

IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF MAINE

THE AMERICAN HOSPITAL ASSOCIATION, *et al.*,

Plaintiffs,

v.

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

Defendants.

No. 2:25-cv-600-LEW

**MOTION FOR A STAY PENDING APPEAL OR, IN THE ALTERNATIVE,
AN ADMINISTRATIVE STAY OF PRELIMINARY INJUNCTION**

Defendants respectfully request a stay pending appeal of this Court's December 29, 2025 order, Doc. No. 90, which granted Plaintiffs' motion for a preliminary injunction. In the alternative, Defendants ask the Court for an administrative stay of the preliminary injunction to allow the First Circuit to rule on the government's forthcoming motion for a stay pending appeal in that Court.

Dated: December 29, 2025

Respectfully submitted,

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**MEMORANDUM IN SUPPORT OF MOTION FOR A STAY
PENDING APPEAL OR, IN THE ALTERNATIVE, AN ADMINISTRATIVE STAY OF
PRELIMINARY INJUNCTION**

Defendants respectfully request a stay pending appeal of this Court’s December 29, 2025 order, Doc. No. 90, which granted Plaintiffs’ motion for a preliminary injunction. In the alternative, Defendants ask the Court for an administrative stay of the preliminary injunction to allow the First Circuit to rule on the government’s forthcoming motion for a stay pending appeal in that Court. The Department of Health and Human Services (HHS) acted reasonably in approving its limited 340B Rebate Pilot Program (the “Pilot Program”). After considering covered entities’ reliance interests and compliance costs, HHS determined that those concerns were outweighed by the need to study the efficacy of 340B rebates and by the desirability of offering rebates as a method to deduplicate 340B and Medicare Drug Negotiation Program discounts. This Court erred in concluding otherwise by characterizing HHS’s declaration, which explained its contemporaneous thinking for these informal adjudications, as “largely . . . post-hoc rationalizations,” Doc. No. 90 at 10, and by demanding a higher level of specificity in the agency’s consideration of compliance costs than what courts have required. Those fundamental errors of administrative law fatally undermine its injunction.

The government respectfully requests a stay pending appeal or an immediate administrative stay in the alternative. To prevent disruption of industry preparation to implement a pair of significant

programs scheduled to take effect on January 1, the government respectfully requests a ruling on this motion as soon as possible so that the government may seek relief from the First Circuit if necessary. If the Court is inclined to deny the motion, the government respectfully requests that the Court do so without waiting for a response from Plaintiffs. The government plans to seek relief from the First Circuit by December 30, 2025 at 6:00 pm if the Court has not ruled by then. *See Boston Parent Coal. for Acad. Excellence Corp. v. School Comm.*, 996 F.3d 37, 44 (1st Cir. 2021). Plaintiffs oppose this motion.

“[T]he factors regulating the issuance of a stay are . . . (1) whether the stay applicant has made a strong showing that he is likely to succeed on the merits; (2) whether the applicant will be irreparably injured absent a stay; (3) whether issuance of the stay will substantially injure the other parties interested in the proceeding; and (4) where the public interest lies.” *Hilton v. Braunskill*, 481 U.S. 770, 776 (1987).

These factors weigh decisively in favor of a stay.

First, as explained in Defendants’ brief in opposition to Plaintiffs’ preliminary injunction motion and at argument, Defendants are likely to succeed on the merits. An agency’s decisions can be overturned only if they are “arbitrary, capricious, an abuse of discretion, or otherwise not in accordance with law.” 5 U.S.C. § 706(2)(A). Review under the “arbitrary and capricious” standard is “narrow,” and the ultimate question is whether the agency’s action was reasonable. *FCC v. Fox Television Stations, Inc.*, 556 U.S. 502, 513 (2009). Review should be particularly circumscribed here because the statute “exudes deference” to the Secretary’s determination as to whether to effectuate 340B prices via rebates or discounts, *see Webster*, 486 U.S. at 600, and the approvals are designed to test the rebate model on a small scale to minimize the costs and risks of such information gathering.

