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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## INTRODUCTION

The Association asks this Court to create a novel rule making it all but impossible for a private party granted approval to participate in a federal regulatory program to intervene under Rule 24 to defend that approval and the federal program. In so doing, the Association distorts Supreme Court holdings, this Court's precedents, and common sense. This Court should decline the Association's invitation and reverse the district court's order denying the Manufacturers' motions to intervene.

The Association doubles down on the district court's fundamental error: applying a rigid presumption that governmental parties adequately represent the interests of non-governmental parties who have direct, concrete interests in the outcome of the case. But this Court has never applied any such presumption to deny intervention to putative intervenors akin to the Manufacturers. To the contrary, this Court has only ever required an "adequate explanation" of inadequacy—a burden that is ***lighter*** for proposed intervenors with interests like the Manufacturers' here. Nevertheless, the district court applied, and the Association defends, a "heightened burden" at odds with precedent. ADD09. Even then, the district court misapplied that "heightened

burden." By the time the district court denied intervention, it was abundantly clear that the Agency was not adequately representing the Manufacturers' interests. What followed—most notably, an injunction without consideration of the Manufacturers' imminent harms, then a settlement—confirms that the Manufacturers' interests were not adequately represented below.

The Association's mootness argument fares no better. The question of whether the Manufacturers were entitled to intervene and defend their interests against the Association's last-minute request for an emergency injunction arose in an inherently short-lived proceeding. That question is likely to arise again in similar circumstances, as the Agency announced its consideration of a revised Pilot Program, and the Association's settlement with the Agency below was structured to facilitate litigation (on a 90-day timeline) challenging any new rebate program.

Should the Court find the appeal moot, however, even the Association agrees that 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.

## ARGUMENT

### I. The District Court Should Have Granted The Manufacturers' Motions To Intervene.

The district court abused its discretion because it denied the Manufacturers' motions to intervene based on an error of law. The Supreme Court has indicated that a presumption of adequate representation is appropriate only in specific circumstances not present here. But even if the presumption applied, the district court wrongly ratcheted the Manufacturers' burden up, when it should instead have been ***lessened***. Alternatively, the district court abused its discretion in denying permissive intervention. Either way, the Manufacturers' interests were impaired in their absence. Had the district court granted intervention, the Manufacturers' interests would have been accounted for, and their distinct legal positions, evidence, and arguments would have been before the court.

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

The Supreme Court has signaled that ***no*** presumption of adequate representation applies under circumstances like these. And even if one did, the district court erroneously imposed a heightened standard.

### 1. After *Berger*, No Presumption Applies Here.

The district court wrongly presumed the Agency would adequately represent the Manufacturers. *See* ADD09. Whatever support may have once existed for that approach, the Supreme Court eroded it in *Berger v. North Carolina State Conference of the NAACP*, 597 U.S. 179 (2022). *See also 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 (9th Cir. 2022). *Berger* reaffirmed *Trbovich v. United Mine Workers*, 404 U.S. 528 (1972), which squarely addressed "a request to intervene by a private party who asserted a related interest to that of an existing government party." *Berger*, 597 U.S. at 195. "Rather than endorse a presumption of adequacy," *Trbovich* held that a "movant's burden in circumstances like these should be treated as minimal." *Id.* at 196 (citation omitted). The district court's "heightened" standard is in obvious and irreconcilable conflict with *Trbovich* and *Berger*.[1]

[1] The Association is unaided by *Lucas County Board of Commissioners v. EPA*, 169 F.4th 689 (6th Cir. 2026). There, the putative intervenors' "plan to raise relevant arguments that conflict with [the government's] interests" easily rebutted any presumption. *Id.* at 701-02. So too here. *See* Appellants' Br. 43-44; *infra* Section I.B.1-2.

The Association disregards *Berger*, stressing that the Manufacturers are not "duly authorized state agent[s]," as was the intervenor in *Berger*, and that *Berger* declined to address the propriety of a presumption where "a member of the public seeks to intervene to defend a law alongside the government." Appellees' Br. 37 (citation modified). That argument elides a critical point underpinning the adequate-representation analysis in *Berger* and in caselaw from this Circuit and beyond: When an intervenor has direct interests in the litigation that are distinct from the general public's, the presumption of adequate representation fades away. *See B. Fernandez & Hnos., Inc. v. Kellog USA, Inc.*, 440 F.3d 541, 546 (1st Cir. 2006).

### 2. Even If A Presumption Survived *Berger*, It Would Impose Only A "Minimal" Burden.

If some presumption of adequate representation survived *Berger*, the district court wrongly imposed a "heightened burden." ADD09. The Manufacturers' interests here should have "***lighte[ned]***" their burden to overcome any such presumption. *B. Fernandez*, 440 F.3d at 546 (emphasis added).

