No. 25-2237

United States Court of Appeals
for the First Circuit

AMERICAN HOSPITAL ASSOCIATION; ST. MARY'S REGIONAL MEDICAL CENTER; MAINE HOSPITAL ASSOCIATION; NATHAN LITTAUER HOSPITAL AND NURSING HOME; UNITY MEDICAL CENTER; DALLAS COUNTY MEDICAL CENTER,

Plaintiffs-Appellees,

v.

ROBERT F. KENNEDY, JR., Secretary of the US Department of Health and Human Services; THOMAS J. ENGELS, Administrator Health Resources and Services Administration; HEALTH RESOURCES & SERVICES ADMINISTRATION; UNITED STATES DEPARTMENT OF HEALTH AND HUMAN SERVICES; UNITED STATES,

Defendants,

ABBVIE INC.; ASTRAZENECA PHARMACEUTICALS LP; PHARMACYCLICS LLC; BOEHRINGER INGELHEIM PHARMACEUTICALS, INC.; NOVO NORDISK INC.; PHARMACEUTICAL RESEARCH AND MANUFACTURERS OF AMERICA,

Interested Parties-Appellants.

On Appeal from the United States District Court for the District of Maine, No. 2:25-cv-00600-LEW, Judge Lance E. Walker

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CORPORATE DISCLOSURE STATEMENT

AbbVie Inc.: No publicly held corporation owns 10% or more of AbbVie Inc.'s stock. AbbVie Inc. is the ultimate parent of Pharmacyclics LLC.

AstraZeneca Pharmaceuticals LP: AstraZeneca Pharmaceuticals LP is a wholly owned subsidiary of AstraZeneca plc, which is a public company organized under the laws of England and Wales and is publicly traded. No other publicly held company owns 10% or more of the voting interest in AstraZeneca Pharmaceuticals LP.

Boehringer Ingelheim Pharmaceuticals, Inc.: Boehringer Ingelheim Pharmaceuticals, Inc. is a wholly owned subsidiary, directly or indirectly, of Boehringer Ingelheim USA Corporation, a privately owned corporation. No publicly held corporation owns 10% or more of Boehringer's stock.

Novo Nordisk Inc.: Novo Nordisk Inc. is a corporation wholly owned by Novo Nordisk US Holdings, Inc. Novo Nordisk US Holdings, Inc. is a corporation wholly owned by Novo Nordisk A/S. Novo Nordisk A/S is a publicly traded corporation. No publicly held company owns 10% or more of the stock of Novo Nordisk A/S.

Pharmaceutical Research & Manufacturers of America ("PhRMA"): PhRMA is a trade association with its headquarters in the District of Columbia. PhRMA has no parent corporation, and no publicly held company owns 10% or more of its stock. PhRMA's member companies are listed on its website at https://phrma.org/en/About.

Pharmacyclics LLC: Pharmacyclics LLC is 100% owned by Appellant AbbVie Inc.

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REASONS WHY ORAL ARGUMENT SHOULD BE HEARD

Pursuant to Federal Rule of Appellate Procedure 34(a)(1) and First Circuit Rule 34.0(a), the Manufacturers respectfully submit that oral argument will assist the Court in resolving this appeal. This appeal raises important questions about the intervention rights of participants in challenged federal programs and parties to challenged agency adjudications. This appeal also presents the Court with an opportunity to clarify when a government official or agency is presumptively an adequate representative of a prospective intervenor's interests.

JURISDICTIONAL STATEMENT

The district court had subject-matter jurisdiction under 28 U.S.C. §§ 1331 and 1346. This Court has appellate jurisdiction to review the district court's order denying the Manufacturers' motions to intervene—both because that order was immediately reviewable and because the district court has since entered a final order. *In re Efron*, 746 F.3d 30, 34 (1st Cir. 2014); 28 U.S.C. § 1291. This appeal is timely because the district court denied the motions to intervene on December 18, 2025, and the Manufacturers filed their notice of appeal on December 30, 2025. ADD13; JA552. As discussed further below, *see infra* Section II, this appeal is not moot.

ISSUES PRESENTED

1. Whether the Manufacturers were entitled to intervene under Federal Rule of Civil Procedure 24 to defend the Agency's approval of their individual applications to participate in a program created so the Manufacturers would not lose billions of dollars in duplicative discounts due to overlapping obligations under two federal drug-pricing schemes.

2. Whether this Court may resolve this appeal, notwithstanding the voluntary dismissal of the district court proceedings, because the Manufacturers' claim on appeal is one capable of repetition but evading review.

3. If this appeal is found moot, whether this Court should vacate, under *United States v. Munsingwear, Inc.*, 340 U.S. 36 (1950), the district court's order denying intervention.

INTRODUCTION

This appeal asks whether companies granted approvals by a federal agency to participate in a regulatory program may intervene under Federal Rule of Civil Procedure 24 to defend those approvals and the program itself. The clear answer is yes, but the district court denied intervention. This Court should reverse.

Two separate federal statutes require Appellants, pharmaceutical manufacturers ("the Manufacturers"), to provide steep discounts on their medications in specific circumstances. Often, a single transaction implicates both statutory schemes, each mandating a different discount. If manufacturers were required to provide both discounts for each such transaction, the double discounts would result in confiscatory and even potentially negative pricing, and the consequences to manufacturers would be severe, amounting to billions of dollars in losses every year. Federal law thus instructs that manufacturers shall not be required to provide discounts on the same transaction—only the higher discount percentage of the two. But determining up front which discount applies is nearly impossible. As a result, the Manufacturers anticipated

suffering up to $4 billion in losses during 2026 alone, the first year both statutory schemes were in effect.

After manufacturers raised concerns about their ability to deduplicate the overlapping discounts, Defendant Health Resources Services Administration (HRSA) proposed a pilot program and approved applications from the Manufacturers to use rebates to effectuate one of the discounts (those under Section 340B), instead of offering reduced prices at the point of sale. The Manufacturers would sell their medications, receive standard data relating to each transaction (called "claims data"), use that data to determine which of the two statutory discounts applies, and issue a rebate for the difference from the purchase price.

Plaintiffs (collectively, "the Association") are a collection of hospitals that want to keep receiving up-front discounts, despite the inherent flaws of that payment mechanism and even though no statute requires it. A month before the Manufacturers' rebate models were to take effect, the Association sued HRSA, along with other federal agencies and officials involved in the two federal drug-pricing schemes (collectively, "the Agency"), for an emergency injunction and vacatur of

the rebate model approvals. The Manufacturers promptly moved to intervene. The Manufacturers sought not only to defend the legality of the models and their rebate approvals but also to show that the Manufacturers' rebate models would not irreparably harm the Association and its members and to demonstrate that the requested injunction would irreparably harm the Manufacturers.

The district court denied the Manufacturers' motions to intervene, presuming that the Agency would adequately represent the Manufacturers' interests in the case. That was error on multiple levels.

As recent precedent confirms, no presumption of adequate representation exists when a regulated party intervenes alongside its regulator. Even if some form of the presumption survives under those circumstances, it is easily rebutted—and the Manufacturers undoubtedly did so here. They obtained regulatory approvals for their rebate models and stood to lose billions of dollars in duplicate discounts and costly operational shifts if those approvals were vacated, as they ultimately were.

The Manufacturers' position was so distinct, in fact, that it should have overcome any version of the presumption. The Manufacturers

adopted a different legal position than the Agency; made arguments that the Agency waived; and submitted evidence about their own harms and refuting the Association's asserted harms while the Agency did not. The district court did not acknowledge any of these facts in denying intervention. Instead, it concluded that because the Manufacturers and the Agency agreed on the overall outcome of the case, the Manufacturers were not entitled to intervene. That conclusion is in direct conflict with this Court's precedents and requires reversal.

The district court's error had an immediate and significant effect on the litigation. The Manufacturers were not parties, so neither the district court nor this Court considered the Manufacturers' losses in evaluating harm, even though those harms were (and continue to be) extraordinary and irreparable. Instead, the district court issued an injunction, and this Court denied a stay pending appeal, on the ground that there would be no harm ***to the Agency*** if the rebate program's implementation were delayed. The Agency then settled with the Association, agreeing to reconsider the federal program instead of continuing to defend it. Because the Manufacturers did not have party status, they did not

participate in the settlement discussions, and those discussions did not account for their interest in avoiding enormous financial harms.

This Court should reverse the district court's erroneous intervention order. The Court has jurisdiction to do so because, notwithstanding the Association and the Agency's settlement, the appeal is not moot. The Association and the Agency are already contemplating litigation over similar issues. But, as here, that litigation will almost certainly play out too quickly for this Court to vindicate the Manufacturers' right to intervene. Expedited proceedings, insulated from review by a settlement, should not extinguish the right to intervene. Should the Court find the appeal moot, however, the proper disposition would be to vacate, under *United States v. Munsingwear, Inc.*, 340 U.S. 36 (1950), the district court's order denying intervention.

STATEMENT OF THE CASE

I. Federal Drug-Pricing Programs.

This case concerns two overlapping federal drug-pricing regimes and the manufacturers subject to their obligations.

One of the programs, Section 340B, requires manufacturers to sign an "agreement" that "meets the requirements of section 256b"—meaning 42 U.S.C. § 256b, the section that establishes the 340B Program—as a

condition of participating in the Medicare Part B and Medicaid programs. 42 U.S.C. § 1396r-8(a)(5)(A). The agreements require manufacturers to "offer" their drugs for sale to certain hospitals and other types of healthcare providers (known as "covered entities") at steeply discounted rates—often pennies on the dollar. *See id.* §§ 256b(a)(1), 1396r-8(c); JA143 (¶3).

The other regime, the "Drug Price Negotiation Program" (DPNP), is a creation of the Inflation Reduction Act (IRA). The DPNP requires the Department of Health and Human Services (HHS) to set a "maximum fair price[]" (MFP) that manufacturers must provide for select drugs when sold to Medicare-covered individuals. *See* 42 U.S.C. §§ 1320f(a), (c)(2), 1320f-2(a)(3). Its pricing provisions took effect January 1, 2026. *See id.* § 1320f(b)(1).

When Medicare beneficiaries receive care at 340B covered entities, manufacturers must decide which price concession to provide. The MFP and 340B discounts are so large that providing both for the same prescription could result in a negative price. JA138 (¶14). To avoid this and similar problems, the IRA mandates that manufacturers "shall not be required to provide" both the MFP and the 340B discounts. 42 U.S.C.

§ 1320f-2(d)(1). Instead, if a transaction could qualify for either discount, manufacturers need only provide the greater of the two. *Id.* But in practice, manufacturers have been forced to sort out which is which, since the agency that administers the DPNP disclaimed "responsibility for deduplicating discounts."[1]

II. HRSA Launches The Rebate Model Pilot Program.

The Manufacturers develop innovative medicines subject to both 340B and MFP pricing obligations.[2] Manufacturers often cannot determine up front which discount applies to a specific transaction. Compounding that complexity is the fact that the two federal programs have different payment processes. Manufacturers may effectuate the MFP through a post-sale rebate. For the 340B ceiling price, however, the

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[1] *See* Ctrs. for Medicare & Medicaid Servs. (CMS), *Medicare Drug Price Negotiation Program: Final Guidance* (Oct. 2, 2024) at 55, https://tinyurl.com/ychztdfu.

[2] The Manufacturers are AbbVie, Inc., Pharmacyclics, LLC, AstraZeneca Pharmaceuticals LP, Pharmaceutical Research & Manufacturers of America (PhRMA), Boehringer Ingelheim Pharmaceuticals Inc., and Novo Nordisk Inc. PhRMA represents the interests of its manufacturer members who are subject to the 340B Program and the MFP scheme and whose Pilot Program applications were approved by HRSA. As it relates to PhRMA, "Manufacturers" describes PhRMA's representation of those members.

program currently operates primarily through manufacturer-provided up-front discounts.[3] *See* 90 Fed. Reg. 38,165, 38,165 (Aug. 7, 2025).

