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

and

NATIONAL ASSOCIATION OF COMMUNITY HEALTH CENTERS, INC.; and
RYAN WHITE CLINICS FOR 340B ACCESS,

Proposed Intervenor-Defendants.

No. 1:26-cv-1190-RDM

REPLY IN SUPPORT OF JOINT MOTION TO INTERVENE BY NATIONAL ASSOCIATION OF COMMUNITY HEALTH CENTERS, INC. AND RYAN WHITE CLINICS FOR 340B ACCESS

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INTRODUCTION

AbbVie, Inc. ("Plaintiff" or "AbbVie") offers no convincing reason to deny the joint motion to intervene (the "Motion") by the National Association of Community Health Centers, Inc. ("NACHC") and Ryan White Clinics for 340B Access ("RWC-340B") (together, the "Proposed Intervenors"). AbbVie has not—and cannot—show that Proposed Intervenors do not have an interest in this matter. Indeed, Proposed Intervenors represent grantee entities whose rights and interests under the 340B Program are directly implicated by the relief AbbVie seeks. A ruling adopting AbbVie's proposed interpretation of the statute would reduce their access to 340B savings and potentially expose them to manufacturer enforcement efforts. Rule 24 of the Federal Rules of Civil Procedure exists to ensure that parties with such direct interests may intervene to protect those interests in litigation. Against this backdrop, AbbVie's various objections to the Motion fail, and this Court should grant intervention.

First, the Motion is timely. It was filed roughly three weeks after Defendants moved to dismiss—before AbbVie's opposition to that motion was due, before any merits ruling, and before summary judgment briefing. This Court routinely grants intervention in such circumstances. Moreover, AbbVie has not shown that the timing of the Motion prejudices its interests—and, indeed, it cannot make such a showing. Further, there is nothing unusual or prejudicial about Proposed Intervenors moving to join Defendants' pending motion to dismiss. Indeed, this Court recently permitted an association to intervene in a very similar posture—allowing the intervenor to join the government's pending motion to dismiss and to file a subsequent reply brief. *Farmer v. U.S. EPA*, 759 F. Supp. 3d 101, 111 (D.D.C. 2024) (granting intervention as of right and permitting the intervenor to join the agency's pending motion to dismiss where the motion to intervene was filed before any merits decision).

Second, AbbVie fails to show that Defendants adequately represent Proposed Intervenors' interests. Defendants' interest in the audit process is institutional: it seeks to ensure that AbbVie proceeds through the required administrative channel and that judicial review occurs only after a final agency decision, as the statute requires. But Proposed Intervenors have a *direct* interest in the outcome of the audit process: their members are the grantee covered entities whose repayment liability, 340B eligibility, and program savings will be determined through the process. The Defendants serve as the adjudicator of Proposed Intervenors' interests—not their advocate. Accordingly, this is precisely the kind of situation where courts look "skeptically" upon government entities purporting to represent the interests of aspiring intervenors. *See, e.g.*, *Crossroads Grassroots Pol'y Strategies v. FEC*, 788 F.3d 312, 321 (D.C. Cir. 2015); *Johnson & Johnson Health Care Sys. Inc. v. Kennedy*, No. 24-cv-3188 (RC), 2025 WL 1411076, at *3 (D.D.C. May 15, 2025).

Third, Proposed Intervenors' legally protected interest and its impairment are plain, and AbbVie cannot defeat them by attempting to artificially narrow the scope of its own case. Although AbbVie describes the suit as a bounded dispute over its own "workplans," Pl.'s Mem. of Law in Opp. to Mot. Intervene at 11–12, 17 (Dkt. 34) ("Opp."), its Prayer for Relief asks this Court to sweepingly declare its reading of "patient of the entity" the "*best meaning of the term as it is used in the 340B statute*"—which would be a program-wide ruling that would govern every covered entity nationwide. Compl. 70 (Prayer ¶ 5) (Dkt. 1) (emphasis added). AbbVie cannot claim program-wide relief to justify its Complaint while disclaiming program-wide effect to defeat intervention. And AbbVie's own framing of "[t]he only question" as "whether AbbVie's workplans reflect the 'best reading' of Section 340B's text, purpose, structure, and history,"

Opp. 17, underscores that what is at stake is a program-wide construction of the statute—and that Proposed Intervenors' interests are directly at risk.

In the alternative, permissive intervention should be granted under this Circuit's flexible standard. AbbVie's suggestion that Proposed Intervenors could instead act as amici is insufficient. Amici have no rights to present arguments, seek relief, or appeal any adverse ruling.

