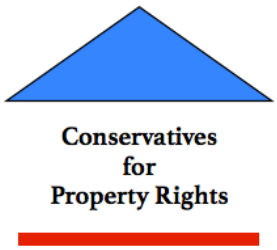

August 5, 2026

Dr. Mehmet Oz
Administrator
Centers for Medicare & Medicaid Services
Department of Health and Human Services
7500 Security Boulevard
Baltimore, MD 21244

Re: Medicare Drug Price Negotiation Program and Medicare Prescription Drug Benefit Program (CMS-4215-P)

Dear Administrator Oz:

Conservatives for Property Rights (CPR) appreciates the opportunity to weigh in on the Centers for Medicare & Medicaid Services' (CMS) proposed modification in CMS-4215-P to the fixed-combination drug policy under the Medicare Drug Price Negotiation Program.

We recognize that CMS has responded to feedback by narrowing the proposal it considered last year. Rather than broadly aggregating many reformulated products, the agency now targets a limited category of fixed drug combinations (FDCs) involving an added active ingredient that enables a change in the route of administration.

While this approach is more precise, it does not resolve our principal concern. The proposed policy still infringes on inventors' rights to enjoy the full value of their patented inventions.

Patents are not regulatory conveniences that agencies may discount when they become politically inconvenient. They are constitutionally grounded property rights that secure the exclusive fruits of innovation. By refusing to recognize separately patented, FDA-approved medicines as distinct products for purposes of Medicare negotiation, CMS would erode those rights and diminish the legal certainty upon which American innovation depends.

America's entire economy depends on a simple principle: private property deserves meaningful legal protection. Intellectual property is no exception. The Constitution empowers Congress to secure exclusive rights for inventors because those rights encourage discovery, investment, and technological progress. A patent is valuable not simply because it exists on paper, but because the owner can reasonably expect to enjoy the economic benefits that accompany it. When government policies substantially diminish those benefits, they weaken the property right itself. That is, without the absolute right to exclude others, including competitors, patent infringers, and the government, from use of that invention without a license at market value, the Founders’

balanced means of “promot[ing] the progress of science and useful arts” is disrupted —a disincentive to all those inventing and commercializing in the same art or technological field.

That principle of secure, reliable, exclusive rights in the newly created property that the “deed” (i.e., the patent) covers is especially important in biomedical research. Developing a new medicine routinely requires more than a decade and requires billions of dollars in investment. The failure rate is extraordinarily high. Only about one in every 10 drugs entering clinical trials ultimately receives FDA approval.

Companies accept those extraordinary risks because the patent system promises that innovation will receive meaningful protection. Undermining that expectation threatens not only individual products but also the integrity of the property-rights framework that has made the United States the world's leader in medical innovation.

CMS's proposal would nevertheless tie the pricing of an approved medicine to an earlier product instead of recognizing it as a distinct innovation. Although the patents would remain legally enforceable, the government would substantially diminish their economic value by denying the invention the independent treatment ordinarily associated with separate patents and FDA approval. Property rights lose meaning when the government preserves formal legal title while stripping away the practical benefits those rights are intended to secure. This proposal breaks faith with the long-established recognition that a new product related to an existing invention is in fact an invention patentable in its own right.

This problem is especially troubling for innovations that improve how patients receive treatment, such as converting intravenous therapies into subcutaneous injections. The addition of an ingredient that enables a change in the route of administration requires additional research, clinical testing, manufacturing investment, regulatory review, and new intellectual effort—not to mention new investment. They can reduce administration time, expand access, ease caregiver burdens, and improve convenience, particularly in rural communities. FDCs are new products; treating them as extensions of older medicines makes intellectual property contingent on administrative preference rather than the rule of law.

Congress established specific timelines and definitions in the Inflation Reduction Act, and nothing authorizes CMS to disregard separately patented, FDA-approved innovations from the same manufacturer simply because they share an active ingredient with an earlier medicine.

For these reasons, Conservatives for Property Rights respectfully urges CMS to revise the proposed modification to the fixed combination drug policy and apply the same standard to all FDCs.

Doing so would protect intellectual property, maintain incentives for innovation, and uphold the legal framework that continues to make the United States the world's leading engine of medical discovery.

Sincerely,

James Edwards, Ph.D.
Founder and Executive Director
Conservatives for Property Rights