No. 25-2237

IN THE 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; and DALLAS COUNTY MEDICAL CENTER,

Plaintiffs-Appellees,

v.

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

Defendants,

ABBVIE INC.; ASTRAZENECA PHARMACEUTICALS LP; PHARMACYCLICS LLC; BOEHRINGER INGELHEIM PHARMACEUTICALS, INC.; NOVO NORDISK INC.; and 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 (Hon. Lance E. Walker)

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RULE 26.1 CORPORATE DISCLOSURE STATEMENT

There is no parent corporation, publicly held corporation, affiliated corporation, limited liability company, partnership, firm, joint venture, trust, or other entity, or any individual, owning 10% or more of the stock of the American Hospital Association, Maine Hospital Association, Nathan Littauer Hospital & Nursing Home, or Unity Medical Center; or having 10% or more ownership interest in any of the aforementioned entities.

St. Mary's Regional Medical Center is a 501(c)(3) nonprofit subsidiary of St. Mary's Health System, of which Covenant Health is the sole corporate member. There is no publicly traded company that owns 10% or more of the stock of any of the aforementioned entities.

Dallas County Medical Center is an Arkansas county entity. There is no publicly traded company that owns 10% or more of the stock of Dallas County Medical Center.

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REASONS WHY ORAL ARGUMENT NEED NOT BE HEARD

This appeal involves straightforward questions of mootness and intervention procedure for which this Court's precedents provide ample guidance. The district court acted well within its discretion, on the record before it, to deny the motions to intervene. Plaintiffs-Appellees accordingly do not believe oral argument is necessary, but stand ready to appear should the Court find argument helpful.

PRELIMINARY STATEMENT

Four drug manufacturers and an industry trade association (collectively, the "Drug Companies") are asking this Court to reverse the denial of their motions to intervene alongside the United States government in a straightforward Administrative Procedure Act ("APA") case that has been closed for months.

In the underlying action, Plaintiffs the American Hospital Association, Maine Hospital Association, and four hospitals challenged the proposed 340B Rebate Model Pilot Program (the "Rebate Program"), an alteration to a decades-old drug pricing program that would have forced all safety-net healthcare providers covered by the program to abandon the decades-old upfront discount model in favor of a back-end rebate system. This change would have inflicted enormous costs and burdens on these safety-net hospitals and their vulnerable patients.

Plaintiffs sued Secretary Kennedy and the relevant HHS agencies and personnel (collectively, the "Government") to halt the implementation of the hastily promulgated Rebate Program. The district court granted a preliminary injunction, which this Court declined to stay when the Government appealed. Both the district court and this Court

noted that the "preview of the administrative record contain[ed] almost no contemporaneous explanation for the Rebate Program." *Am. Hosp. Ass'n v. Kennedy*, 164 F.4th 28, 34 (1st Cir. 2026).

Once it became obvious that further litigation was unlikely to change the outcome on that "threadbare" administrative record, *id.* at 33, the Government agreed to vacatur of the challenged program and remand to the agency. The case closed on February 10, 2026. Because it is impossible for the Drug Companies to intervene in a case that no longer exists, this Court should dismiss this appeal as moot.

If the Court reaches the merits, it should affirm the district court's denial of intervention as an appropriate exercise of its substantial discretion. The district court held that the Drug Companies failed to overcome this Court's well-established presumption that the government adequately represents private parties who share its litigation objective, and that the Drug Companies identified nothing they would add to a case that turned entirely on the Government's barren administrative record. The district court permitted the Drug Companies to participate as *amici curiae*—a status that fully accommodated any legitimate interest they had in making their views known to the Court.

In attempting to reverse that denial, the Drug Companies now focus on events that post-dated the decision on their intervention motions and ignore binding precedent. This Court should reject their efforts to relitigate the underlying dispute and sidestep application of this Circuit's caselaw.

JURISDICTIONAL STATEMENT

The Drug Companies seek reversal of the district court's order denying their motions to intervene in a now-closed case. Brief for All Appellants ("Br.") 10, 67. Because the closure of the district court case in which the Drug Companies sought to intervene makes it impossible for this Court to "provid[e] any relief which will redress the alleged injury," this appeal cannot satisfy Article III's case or controversy requirement and "must be dismissed." *Harris v. Univ. of Mass. Lowell*, 43 F.4th 187, 191–92 (1st Cir. 2022) (quoting *Gulf of Me. Fishermen's All. v. Daley*, 292 F.3d 84, 88 (1st Cir. 2002)).

ISSUES PRESENTED

1. Whether this appeal is moot given that the APA case in which the Drug Companies sought to intervene was closed following the voluntary vacatur of the Rebate Program.

2. Whether the district court abused its discretion in holding that the Drug Companies were not entitled to intervene under Federal Rule of Civil Procedure 24(a)(2) in an APA case where the Government was vigorously defending the agency action.

3. Whether the district court abused its discretion in denying the Drug Companies permissive intervention under Federal Rule of Civil Procedure 24(b) and instead allowing participation as *amici curiae* where the district court found that the Drug Companies were adequately represented by the Government and threatened to delay the proceedings.

STATEMENT OF THE CASE

I. The 340B Program and Its Longstanding Upfront Discount Model

Congress enacted the 340B Drug Pricing Program in 1992 to give safety-net healthcare providers (known as "covered entities"[1]) access to prescription drugs at significantly discounted prices. Pub. L. No. 102-585 § 602 (1992). The savings from these discounts allow covered entities to "stretch scarce Federal resources as far as possible, reaching more

[1] Covered entities include, for example, federally qualified health centers and hospitals that serve a disproportionate share of Medicare, Medicaid, and low income and uninsured patients. 42 U.S.C. § 256b(a)(4).

eligible patients and providing more comprehensive services." H.R. Rep. No. 102-384, pt. 2, at 12 (1992). Under the program, the Health Resources and Services Administration ("HRSA"), an agency within the Department of Health and Human Services ("HHS"), calculates a "ceiling price" for certain drugs, setting the maximum amount drug manufacturers can charge covered entities for them. 42 U.S.C. § 256b(a)(1). This ceiling price is often a fraction of what those drug manufacturers would otherwise charge. To spur drug manufacturer involvement in this voluntary program, Congress conditioned federal health insurance coverage of their products on participation. *Id.* § 1396r-8(a)(1); *id.* § 256b(a).

Since the program's inception more than 30 years ago, HRSA has required participating drug manufacturers to provide statutory discounts at the point of sale—a process known as the "upfront discount." *See id.* § 256b(a)(1); 58 Fed. Reg. 27289, 27291–92 (May 7, 1993). This upfront discount has become a crucial lifeline for many covered entities, like the Plaintiff hospitals here, that operate on nonexistent (or negative) margins and cannot afford market prices for drugs without sacrificing other forms of patient care. *See* JA094. Beyond shoring up operating

costs, the savings from the 340B Program have allowed safety-net hospitals the ability to expand coverage for their patients. Plaintiffs' Complaint detailed programs and benefits throughout Maine (and the United States) that would face cuts if the upfront discount model was discontinued, such as reduced-price outpatient drugs, life-saving opioid intervention services, recently-opened cardiac and pulmonary rehabilitation services, and cancer telehealth clinics. *See, e.g.*, JA073–74, JA109.

II. The Government's Proposed 340B Rebate Program

The ongoing success of this longstanding program was cast into doubt on July 31, 2025, when HRSA abruptly announced a new "340B Rebate Model Pilot Program," followed by a notice in the *Federal Register* ("Notice"). 90 Fed. Reg. 36163 (Aug. 1, 2025); 90 Fed Reg. 36165 (Aug. 7, 2025).[2] The Notice welcomed proposed rebate plans from nine drug companies, which would be allowed under the Rebate Program to mandate that covered entities pay the full wholesale acquisition price for selected 340B drugs at the time of sale and then seek reimbursement

[2] HRSA issued an amended notice on August 7. There were no substantive changes. For citation purposes, "Notice" will refer to the August 7, 2025 amended notice unless otherwise stated.

only after they dispensed those drugs. Although styled as a "pilot" and "voluntary," the Notice provided that the Rebate Program, slated to begin January 1, 2026, would apply to all of the approximately 14,600 covered entities that participate in the 340B program. 90 Fed. Reg. at 38165–66. The Program was voluntary only for the drug companies.

