IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF NEW JERSEY

SANOFI-AVENTIS U.S. LLC, Plaintiff, v. U.S. DEPARTMENT OF HEALTH AND HUMAN SERVICES, *et al.*, Defendants.	Civil Action No. 3:21-CV-634

DEFENDANTS' OPPOSITION TO PLAINTIFF'S MOTION FOR ADMINISTRATIVE STAY

Plaintiff Sanofi-Aventis U.S., LLC ("Sanofi") has filed a purported emergency motion asking this Court to enjoin (under the guise of an "administrative stay") Sanofi's deadline to respond to a new agency action not yet challenged in Sanofi's complaint, not briefed by the parties, and thus not yet within the Court's jurisdiction. Despite Sanofi's claims of exigent circumstances, Sanofi does not identify any authority supporting the propriety of this Court granting an "administrative stay" of Sanofi's deadline to respond to the agency charged with enforcing the statute under which Sanofi is regulated (likely because no authority exists). Nor does Sanofi attempt to brief the requirements that would be necessary for the Court to enjoin agency action (even after new claims challenging that action are pending before the Court, *see* ECF No. 77 (ordering Sanofi to file second amended complaint)). Sanofi's request is procedurally improper, logically incoherent, and should be denied.

As explained in Defendants' Motion to Dismiss or for Summary Judgment ("Mot."), ECF No. 62-1 at 9-12, the present dispute arose in mid-2020 when Sanofi and several other large, global pharmaceutical manufacturers abruptly upended the twenty-five year operation of the 340B Program. Specifically, Sanofi and its peers announced that no longer will they offer (or offer without

manufacturer-imposed, extra-statutory restrictions) access to discounted drugs for safety-net healthcare providers (called "covered entities") and their patients when the patients fill their prescriptions at outside, neighborhood pharmacies. These actions have increased profits for the drug makers, while dramatically curtailing much-needed funding for safety-net providers and, in some cases, forcing patients to pay more for medications or adjust their medication regimen. *See* Br. Amici Curiae, Nat'l Ass'n of Comm. Health Ctrs. *et al.*, *AstraZeneca Pharmaceuticals LP v. Becerra*, No. 21-cv-27 (D. Del.), ECF No. 59 at 10-19 (presenting evidence, supported with numerous declarations, of severe consequences to providers and patients accruing from the manufacturers' actions).

Months before the Advisory Opinion challenged in this action was issued, Sanofi and its peers explicitly were put on notice that the Health Resources and Services Administration ("HRSA"), the component of the Department of Health and Human Services ("HHS") to which oversight and implementation of the 340B Program has been delegated, was "considering whether [manufacturers' new contract-pharmacy] polic[ies] constitute[] a violation of section 340B and whether sanctions apply," including, "but [] not limited to, civil monetary penalties." Letter from Adm. Pedley to D. Asay, Aug. 26, 2020, ADVOP_1098-99; *see also* ADVOP_1110-11; ADVOP_1597. HRSA further warned manufacturers that the new 340B policies "would undermine the entire 340B Program and the Congressional intent behind enactment of the 340B statute," ADVOP_1098-99, and that the newly imposed restrictions "could have the effect of severely limiting access for underserved and vulnerable populations" during a global pandemic. ADVOP_1110-11. Indeed, "[e]ven for those covered entities with in-house pharmacies," manufacturers' new policies "to limit contract pharmacy orders would have the effect of significantly limiting access to 340B discounted drugs for many underserved and vulnerable populations who may reside in geographically isolated areas and rely on a contract pharmacy to obtain their prescriptions." *Id.* Unfazed, Sanofi and its cohort proceeded to implement their new contract-pharmacy restrictions.