As approved applicants for a federal program that provided them with their only reliable deduplication method, the Manufacturers had

distinct interests in the outcome of the case. They were thus situated much more similarly to the state legislators in *Berger*, the targeted company in *B. Fernandez*, the regulated fishing groups in *Mosbacher*, the benefitted police officers in *Cotter* and, of course, the approved applicants in *Driftless Area Land Conservancy* and *Wal-Mart Stores, Inc.* *See* Appellants' Br. 35-37. In each case, the intervenor held a direct, concrete, and personal interest in the outcome of the litigation, unique from any generalized policy-preference interest a member of the public may have held. And in each case, intervention was appropriate.

Nor is this a situation "where a movant's interests are identical to" and "overlap fully" with "those of an existing party." *Berger*, 597 U.S. at 196-97 (citation modified). A regulator does not inherently hold identical, perfectly overlapping interests with the entities it regulates. And in this case, the Manufacturers and the Agency undoubtedly had "sufficiently different" interests. *B. Fernandez*, 440 F.3d at 546; *see also* Appellants' Br. 34-38. The Manufacturers sought to deduplicate discounts as contemplated by statute; the Agency sought to pilot a rebate model in the 340B Program. Appellants' Br. 13 (citing JA371). Likewise, the Manufacturers sought to protect the only reliable method of MFP-340B

deduplication, whereas the Agency acted as an Executive Branch agency safeguarding its claimed regulatory authority. *Id.* at 43. The Manufacturers' interests were also different in degree, as delay costs the Agency little but threatens the Manufacturers with substantial losses from statutory penalties or from providing unnecessary duplicate discounts. *E.g.*, JA126, JA176, JA178. And the Agency ***settled*** the litigation on terms favorable to the Association—but harmful to the Manufacturers. JA555.

The Association invokes *Massachusetts Food Association v. Massachusetts Alcoholic Beverages Control Commission*, 197 F.3d 560 (1st Cir. 1999), but that case does not undermine the fact that a regulator and a regulated entity may have distinct interests, even when they agree that a challenged regulation should be upheld. There, this Court declined to impose a general rule of ***inadequate*** government representation and instead scrutinized the case-specific positions and interests of the government party and the putative intervenor. *Id.* at 567. Such case-by-case assessment of the parties' interests is exactly what the Manufacturers are urging here.

The Association offers no real response. It waves *B. Fernandez* aside, saying it "involved exclusively *private parties*." Appellees' Br. 39. But that ignores that the prospective intervenor and existing party there were corporate affiliates and thus had a particularly close relationship that does not exist between the Manufacturers and the Agency. *See* Appellants' Br. 35 n.7. The Association ironically deems *Driftless Area Land Conservancy* inapposite because the claims there "expressly challeng[ed the intervenors'] use of eminent domain," Appellees' Br. 39, while ignoring that the Association also brought an express challenge to the Manufacturers' planned conduct by seeking to block them from implementing their Agency-approved rebate models.

Tellingly, the Association cannot cite any precedent where a presumption of adequate representation defeated intervention in a case like this one. The Association instead musters cases where intervenors with generalized interests, undifferentiated from the public at large, were denied intervention. *See SEC v. LBRY, Inc.*, 26 F.4th 96 (1st Cir. 2022) (intervenor concerned about litigation's effect on digital assets' value and dubious of defendant's litigation strategy); *Victim Rights L. Ctr. v. Rosenfelt*, 988 F.3d 556, 559-61 (1st Cir. 2021) (advocacy groups

seeking to secure broader constitutional protections on college campuses); *T-Mobile Ne. LLC v. Town of Barnstable*, 969 F.3d 33, 39 (1st Cir. 2020) (landowners worried that a City's defense efforts would be lacking). The Association's (and the district court's) inability to cite anything remotely on point further demonstrates that the district court's decision was incorrect.

So even if some presumption of adequate representation applied, it would pose only the "minimal" burden of "offer[ing] an adequate explanation" of the Agency's potential inability to represent the Manufacturers' interests. *Trbovich*, 404 U.S. at 538 & n.10; *B. Fernandez* 440 F.3d at 546 (citation modified). The Manufacturers' immense financial harms, their distinct legal positions, and their presentation of unique arguments and evidence that the Agency did not and could not present were more than "adequate" to explain why the Manufacturers' interests would not be represented by the Agency.[2]

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[2] The Association's contrary suggestion cannot be squared with hospitals' motions to intervene in litigation by drug manufacturers challenging HRSA's denial of earlier 340B rebate proposals. *See, e.g.*, Order, *Johnson & Johnson v. HHS*, No. 1:24-cv-3188, ECF 50 (D.D.C. May 15, 2025) (granting intervention); Order, *Sanofi-Aventis U.S. LLC v. HHS*, No. 1:24-cv-3496, ECF 32 (D.D.C. Mar. 4, 2025) (same). There, the would-be intervenors argued that HRSA could not

### B. The Manufacturers Were Entitled To Intervene Under Any Standard.

Even if the district court's "heightened burden" were the correct standard (it is not), the Manufacturers carried their burden. In addition to their distinct, concrete interests discussed above, the Manufacturers advanced different legal positions than the Agency and provided relevant factual evidence that only the Manufacturers could offer. But in denying the motions to intervene, the district court simply ignored those important differences. *See Alston v. Town of Brookline*, 997 F.3d 23, 44 (1st Cir. 2021) ("[A]n abuse of discretion occurs when a material factor deserving significant weight is ignored." (citation modified)).

