ORAL ARGUMENT NOT YET SCHEDULED

IN THE UNITED STATES COURT OF APPEALS
FOR THE DISTRICT OF COLUMBIA CIRCUIT

TEVA PHARMACEUTICALS USA, INC., *et al.*, *Plaintiffs-Appellants*, v. ROBERT F. KENNEDY, JR., in his official capacity as SECRETARY OF HEALTH AND HUMAN SERVICES, *et al.*, *Defendants-Appellees*.	No. 25-5425

UNOPPOSED EMERGENCY MOTION TO EXPEDITE

Plaintiffs-Appellants Teva Pharmaceuticals USA, Inc.; Teva Branded Pharmaceutical Products R&D LLC; and Teva Neuroscience, Inc. (Teva) move to expedite this case to the extent of the Court (1) entering the briefing schedule set forth below and (2) directing the Clerk to set the case for argument before the Court's summer break in oral argument.

Teva requests that the Court act on this motion by December 10, 2025, because the proposed briefing schedule calls for Teva to file its opening brief on January 9, 2026, and processing the motion in the normal course risks a decision near to or even after that proposed deadline. *See* Circuit Rule 27(e) (an

"emergency" motion is simply one that requires a decision "in less time than would be required for this court to receive and consider a response"). The Government does not oppose the relief requested in this motion.

1. This appeal arises from the Inflation Reduction Act's "Drug Price Negotiation Program." Under the Program, the Centers for Medicare & Medicaid Services (CMS) imposes a "Maximum Fair Price" (MFP) on certain of the Medicare Program's highest-spend drugs. *See* D. Ct. Dkt. No. 46 at 3-4. CMS determines the highest-spend drugs from among what the Act defines as "qualifying single source drugs." *See* 42 U.S.C. § 1320f-1(a), (d)-(e).

A "qualifying single source drug" is one covered by Medicare Part D or eligible for reimbursement under Medicare Part B and (1) is approved by the Food and Drug Administration "under section 355(c) of Title 21 and is marketed pursuant to such approval"; (2) "at least 7 years [has] elapsed since the date of such approval"; and (3) the drug "is not the listed [brand-name] drug for any [generic] drug that is approved and marketed under" an FDA-approved abbreviated new drug application. *Id.* § 1320f-1(e)(1)(A). Under these statutory requirements, a drug cannot be a qualifying single source drug unless seven years have elapsed since FDA approval. And a qualifying single source drug no longer qualifies once a generic competitor is approved by FDA and "marketed." *Id.*

The Act provides that "[t]here shall be no administrative or judicial review of . . . [t]he selection of drugs . . . , the determination of negotiation-eligible drugs . . . , and the determination of qualifying single source drugs." 42 U.S.C. § 1320f-7(2). The Act also effectively requires a manufacturer to accept CMS's final MFP offer, because a manufacturer who wishes to refuse CMS's offered MFP must either withdraw *all* of its drugs from Medicare and Medicaid or pay an exorbitant excise tax. *See* D. Ct. Dkt. No. 46 at 7.

2. The Inflation Reduction Act directs CMS to implement the Drug Price Negotiation Program through "instruction or other forms of program guidance" for Program initial price applicability years (IPAYs) through 2028. 42 U.S.C. §§ 1320f note, 1320f-1 note. Two aspects of CMS's guidance for IPAY 2027 are relevant to this case. First, the guidance defines a "qualifying single source drug" as any set of drugs "with the same active moiety"—the drug molecule that is "responsible for the [drug's] physiological or pharmacological action," 21 C.F.R. § 314.3—so long as the new drug applications for the drugs are held by the same entity. CMS, *Medicare Drug Price Negotiation Program: Final Guidance, Implementation of Sections 1191-1198 of the Social Security Act for IPAY 2027 and Manufacturer Effectuation of the Maximum Fair Price in 2026 and 2027*, at 167 (Oct. 2, 2024), https://perma.cc/AJ33-F9U4 (2027 Guidance).

Second, the guidance defines "marketing" of a generic as "bona fide marketing," such that "meaningful competition exists on an ongoing basis between a listed drug . . . and a generic drug." *Id.* at 20, 170. This supposedly "holistic inquiry" will be based on the "totality of the circumstances" and "informed by" two inherently time-lagged data sources. *Id.* at 21, 171, 278-280, 293.

