U.S. Chamber of Commerce

1615 H Street, NW
Washington, DC 20062-2000
uschamber.com

April 14, 2023

The Honorable Chiquita Brooks-LaSure
Administrator
Center for Medicare and Medicaid Services
Baltimore, MD 21244

Meena Seshamani, M.D., Ph.D.
Director, Center for Medicare
Center for Medicare and Medicaid Services
Baltimore, MD 21244

Re: Medicare Drug Price Negotiation Program: Initial Memorandum, Implementation of Sections 1191 – 1198 of the Social Security Act for Initial Price Applicability Year 2026, and Solicitation of Comments

Dear Administrator Brooks-LaSure and Director Seshamani:

The U.S. Chamber of Commerce ("the Chamber") in conjunction with the Chamber's Global Innovation Policy Center ("GIPC") urges the Centers for Medicare and Medicaid Services ("CMS") to re-evaluate the approach taken in CMS's Initial Memorandum, implementing certain provisions of the *Inflation Reduction Act* ("IRA"). The Chamber supports appropriate efforts to ensure that every American has equitable access to life-saving medicines at fair market prices, from COVID-19 vaccines to new diagnostics and therapeutics combating some of the world's most debilitating diseases. However, we firmly believe that both the IRA itself, and the implementation contemplated by the guidance document, will harm life-science innovation and limit choices of life-saving medications for Americans.

The Chamber's primary, although by no means exclusive or exhaustive, concerns can be summarized in three points:

1. Analysis and experience in other countries proves that market-restrictive policies like the IRA's price controls deter future innovation, inhibit patient access, and limit patient choice;

2. The actions contemplated by the guidance document are inconsistent with the statute and would even more severely penalize life-science innovation and devalue the role of the living innovation ecosystem; and

3. Under applicable legal provisions and regulatory procedures, the Administration must solicit and then consider stakeholder feedback through a formal request for comment under the appropriate rulemaking mechanism. In addition, the guidance's thirty-day deadline and restricted comment solicitation for only some elements of the implementation fail to give stakeholders adequate time to fully and fairly participate in the regulatory process.

The Chamber's additional concerns are outlined in more detail below.

I. Market-restrictive policies like the IRA's harmful, ill-conceived price controls have a negative impact on innovation that results in restricted access to new, innovative, and life-saving medications by American patients.

In March, the Chamber released its *2023 Patient Access Report (Phase One)* ("The Report"). As GIPC recently explained in a letter to HHS Secretary Xavier Becerra, the Report confirms what proponents of the free market system already know: marketplace competition and effective intellectual property protections give patients greater access to the latest life-saving medicines.[1] In contrast, the Chamber's research shows that market-restrictive policies like artificial price controls deter future innovation, inhibit patient access, and ultimately limit patient choice.

Reducing barriers to access has long been a health policy priority and focus for Congress and the business community. The Chamber supports appropriate, effective efforts to help mitigate and overcome obstacles to life-saving medicines. But, government price setting will create additional access challenges for Americans.

Unfortunately, many have accepted the failed premise that government intervention and price setting is the most effective way to provide patients with access to life-saving innovations. This approach is embodied within the drug pricing provisions of the IRA. While the IRA claims to promote access by controlling prices through so-called "negotiation," the reality is that innovators are forced to comply with the government's arbitrary and coercive price control scheme or face crippling penalties. At the same time, incentives to develop generic and biosimilar medications, one of the key components in the innovative ecosystem in today's biopharmaceutical market, are virtually destroyed – embedding price controls in the U.S. market in a way that would be virtually irreversible for future generations of medicines.

The Chamber's Report cautions that the IRA's drug pricing penalties will harm patients by causing them to forfeit early and extensive access to the best life-saving medications. The Report's methodology shows that in other OECD countries which have implemented price controls, patients see fewer overall biopharmaceutical product launches, including biologics and oncology products, and have delayed access to medicines.[2] For example, prior to the enactment of the IRA's price controls, out of 104 new oncology products released globally, 80% were launched in the U.S., while only 58% were launched in Europe. Similarly, in several benchmark countries, patients can often wait up to several hundred days to receive access to life-saving treatments, waiting an average of 133 days in Germany and up to 500 days in Spain.

