IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF COLUMBIA

ELI LILLY AND COMPANY, *et al.*, *Plaintiffs*, v. ROBERT F. KENNEDY JR., *et al.*, *Defendants*.	Case No. 24-CV-3220 (DLF)
BRISTOL MYERS SQUIBB COMPANY, *Plaintiff*, v. ROBERT F. KENNEDY JR., *et al.*, *Defendants*.	Case No. 24-CV-3337 (DLF)
SANOFI-AVENTIS U.S. LLC, *Plaintiff*, v. UNITED STATES DEPARTMENT OF HEALTH AND HUMAN SERVICES, *et al.*, *Defendants*.	Case No. 24-CV-3496 (DLF)
NOVARTIS PHARMACEUTICALS CORPORATION, *Plaintiff*, v. ROBERT F. KENNEDY JR., *et al.*, *Defendants*.	Case No. 25-CV-0117 (DLF)

PLAINTIFFS' JOINT OPPOSITION TO
340B HEALTH, UMASS MEMORIAL CENTER MOTION, AND GENESIS HEALTHCARE SYSTEM'S MOTION TO INTERVENE

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The federal 340B program requires manufacturers to offer their medicines at reduced prices to certain healthcare providers. Rather than pass on these reduced prices to their patients, 340B hospitals and their for-profit pharmacy partners choose to charge commercial and government payors full price. They then "divvy up the spread between the discounted price and the higher insurance reimbursement rate." *Novartis Pharms. Corp. v. Johnson*, 102 F.4th 452, 457 (D.C. Cir. 2024). As 340B profits have swelled, so have statutory violations—thanks in part to a lack of proper oversight by the Health Resources and Services Administration (HRSA). Two 340B hospitals and their trade association have moved to intervene to defend the broken status quo.

The four Manufacturer-Plaintiffs—Eli Lilly and Company and Lilly USA, LLC (Lilly), Bristol Myers Squibb Company (BMS), Sanofi-Aventis U.S. LLC (Sanofi), and Novartis Pharmaceuticals Corp. (Novartis)—respectfully oppose intervention at this late hour by 340B Health, UMass Memorial Medical Center, and Genesis HealthCare System (Proposed Intervenors). This Court should deny intervention because (1) Proposed Intervenors lack Article III standing; (2) Proposed Intervenors are not entitled to intervene as of right because their motion was not timely filed, they do not have a protected interest warranting intervention, any interests they do have will not be impaired by this action, and the government adequately represents any interests they have; and (3) permissive intervention is unwarranted.

BACKGROUND

The underlying background for this matter is set forth fully in Manufacturer-Plaintiffs' briefs in support of their motions for summary judgment. *See* No. 24-3220, ECF No. 15 (Lilly); No. 24-3337, ECF No. 17 (BMS); No. 25-117, ECF No. 12 (Novartis). Manufacturer-Plaintiffs' suits allege that Defendants—HRSA, the Department of Health and Human Services (HHS), and officials of these agencies—acted in excess of their authority under the 340B statute, 42 U.S.C. § 256b, the Administrative Procedure Act, 5 U.S.C. § 706, and the Constitution, U.S. Const. amend.

V, in prohibiting Manufacturer-Plaintiffs from adopting their cash-replenishment or cash-rebate models through letters to Manufacturer-Plaintiffs and a post on HRSA's website.

The Court has approved a stipulated briefing schedule under which the parties will complete briefing on cross-motions for summary judgment by March 31, 2025. *See* No. 24-3337, Minute Order of December 30, 2024 (BMS); No. 24-3220, Minute Order of January 2, 2025 (Lilly); No. 24-3496, Minute Order of January 6, 2025 (Sanofi); No. 25-117, Minute Order of January 27, 2025 (Novartis). Lilly, BMS, and Novartis filed their summary-judgment motions on February 3, 2025, No. 24-3220, ECF No. 15 (Lilly); No. 24-3337, ECF No. 17 (BMS); No. 25-117, ECF No. 12 (Novartis), while Sanofi will file its summary-judgment motion on February 20, 2025. *See* No. 24-3496, Minute Order of January 6, 2025 (Sanofi). Two days after Lilly, BMS, and Novartis filed their summary-judgment motions, Proposed Intervenors—a 340B hospital association and two 340B hospitals—moved to intervene as defendants. No. 24-3220, ECF No. 18 (Lilly); No. 24-3337, ECF No. 20 (BMS); No. 25-117, ECF No. 15 (Novartis).

