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).

A neighboring provision also instructed the Secretary to establish a 340B Program administrative dispute-resolution ("ADR") process for covered entities and manufacturers:

> [T]he Secretary shall promulgate regulations to establish and implement an administrative process for the resolution of claims by covered entities that they have been overcharged for drugs purchased under this section, and claims by manufacturers … of violations [of provisions prohibiting diversion of drugs and duplicate discounts], including appropriate procedures for the provision of remedies and enforcement of determinations made pursuant to such process through mechanisms and sanctions described [herein].

42 U.S.C. § 256b(d)(3)(A). Congress included several directives regarding the new dispute-resolution mechanism, but largely granted the Secretary discretion to devise a workable system. The final ADR rule was published in the Federal Register on December 14, 2020, and became effective on January 13, 2021. *See* 85 Fed. Reg. 80,632. Both covered entities and drug manufacturers now have a mechanism to resolve before the agency disputes arising under the 340B Program. *See* 85 Fed. Reg. at 80,644.

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

Late in 2020, several pharmaceutical manufacturers, including Novo, unilaterally imposed onerous and non-statutory restrictions on providers' access to 340B discounted drugs. Specifically, Novo announced (more than ten years after HHS's explicit guidance on the subject) that, effective January 1, 2021, it would no longer ship 340B discounted drugs to more than one designated contract pharmacy per covered entity, and it would only ship to a contract pharmacy where the covered entity is without an in-house pharmacy. *See* Novo Nordisk, Notice Regarding Limitation on Hospital Contract Pharmacy Distribution (Dec. 1, 2020), Mot., Ex. J, ECF No. 20-2 at 81. Novo claimed that its "new policy" would only apply to "'hospital' covered entit[ies]," and that no "'grantee' covered entit[ies]" would be "impacted by this change in policy." *Id.*

Naturally, the public outcry to the drug companies' actions was swift. In response, HHS's

General Counsel issued an Advisory Opinion on December 30, 2020, confirming his view—in accord 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 ("AO") at 1, *available at* https://www.hhs.gov/guidance/sites/default/files/hhs-guidance-documents/340B-AO-FINAL-12-30-2020_0.pdf. The AO did not represent a change in the agency's position from the 2010 Guidance.

III. THE COVERED ENTITIES ATTEMPT TO RESOLVE THIS DISPUTE OUTSIDE OF THE STATUTORY SCHEME.

On December 11, 2020, each of the Covered Entities seeking to intervene here sued HHS in the Northern District of California. Compl., *Am. Hosp. Ass'n v. Dep't of Health & Hum. Servs.*, No. 4:20-cv-8806-YGR (N.D. Cal. Dec. 11, 2020), ECF No. 1. That same day the Covered Entities moved for emergency injunctive relief, seeking to compel HHS to enforce the 340B statute against Novo and other manufacturers, including orders "to require the Drug Companies to provide covered outpatient drugs at or below 340B ceiling prices to covered entities when they dispense those drugs through contract pharmacies," along with orders for drug companies to issue refunds, and referral of Novo and other companies' restrictions for the assessment of significant civil monetary penalties. Mot. for Prelim. Inj., *Am. Hosp. Ass'n*, No. 4:20-cv-8806-YGR (N.D. Cal. Dec. 11, 2020), ECF No. 7.

In addition to opposing the Covered Entities' emergency motion, HHS moved to dismiss the suit in its entirety, arguing that claims for 340B violations must be decided, in the first instance, through HHS's newly available ADR process. Defs.' Notice of Mot. & Motion to Dismiss; Mem.

