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

NOVO NORDISK INC., *et al.*, Plaintiffs, v. UNITED STATES DEPARTMENT OF HEALTH AND HUMAN SERVICES, *et al.*, Defendants.	Civil Action No. 3:21-cv-806-FLW-LHG

NOTICE OF DEFENDANTS' MOTION TO DISMISS OR, IN THE ALTERNATIVE, FOR SUMMARY JUDGMENT

Defendants respectfully move to dismiss Plaintiffs' Complaint for Declaratory and Injunctive Relief pursuant to Federal Rule of Civil Procedure 12(b)(1) and 12(b)(6) or, in the alternative, for summary judgment pursuant to Federal Rule of Civil Procedure 56. The grounds for this Motion are set forth in the accompanying Memorandum in Support of Defendants' Motion to Dismiss or, in the Alternative, For Summary Judgment. A proposed order is attached.

Dated: May 11, 2021

Respectfully submitted,

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MEMORANDUM IN SUPPORT OF DEFENDANTS' MOTION TO DISMISS OR, IN THE ALTERNATIVE, FOR SUMMARY JUDGMENT

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This case culminates a brazen strategy by a cohort of large, highly profitable pharmaceutical companies unilaterally to upend the decades-old, settled operation of a statutory program that provides discounted medications to safety-net healthcare providers and their uninsured and underinsured patients. Nearly thirty years ago Congress struck a bargain with drug companies by creating the "340B Program": Participating manufacturers gain valuable access to coverage for their products under Medicaid and Medicare Part B in exchange for providing discounted drugs (at or below a statutory ceiling price) to certain safety-net healthcare providers. The providers, in turn, can generate much-needed revenue through sale of those medications (particularly to patients who are insured) or pass along the discounts directly to patients. The 340B Program has served a crucial role in facilitating healthcare for vulnerable patients ever since.

But late in 2020, Plaintiffs Novo Nordisk Inc. and Novo Nordisk Pharma, Inc. (collectively "Novo") and several of their peers, clearly dissatisfied with the scope of the 340B Program, unilaterally imposed onerous and non-statutory restrictions on providers' access to 340B-discounted drugs. Specifically, the manufacturers announced that they would no longer honor (or honor without significant restrictions) discounted-drug orders placed by eligible healthcare providers but shipped to, and dispensed by, outside pharmacies. These outside-pharmacy arrangements (called "contract pharmacies") have been an integral part of the 340B Program's operation for decades, since the vast majority of 340B-eligible providers do not operate an in-house pharmacy and thus rely on contract pharmacies to serve patients. Novo and other manufacturers' abruptly announced changes—which impact healthcare entities serving the country's most vulnerable patients, in the midst of a global pandemic—have upended the settled operation of the 340B Program and spawned a raft of litigation against the Department of Health and Human Services ("HHS"), the agency to which Congress delegated oversight and implementation of the 340B Program.

Novo's ultimate goal in this suit is clear: It seeks to have this Court sanction Novo's rewrite of its statutory obligations in a way that would severely restrict many providers' access to discounted drugs (and, in so doing, boost Novo's profits). Novo seeks to advance that goal by asking the Court to declare unlawful and set aside a reiteration by HHS's General Counsel of the agency's consistent,

twenty-five-year interpretation of the 340B statute—an interpretation with which Novo and its peers had complied, without challenge or question, for decades.

There is no cause for this Court to grant this request because Novo's claims fail. The Court cannot opine on the merits of the General Counsel's legal advice for two reasons. First, its issuance was not a final agency action. Second, Novo's challenge is time-barred because the General Counsel's analysis broke no new ground and simply reiterated the agency's twenty-five-year, consistent position. Moreover, even if Novo's challenge to the General Counsel's opinion were justiciable, it still would fail on the merits. The opinion did not exceed statutory authority because it imposed no new requirements on manufacturers but instead only confirmed statutory obligations imposed when Congress created the 340B Program. And these obligations that Novo voluntarily assumes by participating in the 340B Program cannot constitute a "taking" of the manufacturer's property. The Court should therefore dismiss each of Novo's claims or grant summary judgment to HHS.

BACKGROUND

I. STATUTORY AND REGULATORY BACKGROUND

In 1992 Congress created a program, administered by the Secretary of HHS, through which certain safety-net healthcare providers, including hospitals, community health centers, and other federally funded entities (collectively known as "covered entities") serving low-income patients could receive drug discounts. *See* Veterans Health Care Act of 1992, Pub. L. No. 102-585, § 602, 106 Stat. 4943, 4967-71 (1992), *codified at* § 340B, Public Health Service Act, 42 U.S.C. § 256b (1992). The program has dual benefits: 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, pt. 2, at 12 (1992) (conf. report), and also may benefit uninsured and underinsured patients, when covered entities opt to pass along the discounts by helping patients afford costly medications. Congress expressly conditioned drug makers' access to an incredibly valuable federal benefit—coverage of their products under Medicaid and Medicare Part B—on manufacturers' choice to participate in this drug-discount scheme, known as the "340B Program." 42 U.S.C. § 1396r-8(a)(1); 42 U.S.C. § 256b(a). Pharmaceutical companies thus may opt out of providing discounted

drugs to safety-net healthcare providers and their low-income patients, but then lose access to a significant portion of their annual revenues through drug coverage in federal health-insurance programs. *See* Compl. at ¶ 27, ECF No. 1.

During the early years of the 340B Program, it became clear that fewer than five percent of the covered entities statutorily eligible to participate in the 340B Program operated in-house pharmacies; instead, the vast majority of safety-net providers relied on arrangements with outside pharmacies, called "contract pharmacies," to dispense prescriptions to patients. *See* Notice Regarding Section 602 of the Veterans Health Care Act of 1992; Contract Pharmacy Services, 61 Fed. Reg. 43,549-01, 43,550 (Aug. 23, 1996) (hereinafter "1996 Guidance"). And because "covered entities provide medical care for many individuals and families with incomes well below 200% of the Federal poverty level and subsidize prescription drugs for many of their patients, it was essential for them to access 340B pricing." *Id.* at 43,549. Covered entities participating in the 340B Program thus began relying on these contract pharmacies to take delivery from manufacturers of drugs purchased by the covered entity and then to dispense those drugs to the covered entities' low-income patients. *Id.*

In 1996 HHS issued interpretive guidance to aid covered entities in best practices for the use of contract pharmacies. 61 Fed. Reg. 43,549. HHS explained that "[i]t would defeat the purpose of the 340B program if these covered entities could not use their affiliated pharmacies in order to participate," because "[o]therwise, they would be faced with the untenable dilemma of having either to expend precious resources to develop their own in-house pharmacies (which for many would be impossible) or forego participation in the program altogether." *Id.* at 43,550. Rather than imposing any new requirements on manufacturers not found in the 340B statute, the 1996 Guidance confirmed: "*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," and that, "[i]f the entity directs the drug shipment to its contract pharmacy," that in no way "exempts the manufacturer from statutory compliance." *Id.* at 43,549-50 (emphasis added). Thus twenty-five years ago HHS interpreted the statute to preclude manufacturers from denying purchases by covered entities using contract pharmacies, and *nothing* in the guidance

suggested that the agency viewed this statutory obligation as voluntary on the part of drug makers. On the contrary, the choice presented under the guidance was for covered entities to determine whether to establish such arrangements because they remain liable and responsible, "under any distribution mechanism, [for] the statutory prohibition on drug diversion." *Id.* at 43,550. HHS explained that restricting covered entities' access to 340B discounts to those operating an *in-house* pharmacy would not be "within the interest of the covered entities, [or] the patients they serve, [or] consistent with the intent of the law." *Id.* Critically, the agency explicitly rejected the argument, suggested in comments to the proposed guidance, that the use of contract pharmacies constitutes an unauthorized expansion of the 340B Program: "The statute is silent as to permissible drug distribution systems," and contains "no requirement for a covered entity to purchase drugs directly from the manufacturer or to dispense drugs itself." *Id.* at 43,549. On the contrary, "[i]t is clear that Congress envisioned that various types of drug delivery systems would be used to meet the needs of the very diversified group of 340B covered entities." *Id.*

The pharmaceutical industry quickly demonstrated its understanding both that HHS considered manufacturers to be *obliged* to honor contract-pharmacy dispensing models and that such transactions involve purchases by *covered entities*, not pharmacies. In 1996 the leading pharmaceutical-industry trade organization, PhRMA, filed suit to challenge the contract-pharmacy guidelines. *See* Compl. ¶ 3, *PhRMA v. Shalala*, No. 1:96-cv-1630 (D.D.C. July 12, 1996).[1] The drug companies (through their association) alleged that "covered entities are permitted to become eligible to obtain access to discounted prices through contracting pharmacies . . . , and pharmaceutical companies, including PhRMA members, are thereby required to make discounted drug sales to these covered entities." *Id.* ¶ 18. They further demonstrated awareness that, "[i]f a manufacturer attempted to

[1] The lawsuit was filed one month before the official Guidance was published in the Federal Register; it challenged guidelines (containing the same statutory interpretation) that first were published on an HHS electronic database. *PhRMA*, Compl. Exs. B, C. This Court can take judicial notice of the complaint and stipulation of dismissal from the *PhRMA* litigation as official judicial records. *See* Fed. R. Evid. 201. Attached to this motion is a true and correct copy from official archives of the Department of Justice. *See* Ex. 1 (Talmor Decl.). Novo Nordisk currently is a member of PhRMA. *See* PhRMA, About, Members, https://www.phrma.org/en/About/Members.

mitigate damages by disregarding the contract pharmacy guidelines in instances where diversion is proven or suspected, *there is a substantial risk that the [Public Health Service] would terminate the manufacturer's agreement with the Secretary of HHS*." *Id.* ¶ 21 (emphasis added). Appended to that complaint was a letter from the Administrator of the Health Resources and Service Administration ("HRSA") confirming that, "recognizing the congressional mandate that all covered entities wishing to participate in the program have access to such discount pricing, [the agency] does not recognize a distinction in a manufacturer's obligation based on the manner in which entities purchase and dispense drugs." *Id.* Ex. D at 2. PhRMA stipulated to dismissal of the suit shortly after filing.

Consistent with HHS's interpretation of the 340B statute and its 1996 Guidance implementing its terms, covered entities have for decades relied on contracts with outside pharmacies to serve their patients and access the discounts Congress provided. Indeed, these arrangements proved so pivotal to covered entities' and their patients' access to drug discounts that, in 2010, HHS issued additional guidance specifying that covered entities need not be limited to a single contract pharmacy. *See* Notice Regarding 340B Drug Pricing Program-Contract Pharmacy Services, 75 Fed. Reg. 10,272-01 (Mar. 5, 2010) (hereinafter "2010 Guidance"). HHS issued that guidance confirming covered entities' rights to rely on contract pharmacies after a demonstration project (*i.e.* a pilot program) showed that such models could benefit patients and safety-net providers "without sacrificing program integrity." *Id.* at 10,273. After issuing notice and soliciting comments, the agency agreed with commenters that "[i]t would be a significant benefit to patients to allow the use of more easily accessible, multiple contract pharmacy arrangements by covered entities" and that, because "some patients currently face transportation barriers or other obstacles that limit their ability to fill their prescriptions," more-flexible use of contract pharmacies "would permit covered entities to more effectively utilize the 340B program and create wider patient access." *Id.* The 2010 Guidance includes "essential elements" to prevent unlawful duplicate discounts or diversion of 340B drugs: a "covered entity will purchase the drug, maintain title to the drug and assume responsibility for establishing its price"; "[a] 'ship to, bill to' procedure [will be] used in which the covered entity purchases the drug; the manufacturer/wholesaler must bill the covered entity … but ships the drug directly to the contract

pharmacy"; "[b]oth the covered entity and the contract pharmacy are aware of the potential for civil or criminal penalties" for violations; and both the covered entity and contract pharmacy must maintain auditable records, track prescriptions to prevent diversion, and verify patient eligibility. *Id.* at 10,277-78. The guidance makes plain that a covered entity bears full responsibility to ensure adherence to 340B Program requirements and can lose eligibility if violations occur. *Id.*

Most importantly for the present case, the 2010 Guidance again confirmed HHS's earlier interpretation that, "if a covered entity using contract pharmacy services requests to purchase a covered outpatient drug from a participating manufacturer, *the statute directs the manufacturer to sell the drug at a price not to exceed the statutory 340B discount price*," regardless whether the covered entity "directs the drug shipment to its contract pharmacy." *Id.* at 10,278 (emphasis added). As before, that interpretation was framed in mandatory terms—the guidance made no suggestion, and in no way supports, the position that manufacturers can choose whether or not to honor 340B purchases by a covered entity that relies on contract-pharmacy arrangements. HHS also explained that the guidance neither created new obligations on manufacturers nor new rights for covered entities because it merely interpreted the 340B statute itself "to create a working framework for its administration," rather than promulgating "a substantive rulemaking under the APA." *Id.* at 10,273. Not only were there *no* legal challenges from pharmaceutical manufacturers or trade associations to the substance of the 2010 Guidance but, for more than a decade, *all* participating pharmaceutical manufacturers have complied with the guidance by honoring orders placed by covered entities regardless of the dispensing mechanism chosen. Thus for years many covered entities have relied on the ability to contract with multiple pharmacies to best serve their patients and maintain flexibility in accessing 340B discounts.

Also in 2010, Congress opted "to strengthen and formalize [HHS's] enforcement authority" over the 340B program. *See Astra USA, Inc. v. Santa Clara Cnty.*, 563 U.S. 110, 121-22 (2011). Specifically, Congress included provisions in the Patient Protection and Affordable Care Act ("ACA"), Pub. L. No. 111-148, 124 Stat. 119 (2010), to amend the 340B Program to "Improve[] … program integrity" related to manufacturer and covered-entity compliance. For example, the Secretary was granted authority to issue new regulations imposing civil monetary penalties on manufacturers that

knowingly and intentionally overcharge covered entities. *See* 42 U.S.C. § 256b(d)(1). Relying on that authority, the Secretary issued a regulation allowing the imposition of monetary penalties, including up to $5,000 for each knowing and intentional instance of overcharging by a drug manufacturer. 42 C.F.R. § 10.11(a).

II. PHARMACEUTICAL COMPANIES UNILATERALLY RESTRICT ACCESS TO 340B DISCOUNTS FOR SAFETY-NET PROVIDERS

During the latter half of 2020 several drug makers took abrupt, unilateral actions to restrict access to their drugs by covered entities that rely on contract pharmacies to take delivery of, and dispense, medications to low-income patients. These actions began with a July 2020 notice by Eli Lilly (another large pharmaceutical company) that, with certain caveats, it would not offer 340B pricing through contract-pharmacy arrangements for only one of its drugs—Cialis, a drug used to treat erectile dysfunction. *See* Compl. ¶¶ 78-80, *Eli Lilly v. HHS*, No. 1:21-cv-81 (S.D. Ind. Jan. 12, 2021), ECF No. 1. But that relatively modest restriction opened the floodgates to further disruptions of the 340B Program: Only one month later, Eli Lilly extended its new contract-pharmacy restrictions to *all* its covered drugs (with a self-imposed and administered "exception process" purporting to allow providers without an in-house pharmacy to contact the manufacturer to designate a single contract pharmacy), *see id.* Ex. G, and several other pharmaceutical companies promptly followed suit.

For its part, Novo announced that it will *deny* sales to certain covered entities for contract-pharmacy dispensing if the covered entity also has an in-house pharmacy. Compl. ¶¶ 55, 58. Novo claims that, for those covered entities that "do[] not have an on-site pharmacy capable of dispensing to outpatients," the manufacturer "will allow" the safety-net provider "to designate a single outside contract pharmacy to dispense the product to the covered entity's patients." *Id.* at 58. Novo's policy targets disproportionate-share hospitals, *id.* ¶¶ 55-60, which include those that "serve a significantly disproportionate number of low-income patients and receive payments from the Centers for Medicaid and Medicare Services to cover the costs of providing care to uninsured patients."[2] Such hospitals can

[2] *See* Health Resources and Services Administration, Disproportionate Share Hospitals, Eligibility, *available at* https://www.hrsa.gov/opa/eligibility-and-registration/hospitals/disproportionate-share-hospitals/index.html.

serve a large geographic area (and can serve as the primary provider for uninsured patients). Novo's restrictions thus will *deny* access to discounted drugs to patients at their neighborhood pharmacies if the hospital itself is capable of dispensing drugs (thus potentially requiring patients to overcome significant transportation barriers to secure drugs from the hospital itself). And even if such a provider lacks an in-house pharmacy and is permitted, under Novo's unilateral restrictions, to designate a *single* outside dispenser, all patients of that hospital will be required to visit that one pharmacy in order to access 340B-discounted drugs, regardless how inaccessible it might be for a particular patient.

Although HRSA published on its official 340B website Eli Lilly's original notice restricting access to Cialis, HRSA refused to post that drug maker's later notice expanding the 340B restrictions or those of other companies. HRSA then told an industry reporter that the agency "is considering whether manufacturer policies … violate the 340B statute and whether sanctions may apply," including, "but not limited to, civil monetary penalties." AR 1597. HRSA further warned that "manufacturers that refuse to honor contract pharmacy orders could significantly limit access to 340B-discounted drugs for many underserved and vulnerable populations who may be located in geographically isolated areas and rely on contract pharmacies"; the agency thus "continues to strongly encourage all manufacturers to sell 340B priced drugs … directly and through contract pharmacy arrangements." AR 1597-98.

In addition to Eli Lilly and Novo, other large, global pharmaceutical companies imposed their own unilateral restrictions on covered entities' access to discounted drugs. Among others, AstraZeneca imposed the same restrictions as Eli Lilly had mandated, and Sanofi-Aventis and Novartis imposed their own, separate restrictions—with the combined impact of creating a new cluster of onerous restrictions for providers to navigate in order to receive the discounts to which they are statutorily entitled. *See* Am. Compl. Exs. A, C, *AstraZeneca Pharm. v. Azar*, No. 1:21-cv-27-LPS (D. Del. Feb. 12, 2021), ECF No. 13; *See* Am. Compl. Ex. 1, *Sanofi-Aventis v. HHS*, No. 3:21-cv-634 (D. N.J. Feb. 2, 2021), ECF No. 17; Novartis 340B Policy Changes, https://www.novartis.us/news/statements/new-policy-related-340b-program.