HRSA's review of Sanofi's policy culminated in a new agency action, in the form of a 340B-violation letter issued May 17, 2021. *See* Letter from D. Espinosa to G. Gleeson, ECF No. 72-2. In that letter, HRSA's acting administrator informed Sanofi that the agency "has determined that Sanofi's actions have resulted in overcharges and are in direct violation of the 340B statute." *Id.* 1. The letter relies exclusively on statutory text to determine that the requirement that Sanofi honor covered entities' purchases "is not qualified, restricted, or dependent on how the covered entity chooses to distribute the covered outpatient drugs" to its patients, and that "[n]othing 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." *Id.* HRSA directs Sanofi to "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," and confirms that civil monetary penalties (CMPs) may be imposed. *Id.* 2. Although the letter instructs Sanofi to "provide an update on its plan to restart selling, without restriction, 340B covered outpatient drugs at the 340B price" by June 1, 2021, that date is *not* tied to the potential imposition of CMPs. *Id.* On the contrary, although "[c]ontinued failure to provide the 340B price to covered entities utilizing contract pharmacies … may result in CMPs," HHS "will determine whether CMPs are warranted *based on Sanofi's willingness to comply with its obligations* under section 340B(a)(1)." *Id.* The letter thus makes clear that HHS has not made any determination as to whether sanctions are warranted at all but, should Sanofi continue to flout its 340B obligations, any such sanctions will not necessarily be limited to violations that occur after June 1.

HRSA's 340B-violation letter is a new agency action that must be challenged and considered independently from previous agency decisions. Sanofi's currently operative complaint challenges legal advice from HHS's Office of General Counsel, which opined generally (and consistently with previous agency guidances) on what the 340B statute requires. That advice did not purport to analyze the legality

of Sanofi's newly imposed restrictions; indeed, it did not itself impose any obligation on manufacturers and thus does not even constitute reviewable final agency action. Mot. 16-19. By contrast, the violation letter embodies a determination by a different entity altogether—HRSA, the component charged with enforcing Congress's mandate—that Sanofi's specific policy is unlawful and may result in sanctions. In its motion Sanofi completely ignores the fact (raised by undersigned counsel in email, *see* Stay Mot. 6 n. 1) that, should Sanofi wish to challenge the agency's determination, it must amend its complaint to set forth the legal theories on which it challenges HRSA's violation letter. This Court agreed and ordered Sanofi to amend its complaint. *See* ECF No. 77. Sanofi cannot shoehorn review of this new agency action into its existing claims and argument challenging the Advisory Opinion; nor can it contend that review of the May 17th letter is somehow encompassed in its challenge to that previous decision.

Moreover, even were this Court to agree with Sanofi that the Advisory Opinion is reviewable *and* that it should be set aside, that would not resolve any challenge to HRSA's letter or its determination that Sanofi is overcharging covered entities. HRSA has made the specific determination that Sanofi is violating the 340B statute—something not encompassed within the General Counsel's advice. Stated plainly, HRSA's violation letter does not rest on the Advisory Opinion, and HRSA's actions to enforce the 340B statute would not be impeded by vacatur of the legal advice. Indeed, the relief sought by Sanofi in its amended complaint would have no bearing on the agency's enforcement efforts. Sanofi asks this Court to declare that the statute "does not require drug manufacturers to provide discounted covered outpatient drugs to contract pharmacies" and "does not prohibit drug manufacturers from imposing conditions on the provision of … drugs to contract pharmacies." ECF No. 17, Am. Compl., Prayer for Relief 4, 5. As explained in HHS's opening brief, the agency agrees that the statute does not allow contract pharmacies to purchase 340B-discounted drugs or otherwise participate in the program. *See* HHS Mot. to Dismiss or for Summ. J. ("HHS Mot."), ECF No. 62-1,

at 14-15 (explaining that Sanofi relies on artful drafting to misportray the General Counsel's conclusion). The actual dispute between the parties—whether Sanofi's newly imposed restrictions violate the 340B statute's prohibition on overcharging covered entities—is squarely presented in the 340B violation letter, demonstrating why the ultimate dispute must be decided on the basis of new claims challenging HRSA's letter and argumentation on its merits.

This Court should deny Sanofi's request for emergency relief on this new action for several reasons.

