

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.

No. 25-5425

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

Defendants-Appellees.

NONBINDING STATEMENT OF ISSUES TO BE RAISED

1. Whether the Centers for Medicare & Medicaid Services’ definition of “qualifying single source drug” unlawfully conflicts with the Inflation Reduction Act’s definition of that term.
2. Whether Teva’s challenge to CMS’s “bona fide marketing” standard is ripe.
3. Whether CMS’s subjective, atextual “bona fide marketing” standard unlawfully conflicts with the Inflation Reduction Act’s definition of “marketed.”

4. Whether the Inflation Reduction Act's Medicare Drug Price
Negotiation Program violates Teva's due process rights.

Respectfully submitted,

/s/ Sean Marotta

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December 2, 2025

CERTIFICATE OF SERVICE

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