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 340B HEALTH, UMASS MEMORIAL MEDICAL CENTER, AND GENESIS HEALTHCARE SYSTEM'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—based on a definition of "patient" as interpreted under the agency's 1996 Guidelines—to enforce any audit findings inconsistent with the Guidelines' definition. 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.

340B Health, UMass Memorial Medical Center, and Genesis HealthCare System (collectively, "Proposed Intervenors") seek to interject themselves into this lawsuit nearly three months after it was filed, and a week after the deadline for answering AbbVie's Complaint. In doing so, they ask to be excused from requirements of 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 assert that they will not participate in the case at this

juncture and "intend to address the merits of this action once the merits are raised by either party." Mot. 21.

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 months to seek intervention. They identify no legally cognizable interest at stake in the pending litigation, raising only concerns common to every covered entity that participates in the 340B program. They also identify no claims, defenses, or arguments that they intend to raise that are 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 about the arguments that Defendants *might* make on the merits.

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

AbbVie respectfully refers the Court to its prior Memorandum in Opposition to the Joint Motion of National Association of Community Health Centers, Inc. and Ryan White Clinics for 340B Access to Intervene, ECF No. 34 at 9-13, and Memorandum in Opposition to Defendants' Motion to Dismiss, ECF No. 37 at 10-27, for a detailed background of the 340B program, its inception and growth, the increasing prevalence of 340B program abuse, and the agency actions that gave rise to AbbVie's Complaint, including HRSA's rejection of AbbVie's workplans based on its continued adherence to the interpretation of "patient" set forth in its 1996 non-binding guidelines, *see* 61 Fed. Reg. 55,156, 55,156-58 (Oct. 24, 1996) (1996 Guidelines).

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 was filed on July 28. ECF No. 37.

[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/.

On June 23, 2026, 76 days after AbbVie filed its suit and 7 days after the (extended) deadline for all defendants to answer or otherwise respond to the Complaint, Proposed Intervenors—an association of 340B hospitals and two individual 340B hospitals—filed a proposed motion to intervene. ECF No. 19. Notably, Proposed Intervenors do not claim that Barrio or Mount Sinai are members. Because Proposed Intervenors stated that 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. Order (June 30, 2026).[3]

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)).

[3] On July 6, 2026, a pair of different covered entity associations also moved to intervene. ECF No. 26. Those proposed intervenors sought to intervene in the midst of briefing in the motion to dismiss, asking to file a reply brief in support of Defendants' motion to dismiss. Their motion to intervene remains pending.

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.

Proposed Intervenors' motion rests on wholly speculative grounds. Proposed Intervenors state that they will not participate in this case until either party raises the merits of AbbVie's Complaint; they simultaneously assert that they should be allowed to intervene now because Defendants will not adequately protect their interests on the merits. *Compare* Mot. 21, *with* Mot. 23-25. But Proposed Intervenors cannot know, and have identified no reason to believe, that Defendants will not adequately represent their interests on the merits—particularly since they fully *agree* with the position that HRSA took in rejecting AbbVie's audit requests, and Defendants have not yet addressed the merits in this litigation. The motion to intervene should be denied.

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 over two and a half months (76 days) after this suit was filed. Their stated purpose for seeking to intervene is "to protect their interests and to ensure that 340B hospitals have adequate access to 340B drugs at the statutorily imposed discount price," and because they are "uniquely positioned to understand the real-world impact of AbbVie's narrower patient definition on patient access." Mot. 10. 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 claim that they "needed to wait to file … until the Government Defendants filed their responsive pleading to the Complaint to see what position the Government Defendants would take in the case." Mot. 21. That

explanation makes little sense. As Proposed Intervenors acknowledge, Defendants' motion to dismiss addressed only "jurisdictional issues," not the merits of the case, so nothing about Defendants' position on the merits has been made clearer. *Id.* If anything, Proposed Intervenors' argument that they need to "see what position the Government Defendants [will] take in this case" indicates that any intervention request should wait until Defendants actually take a position on the merits. In addition, Proposed Intervenors have not filed their own proposed motion to dismiss, and they do not claim that Defendants do not represent their interests at this stage in the proceedings. *Contra Campaign Legal Ctr.*, 2022 WL 2111560, at *2. Proposed Intervenors do not identify any case that excuses a delay where, as here, a movant's interest in the dispute was apparent since the inception of the case and the party on whose side it seeks to intervene has not taken any step contrary to that interest.

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, Proposed Intervenors "would lose access to the 340B statutory discount for many of the eligible patients they treat." Mot. 18. But that interest is shared by *every*

covered entity. *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). Indeed, Proposed Intervenors' purported interest speaks to the potential effect of an adverse decision on *all* "340B hospitals"—and, implicitly, on all covered entities—not just on them. Mot. 22. Notably, *both* sets of proposed intervenors in this case have claimed to be "uniquely positioned" to speak to the harms in this case. *Compare* Mot. 10, *with* ECF No. 26 at 35 ("Proposed Intervenors are also uniquely positioned to describe the impact that AbbVie's proposed patient definition will have on grantee Covered entities and the patients they serve."). The similarities between their motions and arguments for intervention only underscore that neither is an appropriate intervenor in this case, and that their purported interest is really just a generalized "interest in having" a particular interpretation of the 340B statute prevail. *Doe 1 v. FEC*, No. 17-cv-2694, 2018 WL 2561043, at *4 (D.D.C. Jan. 31, 2018).

