What They Are Saying
CMS's Fixed-Dose Combination Proposal

"Providers and patients increasingly benefit from innovations that reduce the time and infrastructure required to administer complex therapies. **A policy that accelerates price regulation for these products may suppress investment precisely where delivery system improvements could expand capacity and improve patient experience.**" – Michael Baker, American Action Forum (AAF)

"CMS reliably revisits the IRA to shatter the hope that policy will support innovation, growth, and consumer welfare. Here we go again…**The cardinal sin of the IRA is price-fixing, and the new policy would essentially bleed a fixed price into even more drugs**. This is literally a step from bad to worse. It makes the disregard for patients and innovation incentives even more dramatic. It is not a step that CMS should take." – Douglas Holtz-Eakin, American Action Forum (AAF)

"The proposal is especially concerning because many important improvements to existing medicines require significant additional research, clinical trials, and separate FDA approval. **Treating these products as if they are no different from the original medicine gives innovators less reason to pursue improvements after a drug first reaches the market**." – Jon Decker, American Commitment

---

"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.**" – Anthony J. Zagotta, Center for American Principles

---

"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**." – James Edwards, Conservatives for Property Rights

---

"CMS should not substitute its own judgment for FDA's in order to expand its pricing authority. New formulations are not mere convenience upgrades. This work requires years of additional research and its own clinical testing. If this rule

is finalized as proposed, improving how a drug is delivered becomes a liability." – Grover Norquist and Isabelle Marchese, Americans for Tax Reform (ATR)

"CMS should not magnify the Inflation Reduction Act's price-control effects by treating meaningful, independently approved improvements as mere extensions of earlier products. **This approach risks sweeping legitimate medical advances into an overbroad aggregation policy and discouraging the development of better treatment options for patients**." – Andrew Langer, Executive Director, Coalition Against Socialized Medicine (CASM)

"CASE strongly urges CMS to reconsider policies in the proposed IPAY 2029 rule that expand the reach of government price controls and maintain separate QSSD treatment for FDA-approved fixed-dose combination products. **Protecting consumers requires lowering healthcare costs today while preserving the innovation necessary to deliver better treatments tomorrow.**" – Gerard Scimeca, President, Consumer Action for a Strong Economy (CASE)

"The proposal is likely to reduce, not increase, long-term savings. Aggregation would weaken CMS's ability to independently capture the value of distinct innovations in future negotiation cycles and would discourage subcutaneous biosimilar development. CMS has published no economic analysis of these effects. Calling the change a "narrow modification" does not substitute for one." – Fred Roeder, Consumer Choice Center (CCC)

"CMS has not been given authority to override the FDA's product-by-product determinations solely to bring more products into the negotiation program. Congress has routinely directed CMS to defer to the FDA on questions of drug identity, and this proposal would stretch CMS's regulatory authority beyond what Congress has clearly authorized." – Timothy H. Lee, Center for Individual Freedom (CFIF)

"Implementing onerous price controls under this proposed policy will increase costs over time and dry up the drug development pipeline. We urge CMS to withdraw this proposed rule and put patients ahead of bureaucrats." – David Williams, Taxpayers Protection Alliance (TPA)

"The resulting harm would not necessarily appear immediately in Medicare spending statistics**. It would appear years later in research programs that were never funded, clinical trials that were never conducted, improved medicines that were never submitted to FDA, and treatment choices that patients never received.** That is too high a price for short-term savings." – Kent Kaiser, Trade Alliance to Promote Prosperity (TAPP)

RetireSafe

"America's healthcare system should never sacrifice future medical breakthroughs or patient autonomy for short-term potential cost savings. **RetireSafe urges the agency to keep seniors' and all patients' well-being at the center of all health policy. Protecting the treatments and cures of tomorrow is essential to that goal**." – Mark Gibbons, RetireSafe

---

NATIONAL TAXPAYERS UNION

"Treating the subcutaneous and intravenous versions of Opdivo as the same drug for the purposes of **Medicare's price setting program undermines the interests of taxpayers by limiting the deployment of a medical innovation that can reduce the time patients spend in costly clinical settings.** For taxpayers, the relevant question is not if Medicare can purchase a drug for a lower, government set price. Rather, it is whether federal health care programs can deliver care at the lowest overall cost over the long-term." – Pete Sepp and Alexander Ciccone, National Taxpayers Union

---

Forbes

"As CMS prepares the program's rules for 2029, the agency is proposing to broaden the criteria used to decide when separately approved medicines should be grouped together for price-control purposes…This isn't a minor technical adjustment. **It could discourage the development of new uses and improved forms of existing medicines, including cancer treatments** that can be administered more conveniently…Yet CMS' proposal would treat these breakthroughs as though little or no additional innovation had occurred. That's **economically foolish and potentially devastating for patients**." – Steve Forbes, Forbes

---

Forbes

"Those improvements take years of additional research, new clinical trials, another round of FDA review, and substantial financial investment…Innovations like Opdivo Qvantig are precisely what CMS is putting at risk…If Medicare shortens the period before price controls apply, that calculation changes. Projects that once made financial sense no longer will…**CMS's proposal would encourage one thing above all else: investing less in improving existing medicines.**" – Sally Pipes, Forbes

---

Gingrich 360

"Unfortunately, the enormous **regulatory machinery created by President Joe Biden's so-called Inflation Reduction Act is threatening to pull the Trump administration in the opposite direction**…For cancer patients and others with serious illnesses, that can replace hours spent traveling to and sitting in an infusion center with shorter, more convenient treatments. Patients lose less time with their families and at work, while doctors, nurses, and infusion centers can care for more people…President Trump has helped unleash an extraordinary new wave of investment in American medicine. He should make

certain that the **bureaucratic remnants of the Biden administration do not smother it**." – Newt Gingrich, Gingrich 360

"Now, career bureaucrats at the Centers for Medicare and Medicaid Services are **considering a policy that could further reduce patient access to innovation**…Treating these advancements as if they were the same drug would reduce incentives to invest in the kinds of improvements that make a real difference for patients…**This harmful law is already disrupting the market and driving up costs**. Career bureaucrats shouldn't use the law to worsen its impact by further limiting patient access to care and future medical innovation. – Joel White and Hannah Anderson, The Hill

---

"But it would shrink the financial reward for improving existing medicines — and give investors reasons to deploy their capital elsewhere…**The victims won't be today's drugmakers. They'll be tomorrow's patients**…CMS shouldn't stretch the statute to make separately approved medicines eligible for government price controls earlier than they otherwise would be…CMS shouldn't shorten that window through administrative reinterpretation." – Sally Pipes, Newsmax