



August 14, 2026

Dr. Mehmet Oz, Administrator
Centers for Medicare & Medicaid Services
Department of Health and Human Services
Baltimore, MD 21244

Re: Proposed Rule for Medicare Drug Price Negotiation Program and Medicare Prescription Drug Benefit Program [[CMS-4215-P](#)]

Dear Administrator Oz:

Thank you for the opportunity to comment on the Centers for Medicare & Medicaid Services' proposed revision to the fixed drug combination policy under the Medicare Drug Price Negotiation Program. The [Center for American Principles](#) (CAP) is a non-profit issue advocacy organization dedicated to promoting free markets and advancing sound policy solutions to the country's most critical challenges.

We are deeply concerned the proposed rule threatens critical investment in continuing medical innovation. Under the [proposal](#), CMS could identify certain fixed drug combinations (FDCs) as the same "Qualifying Single Source Drug" (QSSD) if they have the same manufacturer as an older FDC and an added active ingredient that enables a change in the route of administration.

This approach effectively lumps in new therapies with older products for the purpose of prematurely subjecting a new product to price negotiation. If the older product has already been selected for government price negotiations, the new therapy could become subject to the same price controls as soon as it enters the market. That, in turn, would devalue the newer product's patent protections, eroding the ability of producers to invest in follow-on—or post-FDA-approval—innovation, which carries many of the same costs and risks as pre-approval innovation.

These drugs may share active ingredients, but they are not the same. New products that change the route of administration have a profound impact on patient health. Creating an injectable version of an intravenous drug, for example, can allow patients to self-administer medicines rather than traveling to clinics to receive infusions. That can [help](#) make treatment easier for patients and improve adherence, especially for those who live in rural areas, have mobility limitations, or require frequent treatment.

Importantly, such new products require significant added investment in scientific research, clinical trials, and FDA review. The limited periods of market exclusivity provided by relevant patent rights enable the innovator to recoup development costs and earn a profit. U.S.

pharmaceutical and biotechnology innovators [re-invest](#) a higher share of revenues into research and development than any other U.S. industry.

Companies making decisions about research projects must assess years in advance whether a product will deliver returns. If a new product will immediately be subject to government price controls, the economic case for pursuing such an improvement falls apart. That means less innovation and fewer treatment options for patients.

CAP therefore urges CMS to more narrowly define QSSDs—they should be limited to drugs approved under the same New Drug Application or licensed under the same Biologics License Application. Products that contain an added active ingredient that enables a change in the route of administration should be treated as separate QSSDs. These revisions would help to sustain investment in continuing innovation, enabling companies to continue developing new treatments.

Thank you for the opportunity to comment.

Sincerely,

A handwritten signature in black ink, reading "Anthony J. Zagotta". The signature is fluid and cursive, with the first name "Anthony" and last name "Zagotta" clearly legible.

Anthony J. Zagotta
President, Center for American Principles