ARGUMENT

I. The Motion Is Timely.

As to timeliness, AbbVie incorrectly fixates on the calendar, asserting that the Motion is untimely because it was filed "89 days" after suit and "20 days" after Defendants' extended deadline to respond to the Complaint. Opp. 6, 8–11. But the key consideration that governs the timeliness inquiry is prejudice, and AbbVie fails to show prejudice to any party here.

To the contrary, timeliness is judged under "all the circumstances." *Roane v. Leonhart*, 741 F.3d 147, 151 (D.C. Cir. 2014) (citation omitted). And "the length of time passed" is not "'determinative.'" *Id.* (citation omitted from second quotation). Rather, the touchstone is whether intervention "unduly disrupt[s] litigation, to the unfair detriment of the existing parties." *Id.*; *accord Karsner v. Lothian*, 532 F.3d 876, 886 (D.C. Cir. 2008); *Nat. Res. Def. Council v. Costle*, 561 F.2d 904, 907–08 (D.C. Cir. 1977) (holding the district court abused its discretion in its assessment of timeliness when it relied upon the age of the case and its closeness to settlement).

Here, the Motion is timely. It was filed roughly three weeks after Defendants moved to dismiss, and three weeks *before* AbbVie's opposition to that motion was due. *See* Minute Order (June 22, 2026) (extending response deadline to July 28, 2026). Moreover, no summary judgment briefing has occurred, and this Court has issued no merits ruling. Courts in this District have found motions to intervene timely in similar circumstances. *See, e.g.*, *MGM Glob. Resorts Dev., LLC v. U.S. Dep't of Interior*, No. 19-cv-2377 (RC), 2020 WL 5545496, at *4 (D.D.C. Sep. 16, 2020).

Moreover, AbbVie's attempts to distinguish cases on the grounds that timeliness was not contested, Opp. 9–10, fail. Timeliness is a threshold determination that the Court must make for itself—it does not turn on whether a party chooses to contest timeliness. *See Sierra Club v. Van Antwerp,* 523 F. Supp. 2d 5, 10 (D.D.C. 2007) (independently making a timeliness determination, even though "[t]he timeliness of the motion to intervene is uncontested"). And the cases that Proposed Intervenors cited in their Motion, Mot. 32–33, involved independent timeliness findings. *See MGM Glob. Resorts*, 2020 WL 5545496, at *4; *Cayuga Nation v. Zinke*, 324 F.R.D. 277, 282 (D.D.C. 2018). In *MGM*, the motion to intervene was found timely because the litigation remained in its early stages and intervention would not prejudice existing parties, where movants filed seventy-six days after the complaint and "about two weeks after the Government Defendants filed their motion to dismiss." 2020 WL 5545496, at *4. The same considerations control here: this case remains at the pleading stage, no merits ruling has been issued, and intervention will not prejudice any party.

Farmer is particularly instructive. There, the Court held that a trade association's intervention motion was timely because "the motion was filed before this Court issued any merits decision," so "intervention would not unduly disrupt this litigation." 759 F. Supp. 3d at 110 (citing *Roane*, 741 F.3d at 151). That was so even though—just like here—the association moved to intervene only "following the filing of the plaintiffs' second amended complaint and EPA's motion to dismiss." *Id.* at 107 (internal citations omitted). Moreover, and again like here, the association in *Farmer* asked to join the government's pending motion to dismiss, and the plaintiffs objected. *Id.* at 111. The Court overruled the objection, reasoning that the association's "motion to join raises no new arguments"; it therefore "allow[ed] [the association] to file its motion and permit[ted] the plaintiffs to respond." *Id. Farmer* thus demonstrates both that intervention at this stage is timely

and that allowing an intervenor to join a pending motion to dismiss is neither unusual nor prejudicial.

AbbVie's related contention that the Motion was not accompanied by a "pleading," Opp. 8, fails for the same reason. *See Black v. LaHood*, No. 11-cv-1928 (JEB), 2012 WL 13054502, at *2 (D.D.C. Apr. 30, 2012) (rejecting an identical objection because an intervenor's motion to dismiss "incorporate[ing] other Defendants' arguments does not make it any less a pleading that sets out Intervenors' defenses"); *MGM Glob. Resorts*, 2020 WL 5545496, at *6 ("[C]ourts in this Circuit have not applied this rule particularly rigidly."). If this Court disagrees that Proposed Intervenors may join in Defendants' motion to dismiss, the appropriate remedy would be to require Proposed Intervenors to file an answer. *See Wash. All. of Tech. Workers v. U.S. Dep't Homeland Sec.*, 395 F. Supp. 3d 1, 21 n.4 (D.D.C. 2019) ("Where . . . the position of the movant is apparent . . . and where the opposing party will not be prejudiced, Rule 24(c) permits a degree of flexibility with technical requirements" and "fail[ing] to include" an answer "does not procedurally bar" intervention (citations omitted)). Likewise, if AbbVie takes the position that Proposed Intervenors' anticipated reply brief raises new issues, it may seek to file a sur-reply; it is not appropriate to bar Proposed Intervenors from participating in this case when their Motion was timely filed.

