts on the matter while launching a more thorough assessment; instead, it has offered its unequivocal answer to a legal question.

The availability of administrative dispute resolution ("ADR") proceedings does not render AstraZeneca's challenge to the Opinion unreviewable by this Court. ADR proceedings permit drug manufacturers to pursue claims against ***covered entities*** for alleged drug diversion and duplicate discounts. *See* 340B Drug Pricing Program; Administrative Dispute Resolution Regulation, 85 Fed. Reg. 80,632, 80,645 (Dec. 14, 2020) (the "ADR Rule"). ADR proceedings do not provide a venue for manufacturers to challenge ***agency*** action, as AstraZeneca does in this

litigation. If AstraZeneca (or another manufacturer) tries to raise the legal issue presented here in ADR proceedings, the result is preordained. (*See* D.I. 43 at 18-19).[12]

Accordingly, the Opinion is final and reviewable.

C. AstraZeneca's Challenge Is Not Time-Barred

The parties agree that, to be timely, this lawsuit must have been filed "within six years after the right of action first accrue[d]." 28 U.S.C. § 2401(a). The government contends that AstraZeneca waited too long to challenge the Opinion, even though AstraZeneca initiated this lawsuit only a couple of weeks after HHS issued the Opinion. (*See* D.I. 56 at 13-18) In the government's view, AstraZeneca's right of action accrued approximately 25 years ago with the issuance of the 1996 Guidance. (*Id.* at 14) This argument is unavailing. It is predicated, once again, on the false premise (*see supra* Section I.A) that the government's position has been consistent throughout the history of the 340B Program.

In arguing that AstraZeneca should have brought a version of this lawsuit 25 years ago, the government points to (i) a challenge by the trade association PhRMA to a precursor of the 1996 Guidance and (ii) a contemporaneous letter from the HRSA Administrator. (*See* D.I. 56 at 17-18) This evidence does not alter the Court's conclusions. AstraZeneca did not exist in its current form at the time of the PhRMA litigation (*see* Tr. 51), so the plaintiff before the Court

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[12] AstraZeneca also raises serious concerns about its inability to conduct effective audits of covered entities, which is a prerequisite for manufacturers to engage in the ADR process. *See* 42 U.S.C. § 256b(d)(3); ADR Rule, 85 Fed. Reg. at 80,645; *see also* D.I. 43 at 16; D.I. 65 at 19; Tr. 59-61. The administrative record contains no indication that the government ever grappled with these practical problems with the ADR process. *See generally Eli Lilly & Co. v. Cochran*, 2021 WL 981350, at *7-10, 12 (S.D. Ind. Mar. 16, 2021) (preliminarily enjoining government from enforcing ADR Rule against drug manufacturer given likelihood that ADR Rule is procedurally defective).

cannot fairly be faulted for not filing suit at that time. Moreover, the PhRMA litigation did not challenge the final 1996 Guidance, and it did not (and could not) challenge the Opinion. Once again, the fact that the government has not consistently taken the same position with respect to manufacturers' obligations under the statute defeats the government's suggestion that a challenge to an earlier iteration of its policy (in 1996) would also essentially be a challenge to the government's current policy (as expressed in the Opinion).

Hence, AstraZeneca's challenge is timely..[13] As the Court has jurisdiction to review the Opinion, it must deny the government's motion to dismiss.

II. The Opinion's Analysis Is Not The Only Permissible Interpretation Of The Statute

Turning to the merits of AstraZeneca's declaratory judgment claims, the Court concludes that there is more than one permissible interpretation of the 340B statute..[14] Because the Opinion wrongly determines that purportedly unambiguous statutory language mandates its conclusion regarding covered entities' permissible use of an unlimited number of contract pharmacies, the Opinion is legally flawed.

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[13] The government emphasizes that AstraZeneca and other pharmaceutical manufacturers have historically complied with the government's rules for the 340B Program. (*See, e.g.*, D.I. 56 at 17, 25) While that acquiescence may provide a basis for some skepticism regarding the motivation behind manufacturers' recent efforts to push back against the program, AstraZeneca has neither waived nor forfeited any rights to pursue its legal challenges.