The gap between post-sale rebates and up-front discounts puts manufacturers in a bind. If a manufacturer sells at the 340B price, it issues one discount. The same medication may then be dispensed to an MFP-eligible patient, obliging the manufacturer to provide the MFP discount as a rebate (if the MFP was lower than the 340B price). By that point, though, the manufacturer has no accurate way of detecting whether it has already provided a 340B discount for that transaction. That is because manufacturers lack access to the data that would enable them to make such a determination—and under the current regime, by the time they could access it, it would be too late. *See* JA138 (¶¶13-14).

This tangle of obligations leaves manufacturers with two costly choices. They can either provide the MFP as a duplicate discount by default or they can risk severe civil penalties if they decline to issue the MFP rebate in some circumstances.

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[3] Some of the Manufacturers have taken the position that they need not seek HRSA's approval before implementing rebate models. *See, e.g.*, *Eli Lilly & Co. v. Kennedy*, 2025 WL 1423630, at *8 (D.D.C. May 15, 2025), *appeal filed*, No. 25-5221 (D.C. Cir. June 13, 2025).

Duplicate 340B-MFP discounts could cost the Manufacturers $4 billion in 2026 alone. JA140 (¶18). And that does not account for statutory penalties, which can reach millions of dollars per day. 42 U.S.C. §§ 1320f-6(c), 1320f-2(a)(5). Accordingly, HRSA designed the Rebate Model Pilot Program ("the Pilot Program") to pilot post-sale rebates, in part as an attempt to solve manufacturers' deduplication challenge. *See* 90 Fed. Reg. 36,163, 36,163 (Aug. 1, 2025); 90 Fed. Reg. at 38,165.

The Manufacturers, concerned about their ability to harmonize the current 340B framework with the DPNP's new requirements—and seeking to operationalize Congress's mandate that they "shall not be required to provide" both the MFP and the 340B discounts, 42 U.S.C. § 1320f-2(d)—took the opportunity afforded by the Pilot Program. *See* 90 Fed. Reg. at 38,165.

The Pilot Program had two key features. ***First***, it authorized selected manufacturers to use post-sale rebates to effectuate the 340B price for medications that are also subject to the MFP scheme. 90 Fed. Reg. at 38,165. ***Second***, it required covered entities to provide standard claims data, reflecting the types of records that they are required to

maintain as a condition of participation in the 340B Program. *Id.* at 38,167. So under the Pilot Program, the Manufacturers would sell DPNP-selected drugs to covered entities at the commercial price; covered entities would submit basic claims data to the Manufacturers; and the Manufacturers would review the data to determine the applicable price and then provide the appropriate discount through a rebate. The Manufacturers invested thousands of hours and millions of dollars each to design Pilot Program rebate models. *See, e.g.*, JA139-140 (¶17); JA166 (¶23); JA197 (¶24); JA284 (¶¶25-26). HRSA reviewed the Manufacturers' rebate model proposals and approved nine separate applications in a series of decision letters issued beginning in October 2025. The Pilot Program was set to commence on January 1, 2026, the same day the Manufacturers' DPNP obligations took effect. 90 Fed. Reg. at 38,166.

III. The Association Sues To Overturn The Manufacturers' Approvals On The Eve Of Implementation; The Manufacturers Promptly Move To Intervene.

On December 1, 2025—one month before the Pilot Program and the Manufacturers' DPNP obligations were to begin and months after HRSA announced the Pilot Program—the Association filed this suit seeking an

emergency injunction. The Association claimed that HRSA violated the Administrative Procedure Act when it approved the Manufacturers' applications to participate in the Pilot Program. *See* JA035 (¶29); JA091-106. The Association did not contest HRSA's authority to undertake the Pilot Program or to permit rebate models. Rather, the Association argued that HRSA did not adequately explain the Pilot Program and did not sufficiently consider the covered entities' supposed harms when approving the Manufacturers' applications. *See* JA094, JA104-106 (referencing an "interest-free loan" to manufacturers and contending only specialized staff can collect claims data). The Association requested an immediate injunction that would stay the approvals and prevent the Manufacturers from using their rebate models to deduplicate 340B and MFP discounts. JA91-112.[4]

Appellant AbbVie noticed its intent to intervene and participated in the district court's initial teleconference. JA113-114. Thereafter, AbbVie and the other manufacturers promptly sought intervention under Federal Rule of Civil Procedure 24. *See* JA116, JA156, JA171, JA199,

[4] Defendants are HHS, the HHS Secretary, HRSA, HRSA's Administrator, and the United States of America.

JA400. The Manufacturers argued that, as the entities whose approvals were being challenged and as participants in a federal program who faced billions of dollars in losses without that program, they had a right to intervene under Rule 24(a)(2). They also argued that, at the very least, permissive intervention under Rule 24(b) was warranted. The Agency took no position on the Manufacturers' motion. Dkt. 74. The Association opposed, arguing that the Manufacturers had no cognizable interest in the approval of their applications and that the Agency would "adequately represent any interests [the Manufacturers] have." Dkt. 76 at 2.

Parallel to the intervention briefing, the Association, the Agency, and the Manufacturers briefed the Association's motion for emergency injunctive relief.[5] The Manufacturers and the Agency took markedly different positions when opposing the Association's motion.

The Manufacturers contended the Pilot Program was necessary to reconcile the DPNP's new MFP pricing obligations with their statutory right not to pay duplicate discounts. Through written testimony and

[5] The Manufacturers filed an opposition to the Association's motion pursuant to the case-management discussion during the district court's teleconference held shortly after the Association filed suit. *See* JA287 (n.1).

argument, the Manufacturers explained that the Pilot Program's rebate system was the ***only*** available method to reliably ensure deduplication. *See* JA304-306; JA138 (¶13); JA149 (¶22); JA338-339 (¶¶11, 15). The Agency did not endorse the Manufacturers' position and gave little attention to the deduplication issue or the Manufacturers' imminent MFP obligations. *See* JA371-372, JA379. Instead, the Agency described the Pilot Program as primarily an information-gathering tool for HRSA's ongoing consideration of rebate models within the 340B Program. JA371. The Agency did not even acknowledge in its injunction-opposition brief that a rebate model was the Manufacturers' only available method of reliably achieving 340B-MFP deduplication.

The Manufacturers provided factual evidence to rebut the Association's claims of impending injury; the Agency did not. The Association's theory of "interest-free loan[s]" was factually unsupported because the Manufacturers' rebate models directed rebates to covered entities within 10 days, whereas covered entities typically have a 30-day window to pay drug wholesalers. JA150 (¶24). So covered entities could easily avoid ever paying full price by promptly submitting rebate requests and receiving rebates before payment to the wholesaler came

due. *Id.* The Manufacturers also presented written testimony rebutting the Association's claims of new administrative burdens. The Association's members already collect claims data and share it with business partners and insurers. *See* JA319 (¶8). The software used to do so "precisely mirror[ed]" the software they would use to share rebate-related claims data in the Pilot Program. *Id.* The Pilot Program, then, made use of existing administrative competencies—something the Manufacturers, not the Agency, highlighted for the Court.[6]

Along with this rebuttal of the Association's overstated harms, the Manufacturers provided evidence of the harm they would suffer were the Pilot Program enjoined. AbbVie, for example, discussed the "tens of millions of dollars in losses flowing from duplicative price concessions and civil penalties for compliance mistakes" it could suffer without the

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[6] The Agency submitted a declaration from the Director of HRSA's Office of Pharmacy Affairs. *See* JA384. That declaration discussed the Agency's decision-making process; the Director did not address the factual inaccuracy of the Association's assertions of impending harm. *See, e.g.*, JA391-392 (¶30) (explaining the Agency's decision that commercial-priced purchases would not harm covered entities "***if, as manufacturer commenters state***, the rebate will be paid before the purchase invoice from a wholesaler … is due" (emphasis added)). The district court refused to consider the Director's written testimony. JA524-525. Had the Manufacturers been granted party status, their interests and their evidence would have been properly before the Court.

Pilot Program. JA126. Similarly, PhRMA discussed the "billions of dollars at stake" for its members. JA178. One PhRMA member presented evidence that even a temporary suspension of the Pilot Program would require it "to pay over a hundred million dollars in improper MFP refunds." JA176. Evidence of other concrete harms was presented. *See* JA166 (¶23); JA187-188 (¶¶13, 18).

The Manufacturers' and the Agency's legal arguments in support of the Pilot Program differed too. The Manufacturers urged that HRSA's approval of the Manufacturers' Pilot Program models were informal (and voluntary) adjudications that required no more explanation than the Agency's decision that the "plans all met the requirements as stated in the" original Pilot Program announcement. JA302-303. The Agency opted for a more sweeping assertion of its regulatory authority, asserting it had exercised complete, unreviewable discretion—a position contrary to the Manufacturers' interests, as entities regulated by the Agency and as parties to litigation challenging HRSA's decision not to allow 340B rebates in other contexts. *See* JA366-370.

The Manufacturers also argued for a narrower remedy—remand without vacatur—in the event the district court did find a likely APA

violation. JA311 (citing *Central Me. Power Co. v. FERC*, 252 F.3d 34, 48 (1st Cir. 2001), and *Town of Weymouth v. Mass. Dep't of Env't Prot.*, 973 F.3d 143, 146 (1st Cir. 2020)). The Manufacturers based this position on the irreparable harms that they would suffer if the court set aside the Agency's approval of their applications. *See id.* The Agency did not make such an argument in its injunction-opposition brief.

IV. The District Court Denies Intervention.

On the eve of the injunction hearing, the district court denied the Manufacturers' motions to intervene. ADD13. The district court imposed a "heightened burden" for the Manufacturers to establish that the Agency would not adequately represent the Manufacturers' interests. *Id.* at 9. In its view, "a presumption attach[ed] to [the Agency's] adequacy of representation" because the case involved a challenge to a government program that implicated the Manufacturers' economic interests. *Id.* at 4.

The district court deemed that presumption unrebutted, declaring that the Manufacturers had "offer[ed] no evidence to suggest that their approach to defending the Pilot Program offers the Court any additional insight," that the Manufacturers were "silent on what arguments they would make … that would otherwise be forsaken by Defendants," and

that the Manufacturers had not "suggest[ed] they would inject some missing ingredient into the Agency's defense." *Id.* at 9-10 (citation modified). In short, the district court considered the Manufacturers' concern of inadequate representation as "founded entirely on speculation" without any "tangible basis to support a claim of purported inadequacy." *Id.* at 8. The district court did not acknowledge that the Agency had (1) taken a legal position that differed from the Manufacturers' position, (2) omitted key arguments, (3) decided not to provide meaningful evidence relating either to the Manufacturers' harms or to the Association's assertions of harm, and (4) taken positions contrary to the Manufacturers' own interests. Nor did the court address the remaining elements of intervention of right. *Id.* at 11.

The district court then denied permissive intervention under Rule 24(b) because, for reasons unexplained, it was "possible that intervention would create undue delay in the final disposition of this case involving an important administrative program." *Id.* at 12. The district court did not acknowledge that the Manufacturers had committed to abide by the schedule set for the Agency—and, in fact, had already filed a merits brief on that schedule. Nor did the court identify any other

respect in which the Manufacturers' intervention might affect the case schedule.

The district court permitted the Manufacturers to participate as amici curiae instead, reasoning that amici status "satisfie[d] [the Manufacturers'] interest in providing information regarding the severe harm that would befall [them] if the program were enjoined." *Id.* at 13 (citation modified). The Manufacturers offered evidence that they faced billions of dollars in harm, but the district court ignored that information in its order granting injunctive relief.

V. The District Court Requests, Then Ignores, The Administrative Record.

During the hearing, another issue emerged: The district court wanted to know when it would receive the administrative record. JA443, JA446, JA448. The district court was especially interested in knowing whether the administrative record would reflect HRSA's contemporaneous consideration of potential financial and administrative burdens on covered entities. JA451-452, JA458. It was clear from the district court's questioning that, unless such evidence were part of an administrative record available to the district court before it ruled, an injunction would likely be issued. Shortly after the hearing, the Agency

attempted to provide the district court with documentary evidence of the agency considering purported costs to covered entities. *See* JA411-412.