Amgen Inc. v. Kennedy, No. 24-cv-3571, 2026 WL 202157 (D.D.C. Jan. 27, 2026) (Boasberg, C.J.)—a case that also involves the 340B program and the drug industry's efforts to narrow the definition of "patient," among other things—is also on point. There, over the plaintiff manufacturers' objection that the motion "came in nearly a year after they initiated th[e] lawsuit," this Court granted a covered entity's motion to intervene, explaining that "[t]ime elapsed . . . does not alone render a motion untimely in the absence of any prejudice to the parties." *Id.* at 2. The Court relied on the facts that summary judgment briefing "ha[d] not yet begun" and that the movant

was "prepared to comply with all scheduling orders." *Id.* Both are true here, and Proposed Intervenors filed their Motion considerably earlier.

Finally, the cases cited by AbbVie are readily distinguished and, in fact, support intervention. *Cf.* Opp. 8–9. *Amador County v. U.S. Department of the Interior* is distinguishable because it involved a motion filed "[a]fter nearly six-and-a-half years" of litigation. 772 F.3d 901, 902 (D.C. Cir. 2014). Moreover, the movant in *Amador* "knew that the suit could adversely affect its rights, and questioned the adequacy of the United States' representation," but waited to move to intervene until the parties reported the case "ready for oral argument and decision on the merits." *Id.* at 903–04. Here, in contrast, Proposed Intervenors filed the Motion before AbbVie filed its response to Defendants' motion to dismiss.

Further, in *NAACP v. New York*, movants sought to intervene only after the plaintiff had moved for summary judgment and the United States had consented to a declaratory judgment, creating a significant risk of disruption and prejudice. 413 U.S. 345, 366–67 & n.20 (1973). And the movants in *Campaign Legal Center v. FEC* sought to intervene only after default judgment was entered. No. 20-cv-0809, 2022 WL 2111560, at *2 (D.D.C. May 13, 2022). Here, by contrast, there has been no comparable delay. And the court in *Amarin Pharmaceuticals Ireland Ltd. v. FDA* deferred its decision on a motion to intervene, but still found that the post-judgment motion to intervene was timely when it was filed after the FDA did not appeal the court's adverse decision. 139 F. Supp. 3d 437, 444 (D.D.C. 2015). That does not render Proposed Intervenors' pleading-stage motion untimely.

For AbbVie's remaining authorities (Opp. 8), the denials of intervention were later reversed. *See Karsner*, 532 F.3d at 886 (reversing district court decision finding motion to intervene untimely where motion to intervene was filed "before the district court took any action");

Cameron v. EMW Women's Surgical Ctr., P.S.C., 595 U.S. 267, 279–80 (2022) (reversing denial and permitting intervention even after a court of appeals merits ruling, holding that "the progression of the litigation is . . . not solely dispositive" and measuring timeliness from when the movant's interests were no longer adequately protected (citation omitted)). And for that reason, those decisions likewise support granting intervention here, not denial.

II. Intervention as of Right Is Appropriate.

Proposed Intervenors demonstrated in the Motion that they are entitled to intervene as of right because they hold a direct, legally protected interest that this action will impair, and because Defendants—sitting as the statutory adjudicator of the very dispute—cannot adequately represent them. AbbVie has not seriously disputed those facts. Moreover, Rule 24(a) is construed liberally in favor of intervention, *Fund for Animals v. Norton*, 322 F.3d 728, 735–36 (D.C. Cir. 2003), and AbbVie has not offered any persuasive reason why it should be denied here.

A. Defendants Cannot Adequately Represent Proposed Intervenors Because They Sit as the Statutory Adjudicator of this Dispute.

AbbVie's argument that Defendants adequately represent the interests of Proposed Intervenors fails. *Cf.* Opp. 13–20. Indeed, it rests on a fundamental misunderstanding of the parties' respective roles in the statutory scheme that AbbVie invokes in this litigation. In the administrative auditing process, the covered entity faces direct repayment liability to the manufacturer if a diversion finding is sustained. 42 U.S.C. § 256b(a)(5)(D), (d)(3). And it is Defendants—not AbbVie and not the covered entity—who (1) makes the compliance determination "after notice and hearing"; and (2) "shall provide" for the administrative dispute resolution ("ADR") process that "determine[s]" compliance. *Id.* §§ 256b(a)(5)(D), (d)(1)(A), (d)(3).