[14] During the hearing, counsel for *amici* American Hospital Association and other organizations suggested a helpful way to characterize the two parties' positions: if AstraZeneca is right, then drug manufacturers participating in the 340B Program do not have to provide discounted pricing for ***any*** drugs delivered to contract pharmacies, while if the government is right, then those same manufacturers must give discounted pricing for ***all*** drugs prescribed by covered entities, including drugs delivered to an unlimited number of contract pharmacies or through any other system for obtaining drugs. (*See* Tr. 91) In the Court's view, the statute does not compel either interpretation, yet both are plausible.

The statute is silent as to the role that contract pharmacies may play in connection with covered entities' purchases of 340B drugs. Pharmacies are not mentioned anywhere in the statutory text – neither in § 256b(a)(1), which (as both parties agree) contains the relevant command, nor in § 256b(a)(4), which provides the definition of "covered entity." When a statute does not include even a single reference to the pertinent word (e.g., "pharmacy"), it is highly unlikely (if not impossible) that the statute conveys a single, clear, and unambiguous directive with respect to that word. Here, the absence of any reference to "pharmacies" is a strong indication that the statute does not compel any particular outcome with respect to covered entities' use of pharmacies.

Instead of addressing pharmacies, the first part of the statute – the "purchased by" provision relied on by the government – is directed to the Secretary of HHS, requiring him to "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 ceiling price. 42 U.S.C. § 256b(a)(1) (emphasis added). This provision does not directly act on covered entities and, in any event, says nothing of the permissible role (if any) of contract pharmacies. The next sentence contains the "must offer" requirement, providing that each agreement between the Secretary and a manufacturer "***shall require that the manufacturer offer*** each covered entity covered outpatient drugs for purchase at or below the applicable ceiling price if such drug is made available to any other purchaser at any price." *Id.* (emphasis added). This provision, too, says nothing about the permissible role (if any) of contract pharmacies. Again, the statute is simply silent on this point.

The statute's total omission of contract pharmacies renders it ambiguous with respect to the central issue in this case.

Still, the Opinion asserts that the "***plain meaning***" of the statute "requires manufacturers to sell covered drugs to covered entities at or below the ceiling price, independent of whether the entity opts to use contract pharmacies to dispense the drugs." (AR 2) (emphasis added; capitalization modified) In particular, the government contends that the "purchased by" provision of § 256b(a)(1) imposes this obligation on manufacturers participating in the 340B Program. (*See, e.g.*, Tr. at 64-65) (arguing that "there is . . . no . . . plausible reading of 'purchased by' that would exclude drugs that are purchased by the covered entity but distributed by a contract pharmacy") This is unpersuasive. The "purchased by" language directly imposes an obligation on the Secretary (and only indirectly imposes obligations on manufacturers), and it refers to "covered outpatient drugs . . . purchased by a covered entity" without any reference to the amount of such drugs purchased or the model by which the drugs are distributed. That language simply cannot bear the weight that the government places on it. It is, instead, ambiguous on the points in dispute between the parties.

The Opinion goes on to add: "It is difficult to envision a less ambiguous phrase[,] and no amount of linguistic gymnastics can ordain otherwise." (AR 2; *see also id.* at 3 ("Given the lack of ambiguity in the plain text of the statute, the above analysis is dispositive.")) The Court disagrees. The government may now also disagree, for it acknowledged at the hearing that "Congress could have been more specific that . . . the drugs purchased by a covered entity had to be dispensed in an in-house pharmacy or had to be dispensed through a contract pharmacy or any number of . . . limited arrangements[,] but the fact is it was not specific . . . ." (Tr. 65; *see also*

1996 Guidance, 61 Fed. Reg. at 43,549 ("The statute is silent as to permissible drug distribution systems.")) In any event, it is not at all difficult to imagine a less ambiguous phrase that Congress could have included in § 256b(a)(1). Congress could have explicitly stated that drug manufacturers are required to deliver 340B drugs to an unlimited number of contract pharmacies. Instead, Congress was silent on the issue, and the statute is ambiguous.

If the statute offers any clues on the issue, they militate against the view set out in the Opinion. The Opinion expressly relies on the assumption that contract pharmacies act as agents of covered entities. (*See* AR 6) (noting that "covered entity and contract pharmacy are not distinct, but function as principal-agent").[15] Neither the operative provision in § 256b(a)(1) nor the definition of "covered entity" in § 256b(a)(4) speaks about covered entities' agents – although other provisions in the 340B statute do speak about covered entities' affiliates. For example, § 256b(d)(3)(B)(vi) refers to "associations or organizations representing the interests of" covered entities. If Congress intended to include agents within the definition of "covered entity," it evidently knew how to do so. It is hard to believe that Congress enumerated 15 types of covered entities with a high degree of precision and intended to include contract pharmacies as a 16th option by implication.