The Notice's approach represented an abrupt about-face from HRSA. Just months before, HRSA's attorneys had extolled the benefits of an upfront discount as opposed to a rebate model. *See, e.g.*, Dkt. 41-1 at 18–20, *Johnson & Johnson Health Care Sys. Inc. v. Kennedy*, No. 24-cv-03188 (D.D.C. Apr. 2, 2025) (HRSA briefing noting that the agency "has long envisioned upfront discounts as the preferred price reduction mechanism" and that a rebate model "would 'create significantly higher up-front costs for covered entities'" (citation omitted)).[3]

[3] These statements arose during a series of litigations in which drug companies sued HRSA, asserting that they had authority to unilaterally impose rebate programs, without the need for HRSA's approval. *See also Eli Lilly & Co. v. Kennedy*, 2025 WL 1423630, at *9 n.11 (D.D.C. May 15, 2025); Dkt. 37, *Bristol Myers Squibb Co. v. Kennedy*, No. 24-cv-3337 (D.D.C. Mar. 5, 2025); Dkt. 30, *Novartis Pharms. Corp. v. Kennedy*, No. 25-cv-0117 (D.D.C. Mar. 5, 2025); Dkt. 38, *Sanofi-Aventis U.S. LLC v. HHS*, No. 24-cv-3496, (D.D.C. Mar. 20, 2025). These cases did not involve any dispute over whether *HRSA* had the authority to impose a rebate program.

Despite HRSA's previous position and the Notice's acknowledgment that "rebate models could fundamentally shift how the 340B Program has operated for over 30 years," the Notice provided nearly no explanation for why nearly 15,000 covered entities would be subject to such a seismic change on such short notice. 90 Fed. Reg. at 38165. HRSA explained only that it sought to "test the rebate model on a select group of drugs" and made a passing reference to inquiries from drug companies about deduplication of overlapping 340B and Inflation Reduction Act ("IRA") discounts. 90 Fed. Reg. at 38165.

The Notice did not address covered entities' decades-long reliance on the upfront discount model, the administrative or financial costs the Rebate Program would impose on covered entities, the impact on patient care, or less burdensome alternatives.

The Notice did solicit comments, however, and HRSA received over 1,100 in the 31-day comment period. Commenters detailed extensive harms that the Notice failed to consider—massive administrative and financial burdens of submitting, tracking, recovering, and disputing rebate payments that the drug companies would unilaterally decide; the additional financial burden of floating upfront payments to drug

companies while awaiting statutorily owed rebates; and several less burdensome alternatives. *See* JA097. Despite inviting these comments, HRSA did not respond to a single one, instead plowing on with the Rebate Program and announcing by mid-November that it had approved applications from nine drug companies for ten high-volume, high-cost brand name drugs. *See* JA097–98. Approvals were to take effect in less than two months on January 1, 2026 (with one application scheduled to take effect April 1, 2026).

III. Procedural History

Shortly after the ninth drug company's rebate plan was approved, Plaintiffs on December 1, 2025, filed their Complaint and a motion for a temporary restraining order, alleging that the Rebate Program was arbitrary and capricious in violation of the APA. *See* JA026–090 (Complaint); JA091–112 (Mot. for TRO). Plaintiffs alleged five categories of APA violations: that the agency (i) failed to consider hospitals' significant reliance interests in the 30-year upfront discount model; (ii) failed to consider the substantial administrative, financial, and non-monetary costs the Rebate Program would impose on covered entities and their patients; (iii) failed to consider obvious and less burdensome

alternatives; (iv) put forward a substantively unreasonable program; and (v) improperly sought a predetermined result. *See* JA074–89.

The Motions to Intervene. On December 10, 2025, the Drug Companies filed four separate motions to intervene as defendants in support of the Rebate Program: AbbVie Inc. and Pharmacyclics LLC (JA116); AstraZeneca Pharmaceuticals LP (JA156); the Pharmaceutical Research and Manufacturers of America (PhRMA) (JA171); and Boehringer Ingelheim Pharmaceuticals Inc. and Novo Nordisk Inc. (JA199).[4] The Drug Companies principally sought intervention as of right under Federal Rule of Civil Procedure 24(a)(2) and, alternatively, permissive intervention under Rule 24(b). The Drug Companies contended that the Rebate Program offered their only imminently available way to avoid issuing duplicate discounts under the IRA and 340B Program or risking penalties for non-compliance, and that the Government Defendants would be inadequate representatives because of their lack of financial interest and prior opposition to the Drug

[4] Pharmacyclics LLC is a subsidiary of AbbVie Inc. Br. i.

Companies regarding their unilateral attempts to impose 340B rebate programs. *See* JA117, 124–25, 158, 176, 178, 204, 208.

Plaintiffs opposed both forms of intervention but consented to the Drug Companies' participation as *amici curiae*. *See* Pls.' Omnibus Opp'n, Dkt. 76, *Am. Hosp. Ass'n v. Kennedy*, No. 25-cv-0600 (D. Me. Dec. 15, 2025).[5] The Government took no position. *See* Defs.' Position on Mot. to Intervene, D. Ct. Dkt. 74 (D. Me. Dec. 15, 2025). On December 17, 2025, the Drug Companies filed a joint reply in support of their motions to intervene. JA400.

The District Court's Denial of Intervention as of Right. On December 18, 2025, the district court (Walker, C.J.) denied all four motions to intervene. *See* ADD01–13 ("Intervention Order"). The court began with the Drug Companies' adequacy-of-representation argument. It observed that, under settled First Circuit law, where "'a private party attacks a regulatory statute or administrative rule; the state or its regulators are its defenders; and other parties having an economic interest in the validity or invalidity of the statute or regulation seek to

[5] References to district court filings not included in the Joint Appendix are cited as "D. Ct. Dkt."

intervene,' a presumption attaches to the government's adequacy of representation." ADD04 (quoting *Mass. Food Ass'n v. Mass. Alcoholic Beverages Control Comm'n*, 197 F.3d 560, 566–67 (1st Cir. 1999)). In those circumstances, the would-be intervenor bears the burden of overcoming the presumption by pointing to some tangible concern instead of speculation. *Id.* The court rejected the Drug Companies' contention that *Berger v. North Carolina State Conference of the NAACP*, 597 U.S. 179 (2022), had displaced that presumption, explaining that *Berger* addressed only the distinct context of a "duly authorized state agent" seeking to defend state law and expressly declined to "decide whether a presumption of adequate representation might sometimes be appropriate when a private litigant seeks to defend a law alongside the government." ADD05 n.2 (quoting *Berger*, 597 U.S. at 197).

Having rejected the Drug Companies' reliance on *Berger*, the court held that their adequacy-of-representation argument was "founded entirely on speculation" and that they had offered "no tangible basis to support a claim of purported inadequacy." ADD08 (quotation omitted). The court bolstered this holding with three findings.

First, the district court found that the Government and Drug Companies were aligned in their litigation objective—both supported the implementation of the Rebate Program. It held that the Drug Companies' "unadorned assertions that Defendants' public duty prevents them from adequately representing [the Drug Companies'] industry-based interests" in a case that focuses solely on "whether a federal agency complied with its obligations under the APA" did not satisfy this Circuit's "heightened burden of persuasion for intervention by right where the government defends its own regulation." ADD09. As the court observed, the Drug Companies' own filings confirmed that HRSA promulgated the Rebate Program "primarily to address drug companies' deduplication concerns," undercutting their argument that the agency was inadequately attuned to their interests. ADD08–09.