Unsurprisingly, the pharmaceutical manufacturers' abruptly announced, unilateral restrictions on 340B access caused upheaval to covered entities due to their longstanding reliance on contract-pharmacy arrangements, prompting various safety-net providers to urge HHS to take action by filing emergency motions *against the agency* seeking to compel HHS to reverse the drug makers' changes. *See* Mot. for TRO & Prelim. Inj., *Ryan White Clinics for 340B Access v. Azar*, No. 1:20-cv-2906-KBJ (D.D.C. Nov. 23, 2020)), ECF No. 24-1; Mot. for Prelim. Inj., *Am. Hosp. Ass'n v. HHS*, No. 4:20-cv-8806-YGR (N.D. Cal. Dec. 11, 2020), ECF No. 7 (dismissed Feb. 17, 2021). HHS moved to dismiss those suits for lack of jurisdiction while confirming that its investigation of the manufacturers' actions is ongoing.

In response to the growing public outcry, HHS's General Counsel issued legal advice on December 30, 2020, confirming his view—in complete alignment with the agency's longstanding guidance—"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." HHS Gen. Counsel, Advisory Opinion 20-06 on Contract Pharmacies Under the 340B Program (AR 1, hereinafter "AO") at 1. The General Counsel opined that the 340B statute requires manufacturers, in exchange for access to Medicaid and Medicare Part B, to *offer* discounted drugs for *purchase by* covered entities, with no qualifications or restrictions on the distribution or dispensing arrangements selected by the covered entity. *Id.* at 2. And contract-pharmacy arrangements unequivocally involve purchase by a covered entity, the Advisory Opinion explained, regardless whether the purchased drugs are delivered to, and dispensed by, a pharmacist employed in-house by the covered entity or an outside, neighborhood pharmacy. *Id.* at 3. Moreover, the opinion continues, covered entities have relied on contract pharmacies for decades—and that system is wholly compatible with Congressional intent because "the Program is aimed at benefiting providers that are small, remote, resource-limited, receiving federal assistance, or serving disadvantaged populations," *i.e.*, "the poster children of providers that one would expect to lack an in-house pharmacy." *Id.* at 4. A restriction limiting 340B discounts in the manners newly imposed by drug makers would produce "a bizarre result,"

"inconsistent with the purpose of the Program and common sense." *Id.* The General Counsel confirmed that this interpretation is compelled by the statute itself; as in 1996 and 2010, no rulemaking is required, and no expansion of the 340B Program has been effectuated, because Congress did not permit drug makers to condition access to discounted drugs on covered entities' operation of an in-house pharmacy to take physical delivery of drug purchases. AO at 2-4.

III. PHARMACEUTICAL COMPANIES SUE TO PREVENT HHS's ENFORCEMENT OF THE 340B STATUTE

The pharmaceutical companies' concerted actions to upend the 340B status quo continued in litigation. Three drug makers filed suit on the same day challenging the General Counsel's Advisory Opinion. Compl., *Sanofi*, No. 3:21-cv-634-FLW (D.N.J. Jan. 12, 2021), ECF No. 1; Compl., *Eli Lilly*, No. 1:21-cv-81-SEB-MJD (S.D. Ind. Jan. 12, 2021), ECF No. 1; Compl., *AstraZeneca*, No. 1:21-cv-27 (D. Del. Jan. 12, 2021), ECF No. 1. This suit was filed just days after, *see* Compl., ECF No. 1 (Jan. 15, 2021), and the following week the manufacturers' trade association filed its own 340B-contract-pharmacy-related challenge. *See* Compl., *PhRMA v. Cochran*, No. 8:21-cv-198-GLR (D. Md. Jan. 22, 2021), ECF No. 1.

As for this action, notwithstanding the advisory nature of the General Counsel's legal opinion and the fact that it reiterated guidance the agency long ago had issued (and with which Novo had complied, without challenge, for twenty-five years), Novo now asks this Court to declare the advice unlawful and to bless Novo's intention "*not to transfer or cause its covered outpatient drugs at 340B discounted prices to be transferred to contract pharmacies*." Compl., Prayer for Relief ¶ d (emphasis added). In other words, Novo asks this Court to sanction a substantially more-sweeping change to the 340B Program than the disruptive restrictions Novo and its peers already have imposed.

STANDARD OF REVIEW

To survive a motion to dismiss under Federal Rule of Civil Procedure 12(b)(1), the plaintiff bears the burden to establish a court's jurisdiction. *See Lujan v. Defs. of Wildlife*, 504 U.S. 555, 561 (1992). It is "presume[d] that federal courts lack jurisdiction unless the contrary appears affirmatively from the record." *DaimlerChrysler Corp. v. Cuno*, 547 U.S. 332, 342 n.3 (2006) (citation omitted).

Under both Rules 12(b)(1) and 12(b)(6), a complaint must contain "enough facts to state a claim to relief that is plausible on its face" to defeat a motion to dismiss. *Bell Atl. Corp. v. Twombly*, 550 U.S. 544, 570 (2007). This "plausibility" standard "asks for more than a sheer possibility that a defendant has acted unlawfully." *Ashcroft v. Iqbal*, 556 U.S. 662, 678 (2009) (citation omitted). "Where a complaint pleads facts that are 'merely consistent with' a defendant's liability, it 'stops short of the line between possibility and plausibility of 'entitlement to relief.'" *Id.* (quoting *Bell Atl. Corp.*, 550 U.S. at 557)). And while the Court accepts well-pleaded factual allegations as true, "mere conclusory statements" and "legal conclusion[s] couched as … factual allegation[s]" are not entitled to a "presumption of truth." *Id.* at 678, 681 (citation omitted).

In a case involving review of final agency action under the APA, "the usual summary judgment standard" applicable under Federal Rule of Civil Procedure 56 "does not apply in the sense that the district court does not need to determine whether there are disputed facts to resolve at trial since the administrative agency is the finder of fact." *Neto v. Thompson*, No. 20-00618, 2020 WL 7310636, at * 3 (D.N.J. Dec. 10, 2020) (internal quotation marks and citation omitted). Rather, "the district judge sits as an appellate tribunal, and the entire case on review is a question of law." *Soccer Ctrs., LLC v. Zuchowski*, No. 17-1024, 2017 WL 4570290, at *5 (D.N.J. Oct. 13, 2017) (internal quotation marks and citation omitted). "Summary judgment thus serves as the mechanism for deciding, as a matter of law, whether the agency action is supported by the administrative record and otherwise consistent with the" applicable APA standards. *Id.* (citation omitted). The party challenging an agency's action bears the burden of demonstrating a violation of the APA. *Lomak Petroleum, Inc. v. FERC*, 206 F.3d 1193, 1198 (D.C. Cir. 2000).

ARGUMENT

Novo and its peers are attempting to effect a unilateral sea change in the settled operation of the 340B Program. Congress devised the program to provide affordable medications and much-needed revenue to vulnerable patients and safety-net healthcare providers, and expressly conditioned a valuable federal benefit, coverage of drug manufacturers' products in the nation's largest health-

insurance programs, on the companies' agreement to provide deep discounts on *purchases by* covered entities. Now a cohort of large, highly profitable pharmaceutical companies seek to litigate out of the obligation to comply with their end of the bargain after having created novel restrictions on covered entities' access to 340B discounts, including limitations on the dispensing mechanism chosen by the covered entity. Novo and other manufacturers' abruptly imposed restrictions have caused upheaval by severely curtailing access to the discounts to which covered entities are entitled. Any doubt as to Novo's intent is dispelled by the fact that its complaint is larded with grievances about covered entities' use of contract-pharmacy arrangements—complaints which ignore covered entities' twenty-five-year reliance on such agreements.

Novo's campaign to end reliance on contract-pharmacy dispensing models fundamentally distorts both the agency's interpretation of the statutory obligation imposed on participating manufacturers and the nature of contract-pharmacy arrangements. In its complaint, Novo practically ignores "the core requirement" of manufacturers under the 340B statute, AO at 2: 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," with no restriction on the method by which a covered entity dispenses its drugs to patients. 42 U.S.C. § 256b(a)(1) (emphasis added). Rather than grapple with the mismatch between Novo's new policy and its statutory obligation, Novo instead suggests repeatedly that HHS has imposed a different obligation on manufacturers "to facilitate the *transfer* of their discounted drugs to contract pharmacies." *E.g.*, Compl. ¶ 7 (emphasis added). Aside from finding no support in the General Counsel's opinion (or in any HHS guidance document, for that matter), Novo's contention intentionally invokes an entirely separate provision of the 340B statute to imply that shipping 340B drugs to a covered entity's contract pharmacy would itself constitute an unlawful "*transfer* [of a] drug to a person who is not a patient of the entity." *See* 42 U.S.C. § 256b(a)(5)(B) (emphasis added). But that statutory provision imposes an obligation on *covered entities* to avoid *reselling* discounted drugs to non-patients, and in no way prohibits a covered entity from distributing drugs to *its patients* through a contract pharmacy or some other lawful and common dispensing mechanism. *See* AO 6–7. Nor does the prohibition on unlawful

"transfer" of covered outpatient drugs have any bearing whatsoever on the question whether *Novo* is unlawfully refusing to honor *purchases by* covered entities. Novo's attempt to frame the General Counsel's interpretation of the 340B statute in such terms is mere legerdemain that confuses the purpose of contract pharmacies and the simple statutory question addressed in the challenged opinion. This distorted view of its statutory obligations permeates Novo's claims.

The Court should not condone Novo's extra-statutory self-help efforts to rewrite the legislative scheme devised by Congress to deny covered entities access to the discounts to which they are statutorily entitled.

I. THE ADVISORY OPINION IS NOT REVIEWABLE.

A. The Advisory Opinion does not constitute final agency action.

Because the Advisory Opinion is not "final agency action" subject to review under the APA, *see* 5 U.S.C. § 702, the court lacks jurisdiction to review Novo's challenge to the Advisory Opinion. *See Minard Run Oil Co. v. U.S. Forest Serv.*, 670 F.3d 236, 247 (3d Cir. 2011) (describing "final agency action" as "a jurisdictional issue"). Agency actions are final if two independent conditions are met: (1) the action "marks the consummation of the agency's decisionmaking process" and is not "of a merely tentative or interlocutory nature;" and (2) the action is one "by which rights or obligations have been determined, or from which legal consequences will flow." *Bennett v. Spear*, 520 U.S. 154, 177-78 (1997) (citation omitted). Though failure to satisfy either condition is enough to deprive the court of jurisdiction, the Advisory Opinion fails to satisfy both conditions.

The Advisory Opinion is not an action "by which rights or obligations have been determined, or from which legal consequences will flow." *Id.* To the extent the agency has reached the consummation of its decisionmaking process at all, it did so many years ago, as expressed in the 1996 and 2010 Guidances. The Advisory Opinion merely restates the position expressed in those guidances, and thus "tread[s] no new ground." *Indep. Equip. Dealers Ass'n ("IEDA") v. EPA*, 372 F.3d 420, 428 (D.C. Cir. 2004). "It left the world just as it found it, and thus cannot be fairly described as implementing, interpreting, or prescribing law or policy." *Id.*

The 2010 Guidance made clear that covered entities may enter into "complex arrangements" that include contracts with "multiple pharmacies." 75 Fed. Reg. at 10,277. It also expressly stated that, "[u]nder section 340B, if a covered entity using contract pharmacy services requests to purchase a covered outpatient drug from a participating manufacturer, *the statute directs* the manufacturer to sell the drug at a price not to exceed the statutory 340B discount price." *Id.* at 10,278 (emphasis added). Thus the 2010 Guidance, in no uncertain terms, reflected the agency's position that manufacturers had a statutory obligation to honor the ceiling price when covered entities utilized multiple contract pharmacies. The Advisory Opinion did not deviate from this prior position.[3] It concluded 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." AO at 1.

When, as here, a later restatement of a prior interpretation is challenged, courts routinely hold that the restatement is not final agency action. *See, e.g. Menominee Indian Tribe of Wis. v. EPA*, 947 F.3d 1065 (7th Cir. 2020); *Clayton Cnty.*, 887 F.3d at 1267–68; *Golden & Zimmerman, LLC v. Domenech*, 599 F.3d 426 (4th Cir. 2010); *IEDA*, 372 F.3d at 428. For example, in *Menominee Indian Tribe*, the Seventh Circuit considered whether letters from the Environmental Protection Agency and Army Corps of Engineers were final agency action. 947 F.3d at 1068. The letters reiterated the agencies' positions as set forth in a 1984 document, and thus "did little but restate what the Tribe already knew." *Id.* at 1070. The court explained that each letter "imposes no obligations," "denies no relief," and carries no other "legal consequence[]." *Id.* Because the letters "only reiterated the status quo," there was "nothing for [the court] to review." *Id.*

The Fourth Circuit reached the same conclusion in a similar case, *Golden and Zimmerman, LLC*. In that case, plaintiffs sought review of a document published by the Alcohol, Tobacco, and Firearms

[3] To the extent Novo argues that the language in the AO does not exactly track that of the 2010 Guidance, such semantic differences are irrelevant for the purposes of the finality analysis. *See Clayton Cnty. v. FAA*, 887 F.3d 1262, 1267–68 (11th Cir. 2018) (rejecting arguments that different text of a restatement was relevant when "the meaning was clear" and there was no ambiguity "when read in context").

Bureau ("ATF") designed to help firearm licensees comply with the law, arguing that the answer to one of the Frequently Asked Questions ("FAQ") was "inconsistent" with the Gun Control Act. 599 at 428. The trouble was that the FAQ merely restated the ATF's interpretation published in a revenue ruling 40 years earlier. *Id.* at 428–29. Even though the FAQ did, in fact, "inform the regulated community of what violates the law," the court found that the FAQ did not "itself *determine* the law or the consequences of not following it." *Id.* at 432–33. "Its role, as stated in the publication, is simply to *inform* licensees of what the law, previously enacted or adopted, is, and its publication did not itself alter the legal landscape." *Id.* at 433. As the court explained, "if the ATF had never published [the FAQ]," it "would still have had the authority to prosecute licensees for engaging in the conduct" described in the FAQ because "legal consequences" arise only from the statute and its implementing regulations. *Id.*

So too here. The Advisory Opinion informs the public of the General Counsel's interpretation of the statute, but it does not impose any consequence because it merely restates the interpretation set forth in the 2010 Guidance. In other words, the Advisory Opinion "did little but restate what [Novo] already knew." *Menominee Indian Tribe*, 947 F.3d at 1070. Novo alleges that, as a result of the Advisory Opinion it "will be exposed to enforcement actions, potential allegations of overcharging, and accumulating civil monetary penalties, as well as the possible revocation of its participation in the Medicare and Medicaid programs." Compl. ¶ 92. But even if the Advisory Opinion or the 2010 Guidance had not been issued, covered entities would still be able to challenge Novo's practices through the alternative dispute resolution process set forth in the statute, 42 U.S.C. § 256b(d)(3)(B)(i), and the statute would still impose monetary penalties and other sanctions for Novo's refusal to honor purchases by covered entities. *Id.* § 256b(d)(1)(B)(vi). Indeed, HRSA explicitly communicated to Eli Lilly in August 2020—months before the General Counsel issued his legal advice—that the agency was "considering whether [its] new proposed policy constitutes a violation of section 340B and whether sanctions apply." AR 1098-99. HHS plainly viewed contract-pharmacy restrictions as potentially violative of *the statute* before the Advisory Opinion was issued. Thus the "legal

consequences" arise only from the statute, and not from the Advisory Opinion itself. *See Golden & Zimmerman, LLC.*, 599 F.3d at 433.

Novo's allegations focus on the practical consequences of what it thinks will happen as a result of the Advisory Opinion. Compl. ¶ 92-94. But such "practical consequences," including "the threat of having to defend itself in an administrative hearing" are "insufficient" to render agency action final or reviewable. *IEDA*, 372 F.3d at 428 (citation omitted); *see also Ocean Cty. Landfill Corp. v. U.S. EPA, Region II*, 631 F.3d 652, 656 (3d Cir. 2011) (no final agency action when the decision did not "contemplate immediate compliance"). Where, as here, Novo "continue[s] to operate" its illegal policy until some further action is taken, it cannot claim that the finality test is satisfied. *See Ocean Cty. Landfill Corp.*, 631 F.3d at 656.[4]

Novo's challenge to the Advisory Opinion should be dismissed for lack of final agency action.

B. Novo's Attempt to Upend the Settled Operation of the 340B Program is Time-Barred.

Even if Novo were correct that the agency has imposed new obligations on manufacturers outside those imposed directly by the 340B statute—and it assuredly has not, *see infra* § II.B—Novo's challenge to the General Counsel's legal advice still fails as a matter of law because it is jurisdictionally barred by the six-year statute of limitations. After several pharmaceutical companies engaged in a self-serving attempt to upend the long-settled 340B status quo, the General Counsel issued the Advisory Opinion to reiterate the agency's established statutory interpretation, first published in the Federal Register in 1996 and reaffirmed in 2010, both after public comment—an interpretation with which Novo and its peers had complied ever since. Novo's failure to challenge the agency's statutory interpretation when it was published twenty-five years ago, and republished more than a decade ago, is fatal to its claim here. The General Counsel *repeated* the agency's longstanding position but did not *reopen* the previous interpretations and thus did not restart the six-year limitations clock.

[4] Novo also fails to establish that the AO marks the "consummation of the agency's decisionmaking process," *Bennett*, 520 U.S. at 177-78, because the agency's position on the statutory question has not changed since the 1996 Guidance was issued. *See infra* § I.B.

"[E]very civil action commenced against the United States shall be barred unless the complaint is filed within six years after the right of action first accrues," 28 U.S.C. § 2401(a), and this express limitation on the ability to sue the federal government applies with equal force to challenges to agency action brought under the APA. *Nat'l Ass'n of Mfrs. v. Dep't of Def.*, 138 S. Ct. 617, 626-27 (2018); *see also Paucar v. Att'y Gen. of the U.S.*, 545 Fed. App'x 121, 124 (3d Cir. 2013) ("It is well established that the six-year statute of limitations applies to claims brought pursuant to the APA," and "the right of action first accrues on the date of the final agency action.") (internal quotations omitted). "Once the challenged agency action becomes final and invades a party's legally protected interest, the party's right to redress that injury under the APA accrues, and § 2401(a)'s six-year clock starts ticking." *Herr v. U.S. Forest Serv.*, 803 F.3d 809, 818-19 (6th Cir. 2015). This restriction is not subject to waiver or tolling because the government enjoys sovereign immunity "save as it consents to be sued … and the terms of its consent to be sued in any court define that court's jurisdiction to entertain the suit." *Diliberti v. United States*, 817 F.2d 1259, 1261 (7th Cir. 1987) (citing *Lehman v. Nakshian*, 453 U.S. 156, 160 (1981)). "Courts have consistently held that where the government's consent as sovereign to be sued is conditioned upon the filing of suit within a specified period of time, strict compliance with that condition is a jurisdictional prerequisite." *Id.*; *see also Kannikal v. Att'y Gen. of the U.S.*, 776 F.3d 146, 150 (3d Cir. 2015) (recognizing that § 2401(a) constitutes waiver of sovereign immunity that cannot be expanded by federal courts).

