No. 25-2236

United States Court of Appeals for the First Circuit

THE AMERICAN HOSPITAL ASSOCIATION, *et al.*,

Plaintiffs-Appellees,

v.

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

Defendants-Appellants,

ABBVIE INC., *et al.*,

Movants,

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

MOTION TO INTERVENE ON APPEAL

Matthew S. Owen
Meredith M. Pohl
KIRKLAND AND ELLIS
1301 Pennsylvania Ave NW
Washington, DC 20004
Tel.: (202) 389-5000
matt.owen@kirkland.com

Counsel for AbbVie Inc. and Pharmacyclics LLC

Kwaku A. Akowuah
Madeleine Joseph
SIDLEY AUSTIN LLP
1501 K St NW
Washington, DC 20005
Tel.: (202) 736-8000
kakowuah@sidley.com

Counsel for PhRMA

(Additional counsel on next page)

Allon Kedem
Jeffrey L. Handwerker
ARNOLD & PORTER KAYE SCHOLER LLP
601 Massachusetts Ave NW
Washington, DC 20001
Tel: (202) 942-5000
allon.kedem@arnoldporter.com
jeffrey.handwerker@arnoldporter.com

Counsel for AstraZeneca Pharmaceuticals LP

Kevin F. King
Thomas Brugato
Daniel G. Randolph
COVINGTON & BURLING LLP
One City Center
850 10th St NW
Washington, D.C. 20001
Tel: (202) 662-6000
kking@cov.com
tbrugato@cov.com
drandolph@cov.com

Counsel for Boehringer Ingelheim Pharmaceuticals, Inc. and Novo Nordisk Inc.

TABLE OF CONTENTS

TABLE OF AUTHORITIES

Page(s)

Cases

Statutes & Regulations

Other Authorities

INTRODUCTION

The district court's preliminary injunction threatens to plunge a novel federal drug-pricing program into chaos on January 1, 2026, the first day of its operation, inflicting billions of dollars of losses on drug manufacturers in the process.

The district court's order is manifestly wrong. Many of its errors stem from its failure to acknowledge the major change the Inflation Reduction Act will make in the drug-pricing landscape, beginning January 1. The district court likewise refused to take account of the stake that drug manufacturers have in the proper operation of the IRA, and, having denied them intervention, gave zero weight to the billions of dollars in losses its injunction will inflict on movants. This Court should act now to correct those errors.

Seeking to comply with conflicting statutory obligations and to avoid an estimated **$4 billion in financial losses** in 2026 alone, plus potential statutory penalties, nine drug manufacturers individually sought approval from the Department of Health and Human Services (HHS) to participate in a Pilot Program starting January 1, 2026. That date was not pulled from a hat: It is a statutory deadline when those

same nine manufacturers must begin to provide access to the "maximum fair price" under the "Medicare Drug Price Negotiation Program," part of the IRA.

But the IRA *also* gives manufacturers a right not to provide duplicate discounts on the same prescribed unit of a drug, once under the IRA and then again under a separate drug discount program known as 340B (340B Program). The problem is that—without claims data supplied by covered healthcare providers—there is no accurate and reliable way to deduplicate those discounts.

The Pilot Program solves that problem. It will effectuate the statute's non-duplicate-discount provision by allowing approved manufacturers to supply the 340B discount through a rebate. Under a rebate model, the manufacturer's vendor receives information about the 340B discount claim; uses that information to determine whether a unit of the drug is subject to both an IRA discount and a 340B discount; and, if so, ensures that only one discount is paid.

Despite knowing about the Pilot Program for months, plaintiffs waited until December 1 to sue and seek a universal preliminary injunction, theorizing not that there is any statutory problem with the Pilot,

but that HHS did not adequately explain its reasons for approving the manufacturers' applications.

The manufacturers, who have relied on their participation in the Pilot Program to ensure compliance with two federal laws, sought to intervene in the district court to protect their interests. This Court routinely approves intervention when a private party seeks to defend its *own* regulatory approval against another private party's challenge. *See, e.g.*, *Housatonic River Initiative v. EPA*, No. 22-1398 (1st Cir. June 22, 2022) (granting motions to intervene by permittee and permit beneficiary). So too do courts in other circuits. *E.g.*, *Driftless Area Land Conservancy v. Huebsch*, 969 F.3d 742, 749 (7th Cir. 2020) ("The plaintiffs cite no appellate case, and we know of none, that affirmed a denial of intervention in similar circumstances."). Here, though, the district court improperly denied intervention, concluding that movants had failed to overcome a presumption that the government would adequately represent their interests.