Other statutory provisions also cut against HHS's position. For example, another part of the VHCA (which established the 340B Program) refers specifically to "drugs procured by an agency of the Federal Government" that are "received[,] stored, and delivered" by "a commercial

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[15] During the hearing, the government argued that agency relationships between covered entities and contract pharmacies are merely exemplary. (Tr. 34-35) The Court cannot square that contention with the text of the Opinion, which states that it applies "***to the extent*** contract pharmacies are acting as agents of a covered entity." (AR 1) (emphasis added)

entity ***operating under contract*** with such agency." 38 U.S.C. § 8126(h)(3) (emphasis added). Likewise, a provision in a different health care statute explicitly covers "a person authorized to act as a purchasing ***agent*** for a group of individuals or entities who are furnishing services reimbursed under a Federal health care program." 42 U.S.C. § 1320a-7b(b)(3)(C) (emphasis added). Congress knows how to write statutes that cover agents and contractors, but it did not do so in the 340B statute.

The legislative history is of no greater assistance to the government. When Congress added the "must offer" requirement to the statute in 2010, it specifically contemplated including language referring to drugs "purchased and dispensed by, or ***under a contract entered into for on-site pharmacy services*** with" covered entities. *See* S. Rep. No. 102-259 at 2 (1992) (emphasis added). Congress chose not to include pharmacy services in the version of the bill that it ultimately passed. That omission suggests that Congress did not clearly intend to require manufacturers to deliver 340B drugs to an unlimited number of contract pharmacies..[16]

Both parties agree that only Congress may add requirements to the 340B statute. (*See* Tr. 22, 36, 41-42) Yet both parties' interpretations of the statute effectively, and impermissibly, add requirements to it. Under the government's interpretation, pharmaceutical manufacturers are required to deliver 340B drugs to an unlimited number of contract pharmacies. Under AstraZeneca's interpretation, covered entities are required to purchase their 340B drugs through

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[16] The House Report on the 340B Program states: "Drug discounts enable these entities to stretch scarce Federal resources as far as possible, reaching more eligible patients and providing more comprehensive services." H.R. Rep. No. 102-384(II) at 12 (1992). While that general goal informs the Court's reading of the statute, it does not transform ambiguous statutory language into an unambiguous congressional command.

in-house pharmacies.[17] Neither requirement is contained in the statute, nor (therefore) compelled by it.[18] Thus, on the parties' own views, the Court is not permitted to read either of these requirements into the statute.

In the Court's view, given the ambiguous statutory language, HHS could reasonably choose to opine that manufacturers are not required to deliver 340B drugs to an unlimited number of contract pharmacies when the covered entities themselves never possess the drugs. The Secretary might be motivated to interpret the statute in that manner to deter waste and fraud. (*See generally* D.I. 43 at 5) ("The promise of outsized profits, combined with lax federal oversight, has created a perfect storm for abuse.").[19] Of course, the statutory language does not compel this view, just as it does not compel the view articulated in the Opinion. The point is, once more, that Congress simply has not spoken on the issue.

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[17] Even though AstraZeneca's new policy permits each covered entity that lacks an in-house pharmacy to use a single contract pharmacy, AstraZeneca contends that its agreement to work with any contract pharmacies is voluntary. (*See, e.g.*, Tr. 57-58) Under AstraZeneca's interpretation of the statute, a drug manufacturer participating in the 340B Program is only required to sell covered drugs directly to covered entities.