An agency's reiteration or application of an earlier decision does not constitute a new decision subject to challenge or start the limitations clock anew. In *IEDA*, 372 F.3d at 421-24, as in this case, the plaintiff challenged an agency's statement of its definitive legal interpretation, as set forth in an official letter from an EPA Director to regulated entities. The D.C. Circuit nonetheless explained that, because the most recent interpretation "reflects no change in the position announced" in earlier guidance, it was not a new agency action. *Id.* at 426; *id.* at 427 (the "Letter merely restated in an abstract setting—for the umteenth [sic] time—EPA's longstanding interpretation of the" legal requirements and "neither announced a new interpretation of the regulations nor effected a change … The Letter was purely informational in nature"). The court explained that, under the "reopening doctrine," an

agency's existing legal interpretations and regulations "are not newly reviewable" unless they have been reopened by agency action—*i.e.*, unless the administrative record evinces an intent by the agency to reevaluate and reconsider its earlier position, as opposed to merely explaining the earlier decision and applying it in a new context. *Id.* at 428. "Just as it would be folly to allow parties to challenge a regulation anew each year upon the annual republication of the Code of Federal Regulations, so too it is silly to permit parties to challenge an established regulatory interpretation each time it is repeated," because a contrary rule "would quickly muzzle any informal communications between agencies and their regulated communities." *Id.*

This holding repeatedly has been applied. In *General Motors Corp. v. EPA*, the court of appeals dismissed as untimely a challenge to an agency's legal interpretation, as embodied in official letters reiterating the agency's earlier position. 363 F.3d 442, 451 (D.C. Cir. 2004). Because the letters did not announce any intention to reevaluate the earlier pronouncement and instead "stated that outstanding violations would have to be addressed on the basis of EPA's long-held interpretation," the agency had not reopened its earlier decision. *Id.* at 449-50. Even though the earlier "interpretation was not published in the Federal Register," the court explained, the agency "can inform those affected simply by posting its new guidance or memoranda or policy statement on its website." *Id.* at 451. And because the plaintiff had failed to challenge the agency's interpretation within the applicable period for judicial review, its later attempt to attack that same position when embodied in an official letter was time-barred. Indeed, a contrary rule "to permit review whenever [an agency] reiterates" an interpretation but "has not changed its position," "would allow [plaintiff] to avoid the consequences of its failure to adhere to the congressionally prescribed jurisdictional window" of the relevant statute. *Edison Elec. Inst. v. OSHA*, 411 F.3d 272, 277-78 (D.C. Cir. 2005); *see also Biggerstaff v. FCC*, 511 F.3d 178, 184-85 (D.C. Cir. 2007) (confirming that proper way to challenge a longstanding agency interpretation as violative of a statute is through petition for rulemaking and, in absence of such petition, plaintiff must demonstrate clear intent in administrative record to reopen earlier rulemaking); *Pub. Citizen v. Nuclear Reg. Comm'n*, 901 F.2d 147, 150 (D.C. Cir. 1990) (confirming applicability of reopening doctrine to determination "whether an agency's restatement of an existing rule or policy" in a new format renders

the issue "challengeable anew"); *Peri & Sons Farms, Inc. v. Acosta*, 374 F. Supp. 3d 63, 71-73 (D.D.C. 2019) (rejecting as untimely challenge to 2019 agency notice that "implement[ed] the decisions it made long ago [in 2010 Rule] and reflect[ed] the Department's continued adherence to them"). Stated simply, the reopening doctrine confirms that a policy established in an earlier action is not subject to fresh challenge when reiterated or applied subsequently unless a plaintiff can show that the agency has reopened its previous position for renewed consideration—as distinguished from explication.

Novo's challenge to the Advisory Opinion is an untimely collateral attack on the agency's consistent, twenty-five-year statutory interpretation. As explained *supra*, Background § I, in 1996 HHS concluded that the 340B statute does not allow manufacturers to refuse discounted-drug purchases by covered entities that rely on contract pharmacies. *See* 61 Fed. Reg. 43,549-50 (interpreting 340B statute to affirmatively require drug makers to honor purchases by covered entities, confirming if the "entity directs the drug shipment to its contract pharmacy," that in no way "exempts the manufacturer from statutory compliance"). There is nothing voluntary in that interpretation; on the contrary, the only voluntary aspect of the 1996 Guidance was the choice of covered entities whether to use contract-pharmacy arrangements, given that covered entities remain liable to prevent duplicate discounting and diversion regardless of the dispensing mechanism chosen for covered drugs. *See id.*

Indeed, not only *could* Novo have mounted the same challenge in 1996 that it now brings, a trade association of which it currently is a member did just that. Novo's assertion that the Advisory Opinion "seeks to change the legal requirements that the 340B program imposes on manufacturers," Compl. ¶ 7, by newly requiring manufacturers to honor contract-pharmacy dispensing, is flatly disproven by the legal theories set forth in that twenty-five-year old litigation. PhRMA pleaded on behalf of drug companies that, "[u]nder the contract pharmacy guidelines, [] a manufacturer is *required* to make sales to unlicensed entities [that do not operate a pharmacy] or be in violation of its Pharmaceutical Pricing Agreement with the Secretary—which would jeopardize … the manufacturer's future sales in all states." *PhRMA*, Compl. ¶ 38; *see also id.* ¶ 21 (acknowledging that manufacturer which "disregard[ed] the contract pharmacy guidelines … where diversion is proven or suspected" would face "terminat[ion] [of] the manufacturer's agreement with the Secretary"). PhRMA relied on a

letter from the HRSA Administrator to the entire industry conveying that, when "an eligible covered entity utilizing this mechanism requests to purchase a covered drug from a participating manufacturer, the statute directs the manufacturer to sell the drug at the discounted price," and does not "exempt[] the manufacturer from compliance with the agreement." *Id.* Ex. D. Clearly it is Novo and its cohort—not HHS—that is attempting to transform the program through a counterfactual portrayal of its historical operation.[5]

Again in 2010 HHS promulgated contract-pharmacy guidelines after issuing notice and providing a 60-day comment period for interested parties, such as Novo, to participate. *See* 75 Fed. Reg. at 10,272. Once again HHS definitively set forth its statutory interpretation: "Under section 340B, if a covered entity using contract pharmacy services requests to purchase a covered outpatient drug from a participating manufacturer, *the statute directs the manufacturer to sell the drug* at a price not to exceed the statutory 340B discount price." *Id.* at 10,278 (emphasis added). That mandatory language reiterated the agency's considered decision on what the 340B *statute* requires—not, as Novo portrays, a suggestion from the agency that manufacturers may elect to follow or ignore. *See* Compl. ¶ 43 (inaccurately asserting that "2010 guidance did not purport to impose binding obligations on manufacturers"). Indeed, HHS specifically explained that the 2010 Guidance does not "represent a substantive rulemaking under the APA" because it "neither imposes additional burdens upon manufacturers, nor creates any new rights for covered entities under the law" and instead constitutes "interpretive guidance" *of the statute itself*. 75 Fed. Reg. at 10,273. But as in 1996, there was no ambiguity in the agency's view that manufacturers are obliged to honor purchases by covered entities regardless whether contract pharmacies are used; the guidance made no suggestion that pharmaceutical companies can reject purchases by covered entities that rely on outside dispensers. True, the agency's interpretation of the obligation imposed on manufacturers was coupled with other voluntary guidance, advising covered entities on best practices to structure pharmacy agreements so as to prevent diversion

[5] It matters not that PhRMA's 1996 challenge was dismissed without prejudice and thus not entitled to preclusive effect. It both demonstrates the falsity of Novo's portrayal of the Advisory Opinion's interpretation as novel—and evidences the pharmaceutical industry's historic understanding of its requirements under the statute.

or duplicate discounting. *See, e.g.*, *id.* at 10,279 (outlining "suggested contract provisions … for illustrative purposes … not intended to be comprehensive, exhaustive or required"). But the coupling of HHS's interpretation of the statutory obligations on manufacturers with other, voluntary provisions advising covered entities in no way indicated that manufacturers had a choice unilaterally to opt out of providing 340B discounts whenever a covered entity serves its patients through outside pharmacies.

Had Novo disagreed with the agency's decision that the 340B statute requires manufacturers to honor purchases from covered entities regardless whether a contract-pharmacy model is used, Novo should have brought suit challenging the 2010 Guidance (or the earlier, equally mandatory interpretation in 1996). Likewise, had Novo contended that this obligation exceeded the 340B statute and thus must be imposed through legislative rulemaking, not an interpretive rule, Novo could have mounted a procedural challenge to the 2010 or 1996 Guidance. Indeed, Novo even *admits* that, in its view, the 2010 Guidance "radically changed how covered entities operated under the 340B program," Compl. ¶ 42, yet nowhere does Novo even attempt to excuse its failure to challenge either of the agency's interpretations of manufacturers' statutory obligations (or even to petition the agency to revisit its interpretation) within the six-year statute of limitations. Instead, Novo and other drug companies complied fully with HHS's interpretation for the past two and half decades—a timeframe in which covered entities have relied heavily on contract pharmacies to access 340B-discounted drugs.

Nor did the General Counsel's legal advice reopen those earlier interpretations. Far from making *any* change to the preexisting status quo, as Novo portrays (Compl. ¶ 7), the General Counsel simply reaffirmed the agency's "longstanding interpretation of the statute," AO at 4, in response to havoc wrought by manufacturers' unilateral contract-pharmacy restrictions. The Advisory Opinion does not rely on changed circumstances or even assert that anything *has* changed in the operation of the 340B Program (aside from recent, disruptive restrictions by drug makers). Abjectly false is Novo's claim that the Advisory Opinion "s[ought] to change the legal requirements" on manufacturers. Compl. ¶ 7. Novo cannot ignore the 1996 and 2010 Guidances out of existence. Contrary to its portrayal, the agency could hardly have been clearer in its mandatory phrasing regarding what the statute requires of manufacturers, 75 Fed. Reg. at 10,278, and Novo points to *nothing* in the guidance

to support its assertion that the interpretation was viewed as voluntary. Rather than break any new ground, the General Counsel's recent legal advice simply confirmed the agency's "consistent position over the past 24-plus years." AO at 4. That reiteration does not permit Novo to launch an untimely collateral attack on HHS's 1996 and 2010 decisions interpreting the 340B statute; any claim Novo might have had to challenge the substance or promulgation of the agency's contract-pharmacy interpretation became time barred on March 5, 2016, six years from publication of the 2010 Guidance in the Federal Register. 75 Fed. Reg. at 10,272 (publication date of March 5, 2010).

II. EVEN IF THE ADVISORY OPINION WERE REVIEWABLE, NOVO'S CLAIMS WOULD FAIL.

A. Notice-and-comment rulemaking is not required because the Advisory Opinion is an interpretive rule.

Even if the Advisory Opinion were final agency action, and Novo's claims were not time-barred, its notice-and-comment claim would still fail for the additional reason that the Advisory Opinion is not a legislative rule. The Advisory Opinion is, at most, an interpretive rule that advises the public of HHS's interpretation of a statute, and is exempted from the APA's notice and comment requirements. *See* 5 U.S.C. § 553(b)(3)(A).

"[T]he critical feature of interpretive rules is that they are issued by an agency to advise the public of the agency's construction of the statutes and rules which it administers." *Perez v. Mortg. Bankers Ass'n*, 575 U.S. 92, 97 (2015) (citation omitted). These rules do not "have the force and effect of law," *id.*, or "alter legal rights." *Sekula v. FDIC*, 39 F.3d 448, 457 (3d Cir. 1994); *see also Chao v. Rothermel*, 327 F.3d 223, 227 (3d Cir. 2003) (Interpretive rules "do not themselves shift the rights or interests of the parties, although they may change the way in which the parties present themselves to the agency."). Instead, they "state the agency's view of what existing law requires," "merely clarify[ing] or explain[ing] existing law or regulations." *Sekula*, 39 F.3d at 457.

The Advisory Opinion is a quintessential interpretive rule. It does not "alter legal rights," *id.*, but rather explains the agency's interpretation of the statutory phrase "purchased by." The 340B statute requires the Secretary to enter into agreements with drug manufacturers "under which the

amount required to be paid" for certain drugs "purchased by a covered entity" does not exceed the ceiling price on those drugs. 42 U.S.C. § 256b(a)(1). The Advisory Opinion interprets this unambiguous text to conclude that the phrase "purchased by a covered entity" includes scenarios where "contract pharmacies are acting as agents of a covered entity." AO at 1-2. Noting that the textual analysis is dispositive "given the lack of ambiguity in the plain text of the statute," the Advisory Opinion explains that "neither the agency nor a private actor" is authorized to "add requirements" to the statute. *Id.* at 2–3. It goes on to explain how the purpose and history of the 340B Program also support this conclusion, and how the contrary rationale of certain pharmaceutical manufacturers is unpersuasive. *Id.* at 3-8. Although Novo attempts to paint a different picture, 42 U.S.C. § 256b(a)(1) "was fully operative" without the Advisory Opinion, *see Appalachian States Low-Level Radioactive Waste Comm'n v. O'Leary*, 93 F.3d 103, 113 (3d Cir. 1996), and the AO exists only to "advise the public of the agency's construction of [the statute]," *Mortg. Bankers Ass'n*, 575 U.S. at 97.

Courts routinely identify agency guidance as interpretive rules in analogous circumstances. For example, in *Shalala v. Guernsey Mem'l Hosp.*, 514 U.S. 87 (1995), the Supreme Court considered whether the HHS Secretary's adoption of a Medicare Provider Reimbursement Manual was invalid for failure to comply with the APA's notice-and-comment requirements. *Id.* at 91. The dispute arose when the Secretary relied on the manual to determine that a reimbursable loss by the challenging hospital should be amortized, rather than reimbursed at once. *Id.* at 97. In promulgating the relevant provision of the manual, the Secretary determined "that amortization is appropriate" to ensure compliance with a statutory prohibition on cross-subsidizing health services at one time that were rendered over a number of years. *Id.* at 97-99. Though the court noted the apparent benefits of recognizing the loss at once, it explained that the Secretary's Manual requiring amortization was a "prototypical example of an interpretive rule" because it was simply an "application of the statutory ban on cross-subsidization and the regulatory requirement that only the actual cost of services rendered to beneficiaries during a given year be reimbursed." *Id.* at 99. The court also emphasized that the manual did not adopt "a new position inconsistent with any . . . existing regulations." *Id.* at 100. So too here. The Advisory Opinion simply applies the statutory requirement that drugs "purchased by" covered

entities be reimbursed at a certain price; it does not adopt any "new position" inconsistent with the statute or existing regulations.

Pennsylvania Department of Human Services v. United States, a recent Third Circuit decision, is also instructive. 897 F.3d 497 (3d Cir. 2018). There, the court considered whether a 1994 State Medicaid Director Letter explaining that training program costs were not reimbursable under the Medicaid statute was an interpretive rule. *Id.* at 500. The court noted that, as with the Advisory Opinion, the agency issued the letter after an influx of questions and activities to "reiterate its longstanding policy." *Id.* at 501 (citation omitted). Emphasizing that the letter "explains . . . the statutory requirement," and "reiterates" the agency's interpretation of the statute, the court held that the letter "thus qualifies as an interpretive rule on several levels." *Id.* at 504–05. Because the letter "represent[ed]" what the Secretary "thinks" the statute means, and also "clarifie[d] and explain[ed]" the statute, the letter was an interpretive rule. *Id.* at 505. There can be no meaningful distinction drawn between the Advisory Opinion and the letter at issue in *Pennsylvania Department of Human Services*. Both represent the interpretation of a statutory requirement, and are explanations of what an agency "thinks" the statutory requirement means.

Novo's arguments to the contrary cannot be reconciled with this binding precedent or the language of the Advisory Opinion. In its complaint, Novo alleges that the Advisory Opinion is a "legislative rule" because it "requires drug manufacturers to provide discounted drugs to contract pharmacies" and "expose[s]" Novo to "enforcement actions and civil monetary penalties." Compl. ¶¶ 111–13. But the Advisory Opinion does not suggest that Novo or any other drug manufacturer must "provide discounted drugs to contract pharmacies," *see id.*; rather, it merely confirms in accordance with longstanding HHS guidance that the 340B statute requires a manufacturer to sell discounted drugs to covered entities, regardless of the mechanism by which they dispense those drugs. AO at 1–2. The Advisory Opinion clarified further that no one—including a manufacturer or the agency—is statutorily authorized "to add requirements to the statute." *Id.* Novo surely disagrees with that conclusion. But, the fact that Novo disagrees with the Advisory Opinion's statutory interpretation

does not render the opinion a legislative rule any more than the disagreement of the plaintiffs with the interpretations set forth in the interpretive rules in *Shalala* or *Pennsylvania Department of Human Services*.

Under these circumstances, even if the Court were to determine that the Advisory Opinion was reviewable, Novo's notice-and-comment claim should be dismissed.

B. Novo fails to state a claim on the merits because its obligation to offer discounted drugs to covered entities is imposed by the 340B statute itself.

