June 26, 2025

Chris Klomp
CMS Deputy Administrator
Director, Center for Medicare
7500 Security Boulevard
Baltimore, MD 21244

Re: Request for Comments Regarding the Inflation Reduction Act (IRA) Medicare Drug Price Negotiation Program Draft Guidance (Docket No. CMS-2025-0054)

Dear Director Klomp,

The Alliance of U.S. Startups & Inventors for Jobs (USIJ) respectfully submits these comments on the Centers for Medicare & Medicaid Services' draft guidance for the third cycle of Medicare drug price negotiations.

USIJ is deeply concerned that CMS is considering treating separately patented, FDA-approved reformulated drugs as indistinguishable from their predecessors for pricing purposes. This is not a minor technical matter -- it would operate as a backdoor price control, effectively overriding valid patent rights and weakening the protections that make follow-on innovation economically feasible. If CMS moves forward with this approach, it will discourage investment in exactly the kinds of improvements patients depend on: new formulations, better delivery methods, and expanded indications for existing therapies.

USIJ is a group of inventors, startup companies, venture capitalists, incubators, and research institutions who have come together in the interest of safeguarding our nation's innovation ecosystem. Our members have helped pioneer technologies in fields ranging from medical devices and biotechnology to clean energy and cloud computing. These breakthroughs were made possible because the U.S. patent system provides a clear and reliable framework to protect and commercialize new ideas.

But that framework only works if we respect it. By contemplating whether to group reformulated drugs with older versions based on whether a given component is "therapeutically active," CMS risks ignoring how real-world innovation works -- and how it is evaluated by both the U.S. Patent and Trademark Office and the FDA. These agencies routinely recognize reformulated products as distinct. If CMS blurs that distinction for pricing purposes, a newly approved therapy could face price controls on day one, despite holding its own valid patents and full FDA approval.

The signal this would send is deeply worrying. Why would any company invest in a subcutaneous version of an infused biologic, explore new dosing regimens, or study new uses for an existing compound if the resulting innovation will be lumped into a pricing category with a decade-old product? The answer is simple: they won't. And as a result, patients will lose access to precisely the kinds of incremental advances that improve safety, effectiveness, convenience, and reach.

Innovation depends on clarity. Startups, universities, and investors rely on the expectation that improvements will be judged on their own merits and protected accordingly. Undermining that expectation -- especially through regulatory guidance rather than legislation -- injects risk and uncertainty across the development pipeline for all advanced technologies.

The Inflation Reduction Act does not authorize this policy. Congress carefully structured the statute to contain targeted tools for cost control while minimizing harm to innovation. Nothing in the law empowers CMS to collapse distinct, separately patented drugs into a single pricing category. This reinterpretation exceeds the agency's statutory authority and undercuts the Constitution's commitment to securing exclusive rights for inventors.

This proposal is especially troubling given the broader policy climate, where inventors already face mounting threats to their intellectual property rights, including repetitive administrative patent challenges and proposed legislative constraints. CMS's contemplated reinterpretation of what qualifies as a distinct, single source drug adds another layer of risk.

The implications of this decision extend far beyond Medicare -- and even beyond the life sciences. If one agency can disregard valid patents when they conflict with cost-containment goals, inventors across high-tech sectors will reasonably question whether other parts of government might follow suit. That would erode global confidence in the U.S. innovation system and accelerate the shift of investment, talent, and discovery to more predictable policy environments.

USIJ urges CMS to reconsider this potential policy and publicly commit that FDA-approved, separately patented reformulations will be treated as distinct qualifying single source drugs for purposes of the Medicare Drug Price Negotiation Program. That position aligns with how the USPTO and FDA recognize and evaluate innovation. It would preserve the incentives that fuel continued medical progress and send a clear signal that the United States remains the best place in the world to build, fund, and scale breakthrough technologies.

Thank you for considering these comments.

Sincerely,

Chris Israel
Executive Director
Alliance of U.S. Startups and Inventors for Jobs