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' REPLY IN SUPPORT OF MOTION TO EXPEDITE ORAL ARGUMENT AND DECISION

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The government's response confirms the need for prompt resolution of this appeal. CMS does not dispute that the statute authorizes it to impose price controls on no more than "15 negotiation-eligible drugs" in 2027. 42 U.S.C. § 1320f-1(a)(2). Nor does it deny that the statute defines "negotiation-eligible drug" to mean a "drug product" or "biological product" approved or licensed by FDA. It also cannot deny that, just weeks ago, CMS announced its decision to impose price controls in 2027 on *more than* 15 drug or biological products—including by grouping together as a single "negotiation-eligible drug" *three* different Novo Nordisk products that were separately approved by FDA and are used to treat different patients with different conditions. Indeed, CMS's response makes a telling admission when it states that the agency is subjecting "different forms of semaglutide" to price controls, Dkt. 72 at 2, focusing on the active ingredient (semaglutide) and not the *three* distinct Novo Nordisk products (Ozempic®, Ryblesus®, and Wegovy®) that CMS has unlawfully grouped together.

This appeal is the Court's first opportunity to address whether CMS can ignore the statute's express limit on the number of products subject to price controls. No other appeal before this Court presents the merits

of this statutory question.[1] And the question is both important and pressing: Deciding how many products to subject to price controls—a decision Congress made—requires carefully balancing the benefits of coercive government prices against the substantial harms they will cause to innovation and private rights.

The government argues that CMS's recent decision is no cause for expedition because the next round of price controls "will take effect no earlier than January 1, 2027." Dkt. 72 at 2. But the government cannot refute that its decision has imminent consequences. Novo Nordisk will be forced to sign an agreement *this month* with CMS, will be coerced by March 1 into submitting voluminous and highly confidential data and other information relating to all *three* of these drugs, and will be required over the coming months to participate in a one-sided "negotiation" process controlled by CMS. *See* Dkt. 69 ¶ 9; 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.

[1] While another plaintiff raised a similar statutory challenge before the district court, its arguments on appeal focus only on its Article III standing. *See* Opening Brief at 25–42, *AstraZeneca Pharms., LP v. Becerra*, No. 24-1819 (3d Cir. July 15, 2024), Dkt. 20.

These consequences of CMS's statutory violations more that justify expediting this appeal.

The government next asserts that the Court need not expedite because, in its view, the agency will win on the merits. *See* Dkt. 72 at 2. Novo Nordisk disagrees, *see* Dkts. 18, 67, but in any event, the government is putting the cart before the horse. Before Novo Nordisk is forced to bear the brunt of CMS's actions, this Court should enforce the statutory limits on the agency's power. No court has ever held that CMS's decision to group different products by "active ingredient" or "active moiety" aligns with the IRA's statutory text.

For these reasons and the reasons stated in its motion, Novo Nordisk respectfully requests 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 552 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: February 6, 2025

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CERTIFICATE OF SERVICE

I hereby certify that on February 6, 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.

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