The IRA's anticipated harms have already been revealed through the numerous life-science innovators who have officially ended product research and development programs, citing the new price controls. Anecdotally, for example, Eli Lilly CEO Dave Ricks said the company had already dropped a blood cancer drug from its R&D pipeline because they "couldn't make the math work . . .

[1] Ltr from David Hirschmann, President and CEO, Global Innovation Policy Center, to Secretary Xavier Becerra, March 22, 2023.

[2] The report found that fewer biopharmaceutical products overall launched in Canada, Japan, South Korea, Australia, and European Union member states than in the United States over the past 20 years.

[i]n light of the Inflation Reduction Act, this program no longer met our threshold for continued investment."[3] Similarly, Novartis warned that the new law could discourage research in its most promising areas of research: RNA and radioligands.[4] Finally, Alnylam has stopped the development of a treatment for a rare eye disease due to the need "to evaluate impact of the Inflation Reduction Act." [5]

In addition, research by The Pharmaceutical Research and Manufacturers of America ("PhRMA") shows the IRA's pricing provisions may put the development of more than 400 new medicines at risk.[6] This research indicates these potential medicines under development target some of the most common, yet serious, chronic diseases affecting America's seniors, including Alzheimer's, diabetes, and congestive heart failure.[7] Unfortunately, this report, too, demonstrates the IRA's ill-conceived price controls are already having a "chilling effect" on research and development. According to the report, life science innovators believe the IRA's current framework will undermine advances critical to patient well-being.[8] In fact, when asked, some 82% "or more of companies with pipeline projects in cardiovascular, mental health, neurology and cancers expect substantial impacts on R&D decisions…."[9]

These are but a few of the most prominent examples of the type of innovative, life-saving products whose realization, availability and ultimately access are ironically threatened by the IRA's price controls to purportedly improve access. As more information comes to light, it is likely to become clear that the most vulnerable patients – including older Americans, those diagnosed with rare diseases, and underserved populations– will pay the price for innovation lost to the IRA. To describe these policies as disastrous for American innovation would be an understatement. Government intervention in the market establishment of prices undermines the innovation ecosystem that enabled the U.S. to become one of the most inventive countries in the world. Decisionmakers must consider the implications of price controls for patients before proceeding with the implementation of the IRA's framework, which would jeopardize U.S. leadership on biopharmaceutical innovation and access to treatments. The ability of American patients to access life-saving innovations in a timely manner depends on it. Surely this outcome—less innovative medicines and longer wait times—isn't what any policymaker or advocate wants.

II. Actions contemplated by the guidance are not supported by the statute and further undermine life-science innovation, devalues the living innovation ecosystem, and limits patient access to new, life-saving medications.

As if the IRA's price controls are not harmful enough to America's life-science ecosystem, it appears that interpretations and actions contemplated by the Administration in this guidance go beyond the statutory text and further exacerbate the law's negative effects. For example, the

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[3] Joe Grogan, *The Inflation Reduction Act Is Already Killing Potential Cures*, The Wall Street Journal, November 3, 2022.
[4] Ludwig Burger, *Novartis warns U.S. plan to curb drug prices could hit key research*, Reuters, January 20, 2023.
[5] Grogan, *supra* note 1.
[6] Medicines in Development, 2023 Report, Pharmaceutical Research and Manufacturers Association of America.
[7] *Id.*
[8] *Id.*
[9] *Id.*

proposed guidance anticipates establishing rules that would penalize life-science innovators for investing in extensive research and development to acquire patents for selected medications. Under the proposed guidance, the agency would "consider the length of the available patents…and may consider adjusting the preliminary price downward" if the patents last "for a number of years." Given the timelines set forth in the IRA, this could include both patents on medications originally approved and patents secured for subsequent innovations.

