

UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF MAINE

THE AMERICAN HOSPITAL
ASSOCIATION, et al.,

Plaintiffs,

v.

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

Defendants.

Case No. 1:26-cv-00515-LEW

**PLAINTIFFS’ OMNIBUS OPPOSITION
TO THE MOTIONS TO INTERVENE
FILED BY ABBVIE INC.,
PHARMACYCLICS LLC, BRISTOL-
MYERS SQUIBB COMPANY, AND
BOEHRINGER INGELHEIM
PHARMACEUTICALS, INC. (ECF NO.
15) AND PHARMACEUTICAL
RESEARCH AND MANUFACTURERS
OF AMERICA (ECF NO. 33)**

PRELIMINARY STATEMENT

This Court has seen, considered, and rejected these motions before. This year’s versions are even less persuasive.

Last year, several drug companies and a trade association moved to intervene alongside the government to defend HRSA’s first proposed 340B rebate program. This Court denied intervention because the movants could not articulate “how their participation as a party would illuminate the administrative record on which this case turns entirely.” *Am. Hosp. Ass’n v. Kennedy*, 2025 WL 3677386, at *4 (D. Me. Dec. 18, 2025) (“Intervention Order”), *vacated as moot*, 2026 WL 2913956 (1st Cir. Sept. 25, 2026). This Court also held that claims of inadequate representation were “founded entirely on speculation,” and the movants remained “completely silent” on what arguments the government would forsake. *Id.* It allowed them to proceed as *amici*. *Id.* at *5.

Like last year, this is a straightforward Administrative Procedure Act case centered on an existing administrative record. Yet three drug companies and the same trade group (collectively, “Movants”) again seek to intervene, asking for a different result on the same facts and law. ECF No. 15 (“Mfrs. Mot.”); ECF No. 33 (“PhRMA Mot.”). Intervention remains unwarranted. The

government can present and defend the administrative record; Movants offer nothing meaningful to add to that undertaking. *See Mass. Food Ass’n v. Mass. Alcoholic Beverages Control Comm’n*, 197 F.3d 560, 567 (1st Cir. 1999). And the strong presumption of adequate representation by the government in this kind of regulatory action applies fully (and is unrebutted by Movants). *See id.* at 566–67 (noting presumption); *Victim Rts. L. Ctr. v. Rosenfelt*, 988 F.3d 556, 561–62 (1st Cir. 2021) (same); *Pub. Serv. Co. of N.H. v. Patch*, 136 F.3d 197, 207 (1st Cir. 1998) (same).

This Court’s decision last year was correct. Its vacatur under *United States v. Munsingwear* reflects only the drug companies’ insistence on litigating intervention for seven months after the underlying case had ended. *Am. Hosp. Ass’n*, 2026 WL 2913956, at *3. “Vacatur, unlike a reversal of the district court’s judgment on the merits, does not reflect upon the underlying merits of the parties’ claims, which the court no longer has jurisdiction to determine.” *Diffenderfer v. Gomez-Colón*, 587 F.3d 445, 451 (1st Cir. 2009). The Court’s prior reasoning remains sound, and the motions should be denied. Plaintiffs again do not object to Movants’ participation as *amici*.

ARGUMENT

I. Movants Have No Right to Intervene Under Rule 24(a)(2).

A party seeking intervention as of right must show a concrete interest, a realistic threat to it, “the absence of adequate representation by any existing party,” and timeliness. *SEC v. LBRY, Inc.*, 26 F.4th 96, 99 (1st Cir. 2022); *T-Mobile Ne. LLC v. Town of Barnstable*, 969 F.3d 33, 39 (1st Cir. 2020). “A failure to satisfy any one of these four requirements is sufficient grounds to deny a request for intervention as of right.” *LBRY*, 26 F.4th at 99. Movants fail the first three.

Adequate Government Representation. It is settled law in the First Circuit that when a private party seeks to intervene alongside the government defending some official action, courts “start with a rebuttable presumption that the government will defend adequately its action.”

Rosenfelt, 988 F.3d at 561; *see also Patch*, 136 F.3d at 207. In these circumstances, movants must make “a strong affirmative showing that the [government] agency (or its members) is not fairly representing [their] interests.” *Rosenfelt*, 988 F.3d at 561 (quoting *Patch*, 136 F.3d at 207); *T-Mobile*, 969 F.3d at 39 (private party must make a “strong affirmative showing” to intervene alongside a government defending “some official action”). That showing must rest on “some tangible basis,” not speculation, to support its claim. *Patch*, 136 F.3d at 207.