1. That Defendants are responsible for adjudicating disputes between pharmaceutical manufacturers like AbbVie and covered entities casts doubt on their ability to represent Proposed Intervenors' interests here: A party whose statutory function is to sit in judgment of a dispute cannot simultaneously serve as the zealous advocate for one side of it. *Crossroads*, 788 F.3d at 316–17, 321 ("look[ing] skeptically on government entities serving as adequate advocates for private parties"). The fact that this case focuses on AbbVie's audit workplans rather than an ADR claim is of no consequence. If AbbVie is allowed to apply a narrower definition of patient for auditing purposes, Defendants will surely also allow them to do so when adjudicating diversion claims at the ADR stage.

Moreover, AbbVie attempts to impose a higher burden to demonstrate inadequacy than the law requires. A proposed intervenor need show only that representation "may be" inadequate, and the burden is "minimal." *Trbovich v. United Mine Workers of Am.*, 404 U.S. 528, 538 n.10 (1972); *accord Fund for Animals*, 322 F.3d at 735 (burden "not onerous" (applying *Trbovich*)). And the Supreme Court has confirmed that adequacy of representation should not be presumed where the intervenor's interest diverges from that of the existing party's interest. *See Trbovich*, 404 U.S. at 539.

Here, the statutory roles of Defendants vis-à-vis Proposed Intervenors are structural, not speculative. And Proposed Intervenors represent federal grantees whose statutory rights are measured directly against those of AbbVie. If this Court narrows the definition of "patient" as AbbVie requests, Proposed Intervenors' member entities face both lost 340B savings as well as potential repayment liability. In contrast, Defendants face no such liability.

2. Further, Proposed Intervenors bring supplemental expertise that will be instructive on the merits of the case. The D.C. Circuit has held intervention warranted where a movant's

knowledge of the "impact that regulation can be expected to have upon [its] operations" will serve "as a vigorous and helpful supplement" to the government's defense. *Nat. Res. Def. Council*, 561 F.2d at 912–13. And this is particularly true in cases, like this one, involving "questions of very technical detail and data," where "experience and expertise in [the] relevant fields" aid the court's resolution. *Id.* That is true in spades here.

Proposed Intervenors also intend to contest several of AbbVie's factual assertions about widespread 340B "abuse" and covered-entity noncompliance—which Defendants have not yet addressed. Proposed Intervenors do not fault Defendants for advancing a threshold jurisdictional defense in their motion to dismiss. That is a sound litigating choice, and Proposed Intervenors join it. But Proposed Intervenors have no way of knowing whether Defendants will be willing to contest all of AbbVie's relevant factual assertions if this case moves beyond the pleading stage.

3. Perhaps most critically, Defendants could also narrow, settle, or decline to appeal an adverse ruling or judgment in this case, to the detriment of Proposed Intervenors. Indeed, Defendants have already tried on two occasions to narrow the 340B Program's definition of "patient"—in 2007 and then in 2015—by issuing Federal Register proposals that would have replaced the government's original 1996 Guidance. *See* Notice Regarding Section 602 of the Veterans Health Care Act of 1992 Definition of "Patient", 72 Fed. Reg. 1543 (HHS Jan. 12, 2007); 340B Drug Pricing Program Omnibus Guidance, 80 Fed. Reg. 52,300 (HHS Aug. 28, 2015) (notice). Strong opposition from covered entities blocked those efforts. And, in related contexts, the Secretary of the Department of Health and Human Services ("Secretary"), one of the Defendants in this case, has sometimes litigated directly against covered entities' financial interests. *See*, *e.g.*, *Am. Hosp. Ass'n v. Becerra*, 596 U.S. 724, 729–32 (2022) (HHS litigated to sustain Medicare outpatient prescription drug reimbursement cuts against 340B hospitals); *Genesis*

Health Care, Inc. v. Becerra, 701 F. Supp. 3d 312, 331 (D.S.C. 2023) (HHS unsuccessfully litigating to sustain illegally narrow definition of "patient" under the 340B statute); *Albany Med Health Sys. v. Health Res. & Servs. Admin.*, No. 23-cv-03252 (APM), 2026 WL 592593, at *1, *10–11 (D.D.C. Mar. 3, 2026) (appeal pending) (HHS unsuccessfully litigating to require qualified hospitals' new offsite facilities to register before obtaining drug pricing under 340B).