The district court compounded its error by ignoring evidence submitted by movants that they or their members stand to lose billions of dollars if the Pilot Program is blocked. The court also ignored the

manufacturers' evidence that, without the Pilot Program, they have no reliable way of complying with their conflicting statutory obligations starting January 1. And the district court disregarded precedent establishing that where more agency explanation is required, the proper course is usually to direct the agency to provide more explanation *without* setting aside its decision.

Ultimately, the district court evinced a fundamental misunderstanding of the situation: It concluded that there was "no apparent, actual urgency to the January 1 start date," and that an injunction would "preserve the status quo"—completely ignoring the January 1 MFP start date and the massive financial harms that movants will suffer if the Pilot Program is enjoined. Dkt 96 at 2-3.

The proposed intervenors below—AbbVie Inc., AstraZeneca Pharmaceuticals LP, Boehringer Ingelheim Pharmaceuticals Inc., Novo Nordisk Inc. Pharmaceutical Research & Manufacturers of America (PhRMA), and Pharmacyclics, LLC (collectively, movants)—now move to intervene in the appeal noticed by the government.[1]

[1] Movants have also appealed the district court's denial of intervention. *See* No. 25-2237.

Movants also support the government's request that the Court administratively stay the preliminary injunction and enter an enduring stay pending resolution of the government's appeal.

STATEMENT

A. The 340B Program And The IRA.

The Pilot Program addresses two overlapping drug-pricing programs. First, the 340B Program requires manufacturers participating in Medicaid and Medicare Part B to offer drugs at a discounted "ceiling price" to certain healthcare providers known as "covered entities." 42 U.S.C. § 256b. The "ceiling price" is set by a statutory formula and is often pennies on the dollar. *See id.* § 1396r-8(c); *see also, e.g.*, Dkt. 36-2, ¶ 3. The 340B Program was relatively small at its inception but is now massive. In 2024, covered entities purchased over $81 billion in discounted drugs—up $15 billion from the prior year. *See id.* ¶ 15; Health Resources & Services Administration (HRSA), *2024 340B Covered Entity Purchases*, https://www.hrsa.gov/opa/updates/2024-340b-covered-entity-purchases (Dec. 2025).

Second, the IRA requires HHS to set an MFP for certain drugs dispensed to Medicare-covered individuals. *See* 42 U.S.C. §§ 1320f(a), (c)(2),

1320f-2(a)(3). (The district court incorrectly described the MFP obligations as applying to Medicaid. *See* Dkt. 90 at 3-4.) The MFP obligation applies to a small number of drugs in 2026 but will cover additional drugs in future years. Failure to provide the MFP exposes a manufacturer to civil monetary penalties—potentially millions per day. 42 U.S.C. §§ 1320f-6(c), 1320f-2(a)(5).

The IRA creates a new problem for manufacturers. Starting January 1, 2026, manufacturers must provide the lower of the MFP and the 340B ceiling price—but *not* both discounts, which combined could be so steep as to produce a negative price. *See id.* § 1320f-2(d). The IRA is explicit: Manufacturers "shall not be required to provide" both the MFP and the 340B price. *Id*. Although duplicate discounts are inconsistent with federal law, the government stated it will not "assume responsibility for deduplicating discounts," leaving manufacturers to shoulder that burden.[2]

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

To accurately deduplicate, manufacturers need claims data—transaction-level data about a given drug dispense—to determine which discount (if any) to issue. Covered entities already collect and use precisely this claims data to determine whether their past drug dispenses were 340B-eligible, often sharing that data with their vendors. Dkt. 36-2, ¶¶ 19, 27.

B. The Pilot Program.

The 340B statute expressly contemplates manufacturers' making the 340B price available either through an upfront "discount" or an after-the-fact "rebate." 42 U.S.C. § 256b(a)(1). In response to widespread concern from manufacturers about their new deduplication obligations, the Health Resources and Services Administration (which administers 340B) announced the Pilot Program to test a rebate model for effectuating the 340B price to covered entities while ensuring manufacturers are not burdened with duplicate discounts. *See* 90 Fed. Reg. 36,163 (Aug. 1, 2025). While the statute clearly contemplates broader rebate models, and manufacturers accordingly have advocated for an expansion of rebate models, the Pilot Program is currently limited to manufacturers with competing

MFP and 340B pricing obligations, and only to those manufacturers' IRA-selected drugs.

