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

NOVO NORDISK INC.,
800 Scudders Mill Road,
Plainsboro, NJ 08536

NOVO NORDISK PHARMA, INC.,
800 Scudders Mill Road, Suite 1A-108
Plainsboro, NJ 08536

Plaintiffs,

v.

UNITED STATES DEPARTMENT OF HEALTH AND HUMAN SERVICES
200 Independence Avenue, S.W.
Washington D.C. 20201,

ALEX M. AZAR II,
in his official capacity as
Secretary of Health & Human Services
Office of the Secretary
200 Independence Avenue, SW
Washington, D.C. 20201,

ROBERT P. CHARROW,
in his official capacity as
General Counsel of the United States Department of Health and Human Services,
200 Independence Avenue, S.W.
Washington, D.C. 20201,

HEALTH RESOURCES AND SERVICES ADMINISTRATION
5600 Fishers Lane,
Rockville, Maryland 20852,

THOMAS J. ENGELS, in his official capacity as Administrator of the Health Resources and Services Administration
5600 Fishers Lane,
Rockville, Maryland 20852,

Defendants.

Civil Action No. 3:21-cv-806

COMPLAINT FOR DECLARATORY AND INJUNCTIVE RELIEF

COMPLAINT FOR DECLARATORY AND INJUNCTIVE RELIEF

Plaintiffs Novo Nordisk Inc. and Novo Nordisk Pharma, Inc. (collectively, "Novo"), by and through their undersigned attorneys, allege as follows:

PRELIMINARY STATEMENT

1. This case challenges a final decision by the U.S. Department of Health and Human Services ("HHS") that purports to impose new binding obligations on drug manufacturers, on threat of significant penalties, but exceeds the agency's statutory authority and does not comply with the requirements of reasoned decision-making under the Administrative Procedure Act ("APA").

2. Section 340B of the Public Health Service Act requires pharmaceutical manufacturers to offer their outpatient drugs at deeply discounted prices to an enumerated list of "covered entities" for the purpose of ensuring that vulnerable and low-income patients have better access to prescription medications. Manufacturers that fail to comply with the statute's mandate face enforcement action, significant civil monetary penalties, and potential revocation of the manufacturer's ability to participate in the federal Medicare and Medicaid programs.

3. Under the terms of the statute, and consistent with constitutional limits on forcing private parties to subsidize other private parties, Congress provided that *only* covered entities that meet the statute's requirements are entitled to purchase manufacturers' drugs at discounted prices. *See* 42 U.S.C. § 256b(a)(4). Congress also made clear that covered entities are prohibited from transferring manufacturers' drugs to anyone other than their own patients. *See id.* § 256b(a)(5)(B). This prohibition on "diversion" is essential to ensuring that the program remains within constitutional bounds and serves the statutory purpose of aiding needy patients, not enriching covered entities or commercial third parties at manufacturers' expense.

4. Despite these statutory prohibitions, many covered entities have entered into arm's-length agreements with for-profit, commercial pharmacies—known as "contract pharmacies"—that allow the pharmacies to acquire and dispense manufacturers' discounted drugs and to share in the profits resulting from selling manufacturers' discounted drugs at the full market price to patients who are not uninsured or needy. These contractual arrangements have dramatically increased the size of the 340B program, allowing covered entities and their contract pharmacies to make substantial profits at the expense of manufacturers. It has also made it much harder to ensure compliance with the 340B statute, increasing the risk of 340B drugs being sold to non-patients and the problem of "duplicate discounting," which occurs when the same drug is subject to both a 340B discount and a Medicaid rebate. The systemic abuses resulting from this massive expansion in the use of contract pharmacies is directly contrary to Congress's intent.

