UNITED STATES DISTRICT COURT FOR THE DISTRICT OF COLUMBIA

TEVA PHARMACEUTICALS USA, INC., et al.,

Plaintiffs,

v.

No. 1:25-cv-00113-SLS

ROBERT F. KENNEDY, JR., in his official capacity as SECRETARY OF HEALTH AND HUMAN SERVICES, *et al.*,

Defendants.

RESPONSE TO DEFENDANTS' NOTICE OF SUPPLEMENTAL AUTHORITY

Teva writes in response to the government's notice of supplemental authority regarding *Novo Nordisk Inc. v. HHS*, 154 F.4th 105 (3d Cir. 2025). The case does not undermine Teva's arguments.

First, *Novo Nordisk*'s assessment of whether the Drug Price Negotiation Program forecloses judicial review rests on Third Circuit precedent that differs from D.C. Circuit precedent. The Third Circuit has said that "when a statute prohibits review of a particular 'determination,' the bar extends to the ultimate decision *and* 'the process by which [the agency] reaches this decision.' "*Novo Nordisk*, 154 F.4th at 111-112 (quoting *Bakran v. Secretary, DHS*, 894 F.3d 557, 563 (3d Cir. 2018)). The D.C. Circuit, however, has taken a different approach. Even when an agency's final "determinations are unreviewable, 'general collateral challenges' to the agency's practices and policies still fall within judicial purview." *Castaneira v. Noem*, 138 F.4th 540, 550 (D.C. Cir. 2025) (quoting *McNary v. Haitian Refugee Ctr., Inc.*, 498 U.S. 479, 492 (1991)); *see* Teva's MSJ Reply 8-9. The D.C. Circuit has rejected "attempts to distinguish *McNary* and circuit

precedent," explaining that a judicial-review bar to an agency's final determination does *not* "bar[] challenges to the procedural standards [the agency] applies in reaching its final determination." *Castaneira*, 138 F.4th at 550. Indeed, the D.C. Circuit has applied *McNary* over a dissent that invoked *Bakran* as a reason to deny review. *Compare Grace v. Barr*, 965 F.3d 883, 892-893 (D.C. Circ. 2020), *with id.* at 914-915 (Henderson, J., dissenting). *Novo Nordisk* does not discuss *McNary* or the D.C. Circuit's contrary approach.

Second, *Novo Nordisk* does not warrant rejecting Teva's argument that the Drug Price Negotiation Program violates the Due Process Clause. *Novo Nordisk* does not conduct any analysis beyond citing the Third Circuit's decision in *AstraZeneca Pharms. LP v. HHS*, 137 F.4th 116, 125-126 (3d Cir. 2025), which Teva already addressed in its summary-judgment briefing. Teva's MSJ Reply 39.

Respectfully submitted,

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