

IN THE UNITED STATES COURT OF APPEALS
FOR THE FIRST CIRCUIT

THE AMERICAN HOSPITAL ASSOCIATION, *et al.*,
Plaintiffs-Appellees,

v.

ROBERT F. KENNEDY, JR., Secretary of the U.S. Department of Health and
Human Services, *et al.*,
Defendants-Appellants.

On Appeal from the United States District Court
for the District of Maine (Hon. Lance E. Walker)

**PLAINTIFFS-APPELLEES' OPPOSITION TO ABBVIE INC.,
PHARMACYCLICS LLC, PHRMA, ASTRAZENECA
PHARMACEUTICALS LP, BOEHRINGER INGELHEIM
PHARMACEUTICALS, INC. & NOVO NORDISK INC.'S
MOTION TO INTERVENE ON APPEAL**

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PRELIMINARY STATEMENT

This is a straightforward administrative law case. Plaintiffs allege that the Defendants’ 340B Rebate Model Pilot Program (the “Rebate Program”) violated several of the Administrative Procedure Act’s substantive requirements and sought a preliminary injunction to stop this unlawful agency action from taking effect on January 1, 2026. In a “careful and thorough decision,” the district court “determined that the federal government had failed to consider the hospitals’ reliance interests and other important aspects of the problem in enacting the new program.” Order Denying Stay Pending Appeal, Doc. 00118387963 at 1. Given the “irreparable harm, including potential closure,” that hospitals faced, the district court granted the preliminary injunction. *Id.*

Defendants have vigorously defended their program both in the district court and before this Court. Nevertheless, four drug companies and one drug company trade association (“Movants”) seek to intervene. These Movants unsuccessfully sought to intervene in the district court. In an equally “careful and thorough” opinion, the district court concluded that Movants’ interests in seeing the Rebate Program implemented are adequately represented by the government Defendants. Dkt. 83.¹ Movants are appealing that decision to this Court, *see* No. 25-2237, but separately

¹ Citations to “Dkt.” refer to *Am. Hosp. Ass’n v. Kennedy*, No. 2:25-cv-00600-LEW (D. Me.).

filed this present motion. Movants, however, do not get two bites at the apple; they would need to first win their appeal of the district court’s decision before they can seek to participate as a party in this present appeal. *See Nuclear Regul. Comm’n v. Texas*, 605 U.S. 665, 678-80 (2025). Movants’ maneuver should therefore be denied as premature.²

More generally, Movants have no likelihood of success on their appeal of the district court’s denial of their motion to intervene. It remains the case that the government does not need drug companies to defend its record, reasoning, and reasonableness before this Court. This APA case turns on the *government’s* record—not documents and policy arguments preferred by private parties. *See, e.g., Fla. Power & Light Co. v. Lorion*, 470 U.S. 729, 743-44 (1985) (“The task of the reviewing court is to apply the appropriate APA standard of review, 5 U.S.C. § 706, to the agency decision based on the record the agency presents to the reviewing court.”). And it remains the case that Movants cannot make the requisite “strong affirmative showing” that the government is not representing their interests in the Rebate Program by pointing out that the government does not stand exactly in Movants’ shoes. *Victim Rts. L. Ctr. v. Rosenfelt*, 988 F.3d 556, 561 (1st Cir. 2021).

² As explained in the letter submitted to the Court this morning (Doc. 00118389298), Defendants “plan to dismiss the appeal in short order,” meaning there will be no appeal in which Movants could intervene. Plaintiffs therefore expect it will be unnecessary for this Court to decide this motion but submit this opposition in the event that a decision becomes necessary.

This Court should decline to reward Movants' efforts to avoid litigating the merits of their own intervention appeal by asking to intervene anew in the government's preliminary injunction appeal.

ARGUMENT

I. Movants' Present Motion Should Be Denied As Premature.

As Movants acknowledge, the district court denied their motions to intervene, Mot. 3, and instead considered their submissions as *amicus curiae* briefs in accordance with this Court's precedents. Dkt. 83 at 1, 13 (citing *Victim Rts. L. Ctr.*, 988 F.3d at 564; *Mass. Food Ass'n v. Mass. Alcoholic Beverages Control Comm'n*, 197 F.3d 560, 568 (1st Cir. 1999)). In considering Movants' separate appeal of that denial, this Court will review the district court's decision for abuse of discretion. *E.g.*, *Victim Rts. L. Ctr.*, 988 F.3d at 558. But that appeal is not yet before this Court.