Under the Pilot Program, the manufacturers will sell the selected drugs to 340B covered entities at the commercial price. Those manufacturers will then review certain data to determine whether the MFP or the 340B price applies, including certain claims data from the covered entity (which the covered entity already collects in the regular course) relevant to establishing an entitlement to a 340B discount. Covered entities wishing to purchase MFP-selected drugs at the 340B price will submit claims data to manufacturers through a platform called Beacon, which "precisely mirrors" a platform covered entities (including many of plaintiffs here) already use. Dkt. 75-1 ¶ 8. From that review, the manufacturer will know whether to issue a rebate effecting the MFP or the 340B price. This is currently the *only* accurate and reliable method of identifying claims subject to 340B pricing, preventing duplicate discounts, and ensuring statutory compliance. Dkt. 36-2, ¶ 22. It is undoubtedly the only one that can be operational on January 1, when manufacturers' MFP obligations take effect.

HRSA also explained that the Pilot Program would enable it "to better understand the merits and shortcomings of the rebate model from stakeholders' perspectives," and that the Program would "inform [its] consideration of any future 340B rebate models." 90 Fed. Reg. at 36,164.

The Notice set forth detailed requirements for manufacturers' Pilot Program plans. 90 Fed. Reg. at 36,165. For example, the plans "should ensure that all rebates are paid" or "denied, with documentation in support," within "10 calendar days" of the covered entity submitting the data. *Id.* The Notice limits the grounds on which participating manufacturers can deny rebates, *see id.*, and makes clear that failing to comply with the requirements can result in "revoke[d] approval ... at any time." *Id.* at 36,164.

Nine manufacturers whose products are subject to the IRA applied, and eight applications were approved on October 30, 2025, with the ninth approved in November. The Pilot Program thus implicates only a narrow slice of the 340B Program—a handful of drugs out of thousands. *See* Dkt. 50-4 ¶ 42.

The Pilot Program was set to begin on January 1. HRSA chose that date because that is when the IRA's MFP obligations begin. Movants and

PhRMA's members, after investing thousands of hours and millions of dollars, were set to implement their HRSA-approved rebate models that day. *See, e.g.*, Dkt. 36-1, ¶ 17; Dkt. 39-1, ¶ 23.

C. District Court Proceedings.

On December 1, plaintiffs filed this suit. Plaintiffs sought a preliminary injunction prohibiting the Pilot Program from going into effect.

AbbVie immediately noticed its intent to intervene and participated in the Court's initial teleconference. Dkt. 25; Dkt. 31. Thereafter, AbbVie and the other movants sought intervention under Federal Rule of Civil Procedure 24. *See* Dkts. 36, 39, 45 & 50. Their motions detailed their interests in the Pilot Program and the financial injury they would suffer from its suspension. *See* Dkt. 36 at 5-6; Dkt. 39 at 3; Dkt. 45 at 2-5; Dkt. 50 at 4-6. Movants also explained that their interests—as participants approved for the Pilot Program or a trade association representing participants—were not "adequately represente[d]" by any "existing parties." *See, e.g.*, Dkt. 36 at 6-8; Dkt. 39 at 3.

On December 18, the district court denied intervention on the ground that the government would adequately protect movants' interests. Dkt. 83 at 11.

On December 29, the district court granted plaintiffs' motion for a preliminary injunction. Dkt. 90. The district court ignored movants' harms in granting the injunction.

The district court denied the government's motion for a stay pending appeal. Continuing to ignore movants' impending injuries (and the IRA's January 1 MFP start-date), the district court stated that "there is no apparent, actual urgency to the January 1 start date" for the Pilot. Dkt. 96 at 3.

ARGUMENT

I. MOVANTS ARE ENTITLED TO INTERVENE.

Movants are entitled to intervene in this appeal because their motion is timely; they have significant, protectable interests that are threatened by this lawsuit; and the government does not adequately represent those interests. *Cf.* Fed. R. Civ. P. 24(a).

