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 Motion Date: April 5, 2021

DEFENDANTS' OPPOSITION TO MOTION TO INTERVENE

Proposed intervenors in this case already have tried—and failed—to litigate the legality of Plaintiffs Novo Nordisk Inc. and Novo Nordisk Pharma, Inc. (collectively, "Novo") and other drug manufacturers' unilaterally imposed restrictions on 340B drug discounts in another federal district court. Every one of the associations seeking to intervene here (hereinafter, "Covered Entities") was a plaintiff in a suit, dismissed less than a month ago, that sought unsuccessfully to commandeer Defendants' (collectively, "HHS") enforcement of the 340B statute against Novo and other pharmaceutical companies. Ignoring that court's straightforward holding that the legality of Novo's and its peers' recent restrictions must be decided, in the first instance, in HHS's ADR process (*not* in federal court), the Covered Entities now seek a second bite at the apple by intervening in this suit to again press their interpretation of the statute. But the Covered Entities are no more entitled to litigate the proper interpretation of the 340B statute in this suit than in the one that was just dismissed, and intervention should be denied for several reasons.

First, the Supreme Court unequivocally has held that covered entities, like those seeking to intervene here, *cannot* litigate purported 340B violations because "Congress vested authority to oversee compliance with the 340B Program in HHS and assigned no auxiliary enforcement role to

covered entities." *Astra USA, Inc. v. Santa Clara Cty.* (*Astra*), 563 U.S. 110, 117 (2011). The Covered Entities' attempt to intervene as *defendant* here, in place of the agency charged with enforcing the statute, is simply a creative recasting of precisely the type of suit *Astra* forbade. Second, this Court should not even reach the motion to intervene, because the Court should first address HHS's forthcoming motion to dismiss,[1] which will include arguments demonstrating why this Court lacks jurisdiction to review the interpretation set forth in the Advisory Opinion. Intervention is improper when a court lacks subject-matter jurisdiction over the original action, and the intervention of a new party cannot cure a lack of jurisdiction. Third, even were the Court to reach the motion to intervene, the Covered Entities still do not have an interest in the outcome that is sufficient to meet the requirements of Federal Rule of Civil Procedure 24(a)(2). The Covered Entities have no independent right to defend the legality of government action, and their interests are adequately represented because the government is defending this suit vigorously and seeks the same outcome as would proposed intervenors—a complete denial of relief for the plaintiffs. Instead, the Covered Entities seeking to intervene should present their views as *amici curiae*. Fourth, the Covered Entities cannot even meet the requirements under Rule 24(b)(1)(B) for permissive intervention because they do not have any "claim or defense" for which there is an independent basis for jurisdiction. The Covered Entities do not seek to assert any claim or defense of their own in this action; instead, any "defenses" they may wish to assert would merely consist of defenses they believe HHS should raise against the claims presented by Novo. And both *Astra* and the Covered Entities' own recent, failed suit demonstrate that the Covered Entities *cannot*

[1] The deadline to file a responsive pleading is April 27, 2021. *See* Aff. of Serv. by Cert. Mail, ECF No. 23 (reflecting service on the United States Attorney's Office for the District of New Jersey on February 26, 2021); *see also* Fed. R. Civ. P. 12(a)(2) (requiring a federal defendant to file a responsive pleading within 60 days after service on the United States Attorney).

present any claim for 340B violations against either drug manufacturers or HHS.

Accordingly, the Court should delay consideration of the Covered Entities' motion to intervene until it has decided the jurisdictional issues that will be raised in HHS's forthcoming motion to dismiss. But if the Court reaches the motion to intervene, it should be denied. As HHS already has communicated to the Covered Entities, the Government does not oppose participation by the proposed intervenors as *amici curiae*.

BACKGROUND

I. STATUTORY AND REGULATORY BACKGROUND

In 1992, Congress created a program, administered by the Secretary of Health and Human Services ("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).

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). 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 low-income patients. *Id.*

In 1996, HHS issued non-binding guidance to aid pharmaceutical companies and covered entities in the use of contract pharmacies, explaining 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, that guidance confirmed the Department's *pre-existing* 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," regardless whether the covered entity directs that the drugs be shipped for handling and dispensing to a contract pharmacy. *Id.* at 43,549. And, the agency continued, 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.* at 43,550.

Consistent with HHS's interpretation of the 340B statute and its early guidance implementing the statute's 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) ("2010 Guidance"). 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.* at 10,273.

Also in 2010, Congress opted "to strengthen and formalize [HHS's] enforcement authority" over the 340B Program. *See Astra*, 563 U.S. at 121–22. 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).

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