Here, the agency’s decisions to approve the manufacturers’ applications readily satisfy the arbitrary and capricious standard as applied by courts in the context of informal agency adjudications.¹

¹ *See, e.g., Royal Siam Corp. v. Chertoff*, 484 F.3d 139, 148 (1st Cir. 2007) (“In the absence of an error of law—and we see none here—this case comes down to straight abuse-of-discretion review. Under that standard, the outcome is foreordained.”); *Neustar, Inc. v. FCC*, 857 F.3d 886, 900 (D.C. Cir. 2017) (although Petitioner raised legitimate concerns that might have justified a different decision by the

As explained in the agency’s notice, the agency had previously received a significant amount of feedback from (and on behalf of) both manufacturers and covered entities regarding rebate models, and recognized that a rebate model “could fundamentally shift how the 340B Program has operated for over 30 years.” 90 Fed. Reg. at 36,164. Indeed, for the past several years, drug manufacturers have been aggressively pursuing the unilateral implementation of widespread 340B rebate models, and covered entities have argued just as hard in opposition to rebate models. Given these divergent positions, HHS felt it necessary to test rebates to better understand the merits and shortcomings of a rebate model from stakeholders’ perspectives, while minimizing disruptions to covered entities, and to inform the agency’s consideration of any future 340B rebate models consistent with the 340B statute and the Administration’s goals. *Id.* So it designed a thoughtful Pilot Program that was limited in scope to test “a fair and transparent 340B rebate model process for all stakeholders involved.” 90 Fed. Reg. at 36,164. Further, because one of the goals of the Pilot Program is to address manufacturer concerns regarding 340B and Maximum Fair Price deduplication, HHS chose to limit the scope of the Pilot to the ten drugs with negotiated Maximum Fair Prices set to take effect on January 1, 2026, which account for only 2% of 340B sales. After reviewing applications to participate in the Pilot Program submitted by manufacturers of those drugs, and considering comments received from stakeholders including covered entities, the agency carefully balanced the equities and then decided which specific aspects of each application to approve. Those decisions were reasonable.

1. In refusing to consider HHS’s explanation for approving the rebate applications, this Court erred. In an informal adjudication, “the APA does not specifically require the agency to explain its decision” or provide “a written explanation on the record.” *Neighborhood Ass’n of the Back Bay, Inc. v. Federal Transit Admin.*, 463 F.3d 50, 60 n.4 (1st Cir. 2006) (citing *Pension Benefit Guaranty Corp. v. LTV Corp.*, 496 U.S. 633, 655–56 (1990); *Camp v. Pitts*, 411 U.S. 138, 142 n. 3 (1973)). Rather, in such circumstances, “if the agency’s path may reasonably be discerned,” its decision should be sustained.

agency, the Court was “not to substitute [its] judgment for that of the [agency] Rather, the question [of whether the agency acted arbitrarily and capriciously] is more narrow”).

FCC v. Fox Television Stations, Inc., 556 U.S. 502, 513–14 (2009); *see also Diaz-Valdez v. Garland*, 122 F.4th 436, 443 (1st Cir. 2024). Here, the agency’s declaration explaining its contemporaneous decision-making satisfies that standard. *See* Decl. of Chantelle Britton, Doc. No. 75-1.

This Court abused its discretion in concluding otherwise. *See Koon v. United States*, 518 U.S. 81, 100 (1996) (“A district court by definition abuses its discretion when it makes an error of law.”). As the Supreme Court has explained, when an informal adjudication does not produce the sort of record that would permit “effective judicial review,” a court appropriately should “obtain from the agency, either through affidavits or testimony, such additional explanation of the reasons for the agency decision as may prove necessary.” *Camp*, 411 U.S. at 143; *see Citizens to Preserve Overton Park, Inc. v. Volpe*, 401 U.S. 402, 419–20 (1971). In these circumstances, “the administrative record may be supplemented, if necessary, by affidavits, depositions, or other proof of an explanatory nature,” so long as “the new material” is “explanatory of the decisionmakers’ action at the time it occurred,” rather than a “new rationalization[.]” *Sierra Club v. Marsh*, 976 F.2d 763, 772 (1st Cir. 1992) (cleaned up). Such “illuminat[ions]” of the reasons for agency action are routinely accepted by courts. *Olivares v. TSA*, 819 F.3d 454, 464 (D.C. Cir. 2016).

Here, the decision documents are operational documents that simply outline the terms of the approved rebate program. *See, e.g.*, Doc. No. 36-2 at 14–15. The approval letters do not indicate why HHS acted. *Cf.* Doc. No. 36-2 at 14–15. Instead, the agency has “provide[d] an adequate explanation for [its] action” in the form of a declaration, which is the “only way there can be effective judicial review.” *Overton Park*, 401 U.S. at 420. In other words, considering the agency’s declaration—which “provided the court with an explanation for the agency’s action submitted by the officer who had the authority to act on the application[s]”—was appropriate. *See Bagdonas v. Department of Treasury*, 93 F.3d 422, 426 (7th Cir. 1996). That type of explanation does not violate the *Chenery* principle or the record-review rule. Rather, a “court may properly uphold the [agency]’s decision on the basis of affidavits or testimony by the administrator who made the decision concerning his reasoning at the time of the

decision.” *Sierra Club*, 976 F.2d at 772 (quoting *Manhattan Tankers, Inc. v. Dole*, 787 F.2d 667, 672 n. 6 (D.C.Cir.1986)); *see also id.* at 772–73 (collecting cases). And that is exactly what HHS did.