of Points & Auths. in Supp. Thereof & Opp. to Pls.' Mot. for Prelim. Inj., *Am. Hosp. Ass'n*, No. 4:20-cv-8806-YGR (N.D. Cal. Jan. 11, 2021), ECF No. 64. HHS's motion demonstrated (1) that, under *Astra*, Covered Entities may not sue to enforce 340B requirements (regardless whether the agency or a drug manufacturer is named as the nominal defendant); (2) the Covered Entities could not establish jurisdiction under the Administrative Procedure Act ("APA") because they did not challenge any final agency action; and (3) no jurisdiction exists for a court to review HHS's enforcement of the statute because such decisions are committed to agency discretion under *Heckler v. Chaney*, 470 U.S. 821 (1985). *Id.* at 16–24. Only two days after HHS filed its motion, the court ordered the Covered Entities "to show cause in writing why this case should not be dismissed for lack of subject-matter jurisdiction." Order to Show Cause re: Dismissal for Lack of Subject-Matter Jurisdiction, *Am. Hosp. Ass'n*, No. 4:20-cv-8806-YGR (N.D. Cal. Jan. 13, 2021), ECF No. 70 (font altered). The court also suspended hearing the Covered Entities' preliminary-injunction motion until HHS's motion to dismiss had been decided.

Facing near-certain dismissal, the Covered Entities disavowed their previous request for sweeping injunctive relief requiring HHS to take specified enforcement actions, and instead recast their suit as one seeking to compel HHS to develop a new "enforcement policy." Pls.' Resp. to Order to Show Cause, Opp. to Mot. to Dismiss, & Reply in Supp. of Pls.' Mot. for Prelim. Inj., *Am. Hosp. Ass'n*, No. 4:20-cv-8806-YGR (N.D. Cal. Jan. 25, 2021), ECF No. 81.

The Covered Entities' attempt to transform their suit was unavailing: one month ago, the Northern District of California dismissed the case, specifically agreeing with each of HHS's jurisdictional arguments. *See Am. Hosp. Ass'n v. Dep't of Health & Human Servs.*, No. 4:20-cv-08806-YGR, 2021 WL 616323, at *1–8 (N.D. Cal. Feb. 17, 2021). Importantly for the present action, the court found the Covered Entities' claims barred by *Astra*'s holding that litigation to

enforce 340B requirements is "incompatible with the statutory regime" and that Congress had mandated resolution of disputes under the 340B Program in the agency's ADR process. *Id.* at *5–6 (quoting *Astra*, 563 U.S. at 113). Even though the Covered Entities had "creatively recast their claims," the court found, they "seek precisely that which *Astra* forbids: the *private* enforcement of 340B program requirements." *Id.* at *5. The court then explained:

> Congress made explicit that alleged 340B Program violations are to be first adjudicated by HHS through an established ADR process. This process provides the agency an initial opportunity to develop rules and regulations applicable to the enforcement of the 340B Program requirements. Moreover, the panel consists of decisionmakers *with intimate familiarity, technical knowledge, and understanding of the nuances inherent* in the 340B Program. The judiciary has a prescribed role in this process, but its role comes *only after* the parties have participated in this ADR process. This Court will not otherwise short-circuit the foundational regime that Congress has enacted in the 340B Program.

Id. at *6 (first emphasis added). The court further agreed with HHS that the Covered Entities had not challenged any final agency action, as required to maintain an APA suit, and that the relief sought would invade the unreviewable realm of prosecutorial discretion—even after the Covered Entities had "backtrack[ed] from their own requests for emergency relief." *Id.* at *6–8.

HHS would have no objection to the Covered Entities' participation in this action as *amici curiae*, a role which would permit them to provide this Court with potentially useful information regarding the real-world consequences and purported harms inflicted by Novo's unilateral restrictions on access to discounted drugs. But, despite undersigned counsel having communicated to counsel for the proposed intervenors that the government would not oppose their request to participate as *amici*, the Covered Entities instead have moved to intervene as a defendant—a posture which would allow them to sidestep *Astra* and litigate claims under the 340B statute directly against Novo.