The Association wrongly asserts that the Manufacturers are relying on "hindsight" and "arguments they did not raise … in their motions to intervene but have identified now that the litigation is over." Appellees' Br. 35, 43. To the contrary, the Manufacturers presented to the district court every piece of evidence and argument that they now invoke on

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adequately represent their "financial interests," or "adequately describe the impact that [the] proposed rebate model w[ould] have" on their businesses. Mot. to Intervene, No. 1:24-cv-3188, ECF 14-1 at 18-19 (D.D.C. Jan. 30, 2025); *see also* Mot. to Intervene, No. 1:24-cv-3496, ECF 23-1 at 17–20 (D.D.C. Feb. 5, 2025). The same is true here.

appeal to demonstrate their distance from the Agency. *See* JA306-309 (arguing, based on the Manufacturers' evidence, that the Pilot Program would not create the harms the Association alleged); JA311 (arguing for remand without vacatur); JA402 ("The rebate model endorsed by HRSA's Pilot Program is the only way for Manufacturers to accurately and efficiently prevent duplicate discounts, and thus comply with their statutory obligations, while avoiding statutory penalties or the loss of billions of dollars in improper discounts."); JA405 ("Manufacturers … are the parties who have the actual evidence of the real-world impact of the Program (or its absence), which bears on the equitable and public interest factors of injunctive relief, as well as the merits."); JA406 ("Manufacturers and the government do not see eye-to-eye on all 340B rebate issues. The briefing already filed here underscores that point. Manufacturers provide distinct evidence and arguments regarding the harm that would result if the Pilot Program were enjoined.").[3]

[3] If the Association faults the Manufacturers for relying on arguments raised in their TRO opposition brief (instead of their intervention briefs), that is a meritless distinction. The briefing on intervention and the TRO played out on parallel, expedited schedules because the Association waited until the eleventh hour to bring suit and the Manufacturers promptly moved to intervene and protect their interests, including by filing a proposed TRO opposition. *See*

The district court had all the information it needed to know that the Manufacturers were not adequately represented.

### 1. The Manufacturers Advanced Unique Legal Positions.

The Association overreaches when (like the district court) it asserts that intervention was unwarranted simply because both the Manufacturers and the Agency "wanted the Rebate Program implemented as soon as possible." Appellees' Br. 41. Agreement on the ultimate outcome of the litigation alone cannot defeat intervention. *Crossroads Grassroots Pol'y Strategies v. Fed. Election Comm'n*, 788 F.3d 312, 321 (D.C. Cir. 2015) (warning courts not to "treat[] general alignment as dispositive"); *Bost*, 75 F.4th at 688 ("[A] prospective intervenor must intervene on one side of the 'v.' or the other."). And that surface-level agreement certainly did not override important differences in the Manufacturers' and the Agency's legal positions here.

To be sure, the Manufacturers and the Agency agreed that the Pilot Program was lawful. But their reasonings fundamentally differed

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Appellees' Br. 16 n.6 (acknowledging the district court called for simultaneous intervention and TRO briefing). Everything the Manufacturers point to here was before the district court when it denied intervention.

because their interests were not congruent. The Manufacturers argued that, based on the specific type of agency action at issue (informal adjudication), the Pilot Program satisfied the APA's applicable standards. JA301-03. The Agency predominantly asserted that it had unreviewable discretion over ***all*** 340B matters—a position with which the Manufacturers (as 340B Program participants) ***disagree*** and one they did not want to see prevail. *See* JA366-370.

The Manufacturers and the Agency also disagreed about what should happen if the district court did find an APA violation. The Manufacturers, knowing that the Pilot Program was the only reliable method of deduplication, were especially concerned with avoiding an immediate injunction. To that end, the Manufacturers argued for the narrow, nondisruptive remedy of remand without vacatur. Appellants' Br. 44-45; *see also* JA311. The Agency did not share that sense of urgency and gave less focus (*i.e.*, none until it was too late) to the remedial analysis. The Agency simply "lack[ed] the same drive that motivate[d]" the Manufacturers. *Wineries of the Old Mission Peninsula Ass'n v. Twp. of Peninsula*, 41 F.4th 767, 775 (6th Cir. 2022).