This Court misunderstood the agency’s declaration as an improper post-hoc rationalization. *But see Sierra Club*, 976 F.2d at 774 (citing *Overton Park*, 401 U.S. at 420) (acknowledging that affidavits “containing post-hoc explanations” may be considered critically by courts). But this Court did not offer any reason to think that the Britton Declaration, offered by a key “official[] who participated in the decision,” *Overton Park*, 401 U.S. at 420, did anything other than what it purported to do: explain the agency’s contemporaneous thinking. Britton’s declaration “explained” how her office “took into consideration a variety of factors, including impacts on covered entities and concerns raised in comments, in making decisions on which specific aspects of the plans that it would approve.” Doc. No. 75-1 at 3. There is no basis to dismiss that explanation as a post-hoc litigation rationale.

This Court also faulted the Britton Declaration because it included “rationalizations absent from the administrative record,” Doc. No. 90 at 10. That conclusion was error. First, HHS still “is in the process of compiling the administrative record for this case,” Doc. No. 85-1 at 2, so the Court cannot know what it will eventually comprise. But more importantly, this is not a case “[w]hen an agency’s initial explanation indicates the determinative reason for the final action taken,” *DHS v. Regents of Univ. of Cal.*, 591 U.S. 1, 21 (2020) (cleaned up), and then the agency sought to “provide new ones.” Doc. No. 90 at 10 (quoting *Regents*, 591 U.S. at 21).

This point is even more pronounced in the context of a preliminary injunction. Plaintiffs filed suit on December 1, 2025, and HHS has not yet assembled the administrative record or prepared a certified index. *Cf.* Doc. No. 85 (only partial administrative record assembled). Plaintiffs pushed for immediate relief without waiting for the administrative record. In such circumstances, courts must consider the available evidence regardless of whether it would ultimately be admissible at trial. *See, e.g., Mullins v. City of New York*, 626 F.3d 47, 52 (2d Cir. 2010) (hearsay admissible at preliminary injunction stage). *Cf. University of Texas v. Camenisch*, 451 U.S. 390, 395 (1981) (the decision of whether to award

preliminary injunctive relief is often based on “procedures that are less formal and evidence that is less complete than in a trial on the merits.”). This Court’s understanding of the record-review rule does not comport with the ordinary practice of fully considering all available information before rendering a decision on a preliminary injunction.

2. This Court also erred in misunderstanding how HHS estimated and weighed compliance costs. HHS received and considered comments about the administrative costs plaintiffs would bear in participating in rebate pilots. It took steps to minimize any burden by rejecting manufacturers’ proposals that covered entities submit more specific and thus more burdensome information to claim rebates. It noted that “most covered entities already provide the type of claims data” to their contract pharmacies that “they will need to provide under the Pilot.” Doc. No. 75-1 ¶ 36. And it “considered the non-monetary costs associated with moving to a rebate model.” *Id.* ¶ 41. Ultimately, HHS made the determination that the benefits of running the Pilot Program outweighed these costs.

This Court faulted HHS for continuing to consider the compliance costs. Doc. No. 90 at 16–18. Specifically, the Court pointed to a notice HHS issued pursuant to the Paperwork Reduction Act to collect information about the burdens of submitting rebate claims and other associated administrative tasks. *See* Doc. No. 90 at 16. This Court reasoned that HHS could not have properly considered compliance burdens if it was still studying them. *Id.* That conclusion does not follow from its premise.

The Paperwork Reduction Act generally requires federal agencies to examine the burden on the public before it conducts or sponsors any collection of information. But the Act also provides for emergency approval of agency plans to collect information when normal review procedures are not practical. 44 U.S.C. § 3507(j)(1); *see* 5 C.F.R. § 1320.13. HHS availed itself of that option here, obtaining approval to launch the rebate program on January 1 while undertaking a more extensive study of compliance costs. To hold that HHS acted unlawfully by proceeding before that more

extensive study is complete, as this Court did, is inconsistent with Congress’s express acknowledgement that sometime agencies may proceed on two tracks when considering compliance costs. *See* 44 U.S.C. § 3507(j)(1).

Here, HHS did what agencies must often do: it made a predictive judgment based on the best information available to it. Making a decision without “perfect empirical or statistical data . . . is not unusual in day-to-day agency decisionmaking.” *FCC v. Prometheus Radio Project*, 592 U.S. 414, 427 (2021). Nor is that type of decision improper, *id.* at 427–28; to the contrary, agencies are entitled to increased deference when it comes to matters implicating predictive judgments. *See National Citizens Comm.*, 436 U.S. at 813–14. Accordingly, HHS considered how many hours would be required to collect information necessary to submit rebate claims. And it expressly concluded that “the benefits of the pilot . . . outweighed these costs.” Doc. No. 75-1 at 10.

