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 REQUESTED

PLAINTIFF'S RESPONSE TO DEFENDANTS' NOTICE OF SUPPLEMENTAL AUTHORITY

Plaintiff AbbVie Inc. respectfully submits this response to defendants' notice of supplemental authority regarding the D.C. Circuit's recent decision in *Teva Pharmaceuticals USA, Inc.* v. *Kennedy*, __ F.4th __, 2026 WL 2409591 (Aug. 18, 2026). *See* Dkt. No. 43 (Supp.). Contrary to defendants' assertion, *Teva* does not undermine this Court's jurisdiction but rather confirms it. And although *Teva* addressed a distinct statutory issue, its merits analysis supports AbbVie's argument that the phrase "biological product," as used in the plasma-derived-products exclusion, refers to a whole, finished product. *Teva* also did not address AbbVie's constitutional challenges under the First Amendment, Takings Clause, or unconstitutional-conditions doctrine.

1. In *Teva*, the D.C. Circuit held 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 Teva's claims. The court emphasized that the presumption in favor of judicial review is "particularly" strong where a party contends that an agency has acted "in excess of delegated authority." Op. 17 (quoting *Amgen, Inc.* v. *Smith*, 357 F.3d 103, 111 (D.C. Cir. 2004)). After all, "[i]f agencies could decide for themselves whether their actions fall within a review bar, they could

enlarge their own authority merely by relabeling what they had done," and "Congress rarely builds such a one-way ratchet into a statute." *Id*. (citing *Amgen*, 357 F.3d at 113). Accordingly, the court reaffirmed that a review-limiting provision does not apply "if the agency's action fails to qualify as the kind of action for which review is barred." *Id*. (citing *Southwest Airlines Co.* v. *TSA*, 554 F.3d 1065, 1071 (D.C. Cir. 2009)).

The D.C. Circuit also distinguished the Supreme Court's recent decision in *Mullin* v. *Doe*, 146 S. Ct. 2121 (2026), based both on the text of the review bar and on the nature of the challenges at issue. Op. 20-21. The statute at issue in *Mullin* barred review of "any" determination made "with respect to" certain decisions, and both of those broadening terms "brought the entire decisional process within the ambit of the review bar." Op. 20 (quoting 146 S. Ct. at 2136). By contrast, the IRA limits review only of "'*the* determination' specified in each subsection" and thus lacks the "broadening" language so "consequential" to the outcome in *Mullin*. *Id*. (quoting 42 U.S.C. § 1320f-7(2). In addition, the plaintiffs in *Mullin* "attacked a series of procedural choices" by the government and objected to the government's "exercise of discretion." Op. 21. Those challenges thus concerned "the quality of the [agency's] reasoning" and its "exercise of discretion," "rather than the scope of its authority." *Id*. (quoting *Ardelyx, Inc.* v. *Kennedy*, 179 F.4th 947, 963 (D.C. Cir. 2026)). By contrast, Teva's claim concerned "the scope of CMS's statutory authority, not the quality of the reasoning underlying any such determination." *Id*. *Teva* therefore forecloses defendants' extensive reliance on *Mullin* in its reply brief, *see* Defs.' Reply, Dkt. No. 42, at 4-5, 7-9, 11-12, and confirms that the Court has jurisdiction to review a claim concerning "the scope of CMS's statutory authority." Op. 21.

