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

NOVO NORDISK INC., *et al.*, Plaintiffs, v. UNITED STATES DEPARTMENT OF HEALTH AND HUMAN SERVICES, *et al.*, Defendants.	Civil Action No. 3:21-cv-806-FLW-LHG

DEFENDANTS' OPPOSITION TO PLAINTIFFS' MOTION FOR A TEMPORARY ADMINISTRATIVE STAY

Plaintiffs Novo Nordisk Inc. and Novo Nordisk Pharma, Inc. (collectively "Novo") have filed a purported emergency motion asking this Court to enjoin (under the guise of an "administrative stay") Novo's deadline to respond to a new agency action not previously challenged in this case. Despite its claims of exigent circumstances, Novo does not identify any authority supporting the propriety of this Court granting an "administrative stay" of Novo's deadline to respond to the agency charged with enforcing the statute under which Novo is regulated (likely because no authority exists). Nor does Novo attempt to brief the requirements that would be necessary for the Court to enjoin agency action. Novo's request is procedurally improper, logically incoherent, and should be denied.

As explained in Defendants' Motion to Dismiss or, in the Alternative, for Summary Judgment ("Defs.' Mot."), ECF No. 37-1 at 7–10, the present dispute arose in mid-2020 when Novo and several other large, global pharmaceutical manufacturers abruptly upended the twenty-five year operation of the 340B Program. Specifically, Novo 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, Novo 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 "investigating whether … manufacturer[s'] [new contract-pharmacy] policies … violate[] the 340B statute and whether sanctions may apply," including, but not limited to, civil monetary penalties. ADVOP_1597; *see also* ADVOP_1098-99; ADVOP_1110-11. 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, Novo and its cohort proceeded to implement their new contract-pharmacy restrictions.

HRSA's review of Novo'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. 38-2. In that letter, HRSA's acting administrator informed Novo that the agency "has determined that Novo Nordisk's actions have resulted in overcharges and are in direct violation of the 340B statute." *Id.* at

1. The letter relies exclusively on statutory text to determine that the requirement that Novo 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 Novo 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.* at 2. Although the letter instructs Novo to "provide an update on its plan to restart selling, without restriction, 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 Novo Nordisk'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 Novo 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 considered independently from previous agency decisions. Novo's original 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 Novo's newly imposed restrictions; indeed, it did not itself impose any obligation on manufacturers and thus does not even constitute reviewable final agency action. By contrast, the violation letter embodies a determination by a different entity altogether—HRSA, the component charged with enforcing Congress's mandate—that Novo's specific policy is unlawful and may result in sanctions. In its

motion, Novo completely ignores the fact (raised by undersigned counsel in email, *see* Stay Mot. 7) that, should Novo 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 Novo to amend its complaint. *See* ECF No. 39.

The allegations in Novo's amended complaint that pertain to this new agency action are scant, and they rely largely on the fiction that HRSA's violation letter "seeks to enforce" the Advisory Opinion, *see* ECF No. 40 ¶ 128; *see also id.* ¶ 88, 116, 139, even though HRSA's letter makes no reference to the General Counsel's legal advice. Were this Court to agree with Novo 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 Novo is overcharging covered entities. HRSA has made the specific determination that Novo is violating the 340B statute—something not encompassed within the General Counsel's advice. Stated plainly, HRSA's violation letter does not rely 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 Novo in its amended complaint with respect to the Advisory Opinion would have no bearing on the agency's enforcement efforts. The actual dispute between the parties—whether Novo'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 Novo's request for emergency relief on this new action for several reasons.

First, Novo has not identified any statute, regulation, or Rule of Civil Procedure that would authorize this Court to grant an "administrative stay" in these circumstances. Novo 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). Novo 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. Novo 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* Stay Mot. 5–6 (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. Those cases provide *no* support for Novo'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 Novo 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 Novo to communicate to HRSA its plan to come back into compliance with its 340B obligations. ECF No. 38-2 at 2. Although Novo casts its request as seeking postponement of that deadline to "preserv[e] the Court's ability to resolve the merits of this case" because recent "action taken by Defendants … seeks to interfere with the Court's orderly 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 Novo communicating to the agency in response to the violation letter. Indeed, even were Novo 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 orderly resolution," *id.*, particularly now that the merits of Novo's policy will be