Further underscoring the generalized nature of this interest, Proposed Intervenors have endorsed the same legal position as Defendants—namely, the interpretation of "patient" in HRSA's 1996 Guidelines—and they have failed to carry their burden of demonstrating that Defendants cannot adequately represent that shared interest. *See infra* Part II.B. 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 Enters. v. Raimondo*, 603 U.S. 369, 395 (2024). If Proposed Intervenors want to be sure the Court considers their viewpoint, they are free to file as *amici curiae*, as 340B Health acknowledges it has done in dozens of 340B-related lawsuits. *See* Mot. 17 n.1.

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.

1. Proposed Intervenors' and Defendants' Interests Are Aligned

Proposed Intervenors and Defendants have the same interest in this case. Proposed Intervenors repeatedly acknowledge that this case raises *only* an issue of the proper "interpretation of the statutory term 'patient.'" Mot. 12; *see* Mot. 18 (acknowledging their interest flows from the Court adopting a specific "definition" of "patient"); Mot. 22 (similar). 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 "the government's obligation is to represent the interests of its citizens, as opposed to the interest of private parties." Mot. 24. Here, Defendants' interest is in defending the 1996 Guidelines' definition of "patient"—an interest that Proposed Intervenors admit they share. That shared interest renders this case different from others where a government entity has been found to be an inadequate representative. 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, this case does not carry the same risk of "diverg[ence]" as cases that concerned an agency's "assessment" of certain policy issues or its discretionary choices. *Fund for Animals, Inc. v. Norton*, 322 F.3d 728, 736 (D.C. Cir. 2003). Unlike those other cases where litigants have

been allowed to intervene on the side of administrative agencies, 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 reviews." *Loper Bright*, 603 U.S. at 400, 398 (quoting 5 U.S.C. § 706).

Proposed Intervenors' inability to identify any respect in which their interests are not adequately represented by Defendants is fatal to their intervention request: Even where a movant can show that it "might make different arguments than Defendants," such a showing "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) (cleaned up); *see id.* ("A would-be intervenor is adequately represented when she offers no argument not also pressed by an existing party.") (cleaned up). Indeed, Proposed Intervenors *admit* that they seek to "maintain the position that the 1996 Guidelines represent the best reading of 'patient' under the 340B statute." Mot. 24. 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.[4]

[4] 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 v. Lowenthal*, 302 F. Supp. 3d 312, 323 (D.D.C. 2018) (denying intervention where proposed intervenors "have advanced the same legal theories and arguments as" an existing party).

To be sure, Proposed Intervenors are correct (at 23) 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 cited by Proposed Intervenors 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), on which Proposed Intervenors repeatedly rely, 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, because their 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 this is a statutory interpretation case, 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 "the only entities that can adequately describe the impact that AbbVie's proposed 'patient' definition will have on 340B hospitals and the patients they serve," Mot. 25. 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. 12, 18, 22, 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). Proposed Intervenors admit that 340B Health has done this in nearly one hundred 340B-related cases, *see* Mot. 17 n.1, and their only reason for changing approach here is fear that Defendants *may* take a position with which they disagree on the merits, as discussed *infra*, is not grounds for intervention. 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* ECF No. 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 "Government Defendants" have taken positions in *amicus* briefs in unrelated litigation that were adverse to the interests of covered entities. *See* Mot. 17 n.1; 24-25 (discussing "*amicus* briefs in litigation relating to state laws regulating delivery of 340B drugs to community pharmacies"). 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.

Second, Proposed Intervenors' argument of inadequacy stems from a speculative fear that Defendants may change their position in this case. They claim the change in presidential administration in January 2025 means "there is no assurance that [Defendants] will continue to defend the instant suit nor maintain the position that the 1996 Guidelines represent the best reading of 'patient' under the 340B statute." Mot. 24. Again, that argument makes little sense. AbbVie submitted its audit requests in June and July 2025 to the *current* Administration, which denied those

requests in September 2025 based on the agency's continued adherence to the 1996 Guidelines. *See* Compl. Exs. 1, 4, 5. Nor have Proposed Intervenors identified any reason to believe that the Administration has changed its position since September 2025.

Proposed Intervenors' argument is also 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.

Even if Defendants *could* legally change position mid-litigation, the D.C. Circuit has deemed this kind of conjecture insufficient to justify intervention. There has been no indication whatsoever that this imagined scenario 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 unsupported 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. 5-7, *supra*; they have no legally cognizable interest that would justify intervention at this critical stage, *see* pp. 7-8, *supra*; and their interests are adequately represented by Defendants, *see* pp. 9-15, *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 an argument that they are better positioned to assert than Defendants are, especially considering that the issue presented in this case 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 (citation omitted). While Proposed Intervenors claim that they are "uniquely able to describe the purpose and benefit of the 340B Program," Mot. 25, 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 a 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. 25—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, 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: August 4, 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: August 4, 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 Motion to Intervene by 340B Health, UMass Memorial Medical Center, and Genesis Healthcare System, it is hereby ORDERED that the motion is DENIED.

SO ORDERED this _____ day of _____, 2026.

_____
Randolph D. Moss
United States District Court Judge