No. 25-2236

IN THE 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.

On Appeal from the United States District Court
for the District of Maine

REPLY IN SUPPORT OF MOTION FOR STAY PENDING APPEAL

Of Counsel:

MICHAEL B. STUART
General Counsel

ELIZABETH C. KELLEY
Deputy General Counsel

U.S. Department of Health and Human Services

YAAKOV M. ROTH
Principal Deputy Assistant Attorney General

MICHAEL S. RAAB
MAXWELL A. BALDI
Attorneys, Appellate Staff
Civil Division, Room 7513
U.S. Department of Justice
950 Pennsylvania Avenue NW
Washington, DC 20530
(202) 532-0211

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INTRODUCTION AND SUMMARY OF ARGUMENT

After years of work by the Department of Health and Human Services and drug manufacturers, the Medicare Drug Price Negotiation Program is scheduled to take effect tomorrow. The district court's eleventh-hour injunction, however, undermines those efforts. Manufacturers were planning to rely primarily on the pilot program to avoid giving duplicate discounts under both the 340B Program and the Negotiation Program. Absent relief, they will need to find alternatives in the next few hours. That sudden change risks disrupting the launch of a multibillion dollar federal program with the potential for direct adverse impacts on the prices seniors pay at pharmacies starting January 1. A stay is warranted to avoid those harms.

Plaintiffs' opposition offers no sound basis for denying a stay. Like the district court, plaintiffs fail to recognize that when HHS decides how to implement the 340B Program, it must balance the interests of two industries at loggerheads. Almost every time HHS acts in this area, either covered entities or manufacturers (and often both) can find grounds for complaint. And given the immense scale of the 340B Program, they usually can point to large sums of money at stake. But here, HHS acted cautiously and incrementally, authorizing rebates for drugs accounting for only 2% of 340B sales after thoroughly balancing competing interests. Plaintiffs' overstated view of their

compliance costs does not defeat the harms the government and the public would face from disruption to two significant federal programs.

As for the merits, HHS considered plaintiffs' potential compliance costs and reliance interests and nevertheless decided to proceed with the pilot program. HHS took many actions to minimize costs and burdens on covered entities. But HHS also exercised its policy judgment to conclude that testing rebates for ten drugs and aiding manufacturers in deduplicating discounts for those drugs was worth the tradeoffs. That decision lies within the agency's sound discretion.

It was only by rejecting the Britton Declaration that the district court was able to conclude that the agency failed to consider and weigh the relevant factors. Once it threw out the key explanatory document, the district court found the agency's explanation wanting. But the district court fundamentally misunderstood the APA's record-review rule, and plaintiffs' half-hearted defense of that analysis does nothing to salvage it.

ARGUMENT

I. The equities strongly favor a stay.

1. It is undisputed that prices for the first round of drugs covered by the Negotiation Program take effect tomorrow, that manufacturers have planned to

effectuate those prices, in part, by using rebates to provide 340B pricing, and that the preliminary injunction disrupts these plans. A stay is required to protect the rollout of the Negotiation Program from last-minute instability.

Plaintiffs contend that there is "no true urgency" to launching the rebate program on January 1, Opp.4, but they ignore that manufacturers have relied on their rebate plans and have little time to shift to other alternatives. Plaintiffs point out (Opp.19) that Novartis was not slated to begin offering rebates until April 1, but that fact does not establish a lack of irreparable harm that would arise from the other manufacturers being unable to participate in the pilot program beginning January 1. Those manufacturers planned to use rebates to effectuate negotiated prices, and the district court pulled the rug out from under them three days before the prices take effect. Plaintiffs also assert (Opp.19) that the injunction has no effect on the Negotiation Program, but manufacturers emphatically disagree, Motion to Intervene on Appeal 1-4. The injunction removes a significant tool—perhaps the most effective tool—to prevent discount duplication at a critical moment. This Court should act to restore it.