The Association ignores these facts and likewise glosses over the Fifth Circuit's and D.C. Circuit's persuasive analyses in *Wal-Mart Stores, Inc.* and *Crossroads Grassroots Policy Strategies*. Appellees' Br. 40 n.12. The Fifth Circuit granted intervention because the existing party and putative intervenor had a different "range of arguments" and because the putative intervenors sought different remedies. *Wal-Mart Stores, Inc. v. Tex. Alcoholic Beverage Comm'n*, 834 F.3d 562, 569 (5th Cir. 2016). The D.C. Circuit similarly emphasized the party's and putative intervenor's "different interests," including "disagree[ment] about the extent of the [government party's] regulatory power, the scope of the administrative record, and post-judgment strategy." *Crossroads*, 788 F.3d at 321. The same differences between the Manufacturers and the Agency existed here. Those differences should have given the district court "sufficient doubt about the adequacy of representation to warrant intervention." *B. Fernandez*, 440 F.3d at 547 (citation omitted).

**2. The Manufacturers Advanced Unique Evidence-Based Arguments.**

The Manufacturers' inability to deduplicate 340B and IRA discounts should have been a critical part of the district court's analysis when adjudicating the Association's emergency motion. But the district

court largely ignored that consideration because the Manufacturers were not allowed to intervene. Far from representing the Manufacturers' interests, the Agency directly ***opposed*** the Manufacturers' position that rebates were the Manufacturers' only reliable method of DPNP compliance. More than anything else, that was ***the*** argument the Manufacturers' needed the district court to hear. The Manufacturers' and the Agency's difference on that point alone demonstrated that "enough likelihood of conflict or divergence of interest exist[ed] to defeat any claim that the [Manufacturers'] interest[s] [were] adequately represented by existing parties." *Cotter v. Mass. Ass'n of Minority L. Enf't Officers*, 219 F.3d 31, 35 (1st Cir. 2000) (citation modified). The consequences of that "conflict or divergence," *id.*, manifested when the district court and this Court accepted the Agency's contrary representations. *Am. Hosp. Ass'n v. Kennedy*, 164 F.4th 28, 37 (1st Cir. 2026) ("[T]he federal government has indicated that manufacturers have alternative methods to address the … duplication issue."); JA550 (district court finding "no apparent, actual urgency to the January 1 [Pilot Program] start date").

The Association tries to argue that the deduplication disagreement is irrelevant to the merits of its APA claim. *See* Appellees' Br. 42-43. That is just incorrect: The Association's APA claim challenged the Agency's balancing of the Pilot Program's supposed costs against its benefits. *See, e.g.*, JA030-031(¶11); JA079-082(¶¶142-150); JA103-106. Resolving the Manufacturers' deduplication dilemma was a, if not ***the***, leading benefit of the Pilot Program. 90 Fed. Reg. 38,165 (Aug. 7, 2025). For that reason, the Manufacturers sought to intervene to uphold the Agency's decision on the merits. JA124-25. The Association also ignores that the deduplication issue is central to the intervention issue because the Association sought emergency injunctive relief designed to upend the Manufacturers' only realistic deduplication method. *See B. Fernandez*, 440 F.3d at 546 (emphasizing the "potential for an injunction binding [the intervenor's] future dealings"). So the Manufacturers sought intervention also to ensure that their interests were accounted for in any remedial analysis. Indeed, the Association was able to argue that the Manufacturers' harms should be disregarded only because the district court denied intervention. JA463-464 (the Association arguing that "the drug companies' interests" should not "be any value in the balance of

equities here"). And the district court and this Court were able to conclude that the Pilot Program's implementation was not urgent because no "party" in the case faced the imminent harm that the Manufacturers faced. *See Kennedy*, 164 F.4th at 37 (acknowledging that "the primary cost of any delay … run[s] to the drug manufacturers, not the federal government").

That alone demonstrates the error in denying the Manufacturers' motions to intervene. The Manufacturers had distinct, concrete business interests that would be impaired by a preliminary injunction. Only the Manufacturers could put that information before the district court. The district court then denied intervention, while simultaneously ignoring all those interests in evaluating whether to grant relief on the merits because the Manufacturers were not parties to the case. That cannot be the correct result.

The Manufacturers, unlike the Agency, also put forth factual evidence demonstrating that the Pilot Program would not cause covered entities the harms the Association claimed. The Manufacturers explained that the Manufacturers would provide "free access" to claims-data submission software, JA148 (¶19), and explained that this software

would be familiar to covered entities, JA151 (¶27); *see also* JA319 (¶8), such that the Associations' allegations that the Pilot Program would impose significant administrative burdens were baseless. The Manufacturers also rebutted the Association's assertions that the Pilot Program would create cash-flow issues for covered entities. JA150 (¶24). Now, the Association says that "no one contested" the Association's inflated claims of "unrecoverable administrative costs." Appellees' Br. 44 n.14. But that is only true if "no one" means the formal ***parties*** to the district court proceedings, which the Manufacturers should have been but for the district court's denial of intervention.

