UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF NEW JERSEY

SANOFI-AVENTIS U.S., LLC, *Plaintiff,* *v.* UNITED STATES DEPARTMENT OF HEALTH AND HUMAN SERVICES, *et al.*, *Defendants.*	Civil Action No. 3:21-cv-634 Current Motion Day: June 21, 2021

PLAINTIFF'S NOTICE OF MOTION TO EXPEDITE AND FOR A TEMPORARY ADMINISTRATIVE STAY

PLEASE TAKE NOTICE that Plaintiff Sanofi-Aventis U.S., LLC ("Sanofi") respectfully moves to expedite the Court's consideration of this matter and for a temporary administrative stay. In particular, Sanofi requests that the Court set a date during the week of June 14, 2021, for a hearing on the parties' dispositive motions (ECF 62 and ECF 68) and expedite its ruling on the dispositive motions. In addition, Sanofi requests that the Court enter a temporary administrative stay to preserve the Court's ability to decide the merits of this case. Defendants do not oppose expedition but do oppose a temporary administrative stay.

In support of this Motion, Sanofi relies on the accompanying Memorandum. Sanofi also submits the accompanying Proposed Order.

Dated: May 20, 2021

Respectfully submitted,

s/ Jennifer L. Del Medico

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CERTIFICATE OF SERVICE

I hereby certify that on May 20, 2021, a copy of the foregoing was filed with the Clerk of the Court by using the CM/ECF system. I certify that all participants in this case are registered CM/ECF users and that service will be accomplished by the CM/ECF system.

May 20, 2021 *s/ Jennifer L. Del Medico*

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PLAINTIFF'S MOTION TO EXPEDITE AND FOR A TEMPORARY ADMINISTRATIVE STAY

Plaintiff Sanofi-Aventis U.S., LLC ("Sanofi") respectfully requests that the Court set a date during the week of June 14 for a hearing on the parties' dispositive motions (ECF 62 and ECF 68) and expedite its ruling on those motions in light of recent action taken by Defendants that seeks to interfere with the Court's resolution of this case. In addition, Sanofi requests that the Court enter a temporary administrative stay to preserve the Court's ability to decide the merits of this case. Defendants do not oppose expedition, but do oppose a temporary administrative stay, and asked Sanofi to include their position in this filing. *See infra* n.1.

1. In this case, Sanofi challenges two new rules issued by Defendant, the Department of Health & Human Services ("HHS"), radically altering the 340B drug program, under which Sanofi and other drug manufacturers must offer discounted prices to fifteen categories of "covered entities" enumerated in the statute. The first

new rule at issue is an Advisory Opinion requiring Sanofi and other drug manufacturers—on pain of crippling civil monetary penalties, among other sanctions—to provide 340B-priced drugs to third-party contract pharmacies (who are not mentioned in Section 340B of the Public Health Service Act, 42 U.S.C. § 256b) and prohibiting any conditions on these sales. The second new rule at issue 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.

Sanofi is directly affected by both of these rules. Effective October 1, 2020, Sanofi instituted an integrity initiative to 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). The Advisory Opinion purports to prohibit Sanofi's integrity initiative.

As the Court may recall, Sanofi initially moved for a preliminary injunction of the ADR Rule on the grounds that it violates Articles II and III of the Constitution. ECF 19. After another district court entered a preliminary injunction against the ADR Rule on manufacturer Eli Lilly's motion, the parties jointly asked this Court to hold Sanofi's motion for a preliminary injunction in abeyance—but Sanofi reserved the right to request that the Court rule on its motion for a preliminary injunction, should that prove necessary in light of developments with regard to any ADR

proceeding against Sanofi. ECF 46. The Court agreed to hold Sanofi's motion in abeyance and adopted the parties' proposed expedited schedule for briefing competing dispositive motions on Sanofi's claims. ECF 49. Under that stipulated schedule, the parties have filed their opening briefs, the reply briefs will be filed by June 14, and the Court will hold a hearing on the parties' motions on June 21 or the Court's soonest available date thereafter.