Even if the Advisory Opinion contained any new decisionmaking—rather than simply a reiteration of longstanding agency position—Novo still would fail to state a claim that the Advisory Opinion exceeded statutory authority. Compl. ¶¶ 98-104 (alleging that AO should be set aside under 5 U.S.C. §§ 706(2)(A), (C)). Novo's claim relies on the false premise that "the agency has concluded that drug manufacturers are legally obligated to facilitate the *transfer* of their discounted drugs to contract pharmacies." *Id.* ¶ 7 (emphasis added). This claim finds no support in the Advisory Opinion. Novo also urges this Court to reach the stunning conclusion that when Congress required manufacturers to "offer each covered entity covered outpatient drugs for purchase at or below the applicable ceiling price," 42 U.S.C. § 256b(a)(1), it gave "manufacturers [] discretion to decide when or whether to honor covered entity requests" anytime the safety-net provider lawfully employs the services of an outside drug-dispenser. Compl. ¶ 6. The statute provides no support for the claim that Congress implicitly allowed *manufacturers*—parties with a vested interest in minimizing the volume of deeply discounted sales—unilaterally to exercise any discretion on "when or whether to honor covered entity" purchases, *id.*—indeed, Novo's assertion defies common sense. Far from exceeding lawful authority, the Advisory Opinion merely confirms what would be true in the absence of its advice, and what has been true since the inception of the 340B Program: Manufacturers, including Novo, *must offer* 340B discounted drugs to covered entities in order to remain eligible to participate in Medicaid and Medicare Part B, and any attempt unilaterally to condition those sales to covered entities on particular dispensing models runs afoul of manufacturers' statutory obligation. Because the Advisory Opinion simply confirms a straightforward application of the statute, it was not issued in excess of authority.

The General Counsel's advice hewed closely to the statutory text, which expressly conditions access to Medicaid and Medicare Part B on a manufacturer's agreement 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) (analyzed at AO 2). The Advisory Opinion further noted that each participating manufacturer, including Novo, has signed a contract with HHS embodying its agreement "to charge covered entities a price for each unit of the drug that does not exceed [the ceiling price]," and that "[t]his fundamental requirement is not qualified, restricted, or dependent on how the covered entity chooses to distribute the covered outpatient drugs," only "that the discounted drug be 'purchased by' a covered entity." *Id.* And just as HHS cannot add new requirements or obligations to the statute, the General Counsel explained, nor can manufacturers. "It is difficult to envision a less ambiguous phrase" than "purchased by," and "no amount of linguistic gymnastics" can rework the statutory language into authorization *for Novo* to condition fulfillment of its obligation to make discounted sales on a covered entity's agreement to undertake the expense of operating an in-house pharmacy or selecting any particular drug-dispensing model. In short, the statute is unambiguous in mandating that Novo make sales *to covered entities*, and Novo cannot skirt that obligation by erecting hurdles that limit a safety-net provider's choice among lawful dispensing models to serve its own patients. *Id.*; *see also id.* at 3 ("the medications at issue are sold by the manufacturer to the covered entity; the covered entity takes title and … pays the manufacturer … [t]he situs of delivery, be it the lunar surface, low-earth orbit, or a neighborhood pharmacy, is irrelevant" because the covered entity maintains ownership of the discounted drug until it is dispensed to a qualified patient).

Although that "analysis is dispositive" in light of the total absence of ambiguity in the statute's command to honor *purchases by* covered entities, *id.*, the General Counsel went on to explain how it also fulfills Congress's purpose and comports with the decades-long operation of the 340B Program. When Congress created the program in 1992, only 500 out of 11,500 covered entities in existence operated an in-house pharmacy; the other 95+% relied on outside pharmacies to dispense medications to their patients. AO at 4 (citing 61 Fed. Reg. at 43,550). And because Congress created the 340B

Program for the express purpose of providing much-needed *revenue* to covered entities, it could not possibly have intended to require the overwhelming majority of safety-net healthcare providers to undertake the enormous expense of establishing and maintaining *a pharmacy* in order to access the discounted drugs to which they are statutorily entitled. *Id.* at 3-4 (citing H.R. Rep. No. 102-384, pt.2, at 12 (1992)). Congress legislates against the backdrop of real-world facts and, the General Counsel noted, it directed 340B "at benefiting providers that are small, resource-limited, receiving federal assistance, or serving disadvantaged populations." *Id.* at 4. "To champion a policy" such as Novo now urges, "ungrounded in the language of the statute, that would foreclose 340B discounts to 95 percent of covered entities and foreclose discounts to the neediest of this cohort is inconsistent with [the] purpose of the Program and common sense." *Id.* The General Counsel persuasively explained that, had Congress intended to require the overwhelming majority of covered entities to fundamentally overhaul the method by which they provide drugs to patients (abandoning use of outside pharmacies to obtain all the necessary licensure, controls, employees, etc. to dispense in-house), rather than for covered entities to benefit from discounted drugs *through existing dispensing models*, "it would have used language affirmatively precluding the use of contract pharmacies as arms in the distribution channel." *Id.*

Importantly, the General Counsel also noted that HHS has interpreted the 340B statute "consistent[ly] [] over the past 24-plus years" to require drug makers "to offer ceiling prices even where contract pharmacies are used." AO at 4. Although in this suit Novo inaccurately insists that this interpretation was newly imposed by the Advisory Opinion, Compl. ¶ 7, the Advisory Opinion correctly notes that both the 1996 and 2010 contract-pharmacy guidances are plain that the use of such arrangements are voluntary *for covered entities*, who must structure their contracts to prevent duplicate discounting and diversion—but the obligation for drug companies to fill orders by covered entities is, and always has been, mandatory. *Id.* (citing 1996 Guidance); *id.* (noting that "contract-pharmacy arrangements have been utilized, and honored by manufacturers, *since 1996 and earlier*") (emphasis added). The General Counsel also noted that judicial review of this longstanding position would take into account agency expertise interpreting the statute it administers, the common practice

of regulated entities operating under 340B for decades, and Congressional acquiescence in the agency's settled interpretation.

Finally, the General Counsel demonstrated the folly in certain manufacturers' newfound objection to the 24-plus-year status quo, as reflected in certain communications from manufacturers to the agency. First, Novo and its cohort's "primary rationale offered for cutting off contract pharmacies," AO at 5, to prevent diversion and duplicate discounting, is an extra-statutory self-help mechanism that directly contravenes the express command of Congress. To the extent manufacturers' concerns are sincere (rather than a thinly veiled tactic to shrink the program), the 340B statute spells out precisely how suspected or actual diversion or duplicate discounting must be addressed: The manufacturer "must (1) conduct an audit, and (2) submit the claim to the [ADR] process." *Id.* (citing 42 U.S.C. § 256b(a)(5)(A), (B) and (d)(3)(A)). No language in the statute, however, permits a manufacturer to deny a covered entity's discounted-drug order on the basis of the dispensing mechanism chosen, and the "manufacturers' … unilateral refusal to sell drugs through contract pharmacies is at odds with the structure and intended operation of the statute." *Id.* Second, HHS already has confirmed in a previous, duly promulgated regulation that "[m]anufacturers cannot condition sale of a 340B drug at the 340B ceiling price because they have concerns or specific evidence of possible non-compliance by a covered entity." *Id.* (citing 82 Fed. Reg. 1210, 1223 (Jan. 5, 2017)). Third, the suggestion that covered entities' decades-old reliance on contract pharmacies constitutes "diversion" is specious. AO at 6. The statute provides that "a covered entity shall not resell or otherwise transfer the drug to a person who is not a patient of the entity." *Id.* (citing 42 U.S.C. § 256b(a)(5)(B)). This language quite plainly means that covered entities may not resell discounted drugs to non-patients, nor transfer the drugs to other, non-covered healthcare providers for prescribing to their own patients. But it is "absurd" to suggest that this straightforward prohibition requires a safety-net provider to ensure that 340B drugs are physically dispensed—*i.e.*, individually *handed*—to its patients by a pharmacist employed by that covered entity. AO at 7. Nothing in the statute restricts commonplace, real-world supply-chain logistics or outlaws preexisting dispensing models employed by covered entities at the program's inception, such as the use of outside

pharmacies. Indeed, taken to its logical conclusion, manufacturers' argument that use of contract pharmacies constitutes "diversion" would mean that, "if a covered entity uses a courier service" or mail-delivery service "to send discounted drugs to its patient, this, too, would [] be an illegal 'transfer' to the shipper." AO at 7. It also would mean that, for decades, covered entities have relied upon and manufacturers have acquiesced in a scheme that does violence to the statutory text. Such a radical reworking of the 340B Program's settled operation—driven by a small cohort of supposed competitors—finds no support in the statute. As the General Counsel concluded, "[l]arge portions of the current 340B Program" cannot be made to turn on "solely manufacturers' voluntary choice to offer the ceiling price," rather than "a statutory mandate"; thus, "manufacturers may not refuse to offer the ceiling price to covered entities, even where the latter use distribution systems involving contract pharmacies." AO at 7-8.

The Advisory Opinion plainly did not "expand the 340B program to require manufacturers to facilitate transferring discounted drugs to third parties," Compl. ¶ 103, because it merely confirmed what always has been true—that only covered entities may purchase 340B drugs, but they need not dispense them in-house. Similarly, the Advisory Opinion did not "expose[] Novo to government enforcement actions for alleged noncompliance, including civil monetary penalties … and the revocation of its ability to participate in Medicare and Medicaid," *id.* ¶ 78. Rather, *the 340B statute subjects Novo to these sanctions so long as it continues to refuse purchases made by covered entities, see* 42 U.S.C. § 256b(a)(1), and it contains no provision granting Novo "discretion," Compl. ¶ 6, to refuse to honor such purchases based on the dispensing mechanism lawfully selected by the covered entity.

Novo's allegations to the contrary lack merit. It first criticizes the General Counsel for failing to "identify any statutory provision that requires manufacturers to cause their discounted drugs to be transferred to commercial contract pharmacies." Compl. ¶ 75. That claim is specious; the Advisory Opinion did not purport to require drug companies to *transfer* their drugs to for-profit entities, but rather to *sell* drugs to safety-net providers, regardless whether they dispense in-house or through neighborhood locations. Novo then insists that its new policy satisfies its obligations because it "places *no* limits on the amount of 340B drugs that the covered entity itself is able to purchase at the 340B

ceiling price, delivered to the covered entity itself." Compl. ¶ 81. This assertion is disingenuous; an "offer" to make a purchase, made with onerous and non-statutory conditions (including that a covered entity establish a pharmacy or require its disadvantaged patients to travel great distances to fill prescriptions at a single site) cannot fulfill Novo's obligations. Congress simply did not permit manufacturers to craft their own devices to limit access to discounted drugs, and an "offer" to sell drugs that the overwhelming majority of covered entities cannot, in practice, avail themselves of (or that restricts patients' access to dispensing sites) surely is not what Congress envisioned. Because the General Counsel's analysis faithfully interprets the 340B statute, is grounded in Congressional intent, as expressed in its terms, and in no way expands the statute to require of manufacturers anything not already mandated by law, Novo fails to state a claim that the General Counsel's legal advice exceeded statutory authority. Even were this claim justiciable, it fails as a matter of law and must be dismissed.

C. The Advisory Opinion is neither arbitrary nor capricious.

Novo claims that the Advisory Opinion is arbitrary and capricious under the APA, 5 U.S.C. § 706(2)(A). *See* Compl. ¶ 120–25. Its claims in this respect are meritless.

Judicial review under the APA's arbitrary-and-capricious standard is highly "deferential," requiring only "that agency action be reasonable and reasonably explained." *FCC v. Prometheus Radio Proj.* (*Prometheus*), 141 S. Ct. 1150, 1158 (2021). A court must "presume[] the validity" of the challenged action, *SBC Inc. v. FCC*, 414 F.3d 486, 496 (3d Cir. 2005), "may not substitute its own policy judgment for that of the agency," *Prometheus*, 141 S. Ct. at 1158, and "should uphold a decision of less than ideal clarity if the agency's path may reasonably be discerned," *FCC v. Fox Television Stations, Inc.*, 556 U.S. 502, 513–14 (2009) (citations omitted).

First, several of Novo's arbitrary-and-capricious claims rest on the same misreading of the Advisory Opinion that underlies its statutory arguments. *See* Compl. ¶¶ 120, 122, 124. For example, Novo maintains that the Advisory Opinion failed to adequately consider "the text of the 340B statute" because it imposed on manufacturers the obligation "to offer 340B prices to contract pharmacies," which are not among "the covered entities Congress specifically enumerated" in the statute. *Id.* at

¶ 120, 122. But as explained above, the Advisory Opinion cannot be read to have interpreted the 340B statute to impose such a requirement. Read plainly, the opinion simply acknowledged that drug makers are directed by the statute to sell 340B discounted drugs to *covered entities*, whether these entities distribute those drugs through contract pharmacies or some other method of distribution. *See supra* II.B. Novo's arguments do not appreciate that distinction, and thus they fail to demonstrate that the Advisory Opinion unreasonably or inadequately considered the text of the 340B statute.

Second, contrary to Novo's contentions, the General Counsel was not required to consider claims that covered entities' use of contract pharmacies has resulted in instances of program non-compliance. *See* Compl. ¶ 121. Whether there have been specific cases of non-compliance (*i.e.*, drug diversion or duplicate discounting, *see* Compl. ¶¶ 49–50) under these circumstances is not a "relevant factor[]" in interpreting what is *generally* required of drug makers under the 340B statute, which was the question addressed by the Advisory Opinion. *See NVE, Inc. v. Dep't of Health & Hum. Servs.*, 436 F.3d 182, 190 (3d Cir. 2006). Even so, the General Counsel *did* consider drug makers' concerns regarding drug diversion and duplicate discounting and appropriately directed them to pursue these claims in HHS's administrative dispute-resolution process, *see* AO at 5, the forum in which Congress has required such claims to be adjudicated, *see* 42 U.S.C. § 256b(d)(3)(A).

Third, Novo argues that the Advisory Opinion failed to "reconcile" with HHS's "earlier pronouncements that manufacturers were under no legally enforceable obligation to offer 340B prices to contract pharmacies." *See* Compl. ¶ 122. As an initial matter (and as explained above), HHS has never suggested that drug makers must offer 340B discounted prices to *contract pharmacies*. *See supra* § II.B. The agency has, however, long understood the 340B statute to direct drug makers to sell discounted drugs to *covered entities* regardless whether they use contract pharmacies for distributing those drugs. *See* AR 370–71 (1996 Guidance); *id.* at 392 (2010 Guidance); AO at 2–4. And to the extent Novo is claiming that HHS has at some point considered this *statutory* obligation to be unenforceable,

see Compl. ¶ 122, it cites nothing to support that contention.[6] Novo has thus failed to identify a "dramatic change" in HHS's policy that needed to be "reconcile[d]" in the Advisory Opinion. *See id.*

Fourth, Novo maintains that the Advisory Opinion is "contrary to" the Department of Health and Human Services Good Guidance Practices, 85 Fed. Reg. 78,770-02 (Dec. 7, 2020) (to be codified at 45 C.F.R. pt. 1) ("Good Guidance Rule"). Compl. ¶ 123. But because the Advisory Opinion was issued on December 30, 2020, it is not subject to the Good Guidance Rule's provisions, which did not become effective until January 6, 2021. 85 Fed. Reg. at 78770.

Fifth, Novo faults the General Counsel for not finding that contract pharmacies do *in fact* function as agents of covered entities under "standard criteria for establishing" an agency relationship. Compl. ¶ 76. But that was obviously not the question the Advisory Opinion sought to answer. Indeed, the Advisory Opinion never suggested that a drug maker's obligation to sell discounted drugs to covered entities distributing those drugs through contract pharmacies depends on whether an agency relationship can be established under any "standard criteria" of agency law. *See id.* Rather, it was in rebutting the contention that a covered entity's mere use of a contract pharmacy for distribution is *itself* unlawful drug diversion that the Advisory Opinion explained that the relationship between these entities generally functions like a principal-agent relationship, "in that [a contract pharmacy] would not resell a … drug but rather distribute [it] on behalf of the covered entity" who purchases and retains title to the drug. AO at 6 (quoting AR 371). It was only in that sense that the Advisory Opinion referred to contract pharmacies as "agents" of a covered entity. Analyzing the relationships of individual covered entities and their contract pharmacies to determine whether certain "standard criteria" of agency law is satisfied would have been a useless exercise irrelevant to the narrow question

[6] Novo does cite a July 2020 news report in which HRSA was purported to have acknowledged that agency guidance is not itself legally enforceable. Compl. ¶ 62 (citing Tom Mirga, *HRSA Says its 340B Contract Pharmacy Guidance is Not Legally Enforceable* (July 9, 2020), Compl., Ex. J). But this straightforward proposition in no way conflicts with HHS's twenty-five-year interpretation of the *statutory* obligation on manufacturers to honor purchases. As explained above, the 1996 and 2010 Guidances *did* contain voluntary proposals for covered entities, but in no way suggested that manufacturers' statutory obligations were voluntary. Indeed, Novo's assertion is plainly belied by HHS's letters to Eli Lilly (months before the Advisory Opinion) stating that contract-pharmacy restrictions may result in penalties. AR 1098–99, 1149–50.

the Advisory Opinion addressed. *See NVE*, 436 F.3d at 190.

Novo similarly takes issue with what it describes as the Advisory Opinion's "inapt analog[y]," Compl. ¶ 124, between the use of a contract pharmacy and a "courier service" to distribute 340B discounted drugs, arguing that the General Counsel never explained why he drew this comparison. Compl. ¶ 77. But the reason for this analogy is readily apparent from its context. As just explained, the Advisory Opinion sought to rebut the suggestion that a covered entity's mere use of a contract pharmacy for distribution constitutes unlawful drug diversion. AO at 6. In doing so, the Advisory Opinion explained that such reasoning would make any shipment of 340B drugs to a covered entity's patients—whether through a contract pharmacy, a "courier service," or any other distribution method that "did not involve a physical hand-off from [an] employee of a covered entity to [a] patient"—an unlawful drug diversion under the 340B statute. *Id.* at 7. It was only for that limited purpose that the Advisory Opinion drew the well-reasoned analogy between contract pharmacies and courier services.

D. Novo's takings claims fail as a matter of law.

Novo contends that the Advisory Opinion contravenes the Takings Clause of the Fifth Amendment, which prohibits private property from being "taken for public use, without just compensation." *See* Compl. ¶¶ 127–35; *see also* 5 U.S.C. § 706(2)(B) (requiring final agency action to be set aside when it is "contrary to constitutional right"). Novo articulates two claims in this respect. *First*, it challenges the Advisory Opinion as effecting a "private" regulatory taking of property that no amount of compensation can justify. Compl. ¶¶ 130–31, 133–34. In Novo's view, the Advisory Opinion "forces" Novo to transfer its personal property—*i.e.*, the drugs it manufactures—to contract pharmacies at a "significant financial loss[]," and does so solely for the contract pharmacies' "private benefit." *Id.* ¶¶ 96, 133–34. *Second*, Novo invokes the "unconstitutional conditions" doctrine in arguing that the Advisory Opinion requires Novo to succumb to a private regulatory taking of property in order to obtain coverage of its drugs under Medicaid and Medicare Part B. *Id.* ¶¶ 97, 132, 135.

