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

NOVO NORDISK INC. and NOVO NORDISK PHARMA, INC., Plaintiffs, v. UNITED STATES DEPARTMENT OF HEALTH AND HUMAN SERVICES, *et al.,* Defendants.	Civil Action No. 3:21-cv-00806 Chief Judge Freda L. Wolfson

PLAINTIFFS' REPLY IN SUPPORT OF ITS MOTION
TO EXPEDITE AND FOR A TEMPORARY ADMINISTRATIVE STAY

Plaintiffs Novo Nordisk Inc. and Novo Nordisk Pharma, Inc. (together, "Novo") have moved the Court to enter a temporary administrative stay and expedite its ruling on the parties' dispositive motions because the government in its May 17 letter has commanded Novo to "immediately" abandon its litigation position or else face massive civil monetary penalties as early as June 1. The May 17 letter is a clear announcement that the government intends to enforce the legal position *first* articulated in its December 30 decision, and also represents a direct and immediate threat that the government intends to punish Novo if it does not capitulate to the government's demands and give up its litigation position — even though the

question of the government's authority to bring any such enforcement action depends entirely on the statutory question that this Court has been asked to resolve.

The government does not dispute that it agreed to the summary judgment briefing schedule approved by the Court, and its response provides no reason it should be allowed to interfere with the orderly administrative resolution of this case by bringing an enforcement action that, if this Court agrees with Novo's legal position, would be both meritless and beyond the government's lawful authority. The government's threat to Novo and its refusal to halt further administrative action until the Court resolves the important legal issues in this case is simply incredulous. A temporary administrative stay is warranted to protect the Court's jurisdiction, ensure that litigation proceeds in an orderly fashion, and preserve the status quo pending the Court's decision on the merits.

ARGUMENT

1. ***The Government Does Not Deny That an Expedited Ruling is Warranted.*** The government does not oppose Novo's request for an expedited ruling. The Court should therefore grant the request to expedite and set the hearing on the parties' dispositive motions at its earliest convenience after Novo files its reply brief on July 6. Because the government does not oppose expedition, the primary issue underlying this motion is what should be done during the approximate five-week period between the government's arbitrary June 1 response deadline and

the proposed hearing date. Novo's position is that the government defendants should be precluded from taking administrative action on their May 17 letter until the Court rules on this matter.

2. ***The Court Has Jurisdiction to Consider the May 17 Letter.*** The government contends that the court lacks jurisdiction because HHS's May 17 letter is "new agency action that must be considered independently" from HHS's December 30 decision. HHS Br. 3 (ECF 42). That makes no sense. Novo's complaint seeks declaratory and injunctive relief not only to strike down HHS's December 30 decision and the new substantive rule it seeks to impose, but also to enjoin *any attempt* by the government to enforce that rule. *See* Am. Compl., Prayer. Moreover, as Novo's motion explains, if the government's position were correct, it could forever thwart judicial review by taking new agency action during litigation and conjuring up new legal theories in support of its position. Not surprisingly, the government cites no case that permits such administrative gamesmanship. *See Cuozzo Speed Techs., LLC v. Lee*, 136 S. Ct. 2131, 2142 (2016) (emphasizing that even in the face of a statutory bar on judicial review, courts have authority to review agency "shenanigans" under the Administrative Procedure Act).

In any event, pursuant to the Court's direction, Novo has now filed an amended complaint that challenges the government's May 17 letter. The asserted grounds for challenging the May 17 letter are virtually identical to the asserted

grounds for challenging HHS's December 30 decision. If the Court agrees with Novo that the 340B statute does not unambiguously require manufacturers to transfer discounted 340B drugs to commercial pharmacies, HHS's December 30 decision is unlawful and, for the same reason, the government has no authority to bring the enforcement action threatened in its May 17 letter.

3. ***The Court's Summary Judgment Ruling Will Determine the Legality of Both the Government's December 30 Decision and its May 17 Letter.*** The government next contends that the entity that issued the December 30 decision—the HHS's Office of General Counsel—is a "different entity altogether" from the entity, the Health Resources and Services Administration ("HRSA") that sent Novo the threatening letter. HHS Br. 3. The government also argues that its May 17 letter "does not rely" on its December 30 decision. *Id.* at 4.

These remarkable arguments ignore that HRSA and its Acting Administrator are both defendants in this case subject to the Court's authority. Their attempt to interfere with this litigation is improper and inconsistent with the requirements of reasoned decision-making, much less the respect and deference owed to the judicial process and a coordinate branch of government.

More fundamentally, the suggestion that HRSA is "altogether" separate from the Office of General Counsel cannot be taken seriously. HRSA is an agency of HHS, with delegated authority to oversee the 340B program. The Office of General

Counsel houses the team of lawyers that advises HHS and its agencies, including HRSA. As a statement by HHS's most senior lawyer, the General Counsel's December 30 decision setting forth the agency's definitive position on the requirements of the 340B statute applies to all HHS agencies and personnel, including HRSA and its Acting Director.

Nor is it credible to suggest that the May 17 letter is disconnected from HHS's December 30 decision. Both the letter and the decision reflect the agency's final position on the 340B statute's requirements and, as Novo's amended complaint makes clear, both are substantively and procedurally unlawful. Novo is challenging the December 30 decision because it seeks to impose a new substantive obligation on manufacturers that is not authorized by the 340B statute. Again, if Novo is correct, the government has no authority to pursue an enforcement action against Novo, and the government's May 17 letter is invalid for the same reasons.