Movants insist that no presumption applies to them because they are “targeted regulated parties” that will benefit financially from the Program. Mfrs. Mot. at 6. But First Circuit precedent forecloses that argument. In *Massachusetts Food Association*, the First Circuit affirmed the denial of intervention to trade associations representing regulated parties that were both targets and economic beneficiaries of the challenged liquor-licensing law. 197 F.3d at 568. Despite Movants’ financial interests, the First Circuit recognized the presumption still applies when “a private party attacks a regulatory statute or administrative rule; the state or its regulators are its defendants; and other parties having an economic interest in the validity or invalidity of the statute or regulation seek to intervene.” *Id.* at 566.

Because Movants do not acknowledge that the presumption of adequate representation applies, they never try to make the “strong affirmative showing” required to rebut the presumption. Nor could they. Their arguments do not come close to “produc[ing] some tangible basis to support a claim of purported inadequacy.” *Rosenfelt*, 988 F.3d at 561.

First, Movants argue their interests “differ in degree and kind from those of the government.” Mfrs. Mot. at 7. But “perfect identity of motivational interests between the movant-intervenor and the government [is not] necessary to a finding of adequate representation,” *Rosenfelt*, 988 F.3d at 562, and “[t]he general notion that the [government] represents ‘broader’

interests at some abstract level is not enough,” *Daggett v. Comm’n on Governmental Ethics & Election Pracs.*, 172 F.3d 104, 112 (1st Cir. 1999). Movants share Defendants’ “litigation objective” in full—to ensure the Program takes effect on January 1, 2027. *LBRY*, 26 F.4th at 99.¹

Second, Movants assert three arguments Defendants supposedly will not make: (1) HRSA’s approvals were informal adjudications; (2) the correct remedy last year was remand without vacatur; and (3) it will not “underscore” the deduplication problems drug companies face. PhRMA Mot. at 2–3, 8–9; Mfrs. Mot. at 8. In reality, the government made all three arguments last year, either in motions or at hearings. *See* Emergency Mot. to Stay Injunction at 15–19, *Am. Hosp. Ass’n v. Kennedy*, No. 25-2236 (1st Cir. 2025) (arguing program involved informal adjudication); *id.* at 18 (seeking remand without vacatur); Notice Regarding Portions of the Administrative Record at 1–2, *Am. Hosp. Ass’n v. Kennedy*, No. 2:25-cv-00600 (“*AHA I*”) (D. Me. Dec. 22, 2025), ECF No. 85 (same); Transcript of Oral Argument at 47:25–48:17, *AHA I*, ECF No. 86 (discussing drug companies’ alleged deduplication problems).² The notion that Defendants will forsake these arguments this year is pure speculation. *Daggett*, 172 F.3d at 112 (“[I]t would take more than speculation to show that [the Government] is likely to soft-pedal arguments.”).

Movants also cannot manufacture a basis for intervention by advancing meritless positions. For example, Movants contend that informal adjudication warrants less demanding judicial review.

¹ This Court rejected this exact argument last year. *See* Intervention Order at *4 (Rule 24 does not require a “perfect identity of motivational interest” (quoting *Rosenfelt*, 988 F.3d at 561–62)).

² Movants also suggest the government will not argue that “a rebate model is the only practical way to harmonize the 340B and DPNP obligations.” Mfrs. Mot. at 7. This argument is fatally undermined by the fact that multiple drug companies elected *not* to participate in this year’s Program, Compl. ¶ 179 n.10, meaning those companies have found deduplication to be practicable without the Program. More generally, what the drug companies now believe is irrelevant. The only question is what *the government* believed at the time it took its official action, and the reasonableness of that belief. *Motor Vehicle Mfrs. Ass’n v. State Farm Mut. Auto. Ins. Co.*, 463 U.S. 29, 43, 50 (1983). Here, HRSA articulated a similar view, writing that it “does not believe that any . . . alternatives . . . would adequately achieve the program integrity . . . objectives” at issue. 91 Fed. Reg. 48,883, 48,899 (Aug. 3, 2026). There is every reason to believe Defendants will make that (incorrect) argument in this case.