Both claims fail as a matter of law. For reasons explained above, the Court can summarily reject Novo's contentions. The obligation that Novo ship 340B discounted drugs to contract

pharmacies that distribute those drugs on behalf of covered entities is an obligation imposed by the 340B statute, not the Advisory Opinion. *See supra* § II.B. Because it is not the Advisory Opinion that imposes the challenged obligation, Novo's takings claims fail outright.

However, were the Court to find that the Advisory Opinion (i) is a reviewable final agency action (ii) that imposes a new obligation on Novo—not previously imposed by the 340B statute—to ship discounted drugs to covered entities' contract pharmacies and (iii) is an otherwise lawful action,[7] Novo's takings claims would be meritless nonetheless. *First*, with respect to its private-regulatory-takings claim, Novo has alleged neither a regulatory taking nor a taking without a justifying "public use." Novo cannot base a takings claim on an obligation arising under a regulated government program like the 340B Program in which it voluntarily participates. *See, e.g.*, *Ruckelshaus v. Monsanto Co.* (*Monsanto*), 467 U.S. 986, 1007 (1984). And even if Novo could demonstrate a taking under these circumstances, such a taking would easily satisfy the Fifth Amendment's "public use" requirement. *See, e.g.*, *Kelo v. City of New London*, 545 U.S. 469, 477–78 (2005). *Second*, not only does Novo's failure to allege a viable takings claim defeat its unconstitutional-conditions claim *a fortiori*, *see, e.g.*, *Koontz v. St. Johns River Water Mgmt. Dist.*, 570 U.S. 595, 612 (2013), but the Supreme Court has rejected the very theory underlying this claim, *Monsanto*, 467 U.S. at 1007.

1. Novo fails to state a private-regulatory-takings claim.

i. Novo's voluntary participation in the 340B Program forecloses its private-regulatory-takings claim.

Novo argues that having to transfer its property (*i.e.*, manufactured drugs) to private entities (*i.e.*, contract pharmacies) solely to serve those entities' private interests effects a private regulatory taking that no amount of compensation can authorize under the Fifth Amendment. Compl. ¶¶ 96, 133–34. But an obligation arising under the 340B Program, in which Novo voluntarily participates, cannot constitute a taking—this alone disposes of Novo's private-regulatory-takings claim. *See Rancho de Calistoga v. City of Calistoga*, 800 F.3d 1083, 1089, 1093 (9th Cir. 2015).

[7] A takings analysis presupposes that the underlying government action is otherwise valid. *See Lingle v. Chevron U.S.A. Inc.*, 544 U.S. 528, 537 (2005).

In *Monsanto*, the Supreme Court rejected a regulatory-takings challenge to a federal statute requiring pesticide manufacturers to register their products before selling them domestically. 467 U.S. at 991–96, 1013. The challenged statutory provision obligated manufacturers, as a condition to registration, to submit certain trade secrets with the federal government, which was then authorized to publicly disclose that information. *Id.* at 990, 995–96. The Supreme Court held that, although trade secrets are constitutionally protected property that are destroyed by public disclosure, *id.* at 1003–04, a manufacturer's "voluntary" relinquishment of its property "in exchange for the economic advantages of a registration [could] hardly be called a taking," *id.* at 1007; *see also Horne v. U.S. Dep't of Agric.*, 576 U.S. 350, 365–66 (2015) (confirming that the "voluntary exchange" in *Monsanto* did not result in a taking).

Lower courts have similarly held that an obligation arising under a regulated government program conferring substantial benefits cannot effect a taking of a voluntary participant's property. *See, e.g.*, *Nat'l Lifeline Ass'n v. FCC*, 983 F.3d 498, 515 (D.C. Cir. 2020); *Westinghouse Elec. Corp. v. U.S. Nuclear Regul. Comm'n*, 555 F.2d 82, 95 (3d Cir. 1977). In fact, the courts of appeals have routinely relied on this basic principle in rejecting takings challenges to regulatory obligations affecting property that were imposed as conditions to Medicaid and Medicare Part B coverage. *See Se. Ark. Hospice, Inc. v. Burwell*, 815 F.3d 448, 450 (8th Cir. 2016); *Baker Cty. Med. Servs., Inc. v. U.S. Att'y Gen.*, 763 F.3d 1274, 1278–80 (11th Cir. 2014); *Franklin Mem'l Hosp. v. Harvey*, 575 F.3d 121, 129–30 (1st Cir. 2009); *Garelick v. Sullivan*, 987 F.2d 913, 916–19 (2d Cir. 1993); *Burditt v. U.S. Dep't of Health & Hum. Servs.*, 934 F.2d 1362, 1376 (5th Cir. 1991); *Baptist Hosp. E. v. Sec'y of Health & Hum. Servs.*, 802 F.2d 860, 869–70 (6th Cir. 1986); *St. Francis Hosp. Ctr. v. Heckler*, 714 F.2d 872, 875–76 (7th Cir. 1983) (per curiam); *cf. Managed Pharmacy Care v. Sebelius*, 716 F.3d 1235, 1252 (9th Cir. 2013). As these cases acknowledge, government action must "legally compel[]" an obligation affecting property for it "to give rise to a taking." *Garelick*, 987 F.2d at 916; *accord James v. Global Tel*Link Corp.*, No. 13-4989, 2020 WL 998858, at *3 (D.N.J. Mar. 2, 2020) ("The Constitution prohibits private property from being *taken* for public use, without just compensation. 'Taken' implies legal compulsion . . . ." (internal quotation marks and citation omitted)).

Where a property owner freely assumes an obligation by voluntarily participating in a regulated government program, there is no legal compulsion necessary to support a takings claim. *Id.*

Such is the case here. As Novo admits, its "participation in the 340B Program is optional." Compl. ¶ 27. Indeed, Novo has presumably weighed the substantial revenue that it generates from reimbursements and coverage for its products under Medicaid and Medicare Part B—revenue that is accessible because of its "participation in the 340B Program," Compl. ¶¶ 27, 97—against the cost of complying with the program's requirements. And in doing so, Novo has determined that the substantial benefits it receives because it participates in the 340B Program justifies any attendant obligations. If that calculus were to change—that is, if Novo were to conclude that the benefits of participating in the 340B Program do not outweigh the costs associated with the program's requirements—Novo may terminate its participation in the 340B Program at any time and free itself from those regulatory burdens. *See* AR 50.

Of course, Novo casts its decision to participate in the 340B Program in a different light, claiming to have had no practical choice but to opt in given that it would lose the lucrative benefits of participating in federal health insurance programs if it were to opt out. Compl. ¶¶ 27, 97. "[B]ut the fact that practicalities may in some cases dictate participation does not make participation involuntary." *St. Francis Hosp. Ctr.*, 714 F.2d at 875. Nor is "economic hardship . . . equivalent to legal compulsion for purposes of [a] takings analysis." *Garelick*, 987 F.2d at 917. The realities of Novo's circumstances do not alter the fact that it can discontinue its participation in the 340B Program whenever it believes the program no longer benefits it. Simply put, "[d]espite the strong financial inducement to participate in [the 340B Program], [Novo's] decision to do so is nonetheless voluntary." *See Minn. Ass'n of Health Care Facilities, Inc. v. Minn. Dep't of Pub. Welfare*, 742 F.2d 442, 446 (8th Cir. 1984).

In short, Novo's voluntary participation in the 340B Program in exchange for the substantial economic benefits available under Medicaid and Medicare Part B is dispositive of its private-

regulatory-takings claim.[8] Because the requirement that Novo ship 340B discounted drugs to contract pharmacies "can hardly be called a taking," *see Monsanto*, 467 U.S. at 1007, Novo has failed as a matter of law to allege a regulatory taking of property.

ii. The challenged obligation, even if a taking, is constitutionally justified by a public purpose.

Because Novo has not alleged a taking of property, "it is unnecessary to address whether the [Fifth Amendment's] public use requirement is met." *See Rancho de Calistoga*, 800 F.3d at 1093. However, were the Court to find a taking based on Novo's obligation to ship 340B-discounted drugs to contract pharmacies, such a taking satisfies the "public use" requirement, notwithstanding that Novo's property is transferred "to another private party." *See* Compl. ¶¶ 131, 134.

For well over a century, the Supreme Court has rejected claims that property must be "use[d] by the general public" to justify a taking. *See Kelo*, 545 U.S. at 480, 480 n.10. Instead, a taking satisfies the Fifth Amendment's "public use" requirement if it is "rationally related to a conceivable public purpose." *Haw. Hous. Auth. v. Midkiff*, 467 U.S. 229, 241 (1984). And because "'[i]t is only the taking's purpose, and not its mechanics,' … that matters in determining public use," *Kelo*, 545 U.S. at 482 (citation omitted), even takings that transfer property from one private party to another are valid as

[8] Even if the Court were to evaluate Novo's private-regulatory-takings claim under the factors identified in *Penn Central Transportation Co. v. City of New York*, 438 U.S. 104 (1978)—the character of the government action, its economic impact on the plaintiff, and the extent to which it interferes with distinct investment-backed expectations, *Lingle*, 544 U.S. at 538–39—these do not weigh in Novo's favor. First, the requirement to ship 340B discounted drugs to contract pharmacies is not akin "to a physical invasion," but "instead merely affects property interests through 'some public program adjusting the benefits and burdens of economic life to promote the common good.'" *Id.* at 539 (citation omitted). Regulations like this rarely constitute a taking. *Penn Central*, 438 U.S. at 124. Second, because Novo has been aware of this requirement since at least 2010, there has been no interference with *reasonable* investment-back expectations. *See supra* § I.A. Lastly, although Novo has not alleged facts sufficient to assess the economic impact of this requirement, the substantial revenue Novo generates from reimbursements and coverage for its products under Medicaid and Medicare Part B—revenue that is accessible because of its participation in the 340B Program, Compl. ¶¶ 27, 97—would surely cut against a finding of deleterious economic effects.

long as a public purpose underlies the transfer, *See, e.g.*, *Hughes v. Consol-Pa. Coal Co.*, 945 F.2d 594, 612–13 (3d Cir. 1991); *Berman v. Parker*, 348 U.S. 26, 33–34 (1954).[9]

"[I]n reviewing a legislature's judgment of what constitutes a public use," a court's role "is 'an extremely narrow' one," *Midkiff*, 467 U.S. at 240 (citation omitted), and "the burden on the [government] is remarkably light," *Daniels v. Area Plan Comm'n of Allen Cty.*, 306 F.3d 445, 460 (7th Cir. 2002); *accord Garvie v. City of Ft. Walton Beach*, 366 F.3d 1186, 1189 (11th Cir. 2004). A court must "afford[] legislatures broad latitude in determining what public needs justify the use of the takings power," *Kelo*, 545 U.S. at 483, and it must not disturb a public-purpose determination unless found to "be palpably without reasonable foundation," *Carole Media LLC v. N.J. Transit Corp.*, 550 F.3d 302, 309 (3d Cir. 2008) (quoting *Midkiff*, 467 U.S. at 241); *see also Keystone Bituminous Coal Ass'n v. Duncan*, 771 F.2d 707, 719 (3d Cir. 1985) (explaining that government action effecting a taking need not be the "perfect" plan "or the best possible scheme, or even likely to achieve its intended goal" to satisfy the public-use requirement); *Kelo*, 545 U.S. at 488 ("[E]mpirical debates over the wisdom of takings—no less than debates over the wisdom of other kinds of socioeconomic legislation—are not to be carried out in the federal courts.").

Here, Novo challenges an obligation rooted in the 340B statute, which seeks to "benefit both [uninsured and under-insured] patients, by helping them to afford costly medications, and covered entities [serving those patients], which use the discounts [on drugs] to stretch scarce federal resources and serve a greater number of uninsured and under-insured patients." *See Am. Hosp. Ass'n v. U.S. Dep't of Health & Hum. Servs.*, No. 4:20-cv-08806, 2021 WL 616323, at *1 (N.D. Cal. Feb. 17, 2021); *see also* H.R. Rep. No. 102-384, pt. 2, at 12. The public benefits Congress sought to achieve through the 340B Program and its attendant obligations on manufacturers cannot be gainsaid, and "[i]t is not for [a court] to reappraise them." *See Berman*, 348 U.S. at 33. For it is far from being "palpably" unreasonable to suggest that requiring manufacturers to ship 340B-discounted drugs to contract pharmacies enables

[9] Moreover, "the fact that a taking creates incidental benefits for individual private parties 'does not condemn that taking as having only a private purpose.'" *Carole Media*, 550 F.3d at 309 (quoting *Midkiff*, 467 U.S. at 243–44); *see also Kelo*, 545 U.S. at 485 ("[T]he government's pursuit of a public purpose will often benefit individual private parties.").

covered entities to stretch their scarce federal resources. *See Carole Media*, 550 F.3d at 309. And that Congress chose to achieve these public benefits by requiring private entities to offer their property to other private entities (in exchange for the benefits of participating in federal health insurance programs) is of no constitutional import under the Public Use Clause. *See Berman*, 348 U.S. at 33 (upholding a taking reconveying private property to other private parties because it was part of a legislatively enacted plan found by the legislature to be for the public good); *accord Carole Media*, 550 F.3d at 309–12; *Hughes*, 945 F.2d at 612–13; *Kelo*, 545 U.S. at 483–84.

Therefore, because there can be no question that the challenged obligation is "rationally related to a conceivable public purpose," *see Midkiff*, 467 U.S. at 241, it satisfies the Fifth Amendment's "public use" requirement, and Novo's private-regulatory-taking claim thus fails.

2. Novo fails to state an unconstitutional-conditions claim.

Under the 340B Program, Congress conditioned Medicaid and Medicare Part B coverage of a manufacturer's drugs on its compliance with 340B requirements. *See* 42 U.S.C. § 1396r-8(a)(1). Receipt of this government benefit may therefore depend on a manufacturer's willingness to ship 340B-discounted drugs to contract pharmacies that distribute those drugs on behalf of covered entities. Novo believes—albeit mistakenly—that this obligation violates its rights under the Fifth Amendment by effecting a private regulatory taking of its property. *See supra* § II.D.1. And based on this mistaken assumption, Novo contends further that the challenged obligation places an unconstitutional condition on its access to Medicaid and Medicare Part B coverage. Compl. ¶¶ 132, 135. Essentially, Novo claims that it has been given a choice: succumb to a private regulatory taking by complying with the requirement to ship 340B-discounted drugs to contract pharmacies or forego coverage of its products under Medicaid and Medicare Part B. *Id.* But as explained, Novo has failed to allege that the challenged obligation effects an unconstitutional taking or otherwise implicates its constitutional rights. Therefore, Novo's unconstitutional-conditions claim fails *a fortiori*.

At a "basic level," the unconstitutional-conditions doctrine "prevents the government from awarding or withholding a public benefit for the purpose of coercing the beneficiary to give up a constitutional right or to penalize his exercise of a constitutional right." *Planned Parenthood of Ind., Inc.*

v. Comm'r of Ind. State Dep't of Health, 699 F.3d 962, 986 (7th Cir. 2012); *accord Koontz*, 570 U.S. at 606 ("[T]he unconstitutional conditions doctrine forbids burdening the Constitution's enumerated rights by coercively withholding benefits from those who exercise them."). This "sometimes murky" doctrine is founded on the principle "that what a government cannot compel, it should not be able to coerce"; or said differently, "the doctrine aims to prevent the government from achieving indirectly what the Constitution prevents it from achieving directly." *Planned Parenthood of Ind.*, 699 F.3d at 986; *accord Planned Parenthood of Greater Ohio v. Hodges*, 917 F.3d 908, 912 (6th Cir. 2019) ("Just as the State may not directly order someone to stop exercising his rights, it may not coerce him into 'giving them up' by denying the benefits if he exercises those rights." (citation omitted)).

A "predicate" flows naturally from these principles: "[A]ny unconstitutional conditions claim" must show that "the government could not have constitutionally ordered the person asserting the claim to do what it attempted to pressure that person into doing" by placing a condition on a government benefit. *Koontz*, 570 U.S. at 612. In other words, a condition on a government benefit "cannot be unconstitutional if it could be constitutionally imposed directly." *Rumsfeld v. Forum For Acad. & Institutional Rts., Inc.*, 547 U.S. 47, 59–60 (2006); *accord Planned Parenthood of Greater Ohio*, 917 F.3d at 914 ("[A]n unconstitutional-conditions claim won't get far if the government could have directly ordered the outcome it wishes to incentivize. In that case, there is no right at issue.").

Novo's claim fails to meet this predicate. Novo challenges the obligation to ship 340B drugs to contract pharmacies as a private regulatory taking—that is, a taking that violates the Public Use Clause of the Fifth Amendment.[10] *Planned Parenthood of Ind.*, 699 F.3d at 986 ("The first step in any unconstitutional-conditions claim is to identify the nature and scope of the constitutional right arguably imperiled by the denial of a public benefit."). But Novo fails to show how this requirement effects a taking or lacks a justifying public purpose, and thereby fails to show how this requirement

[10] Novo does not—indeed cannot—claim that its right to "just compensation" is implicated here. Novo seeks only equitable and declaratory relief under the APA. *See* Compl. ¶¶ 126–32. The proper remedy for a just-compensation claim, however, is just that—just compensation—which must be sought from the federal government under the Tucker Act or Little Tucker Act, *see, e.g.*, *Knick v. Twp. of Scott*, 139 S. Ct. 2162, 2175–79 (2019), not the APA, *see* 5 U.S.C. § 702.

directly burdens the constitutional right allegedly imperiled—*i.e.*, the right to be free from private regulatory takings. *See supra* § II.D.1. Because Novo has not demonstrated that the obligation upon which Medicaid and Medicare Part B coverage has been conditioned is itself unconstitutional, its unconstitutional-conditions claim must fail. *See Singer v. City of New York*, 417 F. Supp. 3d 297, 327 (S.D.N.Y. 2019) ("Absent the pleading of facts sufficient to demonstrate a 'taking,' an unconstitutional conditions doctrine claim fails."); *see also Rumsfeld*, 547 U.S. at 59–60.

