UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF NEW JERSEY

NOVO NORDISK INC., *et.al.*, *Plaintiffs*, –v– XAVIER BECERRA, *et al.*, *Defendants*.	Civil Action No. 3:21-cv-00806-FLW-LHG

AMERICAN HOSPITAL ASSOCIATION, 340B HEALTH, AMERICA'S ESSENTIAL HOSPITALS, ASSOCIATION OF AMERICAN MEDICAL COLLEGES, CHILDREN'S HOSPITAL ASSOCIATION, AND AMERICAN SOCIETY OF HEALTH-SYSTEM PHARMACISTS' CONSENT MOTION TO FILE *AMICUS* BRIEF IN SUPPORT OF DEFENDANTS

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American Hospital Association, 340B Health, America's Essential Hospitals, Association of American Medical Colleges, National Association of Children's Hospitals d/b/a the Children's Hospital Association, and American Society of Health-System Pharmacists (collectively, the Proposed *Amici*) move this Court for leave to file the attached *amicus* brief in support of Defendants' opposition to Plaintiffs' cross-motion for summary judgment (Exhibit A). Proposed *Amici* also submit a Proposed Order (Exhibit B). Proposed *Amici* consulted with counsel for Plaintiff and Defendants. Plaintiffs have deferred taking a position on the Motion, and Defendants consent to the Motion.

Although the Federal Rules of Civil Procedure do not directly address the filing of *amicus* briefs, "[d]istrict courts have broad discretion to appoint amicus curiae." *United States v. Farber*, No. 06-2683 (FLW), 2006 WL 2417272, at *1 (D.N.J. Aug. 21, 2006) (citation omitted). "[A] court may grant leave to appear amicus curiae if it deems the proffered information timely and useful," and doing so "may be advisable where third parties can contribute to the court's understanding." *Id.* (citations omitted). Proposed *Amici's* timely brief would aid the Court's understanding by providing a unique perspective, insights, and specific information that the parties cannot otherwise provide. Additionally, if the Court were to grant Plaintiffs' cross-motion for summary judgment, Proposed *Amici's* members would be directly affected, further underlining the value of the *amicus* brief. *See United*

States v. Alkaabi, 223 F. Supp. 2d 583, 592 (D.N.J. 2002) (including whether "the *amicus* has a 'special interest' in the particular case" as consideration for granting *amicus* status).

Proposed *Amici* are six hospital/health system associations whose members use 340B discounts for 340B drugs dispensed through contract pharmacies to support health care programs and services offered by their hospitals. The discounts, for example, allow these members to (1) provide and maintain more patient care services; (2) provide and maintain more uncompensated and unreimbursed care; (3) provide and maintain more services in underserved areas; (4) develop and maintain targeted programs to serve vulnerable patients; and (5) keep their doors open. Am. Decl. of James W. Boyan III in Supp. of Proposed Intervenors' Mot. to Intervene (Boyan Decl.), Ex. A (Decl. of Maureen Testoni in Supp. of Proposed Intervenors' Mot. to Intervene (Testoni Decl.)) ¶¶ 7–9, ECF No. 29. These discounts are the subject of the Department of Health and Human Services (HHS) General Counsel's December 30, 2020 Advisory Opinion[1] and a May 17, 2021 letter from the Acting Administrator of the Health Resources and Services Administration (HRSA),[2] which

[1] Boyan Decl., Ex. G (*Advisory Opinion 20-06 on Contract Pharmacies Under the 340B Program* (Dec. 30, 2020)).

[2] Letter from Diana Espinosa, Acting Administrator, HRSA, to Farruq Jafery, VP, Pricing, Contract Operations & Reimbursement, Novo Nordisk, Inc. (May 17, 2021), https://www.hrsa.gov/sites/default/files/hrsa/opa/pdf/hrsa-letter-novo-nordisk-covered-entities.pdf.

both concluded that the refusal by drug companies to provide 340B providers 340B discounts for drugs dispensed through contract pharmacies is unlawful, in violation of the 340B statute. Plaintiffs Novo Nordisk Inc. and Novo Nordisk Pharma, Inc. (collectively, Novo Nordisk) challenge both the Advisory Opinion and the letter and urge the Court to decide on the merits what the statute requires of drug manufacturers. The Advisory Opinion has since been withdrawn. ECF No. 52.

Proposed *Amici* move for leave to file the attached brief (1) to assist the Court in assessing whether the 340B statute requires drug manufacturers to offer 340B discounts when drugs are dispensed by contract pharmacies; (2) to assist the Court in assessing Novo Nordisk's allegation that HHS has changed its position on the issue of contract pharmacies; (3) to assist the Court in assessing whether Novo Nordisk's alleged concerns about diversion and duplicate discounts provide legal support for its policy of refusing to provide discounts when 340B drugs are dispensed by contract pharmacies; and (4) to provide the Court with information regarding the impact of Novo Nordisk's policy on 340B covered entities such as Proposed *Amici's* members. The proposed *amicus* brief provides the Court information not otherwise offered by the parties regarding 340B covered entities, contract pharmacy arrangements, and the 24-year history of covered entities using contract pharmacies as part of the 340B program and drug manufacturers, including Novo Nordisk, honoring those arrangements.

Indeed, since the beginning of the program, Novo Nordisk and all other major pharmaceutical companies provided 340B discounts for drugs dispensed through both in-house and contract pharmacies to covered entities' patients, and since 2010 they have sold drugs at the required 340B prices to hospitals and other covered entities who used multiple contract pharmacies. For 24 years, between 1996 and December 2020, there is no record that Novo Nordisk ever contested HHS's interpretation of section 340B as allowing 340B drugs to be dispensed by contract pharmacies. Today, a quarter of the benefit that 340B hospitals receive from the 340B discount comes from 340B drugs dispensed through contract pharmacy arrangements. For some the benefit is even higher, such as critical access hospitals (small hospitals in rural areas) that report that an average of 51% of their benefit from the 340B discount comes from drugs distributed through contract pharmacies. Boyan Decl., Ex. A (Testoni Decl.) ¶ 6. Yet Novo Nordisk now asks the Court to rule that it need not honor *any* contract pharmacy arrangements, a result that would harm Proposed *Amici's* members, the patients they serve, and the public interest generally, particularly during the worst public health crisis in a century.