Second, the court found that Drug Companies had offered "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." ADD09. The Drug Companies were, the court emphasized, "completely silent" on what arguments they would

advance that would "otherwise be forsaken" by the Government. ADD09–10 (quotation omitted). Nothing in any of the motions to intervene suggested that Drug Companies "'would inject some missing ingredient into [Defendants'] defense.'" ADD10 (quoting *T-Mobile Ne. LLC v. Town of Barnstable*, 969 F.3d 33, 40 (1st Cir. 2020) (alteration in original)). The court underscored that this was an APA case that "turns entirely" on the administrative record presented by the agency, and the Drug Companies identified no respect in which their participation would "illuminate [said] administrative record." ADD10.

Third, the court rejected the Drug Companies' argument that their adverse positions in unrelated 340B litigation against the Government rebutted the presumption of adequate representation. ADD10. That litigation, the court explained, concerns the distinct question of whether drug manufacturers may "fulfill their 340B discount requirements by issuing rebates rather than upfront discounts without prior agency approval"—a question on which the Drug Companies and the Government are adverse, but which has no bearing on whether HRSA could promulgate the Rebate Program at issue here. ADD10. The Drug Companies and the Government were "in full agreement" about the

Rebate Program. ADD08. The Drug Companies offered no evidence that the Government was not "'zealously interested in upholding the validity'" of its own agency action. ADD11 (quoting *Mass. Food Ass'n*, 197 F.3d at 567). Consequently, the court held that the Government could serve as an adequate representative notwithstanding the Drug Companies' and Government's divergent positions in unrelated cases. ADD10–11.

Because the Drug Companies' failure on the adequacy-of-representation element was independently dispositive, the court declined to reach the remaining Rule 24(a)(2) requirements. ADD11 (citing *Students for Fair Admissions, Inc. v. President & Fellows of Harvard Coll.*, 807 F.3d 472, 474 (1st Cir. 2015)).

The District Court's Denial of Permissive Intervention. The court separately denied permissive intervention under Rule 24(b)(1)(B), explaining that its "denial of intervention as of right based on an intervenor's failure to overcome the presumption of adequate representation by the government [] cuts against [the Drug Companies'] case for permissive intervention." ADD12 (citation omitted). Additionally, the court highlighted that the Drug Companies failed to identify "any missing element" they might add to the Government's

defense. ADD12 (citation omitted). These concerns, coupled with the risk that intervention could "create undue delay" in the proceedings, counseled against permissive intervention. ADD12.

The District Court's Granting of *Amici* Status. The court did not, however, exclude the Drug Companies from the proceedings, contrary to their narrative on appeal. *E.g.*, Br. 24, 51. The district court granted the Drug Companies leave to participate as *amici curiae* and expressly stated that it would "consider their briefs in opposition to Plaintiffs' motion" for preliminary relief. ADD13.[6] In reaching this conclusion, the court explained that "[p]articipation as *amici* satisfies [the Drug Companies'] interest in 'provid[ing] information regarding the severe harm that would befall [them] if the program were enjoined, or the efforts the [Drug Companies] have undertaken [to] prepare for the program's implementation date.'" *Id.* (quoting JA212 (Novo Nordisk Mot.)).

[6] During an initial telephone conference on scheduling, the district court granted one of the Drug Companies, AbbVie, permission to file an opposition to the temporary restraining order so that its opposition would already be docketed in the event that AbbVie's motion to intervene was granted.

The Preliminary Injunction. The day after issuing the Intervention Order, on December 19, 2025, the district court held a hearing on Plaintiffs' motion for emergency injunctive relief. Though only Plaintiffs and Defendants addressed the court at the hearing, the Drug Companies attended and had submitted, across two briefs and four declarations, their collective opposition to Plaintiffs' Motion for a Temporary Restraining Order. JA287–350. Per the court's Intervention Order, these submissions were now *amicus* briefs.

In the aftermath of the hearing, both the Government and AstraZeneca filed "Notice/Correspondences" on the docket. JA411–12; JA466–511; D. Ct. Dkt. 85-1, 85-2, 85-3 (D. Me. Dec. 22, 2025). These two unauthorized sur-reply submissions contained hundreds of pages of information—many of which had no bearing on HRSA's creation of the Rebate Program. Several documents pre-dated the Rebate Program by many months and others were presentations from the Drug Companies to the Government—establishing the Drug Companies' access to agency officials, but providing no insight into the agency's decision-making or considerations. *See* D. Ct. Dkt. 87 (D. Me. Dec. 22, 2025); JA512–13 (Plaintiffs' responses to these filings).

On December 29, 2025, the court issued a preliminary injunction enjoining implementation of the Rebate Program. *See* JA515–38 ("PI Order"). The court found that Plaintiffs were likely to succeed on the merits of their APA claims that the agency (1) failed to consider hospitals' significant reliance interests in the longstanding upfront discount model and (2) failed to consider the administrative and other costs the Rebate Program would impose. JA522, JA528–33. In reaching this conclusion, the court explicitly acknowledged that it considered the untimely Notice/Correspondence submissions from both the Government (which included documents from AbbVie Inc., Janssen Pharmaceuticals, Inc., and Janssen Biotech, Inc.) and *amicus* AstraZeneca Pharmaceuticals LP. JA523, JA525. The court noted that the contributions of a drug company, though a beneficiary of the Rebate Program, "do not constitute the administrative agency record." JA525. It continued that the Drug Companies' documents could be "at best circumstantial evidence of what the Agency might have considered, not evidence that it did" consider anything. *Id.*

The district court further found that safety-net hospitals would face irreparable harm for unrecoverable compliance costs—including the

prospect of curtailing services—absent injunctive relief, JA533–34, and that the balance of equities and public interest weighed decisively in Plaintiffs' favor, JA534–35. Acting under 5 U.S.C. §§ 705 and 706, the court preliminarily set aside the application approvals comprising the Rebate Program. JA536–38.

The Government's Appeal and Motion for a Stay. The Government appealed the PI Order to this Court (No. 25-2236). It also filed a motion in the district court to stay the preliminary injunction pending appeal, urging the court "[t]o prevent disruption of industry preparation to implement a pair of significant programs scheduled to take effect on January 1" and to avoid "forc[ing] manufacturers to scramble to comply with their various pricing obligations." JA539–40, JA547. The district court denied the stay motion, finding that "there is no apparent, actual urgency to the January 1 start date and, based on [the court's] preliminary assessment of the record, the Defendants would be better off attending to the minimal administrative steps the APA imposes in order to fortify the pilot rebate program rather than attempting to lower the bar for administrative action in service to 'industry preparation' interests." JA550.