Instead, Movants now ask this Court to consider their motions to intervene afresh and allow them to participate in the government's merits appeal as if they had been granted party status below. That is not how the process works. Where Movants have been denied intervention at the district-court level, Movants "may not obtain appellate review" of the preliminary injunction order "unless and until the denial of intervention is reversed." *Nuclear Regul. Comm'n*, 605 U.S. at 679-80. Indeed, Movants cite no case in which a party whose motion to intervene was denied by the district court was then permitted to intervene on the merits appeal

while simultaneously appealing the district court’s intervention denial.³

Permitting Movants to proceed that way here would reward “procedural gamesmanship” by allowing Movants to avoid the abuse of discretion standard that properly applies to the district court’s intervention-denial decision. *Richardson v. Flores*, 979 F.3d 1102, 1105 (5th Cir. 2020) (“If we analyzed motions to intervene on appeal using the same framework district courts use to address motions to intervene there, litigants would effectively have *de novo* review . . . [A]llowing intervention on appeal only in an exceptional case for imperative reasons is necessary to prevent such procedural gamesmanship.” (quotation omitted)); *Ne. Ohio Coal. for Homeless v. Husted*, 696 F.3d 580, 589 n.4 (6th Cir. 2012) (“Because [movant’s] appeal remains pending and is the proper avenue to address the intervention arguments raised in the district court, we denied their motion to intervene on appeal and permitted their alternative request to file amicus briefs.”).

And gamesmanship is exactly what Movants appear to be engaged in here. The district court denied Movants’ motion to intervene on December 18, 2025. Dkt.

³ In the one case cited by Movants where parties were allowed to intervene on future appeals despite having motions denied below, this Court explicitly noted the “unusual circumstances” concerning future *en banc* or Supreme Court proceedings and the would-be intervenors’ “helpful advocacy.” *Ruthardt v. United States*, 303 F.3d 375, 386 (1st Cir. 2002). Consequently, this Court decided to “exercise [its] own discretion” to grant intervenor status “on a going-forward basis” after it had already decided the pending appeals. *Id.* No such unusual circumstance exists here.

83. Movants filed a notice of appeal of that denial but still have not filed any substantive documents in that appeal (presumably to avoid abuse-of-discretion review). *See* No. 25-2237. To the extent that Movants claim that timing concerns necessitate deviation from the ordinary course, that is an issue of their own making, as they have waited almost a month to file anything of substance in their proper appeal.

There is no reason to deviate from the ordinary rules governing intervention. Indeed, this Court’s recent denial of the government’s motion for a stay pending appeal moots the majority of the argument in Movant’s brief. *See* Mot. 18-28. And the government’s forthcoming dismissal of this appeal moots the issue altogether. *See supra* at 4 n. 3. To avoid rewarding gamesmanship in this case and incentivizing similar tactics in the future by other putative intervenors, and to avoid a needless use of judicial resources, this Court should summarily deny Movant’s present motion and await their actual (albeit meritless) appeal.

II. Movants Cannot Succeed On Their Intervention Appeal.

Movants state that they will address the district court’s denial of their motions to intervene in their “separate appeal,” Mot. 16, which is the appropriate forum for such arguments. Instead, they offer what they call an “abbreviated” discussion of their arguments in the instant Motion. *Id.* Those arguments are meritless. The district court’s application of Federal Rule of Civil Procedure 24 was well within its

discretion, and that court’s reasoning further illustrates why intervention should be denied here. *See Cameron v. EMW Women’s Surgical Ctr., P.S.C.*, 595 U.S. 267, 276 (2022) (providing that district court intervention standard is instructive in absence of separate standard in Federal Rules of Appellate Procedure).

To intervene as of right in the district court, Movants needed to demonstrate: 1) “a concrete interest in the pending action,” 2) “a realistic threat that the resolution of the pending action will hinder [their] ability to effectuate that interest,” 3) “the absence of adequate representation by any existing party,” and 4) “the timeliness of [their] motion.” *SEC v. LBRY, Inc.*, 26 F.4th 96, 99 (1st Cir. 2022) (cleaned up); *T-Mobile Ne., LLC v. Town of Barnstable*, 969 F.3d 33, 39 (1st Cir. 2020). Movants fell (and continue to fall) short of that standard in numerous ways:

Movants Are Adequately Represented by the Government Defendants.