### 3. Subsequent Events Confirm The Propriety Of Intervention.

The magnitude of the district court's error quickly became apparent. Denied party status, the Manufacturers could not protest when the district court and this Court ignored their billions of dollars in harm and credited the dubious costs asserted by the Association. Nor could the Manufacturers object when the Agency settled the litigation on terms highly favorable to the Association, though the Manufacturers believed that—at worst—less disruptive solutions were feasible and desirable. *See* JA311.

The Association is wrong to label these consequences as irrelevant just because they occurred after the district court issued its order denying intervention. Those post-denial events demonstrate "the particular way[s] in which" the Manufacturers' and the Agency's "divergent interests … impacted the litigation." *Texas v. United States*, 805 F.3d 653, 663 (5th Cir. 2015). The Manufacturers are thus not "second guessing" anything. *Contra* Appellees' Br. 46. The Manufacturers are pointing to subsequent events that confirm the concerns that were apparent all along, which the Manufacturers attempted to raise as soon as the litigation began but were denied the opportunity. So the Association has it exactly backwards: That the Manufacturers' fears came true is strong evidence of "the merits of their appeal." *Contra id.*[4]

### C. The Manufacturers' Interests Were Not "Contingent."

The Association's attempt to paint the Manufacturers' interests as "contingent" falls flat. The Manufacturers each invested thousands of

[4] The Association's own authority simply states that "abuse-of-discretion review *generally* measures the decision below against 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) (citation modified). That "general" principle should not blind this Court to developments bearing out Manufacturers' concerns that happened only days after the Manufacturers' motions were denied.

hours and millions of dollars into their Pilot Program rebate models. *See, e.g.*, JA139-140 (¶17); JA166 (¶23); JA197 (¶24); JA284 (¶¶25-26). The Agency approved the Manufacturers' Pilot Program applications. JA154-155, JA169-170, JA187(¶¶15-16), JA195(¶14), JA269(¶33), JA284(¶24). And the Manufacturers were set to implement their rebate models beginning January 1, 2026. The Manufacturers' interests in obtaining the benefit of their investments by implementing their Agency-approved rebate models were not "contingent" on anything. The Association does not (and could not reasonably) argue otherwise. Invalidation of the Pilot Program directly affected the Manufacturers' concrete legal interests, moreover, because it directly precluded them from going forward with the models.

The Manufacturers also had a concrete interest in avoiding an estimated $4 billion in duplicate discounts. The Association now contests that estimate. Appellees' Br. 47-48. But the Association forfeited its argument. It never disputed the accuracy of the $4 billion estimate below, either when opposing the Manufacturers' intervention or in response to the Manufacturers' opposition to an emergency injunction. *See, e.g.*, *New Jersey v. Trump*, 131 F.4th 27, 43 (1st Cir. 2025)

(arguments not presented during the underlying proceedings are waived). Had the Association properly raised a dispute below, the question could have been litigated and resolved in the district court. The likelihood of manufacturers suffering those losses should have then factored into the district court's preliminary-injunction analysis.[5] So the Association's new argument only proves that the district court should have granted intervention and accounted for the full effect of the injunction the Association sought.

Forfeiture aside, the $4 billion estimate is well-founded. The Berkeley Research Group's (BRG) report, on which the Manufacturers' declarants relied, analyzed "the share of claims that are 340B-eligible within historical Medicare Part D Prescription Drug Event data,

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[5] The Association incorrectly suggests that the Manufacturers could "simply mak[e] the lower of the 340B ceiling price and the Maximum Fair Price available prospectively." Appellees' Br. 48. That is not a harmless solution. If the MFP is lower than the 340B price, but that drug is dispensed to a non-MFP eligible patient, then the manufacturer gave an unnecessarily large discount. The manufacturer would either then have to eat the cost or "initiate [an] after-the-fact chargeback" for the difference between the MFP and the 340B price on that ineligible dispense, which would "impose significant burdens on [the] manufacturer [and] the covered entit[y]." JA270-271 (¶38); *see also* JA295, JA319-321 (¶10), JA403-404.

estimates [based on public data] of the current 340B discount for drugs subject to the MFP, and the 2026 MFPs as reported by CMS." BRG, Implications for Duplication with the 340B Channel (Oct. 23, 2024), https://tinyurl.com/3v3vee7m. The Association accuses the Manufacturers of "conced[ing] to the D.C. Circuit that their real exposure is actually 'potentially millions,'" Appellees' Br. 48 (citation omitted), but points only to a 28(j) response letter in a case where some 340B-participating manufacturers (but not all the Manufacturers here) challenged HRSA's denial of those manufacturers' cash-rebate models. *Id.* (citing No. 25-5177, Doc. #2158962 at 2 (D.C. Cir. Feb. 12, 2026)). Those manufacturers summarized the stakes of that litigation at a high level of abstraction—they did not purport to establish the precise financial effect of the Pilot Program's vacatur. *Id.* Indeed, in support of the "potentially millions" assertion, they cited a passage of their opening brief discussing the potential for *civil penalties*, not duplicate discounts, which was the estimate provided in the BRG report. *See* No. 25-5177, Doc. #2121476 at 16 (D.C. Cir. June 18, 2025) ("And if manufacturers incorrectly deem rebates duplicative, they face millions in civil monetary penalties.").