The Government then filed an emergency motion to stay the injunction pending appeal in this Court. Doc. # 00118385034, *Am. Hosp. Ass'n v. Kennedy*, No. 25-2236 (1st Cir. Dec. 30, 2026). On January 7, 2026, this Court denied the motion to stay, finding that the district court had issued a "careful and thorough decision" and that the Government "failed to carry its burden of making a strong showing that it [was] likely to succeed on the merits." *Am. Hosp. Ass'n*, 164 F.4th at 31 (cleaned up). This Court "agree[d] with the district court that the administrative record previewed below is devoid of evidence that the federal government considered the hospitals' significant reliance interests" and "contains almost no contemporaneous explanation for the Rebate Program." *Id.* at 33–34. To take just one example, this Court noted that "in its briefing to the lower court, the federal government conceded that it was 'currently examining' the hospitals' increased administrative costs from the Rebate Program," even though it was required to consider such an important aspect of the problem before taking any final agency action. *Id.* at 34.[7]

[7] In addressing the other preliminary injunction factors, this Court noted that "the federal government has indicated that manufacturers have alternative methods to address the previously described duplication issue, further underscoring the lack of any substantial injury in the absence of a stay." *Id.* at 37. The 2026 Q1 reports from the Drug

On December 31, 2025, the Drug Companies filed a separate motion to intervene in the Government's merits appeal. Doc. # 00118385287, *Am. Hosp. Ass'n v. Kennedy*, No. 25-2236 (1st Cir. Dec. 31, 2025). In its January 7 Order denying the Government's motion for a stay, this Court did not address the Drug Companies' intervention motion. Nonetheless, on January 12, Plaintiffs opposed the motion to intervene as procedurally improper while this appeal was pending and infirm on the merits. Doc. # 0118389957, *Am. Hosp. Ass'n v. Kennedy*, No. 25-2236 (1st Cir. Jan. 12, 2026). Following discussions between Plaintiffs and the Government regarding vacatur of the Rebate Program and remand to the agency, the Government moved for dismissal of the merits appeal, mooting the Drug Companies' attempt to intervene there. Doc. # 00118392113, *Am. Hosp. Ass'n v. Kennedy*, No. 25-2236, (1st Cir. Jan. 16, 2026).

Companies underscore the lack of any serious injury. *See, e.g.*, AbbVie Inc., AbbVie Reports First-Quarter 2026 Financial Results at 1 (Apr. 29, 2026), available at https://investors.abbvie.com/static-files/223dc800-fb24-45bc-b0ad-7a179610fda5 (reporting first-quarter net revenue of over $15 billion, an increase of 12.4% on a reported basis); AstraZeneca, AstraZeneca Results: Q1 2026 at 1 (Apr. 29, 2026), available at https://www.astrazeneca.com/content/dam/az/PDF/2026/eq1/Q1-2026-results-announcement.pdf (reporting a first quarter revenue increase to over $15.2 billion).

The Joint Motion for Vacatur and Remand. Back in the district court, the Government submitted that, in light of the district court's PI Order and this Court's decision on the stay, it "d[id] not believe the full administrative record would change the outcome of this litigation at summary judgment." JA557. The parties accordingly agreed to jointly request vacatur of the Rebate Program and remand to the agency. JA558. The district court granted that request and the case was closed on February 10, 2026.

The Present Appeal. Notwithstanding that the district court case is closed, the present appeal concerns the district court's December 18, 2025 denial of the Drug Companies' motions to intervene. This Court ordered the Drug Companies to show cause as to why this appeal is not moot and subsequently deferred consideration of jurisdictional issues to the merits panel. Doc. # 0018414130; Doc. # 00118422397.

SUMMARY OF ARGUMENT

I. The Drug Companies cannot intervene in Plaintiffs' now-closed APA challenge to the Government's 340B Rebate Program. Because the reversal of the district court's denial of their motions to intervene that the Drug Companies seek would have no practical effect,

this appeal is moot. And the Drug Companies have not established that the capable-of-repetition-yet-evading-review exception to mootness applies. The claims at issue here were "not 'by nature short-lived' along the lines of elections, pregnancy, or temporary restraining orders." *Lowe v. Gagné-Holmes*, 126 F.4th 747, 760 (1st Cir.) (citation omitted), *cert. denied*, 145 S. Ct. 2795 (2025). There is nothing inherently transitory about denial of intervention in an APA challenge. And the Drug Companies' contention that they will be subject to the same action again rests on an impermissible chain of speculation.

II. The district court did not abuse its discretion in denying the Drug Companies' motions for intervention as of right on the basis that they were adequately represented by the Government. Under this Court's precedents, the Drug Companies were required to make "a strong affirmative showing" that the Government was "not fairly representing" their interests. *Victim Rts. L. Ctr. v. Rosenfelt*, 988 F.3d 556, 561 (1st Cir. 2021) (quoting *Pub. Serv. Co. of N.H. v. Patch*, 136 F.3d 197, 207 (1st Cir. 1998). They failed to do so. The Government and the Drug Companies did not need to have the exact same reasons for supporting the Rebate Program, pursue the same precise legal arguments, or agree on the

overall scope of the Government's authority over the 340B program for the Government to be an adequate representative. And the Drug Companies' after-the-fact criticism of the Government's ultimate litigation strategy does not retroactively render the district court's decision an abuse of discretion. In addition, as an independent basis for denying intervention, the Drug Companies' claimed interests in the Rebate Program were fatally contingent because they were premised on speculation as to how covered entities and the Government would behave in the absence of the Rebate Program. The district court's decision, which is owed substantial deference, should be affirmed.

III. The district court similarly did not abuse its discretion by denying the Drug Companies permissive intervention, and instead allowing participation as *amici curiae*, because the Drug Companies were adequately represented and threatened to delay the proceedings. This Court has instructed that adequacy of representation is an appropriate consideration for adjudicating a motion for permissive intervention, *T-Mobile*, 969 F.3d at 41, and the Drug Companies failed to show that the Government did not adequately represent them. Moreover, the district court was required to consider the risk of delay, Fed. R. Civ. P. 24(b)(3),

and reasonably concluded that multiplying the parties to the proceedings could cause such delay.

For the reasons set forth below, this Court should dismiss for lack of jurisdiction, or if the Court finds it retains jurisdiction, affirm the district court.

STANDARD OF REVIEW

The Court has an "independent obligation" to evaluate whether an appeal has become moot by some intervening event because its "jurisdiction does not encompass claims that have been rendered moot." *Harris*, 43 F.4th at 191 n.7 (citation omitted). Where, as here, "the record reveals mootness may be an issue," the Court assesses whether it retains jurisdiction before turning to the merits. *Id.*; *see In re Ruiz*, 83 F.4th 68, 73 (1st Cir. 2023) (per curiam).

On the merits, this Court "review[s] a district court's denial of a motion for intervention as of right through an abuse-of-discretion lens," and "use[s] the same abuse-of-discretion lens when reviewing the denial of a motion for permissive intervention." *T-Mobile*, 969 F.3d at 38; *Victim Rts. L. Ctr.*, 988 F.3d at 559. "Under this deferential standard, [this Court] cannot substitute [its] judgment for that of the district court."

Torres-Arroyo v. Rullán, 436 F.3d 1, 7 (1st Cir. 2006). Within the abuse-of-discretion lens, "abstract legal rulings are scrutinized *de novo*, factual findings are assayed for clear error, and the degree of deference afforded to issues of law application waxes or wanes depending on the particular circumstances." *T-Mobile*, 969 F.3d at 38. Especially as to permissive intervention, the district "court 'enjoys very broad discretion.'" *Id.* at 40–41 (quoting *Daggett v. Comm'n on Governmental Ethics & Election Pracs.*, 172 F.3d 104, 113 (1st Cir. 1999)).

ARGUMENT

I. This Appeal Is Moot Because There Is No Case in Which to Intervene.

All agree that there has been no district court case in which the Drug Companies could intervene for more than three months now. *See* Br. 24–25; Order to Show Cause, Doc. # 00118414130. Thus, the Drug Companies' request for relief "is at this point neither immediate nor real" because reversal of the denial of their motions to intervene will have no practical effect, and this appeal is thus moot. *Lowe*, 126 F.4th at 755 (quotation omitted). It should accordingly be dismissed. *See U.S. Bancorp Mortg. Co. v. Bonner Mall P'ship*, 513 U.S. 18, 29 (1994); *In re Ruiz*, 83 F.4th at 79.