Proposed *Amici* respectfully request the Court to grant their motion to file an *amicus* brief.

Dated: June 22, 2021 Respectfully submitted,

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American Hospital Association, 340B Health, America's Essential Hospitals, Association of American Medical Colleges, National Association of Children's Hospitals d/b/a Children's Hospital Association, and American Society of Health-System Pharmacists, by and through their undersigned attorneys, hereby file this *amicus* brief in support of Defendants' motion for summary judgment (ECF No. 37).

Amici are six hospital/health system associations whose members use 340B discounts for 340B drugs dispensed through contract pharmacies to support health care programs and services offered by their hospitals to serve the needs of underserved populations. The discounts, for example, allow these members to (1) provide and maintain more patient care services; (2) provide and maintain more uncompensated and unreimbursed care; (3) provide and maintain more services in underserved areas; (4) develop and maintain targeted programs to serve vulnerable patients; and (5) keep their doors open. Am. Decl. of James W. Boyan III in Supp. of Proposed Intervenors' Mot. to Intervene (Boyan Decl.), Ex. A (Decl. of Maureen Testoni in Supp. of Proposed Intervenors' Mot. to Intervene (Testoni Decl.)), ¶¶ 7–9, ECF No. 29. These discounts are the subject of a May 17, 2021 letter from the Health Resources and Services Administration (HRSA), which concluded that the refusal by drug companies to provide 340B providers 340B discounts for drugs

dispensed through contract pharmacies is unlawful, in violation of the 340B statute.[1] Novo Nordisk, Inc. and Novo Nordisk Pharma, Inc. (Novo Nordisk) challenge the letter.[2]

Amici submit this brief (1) to address Novo Nordisk's argument that the 340B statute does not require drug manufacturers to offer 340B discounts when drugs are dispensed by contract pharmacies; (2) to address Novo Nordisk's allegation that HHS has changed its position on the issue of contract pharmacies; (3) to address Novo Nordisk's argument that concerns about diversion and duplicate discounts provide legal support for its policy of refusing to provide discounts when 340B drugs are dispensed by contract pharmacies; and (4) to provide the Court with information regarding the impact of Novo Nordisk's policy on 340B covered entities such as *Amici's* members.

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[1] Letter from Diana Espinosa, Acting Administrator, HRSA to Farruq Jafery, VP, Pricing Contract Operations & Reimbursement, Novo Nordisk, Inc. (May 17, 2021), https://www.hrsa.gov/sites/default/files/hrsa/opa/pdf/hrsa-letter-novo-nordisk-covered-entities.pdf. The letter to Novo Nordisk was the subject of a motion for a temporary administrative stay filed by Novo Nordisk, ECF No. 38, which this Court denied on June 1, 2021, ECF No. 44.

[2] Novo Nordisk also challenged the Department of Health and Human Services (HHS) General Counsel's December 30, 2020 Advisory Opinion, which reached the same conclusion, but which HHS has since withdrawn. Notice, ECF. No. 52.

INTRODUCTION

The 340B program, established by section 340B of the Public Health Service Act, 42 U.S.C. § 256b, requires as a condition of participating in Medicaid and Medicare Part B that pharmaceutical manufacturers sell outpatient drugs at a discounted price to certain public and not-for-profit hospitals, community health centers, and other providers that serve patients with low incomes (340B providers or covered entities). The purpose of the program is to stretch the funding 340B providers have available to meet the needs of their patients. H.R. Rep. No. 102-384(II), at 12 (1992). A 2011 report from the U.S. Government Accountability Office (GAO) found that the 340B program has had this exact effect. Specifically, GAO found that 340B providers have used the benefit made available through the drug discounts to provide critical health care services to communities with underserved populations that could not otherwise afford these services—for instance, by increasing service locations, developing patient education programs, and providing translation and transportation services. GAO, Report to Congressional Committees, GAO-11-836, *Manufacturer Discounts in the 340B Program Offer*

Benefits, but Federal Oversight Needs Improvement 17–18 (Sept. 2011), https://www.gao.gov/assets/gao-11-836.pdf (2011 GAO Report).[3]

Since the beginning of the program, Novo Nordisk and all other major pharmaceutical companies provided 340B discounts for drugs dispensed through both in-house and contract pharmacies to covered entities' patients, and since 2010 they have sold drugs at the 340B prices to hospitals and other covered entities that used multiple contract pharmacies. For 24 years, between 1996 and December 2020, there is no record that Novo Nordisk ever contested HHS's interpretation of section 340B as allowing 340B drugs to be dispensed by contract pharmacies. Today, a quarter of the benefit that 340B hospitals receive from the 340B discount comes from 340B drugs dispensed through contract pharmacy arrangements. For some the