[18] In reaching this conclusion, the Court necessarily rejects AstraZeneca's "first line position" that the Opinion is "objectively wrong" and "contrary" to the plain language of the 340B statute. (Tr. 43; *see also* D.I. 65 at 12)

[19] Under the now-prevalent "replenishment model," pharmaceutical manufacturers ship prescription drugs to pharmacies for dispensing to all patients. At the time of dispensing, the pharmacies do not know whether the prescriptions were written by medical providers at covered entities and qualify for 340B discounts. After 340B eligibility is later determined (typically using an algorithm), the manufacturers process chargebacks to account for the 340B drugs' discounted prices. The covered entities never physically possess the drugs. (*See* D.I. 65 at 11; D.I. 46 at 12-14; *see also* AR 6 n.6 (extending Opinion's reasoning to replenishment model))

If the Opinion had endorsed AstraZeneca's view of its obligations under the 340B statute, it is possible that covered entities would have brought their own suit against HHS to challenge that interpretation. In that hypothetical case, the outcome would have been the same as the one reached here, because the statutory language does not speak to covered entities' use of contract pharmacies. The text no more compels AstraZeneca's interpretation than the government's alternative interpretation.

While HHS's current interpretation of the statute is permissible, the Opinion is based on the "unjustified assumption" that Congress imposed this interpretation as a statutory requirement. *See Am. Lung Ass'n v. EPA*, 985 F.3d 914, 944 (D.C. Cir. 2021). "[D]eference 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). Thus, AstraZeneca is entitled to some relief. *See, e.g.*, *Am. Lung Ass'n*, 985 F.3d at 944 (vacating regulation and remanding for further consideration). Before determining the precise relief to be granted – be it setting aside the Opinion, vacating it with respect to AstraZeneca, remanding to HHS, and/or something else – the Court will benefit from obtaining the parties' views on what is most appropriate given the Court's conclusions.

III. AstraZeneca Has Abandoned Its Fourth Claim For Relief

AstraZeneca originally asked the Court to direct the government to post AstraZeneca's notice to covered entities on HRSA's website. (Am. Compl. at 55) In the government's view, the Court lacks jurisdiction to compel such agency action because it is not required by statute. (D.I. 56 at 30) (citing *Massie v. U.S. Dep't of Hous. & Urb. Dev.*, 620 F.3d 340, 347 (3d Cir.

2010)) AstraZeneca's briefs do not address this claim, and the Court understands that AstraZeneca no longer intends to pursue it. (Tr. 58) Accordingly, the Court will dismiss AstraZeneca's fourth claim.

CONCLUSION

The Court concludes by stressing what it is ***not*** deciding today. The government, *amici*, and others have warned that repudiating the government's interpretation of the 340B statute may make it more difficult for covered entities to serve uninsured or underinsured patients, many of whom live in low-income or rural communities. (*See, e.g.*, AR 3-4; D.I. 59 at 8-19) These concerns are amplified by the fact that the world is still recovering from the worst pandemic in a century. The Court does not take these concerns lightly and hopes that the fears prove unfounded.[20] Congress may very well want pharmaceutical manufacturers to deliver 340B drugs to an unlimited number of contract pharmacies as a condition for manufacturers' participation in the Medicare Part B and Medicaid programs. But that kind of policymaking is for Congress, not this Court. The only issue before the Court is whether Congress has spoken clearly and unambiguously on this arrangement. It has not.

Therefore, and for all the reasons explained above, the Court will deny the government's motion to dismiss, except with respect to AstraZeneca's abandoned fourth claim for relief. To

[20] The government's suggestion that the Court's ruling may entirely eviscerate the benefits of the 340B Program is not convincing. As far as the record reveals, permitting drug manufacturers to implement policies like the one AstraZeneca intends to follow would likely result in benefits to covered entities roughly equal to the benefits that they derived from the program between 1996 and 2010. The government admitted at the hearing that nothing in the record would support a contrary conclusion. (*See* Tr. 83) Whether "turning back the clock" in this manner is good or bad policy is not a matter for this Court to decide.

the extent that the government's motion seeks summary judgment, that portion of the motion remains pending. AstraZeneca's motion for summary judgment also remains pending until the Court receives further input from the parties. Thereafter, the Court will determine the precise relief to be awarded to AstraZeneca.

An appropriate Order follows.