Notably, all this time, neither HHS nor the Health Resources and Services Administration (HRSA) (the agency within HHS that administers the 340B program) gave any indication that it might take enforcement or other action against Sanofi during the pendency of the parties' motions in this Court. But earlier this week, on Monday, May 17, Defendant HRSA surprisingly informed Sanofi by letter that—without waiting for the Court to resolve Sanofi's claims or for any ADR process—it had "completed its review of Sanofi's policy that places restrictions on 340B pricing to covered entities that dispense medication through pharmacies" and "determined that Sanofi's actions have resulted in overcharges and are in direct violation of the 340B statute." Exhibit A, at 1. HRSA commanded that "Sanofi must immediately begin offering its covered outpatient drugs at the 340B ceiling price to covered entities through their contract pharmacy arrangements," ordered that Sanofi must "credit or refund all covered entities for overcharges that have resulted from Sanofi's policy," and warned 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." *Id.* at 2. Those CMPs could be nearly $6,000 "for *each* instance of overcharging." *Id.* at 2 & n.3 (emphasis added). HRSA asked Sanofi to "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.*

2. Defendant HRSA's demand letter is an inappropriate attempt to usurp this Court's consideration of the merits of this case. Sanofi's pending motion for summary judgment asks this 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. ECF 68-1, at 23-33. Instead of waiting for the Court to resolve those questions under the orderly schedule already agreed to by the parties and approved by the Court, HRSA's demand letter makes clear that the agency has no patience to wait for this Court's ruling because HRSA has already decided those questions for itself—and demands that Sanofi comply now. HRSA thus puts Sanofi to a Hobson's choice: acquiesce in HRSA's unlawful interpretation of Section 340B by abandoning its integrity initiative or face crushing penalties. Remarkably, HRSA's letter does not even mention this action, even though HRSA is a party to this suit and is nearly done briefing the very issues raised by its letter.

In light of HRSA's surprising lack of respect for the judicial process, Sanofi respectfully asks the Court to expedite this case by scheduling a hearing date as soon as possible after the June 14 reply deadline on the parties' dispositive motions, and then expediting its ruling on those motions. *See, e.g.*, 28 U.S.C. § 1657(a) (authorizing courts to expedite civil actions "if good cause therefor is shown," *i.e.*, "if a right under the Constitution of the United States or a Federal Statute … would be maintained in a factual context that indicates that a request for expedited consideration has merit"); Fed. R. Civ. P. 57 ("The court may order a speedy hearing of a declaratory-judgment action."). There is ample good cause for this relief because HRSA's demand letter threatens new, devastating civil monetary penalties for Sanofi's continued efforts to ensure integrity in the 340B program, even as the validity of Sanofi's actions is already being litigated in this Court. Until this Court clarifies Sanofi's rights and obligations under Section 340B, Sanofi now faces enormous penalties for every day that it continues operating its integrity initiative. Because of HRSA's apparent eagerness to halt Sanofi's program before the Court has an opportunity to rule through the threat of draconian, potentially unconstitutional penalties—which will inflict untold reputational and financial harm for which Sanofi may never be able to recover if it prevails on the underlying merits questions—there is plainly good cause to expedite this action.

3. Sanofi additionally requests that the Court enter a temporary administrative stay of HRSA's arbitrary June 1 deadline to preserve the status quo, so the Court has

sufficient time to resolve the dispositive motions in an orderly manner before HRSA attempts to take preemptive enforcement action against Sanofi. *See, e.g.*, *Hope v. Warden York Cty. Prison*, 956 F.3d 156, 159 (3d Cir. 2020) (granting the government's motion for "a temporary administrative stay"); *Twelve John Does v. D.C.*, 841 F.2d 1133, 1137 (D.C. Cir. 1988) (granting the government's request for "a temporary administrative stay to permit time for full consideration of the motions"). A temporary administrative stay would not impose any burden on the government, which agreed to an expedited briefing schedule in this Court and has known about Sanofi's integrity initiative since last summer. Given HRSA's warning that it may impose civil monetary penalties any time after June 1, Sanofi also reserves the right to seek a preliminary injunction.[1]

[1] Defendants requested that Sanofi include their position in this motion as follows: "HRSA's May 17, 2021 letter is a new agency action. Sanofi has not amended its complaint to bring a claim challenging that new action, the parties have not briefed any claim related to the letter, and the resolution of Sanofi's pending claims will not determine the legality of HRSA's enforcement of the 340B statute against Sanofi. Defendants thus believe that, should Sanofi wish the Court to review HRSA's recent letter, it promptly should amend its complaint and the parties should file short supplemental briefs regarding any additional claims Sanofi presents. Defendants further request that, should the Court consider entering any stay of the new agency action, Defendants first be permitted to file a response." As Sanofi will explain in its forthcoming reply brief, a favorable ruling on the merits of Sanofi's pending claims *would* resolve the legality of HRSA's May 17, 2021 letter.