Because no rule of appellate procedure directly governs intervention on appeal, courts look to the "policies underlying intervention in the district courts." *Cameron v. EMW Women's Surgical Ctr., P.S.C.*, 595 U.S. 267, 277 (2022); *see Ruthardt v. United States,* 303 F.3d 375, 386 (1st Cir. 2002).

Appellate intervention should be permitted because the Rule 24(a) standards are amply met here. Or alternatively, this Court should exercise its discretion to allow appellate intervention. *Id.*

1. The motion is timely. The government noticed this appeal on December 29. It was docketed on December 30, and this motion was filed as soon as practicable thereafter.

2. Movants have significant, protectable interests that "bear a sufficiently close relationship to the dispute between the original litigants." *Conservation L. Found. of New Eng., Inc. v. Mosbacher*, 966 F.2d 39, 42 (1st Cir. 1992) (cleaned up). The injunction prevents manufacturers with approved applications from participating in the Pilot Program. Those manufacturers will accordingly be unable to reliably and accurately deduplicate their MFP and 340B discounts, as the statute requires—risking costly duplicate discounts or else statutory penalties as a result of their failure to comply with the IRA's requirements. Dkt. 36 at 5-6; Dkt. 39 at 3; Dkt. 45 at 2-3; Dkt. 50 at 5.

3. These interests are plainly threatened by this suit. The injunction jeopardizes movants' interests in avoiding potentially billions of dollars in duplicate discounts, which will not be recoverable later. Dkt. 36 at 6; Dkt. 39 at 3; Dkt. 45 at 4-5; Dkt. 50 at 5-6.

4. Movants' interests are not adequately represented by the government. Only a "minimal" showing is required to demonstrate that an existing party's representation "may be" inadequate. *Trbovich v. UMWA*, 404 U.S. 528, 538 (1972). Although this Court's precedents suggest that a government defendant "defending the validity" of government action "is presumed to be representing adequately the interests of all citizens who support" the action, *Daggett v. Comm'n on Governmental Ethics & Election Practices*, 172 F.3d 104, 111 (1st Cir. 1999), recent Supreme Court precedent calls such presumptions into question, *see Berger v. N.C. State Conf. of the NAACP*, 597 U.S. 179, 195-98 (2022). Regardless, the presumption is overcome here, for multiple reasons.

a. Movants are not mere interested "citizens" who support the challenged action, but instead are the actual *objects* of that action; they thus have "direct private interests" at stake. *Maine v. Dir., U.S. Fish & Wild-*

life Serv., 262 F.3d 13, 20 (1st Cir. 2001). Courts routinely permit regulated parties to intervene where the government has approved the party's *own* application and a third party challenges that approval. *See Driftless*, 969 F.3d at 749; *Wal-Mart Stores, Inc. v. Tex. Alcoholic Beverage Comm'n*, 834 F.3d 562, 568-69 (5th Cir. 2016).

This makes sense because the applicant is adverse to the government in the underlying application process, where the applicant and the government may have (as here) divergent views about applicable law and facts bearing on the application. So the government's and the applicants' "interests and objectives overlap in certain respects but are importantly different." *Driftless*, 969 F.3d at 748.

This action challenges HRSA's approvals of movants' applications to the Pilot Program, so movants have a right to intervene to defend the regulatory approval *they* received. Movants "cannot be forced to rely entirely on *their regulators* to protect their investment in [an] enormous project, which they stand to lose if the plaintiffs are successful." *Id.*

b. The government's representation is also inadequate because the government and movants have adverse positions on consequential legal

questions. The government's stay motion claims (at 13) that "manufacturers have other alternatives to deduplicate discounts." Movants disagree and provided contrary evidence to the district court. *See, e.g.*, Dkt. 39-1 ¶ 23. That dispute alone shows the government cannot adequately represent movants' interests.

The divergence runs deeper still: The government and several manufacturers (including several approved for participation in the Pilot Program) are adverse parties in a case currently pending in the D.C. Circuit. *See Novartis v. Kennedy*, No. 25-5177 (D.C. Cir.). There, manufacturers claim HRSA acted unlawfully in 2024 in purporting to decide that they could not use rebate models to provide 340B discounts unless they receive preapproval from the government. The Pilot Program permits use of a rebate model in narrow circumstances, but this broader dispute remains.