Moreover, Novo's claim relies on virtually identical reasoning rejected by the Supreme Court in *Monsanto*. There, the plaintiff argued that being statutorily required to "give up its property interest in [trade secrets]" to obtain registration for its pesticide products "constitute[d] placing an unconstitutional condition on the right to a valuable Government benefit." *Monsanto*, 467 U.S. at 1007. Responding to this argument, the Court held that, "as long as [the plaintiff] is aware of the conditions under which the data are submitted" (*i.e.*, the property to be relinquished), "and the conditions are rationally related to a legitimate Government interest, a voluntary submission of data by [the plaintiff] in exchange for the economic advantages of a registration can hardly be called a taking." *Id.*

Like the plaintiff in *Monsanto*, Novo objects to having to "give up its property" in the drugs it manufacturers to obtain "the economic advantages of" coverage under Medicaid and Medicare Part B—a "voluntary … exchange" that "can hardly be called a taking." *See id.*; *accord Horne*, 576 U.S. at 365–66. As *Monsanto* explains, in such circumstances, a condition on a government benefit is constitutional as long as the plaintiff has notice and the condition is "rationally related to a legitimate Government interest." 467 U.S. at 1007. There can be no question that Novo is aware (and has been aware for over a decade) that it is required to ship 340B discounted drugs to contract pharmacies or else risk losing coverage of its drugs under Medicaid and Medicare Part B. And, as explained above, this condition is rationally related to the public benefits Congress sought to realize through the 340B Program. *See supra* § II.D.1.ii. Thus, *Monsanto* forecloses Novo's unconstitutional-conditions claim.[11]

[11] Crediting Novo's unconstitutional-conditions theory would also contravene the holdings of at least ten courts of appeals, including the Third Circuit, all of which have upheld conditions on government benefits—like Medicaid and Medicare coverage—against challenges invoking rights under the Takings Clause. *See supra* § II.D.1.i.

In support of this claim, Novo embraces an inapposite (and even unfavorable) line of cases—*Nollan v. California Coastal Commission*, 483 U.S. 825 (1987), *Dolan v. City of Tigard*, 512 U.S. 374 (1994), and *Koontz*—none of which call into question the applicability of *Monsanto*'s holding. These cases "involve a special application" of the unconstitutional-conditions doctrine that "protects the Fifth Amendment right to just compensation for property the government takes when owners [of real property] apply for land-use permits." *Koontz*, 570 U.S. at 604 (emphasis added) (quoting *Lingle*, 544 U.S. at 547). In this context, the Supreme Court has held that, in adjudicating an individual's land-use permit application, the government "may not condition" approval of the permit "on the owner's relinquishment of a portion of his property unless there is a 'nexus' and 'rough proportionality' between the government's demand and the effects of the proposed land use." *Id.* at 599. The Court has gone to lengths to explain that the "rough-proportionality test" of *Nollan*, *Dolan*, and *Koontz* is strictly confined to this "special context of exactions." *City of Monterey v. Del Monte Dunes at Monterey, Ltd.*, 526 U.S. 687, 702–03 (1999). Indeed, a test that requires an assessment of a land owner's "proposed development" of real property could hardly be applied outside the land-use context.

Still, *Nollan*, *Dollan*, and *Koontz* acknowledge the same general principle as *Monstanto*: a condition on a valuable government benefit requiring the relinquishment of property is constitutional as long the government has a sufficient reason for imposing the condition. Or as another court has explained: "What the law of 'unconstitutional conditions' boils down to … is simply that conditions can lawfully be imposed on the receipt of a benefit—conditions that may include the surrender of a constitutional right"—"provided the conditions are reasonable." *See Burgess v. Lowery*, 201 F.3d 942, 947 (7th Cir. 2000); *accord Hall v. Sweet*, 666 F. App'x 469, 476 (6th Cir. 2016) (unpublished). Simply put, even the cases embraced by Novo cut against its position.

CONCLUSION

Because each of Novo's claims is meritless, the Court should dismiss each count or, in the alternative, grant summary judgment for HHS.

Dated: May 11, 2021 Respectfully submitted,

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EXHIBIT 1

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

NOVO NORDISK INC., *et al.*, Plaintiffs, v. UNITED STATES DEPARTMENT OF HEALTH AND HUMAN SERVICES, *et al.*, Defendants.	Civil Action No. 3:21-cv-806-FLW-LHG

DECLARATION

I, Kate Talmor, make the following Declaration pursuant to 28 U.S.C. § 1746, and state that under the penalty of perjury the following is true and correct to the best of my knowledge and belief:

1. In 1996 the Pharmaceutical Research and Manufacturers of America sued the Department of Health and Human Services and its Secretary, challenging the agency's guidelines on use of contract pharmacies under the 340B Program. The docket number is 1:96-cv-1630 (D.D.C.).
2. Attached to this declaration is a true and correct copy, obtained from official archives of the Department of Justice, of the Complaint and Stipulation of Dismissal for that litigation.

Dated: May 11, 2021

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UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF COLUMBIA

PHARMACEUTICAL RESEARCH AND MANUFACTURERS OF AMERICA,
1100 15th Street, N.W.
Washington, D.C. 20005

Plaintiff,

v.

DONNA SHALALA, in her official capacity as Secretary, United States Department of Health and Human Services, and UNITED STATES DEPARTMENT OF HEALTH AND HUMAN SERVICES,
200 Independence Avenue, S.W.
Washington, D.C. 20201

Defendants.

CASE NUMBER 1:96CV01630
JUDGE: June L. Green
DECK TYPE: Civil General
DATE STAMP: 07/12/96

COMPLAINT FOR DECLARATORY AND INJUNCTIVE RELIEF

Plaintiff, Pharmaceutical Research and Manufacturers of America ("PhRMA"), as representative of its member companies, brings this action against Defendants Donna Shalala and the United States Department of Health and Human Services ("HHS"), and for its Complaint alleges:

Nature of the Action, Jurisdiction and Venue

1. This is an action brought pursuant to 5 U.S.C. § 706(2)(A) and 28 U.S.C. §§ 2201 and 2202 for a declaratory judgment that the contract pharmacy

guidelines adopted by the Office of Drug Pricing Program ("ODPP") of the Public Health Service ("PHS") of HHS are arbitrary, capricious, an abuse of discretion, and otherwise not in accordance with law. PhRMA seeks a declaration that HHS has violated the Administrative Procedure Act (the "APA") and the Federal Register Act (the "FRA") by failing to comply with the statutory notice, comment, and publication provisions concerning rulemaking in issuing the contract pharmacy guidelines and that the contract pharmacy guidelines are arbitrary, capricious, an abuse of discretion, and otherwise not in accordance with law. PhRMA also seeks a preliminary and permanent injunction directing HHS to withdraw the contract pharmacy guidelines and to give them no force or effect, and to refrain from facilitating or encouraging any entity from taking action based on the contract pharmacy guidelines in a manner that is contrary to law.

2. Jurisdiction is conferred upon this Court by 28 U.S.C. §§ 1331, 1337, and 1361, and venue is proper in this district under 28 U.S.C. § 1391(e).

Parties and Related Persons

3. The Pharmaceutical Research and Manufacturers of America is an organization that represents the country's leading research-based pharmaceutical and biotechnology companies. Investing nearly $16 billion a year in discovering and developing new medicines, PhRMA companies are the source of nearly all new drug discoveries worldwide. The interests that PhRMA seeks to protect in this litigation are germane to its organizational purposes in representing and protecting the interests of companies that discover, develop and bring

prescription drug products to market. As explained more fully below, members of PhRMA are directly affected by, and suffer substantial injury from, the actions complained of herein.

4. Defendant Donna Shalala is Secretary, United States Department of Health and Human Services, and is sued in her official capacity.

5. Defendant HHS is an agency of the United States within the meaning of the APA and is charged with the responsibility of administering a wide variety of federal programs related to health and human services, including programs implemented by the Public Health Service. The Public Health Service is responsible for overseeing and administering a variety of programs concerned with public health and health care services, including the Health Resources and Services Administration ("HRSA").

6. ODPP, an office of the Health Resources and Services Administration of the Public Health Service, is responsible for implementing the pharmaceutical price controls established by Congress under Section 340B ("Section 340B") of the Public Health Service Act (the "PHS Act"), 42 U.S.C. § 256b.

Factual Allegations

7. Section 340B provides that the Secretary of HHS "shall enter into an agreement with each manufacturer of" outpatient prescription drugs under which the manufacturer agrees to sell such drugs to "covered entities" at a discounted price determined by a statutory formula, for their use in treating "patients of the entity." Under the statutory formula, the discounted price is at

least 15.1 percent lower than the weighted average price available from the manufacturer for drugs distributed to the retail pharmacy class of trade. 42 U.S.C. §§ 256b(a)(1) & 1396r-8(c).

8. Copies of the "Pharmaceutical Pricing Agreement" are available from the Secretary and neither the form nor specific terms may be modified by participating manufacturers. Upon information and belief, certain members of PhRMA have entered into such agreements. Under the statute, if a manufacturer fails to enter into such an agreement, no federal funding will be available to states to pay for that manufacturer's covered outpatient drugs furnished to any Medicaid beneficiaries.

9. Section 340B defines "covered entities" to include a variety of recipients of identified federal grants under the PHS Act, State block grant programs, and various health care providers to whom Congress has given special Medicare and/or Medicaid reimbursement status.

10. Section 340B also includes restrictions intended to protect participating manufacturers from certain types of economic harm that could result from abuse of the pricing program. The statute prohibits diversion of the discounted drugs to the greater commercial market by prohibiting a covered entity from "resell[ing] or otherwise transfer[ing] the drug to a person who is not a patient of the covered entity." 42 U.S.C. § 256b(a)(5)(B). In addition, the statute seeks to protect manufacturers from the harm of "double discounting" by prohibiting a covered entity from submitting a claim for Medicaid reimbursement for drugs

purchased at the discounted price where the state Medicaid agency, under separate statutory authority, will itself claim a comparable rebate from the manufacturer based on its reimbursement of the entity for such drug. 42 U.S.C. § 256b(a)(5)(A)(i).

11. Some entities included on the list of entities that may participate in the PHS pricing program do not purchase or directly furnish outpatient drugs to their patients. Many of these entities are not licensed by the state in which they are located to purchase and dispense prescription drugs and do not employ personnel who are authorized to do so. Historically, some of these entities, such as community health centers, have referred patients to nearby retail pharmacies for prescriptions. Such pharmacies are not "covered entities" under Section 340B and the statute makes no provision for sales of discounted drugs to such pharmacies.

12. In implementing the statute through the standard Pharmaceutical Pricing Agreement signed on behalf of the Secretary on December 14, 1992, PHS made arrangements only to enable participation by those covered entities that can purchase and dispense prescription drugs; it made no arrangements to enable entities that use contract pharmacies to obtain the benefits of the PHS price. PHS acknowledged this in a February 23, 1993 letter to PhRMA (attached as Exhibit A), in which the Director of ODPP stated: "The issue of including contract pharmacies and outside physician dispensing systems in the discount chain is currently being considered. The potential for drug diversion is a consideration, and a mechanism for its prevention has not as yet been developed."

13. PHS published "proposed guidelines" on contract pharmacy issues for notice and comment in the Federal Register on November 1, 1995, with the statement that "[a]fter consideration of the comments submitted, the Secretary will issue the final guidelines."

14. PhRMA and several of its member companies, as well as non-member companies, covered entities and competitors of the covered entities which are ineligible to participate in the PHS pricing program, submitted comments in this proceeding. The comments identified numerous substantive problems with the proposed contract pharmacy guidelines. In particular, comments filed by manufacturers noted that the guidelines provided no effective mechanism for preventing or detecting diversion of drugs to ineligible entities or patients or for preventing duplicate discounting. Some commented that the inclusion of contract pharmacies in the program was in violation of the statute.

15. Some time thereafter, without publicly acknowledging or responding to many of the comments, PHS posted an undated copy of the proposed contract pharmacy guidelines on the electronic bulletin board that ODPP uses to disseminate information necessary for day-to-day operation of the PHS pricing program. This electronic bulletin board, known as the Electronic Data Retrieval System ("EDRS"), is accessed by means of a computer with a modem. While EDRS has been available to manufacturers to verify the eligibility of entities to participate in the PHS pricing program, upon information and belief, PHS is aware that some

manufacturers do not or cannot use EDRS, but obtain current eligibility information by calling ODPP.

16. The electronic file initially posted by PHS (attached as Exhibit B) stated that "[p]ending publication of final regulations, the Office of Drug Pricing has developed the following contracted pharmacy guidelines." PhRMA has met with ODPP and HRSA staff in an attempt to persuade the agency to comply with the notice and comment procedures and to revise the posted guidelines to correct deficiencies before requiring manufacturers to comply with any such guidelines. PhRMA's counsel also has written to the Administrator of HRSA to express PhRMA's concerns and, to no avail, has sought a meeting with the Administrator to discuss these concerns.

17. Some time after the initial posting, in an undated file, PHS revised the preamble of the electronically-posted guidelines to state that the guidelines constitute a "suggested model agreement provided for informational purposes only," and stated that it was reviewing the comments that had been received in response to its initial notice of proposed rulemaking. A copy of the revised posting is attached as Exhibit C.

18. Despite the agency's efforts, in light of the legal inadequacies of its procedures, to minimize the effect of the guidelines by (belatedly) claiming that they were posted only "for informational purposes," the guidelines are currently in effect. Upon information and belief, covered entities are permitted to become eligible to obtain access to discounted prices through contracting pharmacies by

following the requirements of the electronically-posted guidelines, and pharmaceutical companies, including PhRMA members, are thereby required to make discounted drug sales to these covered entities. A letter written by the Administrator of HRSA (attached as Exhibit D), responding to a specific request by PhRMA's counsel for clarification of PHS policy, states: "If an eligible covered entity utilizing this mechanism requests to purchase a covered drug from a participating manufacturer, the statute directs the manufacturer to sell the drug at the discounted price." The guidelines therefore constitute final agency action.

19. Issuance of the contract pharmacy guidelines has had and will have an immediate and detrimental impact upon members of PhRMA. Among other things, as a direct and immediate result of the contract pharmacy guidelines, entities other than those permitted by statute are able to take advantage of the PHS discounted prices by requesting that prescription drugs purchased in the entity's name be shipped to contract pharmacies, which are commercial establishments that are in business to make money on the purchase and dispensing of prescription drugs. Such pharmacies purchase drugs for their own patients at commercial prices, not the discounted prices mandated by section 340B, and the guidelines fail to provide safeguards that would ensure the accountability of these independent businesses for their actions, or for agency oversight or monitoring of contract pharmacy arrangements. The lack of accountability and oversight will subject PhRMA's members to economic harm from the potential diversion of PHS-priced products to patients of the pharmacy, and from potential double discounting

through the combined effect of the PHS discount program and state Medicaid programs.

20. The damage to PhRMA members from implementation of the guidelines is irreparable. While the guidelines provide that a manufacturer may recover economic damages, such damages are payable to the manufacturer only by the covered entity, and recovery is authorized only after the manufacturer audits a covered entity and its contract pharmacy. Neither the statute nor ODPP guidelines provide for the manufacturer to recover the costs of any such audits, or to recover interest on any amount found to have been illegally diverted.

21. The manufacturers, moreover, have no adequate remedy at law. If a manufacturer attempted to mitigate damages by disregarding the contract pharmacy guidelines in instances where diversion is proven or suspected, there is a substantial risk that the PHS would terminate the manufacturer's agreement with the Secretary of HHS. Under the Pharmaceutical Pricing Agreement, a manufacturer is entitled only to a post-termination hearing. A termination would preclude states from receiving federal Medicaid funds to reimburse providers for the manufacturer's products, resulting in both irreparable losses to manufacturers and irreparable problems with continuity of access to covered health care for needy patients. The contract pharmacy guidelines will also cause irreparable damage to the relationship between each member of PhRMA and its commercial customers, such as retail pharmacies and others not eligible for PHS prices, whose business will be captured by those with access to PHS prices.

22. In addition, as explained more fully below, the contract pharmacy guidelines expand the scope of Section 340B by requiring manufacturers to fill orders at the mandatory discount on behalf of entities to whom manufacturers cannot legally sell under the laws of various states. Complying with the guidelines therefore places the members of PhRMA in the position of being required to violate the laws of these states, subjecting themselves to civil and criminal penalties, as well as potential loss of licenses to engage in their primary business of selling prescription pharmaceuticals in interstate commerce.

23. An actual controversy exists between the parties, and PhRMA and its members have no adequate remedy at law.

Count I

24. Plaintiff incorporates by reference the allegations contained in paragraphs 1-23 above as if fully set forth herein.

25. The Federal Register Act requires the publication in the Federal Register of any "order, regulation, rule, certificate, code of fair competition, license notice or similar instrument, issued, prescribed, or promulgated by a Federal agency," 44 U.S.C. § 1501, and of "documents or classes of documents that may be required to be published by Act of Congress." 44 U.S.C. § 1505(a)(3). The APA, in turn, requires the publication in the Federal Register of "substantive rules of general applicability adopted as authorized by law, and statements of general policy or interpretations of general applicability formulated and adopted by the agency." 5 U.S.C. § 552(a)(1)(D).

26. Under these provisions of law, the contract pharmacy guidelines are required to be published in the Federal Register whether they are considered substantive rules of general applicability, statements of general policy, interpretations of general applicability, or an order, regulation, rule or similar instrument issued by PHS.

27. HHS failed to publish the final contract pharmacy guidelines in the Federal Register, in violation of the APA and the FRA.

Count II

28. Plaintiff incorporates by reference the allegations contained in paragraphs 1-27 above as if fully set forth herein.

29. The contract pharmacy guidelines constitute a rule under the APA, which defines a "rule" as "the whole or part of an agency statement of general or particular applicability and future effect designed to implement, interpret, or prescribe law or policy * * * ." 5 U.S.C. § 551(4).

30. Section 340B makes the discounted price available on "purchases" by covered entities, while the guidelines expand the scope of the program to make the benefits of such prices available to entities that cannot, under state law, purchase prescription drugs. For this and other reasons, therefore, HHS in issuing the contract pharmacy guidelines has done more than simply state what it believes the statute means, but has instead attempted to fill in what it views as statutory gaps based on policy rationales. *See* Exhibit D. The contract pharmacy guidelines accordingly do not constitute either interpretive rules or general

statements of policy, but rather substantive rules which the APA requires to be issued only after following notice and comment procedures. 5 U.S.C. § 553. These procedures include a requirement that in issuing final rules the agency must "consider [ ] the relevant matter presented" including comments received, and provide a "statement of their basis and purpose" 5 U.S.C. § 553(c).