AstraZeneca also submitted its correspondence with HRSA, as such documents would (or should) have been part of the administrative record. *See* JA466-467. While the government typically *compiles* an administrative record for litigation, the administrative record simply "consists of all documents and materials directly or indirectly considered by the agency," whether or not the government has yet compiled it. *Bar MK Ranches v. Yuetter*, 994 F.2d 735, 739 (10th Cir. 1993). Even so, the district court concluded AstraZeneca's "contributions do not constitute the administrative agency record" because "the Agency did not incorporate them into the administrative record." JA525. Had the district court granted intervention, the Manufacturers could have moved to complete the record, including by submitting relevant documents within their possession (as AstraZeneca attempted to do). *See Crossroads Grassroots Pol'y Strategies v. Fed. Election Comm'n*, 788 F.3d 312, 321 (D.C. Cir. 2015) (granting intervention in part because intervenors and government defendants "disagree[d] about … the scope of the administrative record"); *Amfac Resorts, L.L.C. v. U.S. Dep't of Interior*,

143 F. Supp. 2d 7, 12 (D.D.C. 2001) (explaining that "a complete administrative record should include all materials that might have influenced the agency's decision" and discussing motions to complete the record (citation modified)).

VI. The District Court Sets Aside The Manufacturers' Approvals And Enjoins The Pilot Program; This Court Denies A Stay.

The consequences for the Manufacturers of the district court's intervention denial were swift and severe. During the injunction hearing the following day, there was no discussion of the financial injuries the Manufacturers would suffer from an injunction. There were only passing references to the deduplication problem that motivated the Agency's January 1, 2026 launch date. *See* JA447, JA459-460. The Agency did not present evidence to rebut the Association's claims of financial or administrative burdens. And the Agency did not argue for remand without vacatur as a potential remedy.

Eleven days after the intervention denial, the district court set aside the Manufacturers' approvals and enjoined the Pilot Program. JA515-538; *see also Am. Hosp. Ass'n v. Kennedy*, --- F. Supp. 3d ---, 2025 WL 3754193 (D. Me. Dec. 29, 2025). The district court took at face value the Association's assertions that it would suffer increased financial costs

and administrative burdens (the Agency had submitted no evidence to contest those assertions). JA533-534. The district court did not consider the harm the Manufacturers would suffer from an injunction against the Pilot Program (after all, the Agency had offered no evidence of such harm). JA535. Nor did the district court consider the Manufacturers' argument that the appropriate remedy was remand without vacatur (after all, the Manufacturers were not parties).

The Agency moved for a stay pending appeal, which the district court denied the following day. JA548-550; *see also Am. Hosp. Ass'n v. Kennedy*, 2025 WL 3764086 (D. Me. Dec. 30, 2025). Again, the district court ignored the Manufacturers' impending harms, explicitly disregarding "'industry preparation' interests" and concluding—remarkably—that "there is no apparent, actual urgency to the January 1 [Pilot Program] start date." JA550.

The Agency asked this Court for a stay pending appeal. *See* Mot. for Stay Pending Appeal, No. 25-2236 (1st Cir. Dec. 30, 2025). The Manufacturers unsuccessfully attempted to participate in the Agency's appeal. *See* Mot. to Intervene on Appeal, No. 25-2236 (1st Cir. Dec. 31, 2025). Their absence once again limited the harms considered and legal

positions presented on appeal. For the first time, the Agency asserted a merits argument similar to one that the Manufacturers made below: "[T]he APA does not specifically require [the federal government] to explain its decisions because the [Pilot] Program is an informal adjudication." *Am. Hosp. Ass'n v. Kennedy*, 164 F.4th 28, 35 (1st Cir. 2026) (citation modified); *see* JA302-303 (citing *Hudson v. FAA*, 192 F.3d 1031, 1034, 1036 (D.C. Cir. 1999), and *Housatonic River Initiative v. EPA*, 75 F.4th 248, 266-67 (1st Cir. 2023)). But this Court deemed that argument "waived because the federal government did not develop it before the district court and instead" had conceded below that it must "provide … adequate explanation for its actions." *Kennedy*, 164 F.4th at 35-36 (citation modified).

As a result, just eight days after the Agency sought a stay pending appeal, this Court denied the stay and allowed the district court's preliminary injunction to remain in effect. Like the district court, this Court accepted as true the Association's claims of administrative burden and financial harm. *Id.* at 32. This Court did acknowledge that "the primary cost of any delay … run[s] to the drug manufacturers, not the federal government." *Id.* at 37. That did not seem problematic to the

Court, however, because "the federal government ha[d] indicated that manufacturers have alternative methods to address the … [de]duplication issue." *Id.* Based on the Agency's representation, this Court thought there was no "substantial injury in the absence of a stay." *Id.* As noted, the Manufacturers have disputed both of those propositions from the outset of this litigation.

VII. The Association And The Agency Settle.

Twenty-nine days after the district court denied intervention, the Association and the Agency voluntarily dismissed the appeal. Consent Mot. to Voluntarily Dismiss, No. 25-2236 (1st Cir. Jan. 16, 2026). The Manufacturers had no ability to take part in that decision because the Manufacturers were not parties to the proceedings.

A mere forty-nine days after the district court's intervention denial, the Association and the Agency jointly moved for vacatur of the Pilot Program and remand. JA555. The Association's and the Agency's agreed-upon resolution contemplates future litigation if HRSA approves a new 340B rebate program. Specifically, "Defendants agree[d] to set any effective date for any new 340B rebate program to no earlier than 90 days following the public announcement of any approval of drug manufacturer

applications" to allow the Association time to bring another suit. JA558 (¶9). HRSA has already begun to consider another 340B rebate program. *See* 91 Fed. Reg. 7,287 (Feb. 17, 2026).

The district court granted the motion to vacate and remand five days later, on February 10, 2026. JA560-561. The district court thus terminated the Manufacturers' approvals to participate in a federal program, as well as the federal program itself in its entirety—without ever considering the Manufacturers' evidence or interests and without this Court having considered the Manufacturers' instant appeal to vindicate their right to intervene. And because the Manufacturers were not parties to the proceedings, the district court did not consider their objections to the nature or scope of the district court's final order—including their objection to vacatur of the Pilot Program during the remand. *See* JA311 (the Manufacturers opposing injunctive relief on the grounds that "the appropriate remedy would be … a remand for supplemental reasoning" without vacatur of the Pilot Program (citing *Central Me. Power Co.*, 252 F.3d at 47)).

This Court subsequently issued an order asking the Manufacturers to show cause "why this appeal should not be dismissed for lack of

jurisdiction," considering "there is no longer a pending case in which [they] could intervene." Order, Mar. 6, 2026. The Manufacturers responded. *See* Resp. to Order to Show Cause, Mar. 20, 2026. The Court then asked for full merits briefing and reserved the jurisdictional question for the merits panel. Order, Mar. 26, 2026.

SUMMARY OF THE ARGUMENT

I. The Manufacturers were entitled to intervene under Federal Rule of Civil Procedure 24.

A. The district court erroneously concluded that the Agency would adequately represent the Manufacturers' interests. The district court first mistakenly imposed a "heightened burden" on the Manufacturers because they sought to intervene alongside government officials and agencies who were already defending the challenged agency actions. ADD09. No such burden, heightened or otherwise, survives recent precedents. At a minimum, the district court got the strength of the presumption backwards. It ignored that the Manufacturers were participants in the challenged federal program, were parties to the challenged agency adjudications, and would be directly affected by the relief the Association sought in this case. Under this Court's well-

established Rule 24 framework, the Manufacturers' tangible and substantial stake in the outcome of the case made their burden ***lighter***, not heavier.

B. Even if the "heightened" standard did govern, the district court misapplied it. A prospective intervenor overcomes a presumption of adequate representation when it has interests different in kind or degree from the existing parties, or when there is reason to expect that the intervenors' legal positions diverge from those of the existing parties. The Manufacturers had arguments and evidence that the parties did not. The Manufacturers were also uniquely positioned to ensure that the district court and this Court understood that the Pilot Program was the Manufacturers' ***only*** reliable way to achieve deduplication of overlapping 340B-MFP discounts. The Agency not only refused to acknowledge that point, but also took a different legal position and made contrary representations that convinced the district court and this Court that there was no urgency to the Pilot Program's implementation. The Manufacturers advanced different interests too: They offered evidence about their own harms, sought to rebut the factual underpinnings of the Association's claims for injunctive relief, and argued for narrower

preliminary remedies than a full-scale vacatur of the Pilot Program. The Agency did not make any of these points.

C. The Agency advanced its own interests, rather than the Manufacturers', when arguing the preliminary injunction motion. At the hearing on that motion, the Agency took legal positions adverse to the Manufacturers' interests, argued for a different remedy, did not rebut the Association's assertions of harm, and declined to present evidence of the harm that the Manufacturers would suffer if their approvals were set aside. Had the Manufacturers been parties, they would have defended their distinct legal positions, argued for remand without vacatur, and presented their own evidence, as they did in their papers. Finally, the Agency's decision to settle with the Association—withdrawing the Pilot Program rather than continuing to defend it—further underscores how the Agency's interests differ from those of the Manufacturers.

D. Even if intervention of right were unavailable, the district court should have granted permissive intervention under Rule 24(b). The district court reasserted its erroneous adequate-representation reasoning, however, and then speculated that the Manufacturers may "possibly" delay a final resolution. The denial of permissive intervention

was thus rooted in errors of law and unexplained speculation. That constitutes an abuse of discretion.

II. This appeal is not moot, because the erroneous denial of the Manufacturers' intervention rights is likely to recur yet evade review.

A. In the context of extremely expedited litigation, important procedural questions, such as the right to intervene, can go unresolved. This case proves the point. The Manufacturers moved to intervene promptly, but the district court entered its final order vacating the Pilot Program approvals months before the parties could brief, let alone argue, this case.

B. Absent review and reversal by this Court in this appeal, the Manufacturers face a substantial risk of again missing out on their right to intervene. The Association and the Agency have signaled they anticipate that more litigation will follow if the Agency proceeds with another rebate program. The Agency has already begun the process of considering such a program. And the Association and the Agency contemplate the next round of litigation operating on an accelerated timeline.

III. If this appeal is considered moot, then this Court should vacate the district court's order denying the Manufacturers' motions to intervene. Vacatur is warranted here because the Manufacturers will have been deprived of appellate review by a settlement executed without the Manufacturers' input—the very sort of exclusion that their intervention aimed to prevent.

STANDARD OF REVIEW

This Court reviews intervention denials for abuse of discretion. "However, the district court has less discretion to deny intervention as of right" than to deny permissive intervention. *Conservation Law Found. of New England, Inc. v. Mosbacher*, 966 F.2d 39, 41 (1st Cir. 1992). This Court will thus "reverse if the district court committed a legal error, or if the court reaches a decision patently out-of-step with the purposes of Rule 24(a)(2)." *B. Fernandez & Hnos., Inc. v. Kellogg USA, Inc.*, 440 F.3d 541, 544 (1st Cir. 2006).

Mootness is a jurisdictional question this Court reviews de novo. *Barr v. Galvin*, 626 F.3d 99, 104 (1st Cir. 2010). Generally, if an appeal is moot, "the established practice is to vacate the [order] below." *ACLU of Mass. v. U.S. Conf. of Catholic Bishops*, 705 F.3d 44, 57 (1st Cir. 2013).

ARGUMENT

I. The District Court Wrongly Denied The Manufacturers' Motions To Intervene.

The Manufacturers were entitled to intervene as of right. A federal "court must permit anyone to intervene who … claims an interest relating to the property or transaction that is the subject of the action, and is so situated that disposing of the action may as a practical matter impair or impede the movant's ability to protect its interest," unless the motion is untimely or "existing parties adequately represent that interest." Fed. R. Civ. P. 24(a)(2).

The Manufacturers satisfied each of Rule 24(a)(2)'s requirements. Their intervention was timely sought, before the parties briefed the preliminary injunction motion. The Manufacturers had significant, protectable interests that "bear a sufficiently close relationship to the dispute between the original litigants." *Mosbacher*, 966 F.2d at 42 (citation modified). The suit threatened the Manufacturers' approved applications to participate in a federal program, jeopardizing the Manufacturers' ability to avoid potentially billions of dollars in duplicate discounts. And the Manufacturers' interests could not be adequately represented by a government agency because, as explained further below,

an agency cannot adequately represent the interests of a regulated party who is the direct beneficiary of a regulatory action—or, at minimum, plainly did not do so under the circumstances of this case.