"These are not mere quibbles with litigation strategy." *Driftless*, 969 F.3d at 749 (cleaned up). "[T]hey reflect very real differences in the interests at stake." *Id.*

5. The district court denied intervention based solely on its view that the government could adequately represent movants' interests. Dkt. 83 at 4. That was error. Movants have appealed and will address the full

extent of the district court's errors in that separate appeal, *see* No. 25-2237, but offer an abbreviated illustration of the district court's errors here.

Most fundamentally, the district court applied the wrong legal principle. As the direct objects of the challenged regulatory approvals, movants claim an interest in those applications and approvals that is different in kind from the government's. Under those circumstances, "the presumption of adequate representation does not apply." *Driftless*, 969 F.3d at 749 (rejecting application of presumption to "permit holders" seeking "to intervene in litigation challenging their permits").

The district court also wrongly concluded that "[m]ovants offer no evidence to suggest that their approach to defending the Pilot Program offers the Court any additional insight" beyond the government's. Dkt. 83 at 9. That ignored the movants' detailed declarations about the harms they would suffer if the Pilot Program is enjoined. *See* Dkt. 36-1, 36-2, 39-1, 45-1, 45-2, 50-4, 50-5, 73-1, 73-2, 73-3. The government's submissions did not explain these harms—at all. Neither here nor in the district court did the government acknowledge the gravity of the financial stakes

for manufacturers. No wonder—it is manufacturers that stand to lose $4 billion in unauthorized duplicate discounts, not the government.

Subsequent events further underscored the need for movants to represent their own interests. For example, movant AstraZeneca submitted documents memorializing its exchanges with HRSA about the burdens from the Pilot Program on covered entities. The government chose not to submit these exchanges as part of the partial administrative record that it compiled. Dkt. 88. The court puzzlingly downplayed AstraZeneca's documents as providing "circumstantial evidence of what the Agency might have considered." Dkt. 90 at 11. But an agency's correspondence with an applicant about its application is *direct* (and telling) evidence of what the agency considered in approving the application. Particularly where the district court has premised a preliminary injunction with massive stakes for manufacturers on doubts about the sufficiency of the government's provision of evidence, movants are entitled to intervene on appeal.

II. A STAY PENDING APPEAL AND AN ADMINISTRATIVE STAY ARE IMPERATIVE.

A. This Court Will Likely Dissolve The Preliminary Injunction.

The district court's preliminary injunction order rests on multiple errors, several of which are outlined in the government's motion for stay. Movants write to reinforce two critical points.

First, the district court erred in disregarding aspects of the administrative record, as well as the government's declaration explaining its contemporaneous decisionmaking. Contrary to the district court, the APA imposes no general obligation on an agency to "develop[] a contemporaneous record." Dkt. 90 at 1. In the district court's view, "before a new program that affects the rights and privileges of the public can be up and running, the agency must undertake the basic task of developing a contemporaneous record." *Id.* But plaintiffs did not challenge the creation of the Pilot Program—only the approval of applications by particular manufacturers to participate in it. And those approvals were informal adjudications, so at most the record would need to show why the agency acted on each application in the way it did. *Camp v. Pitts*, 411 U.S. 138, 142-43 (1973).

Even if a broader requirement applied here, the government's failure to file such a record a few weeks into the litigation was *not* "[a] significant flaw with Defendants' institution of the Rebate Program." Dkt. 90 at 9. While the government typically *compiles* an administrative record for litigation, the administrative record simply "consists of all documents and materials directly or indirectly considered by the agency," whether or not the government has yet compiled it. *Bar MK Ranches v. Yuetter*, 994 F.2d 735, 739 (10th Cir. 1993).

Further, courts have long recognized that government "affidavits, depositions, or other proof of an explanatory nature" may also properly be considered in APA cases, so long as they are "explanatory of the decisionmakers' action at the time it occurred." *Sierra Club v. Marsh*, 976 F.2d 763, 772–73 (1st Cir. 1992). Indeed, the Supreme Court's lodestar preliminary injunction decision placed substantial reliance on "declarations from some of the Navy's most senior officers" in upholding agency action and dissolving a lower court injunction. *Winter v. NRDC*, 555 U.S. 7, 24 (2008). And courts (including this one) have held that such materials may be *required* when the documentary evidence in the administrative record is silent as to whether the agency considered a

relevant factor. *See, e.g.*, *Airport Impact Relief, Inc. v. Wykle*, 192 F.3d 197, 209 (1st Cir. 1999); *Am. Wildlands v. Kempthorne*, 530 F.3d 991, 1002 (D.C. Cir. 2008).