BMS also moved to expedite consideration of the case, on which Defendants took no position, explaining that deadlines arising from BMS's obligations under the Drug Price Negotiation Program established by the Inflation Reduction Act (IRA), Pub. L. No. 117-169, 136 Stat. 1818 (2022)—namely, the IRA's requirement that BMS submit its plan for effectuating the "maximum fair price" by September 1, 2025—weigh in favor of resolving this case by May 1, 2025. No. 24-3337, ECF No. 12.

ARGUMENT

I. PROPOSED INTERVENORS LACK ARTICLE III STANDING.

To intervene under Rule 24, a prospective intervenor must establish standing under Article III by demonstrating, among other things, an injury-in-fact. *Fund For Animals, Inc. v. Norton*, 322 F.3d 728, 732–733 (D.C. Cir. 2003) (citing *Lujan v. Defenders of Wildlife*, 504 U.S. 555, 560–561

(1992)); *see Yocha Dehe v. U.S. Dep't of Interior*, 3 F.4th 427, 430 (D.C. Cir. 2021). And when a party seeks to intervene as a defendant to support government action, it must demonstrate that it would be injured if the government action were set aside. *Fund for Animals*, 322 F.3d at 731–732. Proposed Intervenors do not meet these standards.

A. No Proposed Intervenor Has Article III Standing.

Proposed Intervenors must establish an injury-in-fact that is "concrete and particularized" and "actual or imminent, not conjectural or hypothetical." *Lujan*, 504 U.S. at 560 (internal quotation marks and citations omitted). "For prospective injuries, imminence means that the injury must be 'certainly impending.' " *Ctr. for Biological Diversity v. U.S. Fish & Wildlife Serv.*, 340 F.R.D. 1, 4 (D.D.C. 2021) (quoting *Lujan*, 504 U.S. at 564 n.2). This is a showing the would-be intervenors do not and cannot make.

Proposed Intervenors stake their claimed injury primarily on speculation that Manufacturer-Plaintiffs will use their models to improperly withhold payments on 340B-eligible purchases, insisting that Manufacturer-Plaintiffs are "likely" to "deny legitimate claims," increasing their cost of purchasing medicines. Mot. at 3, 5–7, 12. Proposed Intervenors' conjecture that Manufacturer-Plaintiffs will improperly deny rebates on 340B-eligible purchases cannot establish standing. The 340B statute contains numerous safeguards to ensure 340B hospitals receive a bona fide offer, and provides a remedy if they don't. No manufacturer would risk not only administrative dispute resolution (ADR) claims by covered entities like Proposed Intervenors, but also potentially severe civil monetary penalties, *see* 42 U.S.C. § 256b(d)(1)(B)(vi), by intentionally denying valid rebate claims. Proposed Intervenors give no reason for this Court to believe that Manufacturer-Plaintiffs' models will result in covered entities receiving fewer payments than they are entitled to under the 340B statute; throughout the administrative record, Manufacturer-Plaintiffs explain that all valid 340B claims will be paid under their models. *See*, *e.g.*, AR 272–273, 296, 299, 317–318, 329–330,

338–339, 435. What's more, under the prevailing product-replenishment model, covered entities rarely learn that medicine is 340B-eligible until months after purchasing it at the wholesale price—well after the short turnaround period that Manufacturer-Plaintiffs' models are contemplating—further undercutting Proposed Intervenors' claim that they will be harmed by models. *E.g.*, No. 24-3337, ECF No. 17 ("Under the product-replenishment model, . . . within 14 days, a covered entity often will not even have purported to identify a claim as 340B-eligible for its own purposes."). Proposed Intervenors' declarations do not provide specific facts disputing that compliance will increase; they simply profess to be "extremely concerned" that Manufacturer-Plaintiffs will not comply with their 340B Program obligations. *E.g.*, Desai Decl. ¶ 20. But Proposed Intervenors' "concern" that Manufacturer-Plaintiffs will not comply is not *proof* that Manufacturer-Plaintiffs will not comply. And indeed, the declarations provide no evidence—or even any credible concern—that Manufacturer-Plaintiffs will not live up to their commitment to promptly pay all submitted rebate claims.