The Drug Companies do not dispute that this Court cannot grant them any effectual relief as to the case that has already been closed. They instead argue that they can fit within the narrow mootness exception for cases capable of repetition yet evading review. Br. 59–64. But the Drug Companies "bear the burden of showing that the exception" applies, *Lowe*, 126 F.4th at 756, and they have not carried it here. A court may only apply the capable-of-repetition-yet-evading-review exception where "a plaintiff shows '(1) the challenged action was in its duration too short to be fully litigated prior to cessation or expiration, and (2) there was a reasonable expectation that the same complaining party would be subject to the same action again.'" *In re Fin. Oversight & Mgmt. Bd.*, 16 F.4th 954, 962 (1st Cir. 2021) (quoting *Weinstein v. Bradford*, 423 U.S. 147, 149 (1975)); *see also Lowe*, 126 F.4th at 759. This exception "applies only in exceptional situations." *ACLU of Mass. v. U.S. Conf. of Cath. Bishops*, 705 F.3d 44, 57 (1st Cir. 2013). The appeal of standard motions to intervene is not one of them.

A. The Drug Companies' Challenge Is Not Inherently Time-Limited.

The capable-of-repetition-yet-evading-review exception "applies because of the *nature* of some controversies, not because of the parties' litigating decisions." *FCC v. Consumers' Rsch.*, 606 U.S. 656, 671 n.1 (2025) (emphasis added). As this Court has explained, "appellants must show that the generic types of claims that they seek to pursue are likely to evade review." *Lowe*, 126 F.4th at 759 (citations omitted). Here, the only possible way to describe the "generic" claims at issue are alleged violations of the APA. The Drug Companies must therefore show that the underlying controversy here—an APA dispute regarding changes to the longstanding 340B program—is "inherently transitory" or that there is a "realistic threat that no trial court ever will have enough time to decide the underlying issues." *Corrigan v. Bos. Univ.*, 98 F.4th 346, 353 (1st Cir. 2024) (quoting *Cruz v. Farquharson*, 252 F.3d 530, 535 (1st Cir. 2001)).

They cannot do so. APA cases are not inherently transitory and incapable of review, as evidenced by the myriad of such cases litigated fully in district courts and then reviewed by this Court or even the Supreme Court. *E.g.*, *FCC v. Prometheus Radio Project*, 592 U.S. 414 (2021); *DHS v. Regents of the Univ. of Cal.*, 591 U.S. 1 (2020);

Massachusetts v. Nat'l Inst. of Health, 164 F.4th 1 (1st Cir. 2026); *see also Gulf of Me. Fisherman's All.*, 292 F.3d at 89 (declining to apply exception to mooted APA challenge because, "in practice," most regulations of the challenged variety "are in place for as much as a year"). Though the Government quickly recognized in the case below that "further motions practice would not be fruitful" given the state of its full administrative record, *see* JA557, "[s]uch a quick resolution of the merits through a voluntary remand is not the norm." *Ctr. for Biological Diversity v. Bureau of Land Mgmt.*, 69 F.4th 588, 596, 598 (9th Cir. 2023) ("[D]enials of intervention will not typically evade review because they usually do not become moot before appellate review is complete."); *W. Coast Seafood Processors Ass'n v. Nat. Res. Def. Council*, 643 F.3d 701, 705 (9th Cir. 2011) ("The intervention controversy avoids review here only because [the government] acquiesced . . . not because the controversy is inherently limited in duration." (quotation omitted)).

Put another way, this case was unusual because the Government so clearly violated the APA. As this Court explained, "the preview of the administrative record contain[ed] almost no contemporaneous explanation for the Rebate Program." *Am. Hosp. Ass'n*, 164 F.4th at 34.

Over time, the Government came to agree. That does not happen often, and it is unlikely to happen again here. *See Cruz*, 252 F.3d at 535 ("But the plaintiffs' experience, in and of itself, constitutes too frail a foundation to support the conclusion that they would have us draw. One swallow does not a summer make, and we have no acceptable basis to conclude, without a more substantial factual predicate, that the INS has devised a scurrilous pattern and practice of thwarting judicial review by allowing IRV petitions and associated alien spouse applications to languish and then, when and if a suit ensues, adjudicating them quickly to ensure that no federal court ever will be in a position either to resolve the underlying issues . . . ."). Indeed, precisely because the Government sought voluntary vacatur and remand so that it could correct its mistakes, JA557, HRSA will presumably learn from those mistakes. Consequently, there is no reason to believe that any future litigation regarding a renewed effort to implement a 340B rebate program would end so quickly.[8] *See Seneca Res. Corp. v. Twp. of Highland, Elk Cnty.,*

[8] In fact, Plaintiffs and the Government stipulated that the Government would "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" specifically "to avoid the prospect of any extremely expedited future litigation" even at the temporary

Pa., 863 F.3d 245, 255 (3d Cir. 2017) (dismissing as "speculative at best" the appellants' argument "that they are unable to get a court ruling on their motions to intervene in subsequent litigation because a case *could* become moot before any ruling is issued" (emphasis in original)).

The Drug Companies distort this inquiry to ask whether it would be possible to complete appellate review before a request for emergency injunctive relief is adjudicated. Br. 59–60. But that is not the question here. Unlike in the *Nebraska Press Association* and *Procter & Gamble* cases they cite, the Drug Companies are not seeking (and could not seek) appellate review of an inherently transitory temporary restraining order or preliminary injunction. *See Neb. Press Ass'n v. Stuart*, 427 U.S. 539, 546 (1976) (applying exception to allow review of two-month order prohibiting press coverage of certain pre-trial criminal proceedings); *Procter & Gamble Co. v. Bankers Tr. Co.*, 78 F.3d 219, 224 (6th Cir. 1996) (same to allow review of three-week prior restraint on magazine's ability

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restraining order/preliminary injunction stage. JA558. The Drug Companies suggest that Plaintiffs and the Government "anticipate that litigation over a new rebate program could be fully resolved in ninety days, if not faster." Br. 63. The parties' agreement to avoid unnecessarily imposing time constraints on the district court *at the preliminary relief stage* says nothing about the span of the full litigation.

to report on litigation).[9] Nor does the factual context here involve inherently transitory circumstances like "elections" or "pregnancy." *Lowe*, 126 F.4th at 760. As such, the Drug Companies have failed to establish that this underlying litigation is "by nature short-lived," as is required to avoid mootness of their appeal. *Id.* (quoting *Neb. Press Ass'n*, 427 U.S. at 547).

B. The Drug Companies' Speculation Cannot Establish They Will Be Subject to the Same Action Again.

The Drug Companies have another, dispositive problem in their effort to invoke the capable-of-repetition-yet-evading-review exception: "avoiding mootness cannot rest on speculation about some future potential event." *Harris*, 43 F.4th at 195 (quotation omitted). But a chain of speculation is all the Drug Companies have.

For the Drug Companies to be subject to the same claimed harm again, at least the following uncertain steps must occur: (1) the Government must decide to implement another 340B rebate program; (2) each Drug Company must be eligible to participate in that program; (3)

[9] The Drug Companies have not even tried to seek expedited review of their intervention denial. They waited until after the district court granted Plaintiffs a preliminary injunction to file their notice of appeal, JA551, and have made no effort to accelerate briefing in this case.

each Drug Company must apply and be approved to participate in that program; (4) Plaintiffs must have a basis for challenging that new 340B rebate program; (5) the Drug Companies must again move to intervene in any new litigation challenging that new program; (6) the Drug Companies must make the same arguments for intervention in any new litigation that they made below; (7) the district court must deny intervention; (8) that denial of intervention must be an abuse of the district court's discretion; and (9) Plaintiffs' challenge against the new 340B rebate program must resolve before the Drug Companies could have obtained review of the denial of their motions to intervene. "There are a myriad of possibilities and it may very well be that appellants will never be subjected to" the challenged action again. *Redfern v. Napolitano*, 727 F.3d 77, 85 (1st Cir. 2013) (rejecting application of exception where government planned to redeploy challenged security technology but had not announced where, such that plaintiffs may never encounter it again).