ARGUMENT

1. Intervention by the Covered Entities is barred by *Astra.*

Even after *explicitly* being told by the Northern District of California that their challenge to the legality of Novo's new restrictions must be adjudicated, in the first instance, in HHS's ADR process—not in federal court—the Covered Entities doggedly (and inexplicably) continue to instead pursue the same verboten result: private enforcement of 340B requirements, in direct contravention of Supreme Court authority. The procedural posture of this case, in which the Covered Entities wish to participate as defendants litigating 340B requirements against drug makers, is even more on-point with *Astra* than the recent suit against HHS that was dismissed on these same grounds last month. Intervention must be denied because covered entities, like the proposed intervenors here, cannot litigate 340B requirements outside the ADR process.

The Supreme Court expressly confirmed in *Astra* that covered entities may not litigate 340B Program requirements. *See generally* 563 U.S. 110. In that case, a collection of covered entities had sued drug manufacturers for purported overcharges on 340B-covered drugs. The Court rejected as "incompatible with the statutory regime" the covered entities' efforts to sue to enforce 340B requirements, regardless of the legal theory on which they based their claim. *Id.* at 113. This is because "Congress vested authority to oversee compliance with the 340B Program in HHS and assigned no auxiliary enforcement role to covered entities." *Id.* at 117. The Court further made clear that the legal theory relied on by covered entities mattered not, in light of the evident "incompatibility of private suits with the statute Congress enacted." *Id.* at 121; *see also id.* at 120 ("Far from assisting HHS, suits by 340B entities would undermine the agency's efforts to administer both Medicaid and § 340B harmoniously and on a uniform, nationwide basis," and create a "substantial" "risk of conflicting adjudications").

Finally, the Court noted that Congress had responded to reports of inadequate 340B oversight and enforcement, not by authorizing private suits by covered entities, but instead by providing for the establishment of an ADR process within the agency. *Id.* at 121–22 (citing 42 U.S.C. § 256b(d)). "Congress thus opted to strengthen and formalize" the agency's enforcement "to make the new adjudicative framework the proper remedy for covered entities complaining of 'overcharges and other violations of the discounted pricing requirements,'" with the agency's resolution of ADR complaints subject to review under the APA. *Id*.

The Covered Entities' request to intervene here is barred by this unmistakable Supreme Court precedent. The calculus is not altered by the fact that the Covered Entities purport to ask this Court to allow them to defend the agency's statutory interpretation; intervention will still permit covered entities and manufacturers to litigate between them claims for 340B program violations (here, the legality of Novo's restrictions), which is precisely what the Supreme Court forbade. Stated plainly, *Astra* confirmed that covered entities simply may not sue, on any legal theory, to enforce their statutory entitlement to 340B discounted drugs (and instead must bring claims for violations in the ADR process). Permitting associations of covered entities here to litigate the correctness of the HHS General Counsel's statutory interpretation *against a drug manufacturer* would flout this precedent. Intervention must be denied because it is HHS, not the Covered Entities, to which Congress has assigned oversight and enforcement of 340B. *See id.* at 118 ("A third-party suit to enforce" 340B requirements "is in essence a suit to enforce the statute itself," and "[t]he absence of a private right to enforce the statutory ceiling-price obligations would be rendered meaningless if 340B entities could overcome that obstacle by suing" under creative legal theories). Indeed, the Covered Entities' recent attempt to force HHS to take specified actions against Novo failed on this same ground. *See Am. Hosp. Ass'n*, 2021 WL 616323, at *5 ("Although

plaintiffs here have similarly and creatively recast their claims as an APA action against HHS and the Secretary of HHS, this action is nothing more than an *indirect action* against the drug manufacturers themselves.").[2]

2. The Court should consider the jurisdictional issues raised in HHS's forthcoming motion to dismiss before ruling on the Covered Entities' motion, because there is no basis for intervention in a suit over which the Court lacks subject-matter jurisdiction.

The Court should not even reach the motion to intervene because intervention is not proper in a case where a court lacks subject-matter jurisdiction. The Court should first address HHS's forthcoming motion to dismiss, which will raise jurisdictional and other threshold defenses; HHS respectfully contends that this motion will be meritorious and will demonstrate why the Court lacks jurisdiction to decide, in the first instance, the correctness of the HHS General Counsel's statutory interpretation.

