UNITED STATES DISTRICT COURT
DISTRICT OF NEW JERSEY

NOVO NORDISK INC. and NOVO NORDISK PHARMA, INC., Plaintiffs, v. UNITED STATES DEPARTMENT OF HEALTH AND HUMAN SERVICES, *et al.* Defendants.	Civil Action No. 21-00806 (FLW) **ORDER**

THIS MATTER having been opened to the Court by Plaintiffs Novo Nordisk Inc. ("Novo Nordisk") and Novo Nordisk Pharma, Inc. ("Novo Nordisk Pharma") (collectively, "Plaintiffs"), on a motion to expedite the Court's ruling on the dispositive motions[1] (*see* ECF No. 37) filed by Plaintiffs and Defendants, the United States Department of Health and Human Services ("HHS"); Alex M. Azar, II, in his capacity as Secretary of HHS, ("Secretary" or "Cochran"); Robert P. Charrow, in his capacity as General Counsel of HHS; the Health Resources and Services Administration ("HRSA"); and Thomas J. Engels, in his capacity as Administrator of HRSA (collectively, the "Defendants"), and for a temporary administrative stay ("Motion for a Temporary Administrative Stay"); it appearing that counsel for Defendants have opposed the motion; the Court having reviewed the parties' submissions, pursuant to Fed. R. Civ. P. 78, makes the following findings:

[1] The Court has advised the parties that it will expeditiously consider the dispositive motions.

1. This matter arises from a dispute related to the 340B drug discount program ("340B Program") established by the Public Health Service Act, 42 U.S.C. § 256b. As background, in 1992, Congress established the 340B Program, administered by the Secretary of HHS, through which certain "safety-net healthcare providers," serving low-income patients could receive drug discounts, including hospitals, community health centers, and other federally funded entities (collectively known as "covered entities").

2. In this case, Plaintiffs challenge two rules issued by HHS that have purportedly altered the 340B Program. The first challenged rule is Advisory Opinion 20-06, which according to Plaintiffs, requires it, and other drug manufacturers, to provide 340B-priced drugs to third-party contract pharmacies and prohibits any conditions on these sales. The second challenged rule is an Alternative Dispute Resolution Rule ("ADR Rule") providing for administrative adjudication of claims that drug manufacturers have overcharged covered entities or imposed conditions on 340B-priced drugs delivered to contract pharmacies.

3. Effective January 2021, Plaintiffs instituted an initiative "making clear that it will no longer indiscriminately accept covered entity requests that it transfer 340B-covered outpatient drugs to an unlimited number of third-party commercial contract pharmacies servicing hospital covered entities." (Compl., ¶ 56.) According to Defendants, the Advisory Opinion prohibits Plaintiffs' initiative.

4. On January 15, 2021, Plaintiffs filed their Complaint, which asserts four claims against Defendants, challenging Advisory Opinion 20-06 under the U.S. Constitution and the Administrative Procedure Act ("APA"). Specifically, the Complaint asserts the following causes of action: violation of the APA because the Advisory Opinion is contrary to law and in excess of statutory authority (Count I), violation of the APA based on HHS's failure to

observe the notice-and-comment procedure required by law with respect to the Advisory Opinion (Count II), violation of the APA because the Advisory Opinion is arbitrary and capricious (Count III), and violation of the APA based on the Advisory Opinion's conflict with the U.S. Constitution (Count IV). (Compl., ¶¶ 98-136.)

5. Thereafter, on April 19, 2021, the Court granted the parties' agreed upon briefing schedule for dispositive motions. (ECF No. 35.) Specifically, the April 19th Order provided, in part, that Defendants would move to dismiss Plaintiffs' Complaint for lack of subject-matter jurisdiction and failure to state a claim or, in the alternative, for summary judgment, and that Plaintiffs would oppose Defendants' motion to dismiss and cross-move for summary judgment. (*Id.*)

6. During the pendency of the parties' briefing, Plaintiffs received a letter ("May 17th Letter") from HRSA notifying them that HRSA had completed its review of Plaintiffs' initiative, specifically, their policy that allegedly places restrictions on 340B pricing to covered entities that dispense medications through pharmacies under contract, unless the covered entity lacks an in-house pharmacy. (*See* Exhibit A to Plaintiffs' Motion for an Administrative Stay.) According to HRSA, it has determined that "Novo Nordisk's actions have resulted in overcharges and are in direct violation of the 340B statute." (*Id.*) As a result, HRSA advised that, in its opinion:

> Novo Nordisk must immediately begin offering its covered outpatient drugs at the 340B ceiling price to covered entities through their contract pharmacy arrangements, regardless of whether they purchase through an in-house pharmacy. Novo Nordisk must comply with its 340B statutory obligations and the 340B Program's CMP final rule and credit or refund all covered entities for overcharges that have resulted from Novo Nordisk's policy. Novo Nordisk must work with all of its distribution/wholesale partners to ensure all impacted covered entities are contacted and efforts are made to pursue mutually agreed upon refund arrangements.

