**Nos. 21-3168, 21-3167, 21-3379, 21-3380**

**IN THE UNITED STATES COURT OF APPEALS**
**FOR THE THIRD CIRCUIT**

---

NOVO NORDISK INC. AND NOVO NORDISK PHARMA, INC.

Plaintiffs–Appellants–Cross-Appellees,

v.

U.S. DEPARTMENT OF HEALTH AND HUMAN SERVICES, *et al.*,

Defendants–Appellees–Cross-Appellants.

---

SANOFI-AVENTIS U.S., LLC.

Plaintiff–Appellant–Cross-Appellee,

v.

U.S. DEPARTMENT OF HEALTH AND HUMAN SERVICES, *et al.*,

Defendants–Appellees–Cross-Appellants.

---

On Appeals from the United States District Court
for the District of New Jersey (Nos. 21-634, 21-806)

---

# REPLY BRIEF FOR THE FEDERAL DEFENDANTS

---

BRIAN M. BOYNTON
*Principal Deputy Assistant Attorney General*

PHILIP R. SELLINGER
*United States Attorney*

ALISA B. KLEIN
DANIEL AGUILAR
*Attorneys, Appellate Staff*
*Civil Division*
*U.S. Department of Justice*
*950 Pennsylvania Avenue NW*
*Washington, DC 20530*
*(202) 514-5432*

# TABLE OF CONTENTS

**Page**

ARGUMENT..... 1

CONCLUSION..... 3

# TABLE OF AUTHORITIES

**Page**

**Rules and Regulations:**

58 Fed. Reg. 68922 (Dec. 29, 1993) .....1

## ARGUMENT

Pursuant to Federal Rule of Appellate Procedure 28.1(c)(4), we limit this reply to the issue presented by our cross appeal.

The district court correctly analyzed the 340B statute "with reference to the statutory context, structure, history, and purpose." JA101 (quotation marks omitted). Based on that well-reasoned analysis, JA90-105, the court concluded that drug manufacturers "may not unilaterally create and establish policies—whatever the underlying rationale—wherein they dictate how many contract pharmacies a covered entity may designate to receive delivery of covered drugs," JA105. That conclusion is consistent with the decades-long understanding that the 340B statute does not permit drug manufacturers to deny or restrict access to the statutory discounted price for covered entities. *See* 58 Fed. Reg. 68922, 68925 (Dec. 29, 1993) (explaining that "[a] manufacturer may not condition the offer of statutory discounts upon an entity's assurance of compliance with section 340B provisions"). Thus, the court held that "plaintiffs' policies are impermissible under § 340B." JA102 (capitalization altered).

Despite that conclusion, the district court determined that it was appropriate to remand the matter for HHS to determine in the first instance how many contract pharmacies a covered entity could use to

dispense medications to its patients. JA105-109. That remand order was error. On appeal, Novo Nordisk does not defend it. Sanofi insists that it was necessary for HHS to "explain[] why" the statute "required delivery to unlimited contract pharmacies—as opposed to just one or multiple contract pharmacies." Sanofi Reply Br. 47. But as Sanofi recognized in its opening brief (at 7), HHS lacks substantive rulemaking authority to restrict a covered entity's contract pharmacy arrangements. Thus, this dispute presents a legal question for the Court: either the statute prohibits drug manufacturers from placing unilateral restrictions on covered entities' use of contract pharmacies or it does not. And if "the District Court was correct in finding that Sanofi" was "violat[ing]" the 340B statute, Sanofi Reply Br. 49, HHS adequately explained the reasons for its enforcement letter: HHS had received complaints from covered entities; Sanofi was violating the statute by overcharging covered entities; and the "340B statute does not permit a manufacturer to impose industry-wide, universal restrictions," JA219-20.

Accordingly, this Court should conclusively resolve the dispute between the parties. The 340B statute either allows covered entities to purchase and dispense discounted drugs to their patients through outside pharmacies, or it leaves drug manufacturers free to nullify that

longstanding and near universal method of getting needed medication to poor and underserved communities. There is no intermediate option unless Congress decides to amend the statute. In short, remand is unwarranted, and this Court should definitively construe the statute. For the reasons explained in our principal brief and by the district court, the 340B statute prohibits plaintiffs' policies.

## CONCLUSION

The district court's judgment should be reversed insofar as it vacated the enforcement letters and remanded to HHS. The judgment should otherwise be affirmed.

Respectfully submitted,

BRIAN M. BOYNTON
*Principal Deputy Assistant Attorney General*

PHILIP R. SELLINGER
*United States Attorney*

ALISA B. KLEIN
*/s/ Daniel Aguilar*
DANIEL AGUILAR
*Attorneys, Appellate Staff*
*Civil Division*
*U.S. Department of Justice*
*950 Pennsylvania Avenue NW*
*Washington, DC 20530*
*(202) 514-5432*
Daniel.J.Aguilar@usdoj.gov

June 2022

## COMBINED CERTIFICATIONS

1. Government counsel are not required to be members of the bar of this Court.

2. This brief complies with the type-volume limit of Federal Rule of Appellate Procedure 28.1(e)(2)(C) because it contains 483 words. This brief also complies with the typeface and type-style requirements of Federal Rule of Appellate Procedure 32(a)(5)-(6) because it was prepared using Microsoft Word 2016 in Georgia 14-point font, a proportionally spaced typeface.

3. On July 7, 2022, I electronically filed the foregoing brief with the Clerk of the Court for the United States Court of Appeals for the Third Circuit by using the appellate CM/ECF system.

4. The text of the electronic version of this document is identical to the text of the hard copies that will be provided.

5. This document was scanned for viruses using Symantec Endpoint Protection version 14, and no virus was detected.

*/s/ Daniel Aguilar*
Daniel Aguilar