A court generally should resolve issues of subject-matter jurisdiction before it considers other issues. Moreover, intervention does not affect the jurisdictional analysis. "Intervention cannot cure any jurisdictional defect that would have barred the federal court from hearing the original action. Intervention presupposes the pendency of an action in a court of competent jurisdiction and cannot create jurisdiction if none existed before." 7C Charles Alan Wright, Arthur R. Miller & Mary Kay Kane, Federal Practice and Procedure § 1917 (3d ed. 2007) (footnote omitted); *accord Fuller v. Volk*, 351 F.2d 323, 328 (3d Cir. 1965) ("[S]ince intervention contemplates an existing suit in a court of competent jurisdiction and because intervention is ancillary to the main cause of action, intervention will not be permitted to breathe life into a

[2] The Covered Entities may respond that nothing in *Astra* abrogated the ability to bring APA claims related to the 340B Program. That is true, but irrelevant. The Covered Entities are not suing HHS under the APA (that attempt already has failed), but instead seek to participate as *defendants* against drug maker Novo—which is precisely what the Supreme Court forbade.

'nonexistent' law suit."); *see also McClune v. Shamah*, 593 F.2d 482, 486 (3d Cir. 1979) ("A motion for intervention under Rule 24 is not an appropriate device to cure a situation in which plaintiffs may have stated causes of action that they have no standing to litigate.").

In response to Novo's complaint, HHS expects to present the Court with strong grounds for dismissal. With respect to the Advisory Opinion the Covered Entities seek to "defend," HHS will show that no jurisdiction exists under the APA because the Advisory Opinion is not final agency action and because an adequate alternate remedy has been provided by Congress; and that the Advisory Opinion does not exceed statutory authority because the only obligations imposed on Novo flow directly from the 340B statute. The Court therefore should delay resolution of the Covered Entities' motion until it rules on HHS's forthcoming motion to dismiss, which should be granted.

3. The Covered Entities' interests are adequately represented by HHS.

A separate reason the Covered Entities fail to qualify for intervention as of right is that their interests are adequately represented by HHS—which shares the Covered Entities' goal of repelling this lawsuit. It is the Department of Justice, not private parties like the Covered Entities, that is charged by Congress with the responsibility of defending federal agencies' interpretation of federal law. *See* 28 U.S.C. § 516. Any unique views the Covered Entities wish to present to the Court should be provided through an amicus brief, not participation as a party, because the Department of Justice's representation of HHS's statutory interpretation is more than adequate.

In *United States v. Territory of Virgin Islands*, 748 F.3d 514 (3d Cir. 2014), an inmate imprisoned by the Territory of Virgin Islands sought to intervene alongside the United States in a suit against the Territory to ensure the respect of inmates' Eighth Amendment rights. *Id.* at 516. The Third Circuit reiterated that a "presumption of adequacy" attached given that the aligned party

was a government entity, and held that proposed intervenor failed to show that he was not adequately represented by the government because his interests "not only overlap[ped] with those of the United States," but were "essentially identical." *Id.* at 520, 522. The court noted that the proposed intervenor has the same primary goal as the federal government—to "achieve constitutionally required conditions at the facility." *Id.* at 522.

This case is on all fours with *Territory of Virgin Islands*. The Covered Entities and HHS have the same primary goal in the litigation—to repel Novo's challenge to the Advisory Opinion. This triggers a presumption of adequate representation. *See id.* at 520. HHS's general need to weigh other competing interests and the possibility that the Covered Entities may disagree with HHS about the minutiae of litigation strategy do not come close to rebutting that presumption.