[3] Novo Nordisk cites to articles by and testimony of Adam J. Fein, a longtime critic of the 340B program who is often relied on by the pharmaceutical industry for the proposition that the 340B program is not benefiting patients. Pls.' Combined Mem. in Supp. of Cross-Mot. for Summ. J. & in Opp'n to Defs.' Mot. to Dismiss or, in the Alternative, for Summ. J. (Pls.' Summ. J. Br.) 9, ECF No. 45-1. Dr. Fein's statements are inconsistent with the facts, namely that hospitals provided nearly $42 billion in uncompensated care in 2019, with 340B hospitals providing roughly 68% of that total. In addition, in 2017, 340B hospitals provided $64 billion in total community benefits. These high levels of uncompensated care and community benefits are provided to their communities despite the fact that 340B hospitals operate on razor thin margins, with approximately one out of every four 340B hospitals having a negative operating margin. AHA, *Setting the Record Straight on 340B: Fact vs. Fiction* (Mar. 2021), https://www.aha.org/system/files/2018-04/340BFactvsFiction.pdf. Dr. Fein and the drug industry may disagree with the policy of the 340B program that Congress has adopted, but that is for them to take up with Congress (as Dr. Fein has done), and that disagreement is irrelevant to the legal issues in this case.

benefit is even higher, such as critical access hospitals (small hospitals in rural areas), which report that an average of 51% of their benefit from the 340B discount comes from drugs distributed through contract pharmacies. Boyan Decl., Ex. A (Testoni Decl.) ¶ 6. 340B providers use the 340B benefit to provide services to underserved populations in their communities. Recognizing the value of the 340B program, Congress expanded it as part of the 2010 Affordable Care Act. Patient Protection & Affordable Care Act, Pub. L. 111-148, §§ 7101–7103, 124 Stat. 119, 821–28 (2010) (codified at 42 U.S.C. § 256b(a)(4)(M)–(O)).

Although the 340B statute requires discounts to be offered only to statutorily-defined covered entities, it does not otherwise limit the size of the program or authorize a pharmaceutical company to do so. The Conference Committee Report accompanying the original enactment stated that the HHS Secretary is not authorized to limit in any way the volume of covered entities' purchases of outpatient drugs at the discounted price. H.R. Rep. No. 102–384(II), at 16. Importantly, while the statute requires that the drugs be purchased by a covered entity, it does not limit where the drugs are dispensed. *See* 42 U.S.C. §§ 256b(a)(1), (4).

Nevertheless, starting almost one year ago, in the midst of the most devastating pandemic in 100 years, Novo Nordisk and five other major drug companies (which are among the largest companies in an industry that between 2000

and 2018 generated $8.6 trillion dollars in profits[4]) unilaterally and substantially cut the 340B benefit to public and not-for-profit hospitals that serve large numbers of patients with low incomes.[5]

The types of contract pharmacy arrangements that Novo Nordisk and the other drug companies are refusing to honor have existed since the beginning of the program. When a 340B hospital uses a contract pharmacy outside its premises, it enters into a written contract with the pharmacy. The 340B hospital orders and pays for the drugs, which are shipped directly to the contract pharmacy to be dispensed to the provider's patients. The pharmacy receives a fee for performing this service.

Under this arrangement, some providers use a "separate inventory" model, but most use a "replenishment inventory" model. For the separate inventory model, the provider's 340B drugs are kept in stock at the contract pharmacy, separate from non-340B drugs. The contract pharmacy dispenses those drugs to the provider's patients. For the more common replenishment model, no 340B drugs are kept in stock. When

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[4] Fred D. Ledley et al., *Profitability of Large Pharmaceutical Companies Compared with Other Large Public Companies*, 323(9) J. Am. Med. Ass'n 834–43 (Mar. 3, 2020), https://jamanetwork.com/journals/jama/fullarticle/2762308.

[5] *See* Boyan Decl., Ex. J (Novo Nordisk Notice (Dec. 1, 2020); Boyan Decl., Ex. E (Limited Distribution Plan Notice for Eli Lilly and Company Products (undated)); Boyan Decl., Ex. K (Sanofi Notice (July 2020)); Boyan Decl., Ex. F (Letter from Odalys Caprisecca, Executive Director, AstraZeneca to 340B Partners (Aug. 17, 2020)); Boyan Decl., Ex. L (Novartis Statement (Oct. 30, 2020)); Boyan Decl., Ex. M (Mem. From Kevin Gray, CVP, United Therapeutics Corp. to 340B Covered Entities (Nov. 18, 2020)).

filling prescriptions for the provider's patients, the contract pharmacy uses drugs from its own stock, and the provider purchases replacement drugs at the discounted price to replenish the pharmacy's stock. The replacement drugs are delivered to the contract pharmacy, which then passes on the payments it received when it dispensed the drugs, less an agreed upon dispensing fee, thus ensuring that the provider receives the benefit of the 340B discount as Congress intended.

These arrangements are typically done using a computerized tracking system following rules designed to ensure that only eligible patients of 340B providers are receiving drugs for which the provider receives the 340B discount. *See, e.g.*, Apexus, *340B Split-Billing Software Key Attributes* (July 3, 2019), https://www.340bpvp.com/Documents/Public/340B%20Tools/340b-split-billing-software-key-attributes.docx. Under either arrangement, it is the 340B provider that purchases the 340B discounted drug—not the contract pharmacy. Novo Nordisk has ceased providing 340B discounts to 340B hospitals for drugs distributed under either model.[6]

On May 17, 2021, HHS sent letters to all six pharmaceutical companies, finding that the drug companies' refusal to provide 340B discounts for drugs

[6] According to Novo Nordisk, its policy permits hospitals that do not have their own in-house pharmacy to contract with a single contract pharmacy. Boyan Decl., Ex. J (Novo Nordisk Notice (Dec. 1, 2020)).

dispensed through contract pharmacies is unlawful.[7] Novo Nordisk challenges HHS's letter in its cross-motion for summary judgment. ECF No. 45.

