IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF COLUMBIA

ABBVIE INC., *Plaintiff*, v. ROBERT F. KENNEDY JR., et al., *Defendants*,	Civil Action No. 26-cv-1190

PLAINTIFF ABBVIE INC.'S MEMORANDUM OF LAW IN OPPOSITION TO NATIONAL ASSOCIATION OF COMMUNITY HEALTH CENTERS, INC. AND RYAN WHITE CLINICS FOR 340B ACCESS'S MOTION TO INTERVENE

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INTRODUCTION

This case presents a straightforward question of statutory interpretation under the 340B drug pricing program. It involves a dispute between Plaintiff AbbVie Inc. and the federal agency that administers the program about the meaning of the 340B statute. The agency interpreted the relevant provision by issuing guidance in 1996; maintained that interpretation for three decades; and applied that interpretation to reject administrative requests by AbbVie. Other entities now seek to intervene—not to argue for a *different* interpretation of the statute, but to support the agency in advocating for the *same* one. They have no role to play here.

AbbVie exercised its statutory right under Section 340B to audit two covered entities that it had reason to believe were diverting drugs acquired at 340B-discounted prices "to a person who is not a patient of the entity." 42 U.S.C. § 256b(a)(5)(B). The Health Resources and Services Administration ("HRSA"), the sub-agency of the Department of Health and Human Services ("HHS") that administers the program, refused to enforce any audit findings—based on a definition of "patient" as interpreted under the agency's 1996 Guidelines. But that interpretation is inconsistent with the statute's text, and AbbVie brought suit against HHS, HRSA, and its officials (collectively, "Defendants") to challenge the agency's decision under the Administrative Procedure Act.

The National Association of Community Health Centers, Inc. and Ryan White Clinics for 340B Access (collectively, "Proposed Intervenors") are organizations of 340B-participating covered entities. Proposed Intervenors seek to interject themselves into this lawsuit nearly three months after it was filed, and nearly three weeks after the deadlines for answering AbbVie's Complaint. In doing so, they ignore the Federal Rules of Civil Procedure and this Court's Local Rules, both of which require that a motion to intervene "be accompanied by a pleading that sets out the claim or defense for which intervention is sought." Fed. R. Civ. P. 24(c); *see* LCvR 7(j) (similar). Instead, Proposed Intervenors adopt the extraordinary—and apparently unprecedented—position

that they should be able to join Defendants' already-pending motion to dismiss and to file a reply brief in support of that motion.

The motion to intervene should be denied. The Federal Rules of Civil Procedure impose meaningful limits on intervention, whether sought as of right or by permission. Those limits exist to ensure that litigation remains manageable; that existing parties are not prejudiced by belated efforts to join a case; and that intervention is reserved for those circumstances in which a non-party's legally protected interests merit party status.

Proposed Intervenors cannot satisfy any of those requirements. Their motion is untimely, and they offer no explanation for why they waited nearly three months to seek intervention. They identify no legally cognizable interest at stake in the pending motion to dismiss, which implicates none of their asserted concerns about AbbVie's proposed interpretation of the 340B statute. They also advance no claims, defenses, or arguments distinct from those already raised by Defendants—who are defending the very interpretation that Proposed Intervenors themselves endorse. And they have failed to demonstrate that Defendants cannot adequately represent their interests, offering only baseless speculation that Defendants *might* abandon the agency's longstanding position—even though HRSA repeatedly reaffirmed and relied on that position when it denied AbbVie's audit requests.

At most, Proposed Intervenors claim to offer an additional perspective on the practical consequences of the statutory-interpretation question presented here. That type of contribution is appropriately presented through an amicus brief—not party status. If Proposed Intervenors wish to weigh in on the dispute between AbbVie and HRSA, they can file a motion for leave to file an amicus brief, as another group of covered entities has already done. AbbVie would consent to timely motions for such participation, just as it has consented to amicus participation by other covered entity groups.

BACKGROUND

A. Enacted in 1992, Section 340B of the Public Health Service Act established a federal program that "imposes ceilings on prices drug manufacturers may charge for medications sold [under the Program] to specified health-care facilities," known as covered entities, that provide healthcare to certain underserved populations. *Astra USA, Inc. v. Santa Clara Cnty.*, 563 U.S. 110, 113 (2011). Congress gave manufacturers significant incentives to participate in the 340B program by requiring participation as a condition of receiving reimbursement under Medicaid and Medicare Part B. *See* 42 U.S.C. § 256b(a)(1). But Congress also recognized that manufacturers would nevertheless opt out of the program if the costs of participation were too high. *See* Br. of United States as Amicus Curiae at 23-25, *AbbVie v. Weiser*, No. 25-1439 (10th Cir. Feb. 25, 2026), Dkt. No. 30. Congress accordingly designed the program carefully for the benefit of needy patients, reaching only the healthcare entities that predominantly serve such patients. Congress has identified with particularity fifteen types of covered entities that are eligible to be offered discounted drugs under the 340B program. *See* 42 U.S.C. § 256b(a)(4)(A)-(O).

Congress also included additional safeguards to prevent the program from exceeding permissible bounds. As most relevant here, Section 340B specifies that "a covered entity shall not resell or otherwise transfer [a 340B] drug to a person who is not a *patient* of the entity." *Id.* § 256b(a)(5)(B) (emphasis added). The statute thus prohibits a covered entity, among other things, from selling drugs acquired at federally discounted prices to any individual who receives the drugs for a reason unrelated to the care he or she received from the covered entity. Providing drugs acquired at the federally discounted 340B price to "a person who is not a patient of the entity" is commonly known as "diversion." Engaging in diversion "knowingly and intentionally" is grounds for the imposition of civil monetary penalties by the Secretary of HHS, who administers the program. *Id.* § 256b(d)(2)(B)(v)(I). The 340B statute also provides that covered entities may not

obtain 340B pricing on units of drugs for which a manufacturer also pays a Medicaid rebate. *Id.* § 256b(a)(5)(A). This forbidden practice, commonly known as "duplicate discounting," would result in manufacturers taking a loss on the distribution of their products (taking into account both the 340B discount and the Medicaid rebate).