2. Plaintiffs' asserted compliance costs do not tip the balance of the equities in their favor.

Context is crucial to understand these costs. HHS is positioned between two regulated industries, which have divergent interests in how the 340B program is administered. *See* Add.26 (noting competing "hyperbolic positions" taken by manufacturers and covered entities on desirability and efficacy of rebate models). Whatever HHS does in this area, at least one side will be unhappy. And because the 340B program encompasses $81.4 billion in sales across more than 47,000 pharmaceutical products, Add.30, an industry dissatisfied with HHS's 340B decisions will usually be able to point to large numbers when asserting harms, *e.g.*, *Eli Lilly & Co. v. Kennedy*, No. 21-cv-2608, 2025 WL 1423630, at *3 (D.D.C. May 15, 2025) (manufacturers allege "billions of dollars of losses" from noncompliance and insufficient audit procedures). In this broader context, plaintiffs' allegations (Opp.20) that they will need to spend money to submit rebate claims cannot establish their entitlement to an injunction. Were such routine compliance costs sufficient, HHS would struggle to run the 340B Program because someone's ox will always be gored. But Congress explicitly empowered HHS to provide for rebates; it did not intend for each change in the 340B Program to result in a preliminary injunction.

More specifically, plaintiffs' allegations of harm are overstated. Start with compliance costs. HHS required covered entities to submit to the manufacturers only

the same kinds of information they already provide to contract pharmacies, Add.35-36, through the same platform many of them already use, Add.38. Submitting this data will take some time, as HHS has acknowledged, Add.42, but plaintiffs have not substantiated their assertion that submitting the same type of information to the same platform for the same dispenses would require the use of new full-time employees, *see* Opp.13; *see also, e.g.*, Dkt. 10-8, at 14.[1] Plaintiffs fare no better pointing (Opp.20 & n.10) to the costs of initially purchasing drugs at retail prices before receiving rebates from manufacturers because plaintiffs fail to acknowledge that rebates may often be paid before invoices for drugs purchased at wholesale are due, *see* Add.32-33. Plaintiffs' allegations of catastrophic costs do not withstand scrutiny. *Cf.* Add.20 (rejecting "[p]laintiffs' speculative concerns about delayed receipt and inappropriate denial of rebates").

Context illuminates another flaw in plaintiffs' argument: the pilot program affects *two* regulated industries. The district court wholly ignored manufacturers' costs,

[1] Plaintiffs note (Opp.13 n.5 (citing Dkt. 10-18, at 5; Supp.Add.25-26)) that covered entities may need to submit different claims data in two fields. But these data are "analogous to pharmacy claims data used to identify 340B eligible claims and would therefore not cause additional burden for covered entities to produce as part of their claims submission." Add.36

cf. Add.20-21, which alone is grounds to reverse its injunction, *see Caribbean Marine Servs. Co. v. Baldrige*, 844 F.2d 668, 677 (9th Cir. 1988). And plaintiffs argue (Opp.19) that those harms cannot be considered, ignoring well-established law that a court should deny "injunctive relief" where it "threatens to injure … other interested parties and the public," *Boston Parent Coal. for Acad. Excellence Corp. v. School Comm.*, 996 F.3d 37, 50 (1st Cir. 2021). The manufacturers, however, have presented a credible case that they will be harmed by the injunction. *See, e.g.*, Dkt. 45-1, at 5-6; *see also* Motion to Intervene on Appeal 22-28. At minimum, the manufacturers have devoted months of effort to launching their rebate schemes and will need to turn on a dime to effectuate the negotiated prices without use of 340B rebates. Any problems in making such a rapid shift would harm the government's paramount interest in "implement[ing] duly enacted laws." *District 4 Lodge of the Int'l Ass'n of Machinists v. Raimondo*, 18 F.4th 38, 49 (1st Cir. 2021).

Finally, it is of course true that covered entities play a vital role in providing healthcare to vulnerable and underserved communities. For that reason, HHS has long taken steps to protect their interests against disruptive changes to the 340B Program. *See Eli Lilly*, 2025 WL 1423630, at *11 (successfully opposing manufacturer efforts to unilaterally impose rebates); *Novartis Pharms. Corp. v. Johnson*, 102 F.4th 452, 464

(D.C. Cir. 2024) (unsuccessfully opposing manufacturer efforts to limit covered entities' use of contract pharmacies). It does not follow, however, that covered entities should be able to obtain relief from any unfavorable regulatory change just because they do important work. *Contra* Opp.20-21. Instead, to disrupt two programs with massive benefits for the public, they must demonstrate irreparable harm outweighing any countervailing harms, and they have not done so here.

