August 17, 2026

Dr. Mehmet Oz
Administrator
Centers for Medicare & Medicaid Services
7500 Security Boulevard
Baltimore, MD 21244

RE: Requests for Comments on Medicare Drug Price Negotiation Program and Medicare Prescription Drug Benefit Program Proposed Rule, File Code CMS-4215-P

Dear Administrator Oz,

The Bayh-Dole Coalition appreciates the chance to comment on the Centers for Medicare & Medicaid Services' proposed change to the fixed combination drug policy under the Medicare Drug Price Negotiation Program and Medicare Prescription Drug Benefit Program (CMS-4215-P).

The Bayh-Dole Coalition is a group of innovation-oriented organizations and individuals committed to celebrating and protecting the Bayh-Dole Act, as well as informing policymakers and the public of its many benefits. That bipartisan law enabled universities, federal laboratories, and small businesses to patent, and license, their researchers' federally funded discoveries to private companies that could perform the additional research necessary to turn good initial ideas into tangible products. Bayh-Dole's practical operation depends not only on the ability to obtain patents, but also on the ability of universities, federal laboratories, startups, and their private-sector partners to license and develop inventions under commercially intelligible conditions. Regulatory policies that unexpectedly compress the commercialization window for later-approved, clinically meaningful products can affect those decisions. The resulting technology transfer under Bayh-Dole has helped launch more than 21,000 startups and led to the development of thousands of new products, including over 200 drugs and vaccines.

The Coalition rarely comments on prescription drug pricing policy. CMS' proposed modification to the fixed combination drug policy warrants an exception — because it reaches beyond drug pricing and into the intellectual property framework that supports medical innovation. The proposed change would require certain newly approved fixed-dose combination products to be considered the same qualifying single source drug (QSSD) as an earlier product from the same manufacturer if they share one active ingredient and add another that enables a change in the route of the drug's administration. As a result, the newer product would become eligible for price setting based on the earlier product's approval date rather than its own.

Although the proposal does not alter patent term or FDA exclusivity directly, it would materially reduce the expected commercial value of certain patented, FDA-approved products. That prospect can affect the private investment, licensing, and development decisions that are indispensable to translating federally funded discoveries into products for patients. This would weaken the incentives that drive continued investment in medical research in the United States and encourage critical innovation to shift offshore.

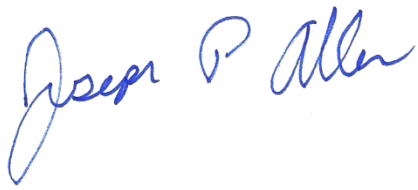
Companies and their investors often make research and development decisions based on expected returns. This is particularly true where a university or federal laboratory licensee must finance clinical development, manufacturing scale-up, and regulatory review. Bayh-Dole has succeeded for more than four decades because innovators can rely on patents protecting successful inventions to retain meaningful economic value. CMS' rule introduces the kind of uncertainty that Congress passed the Bayh-Dole Act to eliminate.

That uncertainty falls hardest on the smaller companies that the Bayh-Dole Act was meant to empower. Small and mid-sized companies accounted for 72% of new FDA drug approvals in 2024. It is these companies — not large, diversified manufacturers — that are least able to absorb a sudden change to a new product's commercial outlook. Roughly 90% of drug candidates that enter clinical trials ultimately fail. Especially at smaller companies, the rare successes must generate enough value to justify taking chances that could lead to massive breakthroughs.

This proposal would make American biotech companies less globally competitive. We must continue to preserve predictable U.S. commercialization conditions for the next era of inventions and global solutions to emerge from federally supported research. China's share of global clinical trials for the world's most innovative drugs has grown sixfold over the past decade. It now rests at 30%, barely behind the U.S. share. America's continued leadership depends on an innovation ecosystem built around strong patents, technology transfer, and private investment. Eroding the commercial predictability that supports patent-based technology transfer, even for a narrow category of products, weakens our Bayh-Dole system.

The Bayh-Dole Act has helped make America the world's leader in life sciences. But our standing is vulnerable. We urge CMS to maintain separate QSSD classifications for FDA-approved fixed-dose combination therapies, including those in which an added ingredient enables a different route of administration — and in doing so, preserve the intellectual property protections that have made America the global leader in medical innovation.

Sincerely,



Joseph P. Allen
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Bayh-Dole Coalition