DISCUSSION

Novo Nordisk devotes much of its brief to mischaracterizing various guidances and statements that HHS has made about the use of contract pharmacies to deliver 340B drugs to patients of 340B providers. It also attempts to distract from the real issue by criticizing how certain arrangements with contract pharmacies

[7] Letter from Diana Espinosa, Acting Administrator, HRSA, to Odalys Caprisecca, Executive Director, US Strategic Price & Operations, AstraZeneca Pharmaceuticals LP (May 17, 2021), https://www.hrsa.gov/sites/default/files/hrsa/opa/pdf/hrsa-letter-astrazeneca-covered-entities.pdf; Letter from Diana Espinosa, Acting Administrator, HRSA, to Derek L. Asay, Senior Director, Government Strategy, Eli Lilly & Company (May 17, 2021), https://www.hrsa.gov/sites/default/files/hrsa/opa/pdf/hrsa-letter-eli-lilly-covered-entities.pdf; Letter from Diana Espinosa, Acting Administrator, HRSA, to Dan Lopuch, Managed Market Finance, Novartis Pharmaceuticals Corporation (May 17, 2021), https://www.hrsa.gov/sites/default/files/hrsa/opa/pdf/hrsa-letter-novartis-pharmaceuticals-covered-entities.pdf; Letter from Diana Espinosa, Acting Administrator, HRSA, to Farruq Jafery, VP, Pricing, Contract Operations & Reimbursement, Novo Nordisk, Inc. (May 17, 2021), https://www.hrsa.gov/sites/default/files/hrsa/opa/pdf/hrsa-letter-novo-nordisk-covered-entities.pdf; Letter from Diana Espinosa, Acting Administrator, HRSA, to Gerald Gleeson, VP & Head, Sanofi US Market Access Shared Services, Sanofi (May 17, 2021), https://www.hrsa.gov/sites/default/files/hrsa/opa/pdf/hrsa-letter-sanofi-covered-entities.pdf; Letter from Diana Espinosa, Acting Administrator, HRSA, to Lynn Robson, VP, Associate General Counsel, Market Access, United Therapeutics Corporation (May 17, 2021) https://www.hrsa.gov/sites/default/files/hrsa/opa/pdf/hrsa-letter-united-therapeutics-covered-entities.pdf. The letter to Novo Nordisk was the subject of a motion for a temporary administrative stay filed by Novo Nordisk, ECF No. 38, which this Court denied on June 1, 2021, ECF No. 44.

function. However, Novo Nordisk's policy makes no distinction among hospitals' contract pharmacy arrangements; the conditions of its policy apply to *all* arrangements, regardless of the particulars. Thus, in order to prevail on its cross-motion for summary judgment, Novo Nordisk would need to show that it is entitled to decline to offer 340B discounts to *all* 340B hospitals that do *any* business with contract pharmacies. Novo Nordisk has failed to do so.

In any event, the central and dispositive issue in this case is whether the 340B statute requires drug companies to provide 340B discounts when the drugs are dispensed by a contract pharmacy on behalf of the 340B provider. Even if its mischaracterization of the guidances and other HHS statements or claims about the specifics of the contract pharmacy arrangements were correct, Novo Nordisk cannot prevail.

I. THE PLAIN MEANING OF THE 340B STATUTE REQUIRES PARTICIPATING DRUG MANUFACTURERS TO GIVE DISCOUNTS ON 340B DRUGS DISPENSED BY CONTRACT PHARMACIES.

As Novo Nordisk recognizes, "the issue[] in this case turn[s] on a straightforward question of statutory interpretation." Pls.' Summ. J. Br. 1. Thus, "[w]e begin with the text. We look to the statutory provision's language and to the ordinary meaning of the words it uses." *Vorchheimer v. Philadelphian Owners Ass'n*, 903 F.3d 100, 105 (3d Cir. 2018). The 340B statute explicitly requires drug manufacturers to offer discounts to 340B covered entities regardless of whether the

drugs are dispensed by the entity or by an outside pharmacy with which the entity has a contract. Specifically, the statute provides that:

> The Secretary shall enter into an agreement with each manufacturer of covered outpatient drugs under which the amount required to be paid . . . to the manufacturer for covered outpatient drugs . . . *purchased by* a covered entity . . . does not exceed an amount equal to the [ceiling price].

42 U.S.C. §256b(a)(1) (emphasis added). The statute does not say "purchased *and dispensed* by" a covered entity, and the fundamental rule of statutory construction is that, when unambiguous, the plain language of the statute controls, irrespective of the legislative history or other tools of statutory construction. *DirectTV v. Pepe*, 431 F.3d 162, 168 (3d Cir. 2005). "[A]s long as the statutory scheme is coherent and consistent, there generally is no need for a court to inquire beyond the plain language of the statute." *United States v. Ron Pair Enters., Inc.*, 489 U.S. 235, 240–41 (1989). Thus, contrary to Novo Nordisk's assertion otherwise, Pls.' Summ. J. Br. 17, the 340B statute's plain language *does* require manufacturers to provide discounts for drugs purchased by 340B providers regardless of whether they are dispensed by contract pharmacies.

In fact, an earlier version of the bill that was not enacted did address how or where the 340B drugs must be dispensed. That unenacted version stated that 340B discounts would be required for drugs "purchased *and dispensed by, or under a contract entered into for on-site pharmacy services with*" a covered entity. S. Rep.

No. 102-259, at 2 (1992) (emphasis added). If that language had been retained, the 340B discounts would have been allowed *only* for on-site pharmacy services, since the drugs would have had to have been "purchased and dispensed by, or under a contract entered into *for on-site pharmacy services*." *Id.* (emphasis added). The elimination of the phrases "dispensed by" and "on-site pharmacy services" changed the provision to render where the 340B drug is dispensed legally irrelevant—all that matters is that the drug be "purchased by a covered entity." 42 U.S.C. § 256b(a)(1). It is not surprising that Congress decided to drop the additional language and to permit dispensing by contract pharmacies because, at the time the bill was passed, fewer than 5% of 340B providers had on-site dispensing services. *See* Notice Regarding Section 602 of the Veteran Health Care Act of 1992; Contract Pharmacy Services, 61 Fed. Reg. at 43,549, 43,550 (Aug. 23, 1996).