Congress further conferred on manufacturers a statutory right to audit covered entities to assess whether diversion or duplicate discounting has occurred. *Id.* § 256b(a)(5)(C)-(D); *see AbbVie Inc. v. Drummond*, 808 F. Supp. 3d 1266, 1272 (W.D. Okla. 2025) (describing the audit provision as Congress's "respon[se]" to the "lack of transparency in the process by which" covered entities and their third-party administrators were submitting 340B claims). Congress authorized participating manufacturers, as well as the Secretary, to audit covered entities regarding their compliance with program integrity requirements:

> A covered entity *shall permit* the Secretary and *the manufacturer* of a covered outpatient drug that is subject to an agreement under this subsection with the entity (acting in accordance with procedures established by the Secretary relating to the number, duration, and scope of audits) to audit at the Secretary's or the manufacturer's expense the records of the entity that directly pertain to the entity's compliance with the requirements described in subparagraphs (A) or (B) with respect to drugs of the manufacturer.

42 U.S.C. § 256b(a)(5)(C) (emphases added).

The audit provision grants drug manufacturers an absolute right to conduct such audits, subject only to procedures related to "the number, duration, and scope of audits." *Id.* Congress did not place any other conditions on a manufacturer's right to audit a covered entity, which occurs "at the . . . manufacturer's expense." *Id.* And Congress did not provide manufacturers with a means by which to enforce audit findings. Instead, the Secretary must take action to remedy findings of misconduct or abuse. The statute provides that, "*[i]f the Secretary finds, after [an] audit*," that a covered entity has engaged in diversion or duplicate discounts, "the covered entity shall be liable

to the manufacturer of the covered outpatient drug that is the subject of the violation in an amount equal to the reduction in the price of the drug." *Id.* § 256b(a)(5)(D) (emphasis added).

Congress also required the Secretary to establish an adjudicatory body to resolve disputes among participants in the 340B program, including "claims by covered entities that they have been overcharged for drugs purchased under . . . section [340B], and claims by manufacturers . . . of violations" by covered entities. 42 U.S.C. § 256b(d)(3)(A). This process is known as the 340B administrative dispute resolution, or ADR, process. The Secretary has delegated his oversight over the 340B program—including the conduct of audits and ADR proceedings—to HRSA.

B. This dispute arises over HRSA's effective denial of AbbVie's requests to audit two covered entities, Barrio and Mount Sinai, neither of which is claimed to be a member of Proposed Intervenors. That denial was based on disagreement over the proper meaning of the term "patient" as used in the diversion prohibition. AbbVie wrote HRSA with reasonable cause to believe that Barrio and Mount Sinai were engaging in diversion, and it requested to audit both covered entities against a definition of the term "patient" that reflected the best reading of that term as Congress used it. Compl. ¶¶ 139-40; 163-65. HRSA informed AbbVie that the patient definition in its work-plan went beyond the interpretation HRSA set forth in its non-binding 1996 Guidelines, *see* 61 Fed. Reg. 55,156, 55,156-58 (Oct. 24, 1996), which, in the agency's view, "[is] the currently operative standard for determining whether an individual is a 340B patient," Compl. ¶ 142. HRSA further informed AbbVie that the agency would not "enforce corrective actions for any findings resulting from AbbVie's application of a patient definition that exceeds the 1996 Guidelines." Compl. ¶¶ 142, 170. HRSA stood by this position during several further rounds of correspondence. Compl. ¶¶ 145, 170, 172.

AbbVie filed the instant action against Defendants on April 8, 2026, raising the purely legal question of whether HRSA's adherence to the 1996 Guidelines' interpretation of the term

"patient"—and its effective denial of AbbVie's audit requests on that basis—is in accordance with law. ECF No. 1. The suit was not a secret: AbbVie issued a press release on the day of filing,[1] and the case received extensive media coverage.[2] The United States Attorney for the District of Columbia was served on April 13, and all Defendants were due to answer on June 12. ECF No. 9. After seeking and receiving a four-day extension of time, *see* ECF No. 12, Defendants moved to dismiss the Complaint on June 16, *see* ECF No. 13. AbbVie's opposition is due on July 28. Order (June 22, 2026).

On June 23, 2026, another group of covered entities—an association of 340B hospitals and two individual 340B hospitals—filed a proposed motion to intervene. ECF No. 19. Because these proposed intervenors stated they did not intend to address the grounds in Defendants' motion to dismiss and only intended to speak to the merits of this case once raised by either party, AbbVie requested, and this Court granted, an extension of time to respond to their proposed motion to intervene, which is now due August 4. Order (June 30, 2026).

On July 6, 2026—89 days after AbbVie filed its suit, and 20 days after the (extended) deadline for all defendants to answer or otherwise respond to the Complaint—Proposed Intervenors filed their motion to intervene. The National Association of Community Health Centers, Inc. is a "membership organization representing [Community Health Centers]," a type of covered entity. Mot. 10. Ryan White Clinics for 340B Access is a "national association of

[1] Press Release, AbbVie, *AbbVie moves to close loopholes and strengthen accountability in 340B program*, (Apr. 8, 2026), https://news.abbvie.com/2026-04-08-AbbVie-moves-to-close-loopholes-and-strengthen-accountability-in-340B-program.