The Drug Companies therefore have failed to establish any exception to mootness, and their appeal should be dismissed.[10]

[10] The Drug Companies request that this Court vacate the district court's Intervention Order if this appeal is dismissed as moot. Br. 64–66. It is their burden to establish "equitable entitlement to the extraordinary

II. The District Court Was Well Within Its Discretion to Deny the Drug Companies' Motions to Intervene.

A. The Drug Companies Had No Right to Intervene.

To intervene as of right in the district court, the Drug Companies needed to demonstrate: (1) "a concrete interest in the pending action," (2) "a realistic threat that the resolution of the pending action will hinder [their] ability to effectuate that interest," (3) "the absence of adequate representation by any existing party," and (4) "the timeliness of [their] motion." *SEC v. LBRY, Inc.*, 26 F.4th 96, 99 (1st Cir. 2022) (cleaned up). "It is black letter law that a failure to satisfy any one of these four requirements sounds the death knell for a motion to intervene as of right." *T-Mobile*, 969 F.3d at 39. The Drug Companies' motions had multiple fatal flaws: they failed to show that they were not adequately represented by the Government and their interests in the Rebate Program were improperly contingent.

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remedy of vacatur." *Bancorp*, 513 U.S. at 26. However, Plaintiffs recognize that this Court has found vacatur appropriate where an appeal has become moot through circumstances not of the appellants' own making and accordingly do not contest vacatur of the Intervention Order with dismissal here. *See ACLU of Mass.*, 705 F.3d at 58; *Redfern*, 727 F.3d at 85.

1. The Drug Companies Were Adequately Represented by the Government.

As the district court correctly held, the Drug Companies were "not entitled to intervene" because they "fail[ed] to demonstrate that [the Government] cannot adequately represent their interests." ADD11. In challenging that holding, the Drug Companies start with an attempt to lower their standard, arguing that they should not be held to this Court's precedents requiring a heightened showing of inadequate representation when a party seeks to intervene alongside the Government. Br. 32–41. Then they assert that they could satisfy any standard, because of the additional arguments they did not raise to the district court in their motions to intervene but have identified now that the litigation is over and their differing view on the Government's overall authority. *See* Br. 42–52. Finally, they argue that events post-dating the denial of intervention "underscore the propriety of intervention." Br. 52. Each of these arguments fails to establish that the district court abused its discretion in denying intervention.

This Court's Presumption of Adequate Representation Applies. This Court has long held that a proposed intervenor faces a heightened burden when seeking to intervene on the side of the

Government. *E.g.*, *Victim Rts. L. Ctr.*, 988 F.3d at 561; *Patch*, 136 F.3d at 207. This presumption applies whenever "a would-be intervenor seeks to appear alongside a governmental body in defense of the validity of some official action," *T-Mobile*, 969 F.3d at 39—including when a regulated party seeks to intervene to defend a regulation that benefits it, *Mass. Food Ass'n*, 197 F.3d at 566-67. *Contra* Br. 38–41.

The Drug Companies seek to evade this precedent, arguing first that "courts no longer apply the presumption of adequate representation in circumstances such as these" following the Supreme Court's decision in *Berger v. North Carolina State Conference of the NAACP*. Br. 32. Despite their assertion that "courts no longer apply the presumption," the Drug Companies have not identified *even one court* that has held that *Berger* eliminated the presumption of adequate representation in a case like this. In fact, earlier this year, the Sixth Circuit rightly held the opposite. *See Lucas Cnty. Bd. of Comm'rs v. EPA*, 169 F.4th 689, 698 (6th Cir. 2026). That is because *Berger* did no such thing.

As the district court correctly explained, the Drug Companies' argument is "misguided" because "the [Supreme] Court made clear its decision [in *Berger*] did 'not decide whether a presumption of adequate

representation might sometimes be appropriate when a private litigant seeks to defend a law alongside the government.'" ADD05 n.2 (quoting *Berger*, 597 U.S. at 197). The Supreme Court recognized that "some lower courts have suggested that a presumption of adequate representation remains appropriate in certain classes of cases," such as "where a member of the public seeks to intervene to defend a law alongside the government," and chose not to disturb lower courts' operative presumptions in those cases. *Berger*, 597 U.S. at 196. Instead, the Supreme Court narrowly held that "a presumption of adequate representation is inappropriate when a duly authorized state agent seeks to intervene to defend a state law." *Id.* at 197.

Given that the Drug Companies are not "duly authorized state agent[s]," *Berger* has no effect on the applicability of this Court's well-established cases applying a presumption of adequate representation where a private party seeks to intervene alongside the government. *E.g.*, *Victim Rts. L. Ctr.*, 988 F.3d at 561–62; *T-Mobile*, 969 F.3d at 39–40. The cases the Drug Companies cite do not imply otherwise, but merely remark in footnotes that *Berger* "calls into question" the applicability of a presumption in hypothetical future cases not yet considered by those

courts (much less this one). *See Bost v. Ill. State Bd. of Elections*, 75 F.4th 682, 688 n.3 (7th Cir. 2023); *Callahan v. Brookdale Senior Living Cmtys., Inc.*, 42 F.4th 1013, 1021 n.5 (9th Cir. 2022).

At bottom, *Berger* did not "*sub silentio* overrul[e] the full sweep of caselaw addressing a presumption of adequate representation;" the Supreme "Court expressly declined to 'decide whether a presumption of adequate representation might sometimes be appropriate when a private litigant seeks to defend a law alongside the government.'" *Lucas Cnty. Bd. of Comm'rs*, 169 F.4th at 698 (quoting *Berger*, 597 U.S. at 197). "Until the Supreme Court does weigh in on that question, [the Courts of Appeals] must continue to follow [their] own binding intervention case law." *Id.*; *Cavallaro v. UMass Mem'l Healthcare, Inc.*, 678 F.3d 1, 7 (1st Cir. 2012) (where a Supreme Court decision does not "foreclose[]" application of existing Circuit precedent, this Court is "bound" to apply that law "[u]ntil the Supreme Court provides more guidance" or the *en banc* Court overturns prior panel decisions).

As a back-up to their *Berger* argument, the Drug Companies repeatedly rely on *B. Fernandez & Hnos., Inc. v. Kellogg USA, Inc.* to assert that the presumption of adequate representation imposes only a

"minimal burden." *E.g.*, Br. 33–34 (citing 440 F.3d 541, 545–47 (1st Cir. 2006)). But that case does not help them either. *B. Fernandez* involved exclusively *private parties* and therefore has no bearing on the burden faced by a party seeking to intervene alongside the Government. *See* 440 F.3d at 547.[11]

The Drug Companies' out-of-circuit cases are similarly inapposite. They rely on *Driftless Area Land Conservancy v. Huebsch*, in which the would-be intervenors, not the defendant regulatory commission, had to defend constitutional claims expressly challenging *their* use of eminent domain. 969 F.3d 742, 744–45 (7th Cir. 2020); *id.* at 748 ("The other two counts, however, attack the use of eminent domain, and that authority belongs to the transmission companies."). The Seventh Circuit found that the would-be intervenors were entitled to defend against the "attack [on] the use of eminent domain," and that the defendant regulatory

[11] Moreover, notwithstanding the factual differences, the district court in this case fully complied with *B. Fernandez*'s holding that a proposed intervenor's "attempt to overcome the presumption of adequate representation should not [be] limited to showing adversity, collusion or nonfeasance." *Id.* The Drug Companies' problem was that they provided nothing but speculation as to inadequacy, ADD08—not that they failed to prove some active harm at the hands of the Government.

commission could "be expected to defend the procedural regularity of its proceedings." *Id.* at 748.[12] There is no such division of claims and interests here. In this case, Plaintiffs challenged *only* the Government defendants' actions under the APA, and the Government vigorously defended those actions as complying with administrative law. Consequently, *Driftless Area Land Conservancy* is inapt.