Bare assertions predicated on ungrounded fears of potential future noncompliance do not satisfy Article III standing: Proposed Intervenors' "alleged injury is prospective," depends on a chain with several speculative links, and "is not 'certainly impending,'" and therefore cannot support intervention. *Ctr. for Biological Diversity*, 340 F.R.D. at 4 (citing *Clapper v. Amnesty Int'l USA*, 568 U.S. 398, 409 (2013)); *see Arpaio v. Obama*, 797 F.3d 11, 21 (D.C. Cir. 2015); *United Transp. Union v. ICC*, 891 F.2d 908, 912 (D.C. Cir. 1989) (explaining that parties making "allegations of future injuries" must "*credibly* allege that [they] face[] a *realistic* threat from the future" noncompliance (citation omitted)). To the extent, then, that Proposed Intervenors' revenue will decline in the face of Manufacturer-Plaintiffs' models, it is because Proposed Intervenors are engaged in the sort of waste and abuse that the models are designed to reduce. But Proposed Intervenors wisely do not contend that not receiving rebates they have no legal right to is an injury

in fact, just as AIDS Drug Assistance Programs have never alleged injury from manufacturers using rebate models in dealing with them. *See* AR 12 (Notice Regarding Section 602 of the Veterans Health Care Act of 1992—Rebate Option, 63 Fed. Reg. 35239, 35240 (June 29, 1998)).

Proposed Intervenors also assert that they would need to hire additional employees to collect and submit claims data to participate in Manufacturer-Plaintiffs' models. Mot. at 6–8, 12–13. But as the administrative record demonstrates, the models require only commercially standard claims data that covered entities already maintain and submit to payors in the ordinary course of their business. *See, e.g.*, AR 56, 61, 76–77, 178, 182–185, 410. Moreover, most covered entities use third-party administrators or dedicated employees to administer the product-replenishment program. The declarations do not say whether Proposed Intervenors administer the product-replenishment model in-house or through third-party administrators, and, if they administer it in-house, fail to explain why those same employees could not fulfill the straightforward administrative duties required by the cash-rebate model—thereby obviating any need to "hire and train new fulltime employees" to handle these tasks. Carr Decl. ¶ 17; *see* Desai Decl. ¶ 17. Again, Proposed Intervenors' concerns about staffing strains are attenuated and do not approach the "certainly impending" injury necessary to demonstrate standing and an intervention-worthy interest. *Ctr. for Biological Diversity*, 340 F.R.D. at 4 (quoting *Clapper*, 568 U.S. at 409) (denying intervention).

Proposed Intervenors also cannot establish standing based on their claimed harms resulting from Manufacturer-Plaintiffs' means of ensuring compliance with the 340B statute's anti-duplication protection, 42 U.S.C. § 256b(d)(3)(A), or the Drug Price Negotiation Program's nonduplication guarantee, 42 U.S.C. § 1320f-2(d). The Proposed Intervenors have not alleged any injury caused by Manufacturer-Plaintiffs' efforts to fulfill these statutory objectives and therefore lack standing for this reason as well. *City of Scottsdale v. Fed. Aviation Admin.*, 37 F.4th 678, 679 (D.C. Cir. 2022) (finding no standing where party "has not identified evidence showing that it has

suffered that harm"). Even if Proposed Inventors could point to some cost they incur in submitting information necessary to avoid duplicate price concessions, the nonduplication requirements come from Congress, and the Proposed Intervenors cannot trace any injury to manufacturers' actions implementing those congressional commands. *See Louie v. Dickson*, 964 F.3d 50, 55 (D.C. Cir. 2020) ("Because petitioners' injuries are not fairly traceable to that action, petitioners lack standing to challenge it.").