In any event, even if vacatur of the Pilot Program merely cost each Manufacturer "millions," rather than billions, that hardly shows that the Manufacturers' interests were unduly "contingent."

### D. The District Court Abused Its Discretion Denying Permissive Intervention; Amicus Participation Was Insufficient.

The Manufacturers would have added critical evidence and advanced important arguments before the district court. The district court denied permissive intervention in large part because it repurposed its flawed adequate-representation reasoning. For all the reasons explained above and in the Manufacturers' opening brief, that analytical misstep alone is sufficient to undermine the district court's conclusion on permissive intervention. *See Top Ent., Inc. v. Torrejon*, 351 F.3d 531, 533 (1st Cir. 2003).

The district court's denial of permissive intervention also rested on unfounded speculation that the Manufacturers would delay the proceedings. But the only evidence before the district court was that the Manufacturers would act quickly and on the accelerated timeline set for the existing parties. The Association says the district court's speculation makes sense for reasons "[a]ny lawyer who has been involved in a multi-

party litigation can understand." Appellees' Br. 52. As a matter of pure addition, more parties may mean more lawyers, more evidence, and more arguments. But on that reasoning, permissive intervention would never be appropriate—or at least, the district court's obligation to exercise reasoned discretion would be meaningless. The district court has discretion, but it must offer a reasoned explanation for its choice. *See Daggett v. Comm'n on Governmental Ethics & Elections Prac.*, 172 F.3d 104, 112-13 (1st Cir. 1994). Here, that obligation was not satisfied.

Nor did "[p]articipation as amici satisf[y]" the Manufacturers' interest in demonstrating their harms. ADD13. Because they were only amici, the district court did not have to address their additional legal arguments and factual evidence. Indeed, the district court overlooked the Manufacturers' billion-dollar harms, did not consider the Manufacturers' statutory de-duplication obligations, did not consider a remand-without-vacatur resolution that would have accommodated the Manufacturers' interests, and ultimately blessed a settlement with terms unfavorable to the Manufacturers. The Association nonetheless asserts that amicus status "fully accommodated any legitimate interest [the Manufacturers] had in making their views known to the Court."

Appellees' Br. 2. Given the gap between the district court's analysis and the factual record it would have been required to consider if it had granted intervention, that assertion is untenable.

In short, the district court abused its discretion when it denied intervention and relegated the Manufacturers to amici curiae.

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

This Court has jurisdiction because the district court's error is capable of repetition yet evading review. The extraordinary pace of the Association's effort to secure a TRO, and then a preliminary injunction, denied the Manufacturers an opportunity to fully litigate their intervention requests. The same series of events is reasonably likely to recur if the Agency launches a second Pilot Program (which it is presently considering). If this Court declines to review the Manufacturers' challenge now, the intervention dispute will have been insulated from appellate review. The Association offers no reason to think otherwise.

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

Emergency injunctions like the one requested by the Association, are "inherently transitory" and thus likely to evade review. *See ACLU of Mass. v. U.S. Conf. of Catholic Bishops*, 705 F.3d 44, 57 (1st Cir. 2013);

*Neb. Press Ass'n v. Stuart*, 427 U.S. 539, 547 (1976) ("[I]f we decline to address the issues in this case on grounds of mootness, the dispute will evade review, or at least considered plenary review in this Court, since these orders are by nature short-lived."). So too with attempts to intervene and defend against the entry of an emergency injunction. Indeed, intervention in a TRO proceeding is definitionally as "inherently transitory" as the TRO itself; anytime the TRO moots out, so too will any intervention motion encompassed within it. TROs come and go in a matter of days or weeks, "a period too short to complete judicial review of [their] lawfulness." *FCC v. Consumers' Rsch.*, 606 U.S. 656, 671 n.1 (2025) (finding that three months was too short to enable judicial review) (citation omitted).

The Association protests that "[t]he claims at issue here were not by nature short-lived," as is the case with "temporary restraining orders." Appellees' Br. 23. But a temporary restraining order is exactly what Plaintiffs sought when they filed this eleventh-hour lawsuit. *See* JA091. Only later did the Association seek to relabel its request as one for preliminary injunctive relief (which is, in any event, merely another form of expedited emergency relief). JA351 & n.1.