Exhibit B

IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF DELAWARE

ASTRAZENECA PHARMACEUTICALS LP, Plaintiff, v. XAVIER BECERRA, DANIEL J. BARRY, DIANA ESPINOSA, U.S. DEPARTMENT OF HEALTH AND HUMAN SERVICES, and HEALTH RESOURCES AND SERVICES ADMINISTRATION, Defendants.	C.A. No. 21-27-LPS

MEMORANDUM ORDER

WHEREAS, in a memorandum opinion dated June 16, 2021, the Court held that AstraZeneca is "entitled to at least some relief" in this case (D.I. 78 at 1-2);

WHEREAS, in a corresponding order also dated June 16, 2021, the Court denied Defendants' motion to dismiss (D.I. 55) with respect to the first three claims of AstraZeneca's amended complaint and granted the motion solely with respect to the fourth claim, which AstraZeneca had withdrawn (*see* D.I. 79);

WHEREAS, the Court directed the parties to meet and confer regarding: (i) the precise relief to be granted to AstraZeneca given the Court's analysis, (ii) what additional order the Court should enter, and (iii) the next steps in this case (*see id.*);

WHEREAS, on June 21, 2021, the parties submitted a joint status report outlining their positions on those issues (D.I. 82), which the Court has carefully considered;

NOW, THEREFORE, IT IS HEREBY ORDERED that:

1. It is **DECLARED** that HHS's withdrawal of the Opinion (*see* D.I. 81) does not moot this litigation. "It is well settled that a defendant's voluntary cessation of a challenged practice does not deprive a federal court of its power to determine the legality of the practice unless it is absolutely clear that the allegedly wrongful behavior could not reasonably be expected to recur." *Buckhannon Bd. & Care Home, Inc. v. W. Va. Dep't of Health & Human Resources*, 532 U.S. 598, 609 (2001) (internal quotation marks omitted); *see also Solar Turbines Inc. v. Seif*, 879 F.2d 1073, 1078-79 (3d Cir. 1989) (holding case not moot despite agency's withdrawal of administrative order because agency "ha[d] not altered its position on the merits"). Here, although HHS withdrew the Opinion, HHS has made it clear that its position on the 340B statute has not changed. (*See* D.I. 81-1 ("[HHS's general counsel] notes that its withdrawal of the Opinion does not impact the ongoing efforts of the Health Resources and Services Administration (HRSA) to enforce the obligations that 42 U.S.C. § 256b places on drug manufacturers . . . ."); *see also* D.I. 82 at 4 ("HRSA intends to continue enforcement proceedings against AstraZeneca pursuant to the 340B statute.")) Because HHS and its sub-agency, HRSA, intend to act in accordance with the withdrawn Opinion, this litigation is not moot. *See Solar Turbines*, 879 F.2d at 1079.[1]

2. With respect to the third claim of the amended complaint, AstraZeneca's motion for summary judgment (D.I. 42) is **GRANTED**, and the government's motion for summary

[1] The government cites only one case in support of its argument that this litigation is now moot. (*See* D.I. 82 at 4) (citing *Marcavage v. Nat'l Park Serv.*, 666 F.3d 856, 861-62 (3d Cir. 2012)) In *Marcavage*, the Third Circuit determined that the alleged constitutional violations were unlikely to recur because the agency had amended the challenged regulations ***before*** the litigation. This case is different: HHS withdrew the Opinion only ***after*** the Court issued its memorandum opinion, and, as described above, HHS has indicated that its position on the 340B statute has not actually changed.

judgment (D.I. 55) is **DENIED**. Because the Court has concluded that AstraZeneca's claims are not moot, and given the Court's conclusions in the Opinion, the government agrees that this relief is proper. (*See* D.I. 82 at 6)

3. With respect to the first and second claims of the amended complaint, AstraZeneca's motion for summary judgment (D.I. 42) and the government's motion for summary judgment (D.I. 55) are **DENIED WITHOUT PREJUDICE**.

4. The Opinion issued by the general counsel of HHS on December 30, 2020, is **SET ASIDE** and **VACATED**.

The Court has considered the parties' other proposals (*see* D.I. 82 at 5-6), but it has determined that the relief granted in this Order is appropriate given the Court's conclusions in the June 16, 2021 Memorandum Opinion.

IT IS FURTHER ORDRED that the parties are directed to meet and confer regarding how this case will now proceed. No later than **July 6, 2021**, the parties shall submit a joint status report outlining their proposed schedule for: (i) AstraZeneca's filing of its second amended complaint, (ii) the government's filing of the administrative record regarding the Violation Letter, and (iii) both parties' filing and briefing of any forthcoming motions to dismiss, motions for summary judgment, or any other motions. Any proposed briefing schedule should take care to limit the number of requested pages to the minimum truly needed, and it should provide each party with at least one opportunity to respond in writing to the other party's arguments.