This policy could penalize America's life-science innovators for engaging in both initial product innovation and in the additional research and development into both new treatments and new applications of existing treatments, in a way that is inconsistent with the United States Government's deliberate, longstanding policy decisions, on which companies and investors have relied for many years, to bolster innovation with patent protection in the U.S. Both theory and reality suggest that more patents in a therapeutic class expand innovation and economic growth, expand patient choice, and advance the public good with better health. Innovation is not a one-time, compartmentalized process. When a life sciences innovator files an initial patent claim it often does so in the early stages of research and development, years before an intended product reaches the market and all aspects of its applications and treatments have been clinically tested. Extensive clinical trials and continuing investments in research and development are required to uncover subsequent health conditions that may be treated by the initial product. The result is living innovation, a tree that continues to bear fruit. From delivery efficacy and patient compliance to dosages, mitigation of side effects, extended-release formulations, and entirely new treatments, so-called "follow-on innovations" deliver invaluable benefits to patients and consumers. [10]

More than 60 percent of oncology medicines approved a decade ago went on to receive additional approvals, and more than 70 percent of these additional approvals occurred seven or more years after initial approval, and as such required significant investment in research and development on the part of the innovator. These new uses provide treatment options for different diseases, including rare diseases, or additional patient populations such as children. However, with the policies laid out in the IRA guidance, instead of these critical advances, companies will have to reconsider whether post-approval research is sustainable, given the commitment of time and resources.

One product that demonstrates the value of living innovation is Botox. When Botox was initially approved, it was to treat two rare eye muscle disorders. Today, there are more than 12 approved indications, including for overactive bladder.[11] Similarly, AZT was originally developed as a failed attempt at cancer treatment.[12] It was only years after its failed application as a cancer treatment—and untold investments in clinical trials and research—that its potential in the fight

[10] Professor Kristen Osenga, *Are "patent thickets" to blame for high drug prices,* Richmond-Times Dispatch, Nov. 30, 2022 ("It's no secret that drug manufacturers regularly continue to innovate drugs long after they're originally proven safe and effective. There are countless legitimate reasons to do so. Sometimes, post-market research suggests that a particular dosage or delivery method could be superior to the original.").

[11] *Id.* AbbVie Inc., Press Release, AbbVie to Showcase Migraine Portfolio and Pipeline During the 16th European Headache Federation Congress (Dec. 6, 2022).

[12] Christopher M. Holman, Why Follow-On Pharmaceutical Innovations Should Be Eligible For Patent Protection, IP-Watch, Sep. 21, 2018, available at https://www.ip-watch.org/2018/09/21/follow-pharmaceutical-innovations-eligible-patent-protection/.

against HIV/AIDS was discovered.[13] Without the ability to engage in follow-on innovation and secure patent protections, it is questionable whether the new treatments for either of these life-science innovations would be available in the future.

Each stage of innovation requires new investment and risk, which is made possible by incentives like the potential for patent protection. According to one study, the median cost of getting a new life science innovation to market was $985 million, with an average overall cost of $1.3 billion.[14] Other studies estimate the cost, based on the amount of research and clinical trials required, could be as high as $2.8 billion.[15] The reality is that cutting-edge medical treatment is costly, and the hope it gives to patients with previously uncurable diseases and illnesses is immense. To justify these substantial costs and investments, many of which never materialize or become profitable, innovators must have access to potential patent protection, and the ability to recoup significant investments to enable future innovations and follow-on uses that arise later in the product's development lifecycle.

Simply put, given the significant costs associated with bringing any iteration of a product to market, without the ability to secure full scope of protection and additional protections for follow-on innovations, life science companies will not invest in new or improved versions of their medicines. Actions contemplated by the guidance, and especially its penalization of companies that secure additional legal rights, would undermine the living life-science innovation ecosystem and prevent new medicines and treatments for existing medicines from entering the market. This would ultimately harm the very people CMS wishes to protect: American patients suffering from debilitating diseases.

To be clear, the Chamber believes that the IRA's price-control provisions are unconstitutional. But the underlying defects in the statute are no justification for CMS to go even farther in guidance and undermine innovation and patient access even more than the IRA itself requires.

III. The thirty-day window for comments contemplated by the guidance is insufficient and provides inadequate notice, which is exacerbated by regulatory overreach in the guidance; stakeholder feedback should be solicited through formal, robust notice and comment mechanisms.