Reliance on declarations is particularly common "at the preliminary injunction stage," where agencies frequently have little time or opportunity to assemble a complete administrative record before judicial review is sought. *Am. Sci. & Eng'g, Inc. v. Kelly*, 69 F. Supp. 2d 227, 235 (D. Mass. 1999). That describes this case, where plaintiffs sought emergency preliminary relief a month ago. The district court's decision to dismiss the government's declaration, its partial administrative record, and AstraZeneca's materials conflicts with commonplace litigation practice.

If the district court did not want to rely on the declaration and wanted more primary sources, it could have simply ordered the government to produce a complete record before ruling on the motion. *See, e.g.*, *Am. Bioscience, Inc. v. Thompson*, 243 F.3d 579, 582 (D.C. Cir. 2001) (the district court "should have required the FDA to file the administrative record" before ruling on a preliminary injunction motion). The district court instead erroneously held that an incomplete record constitutes a

violation of the APA, rather than a circumstance calling for a substitute (such as the declaration it received) or prompt submission of a complete record.

Second, the district court ignored an important remedial principle raised by movants and later seconded by the government. Movants argued that, even assuming HRSA had violated the APA, the appropriate remedy would be a remand to the agency for further consideration and explanation—not an order halting the Pilot Program. Dkt. 72 at 20; *see also* Dkt. 85 at 1 (government echoing this point). Where a court finds a procedural APA violation, "the proper course, except in rare circumstances, is to remand to the agency for additional investigation or explanation." *Fla. Power & Light Co. v. Lorion*, 470 U.S. 729, 744 (1985); *see also, e.g.*, *Cent. Me. Power Co. v. FERC*, 252 F.3d 34, 48 (1st Cir. 2001). Because that is all the relief to which plaintiffs would be entitled after final judgment should they prevail, it was inappropriate for the district court to enjoin the agency's program at the preliminary stage.

B. The Remaining Factors Favor A Stay.

1. Movants will suffer irreparable harm without a stay.

Absent a stay, the manufacturer-movants and several PhRMA members will be subject to conflicting statutory obligations and will incur drastic financial losses beginning on January 1, when the drugs approved for the Pilot Program will be subject to competing 340B and MFP discounts. Those losses will total $4 billion in 2026 alone—absent the Pilot Program. *See* Dkt. 36-1 ¶ 18; Dkt. 45-1 ¶ 18.

By any measure, the harms threatened by the district court's injunction are severe. There are no viable, reliable alternatives to the Pilot Program, let alone viable alternatives that movants could implement by January 1. *See, e.g.*, Dkt. 39-1 ¶ 23. The $4-billion in projected losses do not account for the "significant organizational changes" movants have already made to "prepare for implementation of the rebate model," which have cost them "millions of dollars." Dkt. 50-4 ¶ 33; *see* Dkt. 39-1 ¶ 23; Dkt. 45-1 ¶ 16; Dkt. 45-2 ¶ 24; Dkt. 50-5 ¶ 26. And non-compliance with the IRA would potentially expose movants to yet more financial injury, in the form of statutory penalties. *See* 42 U.S.C. § 1320f-6(a), (c).

These losses are likely irremediable. There is no established mechanism for movants to recover the money they pay in duplicate discounts. *See* Dkt. 39-1 ¶ 25; Dkt. 50-4 ¶ 40. Their "loss of money" qualifies as "irreparable harm" because there is no discernable way to "recoup[]" that loss. *NIH v. Am. Pub. Health Ass'n*, 145 S. Ct. 2658, 2659 (2025) (cleaned up). Worse still, in many cases, that money will remain in the hands of plaintiff hospitals, who have no right to receive an unauthorized duplicate discount, no obligation to return the money, and have put up no meaningful security.

Finally, unlike plaintiffs' claimed harms, movants' injuries "will directly result from the action" that they ask this Court to stay. *Wis. Gas. Co. v. FERC*, 758 F.2d 669, 674 (D.C. Cir. 1985) (per curiam). The Pilot Program is "a reliable way"—indeed, the *only* current reliable way—for movants to "avoid paying duplicate discounts." Dkt. 39-1 ¶ 17.