Defendants contend that, even under *Teva*'s reasoning, the IRA's review-limiting provision bars AbbVie's statutory challenge because it challenges a "drug-specific determination" rather

than the "overarching" legal standards announced in CMS guidance and applied to BOTOX. Supp. 2-3. But although *Teva* favorably cited cases applying the "merger" doctrine (such as *Amgen*, *Southwest Airlines*, and *Ardelyx*), it did not directly address that doctrine, under which a court deciding whether a judicial-review bar applies must "merge consideration of the legality of the [agency's] action with consideration of [the] court's jurisdiction." *Ardelyx*, 179 F.4th at 956 (citation omitted). Instead, *Teva* held that the IRA's review-limiting provision did not apply at all, regardless of the merits. *See* Op. 15-26. And to the extent *Teva* indirectly addressed the merger doctrine, it reaffirmed that the IRA's review-limiting provision does not apply to a claim that "concerns the scope of CMS's statutory authority, not the quality of the reasoning underlying any such determination." Op. 21. That is precisely the nature of AbbVie's statutory claim: AbbVie's complaint alleged that CMS "acted in excess of its statutory authority" and "violate[d] the express statutory mandate of the IRA," Compl., Dkt. 1, ¶¶ 55, 60, and sought a declaration "that CMS has violated the Administrative Procedure Act (or, alternatively, acted *ultra vires*) by exceeding the limitations on its statutory authority set forth in the Inflation Reduction Act of 2022," *id*. at 26.

Defendants nevertheless argue (Supp. 2-3) that AbbVie's claim is precluded under *Teva* because AbbVie seeks vacatur of defendants' selection of BOTOX. But defendants quote the relevant language from *Teva* out of context. There, as noted, the D.C. Circuit explained that the IRA's review-limiting provision would bar a challenge to "particular drug-specific determination[s]" insofar as such a challenge concerns "the reasoning underlying any such determination" rather than "the scope of CMS's statutory authority." Op. 21. In other words, the court treated as "distinct tasks" the acts of "[m]aking the required drug-specific 'determination' " and "interpreting the IRA," and it made clear that the agency's application of the statute must remain reviewable; otherwise, "CMS could rewrite the statute and then shield its rewrite merely

by applying it." Op. 19-20. *Teva* had no occasion to address the circumstances in which a party may directly challenge an agency's determination as exceeding its statutory authority, because no such challenge was before the court. And defendants' expansive reading would bring *Teva* into direct conflict with prior D.C. Circuit cases in which the merger rule *was* presented. For example, *Ardelyx*, 179 F.4th at 957, and *Southwest Airlines Co.* v. *TSA*, 554 F.3d 1065, 1069, 1071 (D.C. Cir. 2009)—both of which *Teva* cited approvingly—addressed the reviewability of challenges to *particular* agency determinations, not just general policies.

Regardless, even under defendants' strained reading, *Teva* still would not require dismissal of AbbVie's claims. That is because AbbVie's complaint specifically requested an order not only "vacat[ing] the selection of BOTOX" but also "declar[ing] that CMS has violated the Administrative Procedure Act . . . by exceeding the limitations on its statutory authority set forth in the Inflation Reduction Act of 2022." Compl. 26. That form of relief—which does not mention the selection of BOTOX—also plainly "concerns the scope of CMS's statutory authority, not the quality of the reasoning underlying any such determination." *Teva*, Op. 21.[*]

2. As to the merits, although *Teva* addressed a distinct statutory issue, its reasoning supports AbbVie's argument that the term "biological product," as used in the plasma-derived-products exclusion, 42 U.S.C. § 1320f-1(e)(3)(C), refers to a whole, finished product, including

[*] Defendants suggest (Supp. 3 & n.2) that AbbVie waived that argument for jurisdiction. That is incorrect for the reasons explained. Moreover, defendants ignore that AbbVie challenged "the selection of BOTOX, *not just* the means by which drugs are determined to be a [QSSD]"—language that makes clear that AbbVie preserved both objections. AbbVie Reply 10 (emphasis added). In fact, AbbVie expressly noted that "[t]his Court would also have jurisdiction to review challenges to CMS's recently unveiled [active ingredient] 'policy.'" *Id.* at 11 n.2. Nor do defendants provide any reason to apply waiver or forfeiture here, where the issue turns on pure questions of law that have been extensively briefed by the parties and where dismissal based on jurisdiction would be without prejudice, meaning that AbbVie could refile its complaint on essentially the same legal grounds.