In addition, as this Court has recognized, in order "[t]o be protected by means of intervention, [an] interest must be a legal interest as distinguished from interests of a general and indefinite character." *Biden v. IRS*, No. 23-2711, 2024 WL 4332072, at *10 (D.D.C. Sept. 27, 2024) (quoting *United States v. Am. Tel. & Tel. Co.*, 642 F.2d 1285, 1292 (D.C. Cir. 1980)) (denying intervention). Even if this Court found that Proposed Intervenors' speculative harms are sufficiently concrete—and they are not—Proposed Intervenors' purported interest in opposing Manufacturer-Plaintiffs' cash-rebate models is shared in common with thousands of covered entities across the country. Granting intervention could therefore risk opening the floodgates to participation by countless other similarly situated entities with the same generalized interest. *See* Tr. of Oral Argument at 36–37, *AstraZeneca Pharms. LP v. Cochran*, No. 21-27 (D. Del. Apr. 26, 2021), ECF No. 51 (denying intervention in part because granting the motion would mean that "every covered entity would also have a right [under Rule 24] to intervene," which "could easily . . . lead to this case getting out of control and falling behind the expedited schedule that has been worked out between the parties"). This Court should not permit intervention based on the speculative and generalized interests that Proposed Intervenors have asserted.

B. 340B Health Lacks Associational Standing

An association has standing to sue on behalf of its members only if "its members would otherwise have standing to sue in their own right," *Friends of the Earth, Inc. v. Laidlaw Env't Servs.*

Inc., 528 U.S. 167, 181 (2000), a test that governs associations who seek to participate as intervenor-plaintiffs and intervenor-defendants alike. *Defenders of Wildlife v. Perciasepe*, 714 F.3d 1317, 1323 (D.C. Cir. 2013) (applying associational standing analysis to organization that sought to intervene as a party defendant); *Cigar Ass'n of Am. v. FDA*, 323 F.R.D. 54, 64 (D.D.C. 2017) (same). To establish associational standing, an association must name at least one member with standing. *Hunt v. Washington State Apple Advertising Comm'n*, 432 U.S. 333, 343 (1977). But the two members that 340B Health identifies—UMass and Genesis—do not have standing because they have not suffered a certainly impending injury in fact. *Supra* pp. 3–6. 340B Health therefore does not have associational standing.

II. PROPOSED INTERVENORS ARE NOT ENTITLED TO INTERVENE AS OF RIGHT.

Standing aside, Proposed Intervenors cannot intervene as of right. To qualify for intervention as of right, Proposed Intervenors must (1) timely file their motion, (2) possess "an interest relating to the property or transaction which is the subject of the action," (3) be "so situated that the disposition of the action may as a practical matter impair or impede [their] ability to protect that interest," and (4) demonstrate their interest is not "adequately represented by existing parties." *Fund For Animals*, 322 F.3d at 731 (quoting *Mova Pharm. Corp. v. Shalala*, 140 F.3d 1060, 1074 (D.C.Cir.1998)). Proposed Intervenors flunk each factor.

A. The Motion Is Untimely.

Proposed Intervenors' motion to intervene should be denied because it is untimely and intervention would prejudice Manufacturer-Plaintiffs. *See* Fed. R. Civ. P. 24(a), (b)(1) (allowing intervention only by "timely motion"). To determine whether the motion was timely, courts consider "all the circumstances, especially weighing the factors of time elapsed since the inception of the suit, the purpose for which intervention is sought, the need for intervention as a means of preserving the applicant's rights, and the probability of prejudice to those already parties in the

case." *Campaign Legal Ctr. v. FEC*, 68 F.4th 607, 610 (D.C. Cir. 2023) (quoting *Karsner v. Lothian*, 532 F.3d 876, 886 (D.C. Cir. 2008)). "[T]he requirement of timeliness is aimed primarily at preventing potential intervenors from unduly disrupting litigation, to the unfair detriment of the existing parties." *Roane v. Leonhart*, 741 F.3d 147, 151 (D.C. Cir. 2014).

