

UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF COLUMBIA

TEVA PHARMACEUTICALS USA, INC., *et al.*,

Plaintiffs,

v.

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

Defendants.

No. 1:25-cv-00113-SLS

RESPONSE TO DEFENDANTS' NOTICE OF SUPPLEMENTAL AUTHORITY

Teva writes in response to the government's notice of supplemental authority regarding *Boehringer Ingelheim Pharmaceuticals, Inc. v. U.S. Department of Health & Human Services*, No. 24-2092 (2d Cir. Aug. 7, 2025), and *National Infusion Center Association v. Kennedy*, No. 1:23-cv-707 (N.D. Tex. Aug. 7, 2025). Neither case addressed claims brought under the Administrative Procedure Act—the crux of Teva's challenge here. *See* MSJ 21-37; MSJ Reply 17-37. And neither case warrants rejecting Teva's argument that the Drug Price Negotiation Program violates the Due Process Clause.

Boehringer Ingelheim and *National Infusion Center* both rested on the premise that participation in Medicare and Medicaid is voluntary. But as Teva explained, voluntariness has no relevance under the Due Process Clause. MSJ Reply 43-45. In holding otherwise, *Boehringer Ingelheim* relied on the very Takings Clause cases Teva distinguished as inapt. *See id.*; *Boehringer Ingelheim*, slip op. at 36-37. And *National Infusion Center* merely relied on *Boehringer Ingelheim*, *NICA*, slip op. at 38. Neither court engaged with the core differences between the Takings and

Due Process Clauses or the Supreme Court caselaw emphasizing that distinction. Both *Boehringer Ingelheim* and *National Infusion Center* also fundamentally erred in holding the Program is voluntary—a decision *Boehringer Ingelheim* concluded was compelled by existing Second Circuit precedent that is plainly not binding on this Court, and which *National Infusion Center* reached by again relying on *Boehringer Ingelheim*. See *Boehringer Ingelheim*, slip op. 25-30; *National Infusion Center*, slip op. 35-38; see also MSJ Reply 45-49.

Moreover, neither *Boehringer Ingelheim* nor *National Infusion Center* prove that Teva lacks a protected property interest as both an innovator and generics manufacturer. *Boehringer Ingelheim* and *National Infusion Center* involved claims relevant only to innovators. See *Boehringer Ingelheim*, slip op. at 20-30; *National Infusion Center*, slip op. at 32-34. *Boehringer Ingelheim* and *National Infusion Center* were wrong to hold that an innovator manufacturer lacks a protected property interest in their patents or the expectation that they will receive prevailing market rates, for the reasons Teva has already explained. MSJ 38-41; MSJ Reply 38-43. That aside, nothing in the two decisions undermines Teva’s claim that the Program substantially impairs Teva’s property rights in its generic products, including the rights conferred by its licenses and settlement agreements with innovator manufacturers. MSJ 40-41; MSJ Reply 37-38. The Drug Price Negotiation Program’s deprivation of Teva’s property rights in those contractual agreements absent constitutionally sufficient protections is an independent reason the Program violates due process.

Respectfully submitted,

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