These are not hypothetical risks. The Secretary routinely narrows, settles, or abandons the defense of contested agency action—often to the direct detriment of covered entities. For example, HHS declined to apply a federal court's statutory construction of "patient" to any covered entity besides Genesis Healthcare, Inc. and applied in audits the narrower standard that court had rejected. *340B Patient Definition Compliance Resources*, Health Res. & Servs. Admin. (Jan. 2024), https://tinyurl.com/mry3n2p2 (stating "HRSA notes that the decision in *Genesis Health Care, Inc. v. Becerra,* Civ. 4:19-cv-01531-RBH (D.S.C. November 3, 2023), is applicable solely to Genesis Health Care"). As another example, the Secretary declined to appeal two decisions narrowing the ability of certain covered entities to purchase orphan drugs with 340B discounts. *See* Docket, *Pharm. Rsch. & Mfrs. of Am. v. U.S. Dep't of Health & Hum. Servs.*, 138 F. Supp. 3d 31 (D.D.C. 2015) (No. 1:14-cv-01685-RC); Docket, *Pharm. Rsch. & Mfrs. of Am. v. U.S. Dep't of Health & Hum. Servs.*, 43 F. Supp. 3d 28 (D.D.C. 2014) (No. 1:13-cv-01501-RC).

In short, as the D.C. Circuit has put it, "doubtful friends may provide dubious representation." *Crossroads*, 788 F.3d at 314, 321. That court has therefore "often concluded that governmental entities do not adequately represent the interests of aspiring intervenors." *Id.* at 314 (quoting *Fund for Animals,* 322 F.3d at 736).

4. AbbVie, in arguing that "Proposed Intervenors have not identified any merits argument that they would make that will 'not also [be] pressed by an existing party,'" Opp. 14,

also ignores that Proposed Intervenors will press an argument no existing party makes—the original plain meaning of "patient." Jt. Mot. to Intervene as Defs. at 6–7, 18, 22, 29–30 (Dkt. 26) ("Mot."). The cases that AbbVie cites (Opp. 13–15) in which intervention was denied because the proposed intervenors did not advance any unique arguments are, therefore, inapposite. *See United States v. All Assets Held at Credit Suisse (Guernsey) Ltd.*, 45 F.4th 426, 432 (D.C. Cir. 2022); *Bldg. & Constr. Trades Dep't v. Reich*, 40 F.3d 1275, 1282 (D.C. Cir. 1994) (this case also predates the Circuit's modern recognition, in *Fund for Animals* and *Crossroads*, that alignment on an outcome does not establish adequacy of representation); *Sevier v. Lowenthal*, 302 F. Supp. 3d 312, 321–23 (D.D.C. 2018); *Aref v. Holder*, 774 F. Supp. 2d 147, 172 (D.D.C. 2011).

Here, Defendants have given no indication that they will defend the original public meaning of "patient" as enacted in 1992. And adherence to this interpretive method is not incidental: the D.C. Circuit has directed that the 340B statute's undefined terms be read according to their "ordinary, contemporary, common meaning" at the time of enactment. *See Novartis Pharms. Corp. v. Kennedy*, --F.4th--, 2026 WL 2093937, at *3 (D.C. Cir. 2026) (quoting *Perrin v. United States*, 444 U.S. 37, 42–43 (1979)); *see also Perrin,* 444 U.S. at 42 (using ordinary meaning at time of enactment of statute). An argument that will not be given "primacy" by an existing party defeats any adequacy of representation presumption. *Fund for Animals*, 322 F.3d at 736–37.

5. The remaining cases that AbbVie cites (Opp. 14, 18–20) are either inapposite or favor Proposed Intervenors. In *Las Americas Immigrant Advocacy Center v. U.S. Department of Homeland Security*, 348 F.R.D. 397, 403–04 (D.D.C. 2025), the Court denied intervention to the State of Texas because its asserted injury was "too attenuated to support Article III standing." *Id.* at 403. And it declined to apply this Circuit's skepticism toward governmental representation for one reason only: Texas is a state, not a private party. *Id.* Here, Proposed Intervenors are private