[2] *See, e.g.*, Reuters, *AbbVie files lawsuit to address 'outdated' drug discount eligibility program* (Apr. 8, 2026), https://www.reuters.com/legal/litigation/abbvie-files-lawsuit-address-outdated-drug-discount-eligibility-program-2026-04-08/..

HIV/AIDS health care clinics and service providers." *Id.* at 11. Neither association claims Barrio or Mount Sinai as a member.

LEGAL STANDARD

Federal Rule of Civil Procedure 24 provides for two methods of intervention: intervention as of right and permissive intervention. Fed. R. Civ. P. 24(a), (b). "[A] district court must grant a motion to intervene if the motion is timely, and the prospective intervenor claims a legally protected interest in the action, and the action threatens to impair that interest, unless that interest is adequately represented by existing parties." *Amador Cnty. v. U.S. Dep't of the Interior*, 772 F.3d 901, 903 (D.C. Cir. 2014).

The Court, "[o]n timely motion . . . may permit anyone to intervene who . . . has a claim or defense that shares with the main action a common question of law or fact." Fed. R. Civ. P. 24(b)(1)(B). "Even where a party clears the claim-or-defense threshold, the Court has 'considerable latitude' to grant or deny intervention based on the particular circumstances of the case." *Ctr. for Biological Diversity v. EPA*, 274 F.R.D. 305, 313 (D.D.C. 2011) (quoting *Crow Tribe of Indians v. Norton,* No. 02-cv-284, 2006 WL 908048, at *2 (D.D.C. Apr. 7, 2006)).

ARGUMENT

Proposed Intervenors do not satisfy the criteria either for mandatory or for permissive intervention. Their motion should accordingly be denied. If Proposed Intervenors nevertheless believe that they possess "relevant expertise" and a "concern for the issues at stake in this case," they are free to seek "leave to participate as amici curiae," as other covered entity groups have already done. *Dist. of Columbia v. Potomac Elec. Power Co.*, 826 F. Supp. 2d 227, 237 (D.D.C. 2011). Proposed Intervenors identify no respect in which amicus status, rather than party status, would leave them worse off or less capable of protecting their interests.

Independent from Proposed Intervenors' failure to satisfy the criteria for intervention, moreover, their motion should be denied because it does not comply with the local rules. Proposed Intervenors did not attach a proposed pleading to their motion, as required by Federal Rule of Civil Procedure 24(c) and by Local Rule 7(j), which explicitly states that a motion to intervene "*shall be* accompanied by an original of the pleading setting forth the claim or defense for which intervention is sought." LCvR 7(j) (emphasis added); *see* Fed. R. Civ. P. 24(c) (similar). Neither set of rules contemplates that a would-be intervenor might file a motion "for Joinder in Defendants' Motion to Dismiss," ECF No. 26-3, a filing that plainly *is not* a pleading.

I. THE MOTION TO INTERVENE IS UNTIMELY

Both mandatory and permissive intervention require a "timely motion." Fed. R. Civ. P. 24(a), (b). "At the threshold," therefore, "[i]f the motion is untimely, the explicit language of the rule dictates that 'intervention must be denied.'" *Amador Cnty.*, 772 F.3d at 903 (quoting *NAACP v. New York,* 413 U.S. 345, 365 (1973)). Timeliness is "judged in consideration of 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)). "The most important circumstance relating to timeliness is whether a party sought to intervene as soon as it became clear that its interests would no longer be protected by the parties in the case." *Id.* (quoting *Cameron v. EMW Women's Surgical Ctr., P.S.C.*, 595 U.S. 267, 279-80 (2022)) (cleaned up).

Here, Proposed Intervenors sought to intervene nearly three months (89 days) after this suit was filed. Their stated purpose for seeking to intervene is "to ensure that the Court hears from the national associations representing the Covered Entities whose operations and patient-care missions

would be adversely affected by the relief that AbbVie seeks," and because "[t]he Government Defendants . . . do not represent the distinct operational, financial, and patient-care interests of Covered Entities." Mot. 16. But those supposed interests were apparent from the face of AbbVie's Complaint—and Proposed Intervenors do not argue otherwise. *Compare Amarin Pharms. Ireland Ltd. v. FDA*, 139 F. Supp. 3d 437, 444 (D.D.C. 2015) (permitting intervention where "the record reflects that Watson moved to intervene the day after it learned that the FDA would not appeal the Court's Order"), *with Campaign Legal Ctr. v. FEC*, No. 20-cv-0809, 2022 WL 2111560, at *2 (D.D.C. May 13, 2022) (denying intervention as untimely where "one cannot find that [the movant] acted as soon as it was clear that no party would represent its interests"). Indeed, Proposed Intervenors offer no explanation whatsoever for their delay. Nor do Proposed Intervenors claim that they "could not have" sought to intervene sooner; that they were "unaware" until recently of this highly publicized suit; or that a "substantial change" in circumstances explains why they "belatedly moved to intervene." *Campaign Legal Ctr.*, 68 F.4th at 610-11 (citation omitted).

In nevertheless arguing that their motion was timely, Proposed Intervenors point to a handful of decisions in which courts granted motions to intervene while motions to dismiss were already pending. Mot. 40-41. But none of those decisions supports intervention under the circumstances presented here. Each is readily distinguishable, and several in fact reinforce the conclusion that Proposed Intervenors' motion is untimely. For instance, in *MGM Global Resorts Development, LLC v. U.S. Department of the Interior,* No. 19-cv-2377, 2020 WL 5545496 (D.D.C. Sept. 16, 2020), Indian Tribes sought to intervene "alongside the Government Defendants on a limited basis to argue that they are an indispensable party to the action which, they say, must be dismissed because their sovereign immunity makes their joinder here impossible." *Id.* at *1. So the tribal intervenors there—unlike Proposed Intervenors here—sought to raise a *different* jurisdictional issue that was unique to them, not to join the Government's pending motion to dismiss. Moreover,

the existing parties there *agreed* that they would not be prejudiced by the intervention, *id.* at *4, and the Court explained that the extra time necessary to brief the would-be intervenors' Rule 19 argument "might [have been] unavoidable in any event" due to the Court's independent obligation "to raise and look into Rule 19 issues *sua sponte*," *id.* at *4 n.3.

