No. 24-2510

UNITED STATES COURT OF APPEALS
FOR THE THIRD CIRCUIT

NOVO NORDISK INC.;
NOVO NORDISK PHARMA, INC.,

Appellants,

v.

SECRETARY, UNITED STATES DEPARTMENT OF HEALTH AND HUMAN SERVICES; UNITED STATES DEPARTMENT OF HEALTH AND HUMAN SERVICES; ADMINISTRATOR, CENTERS FOR MEDICARE & MEDICAID SERVICES; CENTERS FOR MEDICARE & MEDICAID SERVICES.

On Appeal from the United States District Court for the District of New Jersey, No. 3:23-cv-20814, Hon. Zahid N. Quraishi

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APPELLANTS' MOTION TO EXPEDITE ORAL ARGUMENT AND DECISION

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On January 17, 2025, CMS again defied the Inflation Reduction Act's plain text by announcing that it intends to impose a new round of price controls on more products than the statute authorizes, including by aggregating together three separate products that are manufactured by appellants Novo Nordisk Inc. and Novo Nordisk Pharma Inc. (together, "Novo Nordisk"). CMS's continued defiance of the statute's requirements adds urgency to the important issues raised in this appeal. Accordingly, in light of this intervening event, Novo Nordisk respectfully requests under 28 U.S.C. § 1657 and Local Appellate Rule 4.1 that this Court expedite oral argument and decision in this matter.

1. This case involves a challenge to the price-control scheme for certain prescription drug and biological products implemented by the Centers for Medicare & Medicaid Services ("CMS") under the Inflation Reduction Act ("IRA"). *See* Dkts. 18 (opening brief), 67 (reply brief).[1]

2. The IRA imposes specific limits on the number of products on which CMS may set prices. For 2026, CMS may impose price controls on no more than "10 negotiation-eligible drugs." 42 U.S.C. § 1320f-1(a). For

[1] Citations to "Dkt. [#]" refer to the Court of Appeals docket.

2027, CMS may impose price controls on only "15 negotiation-eligible drugs." *Id.* § 1320f-1(b). The statute expressly defines "negotiation-eligible drug" to refer to a drug or biological "product" approved or licensed by the Food & Drug Administration ("FDA") and marketed for at least 7 years (in the case of drug products) or 11 years (in the case of biological products). *Id.* §§ 1320f-1(d)(1), 1320f-1(e)(1).

3. For 2026, CMS exceeded the statute's strict 10-product limit and instead imposed price controls on 15 different products that have been separately approved or licensed at different times by FDA, including products that have not been on the market for the required period. In particular, CMS treated *six* different Novo Nordisk products as a single "negotiation-eligible drug" merely because those six products share the same "active ingredient." *See* Appx172-174.

4. In response to litigation filed by Novo Nordisk, the Court is currently considering the legality and constitutionality of CMS's actions. Novo Nordisk contends that CMS has violated the statute's express numerical limits on how many drugs CMS was permitted to subject to price controls in 2026, and it has shown that CMS's interpretation and

application of the IRA's price-control scheme violates the IRA, the Administration Procedure Act, and the Constitution.

5. Novo Nordisk has sought to advance this appeal at every turn. For example, when Novo Nordisk consented to an extension for the Government's response brief due to extenuating family circumstances for opposing counsel, it "emphasize[d] the importance of having this appeal briefed and decided as expeditiously as possible." Dkt. 22 ¶ 4. Novo Nordisk subsequently filed its reply brief days before the reply deadline. *See* Dkt. 67.

6. As of January 3, 2025, the appeal is fully briefed and ready for oral argument and a disposition. *See id.* Oral argument has not yet been scheduled.

7. Following the completion of briefing, on January 17, 2025, CMS published its new list of products for price controls beginning in 2027. *See* Press Release, HHS, *HHS Announces 15 Additional Drugs Selected for Medicare Drug Price Negotiations in Continued Effort to Lower Prescription Drug Costs for Seniors* (Jan. 17, 2025) ("HHS Press Release"), https://tinyurl.com/yh96jtnz; *see also* 42 U.S.C. § 1320f-1(a)(2)

& (b) (providing for the selection of "15 negotiation-eligible drugs" for 2027).

8. In publishing that list, CMS has again violated the IRA's express numerical limits by seeking to impose price controls on more than 15 products. In particular, CMS has again aggregated multiple different Novo Nordisk products together merely because they share an active ingredient, *semaglutide*, even though the distinct products serve different therapeutic purposes and were approved by FDA as different products at different times to treat patients with different diseases. In CMS's 15-bullet list of products, a single bullet lists three separate Novo Nordisk products — "Ozempic; Rybelsus; Wegovy." *See* HHS Press Release, https://tinyurl.com/yh96jtnz.

9. Novo Nordisk accordingly now faces being forced to participate in another unlawful "negotiation" process, including having to turn over proprietary information to CMS that Novo Nordisk maintains as confidential and would not share with any contracting partner. As part of that process, Novo Nordisk is required to sign an agreement to participate in the "negotiation" by February 28, 2025; submit data to CMS by March 1, 2025; and engage with CMS further

throughout this year. *See* CMS, Medicare Drug Price Negotiation Program: Selected Drugs for Initial Price Applicability Year 2027, at pdf p. 4 (Jan. 2025), *available at* https://tinyurl.com/5h7aka7x.

10. Novo Nordisk's now-impending second round of price "negotiations" is good cause that justifies expediting the remainder of this appeal to clarify Novo Nordisk's rights and CMS's authority under the IRA, the Administrative Procedure Act, and the Constitution. *See* 28 U.S.C. § 1657(a).

11. This motion is timely because it is brought within 14 days of CMS's announcement of its decision to impose price controls on more than 15 products beginning in 2027, including multiple additional Novo Nordisk products, which is a "basis of the motion." 3d Cir. L.A.R. 4.1.

CONCLUSION

Appellants respectfully request that this Court set oral argument as soon as practicable and resolve the appeal expeditiously following argument.

Respectfully submitted,

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CERTIFICATE OF COMPLIANCE

This motion complies with the typeface requirements of Federal Rule of Appellate Procedure 27(d)(2), because it contains 880 words and the type-style requirements of Federal Rule of Appellate Procedure 32(a)(6) and 3d Cir. L.A.R. 32.1(c) because it has been prepared in a proportionally spaced typeface using Microsoft Word 365 ProPlus in Century Schoolbook 14-point font.

Date: January 27, 2025

/s/Ashley C. Parrish
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CERTIFICATE OF SERVICE

I hereby certify that on January 27, 2025, I electronically filed the foregoing document with the Clerk of the Court for the United States Court of Appeals for the Third Circuit by using the CM/ECF system, thereby serving all registered counsel of record.

/s/Ashley C. Parrish
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