The district court said otherwise because, in its view, the Agency adequately represented the Manufacturers' interests in this case. That conclusion rested on two errors. ***First***, it rested on a "presumption" of adequate representation and thus imposed on the Manufacturers a "heightened" burden to establish the inadequacy of the Agency's representation. APP09. No such presumption applies here. But even if it does, the Manufacturers' burden under it was "minimal" because of their distinct, direct, and concrete interests in the outcome of the litigation. ***Second***, even if the district court's "heightened" standard applied, the district court ignored that the full slate of the Manufacturers' legal positions, evidence, arguments, and strategies materially differed from the Agency's. Those differences drove the litigation's outcome: They led the district court and this Court to believe that there was "no apparent, actual urgency to the" commencement of the Pilot Program, JA550, and that the Manufacturers faced no "substantial injury" from an injunction, *Kennedy*, 164 F.4th at 37. They also ultimately led to a

settlement adverse to the Manufacturers' interests. Alternatively, the district court erred in denying permissive intervention under Rule 24(b).

A. Precedent Forecloses The District Court's "Heightened" Standard Of Inadequate Representation.

The district court's opinion suffers from two threshold errors of law. The decision resists the latest precedent indicating ***no*** presumption of adequate representation attaches when a regulated party intervenes on the side of its regulator. And it overlooks that, even under the old regime, the presumption is easily rebutted.

1. *Courts No Longer Apply The Presumption Of Adequate Representation In Circumstances Such As These.*

The Supreme Court recently addressed the "presumption of adequacy" in the context of "a request to intervene by a private party who asserted a related interest to that of an existing government party." *Berger v. N.C. State Conf. of the NAACP*, 597 U.S. 179, 195-96 (2022). In that circumstance, "[r]ather than endorse a presumption of adequacy, the Court [has] held that a movant's burden in circumstances like these 'should be treated as minimal.'" *Id.* at 196 (citation omitted); *id.* at 195 (noting that the Rule's test presents "only a minimal challenge"). That was so—even though the private and governmental parties' interests "might have seemed closely aligned"—because they were not "identical"

interests and the government "had to bear in mind broader public-policy implications." *Id.*

This Court has yet to address *Berger*, but the decision explains why no presumption of adequate representation should exist where a regulated party intervenes in support of a governmental agency to defend a regulatory action in its favor (and, as a result, its interests are never identical to those of the agency). *See Bost v. Ill. State Bd. of Elections*, 75 F.4th 682, 689 n.3 (7th Cir. 2023) (*Berger* has "called into question whether any presumption of adequate representation is appropriate"); *Callahan v. Brookdale Senior Living Cmtys., Inc.*, 42 F.4th 1013, 1021 n.5 (9th Cir. 2022) (same). At a minimum, *Berger* counsels in favor of a narrow interpretation of any such presumption. The district court erred by imposing a "heightened burden" of demonstrating inadequate representation and concluding that the Manufacturers failed to rebut it. ADD09.

2. *Any Presumption Of Adequate Representation Here Would Impose Only A Minimal Burden.*

Even if a presumption did apply, the district court sharply diverged from this Court's precedents, under which the presumption is readily rebuttable where, as here, the would-be intervenor's personal interests

are directly at stake. *See B. Fernandez*, 440 F.3d at 546 (to rebut presumption, "the intervenor need only offer an adequate explanation as to why it is not sufficiently represented by the named party"—for example, by demonstrating "that its interests are sufficiently different in kind or degree from those of the named party" (citation modified)). This Court has explained that the "test[] of inadequacy may vary with the strength of the [prospective intervenors'] interests" in the litigation. *Maine v. Director, U.S. Fish & Wildlife Serv.*, 262 F.3d 13, 20 (1st Cir. 2001). When prospective intervenors have "a tangible and substantial stake in the outcome of [the] case," their "direct interest[s]" make their burden "to show inadequate representation … ***lighter*** than if [their] interest[s] [were] thin and widely shared." *B. Fernandez*, 440 F.3d at 546 (emphasis added; citation modified). Twice over, the Manufacturers demonstrated that their interests in this litigation were the "direct" sort that lessen the burden of demonstrating inadequate representation. *Id.*

First, the Association's requested relief sought to overturn agency adjudications to which the Manufacturers themselves were parties. The Association sought an order vacating HRSA's approvals of the Manufacturers' rebate models. Such an order threatened the

Manufacturers' rights in those approvals and thus the way they could comply with federal law. "[T]he potential for an injunction binding [the Manufacturers'] future dealings" necessarily provided a "sufficient basis for concluding that [the Agency] may not serve as an adequate proxy." *B. Fernandez*, 440 F.3d at 546-47.[7] Moreover, the proceedings below threatened the Manufacturers with unique financial and legal consequences. JA126 (discussing the "tens of millions of dollars in losses flowing from duplicative price concessions and civil penalties for compliance mistakes"); JA178 (noting the "billions of dollars at stake").

Courts faced with similar circumstances have recognized that the targets of regulatory action are entitled to intervene as of right. In *Mosbacher*, for example, commercial fishing groups sought to intervene against a conservation group that sued the federal government seeking "more extensive regulation" that would directly affect their "economic interests" by reducing the amount of fishing permitted. 966 F.2d at 40,

[7] Notably, the existing party in *B. Fernandez* was an affiliate of the prospective intervenor. 440 F.3d at 545. That relationship would more readily give rise to a presumption that the existing party was committed to defending the prospective intervenor's interest than the relationship between the Agency (regulators) and the Manufacturers (regulated entities). Still, this Court reversed a denial of intervention in *B. Fernandez*.

43-44. Before the fishermen could intervene, the conservationists and the federal government "agreed upon the terms of a consent decree." *Id.* at 40. This Court recognized that the fishing groups should have been allowed to intervene, as "the real targets of the suit and … the subjects of the [requested relief]." *Id.* at 43. As in *Mosbacher*, the Manufacturers were "the real targets of the suit," which sought to set aside the approvals they had obtained from the Agency, and "changes in the [Pilot Program would] affect [the Manufacturers'] business, both immediately and in the future," entitling them to defend their own interests. *See id.*

Consistent with *Mosbacher*, other courts routinely permit regulated parties to intervene where the government has approved the party's own application and a third party challenges that approval. *See Driftless Area Land Conservancy v. Huebsch*, 969 F.3d 742, 749 (7th Cir. 2020) ("The plaintiffs cite no appellate case, and we know of none, that affirmed a denial of intervention in similar circumstances."); *Wal-Mart Stores, Inc. v. Tex. Alcoholic Beverage Comm'n*, 834 F.3d 562, 568-69 (5th Cir. 2016).

Second, the Association requested relief that would harm the Manufacturers, because the Pilot Program would have helped the Manufacturers avoid billions of dollars in duplicate discounts. *See*

90 Fed. Reg. at 38,165 (explaining that the Pilot Program originated with "inquiries from manufacturers … address[ing] 340B and Maximum Fair Price (MFP) deduplication"). That makes the Manufacturers like the intervenors in *Cotter v. Massachusetts Ass'n of Minority Law Enforcement Officers*, where minority police officers who received jobs and promotions under an allegedly discriminatory employment policy sought to defend the policy and, by extension, their employment status. 219 F.3d 31, 35-36 (1st Cir. 2000). Indeed, the Manufacturers' interests are even more directly implicated here, where the specific agency action challenged by the Association was approval of the Manufacturers' ***own*** applications, not merely the promulgation of a general agency policy that affected them.

Other courts recognize that direct beneficiaries of agency action are entitled to defend their own interests. For example, the Manufacturers are like the successful intervenors in *Crossroads*, 788 F.3d at 320-21. There, the D.C. Circuit—which this Court has looked to for guidance on Rule 24 issues in APA cases—held that the interests of a "beneficiary of a favorable decision by" a federal agency justified granting intervention of right without imposing a heightened standard. 788 F.3d at 314; *see*

also, e.g., *Mosbacher*, 966 F.2d at 44-45 (relying on *NRDC v. Costle*, 561 F.2d 904 (D.C. Cir. 1977), and *Dimond v. District of Columbia*, 792 F.2d 179 (D.C. Cir. 1986)).

Put simply, the Manufacturers possessed multiple interests, and each was of the type that lowers, not heightens, the inadequate-representation standard. They "had direct private interests" that "the government had … no interest in protecting"—namely, the crucial need to avoid billions of dollars in duplicate discounts, which is equivalent to the "jobs and promotions" or "commercial fishing interests" that this Court has found preclude a presumption of adequate representation. *Maine*, 262 F.3d at 20.

3. *None Of The District Court's Reasons For Applying A Heightened Presumption Are Valid.*

The district court's reasons for applying a presumption here—and a "heighted" one at that—do not withstand scrutiny. While courts sometimes assume that the government will adequately represent a prospective intervenor's interest in upholding a law or regulation when "a prospective intervenor … asserts essentially the public interest, rather than a personal interest," *United Nuclear Corp. v. Cannon*, 696 F.2d 141,

144 (1st Cir. 1982), the Manufacturers assert their own interests, not the public's, so *Cannon* and similar cases are inapposite.

A prospective intervenor (like the environmental interest group in *Cannon*) who simply wants to defend government action for the sake of defending it has interests that "perfectly align" with those of parties who are "defending the [action] in their capacity as members of a representative governmental body." *Pub. Serv. Co. of N.H. v. Patch*, 136 F.3d 197, 207-08 (1st Cir. 1998). Because a generalized interest does not inherently justify a need to intervene, "the burden of persuasion is ratcheted upward" compared to a prospective intervenor with direct, concrete interests in the litigation. *Id.* at 207; *see B. Fernandez*, 440 F.3d at 546.

Here, however, the Manufacturers were the latter sort of prospective intervenors. The district court did not agree, implying that the Manufacturers relied on intangible interests. *See* ADD08. But the Manufacturers were the very subject of the agency action being challenged, and their legal obligations were directly at stake in the litigation. They are unlike would-be litigants who assert only an "undifferentiated, generalized interest in the outcome" shared with the

public. *Patch*, 136 F.3d at 205 (groups seeking lower utility prices); *cf. Students for Fair Admissions, Inc. v. President & Fellows of Harvard College*, 807 F.3d 472, 474 (1st Cir. 2015) ("current and prospective" college applicants broadly interested in gaining admission to a diverse environment).

The district court reached a contrary conclusion only by construing the Manufacturers' interests at an inappropriately high level of generality. *See* ADD08 (surmising the Manufacturers and the Agency have the "same" goal because both want "to implement the Pilot Program"). While other members of the public might have generally supported the Agency's efforts "to implement the Pilot Program," *id.*, the Manufacturers were the only ones whose approvals to participate in the Pilot Program were actually at issue in the litigation, and the only ones whose legal obligations to provide deduplicated discounts were affected when those approvals were vacated. Similarly, and contrary to the district court's suggestions, *see id.* at 8-9, the Manufacturers do not resemble the nervous movant who wants to double-check a party's work, *see T-Mobile Northeast LLC v. Town of Barnstable*, 969 F.3d 33, 37 (1st Cir. 2020) (landowners worried a municipality's defense would become

less robust), or the movant who merely seeks a vehicle for its constitutional theories, *see Victim Rights Law Center v. Rosenfelt*, 988 F.3d 556, 559-61 (1st Cir. 2021) (advocacy groups "want[ed] to secure broad First Amendment and due process rights on college and university campuses").

None of these cases—nor any other in this theme—supports denying the Manufacturers' intervention here. Even if a presumption of adequate representation does apply here, it cannot bar intervention by participants in a challenged program, by parties to a challenged agency adjudication, or by direct beneficiaries of a government action or other entities whose conduct would be affected by the plaintiffs' requested injunction. To the extent such a presumption exists and applies here, it is substantially weakened under circumstances like these. Thus, there is no doubt that the Manufacturers were entitled to intervene and defend their direct, tangible, and substantial interests. This Court can and should reverse on that basis alone.