A similar dynamic was presented in *Cayuga Nation v. Zinke*, 324 F.R.D. 277 (D.D.C. 2018), another case involving proposed intervention by a tribal organization. The timeliness of the motion to intervene there was "not challenge[d]." *Id.* at 282. In addition, unlike Proposed Intervenors here, the would-be intervenor in *Cayuga Nation* had attached, as an exhibit to its intervention motion, a motion to dismiss and supporting memorandum. *See* Mot. to Dismiss, *Cayuga Nation v. Zinke*, No. 17-cv-1923 (D.D.C. Jan. 23, 2018), Dkt. 17-1. Finally, at the time of the proposed intervention, the parties were occupied with "briefing [a] Motion for Preliminary Injunction," so the Court could "conceive of no way in which the timing of [the intervention] motion has prejudiced any of the current parties." 324 F.R.D. at 282.

The Court's analysis in *Washington Alliance of Technology Workers v. Department of Homeland Security*, 395 F. Supp. 3d 1 (D.D.C. 2019), further underscores the untimeliness of Proposed Intervenors' motion here. Although the proposed intervenors in *Washington Alliance* filed their motion to intervene on the same day that the Government filed its motion to dismiss, they noted that they "intend[ed] to proceed in this case *only if the Government's renewed motion to dismiss is denied*." *Id.* at 10 (emphasis added). Under those circumstances, the Court explained, intervention would not unduly disrupt the litigation because the proposed intervenors "represent[ed] that they 'd[id] not intend to make any filings'" on the pending motion to dismiss. *Id.* at 19.

This case is obviously different. Proposed Intervenors waited nearly three months after the Complaint was filed before moving to intervene, including nearly three weeks after Defendants

filed their motion to dismiss. Proposed Intervenors now ask this Court to let them piggyback on Defendants' motion and to file a reply brief—*i.e.*, a last-word brief to which AbbVie will have no ability to respond—in support of that motion. Tellingly, Proposed Intervenors have identified *no case* in which a would-be litigant was allowed to intervene under remotely similar circumstances.

Beyond concerns about sandbagging at this critical pleading stage, Proposed Intervenors' motion risks prejudicing AbbVie by introducing collateral issues. Indeed, one of two things must be true: Either Proposed Intervenors *will not* introduce new arguments in their reply brief, in which case their intervention at this stage is unnecessary; or Proposed Intervenors *will* introduce new arguments on reply, in which case their intervention will be unfairly prejudicial because AbbVie would have no opportunity to respond. Either way, the Court should reject their belated attempt to join this suit—especially given their inability to articulate any justification for failing to file in a timely manner.

II. PROPOSED INTERVENORS CANNOT INTERVENE AS A MATTER OF RIGHT

Proposed Intervenors also cannot satisfy the other criteria for mandatory intervention. In addition to being "timely," a Rule 24(a)(2) motion must establish (1) that the applicant "claims an interest relating to the property or transaction that is the subject of the action," (2) that the applicant "is so situated that disposing of the action may as a practical matter impair or impede the movant's ability to protect its interest," and (3) that no "existing parties adequately represent that interest." Fed. R. Civ. P. 24(a)(2). Proposed Intervenors have not satisfied any of those requirements here.

A. Inability to Intervene Would Not Impair Any Legally Protected Interest of Proposed Intervenors

Proposed Intervenors have not identified a legally cognizable interest that would justify intervention at this critical stage. They argue that if this Court adopts the definition of "patient" articulated in AbbVie's workplans, it will "narrow[] the class of patients to whom they may furnish

340B-priced drugs," thus "directly limit[ing] the 340B savings" they can use the 340B program to generate. Mot. 26. Even assuming *arguendo* that they have properly identified an interest sufficient to support intervention *at the merits*, however, Proposed Intervenors have not articulated any basis for intervening *now*, in the middle of motion-to-dismiss briefing. Indeed, they have not even attempted to identify a cognizable stake in the success of Defendants' jurisdictional arguments.

To the contrary, Proposed Intervenors have represented to the Court that they "do not seek to expand the claims in this action … or to file a separate motion to dismiss," but instead plan to rely wholly on Defendants' motion and opening brief. Mot. 41. As that representation makes clear, Proposed Intervenors have no interest in the jurisdictional issues in Defendants' motion that is distinct from the interest of the public as a whole. *See WildEarth Guardians v. Zinke*, 368 F. Supp. 3d 41, 60 (D.D.C. 2019) ("the interest asserted [must be] more than a mere general interest in the alleged procedural violation common to all members of the public") (cleaned up). To be sure, Proposed Intervenors may not want this Court to adjudicate the merits of AbbVie's claim, for fear that the Court will agree with AbbVie about the proper interpretation of "patient" in Section 340B. But a desire to avoid having the Court articulate "the best reading of a statute" is not a legally protected interest. *Loper Bright Enterprises v. Raimondo*, 603 U.S. 369, 395 (2024).