4. ***A Stay Is Needed to Protect the Court's Jurisdiction and Ensure an Orderly Resolution of this Case.*** The government argues that the Court lacks authority to impose an "administrative stay" because Novo has not yet sought emergency injunctive relief. HHS Br. 4–5. But that overlooks the court's inherent authority to control litigation and the conduct of the parties before it. It also ignores the seriousness of the government's extraordinary demand that Novo "immediately" abandon its litigation position.

Novo is asking for a stay to protect the Court's jurisdiction to resolve the statutory question at the center of this case. A stay is needed to prevent the government from taking any action under its May 17 letter, which effectively seeks to enforce the legal position set forth in the government's December 30 decision, which Novo is challenging in this case. A stay is warranted to ensure that this litigation can proceed without hindrance or improper influence by the government.

There is no need to satisfy the traditional factors for injunctive relief because when a court is asked to prevent the parties before it from taking actions outside of litigation designed to interfere with the judicial process, it is exercising inherent authority to control litigation and the conduct of the parties and their counsel. *See Guedes v. ATF*, No. 19-5042, 2019 WL 1398194, at *1 (D.C. Cir. Mar. 23, 2019) (per curiam) (issuing *sua sponte* administrative stay "to give the Court sufficient opportunity to consider the disposition of this highly expedited appeal"). "Entering temporary administrative stays" so that a court "may consider expedited briefing in emergency cases is a routine practice" that 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." *In re Abbott*, 800 F. App'x 296, 298 (5th Cir. 2020) (mem.) (quoting *Landis v. N. Am. Co.*, 299 U.S. 248, 254 (1936)).

The court's inherent authority "transcends" its "equitable power concerning relations between the parties and reaches a court's inherent power to police itself,"

serving a dual purpose of vindicating judicial authority without resorting to more drastic measures. *Chambers v. NASCO, Inc.*, 501 U.S. 32, 46 (1991); *see also Eash v. Riggins Trucking Inc.*, 757 F.2d 557, 567 (3d Cir. 1985) (discussing courts' "inherent powers" to regulate the parties before it). If a court can issue sanctions to "protect and preserve the sound and orderly administration of justice," *Urban v. United Nations*, 768 F.2d 1497, 1500 (D.C. Cir. 1985) (per curiam) (quoting *In re Martin-Trigona*, 737 F.2d 1254, 1262 (2d Cir. 1984)), it also has authority to stop a government litigant from abusing its position and threatening a private litigant.

5. ***A Stay Will Not Prejudice the Government.*** The government offers no reason why it would be prejudiced by a stay that prevents it from taking any enforcement action until the Court resolves the important statutory question raised in this case. It asserts that Novo has been on notice that the government was considering sanctions, *see* HHS Br. 2, but the letters it cites were sent to other manufacturers, not to Novo. *See* ADVOP_001098, ADVOP_1110. Moreover, the letters did not contend that the other manufacturers were violating any statutory obligation, but only that the government was "considering the issue" — a telling omission that contradicts the government's new position that the statute is clear and unambiguous in favor of the government's position. Indeed, the statements cited by the government conceded then that HRSA "has only limited ability to issue enforceable regulations" and, therefore, could only "encourage" manufacturers to

continue transferring drugs to commercial pharmacies. ADVOP_01597–98; *see also* ADVOP_001592 (reporting government's recognition that its contract pharmacy guidance "is not legally enforceable"). That is a far cry from the definitive positions taken by the government in its December 30 decision and its recent May 17 letter.

The government also does not dispute that its May 17 letter imposes an artificial June 1 deadline for Novo to abandon its position and comply with the government's demands. It nonetheless tries to downplay the June 1 date, asserting that Novo's failure to accede to the government's demands will not necessarily result in sanctions, while also asserting (inconsistently and ominously) that sanctions will depend "on Novo Nordisk's willingness to comply." HHS Br. 3 (emphasis omitted). According to the government, "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." HHS Br. 5

But none of this has anything to do with communicating with the government or responding to the government by June 1. The government already knows Novo's position because that position has been set forth in Novo's complaint. More specifically, the government already knows that Novo objects to the government's attempt to impose extra-statutory requirements on Novo—because that is the issue that is pending before this Court. The problem with the May 17 letter is not its

request for an unnecessary communication, but that the government is threatening to take enforcement action if Novo does not surrender and give in to the government's demands. That is the only purpose of the letter. Indeed, if the letter is not making that threat, there is no reason the government should not wait for the Court to resolve this case on its merits before taking any further enforcement action.

Significantly, the government cites no case where a court has ever permitted the government to initiate an enforcement action in the middle of litigation that has been filed to address the very statutory question on which the government's enforcement action depends. Nor does it offer any credible reason why the government should be allowed to threaten Novo with civil monetary penalties if it does not surrender on the central legal issue the Court has been asked to resolve. The government's role as sovereign does not change that analysis. All parties, including government defendants, should respect the judicial process. Government defendants should not be permitted to undermine the orderly conduct of litigation just because they hold positions of power and authority in the executive branch.

CONCLUSION

The government identifies no reason the Court should not grant a temporary administrative stay to enforce the briefing schedule, preserve the status quo, and protect this Court's jurisdiction. The motion to expedite and for a temporary administrative stay should be granted.

Respectfully submitted,

/s/ Israel Dahan

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Dated: May 26, 2021

CERTIFICATE OF SERVICE

The undersigned hereby certifies that a copy of the foregoing has been filed electronically on the 26th day of May, 2021. Notice of this filing will be sent to counsel of record for the parties by operation of the Court's electronic filing system.

/s/ Israel Dahan
Israel Dahan