Lilly filed its complaint on November 14, 2024, and BMS followed two weeks later. More than two months passed while Proposed Intervenors sat on their hands. They waited until after the Court set summary-judgment briefing schedules in Manufacturer-Plaintiffs' cases, *see* No. 24-3337, Minute Order of December 30, 2024 (BMS); No. 24-3220, Minute Order of January 2, 2025 (Lilly); No. 24-3496, Minute Order of January 6, 2025 (Sanofi); No. 25-117, Minute Order of January 27, 2025 (Novartis), to seek intervention on February 5. *See* No. 24-3220, ECF No. 18 (Lilly); No. 24-3337, ECF No. 20 (BMS); No. 25-117, ECF No. 15 (Novartis).

This Court has made clear that the clock starts running against intervention once "the proposed intervenor knew or should have known that an action could affect [their] interests." *Rubin v. Islamic Republic of Iran*, 270 F.R.D. 7, 11 (D.D.C. 2010) (citing *Catanzano v. Wing*, 103 F.3d 223, 232 (2d Cir. 1996)). Here, timeliness must be measured from the first part of November. Proposed Intervenors were unquestionably following manufacturers' models closely. In August 2024, 340B Health wrote to HRSA to complain about the "administrative burdens and financial harms" of proposed rebate models. *See* AR 565–569, 632–633. Manufacturer-Plaintiffs' filings were no secret; Proposed Intervenors were on notice as soon as Manufacturer-Plaintiffs' filed suit. *See, e.g.*, *Lilly Statement on New 340B Litigation*, Lilly Investors (Nov. 14, 2024), https://investor.lilly.com/news-releases/news-release-details/lilly-statement-new-340b-litigation. Yet Proposed Intervenors nevertheless chose to lie in wait with these cases until after schedules were set and all Manufacturer-Plaintiffs but Sanofi had already filed summary-judgment motions. This Court should not reward Proposed Intervenors' dilatory tactics, which would prejudice

Manufacturer-Plaintiffs by virtue of any delay caused by their late-stage arguments—which include arguments not advanced by HRSA itself, *see infra* p. 12—injected into a case that is on an expedited schedule. Thus, because Proposed Intervenors "had more than sufficient time to" get involved in this litigation earlier, *In re Lorazepam & Clorazepate Antitrust Litig.*, 205 F.R.D. 363, 368 (D.D.C. 2001), and permitting their intervention would prejudice Manufacturer-Plaintiffs, *see Roane*, 741 F.3d at 151, Proposed Intervenors' motion is untimely.

B. Proposed Intervenors Have Not Demonstrated A Legally Protected Interest.

Even if Proposed Intervenors' motion were timely, intervention should still be denied because Proposed Intervenors lack "a legally protected interest in the action." *Karsner*, 532 F.3d at 885; *see Old Dominion Elec. Coop. v. FERC*, 892 F.3d 1223, 1233 (D.C. Cir. 2018).

Astra USA, Inc. v. Santa Clara County bars covered entities from litigating their preferred interpretation of the 340B statute in federal court opposite manufacturers. 563 U.S. 110, 114 (2011). In *Astra*, the unanimous Supreme Court recognized that "Congress vested authority to oversee compliance with the 340B Program in HHS and assigned no auxiliary enforcement role to covered entities." *Id.* at 118.

The Court explained that Congress did not authorize "suits by 340B entities" or intend to "spread the enforcement burden" for the program to nongovernment parties. *Id.* at 119–120. Congress instead "directed HRSA to create a formal dispute resolution procedure, institute refund and civil penalty systems, and perform audits of manufacturers." *Id.* at 121. The statute's ADR process is thus the only "proper remedy for covered entities complaining of 'overcharges and other violations'" of the 340B statute. *Id.* at 122 (quoting 42 U.S.C. § 256b(d)(1)(A)). Suits by covered entities that seek to enforce 340B requirements "are incompatible with the statutory regime." *Id.* at 113.