June 30, 2021
Wilmington, Delaware

HONORABLE LEONARD P. STARK
UNITED STATES DISTRICT JUDGE

Exhibit C

KING & SPALDING

King & Spalding LLP
1700 Pennsylvania Avenue NW
Washington, D.C. 20006

June 1, 2021

BY EMAIL

Ms. Diana Espinosa
Acting Administrator
Health Resources and Services Administration
U.S. Department of Health and Human Services
Rockville, MD 20857

Re: *Novo Nordisk Inc. v. United States Department of Health and Human Services*, No. 3:21-cv-00806 (D. N.J.)

Dear Ms. Espinosa:

We represent Novo Nordisk, Inc. and Novo Nordisk Pharma, Inc. (together, "Novo") in litigation against the Department of Health and Human Services ("HHS") and the Health Resources and Services Administration ("HRSA") in the District Court for the District of New Jersey. We write to respond to your letter to Novo, dated May 17, 2021, threatening to enforce the requirements of HHS's December 30 decision purporting to require manufacturers to transfer 340B discounted drugs to for-profit commercial pharmacies. Because your letter directly relates to pending litigation, all future communications should be sent through counsel.

1. ***The government's attempt to interfere with pending litigation is improper.*** The litigation pending in federal district court challenges the legality of the government's recent actions attempting to impose extra-statutory obligations on manufacturers to transfer their 340B discounted drugs to for-profit, commercial pharmacies. Given the pending litigation, the government's attempt to pressure Novo into abandoning its litigation position is unprincipled, arbitrary and capricious, and contrary to basic requirements of reasoned agency decision-making.

The substance of the government's position, as set forth in both your letter and your December 30 decision, is wrong and contrary to the 340B statute. All of the issues relating to the government's unlawful attempt to rewrite the 340B statute will be addressed in detail in the briefing submitted to the district court. The filings that Novo has made, and the filings it will make, in the litigation referenced above are expressly incorporated herein by reference. HHS must take into account those

filings, and any decision by the court, before it attempts to take any enforcement action against Novo.

2. ***Novo's contract-pharmacy policy complies with the statutory requirements.*** Contrary to your letter's unsupported assertions, Novo's contract-pharmacy policy complies fully with the statutory requirements. Under Novo's policy, every covered entity is offered Novo's covered outpatient drugs at the applicable 340B ceiling price, and every covered entity is able to purchase Novo's covered outpatient drugs at that price. Any suggestions to the contrary in your letter are factually incorrect and misunderstand Novo's policy.

Although your letter asserts that Novo must facilitate the transfer of its 340B discounted drugs to for-profit commercial contract pharmacies, your letter does not identify any provision in the 340B statute that imposes that requirement. The statute provides only that manufacturers must "offer" their drugs to eligible "covered entities" for "purchase" at discounted 340B prices. *See* 42 U.S.C. §§ 256b(a)(1), (a)(5)(B). It is undisputed that for-profit commercial contract pharmacies do not qualify as "covered entities" under the statute. Moreover, under the "replenishment model" used by for-profit commercial contract pharmacies, covered entities never take title to or possession of manufacturers' discounted drugs, even though they are the only entities entitled to participate in the 340B program.

Your letter asserts that the statute does not qualify or restrict how covered entities may distribute the covered outpatient drugs they purchase, but that is irrelevant. The only relevant question is what statutory obligations are imposed on manufacturers. Before a manufacturer's drugs are sold, they belong to the manufacturer, and a manufacturer cannot be forced to transfer or facilitate the transfer of its property unless required by law.

3. ***The government's changing position is arbitrary, capricious, and contrary to law.*** Your letter asserts that "HRSA has made plain, consistently since the issuance of its 1996 contract pharmacy guidance, that the 340B statute requires" manufacturers to transfer their drugs to for-profit commercial pharmacies. That too is incorrect and further confirms that the government is violating the statute and its obligation to engage in reasoned decision-making. The government's position has been anything but consistent.