5. To address these concerns, Novo announced a new initiative, which took effect in January 2021, that it will no longer accept covered entity requests that Novo transfer its covered outpatient drugs (or cause its covered outpatient drugs to be transferred) to an unlimited number of commercial contract pharmacies servicing hospitals. Novo made clear that it will fully comply with the 340B statute by still offering its outpatient drugs at 340B discounted prices to all eligible covered entities. It also made numerous exceptions in its discretion—going beyond what the statute requires—to ensure that federal grantee covered entities are able to purchase Novo's outpatient drugs at the discounted price and dispense them through contract pharmacies. But Novo is no longer willing to allow hospital covered entities and commercial contract pharmacies to abuse the 340B program.

6. Nothing in the statute or any regulation requires manufacturers to facilitate the transfer of their covered outpatient drugs to third parties at a covered entity's request. The statute

requires only that manufacturers "offer" their covered outpatient drugs "for purchase" at discounted prices to eligible "covered entities." 42 U.S.C. § 256b(a)(1). Moreover, although HHS has previously issued guidance permitting covered entities to use contract pharmacies, it repeatedly emphasized that its guidance was non-binding and that the statute itself did not address contract pharmacy arrangements. Under the law, manufacturers have discretion to decide when or whether to honor covered entity requests that their discounted drugs be transferred to third parties, including to for-profit, commercial pharmacies.

7. On December 30, 2021, HHS's Office of General Counsel issued what it labeled an "advisory opinion" but what in fact constitutes a final rule that seeks to change the legal requirements that the 340B program imposes on manufacturers. Without textual support, the agency's decision announces finally and unequivocally that the agency has concluded that drug manufacturers are legally obligated to facilitate the transfer of their discounted drugs to contract pharmacies, which HHS assumed are acting as agents of 340B covered entities. *See* HHS, Office of the Gen. Counsel, *Advisory Opinion 20-06 on Contract Pharmacies under the 340B Program* (Dec. 30, 2020) (Ex. A). According to HHS, because the statute requires manufacturers to offer their drugs for purchase at discounted prices, the agency also has authority to require manufacturers to transfer their drugs to wherever covered entities may demand, "be it the lunar surface, low-earth orbit, or a neighborhood pharmacy." HHS Advisory Opinion, Ex. A at 5.

8. HHS's decision is wrong, contrary to the statute, and inconsistent with the requirements of reasoned decision-making. The 340B statute requires manufacturers to "offer" their covered outpatient drugs to covered entities at 340B prices, and Novo's initiative fully complies with that statutory requirement. Nothing in the 340B statute requires manufacturers to facilitate the transfer of their deeply discounted drugs to an unlimited number of contract

pharmacies. Nor does anything in the statute establish that Congress intended to impose such a significant burden on manufacturers or to allow the 340B program to be abused for commercial gain.

9. As a result of HHS's decision, Novo is exposed to enforcement action, severe and accumulating monetary penalties, and potential revocation of its ability to participate in the Medicare and Medicaid programs. Unless and until HHS's decision is struck down, Novo is exposed to the threat of accumulating greater and greater liability.

10. Novo is therefore bringing this action to seek an order (1) declaring that HHS's December 30 decision violates the Administrative Procedure Act because it is in excess of HHS's statutory authority, was issued without following proper procedure, and is not otherwise in accordance with law, (2) declaring that Novo is not required to facilitate the transfer of 340B discounted drugs to contract pharmacies, and (3) enjoining enforcement of HHS's decision and all actions by HHS inconsistent with that declaratory relief.

THE PARTIES

11. Novo Nordisk Inc. is the United States based affiliate of a global healthcare company, founded in 1923, with the purpose to drive change to defeat diabetes and other serious chronic diseases, such as obesity, and rare blood and rare endocrine diseases. Novo Nordisk Inc.'s headquarters are located in Plainsboro, New Jersey.

12. Novo Nordisk Pharma, Inc. supplies unbranded biologic versions of Novo Nordisk insulin products at a reduced list price to individuals facing affordability challenges. Novo Nordisk Pharma, Inc.'s headquarters are located in Plainsboro, New Jersey.

13. Defendant United States Department of Health and Human Services ("HHS") is an executive branch department in the United States government. It is headquartered in the District of Columbia.

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