The Association also points out that "the Drug Companies are not seeking (***and could not seek***) appellate review of an inherently transitory temporary restraining order or preliminary injunction." Appellees' Br. 31 (emphasis added). That describes precisely why this appeal is not moot. The Manufacturers were unable to seek appellate review of the district court's expedited emergency relief precisely ***because*** they were denied the ability to intervene in the litigation. *See Kennedy*, 164 F.4th 28 (declining to stay the district court's preliminary injunction without addressing the Manufacturers' motion to intervene on appeal). The intervention dispute is tied to the underlying TRO dispute and is thus inherently time-limited. The Association's counterfactual litigation decisions—for example, to "litigate[] fully" its APA challenge instead of settling after a preliminary-injunction ruling, Appellees' Br. 28—do not mitigate the concern that this dispute will evade review.

Indeed, *Nebraska Press Association*, which the Association cites, helps illustrate this. It too involved intervention in a TRO proceeding, and the only reason the intervenors could appeal the underlying order was because the court had ***granted*** intervention. *See* 427 U.S. at 543. Yet the district court denied intervention here, so the fact that the

Manufacturers "could not seek … appellate review" of any underlying order, Appellees' Br. 31, is exactly why the Manufacturers need appellate review now. In other words, the Manufacturers could have appealed the TRO, as did the intervenors in *Nebraska Press Association*, but for the very issue now on appeal.

The Association also objects to the Manufacturers' focus on its TRO request. It contends the "only" way to describe the claims in this litigation is to describe the cause of action: "alleged violations of the APA." Appellees' Br. 28. That is plainly wrong. As the caselaw governing mootness shows—including that cited in the Association's brief—a lawsuit can be characterized in several different ways. One way is to describe the cause of action (an APA claim). But for mootness purposes, a lawsuit can also be characterized by its subject matter (pregnancy, elections) or the relief or remedy sought (a TRO). *See ACLU of Mass.*, 705 F.3d at 57; *Lowe v. Gagné-Holmes*, 126 F.4th 747, 759-60 (1st Cir. 2025). Any of these features may be salient for purposes of whether the litigation is the kind that evades review. Whether considered through the lens of the emergency relief sought, or even the subject matter of the Association's lawsuit (a government ***pilot*** program),

this case involves an inherently time-limited dispute. *E.g.*, *Neb. Press Ass'n*, 427 U.S. at 546; *Kingdomware Techs., Inc. v. United States*, 579 U.S. 162, 170 (2016) (suit against government agency over "short-term contracts" was capable of repetition yet evading review).

The Manufacturers are not "distort[ing]" any "inquiry," by focusing on what they can do before the Association's next "request for emergency injunctive relief is adjudicated." *Contra* Appellees' Br. 31. The Manufacturers are applying basic mootness-exception principles and explaining what was at stake in this litigation—and what will be in the next similar case.

If the Agency debuts a new Pilot Program or something similar, and the Manufacturers are approved for that Program, and the Association or another plaintiff challenges that Program, "the District Court may enter another … order" enjoining its enforcement. *Neb. Press Ass'n*, 427 U.S. at 546. That order itself may be time limited, as with the Association's initial request for a TRO. *See id.* Any decision by the district court to deny intervention will have evaded review and the Manufacturers will have no way to defend their interests before any decision to block a future Pilot Program. And it is no secret that a

preliminary order blocking the Pilot Program will likely be the end of the matter, as it was in early 2026. TROs and preliminary injunctions are "supposed to be only a prediction about the merits of the case," but for better or worse, "[a]ll too often, 'the preliminary injunction [becomes] the whole ball game.'" *Del. State Sportsmen's Ass'n, Inc. v. Del. Dep't of Safety & Homeland Sec.*, 108 F.4th 194, 201 (3d Cir. 2024) (quoting *Winter v. NRDC*, 555 U.S. 7, 33 (2008)); *cf. United States v. Flute*, 951 F.3d 908, 910 (8th Cir. 2020) (settlement between government and private party that "expedited the end of this case" was "almost certainly driven by our panel opinion," not "happenstance").

Unless this Court reviews the intervention question now, it very likely will continue to evade this Court's review. The Association would prefer it that way—keeping the Manufacturers iced out of a future round of litigation—but the Association's preference has no legal basis.

### B. The Manufacturers' Claim Is Likely To Recur.

The Manufacturers have shown "a reasonable expectation or a demonstrated probability that the same controversy will recur involving" these same Manufacturers' right to intervene. *Barr v. Galvin*, 626 F.3d 99, 105 (1st Cir. 2010) (citation modified); *see Turner v. Rogers*, 564 U.S.

