IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF COLUMBIA

ABBVIE INC., *Plaintiff*, v. U.S. DEPARTMENT OF HEALTH AND HUMAN SERVICES, *et al.*, *Defendants*.	**Case No. 1:26-cv-00431 (CJN)** **Oral Argument Scheduled for September 25, 2026**

PLAINTIFF'S RESPONSE TO DEFENDANTS' SECOND NOTICE OF SUPPLEMENTAL AUTHORITIES

Plaintiff AbbVie Inc. respectfully submits this response to defendants' second notice of supplemental authorities (Dkt. No. 45) regarding *AstraZeneca Pharmaceuticals LP* v. *Kennedy*, Civ. No. 25-4212 (D. Md. Aug. 19, 2026); *Merck & Co.* v. *Kennedy*, Civ. No. 23-1615 (D.D.C. Aug. 24, 2026); and *National Infusion Center Association* v. *Kennedy*, __ F. 4th __, 2026 WL 2517285 (5th Cir. Aug. 26, 2026) (*NICA*). If anything, those decisions simply confirm that this Court has jurisdiction to consider AbbVie's claims and that the IRA prohibits the selection of products that contain plasma-derived components. As defendants acknowledge, *AstraZeneca* essentially adopted the D.C. Circuit's reasoning in *Teva Pharmaceuticals USA, Inc.* v. *Kennedy*, __ F.4th __, 2026 WL 2409591 (Aug. 18, 2026). As AbbVie explained in its last submission, that reasoning supports the conclusion that this Court has jurisdiction to review all of AbbVie's claims and that defendants' unlawful action should be set aside. *See* Dkt. No. 44 (AbbVie Response to First Notice of Supp. Authority). In addition, *Merck* is a non-binding decision that rejected First and Fifth Amendment claims by relying on authorities that AbbVie has already distinguished, and

NICA does not address the claims here beyond what *Teva* already decided as to the Due Process Clause.

1. In *AstraZeneca*, a district court in the District of Maryland ruled from the bench that the review-limiting provision in the Inflation Reduction Act (IRA), 42 U.S.C. § 1320f-7, did not deprive the court of jurisdiction to review AstraZeneca's challenge to CMS's "aggregation" policy for qualifying single-source drugs (QSSDs) and that CMS's aggregation policy was lawful under the IRA. *See* Dkt. No. 45-1 (*AstraZeneca* Tr.). With respect to both holdings, *AstraZeneca* expressly followed the D.C. Circuit's reasoning in *Teva*. *See*, *e.g.*, *id*. at 99, 104. And as AbbVie explained in its most recent submission, *Teva* confirms that this Court has jurisdiction and that the IRA's use of the phrase "biological product," as used in the plasma-derived-products exclusion, refers to a whole, finished product, including its inactive components. *See* AbbVie Response to First Notice of Supp. Authority at 1-6.

As to jurisdiction, *Teva* held—and *AstraZeneca* reaffirms—that this Court has jurisdiction to review challenges concerning "the scope of CMS's statutory authority," as opposed to "the quality of the reasoning underlying any such determination." *Teva*, 2026 WL 2409591, at *9. *AstraZeneca* underscores that CMS cannot "shield its interpretations of the IRA" simply by "embedding" an unlawful interpretation within a product-specific determination and then claiming that this determination is unreviewable. *AstraZeneca* Tr. at 102. But that is precisely what defendants seek to do here: based on a previously unannounced active-ingredient policy, they selected a plasma-derived product for price controls despite the IRA's express exclusion of plasma-derived products, then invoked the IRA's review-limiting provision in an attempt to insulate that statutory violation from review. Both *Teva* and *AstraZeneca* foreclose the government's maneuver. It is also foreclosed by the D.C. Circuit's decisions applying the

"merger" doctrine—*i.e.*, the rule that some statutory limitations on jurisdiction merge jurisdictional and merits inquiries—which neither *Teva* nor *AstraZeneca* directly addressed. *See* AbbVie Response to First Notice of Supp. Authority at 2-3; *see also* AbbVie MSJ, Dkt. No. 25, at 16-19 & n.13; AbbVie Reply, Dkt. No. 40, at 6-8.

On the merits, *AstraZeneca* likewise follows *Teva*'s reasoning regarding CMS's "aggregation" policy for QSSDs. *See AstraZeneca* Tr. at 104-108. As AbbVie previously explained, *Teva*'s endorsement of CMS's bundling policy does not resolve the distinct issue in this case about what it means for a biological product to be "derived from human whole blood or plasma" under 42 U.S.C. § 1320f-1(e)(3)(C). *See* AbbVie Response to First Notice of Supp. Authority at 5. And although *Teva* and *AstraZeneca* addressed a different question, both decisions support AbbVie's position that the plasma-derived products exclusion applies when a biological product includes a plasma-derived component, regardless of whether that component is the active ingredient, because the term "drug" "encompass[es] an entire drug product, including both its active and inactive ingredients." *AstraZeneca* Tr. at 108; *see Teva*, 2026 WL 2409591, at *14.

2. In *Merck*, another judge in this district rejected challenges to the Medicare Drug Price Negotiation Program under the Takings Clause, First Amendment, and unconstitutional-conditions doctrine, but its analysis is largely derivative of prior circuit-court decisions that AbbVie discussed at length and distinguished in its summary-judgment briefing. *See Merck*, Op. 8-16 (citing, *inter alia*, *Bristol Myers Squibb Co.* v. *Secretary, HHS*, 155 F.4th 245 (3d Cir. 2025) (*BMS*); *Boehringer Ingelheim Pharmaceuticals, Inc.* v. *HHS*, 150 F.4th 76 (2d Cir. 2025); *Novartis Pharmaceuticals Corp.* v. *Secretary, HHS*, 155 F.4th 223 (3d Cir. 2025)); *see also* AbbVie MSJ 33-44; AbbVie Reply 28-38. *Merck* did not grapple with the counterarguments raised in Judge Hardiman's dissent in *BMS* and in AbbVie's summary-judgment briefing.

3. Finally, in *NICA*, the Fifth Circuit rejected challenges to the Program under the nondelegation doctrine, the Eighth Amendment's Excessive Fines Clause, and the Due Process Clause. With respect to the due-process challenge, the Fifth Circuit expressly relied on *Teva* and reasoned that manufacturers do not have a protected property interest in selling goods to Medicare beneficiaries because they participate in Medicare and Medicaid voluntarily. *See NICA*, Op. 25-26 (citing *Teva*, 2026 WL 2409591, at *18). But like *Teva*, the Fifth Circuit did not address all the reasons set forth by Judge Hardiman (and by AbbVie in its summary-judgment briefs) for why participation in the Program is involuntary. *See* AbbVie Response to First Notice of Supp. Authority at 6 (citing *BMS*, 155 F.4th at 269 (dissenting opinion)). Nor did *NICA* address whether the Program violates the Takings Clause, the First Amendment, or the unconstitutional-conditions doctrine. And the Fifth Circuit's rejection of NICA's nondelegation and Eighth Amendment claims is immaterial because AbbVie raises no such claims in this action.

Date: September 9, 2026

Respectfully submitted,

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CERTIFICATE OF SERVICE

I hereby certify that on September 9, 2026, I electronically filed this document with the Court by using the CM/ECF system, and that this document was distributed via the Court's CM/ECF system.

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