As the district court correctly held, “because Movants fail to demonstrate that Defendants cannot adequately represent their interests,” they “are not entitled to intervene.” Dkt. 83 at 11. “Movants’ unadorned assertions that Defendants’ public duty prevents them from adequately representing Movants’ industry-based interests in this lawsuit, which challenges whether a federal agency complied with its obligations under the APA, does not satisfy the Circuit’s heightened burden of persuasion for intervention by right when the government defends its own regulation.” *Id.* at 9.

This Court has held that a proposed intervenor faces a heightened burden when seeking to intervene alongside the government. *E.g., Victim Rts. L. Ctr.*, 988 F.3d at 561; *Pub. Serv. Co. of N.H. v. Patch*, 136 F.3d 197 (1st Cir. 1998). Movants argue that this Court’s presumption of adequate government representation has been “call[ed] . . . into question” by the Supreme Court’s decision in *Berger v. N.C. State Conference of the NAACP*. Mot. 13. Not so. As the district court rightly explained, Movants’ argument is “misguided” because “the [Supreme] Court made clear its decision [in *Berger*] did ‘not decide whether a presumption of adequate representation might sometimes be appropriate when a private litigant seeks to defend a law alongside the government.’” Dkt. 83 at 5 n.2 (quoting *Berger*, 597 U.S. 179, 197 (2022)). Instead, the Supreme Court narrowly held that “a presumption of adequate representation is inappropriate when a duly authorized state agent seeks to intervene to defend a state law.” *Berger*, 597 U.S. at 197.

Given that Movants are undisputedly not “duly authorized state agents,” *Berger* has no effect on the applicability of this Court’s cases applying a presumption of adequate representation where a private party seeks to intervene alongside the government. *E.g., Victim Rts. L. Ctr.*, 988 F.3d at 561-62 ; *T-Mobile Ne.*, 969 F.3d at 39-40. Where, as here, a Supreme Court decision does not “foreclose[]” application of existing Circuit precedent, this Court is “bound” to apply that law “[u]ntil the Supreme Court provides more guidance” or the *en banc* Court overturns prior panel

decisions. *Cavallaro v. UMass Memorial Healthcare, Inc.*, 678 F.3d 1, 7 (1st Cir. 2012).

Accordingly, Movants continue to face a heightened burden when seeking to intervene alongside the government. They must make “a strong affirmative showing that the [government] agency (or its members) is not fairly representing [their] interests.” *Victim Rts. L. Ctr.*, 988 F.3d at 561 (quoting *Patch*, 136 F.3d at 207). Movants do not dispute that they share the government’s litigation objective of implementing the Rebate Program as soon as possible. *E.g.*, Mot. 1; *T-Mobile Ne.*, 969 F.3d at 39 (representation adequate where proposed intervenor shared defendant’s “same ultimate goal”); *LBRY*, 26 F.4th at 99 (same where proposed intervenor “concedes that it shares [defendant’s] litigation objective”). But Movants argue that the government cannot adequately represent them here because: 1) they are regulated by the government, 2) they disagree with the government on issues not germane to this case, and 3) they wish to make submissions that the government may not. Mot. 13-17. Each argument fails under this Court’s precedents.

First, this Court has expressly rejected the argument that the government “cannot be an adequate representative of [Movants’] interests while it also regulates them.” *Mass. Food Ass’n*, 197 F.3d at 567.⁴ It is not necessary for the government

⁴ The case Movants cite to assert the contrary does not support their position. *See* Mot. 3. *Housatonic River Initiative v. EPA* involved an *unopposed* request to intervene in a direct appeal from an agency order under Federal Rule of Appellate

and Movants to have “perfect identity of motivational interests” spurring their desires to see the Rebate Program implemented for the government to be an adequate representative. *Victim Rts. L. Ctr.*, 988 F.3d at 562; *see also Daggett v. Comm’n on Gov’t Ethics & Election Practices*, 172 F.3d 104, 112 (1st Cir. 1999) (“The general notion that the [government] represents ‘broader’ interests at some abstract level is not enough.”).

Second, the fact that some Movants are engaged in other litigation against the government does not “create a sufficient *case-specific conflict*” to require intervention. *Victim Rts. L. Ctr.*, 988 F.3d at 562 (emphasis added). Defendants and Movants differ in their views on whether drug companies can *unilaterally* implement 340B rebate programs *without* HRSA approval. That entirely distinct legal question is the subject of litigation in the D.C. Circuit, and the district court was careful not to address it in its preliminary injunction decision. Dkt. 90 at 7 (“Assuming without questioning the Secretary’s discretion to choose between discounts and rebates to effectuate 340B price concessions . . .”). Critically, Defendants and Movants *both* endorse the position that HRSA has the authority to implement *this* Rebate Program.