2. The balance of equities favors a stay.

a. The district court wrongly excluded movants' harms from the equitable equation. After acknowledging HRSA's "laudable goal of resolving competing congressional directives" under the 340B Program and the IRA, the district court ignored movants' injuries in its cursory

discussion of the final two preliminary-injunction factors. *See* Dkt. 90 at 1, 20–21. This obvious error is reason on its own for a stay.

The district court was required to consider whether "the injunction would ... substantially injure other interested parties"—like movants. *Chaplaincy of Full Gospel Churches v. England*, 454 F.3d 290, 304 (D.C. Cir. 2006). After all, "the interests of third persons" are part of the balance of the equities and thus something that courts *must* "take into account" before granting an injunction. *Del. River Port Auth. v. Transam. Trailer Transp., Inc.*, 501 F.2d 917, 924 (3d Cir. 1974); *see also, e.g., Finch v. Treto*, 82 F.4th 572, 579 (7th Cir. 2023) (affirming district court's "eminently reasonable judgment" that the harms to third parties outweighed the harms to the plaintiffs). And had the district court done so, it could not have granted the injunction, given that movants will pay billions of dollars in duplicate discounts, or face penalties, without the Pilot Program.

The district court based its injunction on the flawed viewpoint that its preliminary injunction "preserves the status quo." Dkt. 96 at 2. That's not possible. Congress changed the status quo by imposing new MFP discount obligations and directing that manufacturers need not provide

duplicate MFP and 340B discounts. Starting January 1, there will be a new landscape. The Pilot Program exists to allow HHS and manufacturers to reliably navigate it. The only question is whether the district court's injunction will bar them from using that tool. The Court should grant the stay to prevent that outcome and shield the manufacturers from the imminent and severe harm the injunction will otherwise cause. *See Dist. 4 Lodge of the Int'l Ass'n of Machinists & Aerospace Workers Loc. Lodge 207 v. Raimondo*, 18 F.4th 38, 49 (1st Cir. 2021).

b. Granting that stay will not "substantially injure the other parties interested in the proceeding." *Nken v. Holder*, 556 U.S. 418, 434 (2009). Plaintiffs' claimed harms are speculative and not traceable to the Pilot Program. They complain about administrative costs that are necessary for them to participate in the 340B Program and reap the massive discounts available to them under that program. Any such harms are at most a fraction of the billions of dollars that movants stand to lose. Dkt. 90 at 20.

First, the district court correctly found that plaintiffs' "concerns about delayed receipt and inappropriate denial of rebates from drug manufacturers" are "speculative." *Id.* Such "predictions" about misconduct are irrelevant for preliminary-relief purposes. *R.I. Council of Churches v. Rollins*, 158 F.4th 304, 316 (1st Cir. 2025). Plaintiffs' conjecture is especially unfounded because the rules HHS adopted to govern the Pilot Program preclude manufacturers from doing what plaintiffs claim to fear. *See* 90 Fed. Reg. at 36,164–165.

Second, plaintiffs' asserted compliance costs are not traceable to the Pilot Program. Plaintiffs have long had legal obligations to "maintain auditable records sufficient to demonstrate continued compliance with 340B requirements." *Novartis Pharms. Corp. v. Johnson*, 102 F.4th 452, 457 (D.C. Cir. 2024) (quoting 75 Fed. Reg. 10,272, 10,274 (Mar. 5, 2010)); *see* 42 U.S.C. § 256b(a)(5)(C) (requiring covered entities to permit HHS and manufacturers to audit the entities' records). And following HRSA's instruction that "additional administrative costs of running the rebate model shall [not] be passed onto covered entities," 90 Fed. Reg. at 36,164, manufacturers will implement their rebates through software that allows covered entities to use the same claims data that they already collect,

Dkt. 72-1 ¶¶ 7–8. The "marginal cost[s]" of providing certain claims data that plaintiffs "were already required ... to maintain" do not overcome the severe injury from duplicate discounts that movants would suffer if the injunction remains in place. *E. Bridge, LLC v. Chao*, 320 F.3d 84, 90 (1st Cir. 2003). Nor will Plaintiffs be injured by "floating the upfront costs of covered drugs," Dkt. 90 at 19, because Pilot Program rebates must issue within ten days—much sooner than the typical 30-day deadline for covered entities to pay their wholesalers. *See* 90 Fed. Reg. at 36,164–65; Dkt. 50-5 ¶ 45.

