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August 13, 2025

VIA CM/ECF

Patricia S. Dodszuweit
Clerk of Court
United States Court of Appeals for the Third Circuit
James A. Byrne United States Courthouse
21400 U.S. Courthouse
601 Market Street
Philadelphia, PA 19106

Re: Rule 28(j) letter response — *Novo Nordisk Inc, et al. v. Secretary US Dept & Health and Human Services, et al.*, No. 24-2510

Dear Ms. Dodszuweit:

The government submits the Second Circuit's decision in *Boehringer Ingelheim*, but that case does not address the central question presented here—whether CMS may rewrite the statute to impose price controls on more than 10 drug and biological products.

The Second Circuit's conclusion that Congress "expressly exempt[ed]" CMS from the APA to issue binding rules without notice and comment conflicts with the statute's text. Op.48. The IRA directs that CMS "shall implement" the statute "by program instruction or other forms of program guidance." Op.48. "Guidance" refers to non-binding interpretive rules and policy statements, not substantive rules. Novo-Br.39-41; Reply-Br.10-13. Neither the Second Circuit nor the government identify any example of "guidance" referring to binding rules, much less binding requirements promulgated without notice-and-comment procedures. And whatever the merits of that procedural question, the Second Circuit never addressed the lawfulness of the substance of CMS's guidance. CMS has no license to defy Congress's intent and

rewrite the definition of a negotiation-eligible drug to encompass multiple products containing the same ingredient or active moiety.

Concluding that no constitutional constraints apply because Boehringer “voluntarily” agreed to price controls, the Second Circuit improperly relied on its older precedent, *Garelick v. Sullivan*, 987 F.2d 913 (2d Cir. 1993), and set aside the Supreme Court’s voluntariness precedent, limiting cases like *NFIB* to the federalism context, Op.29-30, and *Nollan/Dolan* to the land-use context, Op.46 n.15. But this Court has looked to *NFIB* for guidance in the context of non-state actors. *Doe v. Univ. of Scis.*, 961 F.3d 203, 213 (3d Cir. 2020); *Novo-Br.*61-63. And the Supreme Court held that the *Nollan/Dolan* doctrine applies “in other contexts.” *Sheetz v. County of El Dorado*, 601 U.S. 267, 279 (2024). The Second Circuit’s contention that CMS acts as a mere market participant likewise misses the mark. From forcing confidential disclosures to imposing penalties to rewriting statutory provisions, CMS exercises sovereign powers “that no private actor could wield.” Op.33-34 n.11. The government cannot use a “gun to the head” to force manufactures to participate in an unprecedented price-control scheme, rewrite the statute to extend it beyond Congress’s design, and escape all constitutional limits.

Respectfully submitted,

/s/Ashley C. Parrish

Ashley C. Parrish

Counsel for Appellants

CC: All counsel of record (via CM/ECF)

CERTIFICATE OF COMPLIANCE

I certify that this document complies with the length limitations set forth in Fed. R. App. P. 28(j) because it contains 350 words, as counted by Microsoft Word, excluding the items that may be excluded.

/s/Ashley C. Parrish
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Counsel for Appellants