II. The government is likely to prevail on the merits.

1. Plaintiffs primarily argue (Opp. 10-13) that HHS failed to consider compliance costs, but that is incorrect. HHS noted those concerns, took concrete steps to minimize compliance burdens by rejecting manufacturer requests for covered entities to provide additional data, and concluded that the compliance costs were worth bearing. Add.34-36. The APA requires nothing more.

Plaintiffs' key argument is that HHS is still evaluating the full magnitude of compliance costs. And HHS is in fact continuing to review the paperwork burden, Add.41-43, as Congress expressly contemplated, *see* 44 U.S.C. § 3507(j)(1).[2] The

[2] Plaintiffs' forfeiture argument (Opp.11) lacks merit. Plaintiffs raised their argument concerning HHS's continued review of compliance costs under the Paperwork Reduction Act for the first time in their district court reply brief, Dkt. 82 at 7, so the government could not rebut it in district court briefing. Moreover, at the

Continued on next page.

relevant question is whether HHS's predictive judgment as to compliance costs—made without "perfect empirical or statistical data"—is reasonable and reasonably justifies its policy choice to proceed with the pilot program notwithstanding these costs. *FCC v. Prometheus Radio Project*, 592 U.S. 414, 427 (2021). The answer is yes. HHS made a reasonable effort to estimate costs. And—contrary to plaintiffs' contention (Opp. 12)—it explained the benefits: "gathering information on the feasibility of rebates, helping to collect data for future rebate models consistent with the 340B statute and Administration priorities, improving transparency, addressing manufacturer concerns about 340B-[Negotiation Program] deduplication, and facilitating the prevention of 340B Medicaid duplicate discounts and diversion." Add.34. HHS is not required to quantify those benefits to conclude that they outweigh the compliance burdens.

Further, plaintiffs' reliance on *Ohio v. EPA*, 603 U.S. 279 (2024), is misplaced. That case found fault with an agency's response to comments during a notice-and-comment rulemaking. *Id.* at 287 (citing 42 U.S.C. § 7607(d)(3)). But here, HHS voluntarily sought comments, Add.27, considered them, Add.28-29. 36, and then acted in the context of an informal adjudication where there is no obligation to respond in

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preliminary injunction hearing, the government argued that HHS could make "predictive judgments" while undertaking a more thorough evaluation process. Tr. 42.

writing to comments, *see Pension Benefit Guar. Corp. v. LTV Corp.*, 496 U.S. 633, 654-55 (1990).

2. Plaintiffs also argue (Opp.13-15) that HHS failed to consider their reliance interests, but again the agency plainly did so. HHS expressly acknowledged that covered entities have relied on a discount model for 340B pricing for the past 30 years, Add.47, and noted that covered entities feared harms from the introduction of rebates, Add.26. Because HHS "recognized that a rebate model would be a significant shift from how the 340B program has been operating," it "limited the scope of the [p]ilot [p]rogram," Add.27, and took many steps to minimize disruption to covered entities, *see* Add.31-40. Had the agency not considered plaintiffs' reliance interests, there would be no reason to have taken these steps. Plaintiffs therefore cannot demonstrate that the agency failed to consider their concerns.

HHS also concluded, however, that this incremental pilot program was worth conducting to test rebate models and facilitate deduplication. Add.28, 34. Thus, HHS both demonstrated cognizance of the reliance interests and explained why it was departing from past practice; the APA does not require more. *See MediNatura, Inc. v. FDA*, 998 F.3d 931, 943 (D.C. Cir. 2021).

3. Plaintiffs at times argue (Opp. 16-17) that the district court could not consider the Britton Declaration, though at other times they argue (Opp.17-19) that the district court did in fact consider the declaration. Either way, their arguments are unavailing.

The district court was required to consider the Britton Declaration not merely to provide context but as the agency's explanation for why it approved the rebate plans. The APA imposes "minimal" procedural requirements on federal agencies. *Citizens Awareness Network, Inc. v. United States*, 391 F.3d 338, 349 (1st Cir. 2004). These requirements do not include producing a written explanation of informal adjudications, *Neighborhood Ass'n of the Back Bay, Inc. v. Federal Transit Admin.*, 463 F.3d 50, 60 n.4 (1st Cir. 2006), and courts cannot impose new procedures on an agency, *Citizens Awareness*, 391 F.3d at 349.