Third, plaintiffs "undermine[d]" their own asserted harms by "[d]elay[ing]" their request for preliminary relief until more than a month after the agency started approving rebate models (despite months of notice about the impending approvals) and a few weeks prior to implementation of the Pilot Program. *Tax-Free Fixed Income Fund for P.R. Residents, Inc. v. Ocean Capital LLC*, 137 F.4th 6, 21 (1st Cir. 2021). This unexplained "failure to act sooner undercuts the sense of urgency that ordinarily accompanies a motion for preliminary relief." *Voice of the Arab World, Inc. v. MDTV Med. News Now, Inc.*, 645 F.3d 26, 35 (1st Cir. 2011)

(cleaned up). It also confirms that plaintiffs will not suffer a substantial injury if this Court stays the injunction while deciding the appeal.

3. The public interest favors a stay.

The last factor also favors relief because a stay would serve the public interest identified by Congress. By specifying that manufacturers "shall *not* be required to provide" 340B and MFP discounts on the same unit of drug, 42 U.S.C. § 1320f-2(d)(1) (emphasis added), "Congress has effectively declared the public interest," *Dist. 4 Lodge*, 18 F.4th at 49. The Pilot Program effectuates that congressional command by allowing manufacturers to deduplicate and avoid the billions of dollars in harm duplicate discounts would otherwise inflict. The preliminary injunction thwarts that same command by blocking the Pilot Program—not because of any doubt about whether the agency has authority to adopt the Pilot, but based solely on plaintiffs' criticisms regarding whether the agency sufficiently explained to them its reasons for approving manufacturers' applications and produced a sufficiently complete administrative record during the first few weeks of emergency litigation. The public-interest factor thus strongly favors staying the injunction, which upends a lawful solution to a serious problem on a flimsy basis.

CONCLUSION

The Court should grant the motion to intervene and grant a stay pending appeal and an administrative stay of the district court's preliminary injunction.

December 31, 2025

Respectfully submitted,

/s/ *Kwaku A. Akowuah*

Kwaku A. Akowuah
Madeleine Joseph
SIDLEY AUSTIN LLP
1501 K St NW
Washington, DC 20005
Tel.: (202) 736-8000
kakowuah@sidley.com
Counsel for PhRMA

Matthew S. Owen
Meredith M. Pohl
KIRKLAND AND ELLIS
1301 Pennsylvania Ave NW
Washington, DC 20004
Tel.: (202) 389-5000
matt.owen@kirkland.com
Counsel for AbbVie Inc. and Pharmacyclics LLC

Allon Kedem
Jeffrey L. Handwerker
ARNOLD & PORTER KAYE SCHOLER LLP
601 Massachusetts Ave., NW
Washington, DC 20001-3743
(202) 942-5000
(202)942-5999 - fax
allon.kedem@arnoldporter.com
jeffrey.handwerker@arnoldporter.com
Attorneys for AstraZeneca Pharmaceuticals LP

Kevin F. King
Thomas Brugato
Daniel G. Randolph
COVINGTON & BURLING LLP
One City Center
850 10th St NW
Washington, D.C. 20001
Tel: (202) 662-6000
kking@cov.com
tbrugato@cov.com
drandolph@cov.com
Counsel for Boehringer Ingelheim Pharmaceuticals, Inc. and Novo Nordisk Inc.

CERTIFICATE OF COMPLIANCE

This brief complies with Federal Rule of Appellate Procedure 27(d)(2)(A) because it contains 5,199 words.

This brief complies with Federal Rules of Appellate Procedure 27(d)(1)(E) and 32(a)(5) and (6) because it was prepared in a proportionately spaced typeface using Microsoft Word in 14-point Century Schoolbook font.

/s/ *Kwaku A. Akowuah*
Kwaku A. Akowuah

CERTIFICATE OF SERVICE

I certify that on December 31, 2025, I caused this document to be electronically filed with the Clerk of the Court for the United States Court of Appeals for the First Circuit using the appellate CM/ECF system. Service will be accomplished by the appellate CM/ECF system.

/s/ *Kwaku A. Akowuah*
Kwaku A. Akowuah