B. The Manufacturers Established Inadequate Representation, Regardless Of The Standard Applied.

The Manufacturers established inadequate representation under any standard because they have "offer[ed] an adequate explanation as to

why" they are "not sufficiently represented by the named party." *B. Fernandez*, 440 F.3d at 546 (citation modified). The Manufacturers' core purpose for seeking intervention was to ensure that the district court (and this Court) understood that without the Pilot Program, (1) the Manufacturers lacked a reliable means of identifying drug transactions to which their new, fast-approaching MFP obligations would apply, and (2) the Manufacturers would lose billions of dollars in duplicate discounts or civil penalties. The Agency failed to convey those core points to the district court or this Court—or conveyed the points too late, as when it forfeited its argument for the alternative remedy of remand without vacatur (for which the Manufacturers did advocate). What is worse, although those arguments were obvious—the Manufacturers made them when they sought to intervene, *see* JA311—the Agency declined to raise them. *See W. Watersheds Project v. Haaland*, 22 F.4th 828, 841 (9th Cir. 2022). Thus, no party even nominally represented the Manufacturers' interests. The district court abused its discretion when it reached the opposite conclusion.

1. *The Manufacturers Adopted Unique Legal Positions Because Of Their Direct Stake In The Pilot Program*.

The district court conflated interests that were "different in kind [and] degree." *B. Fernandez*, 440 F.3d at 546. To the Manufacturers, this suit was an urgent threat to their only reliable method of complying with federal law without surrendering their statutory right not to pay unnecessary duplicate discounts.

For the Agency, the deduplication issue was a secondary consideration, at best. The Agency instead opposed the Association's injunction from the perspective of an Executive Branch agency safeguarding its claimed regulatory authority. *See, e.g.*, *Texas v. United States*, 805 F.3d 653, 663 (5th Cir. 2015) ("[T]he Government's interests are in securing the expansive interpretation of executive authority …." (quotations omitted)). To them, the Pilot Program was the Agency's first effort to exercise, via a limited scope, the Secretary's authority to implement 340B discounts through a rebate model. JA371. But the Agency did not see the Pilot Program as an urgent need. Indeed, the Agency took the opposite legal position, disagreeing with the Manufacturers that the Pilot Program was the ***only*** reliable method available for the Manufacturers to achieve deduplication. Mot. for Stay

Pending Appeal, No. 25-2236 (1st Cir. Dec. 30, 2025), at 8 ("Manufacturers have alternate means to deduplicate discounts[.]"); *see Cotter*, 219 F.3d at 35-36 (noting that the "applicants for intervention have expressed an intention to defend" the government action on grounds the existing party has "ample reason … to resist"). So the Manufacturers "certainly ha[d] more to lose … in this litigation—at least insofar as [the Association sought] relief enjoining [the Manufacturers from] performing under the" Pilot Program approvals. *B. Fernandez*, 440 F.3d at 547.

2. *The Manufacturers, Unlike The Agency, Argued For Remand Without Vacatur.*

The Manufacturers focused on the nature of the potential remedy, arguing for the narrower, nondisruptive remedy of remand without vacatur. JA311. That would have given the Association the supplemental reasoning it purportedly desired without subjecting the Manufacturers to billions of dollars in losses and potentially to civil penalties.

From the Agency's perspective, however, the remedy was not an important issue. The Agency preferred not to implement the Pilot Program at all if the alternative was to implement it under a cloud of uncertainty. *See* JA555-558. By contrast, the Manufacturers faced

potentially billions of dollars in costs. They were willing to move forward with the Pilot Program even under uncertain conditions. The Agency thus "lack[ed] the same drive that motivate[d]" the Manufacturers to oppose an immediate injunction. *Wineries of the Old Mission Peninsula Ass'n v. Twp. of Peninsula*, 41 F.4th 767, 775 (6th Cir. 2022).

Those divergent motivations manifested themselves when the Agency did not contest the factual bases of the Association's claim for injunctive relief, did not acknowledge the irreparable harm that the Manufacturers would suffer if their approvals were set aside, did not seek remand without vacatur until it was too late, and ultimately settled with the Association by withdrawing the Pilot Program rather than continuing to defend it. Whether the Agency refused or simply did not realize that it should argue for remand without vacatur, the conclusion is the same. While "the use of different arguments" may not amount to "*per se*" inadequacy, a party's "refusal to present obvious arguments" could on its own justify the conclusion that the party's representation was inadequate—"even in the absence of any conflict of interest." *See Daggett v. Comm'n on Governmental Ethics & Election Pracs.*, 172 F.3d 104, 112 (1st Cir. 1999). The Agency did not adequately represent the

Manufacturers by failing to argue for an alternative remedy that might have mitigated some of their extraordinary harms. *See, e.g.*, *W. Watersheds Project*, 22 F.4th at 841 (concluding intervention should have been granted despite agreement on "the same ultimate objective" based on "several colorable arguments that [a party] did not seek to raise in the proceedings below").

The Manufacturers also put forth evidence rebutting the Association's claims of impending harm and establishing that an injunction would subject the Manufacturers to exponentially greater harm. JA303-305; JA138; JA140 (¶¶13, 18); JA149-150 (¶¶22, 24); JA319 (¶8); JA338-339 (¶¶11, 15). As the entities who were tasked with deduplication and who would be implementing the rebate systems in question, the Manufacturers' evidence was especially relevant to the irreparable harm and balance-of-equities questions. *See Mass. Food Ass'n v. Mass. Alcoholic Beverages Control Comm'n*, 197 F.3d 560, 567 (1st Cir. 1999) (acknowledging intervention would be appropriate if the case "require[d] an evidentiary determination and … the would-be intervenors had information that could only be presented by their participation as parties"); *Utahns for Better Transp. v. U.S. Dep't of*

Transp., 295 F.3d 1111, 1117 (10th Cir. 2002) (overriding presumption of adequate representation when intervenor could "provide expertise the government agencies may be lacking").

3. *The Manufacturers And The Agency Disagreed About The Scope Of The Agency's Authority.*

The Manufacturers advanced arguments consistent with their own views of agency authority. The Manufacturers consistently contended that the informal-adjudication nature of the Pilot Program approvals lessened the burden of providing a reasoned explanation for HRSA's approval decisions. JA303 (citing *Hudson*, 192 F.3d at 1034, 1036, and *Housatonic River Initiative*, 75 F.4th at 266-67). By contrast, the Agency focused on threats to its regulatory authority, with its lead argument being that HRSA has "unreviewable" discretion over 340B rebates. JA359; JA366. Some Manufacturers are currently involved in other 340B litigation against HRSA, where they dispute that HRSA has unreviewable discretion on 340B matters. Those Manufacturers are litigating the scope of HRSA's authority to prevent 340B-participating manufacturers from unilaterally using rebate mechanisms. JA127; JA406; s*ee Maine*, 262 F.3d at 21 (noting that "a prior adversary relationship" can undermine adequacy). That "disagree[ment] about the

extent of [HRSA's] regulatory power" alone should have made the Manufacturers' "different interests" "apparent." *Crossroads*, 788 F.3d at 321; *see also Bost*, 75 F.4th at 689 (noting that the government party "***regulates*** the [intervenors], it does not ***advocate for*** them or represent their interests"); *Wineries of the Old Mission Peninsula*, 41 F.4th at 774 (refusing to apply presumption of adequate representation).

4. *Mere Agreement On An Ultimate Objective Does Not Defeat Intervention.*

The district court concluded that because the Manufacturers and the Agency both sought to defend the Pilot Program, the Manufacturers had no right to intervene. But alignment on the overall outcome is present for every motion to intervene: "After all, a prospective intervenor must intervene on one side of the 'v.' or the other and will have the same general goal as the party on that side." *Bost*, 75 F.4th at 688 (citation omitted).

Courts must do more than identify surface-level agreement to deny intervention of right. *See, e.g.*, *Mosbacher*, 966 F.2d at 44-45; *Crossroads*, 788 F.3d at 321 (explaining that "treating general alignment as dispositive" is improper); *Fund for Animals, Inc. v. Norton*, 322 F.3d 728, 737 (D.C. Cir. 2003) ("[E]ven a shared general agreement … does not

necessarily ensure agreement in all particular respects … or necessarily preclude the intervenor from the opportunity to appear in its own behalf" (citation modified)). This Court has thus cautioned against a "mechanistic application" of the "presumption" of adequate representation and instructed district courts to determine adequacy "in keeping with a commonsense view of the overall litigation." *Maine*, 262 F.3d at 19 (citation omitted); *see also Berger*, 597 U.S. at 197 (explaining that interests "similar to, but not identical with, that of one of the parties" are insufficient to trigger the presumption). The district court did not heed that warning. Indeed, apart from observing that both the Manufacturers and the Agency wanted the Pilot Program upheld, ADD10-11, the court made no effort to evaluate whether their positions, arguments, and interests were the same or otherwise aligned.

5. *The District Court Ignored Important Distinctions.*

Under any standard, the Agency's and the Manufacturers' legal positions, interests, and approaches differed such that intervention was warranted. The Agency's and the Manufacturers' differences on the scope of HRSA's 340B regulatory authority, coupled with the Agency's silence on the ***necessity*** of the Pilot Program to the Manufacturers,

demonstrated "enough likelihood of conflict or divergence of interest exists to defeat any claim that [the Manufacturers'] interest[s] [were] adequately represented by the existing parties." *Cotter*, 219 F.3d at 35 (citation omitted); *see also Maine*, 262 F.3d at 20 (intervention appropriate if intervenors introduce evidence the government "would refuse to present" and make arguments that "require[] presentation of evidence only available through … participation as intervenors"). And the Manufacturers' evidentiary submissions rebutting the Association's claimed harms and demonstrating the threat to the Manufacturers were important considerations that the Agency was not advancing but that should have been considered in the preliminary-injunction analysis.

The district court acknowledged none of this. It did not reason through ***any*** of the Manufacturers' unique interests or contributions. Instead, the district court described the Manufacturers' motions to intervene as being "founded entirely on speculation" and declared that the Manufacturers "offer[ed] no evidence to suggest that their approach to defending the Pilot Program offers the Court any additional insight." ADD08-09. Those statements cannot be squared with the record that was before the district court at the time of its decision. As the

Manufacturers have just explained, the Manufacturers and the Agency had already staked out materially different legal positions, advanced different arguments, and presented different evidence of economic harm that could be found nowhere else in the record. In short, the "arguments [the Manufacturers] … emphasize[d]," on both the merits and remedies, were "different from those that [the Agency] ha[d] pressed and [would] press." *B. Fernandez*, 440 F.3d at 546; *see also, e.g.*, *W. Watersheds Project*, 22 F.4th at 840-41; *Lucas County Bd. of Commissioners v. U.S. EPA*, 169 F.4th 689, 701-02 (6th Cir. 2026).

This failure to consider the arguments and evidence presented by Manufacturers was both a legal error and an abuse of discretion. *See Top Ent., Inc. v. Torrejon*, 351 F.3d 531, 533 (1st Cir. 2003) ("Where a legal error is committed, there is by definition an abuse of discretion."). Indeed, one reason for regulated parties to intervene in litigation challenging agency orders that directly apply to them is to ensure that courts do not overlook critical arguments and the balance of interests. But because the Manufacturers were not permitted to intervene, the district court did not have their different arguments and evidence squarely before it at the preliminary injunction stage.

C. Subsequent Events Underscore The Propriety Of Intervention.

The parties' papers alone made clear the Manufacturers' interests were not adequately represented. Developments during and after the preliminary injunction hearing amplify that conclusion.

During the injunction hearing, the Agency did not assert the Manufacturers' interests. The Agency hardly discussed the deduplication issue. When it did, the Agency described the Pilot Program as "one tool that [the Manufacturers] can use … to achieve" deduplication, still refusing to acknowledge that a rebate system was the only reliable deduplication method available to the Manufacturers. JA460. And the Agency again led with the argument (***adverse*** to the Manufacturers) that HRSA has unreviewable 340B rebate authority. JA439-441.