CMS's approach in implementing the negotiation provisions of the IRA exceeds CMS's statutory authority and encroaches on the authority of other parts of the Executive Branch. Specifically, in assessing whether a biosimilar or generic competitor has come to market, CMS proposes to evaluate its own prescription drug event data to determine if competition is taking place, an authority that cannot be found in the IRA. Similarly, CMS intends to conduct its own assessment of clinical value and product safety in the negotiation process, in a manner that exceeds the limited authority to consider evidence regarding alternative treatments that is set forth in the

[13] *Id.*

[14] *See generally* Wouters OJ, McKee M, Luyten J, *Estimated Research and Development Investment Needed to Bring a New Medicine to Market*, 2009-2018, JAMA, March 3, 2020

[15] Robert Zirkelbach, *The Cost of Innovation*, PHRMA, November 19, 2014.

statute. Evaluation of competition and clinical value assessment in a comprehensive fashion are roles delegated to the FTC and FDA, respectively – not to CMS. By going beyond the statute in these areas, CMS is exceeding its authority and expertise and setting up a slippery slope with even more significant government interference in our health care system and free markets.

CMS has also been touting transparency and stakeholder engagement as CMS moves forward to implement the IRA. Unfortunately, it's not the number of meetings that matters so much as the substance of those meetings. Despite months and months of CMS effort, too many unanswered questions remain that will have significant bearing on the state of the U.S. economy and patients who rely on the Medicare program for access to needed medicines.

As a threshold matter, the Chamber notes that CMS requires stakeholders to submit their comments on the guidance within thirty days, which is half the time typically provided for public comment on initial rules for a new program. Thirty days is far too little time for stakeholders to develop meaningful input on a major new program that CMS itself has described as "novel" and "complex", particularly given the regulatory overreach reflected in the guidance. This limited window hardly allows patients and other stakeholders to provide meaningful input and suggests that CMS is not interested in hearing from relevant parties in a manner that would shape its decisions. These issues are vitally important and deserve an opportunity for meaningful and effective comment by all interested parties.

This critical public policy matter requires a formal, robust notice and comment period. Moreover, CMS should solicit comment on all topics discussed in the Memorandum, not merely on a subset of those topics. Indeed, we recommend that CMS utilize notice and comment rulemaking to obtain public input here, given due process constraints, the Medicare statute's notice and comment requirements, and core public participation values.[16] This is particularly important in light of the obvious legal and practical concerns raised by core aspects of the guidance, as well as serious legal questions about the nature and validity of the statutory provisions being implemented.

IV. Conclusion.

With the passage and implementation of the Affordable Care Act, Congress and the Obama Administration believed that access to health care services and treatments would be achieved by expanding comprehensive health coverage to all Americans. While the Chamber supports increasing the number of Americans with health coverage, we are mindful that barriers persist in a different way as higher deductibles, and out of pocket costs mitigate premium increases but also pose challenges to access. Now with the passage and implementation of the Inflation Reduction Act, it appears that Congress and the Biden Administration are focused on a new false panacea, a mistaken belief that artificially holding down prices will ensure access to therapies. However, with this new form of expanded government intrusion in our health system, our country will see that the IRA imposes new barriers to access as therapeutic pathways and research are quashed.

[16] *See, e.g.,* 42 U.S.C. § 1395hh(a)(2); *Azar v. Allina Health Servs*., 139 S. Ct. 1804, 1808, 1815-16 (2019); *Ralls Corp. v. Comm. on Foreign Inv. in U.S.*, 758 F.3d 296, 318-19 (D.C. Cir. 2014).

The Chamber appreciates the opportunity to submit these comments for the record regarding CMS's IRA implementation guidance. We stand ready and willing to work with this Administration to find lawful and appropriate ways to ensure that life-saving medications are both available and accessible to all Americans. However, the Chamber cannot and will not support misguided, market-restrictive, and legally defective efforts that limit patient access and choice and undermine the living life-science innovation ecosystem. The Chamber strongly urges CMS to withdraw this guidance and instead engage in a formal, robust comment process that is consistent with the statute to ensure that all stakeholder voices are heard and that no adverse action is taken which will undermine American innovation.

Sincerely,

David Hirschmann
President and CEO
Global Innovation Policy Center
U.S. Chamber of Commerce

Neil Bradley
Executive Vice President, Chief Policy Officer,
and Head of Strategic Advocacy
U.S. Chamber of Commerce