UNITED STATES DISTRICT COURT
DISTRICT OF NEW JERSEY

SANOFI-AVENTIS U.S., LLC,

Plaintiff,

v.

UNITED STATES DEPARTMENT OF HEALTH AND HUMAN SERVICES,

NORRIS COCHRAN, in his official capacity as Acting Secretary of Health and Human Services,

DANIEL J. BARRY, in his official capacity as Acting General Counsel of the United States Department of Health and Human Services,

HEALTH RESOURCES AND SERVICES ADMINISTRATION,

DIANA ESPOSITO, in her official capacity as Acting Administrator of the Health Resources and Services Administration,

Defendants.

Civil Action No. 21-634 (FLW)

ORDER

THIS MATTER having been opened to the Court by Plaintiff Sanofi-Aventis U.S., LLC ("Plaintiff"), on a motion to expedite the Court's ruling on the dispositive motions[1] (*see* ECF Nos. 62 and 68) filed by Plaintiff and Defendants, the United States Department of Health and Human Services ("HHS"); Acting Secretary of the HHS, Norris Cochran ("Secretary" or "Cochran"); Acting General Counsel of the HHS, Daniel J. Barry ("Barry"); the Health Resources and Services Administration ("HRSA"); and Acting Administrator of the HRSA, Diana Esposito ("Esposito") (collectively, the "Defendants"), and for a temporary administrative stay ("Motion for a Temporary Administrative Stay"); it appearing that counsel for Defendants have opposed the

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

motion; the Court having reviewed the parties' submissions, pursuant to Fed. R. Civ. P. 78, makes the following findings:

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, Plaintiff challenges two rules issued by HHS that have purportedly "radically" altered the 340B Program. The first challenged rule is Advisory Opinion 20-06, which according to Plaintiff, 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 October 1, 2020, Plaintiff instituted an "integrity initiative" to allegedly address unlawful waste and abuse in the 340B Program by requiring covered entities to submit minimal claims data when 340B-priced drugs are shipped to and dispensed by contract pharmacies (rather than by the covered entity itself). According to Defendants, the Advisory Opinion prohibits Plaintiff's integrity initiative.

4. On January 12, 2021, Plaintiff filed its Complaint, and on February 2, 2021, it filed a First Amended Complaint. (*See*, *e.g.*, ECF Nos. 1 and 17 ("FAC".) The FAC asserts nine claims

against Defendants, challenging the ADR Rule and Advisory Opinion 20-06 under the U.S. Constitution and the Administrative Procedure Act ("APA"). Specifically, the FAC asserts the following causes of action: violation of the APA based on the ADR Rule's violation of Article II of the U.S. Constitution (Count I), violation of the APA based on the ADR Rule's violation of Article III of the U.S. Constitution (Count II), violation of the APA because the ADR Rule is contrary to law and in excess of statutory authority (Count III), violation of the APA based on HHS's failure to observe the notice-and-comment procedure required by law in promulgating the ADR Rule (Count IV), violation of the APA because the ADR Rule is arbitrary and capricious (Count V), violation of the APA based on HHS's failure to observe the notice-and-comment procedure required by law in promulgating Advisory Opinion 20-06 (Count VI), violation of the APA based on HHS's failure to follow its "Good Guidance Rule" (Count VII), violation of the APA because Advisory Opinion 20-06 is contrary to law and in excess of statutory authority (Count VIII), and violation of the APA because Advisory Opinion 20-06 is arbitrary and capricious (Count IX). (FAC, ¶¶ 83-147.)