its active *and* inactive components. In *Teva*, the D.C. Circuit upheld CMS's "aggregation" policy for "qualifying single source drugs" (QSSDs), holding that the IRA permits defendants to bundle multiple drug products that "share the same active moiety and manufacturer" "as one 'qualifying single source drug.'" Op. 3. As defendants acknowledge (Supp. 5), that challenge is distinct from the one raised here. *See* Op. 6 (noting that "none of [the statutory] exclusions" were at issue). *Teva*'s conclusion that CMS can bundle multiple drug products as one QSSD and can aggregate them based on their active moiety does not answer what it means for a biological product to be "derived from human whole blood or plasma." 42 U.S.C. § 1320f-1(e)(3)(C). Indeed, in the same guidance that adopted the QSSD-aggregation policy, CMS took an entirely different approach to the plasma-derived-products exclusion, interpreting it to refer to a "licensed biological product that is derived from human whole blood or plasma, *as indicated on the approved product labeling*." CMS, Medicare Drug Price Negotiation Program: Final Guidance, Implementation of Sections 1191 – 1198 of the Social Security Act for Initial Price Applicability Year 2028 and Manufacturer Effectuation of the Maximum Fair Price in 2026, 2027, and 2028, at 173 (2025) (emphasis added).

In any event, *Teva*'s reasoning reinforces that the plasma-derived-products exclusion uses the term "biological product" to refer to a whole, finished product. The court rejected Teva's argument that a QSSD is defined by a single new drug application (NDA), but it did not hold that a QSSD is defined solely by a product's active ingredient. Rather, in endorsing CMS's practice of bundling products, the court interpreted the term "qualifying single source drug" to encompass all dosage forms, strengths, and formulations of a product with the same active moiety from the same NDA holder. Op. 28-29. Because the bundling policy sweeps in products that differ in their formulation, *Teva*'s reasoning illustrates that all components of a drug or biological product—including inactive ones—are part of a single QSSD. That reasoning is consistent with AbbVie's

argument that the IRA uses the term "biological product" to refer to a whole product in its finished, licensed form, including its active and inactive components; otherwise, there would be no need for CMS to specify that bundling is based on active ingredients.

What is more, the D.C. Circuit recognized in *Teva* that the Supreme Court has held "that a 'drug' could encompass the finished product, including its active and inactive ingredients," regardless of "whether products containing the same active ingredients could 'under some circumstances be the same drug.'" Op. 30-31 (quoting *United States* v. *Generix Drug Corp.*, 460 U.S. 453, 459-461 (1983)). And *Teva* looked to the fact that "[p]atients take drugs, not NDAs," to support its understanding of what constitutes a "drug." Op. 29-30. That whole-product approach, as AbbVie has explained, confirms that the plasma-derived-products exclusion applies when a biological product includes a component derived from human whole blood or plasma, regardless of whether that component is active or inactive in the product.

3. Finally, although the D.C. Circuit rejected Teva's due-process claim, it did not address whether the Drug Price Negotiation Program violates the First Amendment, Takings Clause, or unconstitutional-conditions doctrine—the three other constitutional claims that AbbVie has asserted here. Defendants suggest (Supp. 6) that *Teva* indirectly addressed AbbVie's takings claim, but that decision did not implicitly foreclose a claim not before the court. Nor did *Teva* address the reasons set forth by Judge Hardiman for why, for purposes of the Takings Clause, participation in the Program is involuntary. *See Bristol Myers Squibb Co.* v. *Secretary, HHS*, 155 F.4th 245, 269 (3d Cir. 2025) (dissenting opinion). And defendants themselves appear to concede that *Teva* sheds no light on AbbVie's claims under the First Amendment or unconstitutional-conditions doctrine.

Date: August 28, 2026

Respectfully submitted,

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CERTIFICATE OF SERVICE

I hereby certify that on August 28, 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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