Only after that hearing went poorly did the Agency start to make some of the Manufacturers' arguments. The Agency sought remand without vacatur for the first time in a post-hearing submission to the district court. *Compare* JA311 (the Manufacturers arguing that the Association had failed to show why "the appropriate remedy would be a ***multi-billion dollar injunction*** rather than a remand for

supplemental reasoning"), *with* JA411 (the Agency requesting "remand to the agency for further consideration or explanation without setting aside the agency's decisions"). And the Agency waited until its stay-pending-appeal motion in this Court to develop an argument that the Pilot Program approvals' status as informal adjudications materially affected the APA analysis. Specifically, the Agency argued that "because the [Pilot] Program [was] an informal adjudication," "the APA does not specifically require it to explain its decisions" at all. *Kennedy*, 164 F.4th at 35 (citation modified). The Manufacturers had made a similar—but less agency-deferential—argument in the district court. JA302-303 ("HRSA explained that the approved plans all met the requirements as stated in the August 1 Notice. Nothing more would be required under the APA." (citation modified)).

The Agency's pivots came too late. The district court did not address remand without vacatur, likely considering it a point the Agency forfeited. And this Court explicitly found that the Agency waived an argument that HRSA's explanations in this case were sufficient for the purposes of informal adjudications. *Kennedy*, 164 F.4th at 35-36. Had the Manufacturers been permitted to intervene, by contrast, no such

waiver ruling would have been possible. In other words, the decision to deny intervention was practically determinative.

The Agency also failed to address factual gaps in the Association's position. For example, the Agency never submitted evidence to rebut the factual bases of the Association's request for emergency relief—i.e., that the Association faced imminent financial harm and increased administrative burdens. Because those claims went unchecked, the district court (and eventually this Court) took them at face value. *See* JA534; *Kennedy*, 164 F.4th at 32. The district court and this Court could take the Association's claims as a given because the Manufacturers were not permitted to intervene and put their evidence—drawn from the underlying administrative proceedings—in the record before the district court.

The Agency also never changed its position on the necessity of the Pilot Program for the Manufacturers. The Agency's position that the Manufacturers had other deduplication methods available to them led the district court and this Court to believe that the Manufacturers faced no harm from an injunction. The district court granted an injunction, and denied a stay, in part because it saw "no apparent, actual urgency to

the January 1[, 2026] start date." JA550. This Court acknowledged that "the primary cost of any delay appears to run to the drug manufacturers." *Kennedy*, 164 F.4th at 37. Nevertheless, this Court concluded that there would be no "substantial injury in the absence of a stay," ***because*** "the federal government has indicated that manufacturers have alternative methods to address the … duplication issue." *Id.* Had the Manufacturers been granted party status, their arguments and evidence that "[e]ven a modest delay in the Pilot Program's implementation" would lead to disastrous duplicate discounts and civil penalties would have been before the district court and this Court. JA126; *see also, e.g.*, JA209; JA341 (¶24). Again, the course of litigation would have been different.

It cannot be true that the Agency adequately represented the Manufacturers' interests during the hearing and emergency appeal by (1) taking different legal positions that are adverse to their interests; (2) failing to rebut the Association's assertions of imminent harm; (3) making factual representations that justified ignoring the Manufacturers' interests; and (4) failing to adduce any evidence regarding the harm that the Manufacturers would suffer if their approvals were set aside. The Agency's approach to this case left the

courts' equitable balancing irredeemably tipped against the Manufacturers.

The consequences for the Manufacturers continued after this Court left the district court's injunction in place. Rather than continuing to defend the Pilot Program, the Agency agreed to vacate it and go back to the drawing board. JA557 (¶7). Because the district court denied intervention, the Manufacturers were not parties entitled to participate in the settlement discussions or object to the scope of the relief by, for example, requesting remand without vacatur. The Manufacturers now have no reliable DPNP compliance mechanism for the foreseeable future, and the amount of time they will go without one has been extended by the Agency's agreement with the Association. They will be forced to pay millions—and possibly billions—of dollars in duplicate discounts, which they will never be able to recover. Indeed, the Manufacturers have already begun to suffer those irreparable harms.

D. Alternatively, The Manufacturers Were Entitled To Permissive Intervention.

The district court also erred in denying the Manufacturers permissive intervention under Rule 24(b). The district court's only stated reasons for denying permissive intervention were (1) its conclusion that

the Agency would adequately represent the Manufacturers' interests on the theory the Manufacturers did not "add any missing element to Federal Defendants' defense" and (2) its prediction that it was "possible that intervention could create undue delay in the final disposition of this case." ADD12 (citation modified).

The district court's first ground merely reasserts its conclusion on intervention of right, which was erroneous for the reasons already discussed. *See supra* Section I.A-C. Moreover, while Rule 24(a)(2) references adequacy of representation in setting out the standard for intervention as of right, Rule 24(b)(2) (governing permissive intervention) does not. Accordingly, the district court should not have given weight to these grounds in assessing the Manufacturers' separate and alternative claim for permissive intervention.

The second ground is unfounded speculation. Of course, district courts have broad discretion with respect to permissive intervention and may consider the possibility of delay when denying intervention. *Daggett*, 172 F.3d at 112-13. But that discretion is not unbounded: A court must articulate a justifiable rationale that is actually based on the record. *See id.* Here, there was no factual basis to conclude that the

Manufacturers would delay the case. By the time the district court denied their intervention motion, the Manufacturers had acted with nothing but speed—promptly noticing their intent to intervene and to abide by the schedule set for the Agency, and filing their motions on the district court's expedited schedule. Indeed, the Manufacturers filed their injunction-opposition brief even before the Agency filed its brief. Tellingly, the district court provided no actual reasons for thinking the Manufacturers would cause any delay and in fact admitted that the Manufacturers would not "***immediately*** unduly delay or prejudice the proceedings." ADD12.

The district court's denial of permissive intervention was thus based on an irrelevant and legally incorrect assessment of adequate representation, a disregard of the record, and unfounded speculation about what could "possibly" happen later in the case. That is an abuse of discretion. *See Torrejon*, 351 F.3d at 533; *JRA Architects & Project Managers, P.S.C. v. First Fin. Grp., Inc.*, 375 F. App'x 42, 43 (1st Cir. 2010) (abuse of discretion occurs when a district court fails to provide "some indication of its reasons for rejecting [a party's] colorable arguments" (citation modified)).

II. This Appeal Is Not Moot Because The District Court's Error Is Capable Of Repetition Yet Evading Review.

To determine whether an appeal meets the capable of repetition yet evading review exception, this Court first asks whether "the challenged action was in its duration too short to be fully litigated prior to its cessation or expiration." *United States v. Chin*, 913 F.3d 251, 256-57 (1st Cir. 2019). This Court then assesses whether "there [is] a reasonable expectation that the same complaining party [will] be subjected to the same action again." *Id.* (citation omitted). This appeal satisfies both conditions.

A. The Manufacturers' Claim Is Inherently Time-Limited.

Suits for emergency injunctive relief are a paradigmatic example of the type of "'inherently transitory' claims the Supreme Court has recognized as likely to evade review." *ACLU of Mass.*, 705 F.3d at 57 (citing *Neb. Press Ass'n v. Stuart*, 427 U.S. 539, 542 (1976)). These cases typically reach a resolution in a short amount of time, so "important procedural issues raised by the unusual circumstances" of the case often go unresolved. *Procter & Gamble Co. v. Bankers Tr. Co.*, 78 F.3d 219, 224 (6th Cir. 1996). A decision denying a motion to intervene so that the movant can defend against a claim for emergency injunctive relief is thus

as "inherently transitory" as the request for injunctive relief itself. *ACLU of Mass.*, 705 F.3d at 57. And that means there is a substantial risk that a district court's erroneous denial of a motion to intervene will "always evade review absent this exception to mootness" because the underlying suit likely will be resolved before the would-be intervenors can obtain complete and meaningful appellate review. *Procter & Gamble*, 78 F.3d at 224.

The facts here prove the point. The Manufacturers moved to intervene at the very beginning of the case, but only fifty-four days elapsed from the time the district court denied intervention until the case was resolved. This Court has recognized that even longer spans of time are "'too short' …, given that the appeal process often takes longer than a few months." *Chin*, 913 F.3d at 257 (three months) (citation omitted); *see also In re Grand Jury Proceedings*, 744 F.3d 211, 219 (1st Cir. 2014) (two months). Even "one year is an insufficient amount of time … to adjudicate the typical case." *Bourgeois v. Peters*, 387 F.3d 1303, 1309 (11th Cir. 2004).

The fact that the Association and the Agency settled after this Court denied a stay pending appeal further demonstrates how fast cases

like this one play out. That settlement reflects the Association and the Agency's commonsense conclusion that the district court's injunction and this Court's order effectively affirming that injunction resolved the case. *See* JA556 (¶4). It is not as though this is a one-off situation where the supposedly mooting event "result[ed] from 'happenstance'; it was almost certainly driven by [the] [stay] opinion," which "brought the parties to the table to negotiate [the vacatur and remand] agreement and expedited the end of this case." *United States v. Flute*, 951 F.3d 908, 910 (8th Cir. 2020). The upshot for this Court's mootness analysis is that the expedited orders on injunctive relief, even if styled as preliminary, will be ***the*** definitive rulings in cases like this. Such definitive rulings will typically come too soon for wrongly denied intervenors to obtain appellate review.

Even if the Association and the Agency had not settled, the case may have been litigated to a final judgment before the Manufacturers could obtain appellate review. The Association itself emphasized in the district court that the case could be fully litigated within four months of the complaint being filed. *See* JA416 ("[W]e believe … this case can be heard expeditiously on the merits, likely [by] … April … 2026."); JA431 (same); Dkt. 82 at 13 (explaining that "a few months [would] allow this

Court time to fully consider the merits"). On that timeline, critical steps in the district court would likely have passed while this Court considered whether the Manufacturers had a right to participate in the district court proceedings.

B. The Manufacturers' Claim Is Likely To Recur.

There is "a reasonable expectation or a demonstrated probability that the same controversy will recur involving" the Manufacturers' right to intervene. *Barr*, 626 F.3d at 105 (citation modified). Indeed, recurrence is virtually guaranteed.

In their joint motion for vacatur and remand, the Association and the Agency previewed what is to come if HRSA launches another rebate model program: another round of litigation. The Agency specifically agreed to schedule any new rebate program—the consideration of which is already underway—around the expectation that the Association will challenge it. JA558 (¶9); *see* 91 Fed. Reg. 7,287.

The Manufacturers would have every reason to seek intervention again in any subsequent suit. The new suit (like the prior one) can be expected to challenge HRSA orders approving Manufacturers' rebate model applications. The Manufacturers will still face billions of dollars

in duplicate discounts or statutory penalties and will want to exercise their right to defend their own interests, which—however a potential new rebate program might be structured—are "different in kind [and] degree from" the Agency's interests. *B. Fernandez*, 440 F.3d at 546. There is no reason to think the Association would not again oppose the Manufacturers' intervention and, absent some remedial action by this Court, invoke the district court's intervention denial below in their support. *See* Appellees' Opp'n to Mot. to Intervene on Appeal at 6, No. 25-2236 (1st Cir. Jan. 12, 2026) (arguing that "the district court correctly held" that the Manufacturers' interests were adequately represented by the Agency).

Moreover, the Association and the Agency have structured their settlement to ensure that any future litigation proceeds on a compressed timeline. They anticipate that litigation over a new rebate program could be fully resolved in ninety days, if not faster. *See* JA558 (¶9). That expedited posture would almost certainly replicate the procedural dynamic that deprived the Manufacturers of review here: An intervention denial followed by expedited merits proceedings that concluded before the appellate process could run its course. *E.g.*,

Bourgeois, 387 F.3d at 1309 (one year an insufficient time to obtain review); *Chin*, 913 F.3d at 257 (three months insufficient); *In re Grand Jury*, 744 F.3d at 219 (two months insufficient). If the next case concludes within ninety days—as the Association and the Agency contemplate—the Manufacturers will have no real opportunity to obtain appellate review of another intervention denial before the district court litigation develops significantly. That makes this Court's review now the only meaningful safeguard of the Manufacturers' procedural rights.

In short, this appeal is not moot.

