

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

JOINT MOTION FOR VACATUR AND REMAND

The Parties, having conferred since the Court issued its Order Granting Motion for Preliminary Injunction (“PI Order”), ECF No. 90, jointly and respectfully move for the Court to order vacatur and remand of the agency actions challenged in this matter on the same bases underlying the PI Order.

In support of this joint motion, the parties state the following:

1. Plaintiffs filed their Complaint on December 1, 2025. Compl., ECF No. 1. They allege that “the 340B Rebate Model Pilot Program” announced by Defendants in August 2025 violates the Administrative Procedure Act (“APA”), and they ask this Court to declare the program unlawful, enjoin its implementation, and set it aside under § 706 of the APA. *Id.* ¶¶ 52-62, 130-75, Request for Relief. The Complaint asserted five claims that establishment and implementation of “the 340B Rebate Model Pilot Program” and approval of drug manufacturer applications to participate in that program were arbitrary and capricious, an abuse of discretion, or otherwise not in accordance with law. *Id.* ¶¶ 130-75.
2. Since the filing of the Complaint, the Parties briefed Plaintiffs’ motion for a temporary restraining order, ECF No. 3, which was converted into a motion for preliminary

injunction, *see* PI Order. The Court granted Plaintiffs' motion and enjoined Defendants "from implementing the nine individual applications that comprise the 340B Model Rebate Pilot Program pending further order." *Id.* at 24. Defendants sought a stay of that injunction, ECF No. 92, and the Court denied a stay. ECF No. 96. Defendants appealed the PI Order and subsequently sought a stay from the First Circuit, which denied the request. Order Denying Motion for Stay (First Circuit Order), Case No. 25-2236 (1st Cir.), Doc. No. 00118387963. Defendants have since dismissed their appeal. ECF Nos. 109, 110.

3. Defendants' response to the Complaint was due on February 3, 2026, and, on unopposed motion from Defendants, the Court extended that deadline by 30 days. ECF Nos. 112, 113.
4. The Parties have conferred about next steps in this litigation. After discussion, the Parties ask that the Court order vacatur and remand of the challenged administrative actions. Courts "commonly grant such motions, preferring to allow agencies to cure their own mistakes rather than wasting the courts' and the parties' resources reviewing a record that both sides acknowledge to be incorrect or incomplete." *Ethyl Corp. v. Browner*, 989 F.2d 522, 524 & n. 3 (D.C. Cir. 1993) (citing cases). The Parties agree that, in the circumstances of this case, judicial economy and the interests of the Parties would be best served by a vacatur and remand order rather than further litigation.
5. The Court's PI Order concluded that Plaintiffs' claims are justiciable and that Plaintiffs are likely to succeed on the merits of their claims. PI Order at 6-8, 9-19. Specifically, the Court identified two defects in the portion of the administrative record submitted at the preliminary injunction stage—(1) a failure to provide a reasonable explanation or address significant reliance interests and (2) a failure to consider relevant costs. *Id.* at 12-18. The Court reserved judgment on other potential defects raised by Plaintiffs. *Id.* at 18-19.

6. The First Circuit subsequently denied Defendants' request for a stay of the Court's preliminary injunction, crediting the Court's order as "a careful and thorough decision" that properly resolved the likelihood of success of Plaintiffs' claims. First Circuit Order at 1. The First Circuit, like this Court, concluded that "the preview of the administrative record" demonstrated defects in the agency's explanation and consideration. *Id.* at 3-6.
7. Since this Court and the First Circuit issued these orders, Defendants have considered the documents that would comprise the full administrative record in this matter. Defendants do not believe the full administrative record would change the outcome of this litigation at summary judgment. As a result, the Parties agree that further motions practice would not be fruitful, and instead, it would serve the best interests of judicial economy and the Parties to vacate the challenged actions with a remand to the Health Resources and Services Administration. *See, e.g., Bennett v. Murphy*, No. 14-cv-10275-FDS, 2016 WL 1449571, at *1 (D. Mass. Apr. 13, 2016) ("Voluntary remands are commonly granted because they allow agencies to correct their own mistakes without expending the resources of the court in reviewing a record that is admittedly incomplete or incorrect.").
8. The Parties agree that the vacatur and remand should cover the following agency actions:
 - a. The 340B Rebate Model Pilot Program Application Notice, 90 Fed. Reg. 36163 (Aug. 1, 2025);
 - b. The Corrected 340B Rebate Model Pilot Program Application Notice, 90 Fed. Reg. 38165 (Aug. 7, 2025);
 - c. The approvals of 340B rebate program applications from nine eligible drug manufacturers (Bristol Myers Squibb, Immunex Corp., Astra Zeneca AB, Pharmacyclics, Merck Sharp Dohme, Boehringer Ingelheim, Novo Nordisk Inc., Janssseen Biotech/Janssen Pharmaceuticals, and Novartis Pharmaceuticals Corp.) for ten covered drugs announced between October 30 and November 14, 2025.

9. The Parties have further discussed next steps for the agency following remand. The Parties agree that, if Defendants decide to begin a new 340B rebate program, Defendants will issue a new notice, including soliciting new applications. Furthermore, the Parties agree that Defendants will solicit comments either prior to or concurrently with a new notice, or both. Furthermore, Defendants agree to set any effective date for any new 340B rebate program to no earlier than 90 days following the public announcement of any approval of drug manufacturer applications—to avoid the prospect of any extremely expedited future litigation.

Based on the foregoing, the Parties jointly request that this Court vacate the agency actions listed in paragraph 8 and remand the matter to the agency.¹ The Parties further request that all subsequent deadlines in this case be vacated and the matter be closed.

Dated: February 5, 2026

Respectfully submitted,

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¹ It is the position of the Department of Justice that the APA does not authorize a court to vacate an agency action, and that if vacatur is an available remedy, then like all equitable remedies, such relief must be subject to traditional equitable limitations, including the principle of party-specific relief. The Department acknowledges, however, that there is substantial authority opposing this position in some circuits, though the Supreme Court has not ruled on the issue. In jointly requesting with Plaintiffs that the Court vacate the challenged agency actions, the Department agrees not to pursue this position in this specific case, but it reserves the right to continue to advance this position in other cases. Plaintiffs disagree with the Department's general position regarding courts' authority under the APA, *see, e.g.*, ECF No. 82 at 13-14, but agree that this dispute is irrelevant here given the Parties' joint request for vacatur of the challenged agency actions.

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