431, 440 (2011) ("reasonable likelihood"); *Kingdomware*, 579 U.S. at 170 (same). The Agency has taken multiple steps toward the next iteration of the Pilot Program, including a June 15, 2026 Notice announcing its "inten[t] to introduce a revised 340B Rebate Model Pilot Program." 91 Fed. Reg. 35,989 (June 15, 2026); *see also* 91 Fed. Reg. 7,287 (Feb. 17, 2026).

For that "revised" Pilot Program, the Agency intends to use eligibility criteria that overlaps with the original Pilot Program—"manufacturers with current Medicare Drug Price Negotiation Program Agreements … for the initial price applicability years (IPAY) 2026 and 2027." 91 Fed. Reg. at 35,990; *see* 90 Fed. Reg. at 38,166 (inviting manufacturers with DPNP agreements for 2026 into original Pilot Program). So the Manufacturers will be eligible to participate in the revised Pilot Program—and are likely to do so, given the prospect of $5.23 billion in MFP-340B duplicate discounts in 2027. BRG, Update on Effectuation of the Maximum Fair Price in 2026 and Outlook for 2027 (April 2026), https://tinyurl.com/r3z9fwb7. The Association even structured its settlement with the Agency around an anticipated APA challenge to such a program. That settlement contemplates expedited

litigation concluding in three months or less, meaning the Manufacturers' motions to intervene almost certainly would not receive appellate review in time. *See FCC*, 606 U.S. at 671 n.1 ("[T]hree months [is] too short to complete judicial review[.]") (citation omitted); *see also Anderson v. Cryovac, Inc.*, 805 F.2d 1, 5 (1st Cir. 1985) (mootness analysis conducted "without considering the possibility of expedited review") (citation omitted).[6]

It blinks reality to call this mere "speculation." Appellees' Br. 32. The Association is a well-funded and litigious trade association with members that engage in repeat-player lawsuits around the country. There is no reason to think the Association would not proceed exactly as it did here, given that its member hospitals strenuously and categorically oppose the use of rebates in the 340B Program. Indeed, in response to the Agency's request for information regarding a new Pilot Program, the Association reiterated its position that "a rebate mechanism ***of any kind*** is flawed in both conception and design" and "urge[d the Agency] to

[6] These common-sense conclusions dispel the supposed "uncertain[ty]" over the nine pedantic steps spelled out in the Association's brief. Appellees' Br. 32-33.

abandon the idea altogether." American Hospital Association, *Comment Letter on Proposed 340B Rebate Model Pilot Program (HRSA–2026–03042)*, Comment No. HRSA-2026-0001-1846, at 1 (April 20, 2026), https://tinyurl.com/55rf9yrs (emphasis added). And the Association made clear that it finds the newly proposed Pilot Program as problematic as the original. *See id.* at 1-5 (citing hospitals' purported administrative costs and arguing broadly that "the costs of any switch will massively outweigh any expected benefits"). The Association cannot pretend with a wink here that no one knows what is coming next.

The Association does not, and cannot realistically, suggest that a lawsuit over a revised Pilot Program will involve materially different plaintiffs, different defendants, or different intervenors.[7] In all likelihood, there will be another suit brought by ***these*** plaintiffs, against ***these*** defendants, with ***these*** legal claims, involving a similar government program, leading to an intervention motion from ***these***

[7] *Redfern v. Napolitano*, 727 F.3d 77, 85 (1st Cir. 2013) offers the Association little help. There, the government gave little indication of "whether it intend[ed] to reuse" challenged technology, *id.*, unlike the clear signs here of the same program (with the same Manufacturers) recurring.

proposed intervenors. This litigation is thus a tight fit for, and a textbook example of, a controversy "capable of repetition." *See Barr*, 626 F.3d at 105-06.

Because "the same legal issue in this case is likely to recur in future controversies between the same parties" in similar circumstances "where the period of [expedited proceedings] is too short to allow full judicial review" of any intervention ruling, this Court has jurisdiction. *Kingdomware*, 579 U.S. at 170.

### C. The Parties Agree That *Munsingwear* Vacatur Is Appropriate If This Appeal Is Moot.

The Association concedes that *Munsingwear* vacatur would be appropriate should the Court find this appeal moot. Appellees' Br. 33-34 n.10; *see Munsingwear,* 340 U.S. at 39. So at the very least, the Court should vacate the district court's intervention denial to enable any next round of intervention litigation to proceed on a clean slate.

## CONCLUSION

The district court's order denying the motions to intervene should be reversed. Alternatively, the Court should vacate that order under *Munsingwear*.

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Respectfully submitted,

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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 6,498 words, excluding the parts of the brief exempted by FED. R. APP. P. 32(f).

This brief also complies with the typeface requirements of FED. R. APP. P. 32(A)(5) and the type requirements of FED. R. APP. P. 32(A)(6) because it has been prepared in a proportionally spaced typeface using Microsoft Word in Century Schoolbook font 14-point type face.

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## CERTIFICATE OF SERVICE

I hereby certify that on June 25, 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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