parties, and their members are directly regulated beneficiaries of the challenged statutory framework. Likewise, *Pharmaceutical Research & Manufacturers of America v. U.S. Department of Health & Human Services*, 43 F. Supp. 3d 28, 41 (D.D.C. 2014), confirms that Congress authorized the Secretary to establish the ADR process that AbbVie seeks to bypass. *Id.* And to the extent that AbbVie argues that Defendants' authority to defend the definition of "patient" is contested and narrow, that makes the Government's litigating defense more fragile, not less. Moreover, AbbVie's invocation, Opp. 20, of *Citizens for Responsibility & Ethics in Washington v. FEC*, No. 22-cv-3281-RC, 2023 WL 6141887 (D.D.C. Sep. 20, 2023), and *Motor Vehicle Manufacturers Ass'n v. State Farm Mutual Automobile Insurance Co.*, 463 U.S. 29 (1983), misuses the *Chenery* principle. That doctrine constrains the court's basis of review. *See SEC v. Chenery Corp.*, 332 U.S. 194, 196 (1947). It does not guarantee that the Government will defend vigorously, decline to settle, or pursue an appeal—the very divergence risks *Crossroads* recognizes. 788 F.3d at 318. And *HRH Services, LLC v. Travelers Indemnity Co.*, No. 23-cv-2300 (JDB), 2024 WL 4699925 (D.D.C. Nov. 6, 2024), is an insurance coverage dispute that says nothing about a structural adjudicator conflict that impacts the adequacy of representation.

Finally, AbbVie does not dispute that the D.C. Circuit "look[ed] skeptically on government entities serving as adequate advocates for private parties." *See* Opp. 15 (quoting *Crossroads*, 788 F.3d at 321). AbbVie cites *Crossroads* as "overruled on other grounds," as recognized by *Institutional Shareholder Services, Inc. v. SEC*, 142 F.4th 757, 764 n.3 (D.C. Cir. 2025) ("*ISS*"). Opp. 15. But the decision of the D.C. Circuit in *ISS* refined only a standing point: an intervenor that "seek[s] the same relief sought by at least one existing party need not" independently establish standing. *Id.* (citing *Little Sisters of the Poor Saints Peter & Paul Home v. Pennsylvania*, 591 U.S.

657, 674 n.6 (2020)). In contrast, the D.C. Circuit's holding in *Crossroads* regarding adequacy of representation stands untouched. *See generally id.*, 142 F.4th 757.

To be sure, Proposed Intervenors seek the same relief as Defendants at this time—dismissal of AbbVie's complaint. But this position helps, rather than hurts, Proposed Intervenors with respect to standing, and does not render Defendants an adequate representative of Proposed Intervenors' interests. In addition, if this litigation proceeds beyond the motion to dismiss stage, Proposed Intervenors' arguments would not simply mirror those of the Defendants. Among other anticipated differences, Proposed Intervenors will advance a distinct statutory construction theory—the original plain meaning of "patient." *See supra* at 10.

For all these reasons, Proposed Intervenors have more than met their burden to demonstrate that Defendants may not adequately protect their interests in this litigation.

B. Proposed Intervenors Have a Legally Protected Interest that the Disposition of This Action Will Impair.

AbbVie's arguments against Proposed Intervenors' interest in this litigation, Opp. 11–18, also fail.

1. For example, AbbVie gives short shrift to the relevant standard for a protected interest: that is, a Rule 24(a) movant "need not show anything more than that it has standing to sue in order to demonstrate the existence of a legally protected interest." *Mova Pharm. Corp. v. Shalala*, 140 F.3d 1060, 1076 (D.C. Cir. 1998). And, as this Court has held, "all three components of Article III standing" are satisfied when the plaintiffs' "desired relief would remove a benefit received by the [proposed intervenors] under the challenged policy." *Ass'n of Wash. Bus. v. U.S. EPA*, No. 23-cv-3605 (DLF), 2024 WL 3225937, at *11 (D.D.C. June 28, 2024); *see Forest Cnty. Potawatomi Cmty. v. United States*, 317 F.R.D. 6, 13 (D.D.C. 2016).

That is the case here, where a ruling adopting AbbVie's narrowed "patient" definition would remove benefits that Proposed Intervenors' members receive under the 340B program. *See* Mot. at 18–21 (demonstrating standing). Lost 340B savings are an immediate, non-conjectural financial harm, and "[e]conomic harm to a business clearly constitutes an injury-in-fact." *Carpenters Indus. Council v. Zinke*, 854 F.3d 1, 5 (D.C. Cir. 2017) (citing *Czyzewski v. Jevic Holding Corp.*, 580 U.S. 451, 464 (2017)); *see also Johnson & Johnson Health Care Sys. Inc. v. Kennedy*, No. 24-cv-3188 (RC), 2025 WL 1411076, at *2–4 (D.D.C. May 15, 2025) (granting 340B covered entities and their association intervention as of right against a manufacturer's challenge to HRSA's administration of the 340B Program).