For similar reasons, resolution of Defendants' Motion to Dismiss does not threaten Proposed Intervenors' protected interest. Their interest, as they articulate it, could be impaired only by a merits determination that "narrows the class of patients" for whom they may claim "340B savings." Mot. 26. There is accordingly no need for them to intervene now, for purposes of filing an additional reply brief in support of Defendants' Motion to Dismiss. *Cf. Wildearth Guardians v. Salazar*, 272 F.R.D. 4, 20 (D.D.C. 2010) (Court "may impose appropriate conditions or restrictions upon the intervenor's participation in the action"). And even on the merits, intervention is unnecessary: Proposed Intervenors have openly endorsed the very same legal position as Defendants—

HRSA's 1996 Guidelines interpretation of "patient"—and they have failed to carry their burden of demonstrating that Defendants cannot adequately represent that shared interest. *See infra* Part II.B.

B. Defendants Adequately Represent Proposed Intervenors' Interests

A proposed intervenor "bear[s] the burden of demonstrating that the [existing parties] will inadequately represent their interests." *Aref v. Holder*, 774 F. Supp. 2d 147, 172 (D.D.C. 2011). In order to meet this burden, a movant "must produce something more than speculation as to the purported inadequacy." *Id.* (citation omitted). Here, Proposed Intervenors have offered no non-speculative basis for thinking that Defendants would not adequately represent their interests—either at the motion-to-dismiss stage or on the merits.

1. Proposed Intervenors' and Defendants' Interests Are Aligned

Proposed Intervenors do not seek to file their own motion to dismiss; in fact, they acknowledge that if they *were* to file a separate motion, it would be "duplicative" of Defendants' motion. Mot. 42 n.4. Proposed Intervenors instead seek leave to file a reply brief in support of Defendants' Motion to Dismiss, which of necessity will be limited to the arguments already raised by Defendants. *See Romero v. RBS Constr. Corp.*, No. 18-cv-179, 2022 WL 522989, at *6 (D.D.C. Feb. 22, 2022) ("It is well-established that new issues, arguments, and evidence may not be raised for the first time in a reply brief.") (citation omitted). Nor do Proposed Intervenors even attempt to identify any respect in which the "legal theories and arguments" in their reply brief might differ from those raised by Defendants. *Sevier v. Lowenthal*, 302 F. Supp. 3d 312, 323 (D.D.C. 2018).

Proposed Intervenors have similarly failed to establish the inadequacy of Defendants' representation on the merits. Proposed Intervenors repeatedly acknowledge that this case raises *only* an issue of "statutory interpretation," Mot. 14 ("The question presented in this case is therefore one of statutory interpretation."). Since this Court is bound to "exercise [its] independent judgment

in construing statutes administered by agencies," *Loper Bright*, 603 U.S. at 406, the Court's sole task will be to identify Section 340B's "single, best meaning," *id.* at 400.

For that reason, Proposed Intervenors are wrong that their interests are misaligned because Defendants "must defend HRSA and the United States as institutions—safeguarding the agency's own administrative and enforcement prerogatives—rather than the distinct, provider-specific interest of" covered entities. Mot. 34. Outside of three specified areas, Congress did not give HRSA rulemaking authority with respect to the 340B statute. *See PhRMA v. HHS*, 43 F. Supp. 3d 28, 41-45 (D.D.C. 2014). As a result, no "administrative and enforcement prerogatives" will factor into the analysis in this case; the only merits issue, and the only "interest" that Proposed Intervenors assert, is "in maintaining the plain meaning of the term 'patient.'" Mot. 34. Unlike other cases where litigants have been allowed to intervene on the side of administrative agencies, therefore, this is a case where the dispute must *solely* be resolved based on the "best reading" of a statute as interpreted by "'the reviewing court'—not the agency whose action it resolved." *Loper Bright*, 603 U.S. at 400, 398 (quoting 5 U.S.C. § 706).

Proposed Intervenors assert that Defendants might not make the "grantee-provider-specific arguments" that they intend to make. Mot. 36. Even if true, that would not matter: Whether a movant "might make different arguments than Defendants is immaterial, because the relevant inquiry under Rule 24 is whether [a movant's] interest is adequately represented, not whether its preferred arguments are articulated." *Las Americas Immigrant Advocacy Ctr. v. DHS*, 348 F.R.D. 397, 403 (D.D.C. 2025) (citation omitted).

Regardless, Proposed Intervenors have not identified any merits argument that they would make that will "not also [be] 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); *see id.* ("A would-be intervenor is adequately represented when she offers no argument not also pressed by an existing party.")

(cleaned up).[3] Indeed, Proposed Intervenors *admit* that they "support HRSA's efforts to interpret the term 'patient'" as it "was articulated in its 1996 Guidelines." Mot. 16. Thus, Proposed Intervenors do not merely support the same *outcome* as Defendants; they have endorsed the very same *legal position* on a pure question of statutory interpretation. Proposed Intervenors have identified no case in which intervention was permitted under similar circumstances.

To be sure, Proposed Intervenors are correct (at 37) that the D.C. Circuit has generally "look[ed] skeptically on government entities serving as adequate advocates for private parties." *Crossroads Grassroots Pol'y Strategies v. FEC,* 788 F.3d 312, 321 (D.C. Cir. 2015), *overruled on other grounds as recognized by Institutional S'holder Servs., Inc. v. SEC*, 142 F.4th 757, 764 n.3 (D.C. Cir. 2025). But such skepticism has been grounded in concerns that do not apply to this case. Indeed, the decisions on which Proposed Intervenors rely demonstrate the type of misalignment of interests necessary to show an inadequacy of representation—and their facts and reasoning stand in stark contrast to the circumstances here.