31. While HHS recognized the applicability of the APA's notice and comment procedures when it first proposed the contract pharmacy guidelines -- requesting comments and announcing its intention to publish final guidelines after consideration of comments received -- it has bypassed the required procedures by largely ignoring the comments and purporting to promulgate the guidelines without publicly responding to comments received. HHS failed to comply with the notice and comment requirements of the APA, therefore, by failing to consider many of the comments that were submitted, publicly respond to comments, or publish a statement of the basis for and purpose of the guidelines in light of the comments received.

Count III

32. Plaintiff incorporates by reference the allegations contained in paragraphs 1-31 above as if fully set forth herein.

33. Even if the guidelines are considered to be statements of general policy or interpretive rules, rather than substantive rules, the APA nevertheless requires their publication in the Federal Register "for the guidance of the public" 5 U.S.C. § 552 (a)(1). *See* Count I above. The APA further provides that a person

without actual and timely notice of the terms of any such agency action "may not in any manner be required to resort to, or be adversely affected by, a matter required to be published in the Federal Register and not so published." Id.

34. The EDRS system has failed to provide the actual and timely notice, as required by 5 U.S.C. § 552(a)(1), to bind all manufacturers to honor contract pharmacy arrangements in making Section 340B prices available to covered entities.

35. Upon information and belief, many manufacturers -- including members of PhRMA -- have no actual or timely notice of the contract pharmacy guidelines yet have been or will be adversely affected by the guidelines, in violation of the APA.

Count IV

36. Plaintiff incorporates by reference the allegations contained in paragraphs 1-35 above as if fully set forth herein.

37. Upon information and belief, there are a number of state laws that prohibit manufacturers from selling prescription drugs or controlled substances to covered entities that are not licensed by the state to purchase and dispense such drugs. *See, e.g.*, GA. CODE ANN. § 16-13-72(1) (Any drug manufacturer * * * may sell, give away, exchange, or distribute dangerous drugs within this state, but only to a pharmacy, pharmacist, a practitioner of the healing arts, and educational institutions licensed by the state * * *"); FLA. ADMIN. CODE. ANN. r.10D-45.0365 ("Prohibited Acts. (10) Selling or distributing a medicinal drug

to a person or establishment not licensed, permitted, or otherwise authorized by state law to possess, manufacture, repackage, wholesale, store, stock, distribute, use, sell, offer for sale, expose for sale or use, keep for sale or use, or use medicinal drugs.").

38. Nothing in Section 340B preempts state laws prohibiting manufacturers from selling drugs to unlicensed entities. Under the contract pharmacy guidelines, however, a manufacturer is *required* to make sales to unlicensed entities or be in violation of its Pharmaceutical Pricing Agreement with the Secretary -- which would jeopardize states' ability to receive federal Medicaid funding for the manufacturer's drugs, 42 U.S.C. § 1396r-8(a)(1) & (5), and consequently the manufacturer's future sales in all states.

39. As a result of the issuance of the contract pharmacy guidelines, and without authorization in the PHS Act, HHS has purported to permit entities not authorized under state laws to purchase prescription drugs and controlled substances to make such purchases, and has required manufacturers to sell to such unlicensed entities in ways that would cause manufacturers to be in violation of state licensing laws. This point was raised in the Comments filed by PhRMA in response to the Federal Register notice and has not been addressed by the agency in posting the guidelines and making them binding on manufacturers. The guidelines are for this reason arbitrary, capricious, an abuse of discretion, and otherwise not in accordance with law.

40. Alternatively, if the purchase is construed as a purchase by the pharmacy rather than the covered entity, the contract pharmacy guidelines exceed the authority delegated by section 340B of the Public Health Service Act, and for this reason are arbitrary, capricious, an abuse of discretion, and otherwise not in accordance with law.

Count V

41. Plaintiff incorporates by reference the allegations contained in paragraphs 1-40 above as if fully set forth herein.

42. The agreement entered into by manufacturers with the Secretary of HHS pursuant to Section 340B provides that "covered entity" is defined as specified in the PHS Act and makes the discounted price available for "covered drugs * * * *purchased by* a covered entity." Section 340B(a)(1), 42 U.S.C. § 256b(a)(1). The February 25, 1993 letter from ODPP to PhRMA, quoted above, makes it clear that at the time the agreement was signed, participating manufacturers were not required to make the discounted price available to entities using contract pharmacies. Any modification of the agreement must be in writing and signed by both parties. The contract pharmacy guidelines do not comply with this requirement, but modify and expand the program by making it possible for entities not authorized to purchase prescription drugs and controlled substances to participate in the pricing program.

43. The guidelines for this reason are arbitrary and capricious, an abuse of discretion, and otherwise not in accordance with law.

Count VI

44. Plaintiff incorporates by reference the allegations contained in paragraphs 1-43 above as if fully set forth herein.

45. The contract pharmacy guidelines do not provide adequate protection against diversion of drugs sold at the mandatory discount or double discounting, as required by Section 340B. Accordingly, the guidelines are arbitrary and capricious, an abuse of discretion, and otherwise not in accordance with law.

Claim for Relief

WHEREFORE, plaintiff PhRMA prays that the Court award judgment as follows:

A. Declaring that HHS violated the provisions of the FRA and the APA in failing to publish the contract pharmacy guidelines in the Federal Register, as required by statute.

B. Declaring that HHS violated the APA in issuing the contract pharmacy guidelines, without complying with the statutory notice and comment provisions.

C. Declaring that the contract pharmacy guidelines are arbitrary, capricious, an abuse of discretion, and otherwise not in accordance with law, and that the guidelines are, therefore, null and void;

D. Preliminarily and permanently enjoining HHS and its successors, agents, employees, representatives and others acting in concert with it or them from in any way facilitating or encouraging the purchase of outpatient

drugs through the PHS pricing program by entities not entitled to do so in a manner violative of Section 340B of the PHS Act, 42 U.S.C. § 256b, and ordering HHS during the pendency of this action to withdraw the contract pharmacy guidelines and to give them no force and effect;

E. Awarding Plaintiff PhRMA its costs incurred herein; and

F. Granting Plaintiff PhRMA such other relief as the Court deems appropriate.

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EXHIBIT A

DEPARTMENT OF HEAL[illegible] & HUMAN SERVICES
Public Health Service
BUREAU OF PRIMARY HEALTH CARE

Health Resources and
Services Administration
Rockville MD 20857

FEB 25 1993

Mr..Joel Bobula
Manager, Public Studies
1100 15th Street, N.W.
Washington, D.C. 20005

Dear Mr. Bobula:

You have asked us to respond to a compilation of questions frequently asked by drug manufacturers regarding the implementation of section 602 of the Veterans Health Care Act of 1992. The answers reflect our current understanding of the issues and policy views and may be subject to re-evaluation. The following is a list of the Pharmaceutical Manufacturers Association's (PMA) questions followed by our answers:

1. The Public Health Service (PHS) provisions of this Act require a discount for certain eligible PHS agencies. The Department of Veterans Affairs (DVA) provisions establish another discount system. I am confused over whether those "eligible" PHS agencies can purchase under the DVA discount system instead of the PHS discount system. I am further confused as to whether the "non-eligible" PHS entities can purchase under the DVA discount system. Are PHS entities allowed to select between the PHS discount and the DVA discount? Or does this legislation and the resultant pharmaceutical pricing agreements now establish separate and different prices to the Department of Veterans Affairs and the Public Health Service?

   ANSWER: The entities eligible for discounts under the section 602 program are non-Federal recipients of specific grant assistance and certain disproportionate share hospitals. The section 603 discounts, on the other hand, are for the Federal providers within the PHS (e.g., Indian Health Service, Gillis W. Long Hansen's Disease Center and the National Institutes of Health).

2. Will PHS facilities expect a price list that is separate from (or in addition to) the Federal Supply Schedule (FSS)?

   ANSWER: If your question addresses section 603, we are not in a position to respond. As to section 602, it is the manufacturer's decision whether to provide a separate price list to each covered entity.

3. If State AIDS drug purchasing programs are qualified as PHS entities and contract with wholesaler to purchase drugs off the FSS, would they be eligible for a 24% discount or just the 15.7% price discount?

ANSWER: Unless the State AIDS drug purchasing program is a qualified FSS purchaser, they would only qualify for the PHS statutory discount. However, manufacturers may offer a greater discount, such as that offered to the FSS, if they choose to do so.

4. Section IV(a) of the draft pharmaceutical pricing agreement (page 6) states that if "a manufacturer does not sign a pharmaceutical pricing agreement with a covered entity...[it] will not be deemed to have met the requirements for a Medicaid rebate agreement." This implies a need for a separate agreement with each covered entity? Is this interpretation correct?

ANSWER: No, this was a typographical error. Signing and complying with the PHS Pharmaceutical Pricing Agreement will meet the requirements.

5. Does the PHS discount include both the basic and the CPI-U discount given to Medicaid?

ANSWER: Yes. Section 340B(a)(2)(A)(ii) of the Public Health Service Act (the "Act") describes the rebate percentage as "the average total rebate required under section 1927(c) of the Social Security Act..." Both elements are components of the section 1927(c) discount.

6. Please describe the calculations for determining the PHS discount prices for generic and over-the-counter (OTC) products.

ANSWER: To calculate the price for an over-the-counter or generic drug, the rebate percentage will be 10% of the Average Manufacturer's Price (AMP) for calendar quarters between January 1, 1991 and December 31, 1993 and 11% of the AMP for calendar quarters beginning on or after January 1, 1994. See section 340B(a)(2)(B) of the Act.

7. Is a drug that was classified as innovator multi-source under the Medicaid rebate program that now is sold as an OTC drug discounted differently under the pharmaceutical pricing agreement with PHS?

ANSWER: This determination will follow the same guidelines as utilized by the Health Care Financing Administration (HCFA). It will depend upon how the drug is reported to HCFA. If the drug is reported as an innovator multi-source product, the discount will be determined by reducing the AMP by the rebate percentage (15.7% or "best price" plus CPI-U), section 340B(a) of the Act. If the drug is reported as an OTC, the AMP is reduced by 10% between January 1, 1991 and December 31, 1993. If the drug is reported as an innovator multi-source OTC, the drug will be considered OTC.

8. The Act requires a discount to PHS entities not to exceed the preceding quarter's Medicaid effective discount. Since a quarter's Medicaid discount is not known until 30 days following a quarter, this calculation cannot be done for the first part of the quarter. How will PHS address this issue?

ANSWER: The discount should be calculated utilizing data from the most current quarter available to the manufacturer.

9. What calendar quarter do we use to calculate PHS prices effective December 1, 1992 and January 1, 1993? How often will we need to recalculate?

ANSWER: Calculations are to be performed quarterly utilizing data from the most current quarter available to the manufacturer.

10. What is to be done when the Medicaid basic rebate amount changes a few quarters after the "covered entities" price has been determined and purchases made? Do adjustments need to be made to those units purchased by "covered entities"?

ANSWER: Purchases made when a new quarterly price is in effect are governed by the new price. See section 340B(a)(1) of the Act.

11. Can you please address how PHS will assure the confidentiality of the Medicaid best price (which is assured under the Medicaid Rebate Law) and at the same time provide a discounted price to thousands of PHS entities that is based on the effective Medicaid rebate?

ANSWER: "Best Price" and AMP information will be requested only from those manufacturers who do not participate in the Medicaid program, and then, only for audit purposes to ascertain compliance with statutory requirements. PHS will consider this data and pricing data obtained from HCFA as confidential. Further, the Secretary will require, under a reasonable schedule of implementation, that covered entities not reveal confidential drug pricing information. See the PHS Pharmaceutical Pricing Agreement, section III(f).

12. The Medicaid Rebate Law exempts certain drugs. Does the PHS Act include or exclude such drugs?

ANSWER: Section 340B(b) of the Act refers to section 1927(k) of the Social Security Act for the definition of "covered outpatient drug." The term incorporates both section 1927's general definition, (k)(2), and the limiting definition, (k)(3), of "covered outpatient drug." Section 340B of the Act does not incorporate the list of drugs subject to restriction, section 1927(d)(2) of the Social Security Act; therefore, these are not excluded.

13. How has the interpretation been made that generic drugs are covered under the PHS provisions of the Act, but not under the VA provisions?

ANSWER: Section 340B(b) of the Act refers to section 1927(k) of the Social Security Act for the definition of "covered outpatient drug." This definition does not exclude generic drugs. The DVA program is governed by a different statute.

14. Is the discount to PHS entities for "outpatient" drugs only?

ANSWER: Yes. See section 340B(a)(2) of the Act.

15. Does a manufacturer have to provide discounts to disproportionate share hospitals for "covered outpatient drugs" used by inpatients, or are the discounts limited to drugs utilized by outpatients?

ANSWER: A covered outpatient drug does not include any drug, biological product or insulin provided as part of, or incident to and in the same setting as inpatient services (and for which payment is made

as part of payment for the services and not as direct reimbursement for the drug). See section 340B(b) of the Act and section 1927(k)(3) of the Social Security Act.

16. Is only a portion of the hospital's drug purchases, that is the disproportionate share portion, covered by the Act?

ANSWER: The discount is for all covered outpatient drugs, without regard to whether they are for low-income individuals who are not Medicare or Medicaid beneficiaries.

17. How will PHS validate that a disproportionate share hospital does not obtain outpatient drugs through a group purchasing organization?

ANSWER: After receiving a list of eligible disproportionate share hospitals, a manufacturer may verify what covered outpatient drugs, if any, are purchased through a group purchasing organization or other group purchasing arrangement. See PHS Pharmaceutical Pricing Agreement, section IX(c). These drugs need not be sold at a discount to the hospitals.

18. When will manufacturers receive a list of covered disproportionate share hospitals?

ANSWER: On December 15, 1992, a PHS Pharmaceutical Pricing Agreement along with a computer disc containing a list of covered entities (including a list of covered disproportionate share hospitals) was mailed to all manufacturers participating in the Medicaid program. Other manufacturers will be notified by Federal Register Notice to contact the Drug Pricing Program for a copy of the list.

19. With respect to the other covered entities, how many entities are included? What are their 1991 estimated pharmaceutical purchases?

ANSWER: There are approximately 9,800 entries on the disc of covered entities mailed to Medicaid-participating manufacturers. This disc lists covered entities receiving grant funds in the eligible programs. Because entities can receive funds from several grant programs, this list contains some entities entered more than once. An unduplicated list of approximately 7,000 covered entities has been prepared and will be mailed to manufacturers.

At this time, we do not have the estimated pharmaceutical purchases for the covered entities.

20. When will the pharmaceutical companies receive the list of eligible PHS entities? If it is after December 1, 1992, does the manufacturer need to rebate the entities?

ANSWER: A computer disc of covered PHS entities was mailed to Medicaid-participating drug manufacturers on December 15, 1992. All entities contained on the disc are eligible for drug discounts retroactive to December 1, 1992.

21. What are we supposed to do about customers that say that they are a "covered entity" and entitled to provisions under the law before we have the list of covered entities (between December 1, 1992 and the date the list is available)?

ANSWER: Medicaid-participating drug manufacturers should have received a copy of the disc containing the covered entities. Any manufacturer who has not as yet received a list of covered entities may contact:

Marsha Alvarez, R. Ph.
Director, Drug Pricing Program
Health Resources and Services Administration
Bureau of Primary Health Care
Rm 7A-55 Parklawn Bldg.
5600 Fishers Lane
Rockville, Maryland 20857
Phone: (301) 443-0004

22. If hospitals that initially do not qualify as disproportionate share hospitals later meet the necessary requirements, will HCFA send notices of the newly qualified hospitals eligible for the PHS discounts, or is it up to the hospital and the manufacturer to make this determination?

ANSWER: HCFA will notify PHS of changes in entity eligibility, and the Drug Pricing Program will provide timely notification to participating drug manufacturers of additions to and deletions from the list of disproportionate share hospitals.

23. If we have a question concerning whether a clinic or health center is a covered entity, who can we call and what is their phone number?

ANSWER: Marsha Alvarez, R. Ph.
Director, Drug Pricing Program
Health Resources and Services Administration
Bureau of Primary Health Care
Rm 7A-55 Parklawn Bldg.
5600 Fishers Lane
Rockville, Maryland 20857
Phone: (301) 443-0004

24. When a community health center has multiple service sites, who purchases drugs for those sites? Do they purchase as a group and distribute drugs to individual sites?

ANSWER: For information concerning the community health center drug distribution system, you can contact the National Association of Community Health Centers (tel: (202) 659-8008).

25. What is the PHS intent regarding the discounting of drugs dispensed by retail pharmacies to community and migrant health center patients? Will we be required to give contract prices to all of the covered entities regardless of type of pharmacy (in-house, contracted, physician dispensing)?

ANSWER: Discount pricing for covered outpatient drugs must be offered to all in-house pharmacies and in-house physician dispensing systems of eligible covered entities. The issue of including contract pharmacies and outside physician dispensing systems in the discount chain is currently being considered. The potential for drug diversion is a consideration, and a mechanism for its prevention has not as yet been developed.

26. Since the vast majority of entities listed as community and migrant health centers have contract pharmacies, how can these pharmacies segregate drugs purchased by patients of PHS entities and other patients? It would appear that there is a tremendous potential for diversion, fraud and unfair competition to other local retailers. How will PHS address this issue?

ANSWER: PHS is sensitive to the potential for drug diversion and is currently considering mechanisms for its prevention. The issue of including contract pharmacies in the drug discount chain has yet to be resolved.

27. When a community health center arranges for pharmacy services through a commercial retail pharmacy, who purchases the drug that is dispensed to the patient? Does the community health center "reimburse" the retailer, or does the retailer file the Medicaid claim if the beneficiary is eligible?

ANSWER: For information concerning the community health center drug distribution system you can contact the National Association of Community Health Centers (tel: (202) 659-8008).

28. Hasn't the duplicate discount prohibition of H.R. 5193 financially handicapped PHS clinics with a significant percentage of Medicaid patients?

ANSWER: We interpret section 340B(a)(5)(A)(i) of the Act to refer to Medicaid rebates and not Medicaid reimbursements.

29. How will a PHS covered entity that contracts for pharmaceutical services with a retail pharmacy benefit (if at all) from H.R. 5193?