2. AbbVie's attempt to characterize this lawsuit as one that involves only two audits, Opp. 11, 17, is also a litigating fiction. The relief that AbbVie seeks goes far beyond its two audit workplans: AbbVie expressly asks this Court to declare its construction of "patient" to be the "best meaning of the term as it is used in the 340B statute." Compl. 70 (Prayer ¶ 5). That is program-wide relief that would jeopardize the 340B eligibility of patients of every covered entity, not a bounded, as-applied challenge restricted to two audits. As set forth in the Motion, a judgment for AbbVie would authorize manufacturer audits "under a materially narrower standard than the plain text of the statute and HRSA's guidance," exposing members to "unlawful manufacturer audit findings, repayment demands, and corrective-action disputes." Mot. 11, 19–20 (citing Decl. of K. Rhee in Support of NACHC Mot. Intervene ¶¶ 38, 47–48 (Dkt. 26-1) ("NACHC Decl.")). Accordingly, the harms that Proposed Intervenors identify are concrete, statutorily cognizable, and litigation-caused.

Further, the cases cited by AbbVie to support its argument that Proposed Intervenors have only conjectured differences with Defendants (Opp. 16–17, 20–21) are inapposite because

Proposed Intervenors' harm does not turn on a chain of independent contingencies. *Cf. Deutsche Bank Nat'l Tr. Co. v. FDIC*, 717 F.3d 189, 193–94 (D.C. Cir. 2013) (potential harm to movants' economic interest was not likely to be "actual or imminent" because "at least two major contingencies must occur" before the suit "could result in economic harm" to them); *Crossroads*, 788 F.3d at 317–18; *Campaign Legal*, 68 F.4th at 610. Here, AbbVie's requested relief would, by its own terms in the Complaint, fix the meaning of "patient" program-wide. That puts current, concrete benefits at stake.

3. Nor does AbbVie's argument that Proposed Intervenors' asserted interest is no different "from that of the tens of thousands of other covered entities" apply here. *Cf.* Opp. 22. To the contrary, Proposed Intervenors' members are the direct statutory beneficiaries of the 340B Program and are the providers that establish patient relationships. Those members are the very class that Congress created the Section 340B Program to protect, not undifferentiated members of the public.

And AbbVie's arguments about the overlap between Proposed Intervenors' and Defendants' threshold jurisdictional defenses do not eliminate Proposed Intervenors' independent interest in the litigation. Indeed, shared jurisdictional positions say little about whether the Defendants will adequately represent Proposed Intervenors' broader interests in this litigation. *See supra* at 7–13.

4. Finally, *Loper Bright Enterprises v. Raimondo*, 603 U.S. 369 (2024), does not rescue AbbVie's arguments. Opp. 12, 13–14, 17–18. It addresses the standard of review once a justiciable case is properly before the court; it says nothing about ripeness, finality, or Rule 24. If anything, *Loper Bright*'s command that courts exercise independent judgment on a statute's meaning—and its preservation of respect for an agency's contemporaneous and consistent

interpretations, 603 U.S. at 386, 402—underscores why Proposed Intervenors, who press the original plain meaning that no existing party defends, must be heard.

In short, AbbVie improperly conflates a merits-review standard into both a grant of jurisdiction and a bar to intervention. It is neither. This Court should grant Proposed Intervenors' Motion because they have shown that intervention as of right is warranted.

III. In the Alternative, Permissive Intervention Is Appropriate.

AbbVie's arguments against permissive intervention also fail. *Cf.* Opp. 21–23. The D.C. Circuit's approach to permissive intervention is "flexible" and "generous"—recognizing that courts should allow intervention whenever it would not disrupt the original parties' rights. *EEOC v. Nat'l Children's Ctr., Inc.*, 146 F.3d 1042, 1045–46 (D.C. Cir. 1998). Here, as Proposed Intervenors have already shown (Mot. 35–36), their defense shares common questions of law with the main action and their participation would not delay or prejudice the existing parties.

AbbVie argues otherwise—that Proposed Intervenors add no unique claim or defense, that amicus is the proper vehicle, and that Proposed Intervenors duplicate the hospital movants. Opp. 21–23. But each contention misconstrues the pertinent standard.

First, sharing a defense is not problematic; no unique claim is required. *Sault Ste. Marie Tribe of Chippewa Indians v. Bernhardt*, 331 F.R.D. 5, 14 (D.D.C. 2019). And courts in the D.C. Circuit typically grant organizations permissive intervention precisely because they seek the same outcome as the defendants and their proposed defense shares a common question of law with the main action. *See Campaign Legal Ctr. v. Fed. Election Comm'n,* 334 F.R.D. 1, 6 (D.D.C. 2019) (granting permissive intervention to political action committee because its claim or defense "share[d] with the main action a common question of law or fact." (quoting Fed. R. Civ. P. 24(b)(1)(B))); *Sierra Club*, 523 F. Supp. 2d at 10 (granting permissive intervention where

intervenors "ha[d] defenses with common questions of law and fact" with a parties' claims.). In other words, alignment with a defendant is a reason to *grant* permissive intervention, not to deny it.