5. Thereafter, on February 2, 2021, Plaintiff moved for a preliminary injunction of the ADR Rule, arguing that it violates Articles II and III of the U.S. Constitution. (ECF No. 19.) Prior to the Court's decision on Plaintiff's motion for preliminary injunction, however, the parties jointly requested that the Court hold Plaintiff's motion in abeyance and that such motion be administratively terminated while the parties submit dispositive motions. On March 23, 2021, the Court granted the parties' request and entered the agreed upon briefing schedule for dispositive motions. (ECF No. 49.) Specifically, the March 23rd Order provided, in part, that Defendants would move to dismiss Plaintiff's FAC for lack of

subject-matter jurisdiction and failure to state a claim or, in the alternative, for summary judgment, and that Plaintiff would oppose Defendants' motion to dismiss and cross-move for summary judgment. (*Id.*)

6. During the pendency of the parties' briefing, Plaintiff received a letter ("May 17th Letter") from HRSA notifying it that it had completed its review of Plaintiff's integrity initiative, specifically, its policy that allegedly places restrictions on 340B Program pricing to covered entities that dispense medication through pharmacies, unless the covered entities provide claims data to a third-party platform. (*See* Exhibit A to Plaintiff's Motion for an Administrative Stay.) According to HRSA, it has determined that "Sanofi'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:

> Sanofi 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. Sanofi 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 Sanofi's policy. Sanofi 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 Plaintiff "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, Plaintiff's "[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, Plaintiff filed the instant Motion for a Temporary Administrative Stay on May 20, 2021. (ECF No. 72.) Plaintiff requests that the Court enter a temporary administrative stay to preserve the Court's ability to decide the merits of this case. According to Plaintiff, its pending motion for summary judgment asks the Court to decide, among other things: "(a) whether Section 340B requires drug manufacturers to provide 340B-priced drugs to contract pharmacies, and (b) whether Sanofi's data-collection initiative to promote integrity in the 340B program complies with the statute." (Plaintiff's Motion for an Admin. Stay, at ¶ 2) (citing ECF 68-1, at 23-33). Instead of waiting for the Court to resolve those questions, however, Plaintiff argues that HRSA's May 17th Letter decides those questions and demands Plaintiff's immediate compliance. (*Id.*)

8. On May 24, 2021, the Court directed Defendants to file a response to Plaintiff's Motion for an Administrative Stay by May 25, 2021, and similarly directed Plaintiff to file a second amended complaint to provide additional factual allegations related to Defendants' recent agency action taken against Plaintiff, *i.e.*, the May 17th Letter, by May 25, 2021. (ECF No. 77.)

9. In accordance with the Court's instructions, Plaintiff filed a Second Amended Complaint and Defendants filed opposition to the instant Motion on May 25, 2021. (ECF Nos. 78 and 79.) Plaintiff also filed its reply on May 26, 2021. (ECF No. 80.)

10. In opposition, Defendants argue that the Court should deny Plaintiff's request for an administrative stay for several reasons. (*See* Defendant's Opp. Br. at 5.) Most notably, Defendants contend that Plaintiff has 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 Plaintiff has not demonstrated the necessary elements for a stay pursuant to 5 U.S.C. § 705. (*Id.* at 5-6.) Indeed, Defendants explain that the actions complained of by Plaintiff 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 Sanofi to communicate to HRSA its plan to come back into compliance with its 340B obligations." (*Id.* at 6.) 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 Sanofi 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 Plaintiff's Motion for an Administrative Stay. The Court finds that Plaintiff has failed to adequately address the four traditional preliminary-injunction factors necessary to grant an administrative stay under section 705. More specifically, Plaintiff fails to demonstrate the existence of immediate and irreparable harm if a stay is not issued. In that regard, Plaintiff argues only that the May 17th Letter "command[s] that 'Sanofi must immediately begin offering its covered outpatient drugs at the 340B ceiling price to covered entities through their contract pharmacy arrangements,' order[s] that Sanofi must 'credit or refund all covered entities for overcharges that have resulted from Sanofi's policy,' and warn[s] that '[c]ontinued failure 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 [civil monetary penalties (CMPs)] as described in the CMP final rule.'" (internal quotations removed) (emphasis added.) The May 17th Letter, however, expressly and unambiguously requests that Plaintiff 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 Plaintiff's Motion, that HRSA has not even decided whether to impose CMPs, and that if HRSA did impose such penalties, "Sanofi would receive process before any sanctions were imposed" and those sanctions would be reviewable by a court. Thus, the Court finds that Plaintiff

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, Plaintiff would be permitted to renew the instant Motion for an Administrative Stay.

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

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

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