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VIA ECF

Lyle W. Cayce
Clerk of the Court
U.S. Court of Appeals for the Fifth Circuit
600 S. Maestri Place
New Orleans, LA 70130

Re: *Nat'l Infusion Ctr. v. Kennedy*, 25-50661 (5th Cir.) – Notice of Supplemental Authority Under Federal Rule of Appellate Procedure 28(j)

Dear Mr. Cayce,

Appellants respectfully respond to the government's letter regarding *Novo Nordisk Inc. v. HHS*, No. 24-02510 (3d Cir. 2025) (Op.).

The Third Circuit panel rejected a nondelegation challenge on the theory that, "although there is no price floor," the IRA "limits product selection" and says prices "must be 'justified,' based on certain factors." Op. 20 (citations omitted). But as the Supreme Court recently explained, the lack of an outer constraint (here, a price floor) "pose[s] a constitutional problem." *FCC v. Consumers' Rsch.*, 145 S. Ct. 2482, 2502 (2025). That problem is implicated here because—unlike the *Consumers' Research* statute—the IRA dispenses with notice-and-comment rulemaking and judicial review. Br. 28-39; Reply Br. 2-11. Because CMS has final say on what price is "justified," statutory "factors" do not constrain its *unchecked* discretion to lower prices.

The panel did not consider the IRA's removal of such safeguards, except in a footnote concluding that *Consumers' Research* forecloses challenges based on a "combination" of statutory features. Op. 21 n.3. But *Consumers' Research* acknowledged that features can "combine" to "exacerbat[e]" or "compound" a single delegation to cross "a constitutional line." 145 S.Ct. at 2510-11. Holding otherwise would conflict with precedent emphasizing the importance of procedural guardrails when Congress delegates sweeping authority. *E.g.*, *Bowles v. Willingham*, 321 U.S. 503, 516 (1944).

The panel itself highlighted the importance of procedural safeguards by holding that the IRA forecloses judicial review of Novo Nordisk's argument that "CMS violated the Act when it treated six of Novo Nordisk's products as one negotiation-eligible single-source drug." Op. 13. That holding illustrates that removing procedural constraints vastly expands CMS's delegation. Br. 29-31; Reply Br. 12. CMS can "turn [the Drug Pricing Program] into anything [it] wants." *Consumers' Rsch.*, 145 S. Ct. at 2502.

Finally, the panel reiterated its precedent that manufacturers lack protected interests. Op. 20 (citing *AstraZeneca Pharms. LP v. HHS*, 137 F.4th 116, 125-26 (3d Cir. 2025), *pet'n for certiorari filed*, No. 25-348 (S. Ct.)). But that precedent relied on the notion that the IRA does not regulate the prices charged in "private market transactions," *AstraZeneca*, 137 F.4th at 126, a demonstrably mistaken reading of the statute, Br. 52-55; Reply Br. 23-28.

Sincerely,

/s/ John Elwood
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