In *Fund for Animals, Inc. v. Norton*, 322 F.3d 728 (D.C. Cir. 2003), an environmental group challenged the Interior Department's decision to list a species of Mongolian sheep as threatened rather than endangered, and the environmental ministry of Mongolia sought to intervene in defense of the decision. *Id.* at 730. The environmental group argued that the ministry was adequately represented by the federal defendants because it shared their view that the "current rules and practices are lawful." *Id.* at 736. The D.C. Circuit disagreed, but *not* because the federal defendants represented "broader public and institutional interests." Mot. 34. Instead, the Court explained how their

[3] While a movant cannot satisfy its burden to show inadequacy merely by identifying a different argument that it would make, when a movant is *unable* to identify an "argument not also pressed by" an existing party, the movant's failure to satisfy its burden "is clear." *Bldg. & Const. Trades Dep't, AFL-CIO v. Reich*, 40 F.3d 1275, 1282 (D.C. Cir. 1994); *see, e.g.*, *Sevier*, 302 F. Supp. 3d at 323 (denying intervention where proposed intervenors "have advanced the same legal theories and arguments as" an existing party).

respective positions were misaligned under the relevant merits inquiry: The Endangered Species Act required the federal defendants to "take into account th[e] efforts" of foreign governments to protect a species, 16 U.S.C. § 1533(b)(1)(A) (cleaned up), the Court explained, "[b]ut taking the [ministry's] efforts into account does not mean giving them the kind of primacy that the [ministry] would give them," 322 F.3d at 736 (cleaned up). In addition, the statute required the federal defendants to "apprais[e]" the quality of those efforts, and the federal defendants' "appraisal of the [ministry's] efforts [would not] necessarily match the [ministry's] self-appraisal." *Id.* Under those circumstances, it was "not hard to imagine how the interests of the [ministry] and those of the [federal defendants] might diverge during the course of litigation—when, for example, the [federal defendants] may be required to present [their] assessment of the quality of Mongolia's [sheep] conservation program." *Id.*

A similar divergence existed in *Crossroads*. In that case, Public Citizen "filed an administrative complaint with the FEC against Crossroads GPS," and "the Commission's six members divided evenly" on the charge, causing the complaint to be dismissed. *Crossroads*, 788 F.3d at 315. Public Citizen then filed suit to challenge the dismissal, and Crossroads sought to intervene. *Id.* The D.C. Circuit rejected Public Citizen's argument that "the Commission could adequately represent Crossroads' interests" merely "because their interests were aligned in defending the legality of the dismissal order." *Id.* at 321. Such "general alignment" was not "dispositive," the Court explained. *Id.* Instead, it was "apparent the Commission and Crossroads hold different interests, for they disagree[d] about the extent of the Commission's regulatory power, the scope of the administrative record, and post-judgment strategy." *Id.* Indeed, "the Commission even disagree[d] that Crossroads ha[d] any cognizable interest in th[e] case," and in fact the Commission "could seek to regulate Crossroads directly and immediately after its dismissal order [wa]s revoked." *Id.*

Given that dynamic, the Court explained, Crossroads had established the "inadequacy of [the FEC's] representation." *Id.*

Here, by contrast, Proposed Intervenors have not identified any position on which they and Defendants "disagree." *Id.* And because "[t]he question presented in this case is . . . one of statutory interpretation," Mot. 14, regarding the meaning of a statutory term ("patient") that the agency gets no deference in interpreting, the outcome of the case will not turn on the agency's "assessment" of any factual or legal issue, *Fund for Animals*, 322 F.3d at 736. The only question is whether AbbVie's workplans reflect the "best reading" of Section 340B's text, purpose, structure, and history, or whether Defendants and Proposed Intervenors are instead correct that the 1996 Guidelines offer the "best reading." *Loper Bright*, 603 U.S. at 400.

Finally, Proposed Intervenors cannot establish that Defendants are inadequate representatives on the ground that Proposed Intervenors can better describe the practical consequences of interpreting "patient" in the manner advocated by AbbVie. Proposed Intervenors argue that they are "uniquely positioned to describe the impact that AbbVie's proposed patient definition will have" on covered entities and their patients, as well as to describe the "purpose and benefit of the 340B Program and articulate the real-world harm that will arise should AbbVie's proposed 'patient' definition be enforced." Mot. 35. But regulated parties are *always* able to "describe the impact" on them of regulatory decisions; that fact by itself plainly does not suffice to demonstrate that governmental defendants cannot "adequately represent th[eir] interest." Fed. R. Civ. P. 24(a)(2); *see Las Americas*, 348 F.R.D. at 403 (rejecting Texas's request to intervene in defense of federal immigration agency despite acknowledging that the "effects of federal immigration policy may be concentrated in border states like Texas"). And that justification is particularly unpersuasive where, as here, the dispute concerns the interpretation of a statutory term, Mot. 14, whose

"meaning [was] fixed" by its ordinary, original public meaning "at the time of enactment," *Loper Bright*, 603 U.S. at 400.

In any event, even if Proposed Intervenors had "unique information or perspective that can help the court beyond the help that the lawyers for the parties are able to provide," such information would be better suited for filing in "a brief as amicus curiae." *Las Americas*, 348 F.R.D. at 404 (denying intervention but permitting movant to participate as amicus); *see Friends of Earth v. Haaland*, No. 21-cv-2317, 2022 WL 136763 (D.D.C. Jan. 15, 2022) (similar). AbbVie would not oppose Proposed Intervenors' filing an amicus brief, just as AbbVie did not oppose the filing of an amicus brief by other covered entity associations. *See* Dkt. 32.

2. Proposed Intervenors' Arguments Regarding Inadequacy Fail

Unable to point to any actual divergence of interests in *this* litigation, Proposed Intervenors resort to two fallback theories: that Defendants have taken adverse positions in *other* matters, and that Defendants *might* hypothetically alter their position at some future point. Neither theory withstands scrutiny, and neither comes close to satisfying Proposed Intervenors' burden to "produce something more than speculation as to the purported inadequacy" of Defendants' representation. *Aref*, 774 F. Supp. 2d at 172.