(*Id.*) However, the May 17th Letter simply directed, in light of HRSA's findings, that Plaintiffs "provide an update on its plan to restart selling, without restriction, 340B covered outpatient drugs at the 340B price to covered entities with contract pharmacy arrangements by June 1, 2021[.]" (*Id.*) According to HRSA, Plaintiffs' "[f]ailure to provide the 340B price to covered entities utilizing contract pharmacies, and the resultant charges to covered entities of more than the 340B ceiling price, may result in CMPs [civil monetary penalties] as described in the CMP final rule." (*Id.*) Specifically, the CMP final rule states that "any manufacturer with a PPA that knowingly and intentionally charges a covered entity more than the ceiling price for a covered outpatient drug may be subject to a CMP not to exceed $5,000 for each instance of overcharging." (*Id.*)

7. In response to the May 17th Letter, Plaintiffs filed the instant Motion for a Temporary Administrative Stay on May 21, 2021. (ECF No. 38.) Plaintiffs request that the Court enter a temporary administrative stay to preserve the Court's ability to decide the merits of this case. According to Plaintiffs, the May 17th Letter is an "egregious attempt to disrupt and interfere with ongoing judicial proceedings." (Plaintiffs' Motion for an Administrative Stay at 4.) Further, Plaintiffs submit that "the conclusion reached by Defendants in their May 17, 2021 letter — that Novo's decision not to transfer its discounted drugs to an unlimited number of commercial pharmacies is a violation of the 340B statute — is the central legal issued to be adjudicated by this Court." (*Id.*) Instead of waiting for the Court to resolve those questions, however, Plaintiffs argue that HRSA's May 17th Letter decides those questions and demands Plaintiffs' immediate compliance.

8. On May 24, 2021, the Court directed Defendants to file a response to Plaintiffs' Motion for an Administrative Stay by May 25, 2021, and similarly directed Plaintiffs to file a first

amended complaint to provide additional factual allegations related to Defendants' recent agency action taken against Plaintiffs, *i.e.*, the May 17th Letter, by May 25, 2021. (ECF No. 39.)

9. In accordance with the Court's instructions, Plaintiffs filed a First Amended Complaint and Defendants filed opposition to the instant Motion on May 25, 2021. (ECF Nos. 40 and 42.) Plaintiffs also filed their reply on May 26, 2021. (ECF No. 43.)

10. In opposition, Defendants argue that the Court should deny Plaintiffs' request for an administrative stay for several reasons. (*See* ECF No. 42, Defendant's Opp. Br. at 4.) Most notably, Defendants contend that Plaintiffs have not identified any statute, regulation, or Rule of Civil Procedure that would authorize this Court to grant an "administrative stay" in these circumstances, and further, that Plaintiffs have not demonstrated the necessary elements for a stay pursuant to 5 U.S.C. § 705. (*Id.* at 4-5.) Indeed, Defendants explain that the actions complained of by Plaintiffs in this instance are not appropriate for a stay because the May 17th Letter clearly states that June 1, 2021 is "simply a deadline for Novo to communicate to HRSA its plan to come back into compliance with its 340B obligations." (*Id.* at 5.) Moreover, Defendants emphasize with respect to CMPs that the letter takes no position on the time period for which such penalties may be imposed, if the agency decides to impose them at all. (*Id.*) Thus, it is Defendants' position that the Court's ability to decide the merits of this case is "in no way impeded by Novo communicating to the agency in response to the [May 17th Letter]." (*Id.*)

11. Courts have found that a stay under section 705 requires the movant to establish each of the four traditional preliminary-injunction factors. *See Colorado v. EPA*, 989 F.3d 874, 883 (10th Cir. 2021). In that regard, a party seeking an administrative stay like the one

here, must establish, by a clear showing: (1) a likelihood of success on the merits; (2) that it will suffer irreparable harm if the injunction is denied; (3) that granting preliminary relief will not result in even greater harm to the nonmoving party; and (4) that the public interest favors such relief. *Kos Pharms. Inc. v. Andrx Corp.*, 369 F.3d 700, 708 (3d Cir. 2004). All four factors must favor preliminary relief. *Lanin v. Tenafly*, 515 Fed. Appx. 114, 117 (3d Cir. 2013) (citing *Duraco Products, Inc. v. Joy Plastic Enterprises*, 40 F.3d 1431, 1438 (3d Cir. 1994). "A plaintiff's failure to establish any element in its favor renders a preliminary injunction inappropriate." *NutraSweet Co. v. Vit–Mar Enters., Inc.*, 176 F.3d 151, 153 (3d Cir. 1999).

12. Based upon the Court's review of the parties' submissions and the record in this case, the Court denies Plaintiffs' Motion for an Administrative Stay. The Court finds that Plaintiffs have failed to adequately address the four traditional preliminary-injunction factors necessary to grant an administrative stay under section 705. More specifically, Plaintiffs fail to demonstrate the existence of immediate and irreparable harm if a stay is not issued. In that regard, the May 17th Letter expressly and unambiguously requests that Plaintiffs merely "provide an update on its plan to restart selling, without restriction, 340B covered outpatient drugs at the 340B price to covered entities with contract pharmacy arrangements by June 1, 2021[.]" Indeed, consistent with the May 17th Letter, Defendants represent, in response to Plaintiffs' Motion, that HRSA has not even decided whether to impose CMPs, and that if HRSA did impose such penalties, "Novo would receive process before any sanctions were imposed" and those sanctions would be reviewable by a court. Thus, the Court finds that Plaintiffs will not suffer any substantial prejudice if a stay is not entered.

To be clear, if Defendants were to impose CMPs prior to the Court's resolution of this case, Plaintiffs would be permitted to renew the instant Motion for an Administrative Stay.

IT IS on this 1st day of June, 2021,

ORDERED that Plaintiffs' Motion for an Administrative Stay is hereby **DENIED**.

/s/ Freda L. Wolfson
Hon. Freda L. Wolfson
U.S. Chief District Judge