ANSWER: The issue of including a contract pharmacy in the drug discount chain has yet to be resolved.

30. The duplicate discount provision precludes requests for payments for covered drugs subject to a Medicaid rebate. How will PHS enforce this provision?

ANSWER: The statute gives the Secretary one year from the date of enactment to devise a mechanism to prevent potential duplicate discount/rebates, section 340B(a)(5) of the Act. The Secretary of PHS has agreed to develop this mechanism within 120 days after the effective date of the PHS Pharmaceutical Pricing Agreement or the provisions of section 1927(a)(5)(C) of the Social Security Act will become effective.

31. What is the manufacturer supposed to do about potential duplicate discounts before an enforcement mechanism is in place?

ANSWER: The manufacturer and the entity can, in good faith, attempt to resolve the dispute. If unsuccessful, the manufacturer may provide written notice of the discrepancy to the Secretary. The manufacturer and the Secretary will devote their best efforts to resolving the dispute within sixty days. If the Secretary believes that a violation

has occurred, the Secretary will initiate the notice and hearing process. If a violation is found to have occurred, the entity will be liable to the manufacturer of the covered drug that is the subject of the violation in an amount equal to the reduction in the price as required by section 340B(a) of the PHS Act. See the PHS Pharmaceutical Pricing Agreement, section VI(a).

32. How are manufacturers to know that the PHS clinics are only purchasing products for non-Medicaid use?

ANSWER: A drug discount is available for all clinic patients, Medicaid or not, provided that a Medicaid rebate is not also requested for the discounted drug.

33. Example: In March a clinic is added as a covered PHS entity, and as of March the state excludes the clinic's drug purchases from Medicaid rebate invoices. Do we have to provide that clinic the "effective Medicaid price" for sales that occurred in January or February? If so, why, especially given that the manufacturer has already paid a rebate to the state. In general, who comes first, the state or the clinic?

ANSWER: Only those entities included on the initial computer list mailed to drug manufacturers on December 15, 1992, are eligible for retroactive drug discounts to December 1, 1992. All entities added to the list of covered entities at a later date will be eligible for drug discounts as of the date of their inclusion on the list.

34. Is the manufacturer permitted to terminate an agreement to any PHS facility that violates the resale prohibition?

ANSWER: No. See answer #31.

36. Some manufacturers do not sell to retail pharmacies, doctors and other entities identified in H.R. 5193. How can these entities participate in a prime vendor arrangement?

ANSWER: The prime vendor program has not as yet been developed.

37. Is the "prime vendor" requirement applicable only to specifically identified PHS eligible entities?

ANSWER: The prime vendor program has not as yet been developed.

38. Do manufacturers have the right to audit wholesalers under the prime vendor requirement? Where is this spelled out for the parties in question?

ANSWER: The prime vendor program has not as yet been developed.

We hope the answers have clarified our current position regarding implementation of the Act. If you have any further questions, please do not hesitate to contact Kathryn Lotfi, Office of General Counsel (tel: (301) 443-2006).

Sincerely yours,

Marsha Alvarez

Marsha Alvarez, R. Ph.
Director, Drug Pricing Program

EXHIBIT B

Guideline: Contracted Pharmacy Services

Pending publication of final regulations, the Office of Drug Pricing has developed the following contracted pharmacy service guidelines. These guidelines are designed to facilitate program implementation in covered entities that wish to utilize contracted pharmacy services to dispense section 340B outpatient drugs but do not have access to an "in-house" pharmacy. The agreement between the covered entity and the pharmacy should include the following provisions:

(a) The covered entity will purchase the drug. A "ship to - bill to" procedure may be used in which the covered entity purchases the drug, the manufacturer bills the covered entity for the drugs that it purchased but ships the drugs directly to the contracted pharmacy.

(b) The contractor will provide all pharmacy services (e.g., dispensing, record keeping, drug utilization review, formulary maintenance, patient profile, counseling). Each facility which purchases its covered outpatient drugs has the option of individually contracting for pharmacy services with the pharmacy of its choice. The limitation of one pharmacy contractor per facility 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. [The Office of Drug Pricing will be evaluating the feasibility of permitting these facilities to contract with more than one site and contractor.]

(c) If the patient does not elect to use the contracted service, the patient may obtain the prescription from the pharmacy provider of his/her choice.

(d) The contractor may provide the covered entity services, other than pharmacy, at the option of the covered entity (e.g., home care, reimbursement services).

(e) The contractor and the covered entity will adhere to all Federal, State, and local laws and requirements. Additionally, all PHS grantees will adhere to all rules and regulations established by the grant funding

office.

(f) The contractor will provide the covered entity quarterly financial statements, a detailed status report of collections, and a summary of receiving and dispensing records.

(g) The contractor will establish and maintain a tracking system suitable to prevent diversion of section 340B discounted drugs to individuals who are not patients of the covered entity.

(h) Both parties agree that they will not resell or transfer a drug purchased at section 340B pricing to an individual who is not a patient of the covered entity. See section 340B(a)(5)(B). If a contract pharmacy is found to have violated this prohibition, the pharmacy will pay the entity the amount of the discount in question so that the entity can reimburse the manufacturer.

(i) A covered entity using contracted pharmacy services will not use drugs purchased under section 340B to dispense Medicaid prescriptions unless the contract pharmacy and the state medicaid agency have established an arrangement which will prevent duplicate discounts/rebates.

(j) Both parties understand that they are subject to audits (by the PHS and participating manufacturers) of records that directly pertain to the entity's compliance with the drug resale or transfer prohibition and the prohibition against duplicate Medicaid rebates and PHS discounts. See section 340B(a)(5).

(k) Upon request, a copy of this contracted pharmacy service agreement will be provided to a participating manufacturer which sells covered outpatient drugs to the covered entity. All confidential propriety information may be deleted from the document.

In negotiating and executing a contracted pharmacy service agreement pursuant to these guidelines, contractors and covered entities should be aware of and take into consideration the provisions of the Medicare and Medicaid anti-kickback statute, 42 U.S.C. 1320a-7b(b). This statute makes it a felony for a person or entity to knowingly and willfully offer, pay, solicit, or receive remuneration with the intent to induce, or in return for the referral of, Medicare or a State health care program business. State health care programs are Medicaid, the Maternal and Child Health Block Grant program, and the Social Services

Block Grant program. Apart from the criminal penalties, a person or entity is also subject to exclusion from participation in the Medicare and State health care programs for a knowing and willful violation of the statute pursuant to 42 U.S.C. 1320a-7(b)(7).

The anti-kickback statute is very broad. Prohibited conduct covers not only remuneration intended to induce referrals of patients, but also includes remuneration intended to induce the purchasing, leasing, ordering, or arranging for any good, facility, service, or item paid for by Medicare or a State health care program. The statute specifically identifies kickbacks, bribes, and rebates as illegal remuneration, but also covers the transferring of anything of value in any form or manner whatsoever. This illegal remuneration may be furnished directly or indirectly, overtly or covertly, in cash or in kind and covers situations where there is no direct payment at all, but merely a discount or other reduction in price of the offering of a free good(s).

Arrangements between contractors and covered entities that could violate the anti-kickback statute would include any situation where the covered entity agrees to refer patients to the contractor in return for the contractor agreeing to undertake or furnish certain activities or services to the covered entity at no charge or at a reduced or below cost charge. These activities or services would include the provision of contracted pharmacy services, home care services, money or grants for staff or service support, or medical equipment or supplies, and the remodeling of the covered entity's premises. For example, if a contractor agreed to furnish covered outpatient drugs in return for the covered entity referring its Medicaid patients to the contractor to have their prescriptions filled, the arrangement would violate the anti-kickback statute. Similarly, if the contractor agreed to provide billing services for the covered entity at no charge in return for the covered entity referring its patients to the contractor for home or durable medical equipment, the statute would be violated.

Pursuant to the authority in 42 U.S.C. 1320a-7b(b)(3), the Secretary of HHS has published regulations setting forth certain exceptions to the anti-kickback statute, commonly referred to as "safe harbors". These regulations are codified at 42 C.F.R. 100.952. Each of the safe harbors sets forth various requirements which may be met in order for a person or entity to be immune from prosecution or exclusion for violations of the anti-kickback statute. Two of the safe harbors that may pertain

to arrangements between contractors and covered entities involve discounts and personal services or management contracts.

Covered entities which elect to utilize this contracted pharmacy mechanism must submit to the Office of Drug Pricing a certification that they have signed an agreement with the contracted pharmacy containing the aforementioned provisions.

File: CONTRACT.GDL

EXHIBIT C

Guideline: Contracted Pharmacy Services

The following is a suggested model agreement provided for informational purposes. The Department is currently reviewing comments to the proposed contract pharmacy model agreement published in the Federal Register on November 1, 1995 (60 FR 55586). All comments received in response to the notice will be considered in developing the final model agreement. Covered entities that do not have access to an appropriate "in-house" pharmacy, and wish to use contracted pharmacy services to access section 340B pricing, are encouraged to sign and have in effect an agreement with the pharmacy contractor which includes the following provisions:

(a) The covered entity will purchase the drug. A "ship to - bill to" procedure may be used in which the covered entity purchases the drug, the manufacturer bills the covered entity for the drugs that it purchased but ships the drugs directly to the contracted pharmacy.

(b) The contractor will provide all pharmacy services (e.g., dispensing, record keeping, drug utilization review, formulary maintenance, patient profile, counseling). Each entity which purchases its covered outpatient 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. [The Office of Drug Pricing will be evaluating the feasibility of permitting these entities to contract with more than one site and contractor.]

(c) If the patient does not elect to use the contracted service, the patient may obtain the prescription from the pharmacy provider of his/her choice.

(d) The contractor may provide the covered entity services, other than pharmacy, at the option of the covered entity (e.g., home care, reimbursement services).

(e) The contractor and the covered entity will adhere to all Federal, State, and local laws and requirements. Additionally, all PHS grantees will adhere to all rules and regulations established by the grant funding office.

(f) The contractor will provide the covered entity quarterly financial statements, a detailed status report of collections, and a summary of receiving and dispensing records, if applicable.

(g) The contractor will establish and maintain a tracking system suitable to prevent diversion of section 340B discounted drugs to individuals who are not patients of the covered entity.

(h) Both parties agree that they will not resell or transfer a drug purchased at section 340B pricing to an individual who is not a patient of the covered entity. See section 340B(a)(5)(B). If a contract pharmacy is found to have violated this prohibition, the pharmacy will pay the entity the amount of the discount in question so that the entity can reimburse the manufacturer.

(i) A covered entity using contracted pharmacy services will not use drugs purchased under section 340B to dispense Medicaid prescriptions unless the contract pharmacy and the state medicaid agency have established an arrangement which will prevent duplicate discounts/rebates.

(j) Both parties understand that they are subject to audits (by the PHS and participating manufacturers) of records that directly pertain to the entity's compliance with the drug resale or transfer prohibition and the prohibition against duplicate Medicaid rebates and PHS discounts. See section 340B(a)(5).

(k) Upon request, a copy of this contracted pharmacy service agreement will be provided to a participating manufacturer which sells covered outpatient drugs to the covered entity. All confidential propriety information may be deleted from the document.

In negotiating and executing a contracted pharmacy service agreement pursuant to these guidelines, contractors and covered entities should be aware of and take into consideration the provisions of the Medicare and Medicaid anti-kickback statute, 42 U.S.C. 1320a-7b(b). This statute makes it a felony for a person or entity to knowingly and willfully offer, pay, solicit, or receive remuneration with the intent to induce, or in return for the referral of, Medicare or a State health care program business. State health care programs are Medicaid, the Maternal and Child Health Block Grant program, and the Social Services Block Grant program. Apart from the criminal panalties, a person or entity is also subject to exclusion from participation in the Medicare and State health care programs for a knowing and willful violation of the statute pursuant to 42 U.S.C. 1320a-7(b)(7).

The anti-kickback statute is very broad. Prohibited conduct covers not only remuneration intended to induce referrals of patients, but also includes remuneration intended to induce the purchasing, leasing, ordering, or arranging for any good, facility, service, or item paid for by Medicare or a State health care program. The statute specifically identifies kickbacks, bribes, and rebates as illegal remuneration, but also covers the transferring of anything of value in any form or manner whatsoever. This illegal remuneration may be furnished directly or indirectly, overtly or covertly, in cash or in kind and covers situations where there is no direct payment at all, but merely a discount or other reduction in price of the offering of a free good(s).

Arrangements between contractors and covered entities that could violate the anti-kickback statute would include any situation where the covered entity agrees to refer patients to the contractor in return for the contractor agreeing to undertake or furnish certain activities or services to the covered entity at no charge or at a reduced or below cost charge. These activities or services would include the provision of contracted pharmacy services, home care services, money or grants for staff or service support, or medical equipment or supplies, and the remodeling of the covered entity's premises. For example, if a contractor agreed to furnish covered outpatient drugs in return for the covered entity referring its Medicaid patients to the contractor to have their prescriptions filled, the arrangement would violate the anti-kickback statute. Similarly, if the contractor agreed to provide billing services for the covered entity at no charge in return for the covered entity referring its patients to the contractor for home or durable medical equipment, the statute would be violated.

Pursuant to the authority in 42 U.S.C. 1320a-7b(b)(3), the Secretary of HHS has published regulations setting forth certain exceptions to the anti-kickback statute, commonly referred to as "safe harbors". These regulations are codified at 42 C.F.R. 100.952. Each of the safe harbors sets forth various requirements which may be met in order for a person or entity to be immune from prosecution or exclusion for violations of the anti-kickback statute. Two of the safe harbors that may pertain to arrangements between contractors and covered entities involve discounts and personal services or management contracts.

Covered entities which elect to utilize this contracted pharmacy mechanism must submit to the Office of Drug Pricing a notarized self certification that they have signed an agreement with the contracted pharmacy containing the aforementioned provisions.

EXHIBIT D

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Health Resources and
Services Administration
Rockville MD 20857

MAY 7 1996

Mr. Russel A. Bantham
General Counsel and Senior Vice President
Pharmaceutical Research
and Manufacturers of America
1100 Fifteenth Street, N.W.
Washington, D.C. 20005

Dear Mr. Bantham:

This is in response to your letter of April 4 concerning the contracted pharmacy interpretative policy guideline drafted by the Office of Drug Pricing (ODP). These guidelines were published in the Federal Register for notice and comment on November 1, 1995.

You state that the ODP "has gone forward without modifications of its proposal as if no comments were received." On the contrary, PhRMA comments, as well as all other comments submitted in response to the request for public comment, were considered in drafting the final contracted pharmacy services guideline. During this review process, the ODP revised the guideline in response to comments and placed the revised guideline on the Electronic Data Retrieval System (EDRS).

Public comments with program responses will be posted on the EDRS in the near future. We anticipate publishing a further notice in the Federal Register which will include a discussion of the comments received and the reasons for accepting or not accepting particular comments.

In addition, you characterize the contracted pharmacy services guideline as a "substantive rule," subject to the rule-making requirements of the Administrative Procedure Act. We believe this guideline is an interpretative policy guideline and was published in the Federal Register for informational purposes and to determine any need for further safeguards. Therefore, we do not believe this guideline generates regulatory concern.

It is important to understand that section 340B requires manufacturers to use a ceiling price for covered outpatient drugs purchased by the covered entity. The statute is silent as to permissible drug distribution systems and does not require the entity to purchase directly from the manufacturer or dispense the drug itself. It is apparent that Congress envisioned various types of drug delivery mechanisms - those that would be appropriate to meet the needs of the various covered entities.

In addition, the legislation would be advantageous only to a very small percentage of the covered entities, if it were to limit the program to only those entities which use in-house pharmacies. Therefore, recognizing the congressional mandate that all covered entities wishing to participate in the program have access to such discount pricing, ODP does not recognize a distinction in a manufacturer's obligation based on the manner in which entities purchase and dispense drugs. However, because of concerns expressed to ODP about the potential for drug diversion in the contract pharmacy approach, ODP thought it wise to develop guidelines (with public input) which would recognize at least one arrangement for contract pharmacy services that greatly reduces the risk of such diversion.

The guidelines were made available for the benefit of both participating manufacturers and covered entities. The mechanism described in the guidelines has been used by a number of large organizations such as the American Red Cross, the National Association of Community Health Centers, the Association for Utah Community Health Center, and the New York Blood Consortium.

Of course, this mechanism is not the only method of reducing the potential for drug diversion, but it is the system developed by ODP. If entities can propose other systems which would be equally as effective, ODP is very willing to review all proposed mechanisms.

If an eligible covered entity utilizing this mechanism requests to purchase a covered drug from a participating manufacturer, the statute directs the manufacturer to sell the drug at the discounted price. If the entity directs that shipment to its contracted pharmacy, we see no basis to conclude that section 340B precludes this type of transaction or otherwise exempts the manufacturer from compliance with the agreement.

We hope that this information has been helpful. Should you have further questions, please do not hesitate to call Stephen Wickizer, Acting Director, ODP, at (301) 594-4353.

Yours sincerely,

Ciro V Sumaya

Ciro V. Sumaya, M.D., M.P.H.T.M.
Administrator

UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF COLUMBIA

PHARMACEUTICAL RESEARCH AND MANUFACTURERS OF AMERICA,

Plaintiff,

v.

DONNA SHALALA, et al.

Defendants.

Let this be filed this 7th day of Oct. 1996

C.A. No. 96-1630 (JLG)

FILED

OCT 07 1996

CLERK, U.S. DISTRICT COURT
DISTRICT OF COLUMBIA

STIPULATION OF DISMISSAL

The parties to this litigation hereby stipulate, pursuant to Federal Rule of Civil Procedure 41(a)(1), to the dismissal without prejudice of this action and all claims asserted herein, each party to bear its own attorney's fees and costs.

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

NOVO NORDISK INC., *et al.*, Plaintiffs, v. UNITED STATES DEPARTMENT OF HEALTH AND HUMAN SERVICES, *et al.*, Defendants.	Civil Action No. 3:21-cv-806-FLW-LHG

PROPOSED ORDER

Upon consideration of Defendants' Motion to Dismiss or, in the Alternative, for Summary Judgment and Plaintiffs' cross-motion, the Court hereby GRANTS Defendants' motion and dismisses each count of Plaintiffs' Complaint for Declaratory and Injunctive Relief.

SO ORDERED.

Dated: _____

Signed:_____
The Honorable Freda L. Wolfson
Chief Judge