First, Sanofi has not identified any statute, regulation, or Rule of Civil Procedure that would authorize this Court to grant an "administrative stay" in these circumstances. Sanofi has not pointed to 5 U.S.C. § 705, and for good reason, since that provision only allows a court "to the extent necessary to prevent irreparable injury" to "issue all necessary and appropriate process to postpone the effective date of an agency action or to preserve status or rights pending conclusion of the review proceedings." A stay under § 705 also 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) (collecting authority). Sanofi does not seek to postpone the *effective* date of agency action (HRSA's letter already is in effect), it has not argued that it is irreparably harmed by HRSA's letter, nor has it attempted to meet the other injunction factors. Sanofi points to no other statutory or regulatory source to support its request for "an administrative stay," but instead relies entirely on two wholly inapposite opinions. *See* Sanofi Mot. 6 (citing *Hope v. Warden York Cty. Prison*, 956 F.3d 156, 159 (3d Cir. 2020) and *Twelve John Does v. D.C.*, 841 F.2d 1133, 1137 (D.C. Cir. 1988)). But in both of those cases, circuit courts of appeal granted temporary administrative stays, on the request of the federal government, of lower courts' mandatory injunctions in order to preserve the status quo while considering the government's emergency appeal. Although "it has always been held … that as part of its traditional equipment for the administration of justice, a federal court can stay the enforcement of a judgment *pending the outcome of an appeal*," *Nken*

v. Holder, 556 U.S. 418, 421 (2009) (citation omitted and emphasis added), that does not support Sanofi's position that this Court has inherent authority to issue an "administrative stay" of *an agency's* ongoing enforcement of a statute it administers.

Moreover, the action Sanofi seeks to forestall is not even appropriate for such a stay. The violation letter makes plain that the June 1 date is simply a deadline for Sanofi to communicate to HRSA its plan to come back into compliance with its 340B obligations. ECF No. 72-2 at 2. Although Sanofi casts its request as seeking postponement of that deadline "to preserve the Court's ability to decide the merits of this case" because "recent action taken by Defendants [] seeks to interfere with the Court's resolution of this case," Stay Mot. 1, those assertions defy reality. This 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 violation letter. Indeed, even were Sanofi to suspend operation of its contract-pharmacy restrictions while the matter is being litigated (as it should) that would neither "interfere with the Court's resolution," *id.*, particularly now that the merits of Sanofi's policy will be before the Court, nor would it prevent Sanofi from re-imposing its restrictions in the unlikely event that the Court finds HRSA's letter to be unlawfully issued. Furthermore, any subsequent decision by the agency to impose CMPs if Sanofi remains noncompliant are not tied to post-June 1 purchases—the letter takes no position on the time period for which CMPs may be imposed, if the agency decides to impose them. Defendants are unaware of, and Sanofi certainly has not provided, *any* authority suggesting this Court can issue an administrative stay of a deadline for a regulated entity to communicate with an agency regarding its statutory compliance, which is all the June 1 deadline entails.

Second, Sanofi essentially asks for equitable relief without endeavoring even to address the factors that would be necessary to support such a request. Sanofi claims that HRSA's violation letter "is an inappropriate attempt to usurp this Court's consideration of the merits of this case," Stay Mot. 4 (a baseless claim, given that Congress entrusted HHS with enforcement of the 340B statute and the

agency had not previously determined Sanofi to be non-compliant, the first step in an enforcement action), but Sanofi's motion contains *not a word* addressing the likelihood of success on the merits of a challenge to HRSA's violation letter. Then again, given that Sanofi has not yet presented claims challenging the letter, it would be difficult for either party at this time to brief the merits. Similarly, Sanofi speculates that HRSA's "threat of draconian, potentially unconstitutional penalties" will cause "untold reputational and financial harm for which Sanofi may never be able to recover," Stay Mot. 5, yet nowhere does Sanofi brief the irreparable-harm or balance-of-equities factors that would justify emergency relief. (Any claim of irreparable harm would be meritless at this point, given that the agency has not decided to impose CMPs, Sanofi would receive process before any sanctions were imposed, 42 C.F.R. § 10.11(a) (citing 42 C.F.R. Part 1003), any sanctions would be reviewable by a court, and the purported "crushing penalties," Stay Mot. 4, Sanofi faces stem entirely from its unilateral decision to alter the status quo and cut off access to discounted drugs for needy patients and providers. In light of Sanofi's insistence on imposing its so-called "integrity initiative," in contravention of decades of past practice and defiance of the agency's warning, it is plain that any harm accruing to Sanofi is self-inflicted.) Equitable relief "is an extraordinary remedy never awarded as of right," and the movant bears a heavy burden. *Winter v. Nat. Res. Def. Council*, 555 U.S. 7, 24 (2008). Sanofi cannot obtain equitable relief without establishing its entitlement. Nor can it evade that requirement by styling its request as a "stay" motion. *Coleman v. Paccar, Inc.*, 424 U.S. 1301, 1305 (1976) (Rehnquist, J., in chambers) ("A court in staying the action of … an administrative agency, must take into account factors such as irreparable harm and probability of success"); *Mexichem Specialty Resins, Inc. v. EPA*, 787 F.3d 544, 557 (D.C. Cir. 2015) (denying request for stay of agency action due to failure to demonstrate irreparable harm); *Wisc. Gas Co. v. FERC*, 758 F.2d 669 (D.C. Cir. 1985) (holding that petitions to stay effectiveness of agency orders were "abuse of judicial process" and waste of "time and resources of th[e] court" due to absence of irreparable harm sufficient to warrant a stay); *In re ANR Pipeline Co.*,