In its non-binding 1996 guidance, the government acknowledged that "[the 340B] *statute is silent* as to permissible drug distribution systems." To address the issue, HHS stated that, if a covered entity lacked an in-house pharmacy, the agency would not prevent it from entering into a contractual relationship *with a single outside pharmacy* to dispense covered outpatient drugs to the covered entity's patients. 61 Fed. Reg. 43,549 (Aug. 23, 1996). That exercise of enforcement

discretion as to covered entities' compliance with the program could not and did not create enforceable obligations against manufacturers.

If you were correct that the statute requires manufacturers to transfer 340B drugs to an unlimited number of for-profit commercial pharmacies, the 1996 guidance that applied for almost 15 years would have been facially invalid. Indeed, at a recent hearing, despite arguing that the government's position has been consistent for 25 years, the government's counsel conceded that the 1996 guidance is contrary to the position set forth in your letter and your December 30 decision, asserting now that the 1996 guidance's "reading of the statute is incorrect." *AstraZeneca Pharm LP v. Becerra*, No. 21-cv-27, Hrg. Tr. 66:18-21 (May 27, 2021). That dramatic change in position—an acknowledgment that the position taken in your letter and in litigation has not been consistent—further underscores that the government's attempts to rewrite the statute and threaten civil monetary penalties are arbitrary, capricious, and contrary to law.

Your letter states that the agency has "determined that Novo Nordisk's actions have resulted in overcharges and are in direct violation of the 340B statute," but it provides no basis for that conclusion. Neither your letter, nor the December 30 decision it seeks to enforce, provide any response to the many serious objections to your approach. To provide only a few examples: Neither your letter nor the December 30 decision acknowledges that the statute is silent as to manufacturers' obligations to service for-profit commercial contract pharmacies. Neither your letter nor the December 30 decision has followed the necessary procedures under the Administrative Procedure Act for imposing new substantive obligations on regulated parties. Neither your letter nor the December 30 decision explains HHS's departure from earlier public statements acknowledging that the agency has no authority to force manufacturers to honor contract pharmacy arrangements. Neither your letter nor the December 30 decision addresses the significant abuses that result from allowing commercial pharmacies to participate in the 340B program.

4. ***Novo has not overcharged any covered entity.*** Your letter threatens the possibility of imposing civil monetary penalties if Novo does not abandon its litigation position. But under Novo's contract pharmacy policy, no covered entity has been charged more than the statutorily mandated price for a covered outpatient drug. Novo's refusal to transfer drugs to contract pharmacies does not result in a charge to covered entities, let alone an overcharge. Because there has been no charge to any covered entity in the first instance, there has been no overcharge and the agency has no authority to impose penalties. The statute permits penalties to be imposed only when a manufacturer charges too much for its drugs, not when there is a good-faith dispute over which entities are entitled to access its drugs and participate in the 340B program. It would be contrary to law,

in excess of HHS's lawful authority, and arbitrary and capricious for HHS to seek to impose penalties for alleged statutory violations that have not resulted in overcharges.

5. ***The government has no authority to impose monetary penalties.*** The standard for civil monetary penalties is a "knowing and intentional" overcharge. There can be no doubt that Novo's good faith attempts to have its position on contract pharmacies considered in a federal court of competent jurisdiction belies any accusation of a "knowing and intentional" overcharge. Indeed, as the pending litigation brought by manufacturers has shown, the government has not been consistent in its approach to the statute, making it inappropriate to suggest that manufacturers are engaged in knowing violations. Moreover, even under HHS's position in the December 30 decision (were it to be upheld, which it should not be), Novo has not knowingly violated the statutory requirements because, on information and in good faith belief, the contract pharmacies do not owe the covered entities any fiduciary obligations, are not controlled by the covered entities, and by any measure are not in "agency" relationships with the covered entities. Any attempt to impose civil monetary penalties would not only exceed the agency's lawful authority but would be excessive and raise significant constitutional concerns.

The government should refer to Novo's briefing and authorities for further detail and support on Novo's response to your letter. Novo expects to receive adequate notice before the government takes any further steps to initiate an enforcement action or otherwise prejudice Novo's ability to litigate the issues on the schedule approved by the Court. Novo reserves its right to seek a temporary restraining order, an injunction, and any other appropriate relief that may be necessary to respond to the government's improper and unjustified threats against the company.

Sincerely,

Graciela M. Rodriguez
Ashley C. Parrish
John D. Shakow

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

cc: Jody D. Lowenstein, Esq.
Kate Talmor, Esq.