First, Proposed Intervenors argue that HRSA has taken positions in unrelated litigation that were adverse to the interests of covered entities. *See* Mot. 36 (citing *Am. Hosp. Ass'n v. Becerra*, No. 18-cv-2084, 2023 WL 143337, at *1 (D.D.C. Jan. 10, 2023); *Johnson & Johnson Health Care Sys. Inc. v. Kennedy*, No. 24-cv-3188, 2025 WL 1411076, at *4 (D.D.C. May 15, 2025)). But that argument "miss[es] the mark." *HRH Servs. LLC v. Travelers Indem. Co.*, No. 23-cv-2300, 2024 WL 4699925, at *10 (D.D.C. Nov. 6, 2024). Rather, all that matters is "whether [an existing litigant] would adequately represent [the movant's] interest *in this* underlying litigation." *Id.* (emphasis added); *see id.* (rejecting claim of inadequacy based on argument that existing party

"ha[d] taken adverse positions to [a movant] in two other litigations"). Indeed, in an industry as pervasively regulated as healthcare, it would be hard to find a regulated entity whose interests *did not* diverge from the government's litigating position at some point.

Proposed Intervenors' reliance on *Johnson & Johnson* is particularly misplaced; far from helping their cause, it highlights precisely why intervention is unwarranted here. Proposed Intervenors cite that decision as "acknowledging that provider interests are distinct from the government's interests," Mot. 36, but the Court permitted intervention in *Johnson & Johnson* only because the providers and the government had "urge[d] this Court to adopt different constructions of the statute at issue in this case." 2025 WL 1411076, at *3 (emphasis added). In other words, the proposed intervenors there advocated a legal position that no existing party was advancing—the very circumstance that is absent here. By contrast, Proposed Intervenors openly "support HRSA's efforts to interpret the term 'patient'" as it "was articulated in its 1996 Guidelines," Mot. 16—which is the *identical* interpretation on which HRSA relied when it denied AbbVie's workplans. *Johnson & Johnson* thus compels the opposite conclusion from the one Proposed Intervenors draw: Because they and Defendants share the same statutory construction, intervention is unnecessary.

Second, Proposed Intervenors assert that HRSA *previously* adopted an "enforcement posture" in which the agency interpreted "'patient'" in a manner that was narrower than the 1996 Guidelines. Mot. 38 (referring to the administrative proceedings underlying *Genesis Health Care, Inc. v. Becerra*, 701 F. Supp. 3d 312 (D.S.C. 2023)). Proposed Intervenors argue that "Defendants cannot be expected to disclaim an enforcement posture their own agency has developed and employed in the past." Mot. 38. But Proposed Intervenors "ha[ve] not shown that Defendants have failed or will fail to vigorously defend" the agency action being challenged here. *Las Americas*, 348 F.R.D. at 403. To the contrary, the record in this case affirmatively refutes their concern. When the agency rejected AbbVie's workplans, it made clear—repeatedly and unambiguously—that the

1996 Guidelines "continue[] to guide HRSA's and manufacturers' audit activities." Compl. Ex. 4; *see* Compl. ¶ 142 (HRSA informing AbbVie that the 1996 Guidelines are "the currently operative standard for determining whether an individual is a 340B patient").

Proposed Intervenors fare no better with their speculation that Defendants' interpretation might diverge from theirs regarding "the third prong of HRSA's 1996 Guidelines—the scope of the grant test." *See* Mot. 35. This argument is entirely hypothetical. Proposed Intervenors offer no reason—and there is none—to believe that Defendants, having repeatedly invoked the 1996 Guidelines as the "operative standard for determining whether an individual is a 340B patient," Compl ¶ 142, would suddenly abandon any aspect of those Guidelines mid-litigation. Nor could Defendants do so, given the "bedrock principle of administrative law that 'an agency's action must be upheld, if at all, on the basis articulated by the agency itself.'" *CREW v. FEC*, No. 22-cv-3281, 2023 WL 6141887, at *13 (D.D.C. Sept. 20, 2023) (quoting *Motor Vehicles Mfrs. Ass'n of U.S. v. State Farm Mut. Auto. Ins. Co.*, 463 U.S. 29, 50 (1983)). Defendants are legally constrained to defend the 1996 Guidelines as the basis for the challenged action; Proposed Intervenors' suggestion that they might do otherwise is contradicted by both the record and binding administrative-law principles.

Finally, Proposed Intervenors hypothesize that differences of position between them and Defendants might materialize at some unspecified future date, speculating that "Government Defendants could narrow their defense, settle, or decline to appeal an adverse ruling without regard to the distinct consequences for Covered Entities that could stem from this case." Mot. 38. This epitomizes the kind of conjecture that the D.C. Circuit has deemed insufficient to justify intervention. There has been no indication whatsoever that any of these imagined scenarios will arise—and "[t]he D.C. Circuit has looked skeptically on intervention that hinged on the possibility of an unfavorable settlement as 'hopelessly conjectural.'" *Friends of Earth*, 2022 WL 136763, at *5

(quoting *Deutsche Bank Nat. Tr. Co. v. FDIC*, 717 F.3d 189, 193 (D.C. Cir. 2013)). In all events, if such a "substantial change" in circumstances ever *did* arise—such that it "became clear [their] interests would no longer be protected" by Defendants—Proposed Intervenors would remain free to seek leave to intervene at that time. *Campaign Legal Ctr.*, 68 F.4th at 610. That is the appropriate course—not granting preemptive party status based on speculation about what Defendants *might* do in the future.