III. If This Court Deems The Appeal Moot, *Munsingwear* Vacatur Is Appropriate.

If "mootness has prevented [review of] the district court's order denying intervention," then this Court should "remand to the district court with instructions to vacate that order to avoid its having preclusive or precedential effect." *Bay Area Nuclear Waste Coal. v. Lujan*, 42 F.3d 1398, at *3 (9th Cir. 1994) (Table Op.) (citing *Munsingwear*, 340 U.S. at 39). It is common practice in the courts of appeals to vacate orders denying intervention when appeals from such orders become moot—such that no further litigation was anticipated—before the appellate process concludes. *See Church v. Missouri*, 2020 WL 8255313, *1 (8th Cir. July

8, 2020) ("The case is remanded to the district court with instructions to vacate the … order denying the Attorney General's motion to intervene."); *cf. Animal Legal Defense Fund, Inc. v. U.S. Dep't of Agric.*, 2020 WL 4873759, *1 (D.C. Cir. June 11, 2020) ("[T]he case is remanded with instructions to dismiss the complaint and to vacate the agency's … order denying appellant's motion to intervene in the underlying enforcement action." (citing *Munsingwear*, 340 U.S. at 39)). Doing so will "clear the path for future relitigation," ensuring that "the rights of all parties are preserved and none is prejudiced by a decision which … was only preliminary." *ACLU of Mass.*, 705 F.3d at 58 (citation modified).

Munsingwear vacatur is warranted when "[a] party who seeks review of the merits of an adverse ruling … is frustrated by the vagaries of circumstance," such that the party "ought not in fairness be forced to acquiesce in the" appealed ruling. *Id.* at 57-58 (citation omitted). That is precisely what will happen here if this Court dismisses for mootness: The Manufacturers sought review of the district court's intervention denial but were cut off by the agreement between the Association and the Agency to vacate and remand. The Manufacturers did not participate in

that agreement and had no right to do so because their motion to intervene had been denied.

This case is thus unlike *U.S. Bancorp Mortgage Co. v. Bonner Mall Partnership*, 513 U.S. 18 (1994). There, the Supreme Court held that vacatur is unwarranted when "the losing party has voluntarily forfeited his legal remedy by the ordinary processes of appeal," such as "[w]here mootness results from settlement" by the losing party. 513 U.S. at 25-26. The Manufacturers did not voluntarily forfeit their rights to appeal or partake in "the settlement that caused the mootness." *Id.* at 26; *see also, e.g.*, *N. Cal. Power Agency v. Nuclear Regul. Comm'n*, 393 F.3d 223, 225-26 (D.C. Cir. 2004) (*Bancorp* inapplicable where entity seeking vacatur "was not a party to the settlement"); *Atlanta Gas Light Co. v. FERC*, 140 F.3d 1392, 1403 n.11 (11th Cir. 1998) ("*Bancorp* does not control this case because Atlanta Gas was not a party to the settlement."). If this case is deemed moot, it will be because of the "unilateral action" taken by the Association and the Agency, not because of anything the Manufacturers have done. *Bancorp*, 513 U.S. at 25.

CONCLUSION

This Court should reverse the erroneous denial of the Manufacturers' motions to intervene. Alternatively, the Court should vacate, under *Munsingwear*, the district court's order.

DATED: May 5, 2026

Respectfully submitted,

/s/ Matthew S. Owen

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CERTIFICATE OF COMPLIANCE

This brief complies with the type-volume limitation of FED. R. APP. P. 32(A)(7)(B) because it contains 12,905 words, excluding the parts of the brief exempted by FED. R. APP. P. 32(f).

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/s/ Matthew S. Owen
Matthew S. Owen

CERTIFICATE OF SERVICE

I hereby certify that on May 5, 2026, I electronically filed the foregoing document with the United States Court of Appeals for the First Circuit by using the CM/ECF system. Participants in the case who are registered CM/ECF users will be served by the CM/ECF system.

/s/ Matthew S. Owen
Matthew S. Owen

Addendum

Order Denying Motions to Intervene (ECF No. 83).....ADD01

UNITED STATES DISTRICT COURT

DISTRICT OF MAINE

AMERICAN HOSPITAL ASSOCIATION, et al.,	)	
Plaintiffs	)	
v.	)	No. 2:25-cv-00600-LEW
ROBERT F. KENNEDY, JR., SECRETARY OF THE UNITED STATES DEPARTMENT OF HEALTH AND HUMAN SERVICES, *et al*.,	)	
Defendants	)	

ORDER ON MOTIONS TO INTERVENE

In a lawsuit challenging agency action under the Administrative Procedure Act, several pharmaceutical manufacturers move to intervene in support of the agency's action. Because the pharmaceutical manufacturers fail to demonstrate that the government will not adequately represent their interests in defending against the lawsuit, the court denies their motions. However, the Court will permit the pharmaceutical manufacturers to participate as amici curiae.

BACKGROUND

On December 1, 2025, the American Hospital Association (AHA) and the Maine Hospital Association (MHA), along with several of AHA's and MHA's members, (collectively, Plaintiffs) filed a complaint and a motion for temporary restraining order,

seeking to enjoin the implementation of a new federal drug pricing program, the 340B Rebate Model Pilot Program (the Pilot Program). Compl. for Decl. and Inj. Relief (ECF No. 1); Mot. for TRO (ECF No. 3). Plaintiffs allege that Defendants' promulgation of the Pilot Program violates the Administrative Procedure Act (APA) and ask this Court to declare the program unlawful under § 706 of the APA. Compl. ¶¶ 34-39, 52-62, 130-175.

On December 10, 2025, several pharmaceutical manufacturers (hereafter, "Movants") moved to intervene in this action. AbbVie Inc.'s and Pharmacyclics LLC's Mot. to Intervene (ECF No. 36) ("AbbVie Mot."); AstraZeneca Pharmaceuticals LP's Mot. to Intervene (ECF No. 39) ("AstraZeneca Mot."); Pharmaceutical Research and Manufacturers of America Mot. to Intervene (ECF No. 45) ("PhRMA Mot."); Boehringer Ingelheim Pharmaceuticals, Inc.'s and Novo Nordisk Inc.'s Mot. to Intervene (ECF No. 50) ("Novo Nordisk Mot."). Plaintiffs have opposed the motions. Pls.' Omnibus Opp'n to the Mots. to Intervene (ECF No. 76) ("Pls.' Opp'n"). Defendants have taken no position. Defs.' Position on Mot. to Intervene (ECF No. 74). Movants assert that they are entitled to intervene as a matter of right to represent what they claim are substantial and distinct interests. AbbVie Mot. at 5-9; AstraZeneca Mot. at 2-3; PhRMA Mot. at 2-6; Novo Nordisk Mot. at 4-9. Alternatively, Movants seek permissive intervention, arguing their intervention will not unduly delay or prejudice the adjudication of Plaintiffs' or Federal Defendants' rights. AbbVie Mot. at 9-10; AstraZeneca Mot. at 2-3; PhRMA Mot. at 6-7; Novo Nordisk Mot. at 10.

Plaintiffs oppose Movants' intervention, contending they have no right to intervene to protect contingent interests adequately represented by Federal Defendants. *Pls.' Opp'n*

at 2-8. As to permissive intervention, Plaintiffs aver Movants' intervention would complicate and delay proceedings without adding value to the Court's consideration of Federal Defendants' or Plaintiffs' arguments in this case. *Id.* at 8-10. Plaintiffs consent to the Court permitting Movants to participate as amici curiae, however. *Id.* at 10.

DISCUSSION

Under Federal Rule of Civil Procedure 24(a)(2), "[o]n timely motion, the court must permit anyone to intervene who . . . claims an interest relating to the property or transaction that is the subject of the action, and is so situated that disposing of the action may as a practical matter impair or impede the movant's ability to protect its interest, unless existing parties adequately represent that interest." Fed. R. Civ. P. 24(a)(2). "[A] would-be intervenor must demonstrate that: (i) its motion is timely; (ii) it has an interest relating to the property or transaction that forms the foundation of the ongoing action; (iii) the disposition of the action threatens to impair or impede its ability to protect this interest; and (iv) no existing party adequately represents its interest." *Ungar v. Arafat*, 634 F.3d 46, 50 (1st Cir. 2011). "Failure to satisfy any one of the four requirements defeats intervention by right." *Students for Fair Admissions, Inc. v. President and Fellows of Harvard Coll.*, 807 F.3d 472, 474 (1st Cir. 2015).

Alternatively, under Federal Rule of Civil Procedure 24(b)(1)(B), a district court may permit intervention when the putative intervenor "has a claim or defense that shares with the main action a common question of law or fact" and timely moves for intervention. Fed. R. Civ. P. 24(b)(1)(B); *Victims Rts. L. Ctr. V. Rosenfelt*, 988 F.3d 556, 561 (1st Cir. 2021). District courts enjoy broad discretion to grant or deny motions for permissive

intervention. *T-Mobile Ne. LLC v. Town of Barnstable*, 969 F.3d 33, 42 (1st Cir. 2020). Although "the court may 'consider almost any factor rationally relevant' to the intervention determination," the district court at least "'must consider whether the intervention will unduly delay or prejudice the adjudication of the original parties' rights.'" *Id.* at 40 (first quoting *Daggett v. Comm'n on Governmental Ethics and Election Pracs.*, 172 F.3d 104, 113 (1st Cir. 1999), and then quoting FED. R. CIV. P. 24(b)(3)).[1]

A. Intervention by Right

Regarding intervention by right, I narrow my focus to Movants' argument that Defendants cannot adequately represent their interests in this case. *T-Mobile*, 969 F.3d, 39 (starting and ending intervention by right analysis with adequacy of representation). "To demonstrate inadequate representation, a putative intervenor must show that no existing party fairly represents her interests." *Id.* (citing *Students for Fair Admissions*, 807 F.3d at 475). In cases, like this one, where "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," a presumption attaches to the government's adequacy of representation, which the movant bears the burden of overcoming with a sufficient "showing to the contrary." *Mass. Food Ass'n v. Mass. Alcoholic Beverages Control Comm'n*, 187 F.3d 560, 566-67 (1st Cir. 1999); *accord T-Mobile*, 969 F.3d at 39 (collecting cases). The movant "must

[1] As Plaintiffs concede, there is no question that Movants satisfy the timeliness requirement. Pls.' Mot. at 3 n.3.

produce some tangible basis" as opposed to mere speculation, to support their claim of inadequate representation. *Pub. Serv. Co. of N.H. v. Patch*, 136 F.3d 197, 207 (1st Cir. 1998).[2]

Movants advance two arguments that Defendants inadequately represent their interests, neither of which is convincing. First, they claim Defendants cannot adequately represent Movants' distinct financial interests related to losses from duplicative discounts and civil penalties for noncompliance with their competing directives under two federal drug pricing laws. AbbVie Mot. at 6-8; AstraZeneca Mot. at 2-3; PhRMA Mot. at 5; Novo Nordisk Mot. at 7-9. Second, they point to Defendants' adverse position in separate litigation against Movants concerning the statute governing the 340B pricing program as evidence of Defendants' inadequacy to represent their interests in this case. AbbVie Mot. at 8; AstraZeneca Mot. at 2-3; PhRMA Mot. at 5-6.