1997 WL 362757, at *1 (D.C. Cir. May 21, 1997) (confirming that "extraordinary writ staying an agency order" requires showing likelihood of success and irreparable harm).

Third, Sanofi's suggestion that its procedurally improper motion was somehow contemplated in the stipulated schedule is inaccurate. Sanofi falsely claims that, after another district court enjoined an entirely different final rule (the ADR Rule) against a different plaintiff, "the parties jointly asked this Court to hold Sanofi's motion for a preliminary injunction in abeyance." Stay Mot. 2. On the contrary, undersigned counsel repeatedly declined to join Sanofi in asking this Court to hold Sanofi's prior emergency motion in abeyance, explaining that (1) the preliminary injunction entered by a different court had no bearing on agency action that might be taken against Sanofi, and (2) the agency would not suspend any agency action against Sanofi on the basis of that injunction. Those discussions resulted in the parties making clear in their joint stipulation that: "*Sanofi requests that, in light of the parties' agreement to brief the merits of Sanofi's claims in an expedited fashion and the Eli Lilly decision,* the Court hold in abeyance its motion for a preliminary injunction pending notification from Sanofi that a ruling on that motion is necessary." ECF No. 46 at 2. No ADR proceedings have advanced against Sanofi to date. And Sanofi's unilateral contemplation of reviving its preliminary-injunction motion had those proceedings advanced does not grant Sanofi ground to ask this Court to forestall a new agency action without the benefit of briefing or an amended complaint. Given the agency's clear statements that it was considering the lawfulness of Sanofi's policy—not to mention the fact that Sanofi never sought injunctive relief on the Advisory Opinion, and that challenging an agency's interpretation does not, absent injunctive relief, entitle a plaintiff to forestall further agency action—Sanofi's claimed surprise at receiving the violation letter is baseless.

Fourth, Sanofi's contention that an administrative stay is warranted "to preserve the status quo," Stay Mot. 5, strains credulity. The status quo was toppled less than a year ago when Sanofi and its peers "radically alter[ed] the 340B drug program," Stay Mot. 1, by upending the twenty-five-year,

settled operation of the 340B Program and began denying purchases by covered entities using contract pharmacies. And the June 1 deadline is simply an instruction for Sanofi to communicate to HRSA *its plan* to resume making sales to covered entities regardless of dispensing mechanism; communicating to the agency certainly won't upset any "status quo." (Indeed, as noted above, even were Sanofi to hedge its bets by suspending its restrictions, nothing would prevent it from reversing course in the unlikely event it prevails.) Finally, this calculus is not changed by Sanofi's portrayal of HRSA's letter as "attempts to take preemptive enforcement action against Sanofi." *Id.* 6. There is nothing preemptive about HRSA's actions; the violation letter is the first step in an *enforcement action*. Nor is there anything improper, as Sanofi charges, in HRSA having "decided … for itself" whether Sanofi is violating the statute. Stay Mot. 4. HRSA is tasked with enforcing the statute, and it is the role of this Court to review that determination (when properly presented), not to determine, in the first instance and before the regulator, whether conduct constitutes a violation. In other words, this sequence of events represents the proper functioning of administrative law, not "an inappropriate attempt to usurp this Court's consideration of the merits." *Id.* Sanofi's complaint that HRSA "gave [no] indication that it might take enforcement or other action against Sanofi during the pendency of the parties' motions," *Id.* 3, is factually inaccurate and legally groundless, since the agency is under no obligation to have the Court pre-approve its enforcement actions, as opposed to reviewing those efforts when properly challenged. (This is *particularly* true here, where the Advisory Opinion did not determine the merits of Sanofi's policy and is not final agency action, so Sanofi's complaint itself presented an improper attempt to preempt agency enforcement).[1]

