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August 24, 2026

<u>VIA ECF</u>

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.) – Response to Notice of Supplemental Authority regarding *Teva Pharmaceuticals USA, Inc. v. Kennedy*, No. 25-5425 (D.C. Cir.)

Dear Mr. Cayce,

Teva did not address excessive fines or nondelegation claims. Its due-process analysis overlooks both the distinct provider and patient interests here and this Court's recognition that the IRA regulates *private-market* transactions—not merely government purchases as a "proprietor." Op. 42.

First, *Teva* found no protected interest because it concluded that the Program sets prices "the Government pays." Op. 40 (cleaned up). But CMS does *not* pay the prices it sets; it merely *subsidizes part* of what *private buyers* pay. 42 U.S.C. § 1320f-2(a)(1)-(3); *id.* § 1395w-115(a), (b); Gov't Br. 17, *AstraZeneca v. Kennedy*, No. 25-348 (S.Ct. Dec. 31, 2025). The IRA "sets rules for the entire ecosystem," replacing "free market" pricing with "a government-run process" backed by "severe" consequences. *NICA*, 116 F.4th 488, 494, 499-500, 503 (5th Cir. 2024). CMS is a "regulator," not merely a "proprietor," *contra* Op. 42 (citing *Bowles v. Willingham*, 321 U.S. 503 (1944)), because setting prices in private transactions and deploying massive penalties are regulatory "tool[s] … only a government can wield." *Am. Trucking Ass'ns v. City of Los Angeles*, 569 U.S. 641, 651 (2013). That *Bowles* involved "a war emergency," Op. 42, supports Plaintiffs, because that emergency *enhanced* agency authority, *see Bowles*, 321 U.S. at 520.

Second, *Teva* deemed the Program "voluntary" because it considered "coercion" concerns in *NFIB v. Sebelius*, 567 U.S. 519 (2012), inapplicable "to private businesses." Op. 41. But businesses—dependent on profits to survive—are *more* vulnerable than states to "economic dragooning." Reply 29. Regardless, withdrawal from the Program was "impossible" in the initial cycle. *BMS*, 155 F.4th 245, 276 (3d Cir. 2025) (Hardiman, J., dissenting). And *Teva* never addressed Plaintiffs' argument that *Goldberg v. Kelly*, 397 U.S. 254 (1970), requires adequate process even for voluntary programs. Br. 62-64; Reply 30. Here, the Government admits "there's not process." Oral Arg. 18:43-19:10.

Finally, *Teva* invoked *BIO v. DC* for the proposition that patents confer no right to sell. Op. 43 (quoting 496 F.3d 1362, 1372 (Fed. Cir. 2007)). But *BIO* held that statutory price controls for patented products "conflict[] with Congress's intention to provide … patent holders with the pecuniary reward that follows from the right to exclude." 496 F.3d at 1372.

Sincerely,

<u>/s/ John Elwood</u>
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