Plaintiffs believe that they will need to spend more time to claim rebates, *e.g.*, Doc. No. 7 at 9, but they fail to explain this conclusory assertion, *see, e.g.*, Doc. No. 10-8 at 14. That failure is striking in light of the substantial overlap between the information required to obtain rebates and the information covered entities already submit to their contract pharmacies. *See* Doc. No. 75-1 at 10–11. Moreover, some of the bases plaintiffs assert for their inflated views of compliance costs did not materialize in the approved proposals. *Compare* Doc. No. 10-8 at 14 (raising concerns about different IT platforms, *with* Doc. No. 75-1 at 14 all manufacturers selected same IT platform). These underbaked objections fail to show that HHS took an “[ir]rational view of the record,” and thus the agency’s decision must be sustained. *Atieh v. Riordan*, 797 F.3d 135, 138 (1st Cir. 2015).

3. This Court erred as well in concluding that the “administrative record is also silent on the cost of floating the full price of covered drugs until 340B entities receive their rebate.” Doc. No. 90 at 17. But the Court only reached that conclusion by discounting the Britton Declaration. *See id.* Had this Court properly looked to the agency’s explanation, it would have found that HHS designed the rebate program to account for such concerns. *See* Doc. No. 75-1 at 7–9.

Second, Defendants will be irreparably harmed absent a stay, and the equities strongly favor a stay. “Any time a government is enjoined by a court from effectuating statutes enacted by representatives of its people, it suffers a form of irreparable injury.” *District 4 Lodge of the Int’l Ass’n of Machinists v. Raimondo*, 18 F.4th 38, 47 (1st Cir. 2021) (cleaned up). Here, Congress explicitly granted HHS authority to choose between rebates or discounts in administering the 340B program,² and this Court disabled the agency from making that choice and “improperly intrud[ed]” on the Executive Branch’s authority and ability to enforce the law, *Trump v. CASA, Inc.*, 606 U.S. 831, 859 (2025) (cleaned up). HHS is also injured by the inability to test manufacturers’ claims that the rebate model could reduce alleged fraud in the program.

In contrast, plaintiffs have shown no irreparable harms. Plaintiffs will obtain the same 340B discounts they are entitled to under the statute. They will receive rebates within 10 days of submitting claims, and they have not shown that such a minor delay will cause them significant harm, especially given the limited scope of the Pilot Program and the likelihood that for most purchases covered entities will receive rebates before any payment is due to the wholesaler. *See* Doc. No. 75-1 at 7. Nor can plaintiffs rely on compliance burdens to overcome the serious harms to the government and the public interest resulting from the injunction, especially when plaintiffs have not shown how submitting the same kinds of information they already provide to contract pharmacies, *id.* at 10–11, could possibly create a significant burden. And to the extent that plaintiffs speculate about harm resulting from manufacturers’ denial of rebate claims, they fail to recognize that HHS “severely limit[ed] the bases for the denial of claims.” *Id.* at 9; *see also Narragansett Indian Tribe v. Guilbert*, 934 F.2d 4, 6–7 (1st Cir. 1991) (“[S]peculative injury does not constitute a showing of irreparable harm.”).

In the alternative, Defendants are entitled to an administrative stay. An administrative stay “minimize[s] harm while an appellate court deliberates” whether to issue a stay pending appeal by

² *See* 42 U.S.C. § 256b(a)(1); *see also Eli Lilly & Co. v. Kennedy*, 2025 WL 1423630 (D.D.C. May 15, 2025), *appeal filed*, No. 25-5221 (D.C. Cir. June 13, 2025); *Johnson & Johnson Healthcare Sys. Inc. v. Kennedy*, 2025 WL 1783901 (D.D.C. June 27, 2025), *appeal filed*, No. 25-5236 (D.C. Cir. June 30, 2025).

preserving the status quo. *United States v. Texas*, 144 S. Ct. 797, 798 (2024) (Barrett, J., concurring). Here, the status quo was that manufacturers would begin offering rebates and using the rebate program to deduplicate Negotiation Program discounts starting January 1. *See, e.g., Oregon v. Trump*, 154 F.4th 1161, 1164 (9th Cir. 2025) (looking to situation before injunctive relief granted). Disrupting the status quo would seriously complicate the years-long progress towards the rollout of negotiated prices for Medicare drugs and force manufacturers to scramble to comply with their various pricing obligations. Immediate relief is necessary to avoid that result while the First Circuit considers the government's forthcoming stay motion.

Dated: December 29, 2025

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