The Covered Entities make no serious attempt to address this standard. Instead, they assert in conclusory fashion that "Defendants' interests . . . diverge, as they disagree with Proposed Intervenors that HHS has the authority and obligation to enforce" the 340B statute, as interpreted by the Advisory Opinion. Mot. 11. Not so. In defending against the Covered Entities' suit in the Northern District of California, HHS confirmed that covered entities must challenge Novo's recent restrictions—as Congress mandated—in the agency's ADR process. But once an ADR panel has determined whether Novo's policy comports with the 340B statute, either side can seek judicial review of that ruling under the APA *and* HRSA can pursue various types of enforcement action if a violation is found. The Covered Entities' suggestion that HHS has abdicated responsibility for enforcing the statute is meritless. Moreover, the Covered Entities purport to seek intervention to defend the legality of the statutory interpretation set forth in the Advisory Opinion—*not* to relitigate the scope of HHS's enforcement efforts. HHS has not backed away from the Advisory Opinion's interpretation. And if the Court reaches the merits of Plaintiff's claims, HHS will rely

on the Advisory Opinion's reasoning in defending its interpretation. So, there is no divergent interest whatsoever between the Covered Entities and HHS regarding the only matter about which the Covered Entities seek to intervene.

The Covered Entities' threadbare speculation that it is "quite conceivable that the government's defense . . . may be inadequate," Mot. 14, is wrong as a matter of both law and fact. HHS, the agency charged by Congress with implementing and enforcing the 340B statute, is fully and forcefully defending its interpretation of the statute in this suit and those brought by other manufacturers in other districts. Equally false is the Covered Entities' assertion that "HHS has never taken the position that it can or will enforce the statutes as interpreted." Mot. 14. HHS successfully rebutted that same assertion in the Northern District of California litigation, and it is the Covered Entities that inexplicably refuse to bring a claim for relief before the agency where the legality of Novo's policy and, if necessary, appropriate enforcement must be decided.

To the extent that the Covered Entities may be seeking intervention in a misguided attempt to once again litigate *against HHS*—for example, by moving for relief enjoining HHS to enforce the 340B statute in the manner, and on the timeframe, the Covered Entities prefer—any such attempt would once again be barred by *Astra* and principles of agency discretion and, now, *res judicata*.

The Covered Entities therefore cannot meet the standard for intervention as of right under Federal Rule 24(a)(2). Moreover, any interest they have in providing to the Court *facts* in their possession regarding the harms inflicted by Novo's restrictions can adequately be protected by filing a brief as *amici curiae*.

4. The Covered Entities cannot seek permissive intervention because they have no "claim or defense" of their own for which there would be an independent basis for jurisdiction.

The Covered Entities also do not meet the requirements for permissive intervention under Rule 24(b)(1)(B) because they do not seek to present any claim or defense for which there is independent jurisdiction.

Under Rule 24(b)(1)(B), a person seeking permissive intervention must present a "claim or defense." It must be the kind of claim or defense "that can be raised in courts of law as part of an actual or impending" lawsuit, *Amchem Prods., Inc. v. Windsor*, 521 U.S. 591, 623 n.18 (1997) (citation omitted), and for which the court has "independent jurisdictional grounds," *Beach v. KDI Corp.*, 490 F.2d 1312, 1319 (3d Cir. 1974) (citation omitted). In this case, there are no claims that have been raised or could be raised between Novo and the Covered Entities. Again, the dispute between those parties *must* be decided in the agency's ADR process. *See Astra*, 563 U.S. at 122.

One is left to surmise, however, what claims or defenses the Covered Entities wish to assert in this case, because the proposed answer appended to their motion is for a complaint filed in a *separate* case between HHS and a different drug manufacturer. *See* Prop. Answer in Intervention to Pl.'s First Am. Compl., Ex. B, ECF No. 20-2 at 1 (answering the First Amended Complaint filed in *Sanofi-Aventis U.S., LLC v. Cochran* (*Sanofi*), No. 3:21-cv-634 (D.N.J.)). To be sure, the plaintiff in *Sanofi* challenges the Advisory Opinion on grounds similar to those asserted by Novo here, with a few exceptions. But even so, the Covered Entities have not provided the Court or the parties with a clear indication of the particular claims or defenses they intend to raise in response to *Novo's* complaint if their motion to intervene is granted.