Second, contrary to AbbVie's assertions, Opp. 2, 7, 18, 23, *amicus* status is not a sufficient substitute to intervention. *Amici* cannot make requests, file motions, present evidence, or appeal. So *amicus* participation cannot protect grantee covered entities' interests in their institutional survival, particularly where the only party defending the administrative process is the adjudicator of it. *See supra* at 7–8. And AbbVie's own authority makes the point: in *Campaign Legal Center*, the court previously admonished the movant that "[t]he amicus is not a party to this case, so to the extent the brief goes beyond offering its position on whether the pending motion . . . should be granted or denied, and it seeks affirmative relief . . . it is improper." 2022 WL 2111560, at *4 (quoting Min. Order (Jan. 24, 2022)).

Third, AbbVie's argument that Proposed Intervenors' Motion should be denied because their participation is "duplicative" of the other proposed intervenors is also wrong. The other proposed intervenors, including 340B Health, represent hospitals. In contrast, NACHC and RWC-340B represent grantee covered entities that, unlike hospitals, are subject to the third prong of the 1996 Guidance on "patient" definition, commonly referred to as the "scope-of-grant" test. Notice Regarding Section 602 of the Veterans Health Care Act of 1992 Patient and Entity Eligibility, 61 Fed. Reg. 55156, 55157–58 (HHS Oct. 24, 1996) (final notice); Mot. at 21 n.3, 27.

Moreover, courts routinely permit multiple aligned intervenors representing distinct constituencies. *See, e.g.*, *WildEarth Guardians v. Salazar*, 272 F.R.D. 4 (D.D.C. 2010) (authorizing multiple intervenors); *Ctr. for Biological Diversity v. Regan*, 734 F. Supp. 3d 1 (D.D.C. 2024) (same), *aff'd sub nom. Ctr. for Biological Diversity v. Zeldin,* 171 F.4th 356 (D.C. Cir. 2026). In such circumstances, any efficiency concern is met by conditions—consolidated,

page-limited briefing and adherence to the schedule—as imposed in *Farmer*. 759 F. Supp. 3d at 111.

AbbVie's reliance on authorities from outside this circuit is likewise unpersuasive. *Cf.* Opp. 21–22 (citing *Hodes & Nauser, MDs, P.A. v. Moser*, No. 2:11-cv-02365-CM-KMH, 2011 WL 4553061 (D. Kan. Sep. 29, 2011); *McLean v. Arkansas*, 663 F.2d 47 (8th Cir. 1981); *New Orleans Pub. Serv., Inc. v. United Gas Pipe Line Co.*, 732 F.2d 452 (5th Cir. 1984) (en banc)). Those authorities do not displace this Court's settled, flexible practice on permissive intervention.

And the Supreme Court's decision in *Allen Calculators, Inc. v. National Cash Register Co.*, 322 U.S. 137 (1944), is inapposite. *Cf.* Opp. 22. There, the district court determined that intervention would "unduly delay or prejudice the adjudication of the rights of the original parties," and the Supreme Court determined that finding was not an abuse of discretion. *Allen Calculators*, 322 U.S. at 141–42. Here, AbbVie has not—and cannot—show that Proposed Intervenors' participation in this case will cause any undue delay or prejudice.

Finally, AbbVie's arguments underscore why Proposed Intervenors have a direct stake in this litigation. Congress prescribed a specific administrative process for resolving diversion disputes, including audit, notice and hearing, a compliance determination, and administrative dispute resolution. 42 U.S.C. § 256b(a)(5)(C)–(D), (d)(3). Proposed Intervenors' members are among the covered entities whose rights and liabilities are adjudicated through that process. AbbVie's effort to bypass those procedures and obtain an immediate judicial declaration concerning the meaning of "patient," therefore, affects interests that belong not only to Defendants, but also to the covered entities that Proposed Intervenors represent.

CONCLUSION

Because Proposed Intervenors have vital interests at stake in this litigation that Defendants do not adequately represent, they respectfully request that the Court grant their Joint Motion to Intervene as of right under Rule 24(a)(2) or, in the alternative, grant permissive intervention under Rule 24(b).

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Respectfully submitted

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