IN THE 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*.	Civil Action No. 25-113 (SLS)

JOINT MOTION TO VACATE THE ANSWER DEADLINE
AND SET SUMMARY JUDGMENT BRIEFING SCHEDULE

The parties jointly move to vacate Defendants' deadline to answer Plaintiffs' complaint and to set a briefing schedule for motions for summary judgment.

1. Teva Pharmaceuticals USA, Inc.; Teva Branded Pharmaceutical Products R&D, LLC; and Teva Neuroscience, Inc. (collectively, Teva) brought this lawsuit challenging certain aspects of the drug-pricing provisions of the Inflation Reduction Act of 2022 and related guidance issued by the Centers for Medicare & Medicaid Services (CMS).

2. Teva filed its complaint on January 15, 2025. ECF No. 1. Teva then filed an amended complaint on February 10, 2025. ECF No. 9. Defendants' deadline to answer Teva's First Amended Complaint is March 18, 2025. *See* ECF No. 5; Fed. R. Civ. P. 15(a)(3).

3. The parties have conferred regarding the most efficient approach to this litigation. The parties agree that none of Teva's claims will require discovery, witness testimony, or trial, and should instead be resolved on dispositive motions. The parties further agree that Defendants will not submit an administrative record in this matter. To the extent the parties intend to reference any administrative documents not already publicly available, they will submit them to the Court

by attaching them as exhibits to their briefs. The parties reserve the right to object to any documents submitted in this way.

4. The parties have agreed to the briefing schedule and page limitations set forth below and respectfully request that the Court adopt the schedule and page limitations by order.

a. Teva will file a motion for summary judgment, not to exceed 45 pages, by February 26, 2025;

b. Defendants will file a combined response to Teva's motion and cross-motion for summary judgment, not to exceed 55 pages, by April 3, 2025;

c. Teva will file a combined response to Defendants' cross-motion and any reply in support of its motion, not to exceed 50 pages, by April 28, 2025; and

d. Defendants will file any reply in support of their cross-motion, not to exceed 35 pages, by May 21, 2025.

5. Because this case involves the facial constitutionality of a federal statute and related claims under the Administrative Procedure Act, the parties further respectfully request that the Court dispense with Local Civil Rule 7(h)(1)'s requirement that motions for summary judgment be accompanied by separate statements of material facts. The parties do not believe those statements would serve a useful purpose in this matter.

6. For essentially the same reasons, the parties respectfully request that the Court also dispense with Defendants' obligation to file an answer to the complaint.

7. Teva respectfully requests the Court's decision on the parties' cross-motions for summary judgment by **June 30, 2025**. CMS has selected Teva's innovator products AUSTEDO and AUSTEDO XR for inclusion in the Drug Price Negotiation Program beginning this year. By

June 30, 2025, Teva must provide CMS with its counter-offer as part of the process of determining the statutory Maximum Fair Prices that will apply to AUSTEDO and AUSTEDO XR. A decision from this Court by June 30, 2025, would provide helpful guidance that would inform Teva's approach to doing so. If the Court invalidates CMS's guidance regarding the definition of Qualifying Single Source Drug, Teva's AUSTEDO XR will no longer be subject to the negotiation process because its New Drug Application is fewer than seven years old. Even assuming that Teva's AUSTEDO remains selected for negotiation, Teva's counter-offer will be completely different if it is proposing a price for AUSTEDO alone rather than AUSTEDO and AUSTEDO XR. Moreover, if the Court invalidates CMS's "bona fide marketing" standard, that will inform Teva's ongoing evaluation of whether to continue its investment and preparation for generic launches that will compete with branded drugs selected for negotiation. Defendants do not join in this request. Defendants take no position on when the Court should issue any decision, do not believe that expedited decision is warranted, and defer to the Court about how best to manage its docket.

8. A proposed order is attached.

Dated: February 21, 2025

Respectfully submitted,

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