Novo Nordisk's principal statutory argument appears to be that manufacturers are only obligated to offer covered entities their drugs at discounted prices, and that this obligation does not require them to deliver those drugs to the covered entity's contract pharmacy. Pls.' Summ. J. Br. 20. This distinction does not survive analysis. First it is typically a wholesaler or distributor, not the manufacturer, that is delivering the drugs. Second it is unclear whether Novo Nordisk's distinction would allow it to refuse to give the discount for drugs delivered directly to the covered entity if the covered entity then shipped the drugs to a contract pharmacy that was more

convenient for the patient. In fact, refusing delivery is the same as refusing to provide the discounted drug.

Novo Nordisk supports its argument by claiming that being required to offer discounts on 340B drugs dispensed by contract pharmacies is inconsistent with the statute because contract pharmacies are not listed as covered entities, Pl. Summ. J. Br. 18, but this argument side steps the real issue. A contract pharmacy is not a covered entity under the 340B statute, and neither HHS nor *amici* have ever argued otherwise. And the 340B drugs are *not* being sold to the contract pharmacies; they are being sold to 340B hospitals and other covered entities, which is what the statute requires. The statute does not dictate how or where 340B drugs must be dispensed to a covered entity's patients nor does it permit manufacturers to do so.

Novo Nordisk also wrongly argues that HHS's "agency" theory has no basis in the statute and that Congress would have specified contract pharmacies in the statute if it wanted them to be covered. *Id.* at 28. The nomenclature used to characterize the relationship between a covered entity and a contract pharmacy is irrelevant so long as the statutory requirement that the drug is "purchased by a covered entity" for its patients is met. Novo Nordisk's reference to provisions in the statute that refer to other "agency-like relationships" identified in the statute, *id.*, also does not support its claim that Congress would have referenced contract pharmacies

if it had meant them to be part of the statutory scheme, and the examples provided by Novo Nordisk are inapposite.

The reason the statute specifically provides at subsection (d)(3)(B)(vi) that associations or organizations that represent the interests of covered entities can bring claims on the covered entities' behalf through the Alternative Dispute Resolution (ADR) process is because without it, associations could not bring claims at all, because they are not covered entities. Similarly, the reason the statute at subsection (d)(1)(B)(v) references wholesalers as being subject to auditing is because without that reference, the wholesalers would not be subject to auditing, because they are not drug manufacturers. For the same reason, Congress referenced distributors in subsection (d)(2)(B)(iv) because they, like manufacturers, need to be able to identify covered entities. The fact that Congress references entities other than drug manufacturers and covered entities in three places in the statute is irrelevant to whether the statute requires drug manufacturers to provide 340B discounts for drugs dispensed by contract pharmacies. Likewise, the absence of references to contract pharmacies in the statute is irrelevant because contract pharmacies are not purchasing the 340B drugs, and a covered entity's entitlement to the 340B discount does not depend on how or where the drug is dispensed to its patients.

Finally, Novo Nordisk argues that the government's reliance on the relationship between contract pharmacies and covered entities as generally

functioning like a principal-agent relationship has no support in the record. Pls.' Summ. J. Br. 28–29. The government has never suggested that in order for drug manufacturers to be required to offer drugs at 340B discounts there needs to be a state-by-state, contract-by-contract analysis of whether a common-law agency relationship exists between the covered entity and the contract pharmacy. It is not unusual for the terms "agency" or "agent" to be used without meaning to invoke the common-law definition. As explained in the Restatement (Third) of Agency, "[s]ome statutes and many cases use agency terminology when the underlying relationship falls outside the common-law definition. Moreover, the terminology of agency is widely used in commercial settings and academic literature to characterize relationships that are not necessarily encompassed by the legal definition of agency." Restatement (Third) of Agency § 1.01 cmt. (2006).

Novo Nordisk's assertion that under the government's view "the covered entity does nothing more than lend its name to the prescription" is wrong. *See* Pls.' Summ. J. Br. 29. The statute requires the covered entity to purchase the drug that is the subject of the 340B discount and to ensure that it is not being provided to a person who is not a patient of the covered entity. 42 U.S.C. §§ 256b(a)(1), (5)(B). A covered entity can comply with these requirements when it uses a contract pharmacy. What the statute does *not* dictate is that the drug can *only* be delivered directly to the

covered entity or that the covered entity must provide the drug directly to the patient. Novo Nordisk has no authority to add requirements to the statute.[8]

II. THE HRSA LETTER REITERATES HHS'S LONSTANDING POLICY ON CONTRACT PHARMACIES.

Since the inception of the 340B program, HHS has repeatedly recognized the statutory requirement to offer 340B providers covered drugs at or below the ceiling prices when they are dispensed by a contract pharmacy. As detailed below, these statements have been consistent and comprehensive and demonstrate that HHS has never wavered in its interpretation of the statute. Novo Nordisk's claim otherwise is wrong.

In 1996, HRSA issued "final guidelines" specifically addressing the use of contract pharmacies. Those guidelines recalled that since the beginning of the 340B program, HHS had recognized that 340B providers were permitted to use contract pharmacies to dispense 340B drugs, so long as they comply with the prohibition on drug diversion. 61 Fed. Reg. at 43,550 ("As early as 1993, several covered entity

[8] Last week's decision in *Astra Zeneca LP. v. Becerra*, No. 1:21-cv-27 (D. Del. June 16, 2021) ECF No. 79, does not support Novo Nordisk's argument. Reviewing AstraZeneca's challenge to the Advisory Opinion, which HHS subsequently withdrew, the court rejected both the government's and AstraZeneca's arguments that the statute was clear as to whether pharmaceutical companies participating in the 340B program are required to provide discounts for 340B drugs sold at contract pharmacies, but held that "HHS's current interpretation of the statute is permissible." *Id.* at 23. The court directed the parties to discuss whether vacating the opinion as to AstraZeneca, remanding the case, or some other relief would be appropriate. *Id.*

groups . . . came forward to assist the Department in developing a workable mechanism to use outside pharmacies. . . .”). At the same time, HRSA noted that “[t]here is no requirement for a covered entity to purchase drugs directly from the manufacturer or to dispense drugs itself” and that “[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.* at 43,549.