Accordingly, to have intervened alongside the Government, the Drug Companies needed to make "a strong affirmative showing that the [government] agency (or its members) is not fairly representing [their] interests." *Victim Rts. L. Ctr.*, 988 F.3d at 561 (quoting *Patch*, 136 F.3d at 207). The district court correctly found that they did not and did not abuse its discretion in doing so.

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[12] Nor is the Fifth Circuit's decision in *Wal-Mart Stores, Inc. v. Texas Alcoholic Beverage Commission*, 834 F.3d 562, 569 (5th Cir. 2016), instructive, as it turned on that court's "broad policy favoring intervention" that is not shared by this Court's precedents, particularly where the Government is defending its own regulatory action. The same is true of *Crossroads Grassroots Pol'y Strategies v. Fed. Election Comm'n*, 788 F.3d 312, 321 (D.C. Cir. 2015), which applied the D.C. Circuit's "skeptic[ism] on government entities serving as adequate advocates for private parties." This Circuit takes the opposite view. *E.g.*, *Victim Rts. L. Ctr.*, 988 F.3d at 561.

The Drug Companies Failed to Rebut the Presumption of Adequate Representation With Any "Strong Affirmative Showing." The Drug Companies and Government both wanted the Rebate Program implemented as soon as possible. *See T-Mobile*, 969 F.3d at 39 (representation adequate where proposed intervenor shared defendant's "same ultimate goal"); *LBRY, Inc.*, 26 F.4th at 99 (same where proposed intervenor "concedes that it shares [a party's] litigation objective" (quotation omitted)). Their interests in defending the Rebate Program were well-aligned because, as the Drug Companies argued to the district court, the Government "promulgated the Pilot Program primarily to address manufacturers' need to de-duplicate 340B and IRA discounts." ADD08–09 (quoting JA206 (internal quotation omitted)).

But the Drug Companies now blame the Government for their collective failure to achieve that shared goal of Rebate Program implementation, asserting that the Government could not have adequately represented them because it (1) failed to make certain legal and factual arguments the Drug Companies favor and (2) has a generally broader view of Government power than the Drug Companies do. Br. 41–51. Both arguments fail under this Court's precedents.

First, the fact that the Government did not make every legal argument the way the Drug Companies would have preferred or adopt the Drug Companies' professed harms as its own does not render it an inadequate representative.[13] This is not a case like *Conservation Law Foundation of New England, Inc. v. Mosbacher*, where the Court's concern about inadequate representation arose from the government's decision to not even answer the complaint, but instead to "accept[a] consent decree which provides for virtually all the relief sought." 966 F.2d 39, 44 (1st Cir. 1992). Nor is it like *Cotter v. Massachusetts Association of Minority Law Enforcement Officers*, where minority police officers sought to intervene to defend the Boston Police Department's promotion policies against a challenge by white officers with an argument that it was clear from the start of the case the government could not and would not make—that its employee assessments "are currently in violation of law." 219 F.3d 31, 36 (1st Cir. 2000). Here, the Government fully defended this case, including through an emergency appeal to this Court. The Drug

[13] Notably, the Government did, in fact, emphasize harms to the Drug Companies in its submissions. Doc. # 001185034 at 9–10, *Am. Hosp. Ass'n v. Kennedy*, No. 25-2236 (1st Cir. Dec. 30, 2025); Doc. # 00118385633 at 3*, Am. Hosp. Ass'n v. Kennedy*, No. 25-2236 (1st Cir. Dec. 31, 2025).

Companies' contention that they may, in hindsight, have done so in a different manner does not warrant reversal. *E.g.*, *Victim Rts. L. Ctr.*, 988 F.3d at 561–62 (affirming denial of motion to intervene even though putative intervenor raised additional legal arguments); *LBRY, Inc.*, 26 F.4th at 99–100; *Mass. Food Ass'n*, 197 F.3d at 567.

This is especially so where the "core" issues that the Drug Companies wanted the district court (and this Court) to focus on—their purported inability to deduplicate 340B and IRA discounts and claimed financial harms, Br. 42—were not relevant to determining whether or not the Government acted arbitrarily and capriciously in implementing the 340B Rebate Program. The district court correctly understood that this APA case "turns entirely" on the administrative record, ADD10, and the Drug Companies' "contributions do not constitute the administrative agency record," JA525. *See, e.g.*, *Fla. Power & Light Co. v. Lorion*, 470 U.S. 729, 743–44 (1985) ("The task of the reviewing court is to apply the appropriate APA standard of review, 5 U.S.C. § 706, to the agency decision based on the record the agency presents to the reviewing court."); *Murphy v. Comm'r of Internal Revenue*, 469 F.3d 27, 31 (1st Cir. 2006) (recognizing the Supreme Court's instruction to limit review of agency

action to the decision of the agency and the evidence on which it was based).[14] The district court did not abuse its discretion in finding that the Government could adequately represent the Drug Companies as it defended its own administrative record and final agency action.

Second, it was not necessary for the Government and the Drug Companies to have "perfect identity of motivational interests" spurring their desires to see the Rebate Program implemented for the Government to be an adequate representative. *Victim Rts. L. Ctr.*, 988 F.3d at 562; *see also Daggett*, 172 F.3d at 112 ("The general notion that the [government] represents 'broader' interests at some abstract level is not enough." (quoting *Patch*, 136 F.3d at 207–08)). The Drug Companies argue that the Government could not be both their regulator and representative, Br.

[14] The Drug Companies also complain that they "provided factual evidence to rebut the [Plaintiffs'] claims of impending injury" and the Government did not. Br. 13–14. This so-called "factual evidence" consists of drug and software company executives' statements about how they "understand[]" the 340B program to "usually" work for hospitals, which the Drug Companies apparently expect to have been credited over sworn declarations from hospital leaders regarding impending harms for their hospitals. *See* JA150 ¶ 24; *see also* JA319 ¶ 8. Even setting aside the issues with that expectation, the Drug Companies omit that no one contested that hospitals would incur hundreds of millions of dollars in unrecoverable administrative costs according to the agency's own estimate. *See* JA052.

48, but this Court has expressly rejected the argument that the government "cannot be an adequate representative of [an intervenor's] interests while it also regulates them." *Mass. Food Ass'n*, 197 F.3d at 567.

Moreover, the fact that some Drug Companies are engaged in other litigation against the government does not "create a sufficient *case-specific conflict*" to require intervention. *Victim Rts. L. Ctr.*, 988 F.3d at 562 (emphasis added); *see also Maine v. Dir., U.S. Fish & Wildlife Serv.*, 262 F.3d 13, 20 (1st Cir. 2001) (explaining in affirming denial of intervention that "[a]n earlier adverse relationship with the government does not automatically make for a present adverse relationship."). The Government and the Drug Companies differ in their views on whether drug companies can *unilaterally* implement 340B rebate programs *without* HRSA approval. That entirely distinct legal question is the subject of litigation in the D.C. Circuit, and the district court was careful not to address it in its PI Order. JA522 ("Assuming without questioning the Secretary's discretion to choose between discounts and rebates to effectuate 340B price concessions . . . ."). Critically, the Government and the Drug Companies *both* agreed that HRSA has the authority to implement *this* Rebate Program.

Ultimately, the district court appropriately exercised its discretion in finding the Drug Companies had made no affirmative showing that the Government would not adequately represent their interests.

"Subsequent Events" Are Irrelevant to the Abuse of Discretion Inquiry. Finally, the Drug Companies devote pages to criticizing the Government's litigation choices after they were denied intervention, arguing that "subsequent events underscore the propriety of intervention." Br. 52–56; *see also*, *e.g.*, Br. 18–25, 45. But this Court's abuse-of-discretion review considers "the existing record before the district court when it ruled." *Ministeri v. Reliance Standard Life Ins. Co.*, 42 F.4th 14, 34 (1st Cir. 2022) (quotation omitted); *see also Crawford v. Clarke*, 578 F.3d 39, 44 (1st Cir. 2009) (the "district court is not a mind reader" and accordingly does not abuse its discretion by not considering information unavailable to it at the time of its decision). The Drug Companies' second guessing of the Government's later litigation decisions cannot establish that the district court erred in finding them adequately represented when they moved to intervene. This alone is fatal to the merits of their appeal.