Astra precludes intervention by Proposed Intervenors here. Their only concern is that Manufacturer-Plaintiffs' models will result in overcharges—either because 340B hospitals must pay market price for medicines initially, or speculative administrative costs effectively raise the price above the 340B price. AR 568. But any challenge to the overcharges about which Proposed Intervenors are "concerned," including claims allegedly arising from the cash-rebate model, must be "first adjudicated by HHS" through the ADR process—*if* such overcharges occur. *Am. Hosp. Ass'n v. HHS*, No. 4:20-cv-08806, 2021 WL 616323, at *6 (N.D. Cal. Feb. 17, 2021). If covered entities attempted to sue Manufacturer-Plaintiffs directly, asserting the cash-rebate model is impermissible because it causes them monetary harm, *Astra* would require dismissal. In the same way, intervening to defend HRSA and assert as a legally protectable interest concerns about possible future overcharges is little more than a "creative recasting" of the same case that Proposed Intervenors could not bring against Manufacturer-Plaintiffs as plaintiffs. *Id.* at *5.

"*Astra* forbids[ ] the *private* enforcement of 340B program requirements" in all forms, including any action in which the covered entities' positions and remedies sought "are entirely premised on the enforcement of the 340B Program requirements against . . . allegedly non-complying drug companies." *Id.* For that reason, covered entities may not litigate against manufacturers to enforce the 340B statute, "[n]o matter the clothing in which [they] dress their claims." 563 U.S. at 114 (quoting *Tenet v. Doe*, 544 U.S. 1, 8 (2005)). That ends the second-element analysis.

C. Disposition Of This Action Will Not Impair Proposed Intervenors' Ability To Protect Their Claimed Interests.

Separately, Proposed Intervenors are unable to demonstrate that "disposing" of this case in their absence would "impair or impede [their] ability to protect [their purported] interest." *Yocha Dehe*, 3 F.4th at 430 (quoting Fed. R. Civ. P. 24(a)(2)).

As discussed above, Proposed Intervenors' characterization of the financial harm they potentially face is overblown and unsupported by the administrative record. *Supra* pp. 3-6. And again, the ADR process remains available to covered entities in the unlikely event any overcharges ever occur. *See Am. Hosp. Ass'n*, 2021 WL 616323, at *6; 42 U.S.C. § 256b(d). More importantly, Proposed Intervenors *assert no valid, protectable interest*: They cannot reasonably complain about the alleged costs of transitioning to Manufacturer-Plaintiffs' models, which are expressly contemplated by the 340B statute, when their product-replenishment model was itself never preapproved and covered entities must incur the costs of preventing duplication and diversion to remain eligible as covered entities. *See* 42 U.S.C. § 256b(a)(5) (detailing compliance requirements that covered entities must abide by in order to retain Program eligibility). Any expectation that the unapproved, unilaterally imposed product-replenishment model—which has precipitated pervasive abuse in the 340B Program, *see*, *e.g.*, BMS Compl. ¶ 4—would indefinitely remain intact was unreasonable from the outset. Thus, Proposed Intervenors cannot now claim impairment from having to transition to a compliant model. Proposed Intervenors' self-inflicted harm—in the form of unreasonable reliance on an unsanctioned, problematic model—cannot justify intervention.

D. Proposed Intervenors Have Not Demonstrated Inadequate Representation.

Finally, Proposed Intervenors have not shown that the Government is not adequately representing their interests in its defense of HRSA's decisions rejecting Manufacturer-Plaintiffs' proposed cash-rebate models. "An applicant does not possess a right to intervene . . . if its 'interest is adequately represented by existing parties." *In re Sealed Case*, 237 F.3d 657, 663 (D.C. Cir. 2001) (quoting Fed. R. Civ. P. 24(a)). And "[a] would-be intervenor is adequately represented when [it] 'offer[s] no argument not also pressed by' an existing party." *United States v. All Assets Held at Credit Suisse (Guernsey) Ltd.*, 45 F.4th 426, 432 (D.C. Cir. 2022) (quoting *Bldg. & Constr. Trades Dep't v. Reich*, 40 F.3d 1275, 1282 (D.C. Cir. 1994)).