before the Court, nor would it prevent Novo 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 Novo 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 Novo 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, Novo essentially asks for equitable relief without endeavoring even to address the factors that would be necessary to support such a request. Novo claims that a stay of the June 1 deadline "is important to ensur[e] that the Court has time to consider the merits of the [parties'] arguments," Stay Mot. 6, but Novo'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 Novo filed its motion before presenting claims challenging the letter, it would have been difficult for it to brief the merits of any such claims. Similarly, Novo speculates that it "faces the risk of substantial penalties for every day that it refuses to comply with Defendants' unlawful demands," Stay Mot. 7, yet nowhere does Novo 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, Novo 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 "massive … penalties," Stay Mot. 5, Novo 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 Novo's insistence on imposing its contract-pharmacy policy in contravention of decades of past practice and defiance of the agency's warning, it is plain that any harm accruing to Novo 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). Novo 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, to the extent Novo suggests that an administrative stay would preserve the status quo, *see* Stay Mot. 3, 5, such an argument strains credulity. The status quo was toppled less than a year ago when Novo and its peers upended the 340B program's twenty-five-year, settled operation and began denying purchases by covered entities using contract pharmacies. And the June 1 deadline is simply an instruction for Novo 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 Novo 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 the fact that HRSA's letter is the first step in an enforcement action. Nor is there anything improper, as Novo suggests, in HRSA having determined that Novo has violated the 340B statute. Stay Mot. 3–4. HRSA is tasked with enforcing the statute, and it is the role of this Court to review that determination, 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 "attempt to disrupt and interfere with ongoing judicial proceedings." *Id.* at 4. Novo's complaint that HRSA "ha[d] never before given any indication that" it might "take enforcement action against Novo" during the pendency of this litigation, *id.* at 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 Novo's policy and is not final agency action, so Novo's original complaint presented an improper attempt to preempt agency enforcement).[1]

Fourth, far from "preserving the Court's ability to resolve the merits of this case" (an assertion Novo makes no attempt to explain or support), *id.* at 1, a stay of the June 1 deadline would have *no practical impact* on Novo's vulnerability to "civil monetary penalties," *id.* at 4. As noted above, the agency has not determined whether CMPs are warranted, process would be due before penalties were imposed, and Novo could seek judicial review of such a determination. Thus, while the violation letter makes plain that continued intransigence by Novo 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 Novo'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

[1] In its stay motion, Novo asserts that it "reserves [the] right to file a motion for a preliminary injunction or to seek other emergency relief." Stay Mot. 9. Any attempt to file yet another emergency motion should not be countenanced; Novo 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 Novo's motion was improper. Novo should not receive another bite at the apple.

was "stayed." Correspondingly, in the unlikely event Novo 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[] to impose massive civil monetary penalties," *id.* at 3, will remain. Relatedly, Novo cannot credibly claim that it would face any irreparable harm should it proceed prudently by abandoning its contract-pharmacy restrictions while this litigation proceeds. Novo can always re-impose these 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, Novo had complied with its statutory obligation to sell discounted drugs to covered entities regardless of dispensing mechanism for several years before it abruptly changed course mid-2020.

In conclusion, Defendants respectfully suggest that this Court lacks authority to administratively stay HRSA's instruction for Novo 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, Novo would not be entitled to any relief due to its failure to brief the factors that would be necessary to support it. This Court should therefore deny the administrative stay and allow the parties to submit short supplemental briefs, before the July 6, 2021 date on which briefing closes, addressing the new claims Novo added to its complaint related to the violation letter.

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Respectfully submitted,

BRIAN D. NETTER
Deputy Assistant Attorney General

MICHELLE R. BENNETT
Assistant Branch Director

/s/ Jody D. Lowenstein
JODY D. LOWENSTEIN
Mont. Bar No. 55816869
KATE TALMOR
RACHAEL L. WESTMORELAND

Trial Attorneys
United States Department of Justice
Civil Division, Federal Programs Branch
1100 L Street NW
Washington, D.C. 20005
Phone: (202) 598-9280
Email: jody.d.lowenstein@usdoj.gov

Attorneys for Defendants