2. *The Drug Companies' Interests in the Rebate Program Were Fatally Contingent.*

In addition, although the district court did not need to reach this issue, the record reflects that the Drug Companies failed to meet another requirement for intervention as of right because they lacked a "direct, not contingent" interest in the Rebate Program. *Travelers Indem. Co. v. Dingwell*, 884 F.2d 629, 638 (1st Cir. 1989). The Drug Companies continue to claim that, without the Rebate Program, they will lose $4 billion in duplicate discounts in 2026 and risk penalties for failing to provide statutorily required discounts. *E.g.*, Br. 9, 42, 44. Though the Drug Companies cite the $4 billion figure often, they *never* explain how it was calculated or what assumptions it relies on, except to note that it came from Berkeley Research Group, the parent company of Beacon (the software vendor they hired to administer the Rebate Program), which has its own financial self-interests here. *E.g.*, JA140 ¶ 18 n.13; JA188 ¶ 18.[15]

Moreover, the Drug Companies have hedged in other cases about the impact of the claimed deduplication issue. Though they have

[15] This $4 billion figure also predates the announcement of the Rebate Program by ten months, having been estimated in October 2024. *See* JA140 ¶ 18 n.13.

principally reverted back to the inflated estimation of $4 billion in harm for this appeal, the Drug Companies have conceded to the D.C. Circuit that their real exposure is actually "potentially millions." No. 25-5177, Doc. # 2158962 at 2 (D.C. Cir. Feb. 12, 2026).[16] The Drug Companies never explain why they represented to the D.C. Circuit that they were facing only "potentially millions" in losses if the Rebate Program did not take effect—nowhere near $4 billion.

In addition, whatever expectations are baked into their arguments, the Drug Companies' purported financial estimate necessarily hinges on the assumption that covered entities will improperly attempt to claim both 340B and IRA discounts, but they offered no actual evidence that this misbehavior will occur. Nor have the Drug Companies offered any actual evidence that the vacatur of the Rebate Program is exposing them to statutory penalties, as such penalties can be avoided by simply making the lower of the 340B ceiling price and the Maximum Fair Price available prospectively. *See* 42 U.S.C. § 1320f-6(a) (no penalty for providing drug

[16] The Drug Companies' opening brief also admits once that "they will be forced to pay millions—and possibly billions—of dollars in duplicate discounts." Br. 56.

at price lower than Maximum Fair Price). Instead, this is "a case in which these would-be intervenors root their professed economic interest in an as yet unrealized expectancy" of government penalties or discount savings lost to unproven non-compliance. *Patch*, 136 F.3d at 205–06. "[N]umerous market variables" make it "anybody's guess" whether, when, and how the Drug Companies' economic interests actually will be harmed. *Id.* at 206 Consequently, their asserted interests are "fatally contingent." *Id.* The district court would have been within its discretion to deny intervention on this basis as well.

B. The District Court Was Well Within Its Discretion to Deny Permissive Intervention.

The district court had "very broad" discretion to also deny the Drug Companies' alternative request for permissive intervention. *T-Mobile*, 969 F.3d at 42. It exercised that discretion appropriately in denying the motion because (1) the Drug Companies had failed to establish that they were not adequately represented by the Government, (2) intervention could "create undue delay in the final disposition of this case involving an important administrative program," and (3) the Drug Companies had not demonstrated "how they might 'add any missing element'" to the Government's defense. ADD12 (quoting *T-Mobile*, 969 F.3d at 40). The

district court instead allowed the Drug Companies to participate as *amici curiae* and confirmed that it would consider their submissions in opposition to Plaintiffs' motion for preliminary relief as *amicus* briefs. ADD13.

The Drug Companies advance two arguments to challenge the court's holding: (1) "the district court should not have given weight to" adequacy of representation "in assessing the [Drug Companies'] separate and alternative claim for permissive intervention," and (2) the district court "provided no actual reasons" for its concerns about the Drug Companies' intervention unduly delaying the case. Br. 57–58. Both run directly counter to this Court's precedents.

First, this Court has counseled 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 (emphasis added).[17] And it has affirmed denials of permissive intervention based on

[17] It is difficult to understand how the Drug Companies argue the opposite to this Court given that the district court specifically cited this language from *T-Mobile*. ADD12.

nothing more than conclusions that "the movant-intervenors did not show that the government would not adequately represent their interests and the amicus procedure provide[d] sufficient opportunity for them to present their view." *Victim Rts. L. Ctr.*, 988 F.3d at 564; *see also Mass. Food Ass'n*, 197 F.3d at 568. The Drug Companies do not cite a single case supporting their argument that it was improper for the district court to give weight to adequacy of representation in accordance with this Court's binding precedents.

Second, this Court has repeatedly rejected challenges premised on a supposed lack of specificity in a district court's reasoning based on far less detailed decisions than the thirteen-page opinion at issue here. In *T-Mobile*, the district judge "summarily denie[d]" the motion for permissive intervention without any explanation and this Court nevertheless affirmed based on the available record. 969 F.3d at 38, 42. Similarly, in *Victim Rights Law Center*, this Court found a "terse" summary order identifying concerns about existing adequate representation sufficient to warrant affirmance. 988 F.3d at 564.

Here, the district court was required to "consider whether the intervention will unduly delay or prejudice the adjudication of the

original parties' rights," Fed. R. Civ. P. 24(b)(3), and found that the Drug Companies' intervention may well do so, ADD12. Any lawyer who has been involved in multi-party litigation can understand why. The Drug Companies are four separate companies and a trade association, represented by four separate sets of counsel. The participation of five more independent litigants and four more groups of lawyers would have at least complicated scheduling, multiplied the volume of submissions the district court needed to review before issuing any decision, and extended the time and space needed for hearings.

It also would have increased the burden on the original parties to the litigation, who would have had to continue expending resources responding to the Drug Companies' attempts to introduce arguments and additional documents that were not relevant to the adjudication of Plaintiffs' straightforward APA claims. As much as they may have wanted to, the Drug Companies could not have proven that the Government complied with the APA when the Government's own administrative record (or lack thereof) showed that it had failed to weigh key considerations or adequately explain its decision. *See supra* 18–20; *see also Mass. Food Ass'n*, 197 F.3d at 567 ("This is not a case where . . .

the would-be intervenors had information that could only be presented by their participation as parties."); *Maine*, 262 F.3d at 20 ("[R]eview of federal agency administrative actions is usually confined to the record before the agency . . . And there is no suggestion the case requires presentation of evidence only available through [the Drug Companies'] participation as intervenors.").

The district court committed no abuse of its broad discretion in denying permissive intervention and, if this Court reaches the merits, it should affirm.

CONCLUSION

This Court should dismiss this appeal as moot or, if the Court finds that it has jurisdiction, affirm the district court's denial of the Drug Companies' motions to intervene.

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Respectfully submitted,

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CERTIFICATE OF COMPLIANCE

This brief complies with the type-volume limit of Federal Rule of Appellate Procedure 32(a)(7)(B) because it contains 10,523 words, excluding the parts of the brief exempted by Federal Rule of Appellate Procedure 32(f). This brief also complies with the typeface and type-style requirements of Federal Rule of Appellate Procedure 32(a)(5)-(6) because it was prepared using Microsoft Word in Century Schoolbook 14-point font, a proportionally spaced typeface.

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CERTIFICATE OF SERVICE

I hereby certify that on June 4, 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.

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