[1] In its stay motion Sanofi asserts that it "reserves the right to seek a preliminary injunction." Stay Mot. 6. Any attempt to file yet another emergency motion should not be countenanced; Sanofi made the decision to seek an "administrative stay" without amending its complaint and without attempting to brief the requirements that would be necessary to enjoin agency action, notwithstanding HHS's position that Sanofi's motion was improper. Sanofi should not receive another bite at the apple.

Fifth, Sanofi's assertion that 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," Stay Mot. 6, is specious. It is Sanofi that has known since last summer that HRSA actively was investigating whether Sanofi's policy was unlawful and whether sanctions would apply, ADVOP_1597, yet Sanofi proceeded with its restrictions. The fact that *Sanofi* tried to preempt HRSA's administrative process by filing suit to challenge the Advisory Opinion issued by a different HHS component, reiterating the agency's consistent statutory interpretation, does not now allow Sanofi to leapfrog the procedural hurdle of actually challenging and briefing the merits of the agency action it wants this Court to "stay."

Sixth, far from "preserv[ing] the Court's ability to decide the merits of this case" (an assertion Sanofi makes no attempt to explain or support), *id.* 1, a stay of the June 1 deadline would have *no practical impact* on Sanofi's vulnerability to "civil monetary penalties," *id.* 5. As noted above, the agency has not determined whether CMPs are warranted, process would be due before penalties were imposed, and Sanofi could seek judicial review of such a determination. Thus, while the violation letter makes plain that continued intransigence by Sanofi will lead to the imposition of sanctions, that determination will not be made on June 1 and will not necessarily be limited to post-June 1 conduct (but will instead be determined based on Sanofi's entire course of conduct). Defendants respectfully contend that they fully expect to prevail on the statutory-interpretation question, *i.e.*, whether manufacturer-imposed restrictions on covered entities' access to 340B discounts violates the statute. If the government prevails on the merits, an administrative stay would not prevent the imposition of CMPs once the litigation concludes, including for the time period during which the June 1 deadline was "stayed." Correspondingly, in the unlikely event Sanofi prevails, no CMPs would be imposed with or without the stay. At bottom, a temporary stay of HRSA's violation letter would be meaningless in practice, since HRSA's "threat[] [of] devastating civil monetary penalties," *id.* 5, will remain. Relatedly,

Sanofi cannot credibly claim that it would face any irreparable harm should it proceed prudently and "abandon[] its integrity initiative," *id.* 4, while this litigation proceeds. Sanofi can always re-impose its contract-pharmacy restrictions should it prevail. But it cannot articulate any irreparable harm that would result from suspending its non-statutory restrictions temporarily and thus removing the threat of further CMPs if its interpretation proves erroneous. Indeed, Sanofi had complied with its statutory obligation to sell discounted drugs to covered entities regardless of dispensing mechanism for more than a decade before it abruptly changed course mid-2020.

In conclusion, Defendants respectfully suggest that this Court lacks authority to administratively stay HRSA's instruction for Sanofi to submit a proposal to come back into statutory compliance, and that, even if there were a statutory or procedural basis for such a stay, Sanofi would not be entitled to any relief due to its failure to brief the factors that would be necessary to support it. Moreover, the legality of HRSA's violation letter could not be resolved through the current briefing or through the declarations sought in Sanofi's current complaint. This Court should deny the administrative stay and allow the parties to submit short supplemental briefs, before the July 6, 2021 date on which briefing closes in *Novo Nordisk v. HHS*, No. 3:21-cv-806, addressing the new claims Sanofi has added to its complaint related to the violation letter.

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Respectfully submitted,

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