Procedure 15(d), which the Clerk of Court granted without any discussion. No. 22-1398, Doc. 00117890595 (1st Cir. June 22, 2022). This non-precedential order cannot overcome this Court’s cases establishing regulated entities are not entitled to intervene simply by virtue of being regulated by the government. Nothing about *Housatonic River Initiative* changes the fundamental principle that a party—regulated or otherwise—has no right to intervene absent a showing of inadequate representation in the particular case.

Furthermore, Movants’ protestations that they did not, as of December 31, 2025, have alternative ways to deduplicate discounts, Mot. 14-15, has no bearing on the merits of Plaintiffs’ claims that the government violated the APA.

The district court correctly understood that this APA case “turns entirely” on the administrative record, Dkt. 83 at 10, and Movants’ “contributions do not constitute the administrative agency record,” Dkt. 90 at 11. *See, e.g., Fla. Power & Light Co.*, 470 U.S. at 743-44 (“The task of the reviewing court is to apply the appropriate APA standard of review, 5 U.S.C. § 706, to the agency decision based on the record the agency presents to the reviewing court.”). The government has offered a “vigorous, no-holds-barred defense” of its own program, and Movants offer nothing but “speculation and surmise” that their tangential disagreements with the government will impact their representation. *See T-Mobile Ne.*, 969 F.3d at 39-40.

Third, and relatedly, the fact that Defendants are not attempting to submit Movants’ documents as the administrative record and adopting Movant’s professed harms as their own does not render them inadequate representatives.⁵ This Court has affirmed denials of motions to intervene even where putative intervenors have raised relevant additional legal arguments. *E.g., Victim Rts. L. Ctr.*, 988 F.3d at 561-62;

⁵ Notably, the government has, in fact, emphasized harms to Movants in its submissions. Doc. 001185034 at 9-10; Doc. 00118385633 at 3. Movants are therefore flat wrong that “[t]he government’s submissions did not explain these harms—at all.” Mot. 16.

LBRY, 26 F.4th at 99-100; *Mass. Food Ass'n*, 197 F.3d at 567. So the government's representation certainly remains adequate here where Movants' complaint is that they are not being permitted to break the well-established rule limiting review of agency actions to the *agency's* administrative record.⁶ *Murphy v. Comm'r of Internal Revenue*, 469 F.3d 27, 31 (1st Cir. 2006); *Fla. Power & Light Co.*, 470 U.S. at 743-44.

Movants ignore this Court's recent cases affirming denials of attempts to intervene alongside the government. *See* Mot. 11-17. Instead, they rely heavily on an out-of-circuit opinion, *Driftless Area Land Conservancy v. Huebsch*, 969 F.3d 742, 749 (7th Cir. 2020). But the Seventh Circuit's decision in *Driftless* does not help Movants either. There, the would-be intervenors, not the defendant regulatory commission, had to defend constitutional claims expressly challenging their use of eminent domain. *Id.* at 744-45, 749. The court of appeals found that the would-be intervenors were entitled to defend against the "attack [on] the use of eminent domain," and that the defendant regulatory commission could "be expected to

⁶ Movants repeatedly argue that the district court ignored their submissions. *E.g.*, Mot. 1, 11, 23. That is not true. The district court considered the hundreds of pages Movants filed as *amicus* submissions, Dkt. 83 at 13, and expressly explained in its preliminary injunction decision why Movants could not submit their own documents as the "administrative record," Dkt. 90 at 11. In fact, Plaintiffs argued that the court should disregard Movants' documents because they were submitted *after* the close of briefing and oral argument. Dkt. 89. The district court nonetheless specifically addressed those documents in its opinion.

defend the procedural regularity of its proceedings.” *Id.* at 748.⁷ There is no such division of claims and interests here. In this case, Plaintiffs challenge *only* the government defendants’ actions, and the government has vigorously defended those actions. Consequently, *Driftless Area Land Conservancy* is inapt, and Movants have failed to overcome the presumption that the government Defendants will adequately represent their interests. The motion can and should be denied on that basis alone. *See T-Mobile Ne.*, 969 F.3d at 39 (holding that courts may “start—and end—” with adequacy of representation).

Movants’ Interests in the Rebate Program Are Fatally Contingent.