HRSA also recognized that “[a]s a matter of State law, entities possess the right to hire retail pharmacies to act as their agents in providing pharmaceutical care to their patients” and that “even in the absence of Federal guidelines, covered entities have the right to contract with retail pharmacies for the purpose of dispensing 340B drugs.” *Id.* at 43,550. HRSA agreed with commenters that “[b]y issuing guidelines [the Office of Drug Policy, a Division of HRSA, was] not seeking to create a new right but rather [was] simply recognizing an existing right that covered entities enjoy under State law.” *Id*. Finally, HRSA stated that “[u]nder section 340B, . . . *if a covered entity using contract pharmacy services requests to purchase a covered drug from a participating manufacturer, the statute directs the manufacturer to sell the drug at the discounted price*.” *Id.* at 43,555 (emphasis added). In 2010, HRSA again acknowledged 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." Notice Regarding 340B Drug Pricing Program—Contract Pharmacy Services, 75 Fed. Reg. 10,272, 10,278 (Mar. 5, 2010) (emphasis added). HRSA's recent letter to Novo Nordisk restates this longstanding position.

Despite HHS's longstanding and consistent application of the statutory requirements, Novo Nordisk tries to argue otherwise. Pls.' Summ. J. Br. 23–26. First, Novo Nordisk downplays the statements made in the 1996 and 2010 guidance documents because they were "isolated." *Id.* at 23. As the language quoted above demonstrates, both guidances clearly recognized the manufacturers' statutory obligation to provide discounts when contract pharmacies are used. Not only did both start by citing to the statute, but both also included the almost identical statement that "[u]nder section 340B, . . . 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." 61 Fed. Reg. at 43,555; *see also* 75 Fed. Reg. at 10,278. HHS could not have been clearer that the statute requires pharmaceutical companies that choose to participate in the 340B program to provide discounts for drugs delivered at contract pharmacies. The fact that HHS did not feel the need to repeat that clear point numerous times does not make it any less of a requirement.

Second, it is also irrelevant that HRSA repeatedly stated that its guidance is not binding and that its authority to enforce 340B guidances is limited. *See* Pls.' Summ. J. Br. 24. Although they have value in informing the regulated industry of the agency's thinking and of its interpretation of the statute, guidances are never binding and cannot by themselves be enforced. The statute, however, *is* binding, and here the statute requires manufacturers to sell 340B drugs at discounted prices to providers that contract to have the drugs they prescribe dispensed to their patients at pharmacies not on their premises.[9] Finally, the fact that HHS did not immediately enforce the statute or tell Novo Nordisk that its policy violates the statute is also, contrary to Novo Nordisk's assertion, irrelevant. *See id.* An agency's delay in enforcing a statutory requirement does not make that requirement disappear.

Novo Nordisk also argues that the 1996 guidance does not reflect HHS's current position because in that guidance, it limited 340B providers to a single contract pharmacy. *Id.* at 25. *Amici* question whether HHS had the authority to impose such a limitation, which was never challenged by 340B providers. Moreover, as discussed above, HHS corrected any such error in 2010 when it eliminated any

[9] In its brief, Novo Nordisk cites to an article published in 340B Report (ADVOP_001592–93) as support that HHS said that it could not "compel[]" manufacturers "to provide 340B discounts on drugs dispensed by contract pharmacies." Pls.' Summ. J. Br. 13. In fact, that article does *not* include such a quote from HHS. Rather it is the author's conclusion on the basis of HHS saying that guidance is not enforceable. As discussed herein, guidances are never enforceable, but as HHS has repeatedly recognized, statutes are.

limitation on the use of contract pharmacies, as required by the plain language of the statute, which is controlling. The important thing is that the 1996 guidance, like the 2010 guidance and the May 17 letter, consistently provided 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.

III. THE STATUTORY PROHIBITIONS ON DIVERSION AND DUPLICATE DISCOUNTS DO NOT PRECLUDE THE USE OF CONTRACT PHARMACIES.

Novo Nordisk's argument that covered entities' use of contract pharmacies violates the statutory prohibition on diversion also has no merit. The statutory prohibition on diversion provides that "a covered entity shall not resell or otherwise transfer [a 340B] drug to a person who is not a patient of the entity." 42 U.S.C. § 256b(a)(5)(B). As the government recognizes in its motion for summary judgment, Mem. in Supp. of Defs.' Mot. to Dismiss or, in the Alternative, for Summ. J. (Defs.' Summ. J. Br.) 28–29, ECF No. 37-1, this prohibition imposes an obligation on covered entities to avoid reselling discounted drugs to nonpatients or transferring drugs to other non-covered healthcare providers for prescribing to their patients. It does not require a safety net provider to ensure that 340B drugs are physically dispensed by the employees of the covered entity. *Id.* When a covered entity contracts with a pharmacy to dispense its 340B drugs, the contract pharmacy is, on

behalf of the covered entity, selling the 340B drug to a person who *is* a patient of the covered entity, and thus is acting in a manner consistent with the statute. There is no diversion, no matter how many times Novo Nordisk chooses to use the word "transfer" in its brief.