To the extent the Covered Entities wish to lodge virtually identical "defenses" as those asserted in their proposed answer to the *Sanofi* complaint, these are not defenses that could be

asserted by the Covered Entities against claims brought by Novo. *See* Prop. Answer in Intervention to Pl.'s First Am. Compl., Ex. B, ECF No. 20-2 at 31. Rather, they can only be viewed as defenses that the Covered Entities wish for HHS to raise against Novo's claims. The Covered Entities have no authority whatsoever to raise defenses on the government's behalf—nor to defend a federal agency's interpretation of a federal statute on the agency's behalf—and intervention does not give them any such authority. This principle is illustrated by the fact that the Covered Entities seek to file an *answer* to Novo's complaint—which would tee up resolution by this Court of the merits of the contract-pharmacy dispute—whereas HHS repeatedly has explained (and will demonstrate in its forthcoming motion to dismiss) that the matter must be decided, in the first instance, in HHS's ADR process, not by this Court.

At bottom, the Covered Entities could not state a claim (or raise a defense) against Novo, because litigation by covered entities over 340B Program violations unequivocally is foreclosed by *Astra*. And the Covered Entities cannot state a claim (or raise a defense) against HHS for similar reasons, as borne out by the recent dismissal of the Covered Entities' attempt to do just that. There is simply no claim the Covered Entities could litigate (as plaintiff or defendant) under the 340B statute over which the Court would have jurisdiction, unless and until an ADR panel renders a final agency decision that may be challenged under the APA. Stated plainly, the Covered Entities have no "claim or defense" in common with HHS or Novo and therefore cannot meet the prerequisite for permissive intervention. The Covered Entities' statutory *right* to 340B-discounted drugs does not give them a *claim* capable of resolution in federal court. *Astra*, 563 U.S. at 121. The Covered Entities could serve a helpful role as *amici*, fleshing out the facts surrounding the 340B Program—but cheering on HHS and hoping it prevails in litigation does not justify participation as a party in this litigation.

Even if the Covered Entities could meet the requirement for intervention—and they cannot—the Court should exercise its discretion to deny permissive intervention given the potential for the addition of another party to complicate the proceedings and further burden the Court and the parties. Permissive intervention under Rule 24(b) is "highly discretionary." *Brody ex rel. Sugzdinis v. Spang*, 957 F.2d 1108, 1115 (3d Cir. 1992). This is particularly true when the agency already is burdened by defending similar, meritless suits, brought by separate pharmaceutical companies, now pending in various district courts.

Finally, the Court should deny permissive intervention for the additional reason that allowing private parties, like the Covered Entities, to litigate the proper interpretation and application of a federal statute alongside the agency charged with implementing that statute would severely curtail the discretion and authority Congress bestowed. As will be demonstrated in HHS's forthcoming motion to dismiss, the proper application of the 340B statute to Novo's restrictions must be decided, in the first instance, by the agency—not in this Court, in competing briefs between interested parties such as the Covered Entities and Novo. The attendant harms that may accrue to the agency from the Covered Entities' participation is borne out by their attempt to *answer* Novo's complaint, whereas HHS intends to demonstrate that the Advisory Opinion is not reviewable final agency action subject to challenge in this Court.

CONCLUSION

The Court should delay resolution of the Covered Entities' intervention request until it has resolved the jurisdictional issues that will be raised in HHS's forthcoming motion to dismiss. If the Court reaches the motion to intervene, the request should be denied because the Covered Entities do not meet the requirements for intervention. Conversely, the Covered Entities should, if they choose, move to participate as *amicus curiae*.

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Respectfully submitted,

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CERTIFICATE OF SERVICE

I hereby certify that on March 22, 2021, a copy of the foregoing document was served on all counsel of record for the parties via the Court's electronic case filing system.

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