Though the district court did not need to reach this issue, Movants also fail to meet the requirements for intervention as of right because they lack a “direct, not contingent” interest in the Rebate Program. *Travelers Indem. Co. v. Dingwell*, 884 F.2d 629, 638 (1st Cir. 1989). Movants claim that, without the Rebate Program, drug companies will lose \$4 billion in duplicate discounts in 2026 and risk penalties for failing to provide statutorily required discounts. Mot. 1. Though Movants cite the \$4 billion figure often, they *never* explain how it was calculated or what assumptions it relies on, except to note that it came from the parent company of Beacon (the

⁷ Nor is the Fifth Circuit’s decision in *Wal-Mart Stores, Inc. v. Texas Alcoholic Beverages Commission*, 834 F.3d 562 (5th Cir. 2016), instructive, as it turned on that court’s “broad policy favoring intervention” that is not shared by this Court’s precedents, particularly where the government is defending its own regulatory action.

software vendor they hired to administer the Rebate Program), which has its own financial self-interests here. *E.g.*, Dkt. 36-1 ¶ 18; Dkt. 45-1 ¶ 18.⁸ In addition, whatever expectations are baked into their arguments, Movants' purported financial estimate necessarily hinges on the assumption that covered entities will improperly attempt to claim both 340B and Inflation Reduction Act discounts, but they offer no actual evidence that this misbehavior will occur. And perhaps most important, it is not clear whether Movants' figure accounts for the fact that they have other ways to deduplicate discounts. The government has clarified—in both this Circuit and the D.C. Circuit—that the Rebate Program is *not* the only way drug companies can comply with the Inflation Reduction Act and 340B. Doc. 00118385034 at 8, 13; *Novartis Pharm. Corp. v. Kennedy*, No. 25-5177 (D.C. Cir.), Doc. 2152409 at 2. Movants do not appear to account for those alternative deduplication mechanisms when claiming their costs are non-contingent.

Nor do Movants offer any actual evidence that the preliminary injunction against the Rebate Program will expose them to statutory penalties, as such penalties can be avoided by simply making the lower of the 340B ceiling price and the Maximum Fair Price available prospectively. *See* 42 U.S.C. § 1320f-6(a) (no penalty for providing drug at price lower than Maximum Fair Price). Instead, this is “a case

⁸ This \$4 billion figure is also more than a year old, having been estimated in October 2024. It predates the announcement of the Rebate Program by ten months.

in which these would-be intervenors root their professed economic interest in an as yet unrealized expectancy” of government penalties or discount savings lost to unproven non-compliance. *Patch*, 136 F.3d at 205-06. “[N]umerous market variables” make it “anybody’s guess” whether, when, and how Movants’ economic interests actually will be harmed. *Id.* at 206. Consequently, their asserted interests are “fatally contingent.” *Id.*

Movants’ Intervention Risks Prejudicing the Existing Parties and Would Not Aid This Court. In addition to their failure to satisfy the elements for intervention as of right, Movants should not be permitted to intervene. Such intervention would contravene the policy underlying permissive intervention in district courts, which requires “consider[ation of] whether the intervention will unduly delay or prejudice the adjudication of the original parties’ rights.” Fed. R. Civ. P. 24(b)(3). As discussed *supra* pp. 6-12, Movants are adequately represented by the government for purposes of litigating Plaintiffs’ APA claims actually at issue here, and that adequate representation counsels against permissive intervention. *T-Mobile Ne.*, 969 F.3d at 41-42.

Movants still seek to intervene to introduce arguments and additional documents that are not relevant to the adjudication of Plaintiffs’ APA claims. As unhappy as they may be, Movants cannot rewrite the agency’s decision-making or record. *See Mass. Food Ass’n*, 197 F.3d at 567 (“This is not a case where the

complaint was framed so as to require an evidentiary determination and where the would-be intervenors had information that could only be presented by their participation as parties."); *see also T-Mobile Ne.*, 969 F.3d at 41 (putative intervenor's ability to assist case development is properly considered in permissive intervention inquiry). And neither Plaintiffs nor the government Defendants should have to waste resources continuing to respond to Movants' inapposite submissions.

CONCLUSION

This Court should deny the motion to intervene.

Dated: January 12, 2026

Respectfully submitted,

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CERTIFICATE OF COMPLIANCE

This brief complies with the type-volume limit of Federal Rule of Appellate Procedure 27(d)(2)(A) because it contains 3,562 words. This brief also complies with the typeface and type-style requirements of Federal Rule of Appellate Procedure 32(a)(5)-(6) because it was prepared using Microsoft Word in Times New Roman 14-point font, a proportionally spaced typeface.

/s/ L. Rush Atkinson

L. Rush Atkinson