Thus, when it comes to informal adjudications, an agency often will not exhaustively document its decision-making process in a document that resembles a final notice-and-comment rule. And depending on the adjudicatory process, the written record may similarly not cover certain topics. But the absence of express discussion of some factors from an informal record does not mean the agency did not consider them. After all, an agency's internal deliberative documents do not form part of the administrative record. *Oceana, Inc. v. Ross*, 920 F.3d 855, 865 (D.C. Cir. 2019). So,

when approving an application, if an agency does not address the concerns of third parties directly with an applicant, the record may be silent as to those concerns. The proper response in such circumstances is to enable effective judicial review by allowing a decisionmaker to document the agency's thinking when it made the decision. *See Sierra Club v. Marsh*, 976 F.2d 763, 772 (1st Cir. 1992).[3]

Plaintiffs instead ask this Court to ignore the teaching of *Vermont Yankee* and to effectively impose on agencies an obligation to produce decision documents akin to final rules when they undertake informal adjudications or else be unable to defend their decisions in litigation. The APA does not require that result. *See Pension Benefit Guar. Corp.*, 496 U.S. at 654-55. And beyond their misunderstanding of *Overton Park*, plaintiffs offer no reason to doubt the veracity of the Britton Declaration. Simply repeating the phrase "post hoc" does not change the fact that the declaration is "explanatory of the decisionmakers' action at the time it occurred," *Sierra Club*,

[3] Plaintiffs imply (Opp.17) that in *DHS v. Regents of the University of California*, 591 U.S. 1 (2020), the Supreme Court silently overruled cases permitting reliance on agency declarations in circumstances like these. But *Regents* applied *Citizens to Preserve Overton Park, Inc. v. Volpe*, 401 U.S. 402, 419-20 (1971), which allowed that agency decisionmakers may need to explain their thinking after-the-fact to enable judicial review. In any event, there was not a change in rationale here like the Supreme Court identified as problematic in *Regents*. *See* 591 U.S. at 23.

976 F.2d at 772. Nor do plaintiffs gain any ground by pointing to lacunae in the partially assembled administrative record because, as explained, the type of adjudication conducted here will not produce a written record documenting the agency's consideration of all relevant factors.

Finally, if the district court had taken proper account of the Britton Declaration, it would have found thorough consideration of compliance costs and reliance interests. Plaintiffs contend that the declaration was "silent on the cost of floating the full price of covered drugs until 340B entities receive their rebate." Opp.18 (quoting Add.17). That is incorrect. *See* Add.31-33 (addressing these potential costs and explaining how agency sought to mitigate them). And, as discussed, the agency accounted for plaintiffs' reliance interests. *See* Add.27-28, 31-36; *see also* Add.47.

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HHS carefully considered a variety of competing perspectives to reach a sound policy judgment entrusted to it by Congress, and plaintiffs' dissatisfaction with the agency's policy judgment is not a basis for an injunction.

CONCLUSION

This Court should stay the injunction pending appeal.

Respectfully submitted,

YAAKOV M. ROTH
*Principal Deputy Assistant Attorney General**

MICHAEL S. RAAB

/s/ Maxwell A. Baldi
MAXWELL A. BALDI
Attorneys, Appellate Staff
Civil Division, Room 7513
U.S. Department of Justice
950 Pennsylvania Avenue NW
Washington, DC 20530
(202) 532-0211
maxwell.baldi@usdoj.gov

Of Counsel:

MICHAEL B. STUART
General Counsel

ELIZABETH C. KELLEY
Deputy General Counsel

U.S. Department of Health and Human Services

December 2025

* The Assistant Attorney General is recused in this matter.

CERTIFICATE OF COMPLIANCE

This brief complies with the type-volume limit of Federal Rule of Appellate Procedure 27(d)(2)(C) because it contains 2,586 words. 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 Word for Microsoft 365 in EB Garamond 14-point font, a proportionally spaced typeface.

/s/ Maxwell A. Baldi
MAXWELL A. BALDI