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 REPLY IN SUPPORT OF MOTION FOR A TEMPORARY ADMINISTRATIVE STAY

Just last week, in the midst of summary judgment briefing, Defendant HRSA commanded Sanofi to "immediately begin offering its covered outpatient drugs at the 340B ceiling price to covered entities through their contract pharmacy arrangements" or face crushing financial penalties as soon as June 1. HRSA Letter at 1. HRSA's letter attempts to interfere with this Court's consideration of the merits of this case by pressuring Sanofi to abandon its integrity initiative and acquiesce in HRSA's unlawful interpretation of Section 340B. In response to HRSA's lack of respect for the judicial process, Sanofi requests modest relief—a temporary administrative stay preserving the status quo until the Court can rule on the pending motions.

Stripped of its bombast, the government's response principally argues (1) that Sanofi was already on notice that it would face financial penalties for its integrity initiative, (2) that the June 1 deadline is immaterial, (3) that HRSA's recent letter is not

properly before the Court, and (4) that this Court purportedly lacks the authority to enter an administrative stay. None of these points supports denying Sanofi's motion.

First, the government's revisionist history that HRSA notified Sanofi last summer that it may impose sanctions for Sanofi's integrity initiative is false and misleading. The government cites HRSA's letters to drug manufacturers Eli Lilly and AstraZeneca, ADVOP_1098-99; ADVOP_1110-11, but HRSA never sent such a letter to Sanofi. Nor does the government acknowledge the significant differences between the manufacturers' various 340B initiatives—including that Sanofi, unlike some other manufacturers, will provide 340B-priced drugs to all contract pharmacies when covered entities provide the requested minimal claims data. The May 17 Letter is thus the first time HRSA has directly threatened Sanofi since the integrity initiative was announced in July 2020. Similarly, the HRSA statement cited by the government does not mention Sanofi—and, moreover, concedes that HRSA "has only limited ability to issue enforceable regulations" under Section 340B, so HRSA could do nothing more than "strongly encourage[] all manufacturers to sell 340B priced drugs to covered entities directly and through contract pharmacy arrangements." ADVOP_1597-98. HRSA's hortatory statement last summer is thus a far cry from the commands in the Advisory Opinion and May 17 Letter.

Second, the government's attempt to downplay HRSA's June 1 deadline after being called to account is telling. Despite HRSA's explicit threat of severe penalties after June 1, the government now says there is nothing to see here—June 1 is merely a

communication deadline, and HRSA has not decided whether sanctions are warranted. But if the June 1 deadline is as inconsequential as the government now claims—and as arbitrary as it appears to be—then HRSA will suffer no prejudice from a temporary administrative stay that extends the deadline and maintains the status quo that has persisted since Sanofi's integrity initiative took effect in October 2020. As the government concedes, "an administrative stay would not prevent the imposition of CMPs once the litigation concludes" if the government prevails on the merits, ECF 79 at 10, but a stay *would* protect Sanofi from crushing financial and reputational harms while the Court considers the merits of Sanofi's claims. And the consideration and imposition of any penalties on Sanofi would prove to be an unnecessary and unlawful waste of time if Sanofi prevails on the merits. The government's suggestion that Sanofi should temporarily pause its integrity initiative would perversely reward HRSA's interference with the judicial process and encourage more of the same in the future.

Third, now that Sanofi has amended its complaint to challenge HRSA's Letter, ECF 78, the government has no basis to complain that the Court lacks jurisdiction to review this final agency action. As explained in the Second Amended Complaint, HRSA's letter is substantively and procedurally unlawful for the same reasons that the Advisory Opinion is unlawful. ECF 78, ¶¶ 16, 166, 174, 182.

Finally, the government's argument that the Court lacks inherent authority to grant a temporary administrative stay—relief that the government itself routinely

seeks and obtains—is easily dismissed. The Court has inherent authority to grant such a short-term stay as a matter of judicial discretion, in order to maintain the status quo regarding a matter that is actively being litigated. *See, e.g.*, *Nat'l Urban League v. Ross*, 977 F.3d 698, 702 (9th Cir. 2020) ("When considering the request for an administrative stay, our touchstone is the need to preserve the status quo. We defer weighing the *Nken* factors until the motion for stay pending appeal is considered.") (citing *Doe #1 v. Trump*, 944 F.3d 1222, 1223 (9th Cir. 2019)); *In re Abbott*, 800 F. App'x 296 (5th Cir. 2020) (*per curiam*) ("Entering temporary administrative stays so that a panel may consider expedited briefing in emergency cases is a routine practice in our court … This routine action falls within the 'power inherent in every court to control the disposition of the causes on its docket with economy of time and effort for itself, for counsel, and for litigants.'") (quoting *Landis v. N. Am. Co.*, 299 U.S. 248, 254 (1936)); *Guedes v. ATF*, No. 19-5042, 2019 WL 1398194, at *1 (D.C. Cir. Mar. 23, 2019) (issuing sua sponte administrative stay "to give the Court sufficient opportunity to consider the disposition of this highly expedited appeal"); *FTC v. Beatrice Foods Co.*, 587 F.2d 1225 (D.C. Cir. 1978) (*per curiam*) (recognizing authority to issue "an administrative stay to preserve the status quo to permit the court to consider the matter more fully"). The government cites no authority for its self-serving suggestion that this inherent authority is somehow limited to appeals or inapplicable to agency litigants.

If the Court is not inclined to grant a temporary administrative stay, the Court should at least order the government's counsel to provide both the Court and Sanofi with at least 30 days' notice before HRSA takes *any* further action against Sanofi after June 1. The government could not possibly dispute that the Court has "inherent power" to "regulate the conduct of the members of the bar as well as to provide tools for docket management." *Eash v. Riggins Trucking Inc.*, 757 F.2d 557, 561 (3d Cir. 1985). Given the government's attempt to walk back HRSA's explicit threat of sanctions, this short window of time would provide breathing space to allow Sanofi the opportunity to seek emergency injunctive relief, if necessary, and the Court sufficient time to rule on that motion or the pending summary-judgment motions that will soon be fully briefed. *See, e.g., Trump v. Committee on Ways and Means*, 415 F. Supp. 3d 38, 50 (D.D.C. 2019) (ordering Committee to provide similar notice); *AstraZeneca Pharms. LP v. Burwell*, 197 F. Supp. 3d 53, 56-57 (D.D.C. 2016) (ordering FDA to provide notice before issuing decision on pending citizen petition). Such an order would impose no burden on HRSA, given the government's suggestion that sanctions are not imminent, but would allow this litigation to proceed to final judgment in an orderly and efficient manner—hopefully, with no more unnecessary disruptions caused by Defendant HRSA.

Dated: May 26, 2021

Respectfully submitted,

s/ Jennifer L. Del Medico

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