Dated: May 20, 2021

Respectfully submitted,

s/ Jennifer L. Del Medico

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Sanofi-Aventis U.S. LLC

EXHIBIT A

DEPARTMENT OF HEALTH & HUMAN SERVICES
Health Resources and Services Administration
Rockville, MD 20857

May 17, 2021

Mr. Gerald Gleeson
VP & Head, Sanofi US Market Access Shared Services
Sanofi
55 Corporate Drive
Bridgewater, NJ 08807

Dear Mr. Gleeson:

The Health Resources and Services Administration (HRSA) has completed its review of Sanofi's policy that places restrictions on 340B pricing to covered entities that dispense medication through pharmacies, unless the covered entities provide claims data to a third-party platform. After review of this policy and an analysis of the complaints HRSA has received from covered entities, HRSA has determined that Sanofi's actions have resulted in overcharges and are in direct violation of the 340B statute.

Section 340B(a)(1) of the Public Health Service (PHS) Act requires that manufacturers "shall…offer each covered entity covered outpatient drugs for purchase at or below the applicable ceiling price if such drug is made available to any other purchaser at any price." This requirement is not qualified, restricted, or dependent on how the covered entity chooses to distribute the covered outpatient drugs. Nothing in the 340B statute grants a manufacturer the right to place conditions on its fulfillment of its statutory obligation to offer 340B pricing on covered outpatient drugs purchased by covered entities. Furthermore, the 340B statute does not permit manufacturers to impose conditions on covered entities' access to 340B pricing, including the production of claims data. Section 340B(a)(1) of the PHS Act also requires manufacturers that have signed a Pharmaceutical Pricing Agreement (PPA) and PPA addendum to comply with these requirements. Sanofi is bound by the terms of the PPA and must ensure that the 340B ceiling price is available to all covered entities.

Also consistent with section 340B(a)(1) of the PHS Act, manufacturers are expected to provide the same opportunity for 340B covered entities and non-340B purchasers to purchase covered outpatient drugs. This extends to the manner in which 340B drugs are made available to covered entities (e.g., access to 340B ceiling prices through wholesalers that make products available at non-340B ceiling prices).[1] The 340B Program Ceiling Price and Civil Monetary Penalties Final Rule (CMP final rule)[2] further specifies that a manufacturer's failure to provide 340B ceiling prices through the manufacturer's distribution agreements with wholesalers may violate a manufacturer's obligation under the 340B statute. HRSA has made plain, consistently since the issuance of its 1996 contract pharmacy guidance, that the 340B statute requires manufacturers to honor such purchases regardless of the dispensing mechanism.

[1] 82 Fed. Reg. 1210, 1230 (Jan. 5, 2017); 42 C.F.R. §10.11(b)(2)
[2] 82 Fed. Reg. 1210, 1230 (Jan. 5, 2017)

Sanofi purports that the rationale for its restrictive action is to prevent diversion and duplicate discounts. The 340B statute provides a mechanism by which a manufacturer can address these concerns. Specifically, the manufacturer must (1) conduct an audit and (2) submit a claim through the Administrative Dispute Resolution process as described in section 340B(d)(3)(A) of the PHS Act. The 340B statute does not permit a manufacturer to impose industry-wide, universal restrictions.

For the reasons set forth above, 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.

Continued 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 CMPs as described in the CMP final rule. 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.[3] Assessed CMPs would be in addition to repayment for an instance of overcharging as required by section 340B(d)(1)(B)(ii) of the PHS Act. The Department of Health and Human Services will determine whether CMPs are warranted based on Sanofi's willingness to comply with its obligations under section 340B(a)(1) of the PHS Act.

HRSA requests that Sanofi 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**, to 340Bpricing@hrsa.gov.

Thank you for your commitment to the 340B Program.

Sincerely,

Diana Espinosa
Acting Administrator

[3] Note, the Department of Health and Human Services publishes inflation-adjusted increases for various CMPs annually. The 2020 inflation adjusted penalty for 340B overcharging violations is $5,883. 85 Fed. Reg. 2,869, 2,873 (Jan. 17, 2020).

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Defendants.

Civil Action No. 3:21-cv-634

[PROPOSED] ORDER

Upon consideration of Plaintiff Sanofi-Aventis U.S., LLC's Motion to Expedite and for a Temporary Administrative Stay, it is ORDERED that the Motion is GRANTED.

It is further ORDERED that the parties shall appear for a hearing on their dispositive motions (ECF 62 and ECF 68) at _____ on June ___, 2021.

It is further ORDERED that the June 1 deadline set forth in Defendant Health Resources and Services Administration's May 17, 2021 letter to Plaintiff Sanofi is hereby administratively stayed pending further order of the Court.

SO ORDERED.

Date: _____

_____
Hon. Freda L. Wolfson
United States District Judge