Although Novo Nordisk argues that shipping drugs to a contract pharmacy constitutes an unlawful "transfer" of a drug to a person who is not a patient of a covered entity, it does not explain why shipping drugs to a single contract pharmacy for delivery to a 340B patient or to replenish a drug delivered to a 340B patient (which is permitted under its policy) would not be an unlawful transfer constituting diversion. This makes no sense. Delivery to contract pharmacies either constitutes diversion or does not (it does not).[10]

Even if Novo Nordisk had legitimate concerns about diversion, the statute treats diversion as a separate issue and dictates how it is to be addressed. These concerns are not a legitimate justification for refusing to provide discounts to covered entities that use contract pharmacies, as Congress did not give drug manufacturers the authority to unilaterally halt providing discounts to covered entities on this basis. Instead, it provided both drug manufacturers and HHS with

[10] Contrary to Novo Nordisk's claim, Pls.' Summ. J. Br. 7, HHS has never claimed that permitting contract pharmacies to dispense discounted drugs on behalf of covered entities is an exercise of enforcement discretion. There is no such statement on the page of the Federal Register to which Novo Nordisk cites. *See* 61 Fed. Reg. at 43,554.

authority to address suspected diversion through audits, in accordance with procedures established by the Secretary, not the manufacturer. 42 U.S.C. §§ 256b(a)(5), (d)(2). If after an audit and a hearing, the Secretary (not the manufacturer) finds that the covered entity has violated the prohibition on diversion or duplicate discounts, the covered entity must pay a refund to the manufacturer. *Id.*; *see also* Manufacturer Audit Guidelines and Dispute Resolution Process 0905-ZA-19, 61 Fed. Reg. 65,406 (Dec. 12, 1996) (establishing guidelines for audits, as required by section 256(a)(5)(C)). Congress therefore clearly considered the risk of diversion in the 340B program and specifically addressed it.

In order to protect 340B providers from the potentially onerous burdens that giving unlimited audit authority to manufacturers would have permitted, Congress required that audits only be done in accordance with guidance from HHS regarding the number, duration, and scope of the audits. *Cf. Fin. Planning Ass'n v. SEC*, 482 F.3d 481, 488 (D.C. Cir. 2007) (agency not allowed to broaden statutory exemptions where "legislative 'intent' does not support an exemption . . . broader than the exemption set forth in the text of [the statute]" and where Congress "already expressly addressed" the issue in another provision of the statute); *id.* at 490 (finding statutory scheme inconsistent with interpretation that gives agency authority to expand provision's coverage). Novo Nordisk identifies no authority that would allow for a different conclusion. As HHS stated in the preamble to its final regulation

establishing civil money penalties, drug manufacturers cannot lawfully impose conditions on the sale of 340B drugs to 340B providers. 340B Drug Pricing Program Ceiling Price and Manufacturer Civil Monetary Penalties Regulation, 82 Fed. Reg. 1,210, 1,223 (Jan. 5, 2017). Novo Nordisk's arguments to the contrary are wrong.

Equally unavailing is Novo Nordisk's attempt to tie its policy to a desire to curb duplicate discounts. Pls.' Summ. J. Br. 11. As with diversion, Congress did not give drug manufacturers the authority to unilaterally halt providing discounts to covered entities because they have concerns regarding duplicate discounts. Again, Congress provided them and HHS with the authority to address suspected duplicate discounts through audits. 42 U.S.C. §§ 256b(a)(5), (d)(2).

Although not relevant to whether the statute allows it to attempt to unilaterally address duplicate discounting concerns—it does not—Novo Nordisk claims that contract pharmacies dramatically increase the risk of duplicate discounts and that HRSA audits have "uncovered numerous violations linked to the use of contract pharmacies." Pls.' Summ. J. Br. 11. In fact, the audit findings included covered entities that were found to *potentially* have duplicate discount issues, without indicating whether any duplicate discounts occurred with drugs dispensed at contract pharmacies, and in many cases noting that it was later determined that duplicate discounts had not in fact occurred. *See* Program Integrity: FY19 Audit Results, HRSA (updated May 19, 2021), https://www.hrsa.gov/opa/program-integrity/audit-

results/fy-19-results. The most recent GAO report addressing this issue indicated that between 2012 and 2019, *only 23* of the 429 duplicate discount findings related to contract pharmacies. GAO, HHS Uses Multiple Mechanisms to Help Ensure Compliance with 340B Requirements, GAO-21-107, at 14 (Table 1) (Dec. 2020), https://www.gao.gov/assets/gao-21-107.pdf.

IV. REQUIRING DRUG MANUFACTURERS TO HONOR CONTRACT PHARMACY ARRANGMENTS DOES NOT RENDER THE STATUTE UNCONSTITUTIONAL.

Novo Nordisk argues that the government and *Amici's* interpretation of the 340B statute "should also be rejected because it would render the statute unconstitutional." Pls.' Summ. J. Br. 29. In so doing, Novo Nordisk misrepresents Supreme Court precedent and sidesteps the fact that requiring drug manufacturers to provide 340B discounts to covered entities even if a contract pharmacy dispenses the drugs does not constitute "a naked transfer of property from private party *A* to *B* solely for *B's* private use and benefit." *Id.* (quoting *Carole Media LLC v. N.J. Transit Corp.*, 550 F.3d 302, 311 (3d Cir. 2008)). For one, Novo Nordisk voluntarily participates in the 340B program "in exchange for the economic advantages" of participating in Medicaid and Medicare Part B, has honored unlimited contract pharmacy arrangements since at least 2010, and therefore "can hardly" allege a taking. *Ruckelshaus v. Monsanto Co.*, 467 U.S. 986, 1007 (1984). But even assuming for the sake of argument that a taking occurs when drug manufacturers comply with

their statutory obligation to deliver 340B drugs to contract pharmacies to be dispensed to the purchasing 340B provider's patients, that taking is for a legitimate public purpose and therefore raises no constitutional concerns.[11]