PhRMA Mot. at 8. But that position is squarely at odds with § 706 of the APA and well-considered caselaw. *See Butte Cnty. v. Hogen*, 613 F.3d 190, 195 (D.C. Cir. 2010); *Grand Canyon Air Tour Coal. v. FAA*, 154 F.3d 455, 468–69 (D.C. Cir. 1998). Similarly, Defendants agreed to vacatur (rather than remand) last time because, as this Court recognized, attempting to “advanc[e] the pilot on [that] timetable” would have been an “arbitrary undertaking” given the “anemic administrative record.” *Am. Hosp. Ass’n v. Kennedy*, 2025 WL 3764086, at *1 (D. Me. Dec. 30, 2025) (“Stay Order”). But as the First Circuit recently held, “there is no indication that future litigation concerning a new drug rebate program would end so abruptly. . . . [T]he government may not agree to vacatur of a future program as quickly[.]” *Am. Hosp. Ass’n*, 2026 WL 2913956, at *2. A movant’s mere desire to raise additional arguments does not make the government’s representation inadequate. *E.g., Rosenfelt*, 988 F.3d at 561–62; *Mass. Food Ass’n*, 197 F.3d at 567.

Third, Movants suggest that last year’s “[e]xperience has demonstrated” the government is not interested in zealously defending Movants’ interests. Mfrs. Mot. at 8; *see* PhRMA Mot. at 8. The government’s actions prove the opposite. Defendants unreservedly defended the first iteration of the rebate program. Besides offering a forceful defense before this Court, they sought an emergency stay of this Court’s preliminary injunction over the Christmas holiday. *AHA I*, ECF No. 92. When both this Court and the First Circuit noted the total absence of an administrative record on which to justify the Program, the government followed this Court’s advice and quickly tried (unsuccessfully) to “fortify the pilot rebate program” through a new administrative process. Stay Order at *1. This history shows the government’s commitment to defending the drug industry’s interests in a rebate program, so much so that this Court faulted it for “attempting to lower the bar for administrative action in service to ‘industry preparation’ interests.” *Id.*

Fourth, Movants offer factual allegations extrinsic to the administrative record and policy

arguments about the Program. But “the focal point for judicial review should be the administrative record already in existence, not some new record made initially in the reviewing court.” *Camp v. Pitts*, 411 U.S. 138, 142 (1973) (per curiam). This case “turns entirely” on the existing administrative record, Intervention Order at *4, not points introduced through Movants’ litigation filings. Movants, for example, propose to “explain . . . the need for the Pilot Program, from the perspective of manufacturers.” PhRMA Mot. at 9–10. But the time for that explanation was during the Program’s comment period, not now. Under the APA, it was up to the government defendants to “do their own homework, build an administrative record, and then demonstrate the application of something resembling a thought process in regard to what the record contains.” *Am. Hosp. Ass’n v. Kennedy*, 820 F. Supp. 3d 30, 42 (D. Me. 2025). Movants cannot now salvage the government’s legally deficient work through intervention.

That leaves Movants’ purported evidence of their own purported harm. Drug-company Movants argue that this evidence goes to “the Court’s balancing of the equities.” Mfrs. Mot. at 5. But that evidence also does not require “participation as parties” for the entire case. *Mass. Food Ass’n*, 197 F.3d at 567. As this Court explained last year, “[p]articipation as *amici* satisfies Movants’ interest in providing information regarding the severe harm that would befall the Manufacturers if the program were enjoined.” Intervention Order at *5 (cleaned up).

Finally, Movants rely on the same cases this Court found unpersuasive last year. None undermine the Court’s prior conclusion:

- Movants (again) rely heavily on *B. Fernández & Hnos., Inc. v. Kellogg USA, Inc.*, but that case involved only *private* parties and no government defendant, so the presumption of adequate representation was never at issue. 440 F.3d 541 (1st Cir. 2006).
- Movants (again) cite *Conservation Law Foundation v. Mosbacher*, 966 F.2d 39 (1st Cir.

1992), but as the First Circuit explained, there the “intervenors overcame the presumption of adequate representation by the government defendant because, *inter alia*, the agency had not filed an answer to the complaint but had instead accepted a consent decree providing for virtually all the relief sought” before the district court had ruled on the pending motions to intervene. *Mass. Food Ass’n*, 197 F.3d at 567 (discussing *Mosbacher*). The government here has not made any concessions akin to those in *Mosbacher*—quite the opposite, in fact.

- Movants (again) invoke *Cotter v. Massachusetts Association of Minority Law Enforcement Officers*, 219 F.3d 31 (1st Cir. 2000), but in that case, the intervenors overcame the presumption of adequate government representation by explaining their intention to argue a position the court found the government unlikely to advance. *Id.* at 35–36. Movants here have not identified any argument that the government is unwilling to make.