3. Teva markets both AUSTEDO and AUSTEDO XR, drugs that are indicated to treat two movement disorders: tardive dyskinesia, a disease associated with long-term use of antipsychotic medications; and Huntington's disease chorea, a rare, terminal genetic disease. Although AUSTEDO and AUSTEDO XR were approved under separate new drug applications held by distinct Teva entities and AUSTEDO XR has been FDA-approved for fewer than seven years, they share the same active moiety—deutetrabenazine. *See* D. Ct. Dkt. No. 46 at 10. CMS therefore classified AUSTEDO and AUSTEDO XR as a single qualifying single source drug and selected them to receive an MFP beginning on January 1, 2027. *See id.*

Teva also plans over the next several years to launch generics that will compete with innovator drugs that have been selected for an MFP. D. Ct. Dkt. No. 15-1 at 17-20; D. Ct. Dkt. No. 15-3 ¶¶ 22-27. But CMS's formless bona fide marketing test makes it impossible for Teva to know in advance whether its generics will be considered "marketed" in time to end the innovator drug's MFP,

which is necessary for Teva's generics to obtain sufficient market share at launch. D. Ct. Dkt. No. 15-3 ¶¶ 44-46.

4. Teva sued CMS, alleging that the guidance's atextual definitions of "qualifying single source drug" and "marketed" are contrary to the Inflation Reduction Act and unlawful under the Administrative Procedure Act. D. Ct. Dkt. No. 46 at 12. Teva also alleged that the Inflation Reduction Act's draconian penalties for manufacturers resisting CMS's MFP—particularly when combined with the Act's limitations on judicial review—violated the Fifth Amendment's due process guarantees. *Id.* Teva and the Government cross-moved for summary judgment, with the Government contending that the Act's judicial-review bar precluded review of Teva's APA claims. *Id.*

5. The District Court held that the Act's judicial-review bar did not apply to Teva's APA claims. *Id.* at 12-19. But the District Court disagreed that CMS's definition of qualifying single source drug was unlawful. *Id.* at 19-25. The District Court further held that Teva's challenge to CMS's bona fide marketing definition was unripe—a contention that the Government had not even raised. *See id.* at 25-30. And the District Court held that Teva did not have a constitutionally protected property interest that would trigger due-process scrutiny. *Id.* at 30-36. Teva appealed to this Court the same day. D. Ct. Dkt. No. 48.

6. Expedition is warranted so that this Court can decide Teva's appeal before the end of 2026. Although CMS determines a drug's MFP, Medicare Part D drugs are paid for by Medicare Part D plan sponsors, which are private companies. *See* D. Ct. Dkt. No. 46 at 2-3. A decision before the end of 2026 will allow the Court and the parties to avoid any remedial questions that might arise if Teva were to prevail after AUSTEDO and AUSTEDO XR's MFP goes into effect on January 1, 2027.

7. Teva proposes the following briefing schedule:

Teva's Opening Brief:	January 9, 2026.
Joint Appendix:	January 9, 2026.
Government's Response Brief:	March 10, 2026.
Teva's Reply Brief:	March 31, 2026.

8. Teva further requests that the Court direct the Clerk to schedule oral argument in May before the Court ceases hearing oral argument over the Summer. *See D.C. Circuit Handbook of Practice & Internal Procedures* 47 (Aug. 11, 2025). If the Court does not hear oral argument before the Summer break, oral argument will not occur before September 2026, which will make it difficult for the Court to render its decision before the end of 2026.

9. Neither the Government nor the Court will be prejudiced by this schedule. The proposed briefing schedule ensures that the Government receives

the full 60 days for its brief that it usually requests in civil appeals, and the Government does not oppose the motion. The Court will also not be prejudiced because briefing will be complete before April, allowing the Court adequate time to prepare for a May oral argument.

For the foregoing reasons, the motion should be granted.

Respectfully submitted,

/s/ Sean Marotta
SEAN MAROTTA
DANIELLE DESAULNIERS STEMPEL
DANA A. RAPHAEL
KATHERINE T. MCKAY
HOGAN LOVELLS US LLP
555 Thirteenth Street, N.W.
Washington, D.C. 20004
(202) 637-4881
sean.marotta@hoganlovells.com

Counsel for Plaintiffs-Appellants

December 2, 2025

CERTIFICATE OF COMPLIANCE

1. This document complies with the type-volume limits of Fed. R. App. P. 27(d)(2) because, excluding the parts of the document exempted by Fed. R. App. P. 32(f), this document contains 1305 words.

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/s/ Sean Marotta
Sean Marotta

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I hereby certify that on December 2, 2025, the foregoing was electronically filed through this Court's CM/ECF system, which will send a notice of filing to all registered users.

/s/ Sean Marotta
Sean Marotta