U.S. Chamber of Commerce

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Stephanie Carlton
Acting Administrator
Center for Medicare and Medicaid Services
7500 Security Boulevard
Baltimore, MD 21244

Dear Acting Administrator Carlton:

The U.S. Chamber of Commerce ("the Chamber") writes to express its deep concern regarding the Centers for Medicare and Medicaid Services' ("CMS") recent selection of a new group of medicines for price setting, to take effect in 2027, under the Inflation Reduction Act ("IRA").[1]

This second cycle of price setting includes medicines which compete in two classes with multiple brands and generics. Just as the approach that CMS took in the previous drug-selection cycle, CMS's approach continues to discourage treatment choice and constrain the development of the next generation of treatments and cures. Policies that jeopardize invaluable treatments, including treatments for the prevention of chronic diseases and cancers, are counterproductive to the health and well-being of Americans and the overarching goal of controlling healthcare costs.

Price setting restricts the opportunity that propels market driven research and comes at a significant cost increase to the consumer. The Chamber's research, as well as independent studies, underscores the detrimental impact of price controls on innovation, patient access, and the long-term sustainability of the life science ecosystem. The 2027 drug selection list exemplifies these concerns, including for chronic disease patients who rely on flexibility in treatment options.

[1] For further background, the Chamber encloses the letter objecting to this decision that the Chamber sent to the outgoing Secretary of Health and Human Services and outgoing Administrator of CMS on January 17, 2025, the day the decision was announced. As noted in that letter, this important decision was made one business day before the Trump Administration took office, well in advance of the February deadline for doing so. As the Chamber emphasized, the selection decision appears to be nothing more than a "midnight rule," intended to hamstring the new Administration's ability to reform the program and to safeguard America's leadership in medical innovation. In addition, the selection decision highlights the legal defects in the statutory scheme as signed into law by President Biden, which the Chamber and other parties have challenged in federal court as unconstitutional on several grounds. The IRA's price control scheme should be repealed.

The Biden Administration's overbroad and statutorily unfounded interpretation of medicines eligible for selection under the IRA included new treatments for cancer[2] and rare disease as well as improved dosage forms and formulations that may be better tolerated or efficacious, effectively undermines incentives to develop new therapies. In particular, as reflected in the 2027 Initial Price Applicability Year (IPAY) guidance and drug selection list (as well as the 2026 IPAY guidance and drug selection list), CMS has treated a *group* of medicines containing the same active ingredient or moiety as *one* selected drug for price setting, even if various drugs within that group were approved under different marketing applications in accordance with applicable FDA guidance. Under CMS's approach, one "drug" therefore includes products with different dosage forms and strengths, that were subject to separate clinical trials, that help different patient populations, and that have different treatment indications.

This remarkably broad interpretation has enabled the inclusion in the 2027 list of 26 distinct drug products across 26 different marketing applications, including seven separately approved diabetes and obesity products. This approach discourages critical additional research and development (R&D) investments that could result in meaningful new treatment options for patients.

For example, CMS's flawed interpretation has allowed the selection of three distinct GLP-1 products containing the same active ingredient as if they were a single "drug" for price setting, even though one of these products is specifically approved for the treatment of obesity and was approved four years after the initial approval of one of the other products. Each of these distinctly branded products was developed under separate clinical development programs and approved to treat different chronic diseases and patient populations in different dosages. By treating these very unique and distinctive products as interchangeable, CMS not only undermines the value of innovation but also jeopardizes the development of future treatments. This is particularly concerning for patients with chronic diseases, who often require tailored treatment options to address their unique health needs.

The previous Administration created further uncertainty and issues regarding American healthcare through the IRA program. For example, the Biden Administration's CMS selected several medicines for price setting that would face generic and/or biosimilar competition *prior* to the price for those medicines even being announced. It is especially obvious that price setting for these branded medicines will lead to limited benefits and savings for patients and for the government, a waste of essential government resources, and greatly disincentivize competition and innovation.

[2] Unintended Consequences of the Inflation Reduction Act: Clinical Development Toward Subsequent Indications

Further, in IPAY 2026 and reinforced in IPAY 2027, CMS created the extra-statutory "bona fide" marketing concept. As a general matter, the law states that only single-source drugs and biologics are eligible for selection for price controls, and excludes drugs and biologics that are the reference listed product for an approved and marketed generic. CMS decided to limit this exclusion only to generics that CMS determines are being marketed "bona fide," which requires CMS to assess whether, in its view, meaningful competition from generics or biosimilars actually exists. Not only does this "bona fide" marketing concept violate the plain text of the law, but CMS has announced no objective criteria under which CMS is applying this concept.

Research from the Chamber consistently shows that shortsighted price setting policies, such as the policies reflected in the IRA statutory program and in the previous Administration's interpretation of the statute, can be expected to reduce the development of medicines in the future and hamper the cost-saving potential offered by improved health outcomes. Countries with similar policies experience fewer biopharmaceutical product launches, longer wait times for new treatments, and reduced patient access to innovative medicines. For example, while 80% of new oncology products were launched in the United States, only 58% were made available in Europe, where price controls are prevalent. In addition, patients in Germany waited an average of 133 days for access to new medicines, while those in Spain faced delays of up to 500 days.

The IRA's price setting provisions risk replicating these outcomes in the United States, turning our innovation ecosystem into a research desert. The Chamber's *From Innovation Oasis to Research Desert* report demonstrates that price controls could lead to a dramatic decline in U.S. clinical trial activity, with private sector research funding potentially slashed by up to 75%. This decline will disproportionately impact research into chronic diseases such as diabetes and obesity, where innovation is most urgently needed.

For these reasons, the Chamber urges CMS to reconsider the previous Administration's overbroad interpretation of medicines eligible for price setting under the IRA, as well as other problems introduced by the prior Administration into the program. CMS should recognize the distinct clinical development programs and patient populations served by separately approved medicines, even if they share the same active ingredient or moiety. Moreover, CMS should avoid policies that discourage investment in new dosage forms and formulations, which are critical for addressing the diverse needs of chronic disease patients. Finally, CMS should engage in a transparent, evidence-based process that prioritizes patient access, innovation, and the long-term sustainability of the biopharmaceutical industry.

Thank you for the consideration of our comments. The Chamber stands ready to work with CMS to develop market-oriented solutions that enhance affordability and access without compromising the innovation that drives life-saving breakthroughs. However, the Chamber cannot and will not support failed price-control policies that ultimately harm patients. Accordingly, the Chamber urges the Trump Administration to undertake a careful review of the unwise approach reflected in the Biden Administration's 2027 IPAY guidance and, more generally, to revisit the deeply flawed IRA statutory scheme, which was enacted by Congress on a bare party-line vote and signed into law under the prior Administration.

Sincerely,

Brad Watts
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U.S. Chamber of Commerce