Put simply, the divergence of interests present in *Cotter* and *Mosbacher* does not exist here.³ The government has given the Court no reason to doubt that it will vigorously defend its Program and adequately represent Movants’ interests. Movants thus have no right to intervene under Rule 24(a).

Movants’ Interests Remain Contingent and Suffer No Concrete Threat. To intervene as of right, a movant must establish a “direct, not contingent” interest that is “substantial[] and legally protectible.” *Travelers Indem. Co. v. Dingwell*, 884 F.2d 629, 638 (1st Cir. 1989) (cleaned up). Movants’ asserted interest is in the Program’s implementation, which they argue will prevent

³ None of Movants’ remaining cases are on point. In *Driftless Area Land Conservancy v. Huebsch*, 969 F.3d 742 (7th Cir. 2020), the Seventh Circuit agreed that the government “c[ould] be expected to defend the procedural regularity of its proceedings” but held the presumption of adequate representation did not apply because the other two causes of action attacked the transmission companies’ own eminent-domain authority, making their “interests and objectives . . . materially different than the Commission’s.” *Id.* at 748. This case, by contrast, singularly revolves around APA claims. In *Wal-Mart Stores, Inc. v. Texas Alcoholic Beverage Commission*, 834 F.3d 562 (5th Cir. 2016), the proposed intervenors and the government entity disagreed on whether to defend the entire litigation, and the proposed intervenors sought prospective relief. Neither is true here. And *Animal Protection Institute v. Martin*, 241 F.R.D. 66 (D. Me. 2007), did not address the presumption of adequate representation at all.

them from incurring losses and civil penalties. *See* Mfrs. Mot. at 5; PhRMA Mot. at 4–6. But this “professed economic interest in an as yet unrealized expectancy” is based on plans that have not yet been acted upon and on “numerous market variables.” *Patch*, 136 F.3d at 205–06.

Whether Movants will actually experience any impact on alleged duplicate discounts depends on variables Movants cannot control or predict. In fact, there is strong reason to believe that the Program will have *no incremental impact* on Medicaid duplicate discounts because Movants (or PhRMA’s members) will have to follow the same statutory audit-and-ADR process they otherwise would go through absent the Program. Compl. ¶ 142. And whether Movants will be subject to any civil penalties—to date they have not—depends on CMS’s discretion. Under First Circuit caselaw, these kinds of interests are “fatally contingent.” *Patch*, 136 F.3d at 206.

Movants again contend that the Program is “the only available method” to avoid paying duplicate discounts under the IRA and 340B. Mfrs. Mot. at 5; PhRMA Mot. at 5. But that is even less believable than last year. Every drug company that participates in the MDPNP (including the manufacturer Movants) has administered both programs without a rebate mechanism since January 1, 2026, but Movants have not pointed to a single, specific duplicate discount. *Cf.* Marsh Decl. ¶¶ 47, 58–59 (Boehringer “develop[ed] an alternative process”). In fact, two drug companies voluntarily chose *not* to include eligible drugs in the Program, clearly disagreeing with Movants’ categorical contention that a rebate mechanism is the “only” solution. Golder Decl. ¶ 44. Movants may believe their alternatives inferior, Marsh Decl. ¶ 47, but a preference is not a necessity.

Likewise, Movants’ asserted losses again hinge on the assumption that covered entities will improperly claim both discounts, but Movants offer no actual evidence this occurs. *AHA I*, ECF No. 76 at 3. HRSA itself concedes there is no “federal estimate of . . . duplicate discounts in 340B.” 91 Fed. Reg. at 48,887. And despite the characterizations in their briefs, Movants’ estimated losses

are all projections—not actual losses. Scheidler Decl. ¶ 42; McCarthy Decl. ¶ 34; Marsh Decl. ¶ 61.⁴ Movants also allege that CMS will penalize them for deduplication errors, *see* Mfrs. Mot. at 2–3, 5; Stansel Decl. ¶ 14, but in the nearly ten months of MFP effectuation without a rebate mechanism, Movants’ declarations identify no penalty imposed or even threatened.

In sum, this remains “a case in which these would-be intervenors root their professed economic interest in an as yet unrealized expectancy” of penalties or discounts lost to unproven 340B Program noncompliance. *Patch*, 136 F.3d at 205–06. Because “numerous market variables” make it “anybody’s guess” whether that expectancy will materialize, Movants’ interests are “fatally contingent.” *Id.* at 206.

