U.S. Chamber of Commerce

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uschamber.com

January 17, 2025

The Honorable Xavier Becerra
Secretary of Health and Human Services
200 Independence Avenue, SW
Washington, DC 20201

The Honorable Chiquita Brooks-LaSure
Administrator, Centers for Medicare and Medicaid Services
7500 Security Boulevard
Baltimore, MD 21244

Dear Secretary Becerra and Administrator Brooks-LaSure:

The U.S. Chamber of Commerce ("the Chamber") writes to express its deep concern and opposition to the Department of Health and Human Services' (HHS's) and the Centers for Medicare and Medicaid Services' (CMS's) decision to select and announce the next set of medicines subject to the Inflation Reduction Act's (IRA's) drug pricing "negotiation" provisions. This announcement is well in advance of the February deadline for doing so, one business day before the incoming Trump Administration takes office. The Biden Administration's rushed decision seems to be nothing more than a "midnight rule," undermining transparency, accountability, and sound policymaking while hamstringing the incoming Administration's ability to reform the program and safeguard America's leadership in medical innovation. Moreover, the unusual timing of this decision further highlights the legal defects in the underlying statutory scheme, which allows for arbitrary, politicized decision-making in the price-setting process.[1]

The Chamber has consistently supported efforts to ensure that every American has equitable access to life-saving medicines. However, the IRA's price control provisions, and the flawed way they are being implemented, threaten to stop innovation, limit patient access, and jeopardize the future of medical research and development.

[1] As HHS and CMS are aware, the Chamber and other parties have challenged the IRA's price-control program in federal court as unconstitutional on several grounds. The Chamber respectfully submits that even if the IRA program were lawful (which it is not), HHS and CMS would be required, on policy as well as legal grounds, to reconsider today's ill-timed selection decision, as explained in this letter.

The Chamber's research, including the *Patient Access Report, Phase 1* and *Phase 2*, as well as the *From Innovation Oasis to Research Desert* report, underscores the devastating consequences of price controls on the biopharmaceutical ecosystem.

The *Patient Access Report, Phase 1* revealed that in countries with price control mechanisms, patients face significantly reduced access to new treatments and endure longer wait times. 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. 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 *Phase 2* report further projects that the IRA's price controls will result in a 29% to 44% reduction in the number of new medicines launched in the U.S., depriving patients of life-saving innovations.

Moreover, the Chamber's *From Innovation Oasis to Research Desert* report highlights how price controls will 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 orphan diseases, cancer, and obesity—areas where innovation is most urgently needed. And as the Chamber has repeatedly noted, the IRA's provisions are already discouraging investment in promising obesity-related clinical trials and cutting-edge cancer treatments, as companies reevaluate the feasibility of pursuing costly, high-risk research.

In essence, at their core, the IRA's price controls disregard the foundational principles of free enterprise and undermine the innovation ecosystem that has made the United States a global leader in medical advancements.

The Chamber is also alarmed by the lack of stakeholder engagement and the absence of a robust analysis of the negative consequences of these policies. The rushed selection and announcement of the next set of medicines subject to price controls, which seems clearly designed to prevent the incoming Administration from making the important decisions at issue here, sets a dangerous precedent. We urge HHS and CMS to reconsider this approach and to engage in a transparent, evidence-based process that prioritizes patient access, innovation, and the long-term sustainability of the biopharmaceutical industry.

The Chamber stands ready to work with the incoming Administration to develop market-oriented solutions that enhance affordability and access without compromising the innovation that drives life-saving breakthroughs.

Sincerely,

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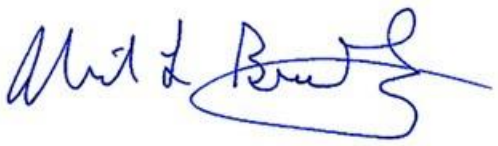

Neil L. Bradley
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and Head of Strategic Advocacy
U.S. Chamber of Commerce