To support their inadequate-representation argument, Proposed Intervenors offer three flawed contentions. First, Proposed Intervenors seek to advance a novel argument not raised by HRSA in the administrative record: Manufacturer-Plaintiffs' "proposed rebate model[s] [are] unlawful *per se*, and [ ] HRSA would have no authority to approve any rebate model." Mot. at 19. But because that rationale is nowhere to be found in the administrative record, it cannot be deployed as a post hoc rationalization for HRSA's rejection of Manufacturer-Plaintiffs' cash-rebate models. *See Bhd. of Locomotive Eng'rs & Trainmen v. Fed. R.R. Admin.*, 972 F.3d 83, 117 (D.C. Cir. 2020) (citing *Dep't of Homeland Sec. v. Regents of the Univ. of Cal.*, 591 U.S. 1, 20–24 (2020)) (parties cannot rely on arguments not presented by agency below); *Illinois Bell Tel. Co. v. FCC*, 911 F.2d 776, 786 (D.C. Cir. 1990) (intervenor cannot raise matters not presented by the parties). In other words, Proposed Intervenors press factual and legal arguments this Court cannot consider: Review here is limited to the record as the agency marshaled it, *Camp v. Pitts*, 411 U.S. 138, 142 (1973), and is confined to the agency's rationale as HRSA articulated it, *SEC v. Chenery*, 332 U.S. 194, 196 (1947). So, while Proposed Intervenors advance points not already raised by the Government in an attempt to justify intervention, those arguments are out of bounds, as Proposed Intervenors *cannot* press justifications for HRSA action that HRSA did not assert for itself.

Second, Proposed Intervenors argue that the Government's representation is inadequate because Proposed Intervenors are the "only entities that can adequately describe the impact that [Manufacturer-Plaintiffs'] proposed rebate model[s] will have on 340B hospitals and the patients they serve." Mot. at 19. But the purported practical impact of Manufacturer-Plaintiffs' models on covered entities' "financial interests," Mot. at 18, does not bear on whether HRSA has the statutory authority to reject Manufacturer-Plaintiffs' proposed models. Proposed Intervenors' ancillary concerns belong at most in an amicus brief. *See District of Columbia v. Potomac Elec. Power Co.*, 826 F. Supp. 2d 227, 234 (D.D.C. 2011) ("Since the Court will grant the proposed intervenors leave

to participate as amici curiae, . . . the Court will have the opportunity to consider all of the proposed intervenors' objections . . . ."). Regardless, the administrative record reflects that the government *is* adequately representing Proposed Intervenors' interests on this issue: HRSA is aware of contentions that covered entities will shoulder new administrative costs under rebate models and has discussed those concerns with hospital groups. *See* AR 66–68, 75–76, 292–293, 342–343, 380–382, 439–440, 573, 583–584, 586, 644. Indeed, HRSA has expressly solicited input from covered entities that the agency could use to oppose Manufacturer-Plaintiffs' cash-rebate models. *See* AR 586 (internal HRSA correspondence revealing that HRSA expressed "it would be helpful if [covered entities] could gather some more specific information from [their] members about how changes to 340B policies would affect [their] members").

Third, Proposed Intervenors speculate that the new administration will not "defend the instant suit nor maintain the position that [Manufacturer-Plaintiffs'] proposed rebate model[s] violate[ ] the 340B statute." Mot. at 18. But a putative intervenor "must produce something more than speculation as to the purported inadequacy" to satisfy this factor. *Aref v. Holder*, 774 F. Supp. 2d 147, 172 (D.D.C. 2011) (quoting *Moosehead Sanitary Dist. v. S.G. Phillips Corp.*, 610 F.2d 49, 54 (1st Cir. 1979)). And courts have made clear that "the mere change from one . . . administration to another, a recurrent event in our system of government, should not give rise to intervention as of right in ongoing lawsuits." *League of United Latin Am. Citizens*, 131 F.3d 1297, 1307 (9th Cir. 1997) (citation omitted). If this Court were to find that "speculation about the effects of a change of administration were sufficient to meet [Proposed Intervenors'] burden of demonstrating inadequate representation, then proposed intervenors could *always* satisfy the third prong of Rule 24(a)(2) if the defendant were a [ ] government entity." *Id.* (citation omitted).