II. The Court Should Deny Permissive Intervention.

Permissive intervention lies in the Court’s “very broad discretion.” *T-Mobile*, 969 F.3d at 40–41. 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). Three points counsel denial.

First, the risk of delay and prejudice is real and not confined to briefing deadlines. *Cf.* Mfrs. Mot. at 10; PhRMA Mot. at 10. “Multiplying the number of parties in a case will often lead to delay.” *T-Mobile*, 969 F.3d at 41. The Court recognized last year, “beyond January 1, it is possible that intervention would create undue delay in the final disposition of this case involving an

⁴ For example, AbbVie’s measure of loss is calculated by multiplying the net revenue of its drug (Vraylar) by an assumed 30% duplication rate, a figure AbbVie borrows from a trade-press article sponsored by a drug-industry vendor. Scheidler Decl. ¶¶ 40–41 & n.20; *see also* Compl. ¶ 139.

More generally, the numbers associated with purported losses from duplication have been all over the map in this litigation. In December 2025, Movants told this Court manufacturers would lose “\$4 billion” in 2026 without a rebate program. *E.g.*, Aynilian Decl. ¶ 18, *AHA I*, ECF No. 36-1. Two months later, manufacturers told the D.C. Circuit the exposure was “potentially millions.” Doc. 2158962 at 2, *Novartis Pharms. Corp. v. Kennedy*, No. 25-5177 (D.C. Cir. Feb. 12, 2026). By May, the number was back to \$4 billion. Br. for All Appellants at 9, *Am. Hosp. Ass’n v. Kennedy*, No. 25-2237 (1st Cir. May 7, 2026). And now, the three manufacturer Movants “seek to avoid tens of millions of dollars” in losses. Mfrs. Mot. at 6. A projected loss that grows and shrinks by orders of magnitude is not reliable evidence of a concrete injury.

important administrative program,” a concern “amplified by Movants’ failure to demonstrate how they might ‘add any missing element’ to Federal Defendants’ defense.” Intervention Order at *5.

Movants’ conduct since then confirms the concern. After the 2025 case closed on February 10, 2026, Movants spent *seven months* litigating their right to intervene in that case until the First Circuit dismissed the appeal on September 25, 2026. *Am. Hosp. Ass’n*, 2026 WL 2913956, at *3. A party that will litigate intervention for seven months in a case with, in the words of the First Circuit, “nothing left . . . to defend,” *id.* at *2, cannot be expected to confine itself to the narrow issues or otherwise streamline this APA case.

Second, the Court “should ordinarily give weight to whether the original parties to the action adequately represent the interests of the putative intervenors.” *T-Mobile*, 969 F.3d at 41. They do. As the Court held last year, a “denial of intervention as of right based on an intervenor’s failure to overcome the presumption of adequate representation by the government” “cuts against [Movants’] case for permissive intervention.” Intervention Order at *5 (citation omitted).

Third, Movants will not “add any missing element” that *amicus* participation cannot supply. *T-Mobile*, 969 F.3d at 40. When the government is defending its own action, “the amicus procedure provides sufficient opportunity” for would-be intervenors “to present their view.” *Rosenfelt*, 988 F.3d at 564. This Court provided Movants that opportunity last year. *See* Intervention Order at *5. Nothing about this case calls for a different approach.⁵

CONCLUSION

The Court should deny both motions to intervene and grant Movants leave to participate as *amici curiae*.

⁵ PhRMA’s authorities do not suggest otherwise. In *Dinner Table Action v. Schneider*, the court allowed intervention because the proposed intervenors sought to present an argument the defendants had “explicitly disavowed.” 2025 WL 604885, at *2 (D. Me. Feb. 25, 2025). Movants identify nothing comparable here.

Dated: October 21, 2026

Respectfully submitted,

/s/ L. Rush Atkinson

Karen L. Dunn*

L. Rush Atkinson*

Jude Volek*

Lyle W. Gruby*

Jenifer N. Hartley*

Dunn Isaacson Rhee LLP

401 9th Street, NW

Washington, DC 20004

(202) 240-2900

ratkinson@dirllp.com

Counsel for Plaintiffs

*Admitted pro hac vice

Melissa A. Hewey

Drummond Woodsum

84 Marginal Way, Suite 600

Portland, ME 04101

(207) 253-0528

mhewey@dwmlaw.com