As the Supreme Court has made clear, "one person's property may not be taken for the benefit of another private person *without a justifying public purpose*." *Haw. Hous. Auth. v. Midkiff*, 467 U.S. 229, 241 (1984) (emphasis added) (citation omitted). This "public use" requirement is satisfied where the exercise of government power "is rationally related to a conceivable public purpose," and "a federal court should not 'substitute its judgment for a legislature's judgment as to what constitutes a public use unless the use be palpably without reasonable foundation.'" *Carole Media*, 550 F.3d at 309 (quoting *Midkiff*, 467 U.S. at 241). It is undisputable that Congress enacted the 340B program for the benefit of the public, meaning that any purported taking to effectuate the program has a justifying public purpose. *See* H.R. Rep. No. 102-384(II), at 12 (1992) (purpose of 340B discounts is

[11] Novo Nordisk's unconstitutional conditions doctrine argument fails for the same reasons outlined here. The doctrine "vindicates the Constitution's enumerated rights by preventing the government from coercing people into giving them up." *Koontz v. St. Johns River Water Mgmt. Dist.*, 570 U.S. 595, 604 (2013). Novo Nordisk does not argue that it has a constitutional right to participate in Medicaid or Medicare Part B. Instead, Novo Nordisk points to its "right to retain [its] own property unless properly taken by the government (*i.e.*, taken for a public purpose and reimbursed)." Pls.' Summ. J. Br. 32. Thus, because any alleged taking here occurs "for a public purpose," Novo Nordisk has failed to show that the government is imposing any unconstitutional conditions.

to assist covered entities "to stretch scarce Federal resources as far as possible, reaching more eligible patients and providing more comprehensive services"). The statutory requirement that drug manufacturers deliver to contract pharmacies 340B drugs purchased by covered entities at the 340B price "is rationally related to a conceivable public purpose" and therefore does not run afoul of the Constitution. *Midkiff*, 467 U.S. at 241.

As in *Midkiff*, where the Supreme Court found that "[t]he Hawaii Legislature enacted its Land Reform Act not to benefit a particular class of identifiable individuals but to attack certain perceived evils of concentrated property ownership in Hawaii—a legitimate public purpose," *id.* at 245, so too here. Congress enacted the 340B statute—and its requirement that drug manufacturers provide covered entities with 340B discounts regardless of how the drugs are dispensed—not to benefit contract pharmacies or any other "particular class of identifiable individuals" but to allow covered entities to "reach[] more eligible patients and provid[e] more comprehensive services." H.R. Rep. No. 102-384(II), at 12. The fact that covered entities provide a fee to contract pharmacies for their services does not alter this result. *See Kelo v. City of New London*, 545 U.S. 469, 485 (2005) ("[T]he government's pursuit of a public purpose will often benefit individual private parties."); *Carole Media*, 550 F.3d at 309 ("[T]he fact that a taking creates incidental

benefits for individual private parties 'does not condemn that taking as having only a private purpose.'") (quoting *Midkiff*, 467 U.S. at 243–44).

Finally, Novo Nordisk's concerns that "contract pharmacies are receiving a windfall in private benefits," Pls.' Summ. J. Br. 30—even if they were valid, and there is no evidence in this case that they are—do not render the 340B statute unconstitutional. "When the legislature's purpose is legitimate and its means are not irrational, our cases make clear that empirical 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." *Midkiff*, 467 U.S. at 242–43. Indeed, "the Supreme Court has made it clear that 'the means of executing the project resulting in a taking are for the legislature alone to determine, once the public purpose has been established.'" *Carole Media*, 550 F.3d at 311 (alterations omitted) (quoting *Berman v. Parker*, 348 U.S. 26, 33 (1954)).

By enacting the 340B statute, Congress decided to require drug manufacturers that wish to participate in Medicaid and Medicare Part B to offer discounts to 340B providers regardless of how the drugs are dispensed to their patients. Congress was entitled to make that decision, and the courts (and drug manufacturers) may not second-guess it simply because drug manufacturers are concerned that contract pharmacies receive some benefit from 340B providers. *Cf. id.*, 550 F.3d at 311–12 ("To the extent that Carole Media merely argues that All Vision will receive an

excessive payment for its role as management agent for NJ Transit, that argument simply fails to demonstrate that NJ Transit's alleged taking was not 'rationally related to a conceivable public purpose.'") (quoting *Midkiff*, 467 U.S. at 241).

CONCLUSION

Novo Nordisk's refusal to offer 340B drugs at discounted prices when dispensed through contract pharmacies is at odds with the 340B statute and with HHS's longstanding interpretation of the statute and, worse, jeopardizes 340B hospitals' ability to care for patients during the most serious public health crisis in the last century. For the reasons set forth above, this Court should uphold HHS's correct interpretation of the statute and deny Novo Nordisk's cross-motion for summary judgment.

Dated: June 22, 2021

Respectfully submitted,

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UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF NEW JERSEY

NOVO NORDISK INC., *et.al.*, *Plaintiffs*, –v– XAVIER BECERRA, *et al.*, *Defendants*.	Civil Action No. 3:21-cv-00806-FLW-LHG

[PROPOSED] ORDER GRANTING MOTION FOR LEAVE TO FILE *AMICUS* BRIEF

Upon consideration of the Motion for Leave to File *Amicus* Brief in Support of Defendants, filed by American Hospital Association, 340B Health, America's Essential Hospitals, Association of American Medical Colleges, National Association of Children's Hospitals d/b/a Children's Hospital Association, and American Society of Health-System Pharmacists, it is hereby

ORDERED that the motion is GRANTED; it is

FURTHER ORDERED that the Clerk shall cause the *amicus* brief attached to the motion to be filed and entered on the docket in the above-captioned proceeding.

Dated: _____, 2021

_____
The Honorable Freda L. Wolfson
United States District Judge