III. THE UNTIMELY REQUEST FOR PERMISSIVE INTERVENTION SHOULD BE DENIED

Under Rule 24(b)(1)(B), the Court, in its discretion, may grant a "timely" motion for permissive intervention where the movant "has a claim or defense that shares with the main action a common question of law or fact." But "[i]n exercising its discretion, the court must consider whether the intervention will unduly delay or prejudice the adjudication of the original parties' rights." Fed. R. Civ. P. 24(b)(3). The decision whether to grant permissive intervention is "an inherently discretionary enterprise," in which courts consider "such factors as the nature and extent of the applicant's interests, the degree to which those interests are adequately represented by other parties, and whether parties seeking intervention will significantly contribute to the just and equitable adjudication of the legal questions presented." *Las Americas*, 348 F.R.D. at 401 (citations omitted).

Permissive intervention is unwarranted here. As explained above, Proposed Intervenors' request is untimely, *see* pp. 8-11, *supra*; they have no legally cognizable interest that would justify intervention at this critical stage, *see* pp. 11-13, *supra*; and their interests are adequately represented by Defendants, *see* pp. 13-21, *supra*.

Under the permissive intervention rule, moreover, "defenses [that] are not unique" to the movant and "can be adequately represented by [the named] defendants" do not justify permissive intervention; otherwise, "numerous third-parties [could] seek intervention on the same bases."

Hodes & Nauser, MDs, P.A. v. Moser, No. 2:11-cv-02365, 2011 WL 4553061, at *4 (D. Kan. Sept. 29, 2011); *see, e.g.*, *McLean v. Ark.*, 663 F.2d 47, 48 (8th Cir. 1981) ("The District Court did not abuse its discretion in denying permissive intervention" where "the Attorney General of Arkansas will properly defend the validity of [challenged law]"); *New Orleans Pub. Serv., Inc. v. United Gas Pipe Line Co.*, 732 F.2d 452, 472-73 (5th Cir. 1984) (en banc) (similar); *Menominee Indian Tribe of Wis. v. Thompson*, 164 F.R.D. 672, 678 (W.D. Wis. 1996) (similar); *see also Allen Calculators v. Nat'l Cash Register Co.*, 322 U.S. 137, 141-42 (1944) (explaining that permitting a "multitude" of interventions in a case "of large public interest . . . may result in accumulating proofs and arguments without assisting the court"). Such is the case here: Proposed Intervenors have not identified any defense that is unique to them—or even a defense that they are better positioned to assert than Defendants are, especially considering that the issue presented is a purely legal one about the best meaning of a statutory term. Nor is their asserted interest in HRSA's continued adherence to the 1996 Guidelines different from that of the tens of thousands of other covered entities (and organizations representing covered entities).

Granting Proposed Intervenors party status also would not "significantly contribute to . . . the just and equitable adjudication of the legal question presented." *Ctr. for Biological Diversity*, 274 F.R.D. at 313. Nothing about Proposed Intervenors' motion is "just and equitable." They waited nearly three months to move to intervene; declined to file their own pleading in contravention of the rules; and now ask the Court to allow them to file a reply brief in support of someone else's motion to dismiss. *Cf. Novak v. Cap. Mgmt. & Dev. Corp.*, No. 01-cv-39, 2003 WL 27383676, at *3 (D.D.C. Mar. 31, 2003) (explaining the unfairness of a party waiting to raise arguments until reply). While Proposed Intervenors claim that they can add a "unique perspective" to the case, Mot. 44, they cannot "significantly contribute" without offering arguments distinct from those offered by Defendants—distinct arguments that, in any event, Proposed Intervenors

have not identified. *See Ctr. for Biological Diversity*, 274 F.R.D. at 313 (although proposed intervenors had "substantial expertise and unique perspective" regarding *certain* issues, on the legal question before the court, they "offer[ed] no more than conclusory assertions that their participation will be helpful").

Rather than grant party status to Proposed Intervenors, despite their being identically situated to numerous other covered entities and organizations, the more appropriate course would be to permit them to participate as amici curiae. That approach would allow consideration of Proposed Intervenors' views—including their self-described unique perspective on the supposedly harmful "impact" of adopting a textually faithful interpretation of Section 340B, Mot. 35—while minimizing any disruption to the proceedings already well underway. Proposed Intervenors identify no respect in which amicus status would leave them any worse off or any less capable of protecting their interests.

CONCLUSION

For the foregoing reasons, the Court should deny Proposed Intervenors' motion to intervene. Proposed Intervenors' motion is untimely, unsupported by any legally cognizable interest at this stage, and duplicative of the defense already mounted by Defendants. To the extent Proposed Intervenors wish to present their perspective to the Court, amicus participation—to which AbbVie would not object—is the appropriate vehicle.

Dated: July 20, 2026

Respectfully submitted,

/s/ Allon Kedem

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CERTIFICATE OF SERVICE

In accordance with LCvR 5.3, undersigned counsel hereby certifies that the above brief was filed via the Court's electronic filing system.

Dated: July 20, 2026

By: /s/ Allon Kedem
Allon Kedem

IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF COLUMBIA

ABBVIE INC.,

Plaintiff,

v.

ROBERT F. KENNEDY JR., in his official capacity, et al.,

Defendants.

Civil Action No. 26-cv-1190-RDM

[PROPOSED] ORDER

Upon consideration of the Joint Motion to Intervene by National Association of Community Health Centers, Inc. and Ryan White Clinics for 340B Access, it is hereby ORDERED that the motion is DENIED.

SO ORDERED this _____ day of July_____, 2026.

_____
Randolph D. Moss
United States District Court Judge