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

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

Plaintiffs Novo Nordisk Inc. and Novo Nordisk Pharma, Inc. (together, "Novo") respectfully provide notice to the Court of the attached letter they received yesterday, September 22, 2021, from defendant Health Resources and Services Administration ("HRSA"). *See* Exhibit A. The letter is relevant to the issues addressed in the pending dispositive motions.

As the Court is aware, on December 30, 2020, the government issued an "Advisory Opinion" that for the first time in the history of the 340B program sought to impose an affirmative obligation on drug manufacturers to transfer their drugs at deeply discounted prices to an unlimited number of commercial pharmacies. The

government has never identified any statutory provision or regulation that authorizes the government to impose that obligation. Nonetheless on May 17, HRSA sent a letter to Novo claiming that the company had violated the 340B statute and threatening to impose civil monetary penalties if Novo did not accede to its demands.

On June 16, 2021, Chief Judge Stark held that the 340B statute is "silent" on the issue of contract pharmacies, and that the government's Advisory Opinion was "legally flawed" because it "wrongly determine[d] that purportedly unambiguous statutory language mandates" that manufacturers transfer their drugs to contract pharmacies. *AstraZeneca Pharms. LP v. Becerra,* No. CV 21-27-LPS, 2021 WL 2458063, at *10–11. In response to that decision, the government withdrew its Advisory Opinion, but indicated that it intended to continue defending its May 17 letter. That letter, like the Advisory Opinion, relies on the same legally flawed position — that the statute imposes an unambiguous obligation on manufacturers to transfer their drugs to contract pharmacies. The legality of the May 17 letter has been fully briefed by the parties and the issues are ripe for this Court's decision.

Without waiting for the Court, HRSA's recent letter refers Novo to "the HHS Office of the Inspector General (OIG) in accordance with the 340B Program Ceiling Price and Civil Monetary Penalties Final Rule." The letter is an abuse of the agency's authority, as the OIG may impose civil monetary penalties only when there has been a *willful* violation of the law. *See* 42 U.S.C. § 256b(d)(1)(B)(vi). Novo

could not have willfully violated the 340B statute given that, as Chief Judge Stark has properly concluded, the statute does not unambiguously support the government's position and there is no binding legal authority requiring manufacturers to transfer discounted drugs to commercial pharmacies. HRSA should not be permitted to circumvent this Court's authority to decide critical questions of statutory interpretation by insisting — before the Court has ruled — that Novo capitulate or else be subject to civil monetary penalties.

In light of HRSA's recent action, Novo respectfully reiterates its request that the Court expedite its ruling on the pending dispositive motions and provide clarity on the scope of the government's authority under the 340B statute.

Respectfully submitted,

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Counsel for Novo Nordisk Inc. and Novo Nordisk Pharma, Inc.

Dated: September 23, 2021

CERTIFICATE OF SERVICE

The undersigned hereby certifies that a copy of the foregoing has been filed electronically on the 23rd day of September, 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