Proposed Intervenors admit that "there has been no suggestion yet that the new administration will take a different position on this matter" than the previous administration. Mot.

at 18; *see also id.* at 11 n.4 (suggesting intervention is necessary because of "uncertainty regarding the legal positions that the Government Defendants *may* take as the litigation proceeds" (emphasis added)). Without any evidence that the new administration will abandon HRSA's prior decisions on Manufacturer-Plaintiffs' cash-rebate models, Proposed Intervenors cannot show that the Government does not adequately represent their interests. Speculation over a future change in position aside, Proposed Intervenors still fail to make the required showing of inadequate representation for the reasons already explained. Intervention as of right should be denied.

III. PERMISSIVE INTERVENTION IS UNWARRANTED.

Proposed Intervenors also do not meet the requirements for permissive intervention, as they have neither (1) an independent ground for subject-matter jurisdiction, (2) a conditional right to intervene under a federal statute, nor (3) a claim or defense that shares "a common issue of law or fact" with the main action. Fed. R. Civ. P. 24(b)(1); *EEOC v. Nat'l Child.'s Ctr., Inc.*, 146 F.3d 1042, 1046 (D.C. Cir. 1998).

The would-be intervenors lack standing for the reasons described above. They also do not claim they enjoy a conditional statutory right to intervene in this case under a federal statute. To the contrary, the 340B statute makes ADR the *exclusive* means for redressing Proposed Intervenors' concerns. *See Am. Hosp. Ass'n*, 2021 WL 616323, at *6; 42 U.S.C. § 256b(d). And Proposed Intervenors do not explain the claim or defense they will present that shares "a common issue of law or fact" with the main action, much less how such a claim or defense would overcome *Astra*. Fed. R. Civ. P. 24(b)(1).

Ultimately, however, because "permissive intervention is an inherently discretionary enterprise," *EEOC*, 146 F.3d at 1046, this Court retains the discretion to deny a request to intervene permissively, even if the proposed intervenor satisfies the traditional criteria. *Id.* at 1048. "The Rule 24(b) requirements are the floor where the Court's discretion begins, not the ceiling where it

ends." *United Mexican States v. Lion Mex. Consol., L.P.*, __ F. Supp. 3d ___, 2024 WL 4753800, at *13 (D.D.C. Nov. 8, 2024). This Court should therefore exercise its discretion here to deny intervention.

Proposed Intervenors' motion is untimely, particularly set against the backdrop of this case. Nothing prevented Proposed Intervenors from moving to intervene promptly upon learning of these cases more than three months ago. The delay is all the more vexing here, when it was clear by late December that the parties had agreed—and this Court had adopted—an expedited summary-judgment briefing schedule that would ensure the cases are fully briefed by the end of March. *See, e.g.*, No. 24-3337, Minute Order of December 30, 2024 (ordering briefing schedule in BMS case).

There are practical considerations that cut against intervention, too. If this Court finds that Proposed Intervenors may participate, other covered entities—particularly those who the record reveals complained to HRSA about Manufacturer-Plaintiffs' models—may not be content to remain on the sidelines. The ensuing storm of covered-entity intervenors would be unwieldy and unworkable, and would undermine Manufacturer-Plaintiffs' right to be heard in a timely fashion. *See Ctr. for Food Safety v. EPA*, No. 23-cv-1633, 2024 WL 1299338, at *10 (D.D.C. Mar. 26, 2024) (denying permissive intervention where it would "result in an inefficient use of judicial resources" all "while not significantly contributing to the just and equitable adjudication of the legal question presented").

Ultimately, Proposed Intervenors can have their voices heard short of intervention. The Court has permitted amicus participation in these cases, and Manufacturer-Plaintiffs consent to any brief Proposed Intervenors may wish to file being considered as an *amicus curiae* brief if it complies with this Court's Rule 7(o).

CONCLUSION

For the foregoing reasons, Proposed Intervenors' motion to intervene should be denied.

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Respectfully submitted,

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