As Movants explain, the Pilot Program's rebate model is intended to resolve the competing mandates under federal drug pricing laws that threaten their financial interests. Under the current 340B discount program, Movants must offer upfront discounts at the

[2] Novo Nordisk's reliance on *Berger v. N.C. State Conf. of the NAACP*, 597 U.S. 179 (2022) for the proposition that the Supreme Court disfavors the First Circuit's presumption of adequate representation in these circumstances is misguided. Novo Nordisk Mot. at 6-7. In that case, the Supreme Court held that "a presumption of adequate representation is inappropriate when a duly authorized state agent seeks to intervene to defend a state law." *Id.* at 197. In reaching that holding, the Court made clear its decision 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." *Id.* Rather, the Court's decision trained on the narrow category of "adverse presumptions" that "displace a State's prerogative to select which agents may defend its laws and protect its interest," a situation entirely distinct from the circumstances under which Movants seek to intervene in this case. *Id.*

point of sale to certain "covered entities," such as Plaintiffs. AbbVie Mot. at 2; Novo Nordisk Mot. at 2. Starting on January 1, 2026, Movants will also be required to offer discounts on select drugs under Medicare as part of the Inflation Reduction Act's Drug Price Negotiation Program, where the Secretary of Health and Human Services sets the "maximum fair price" available to certain Medicare-eligible individuals through a rebate (the "IRA discount program"). AbbVie Mot. at 2; Novo Nordisk Mot. at 2. Where these separate required discounts overlap, the IRA mandates Movants offer the lower of these two discounts. 42 U.S.C. § 1320f-2(d); Abbvie Mot. at 3; Novo Nordisk Mot. at 2-3. Consequently, Movants estimate significant financial losses in the form of duplicative discounts, once at the point of sale to covered entities under 340B and second through a rebate if those discounted drugs are later disbursed to an eligible patient under the IRA discount program. Novo Nordisk Mot. at 2-3. Movants also estimate significant financial loss from civil penalties where they fail to comply with the directive to offer the lower of the two prices. AbbVie Mot. at 3. The Pilot Program's rebate model for 340B covered transactions, effective January 1, 2026, resolves this problem by allowing Movants to analyze claims data after the covered entity dispenses the drugs to a patient (i.e., not at the point of sale) to determine which of the two discount programs applies. AbbVie Mot. at 3-4; Novo Nordisk Mot. at 3.

Because Defendants do not face the specter of duplicate discounts and civil penalties, Movants argue Defendants cannot adequately represent their "distinctly commercial and industry-based" interests in defending the implementation of the Pilot Program. AbbVie Mot. at 7; PhRMA Mot. at 5; Novo Nordisk Mot. at 6. Movants have

invested substantial resources in anticipation of the Pilot Program's January 1, 2026 implementation, and Defendants broader responsibilities to the public welfare cannot fully account for those interests, such that it can stand in for Movants. AbbVie Mot. at 7; PhRMA Mot. at 5; Novo Nordisk Mot. at 7-8.

Movants further assert Federal Defendants' representation is inadequate because separate litigation between Defendants and Movants demonstrates they "often disagree[ ] . . . and [do] not share [Movants'] view of the 340B statute or the role that rebates may play." AbbVie Mot. at 8. Indeed, some of the movants "are currently adverse to the government in litigation about HRSA's claimed authority to decide whether and when manufacturers may use rebates rather than up-front discounts to effectuate the 340B price for all of a manufacturer's drugs, not just those in the Pilot Program." PhRMA Mot. at 5-6 (citing *Novartis Pharms. Corp. v. Kennedy*, No. 25-5177 (D.C. Cir.)). According to Movants, their divergent views on the broader statutory framework governing the 340B drug pricing scheme is evidence of Federal Defendants' inadequacy to represent their interests in this litigation. AbbVie Mot. at 8; AstraZeneca Mot. at 2; PhRMA Mot. at 5-6.

Plaintiffs contend Movants' reasoning is inconsistent with First Circuit caselaw. Pls.' Opp'n at 5-6. According to Plaintiffs, simply "identifying different reasons for supporting a government program is not enough to satisfy this intervention requirement." *Id.* at 6. Moreover, despite Movants' representations of distinct economic interests, they ultimately "share the same objective" as Defendants: ensuring the Pilot Program goes into effect on January 1, 2026. *Id.* at 5. Finally, Plaintiffs maintain that Movants' silence as to any additional, distinct arguments they might offer the Court in this "straightforward

administrative law case," *id.* at 1, "that rises and falls based on the administrative record" is "near dispositive" of Defendants' adequacy to represent Movants' interest in this case. *Id.* at 6.

Plaintiffs also counter that Movants' and Defendants' adverse positions in separate litigation does not compel Movants' assertion that Defendants cannot adequately represent their interest. As Plaintiffs explain, in separate litigation, Movants and Defendants "differ in their views on whether drug companies can unilaterally implement 340B rebate programs *without* HHS approval." *Pls.' Opp'n* at 6 (emphasis in original). Whereas here, both parties' "goals are now the same." *Id.* Movants and Defendants not only do not disagree but are "in full agreement" that Defendants have authority to implement the Pilot Program. *Id.*

The Court agrees with Plaintiffs. Even when considering Movants' financial and adverse litigation arguments together, their position is "founded entirely on speculation" of Defendants' inadequacy. *T-Mobile*, 969 F.3d at 40. More is required for intervention as of right. *See Students for Fair Admissions*, 807 F.3d at 475 ("putative intervenors [must] produce something more than speculation as to the purported inadequacy of representation"). Movants offer no "tangible basis to support a claim of purported inadequacy." *Pub. Serv. Co. of N.H. v. Patch*, 136 F.3d 197, 207 (1st Cir. 1998) (citation omitted).

First, Movants' own representations cut against their argument that Defendants are inadequately attuned to their financial interest in this case. As Movants explain, Defendants promulgated the Pilot Program "'primarily to address' manufacturers' need to

'de-duplicate' 340B and IRA discounts." Novo Nordisk Mot. at 3 (quoting 90 Fed. Reg. 38,165, 36,163 (Aug. 7, 2025)); *see also* AbbVie Mot. at 3 (explaining Defendants promulgated the Pilot Program because of "widespread concern about the significant compliance burdens borne by manufacturers" subject to 340B and IRA mandatory pricing schemes). Instead, this record demonstrates Defendants are aligned with Movants concerns about their dual mandates under 340B and the IRA. 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 where the government defends its own regulation. *See Daggett*, 172 F.3d at 112 (rejecting "[t]he general notion" that the government's broader interest in representing the public "at some abstract level" demonstrates inadequate representation); *accord Rosenfelt*, 988 F.3d at 561-62 (explaining that a lack of "perfect identity of motivational interest between the movant-intervenor and the government" is not required for a finding of adequate representation) (citing *Mass. Food Ass'n*, 197 F.3d at 567); *Patch*, 136 F.3d at 207 ("the adequacy of interest requirement is more than a paper tiger").

Second, Movants offer no evidence to suggest that their approach to defending the Pilot Program offers the Court any additional insight into the legal challenge at the heart of this lawsuit—whether Defendants complied with their statutory obligations under the APA. Movants are completely silent on "what arguments [they would] make in this Court that would otherwise be forsaken by [Defendants]." *Me. Republican Party v. Dunlap*, No.

1:18-cv-00179-JDL, 2018 U.S. Dist. LEXIS 82461, at *4 (D. Me. May 16, 2018). Instead, Movants "advocat[e] for the general validity and enforcement of" the challenged agency action, "and it appears that both parties would have the same approach." *Id.* (citing *Trbovich v. United Mine Workers of Am.*, 404 U.S. 528, 539 (1972). There is nothing in any of Movants' motions suggesting they "would inject some missing ingredient into [Defendants'] defense," nor do they identify any arguments Defendants are unlikely to advance absent their intervention, such that Federal Defendants' defense would be inadequate to protect Movants' interests. *T-Mobile*, 969 F.3d at 40. Plaintiffs' complaint alleges five violations of the APA against Federal Defendants, but Movants fail to state how their participation as a party would illuminate the administrative record on which this case turns entirely. *Compl.* ¶¶ 130-175.

Finally, the adverse positions between Movants and Defendants in separate 340B litigation is insufficient to rebut the presumption against adequate representation. Again, Movants' own representations undermine their position. As PhRMA explains, some of its members "are currently adverse to the government in litigation about HRSA's claimed authority to decide whether and when manufacturers may use rebates rather than up-front discounts to effectuate the 340B price for all of a manufacturer's drugs, not just those in the Pilot Program." PhRMA Mot. at 5-6 (citing *Novartis Pharms. Corp. v. Kennedy*, No. 25-5177 (D.C. Cir.)). However, that litigation concerns Movants' position that they can fulfill their 340B discount requirements by issuing rebates rather than upfront discounts without prior agency approval. Nothing from Movants' description of that litigation indicates that they are misaligned with Defendants on whether Defendants may promulgate

the Pilot Program in this case. Indeed, the parties' divergent positions on whether the 340B statute, 42 U.S.C. § 256b(a)(1), authorizes pharmaceutical manufacturers to determine unilaterally how covered entities receive their discounted drugs does not suggest Defendants will not vigorously defend that their promulgation of the Pilot Program complied with their statutory obligations under the APA. In other words, Movants fail to demonstrate that, despite their adverse positions in separate litigation, they are not entirely aligned with Defendants' position in this administrative law action under the APA, where both Movants and Defendants maintain the agency action is lawful, and Movants offer no evidence that Defendants are not "zealously interested in upholding the validity" of the agency action. *Mass. Food Ass'n*, 197 F.3d at 567; *see also Dunlap*, 2018 U.S. Dist. LEXIS 82461, at *4 (rejecting movant-intervenor's argument that adverse positions in a separate related lawsuit renders the government an inadequate representative where both "advocat[e] the general validity and enforcement" of the challenged government action).

Accordingly, because Movants fail to demonstrate that Defendants cannot adequately represent their interests, the Court finds that Movants are not entitled to intervene as of right. The Court's analysis need go no further. *Students for Fair Admissions,* 807 F.3d at 474 ("Failure to satisfy any one of the four requirements defeats intervention by right").

B. Permissive Intervention

Under Rule 24(b)(1)(B) this Court may, in its discretion, allow the intervention of any party 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). "When deciding whether or not to allow

permissive intervention," the Court "'must consider whether the intervention will unduly delay or prejudice the adjudication of the original parties' rights.'" *T-Mobile*, 969 F.3d at 40. Additionally, the Court may "consider almost any factor rationally relevant" to the proposed intervention. *Daggett*, 172 F.3d at 113.

Particularly relevant here is the Court's "denial of intervention as of right based on an intervenor's failure to overcome the presumption of adequate representation by the government," which "cuts against [Movant's] case for permissive intervention." *Dunlap*, 2018 U.S. Dist. LEXIS 82461, at *5 (citing *Tutein*, 43 F. Supp. 2d at 131). The First Circuit is clear that "a district court considering requests for permissive intervention 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 (citing *Kowal v. Malkemus (In re Thompson)*, 965 F.2d 1136, 1142 n.10 (1st Cir. 1992)); *Rosenfelt*, 988 F.3d 556 at 564 (same); *Mass Food Ass'n*, 197 F.3d at 568 (same). Thus, although in this early stage of litigation, and notwithstanding the Pilot Program's fast-approaching January 1, 2026 implementation date, the Court does not believe that Movants' intervention necessarily will *immediately* unduly delay or prejudice the proceedings. However, looking beyond January 1, it is possible that intervention would create undue delay in the final disposition of this case involving an important administrative program. That concern, amplified by Movants' failure to demonstrate how they might "add any missing element" to Federal Defendants' defense of the agency action, leads the Court to deny Movants' request for permissive intervention. *T-Mobile*, 969 F.3d at 40.

C. Amicus Status

Although Movants may not intervene in this case as parties, I will permit them to participate as amici curiae. Participation as amici satisfies Movants' interest in "provid[ing] information regarding the severe harm that would befall the Manufacturers if the program were enjoined, or the efforts the Manufacturers have undertaken [to] prepare for the program's implementation date." Novo Nordisk Mot. at 9; *accord Rosenfelt*, 988 F.3d at 564; *Mass. Food Ass'n*, 197 F.3d at 568; *Students for Fair Admissions, Inc. v. President and Fellows of Harvard Coll.*, 308 F.R.D. 39, 52 (D. Mass. 2015).

CONCLUSION

For the foregoing reasons, the Court DENIES AbbVie Inc.'s and Pharmacyclics LLC's Motion to Intervene (ECF No. 36), AstraZeneca Pharmaceuticals LP's Motion to Intervene (ECF No. 39), Pharmaceutical Research and Manufacturers of America Motion to Intervene (ECF No. 45), and Boehringer Ingelheim Pharmaceuticals, Inc.'s and Novo Nordisk Inc.'s Motion to Intervene (ECF No. 50). However, the Court GRANTS Movants leave to proceed as amici curiae, and the Court will consider their briefs in opposition to Plaintiffs' motion (ECF Nos. 72, 73) as amicus briefs.

SO ORDERED.

Dated this 18th day of December, 2025.

/S/ Lance E. Walker
CHIEF U.S. DISTRICT JUDGE