Congress of the United States
Washington, DC 20515

April 12, 2023

The Honorable Xavier Becerra
Secretary
Department of Health and Human Services
200 Independence Avenue, SW
Washington, D.C. 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:

We write to express disappointment and concern with recent implementation guidance for the drug price-setting provisions included in the Inflation Reduction Act (IRA, Pub. L. 117-169). This guidance exacerbates the law's statutory flaws and compounds the profound uncertainty and risk posed by the legislation's sweeping drug price controls. We encourage you to reconsider the many components of the initial guidance that will otherwise stifle medical innovation and quality improvement, discourage proven public-private partnerships, undermine American intellectual property (IP) protections, and provide unacceptable conditions for public feedback. If finalized as proposed, these provisions will serve to make bad policy worse, harming patients, caregivers, and health care providers across the United States for generations to come.

The Administration's guidance clearly values government power and overreach above precedent and statute, at the expense of patients seeking potentially life-saving treatments. In an apparent effort to subject as many medications as possible to the IRA's price-setting program, the guidance uses an unusual definition of "qualifying single-source drugs" that aggregates entirely different medications according to their active ingredient or moiety, thereby discouraging research into future drug indications. This approach will blunt incentives for meaningful product improvements, in addition to punishing products that treat more than one disease.

The Centers for Medicare and Medicaid Services' (CMS) misguided drug definition will chill efforts to mitigate side effects, improve adherence, bolster quality, and identify new uses and patient populations that might benefit from a given product. As outlined by Professor Erika Lietzan in a 2018 study, "Development of new uses for already approved drugs, in particular, can make profound contributions to the public health."[1] Another analysis, released that same year, details a lengthy list of examples along these lines, such as a "failed attempt to a cancer drug" repurposed decades later to become "the first breakthrough in AIDS therapy."[2] By reducing complex drugs and biologics to their active ingredients and collapsing new drug applications into a single product for price-setting purposes, the definition included in CMS' guidance will decrease the likelihood of these types of groundbreaking developments moving forward. In light

[1] https://papers.ssrn.com/sol3/papers.cfm?abstract_id=3103293
[2] https://www.liebertpub.com/doi/pdf/10.1089/blr.2018.29073.cmh

of this risk, we urge CMS to adopt a more conventional definition with a credible basis in the statute.

Even more alarmingly, this guidance appears to serve as a backdoor mechanism for achieving partisan policy goals, to the detriment of Americans' health care. Specifically, the guidance treats federal financial support at any stage of drug discovery or development as grounds for further price manipulation by the Secretary under the program, resulting in a de facto expansion of so-called "march-in" authority, as referenced, but never imposed, under the Bayh-Dole Act. This effort comes despite consistent rejections, including by the Biden Administration,[3] of attempts to rely on federal funding for a drug as grounds to impose price controls.[4] In fact, the Bayh-Dole Act's bipartisan authors repeatedly affirmed that their framework aimed to incentivize public-private partnerships and accelerate access to meaningful medical innovations, rather than to discourage such collaborations or to punish innovators and research centers through pricing restrictions.[5] The price-setting program's treatment of federal support risks undercutting private-sector interest in partnering with the government, further harming American patients.

Anti-innovation policymaking pervades the agency's initial guidance. Drugs with longer remaining patent terms or exclusivities, for instance, will see a downward adjustment in their Secretary-mandated prices, inverting the IP incentive structure that has driven most major inventions and breakthroughs since our nation's founding. Research and development costs, meanwhile, would receive insufficient consideration during the price-setting process, with a narrow definition that ignores the complexities of drug development. In this way, CMS perpetuates a troubling pattern of mission creep, whereby the agency bypasses Congress and other federal departments to pursue goals outside of its jurisdiction.[6, 7]

In addition to these and other substantive policy concerns with the Administration's drug price-setting program, we also urge CMS to incorporate meaningful transparency and accountability into every stage of the new initiative's implementation. Already, we find the opportunity for public comment and its unduly brief response period leaving patients, caregivers, and other stakeholders inadequate time and opportunity to review and consider the vast new government rules and regulations at stake. CMS should provide longer comment periods and should not attempt to shield any portions of its regulatory proposals from public feedback or engagement. Furthermore, in implementing the price-setting program, the agency has an obligation to extend offers for additional meetings to hear feedback and input directly from those subjected to or otherwise affected by the process. For any number of conditions, from Alzheimer's disease and cancer to the 95 percent of rare diseases that currently lack an approved treatment option, CMS must also ensure that patients can play a proactive and consistent role in the decision-making process.

Additionally, we have major concerns with the guidance's severe limitations on basic due process protections, including for small businesses. The proposed policies would prohibit the

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[3] https://www.keionline.org/wp-content/uploads/NIH-rejection-Xtandi-marchin-12march2023.pdf
[4] https://www.aamc.org/media/61966/download?attachment
[5] https://www.washingtonpost.com/archive/opinions/2002/04/11/our-law-helps-patients-get-new-drugs-sooner/d814d22a-6e63-4f06-8da3-d9698552fa24/
[6] https://www.finance.senate.gov/imo/media/doc/crapo_letter_to_cms_on_final_coverage_decision.pdf
[7] https://www.finance.senate.gov/imo/media/doc/letter_on_medicare_and_accelerated_approval.pdf

disclosure of materials sent by the agency during the price-setting process, and manufacturers would ultimately need to destroy any such information, effectively undercutting the potential for the predictability, precedent, and stability that govern virtually all adjudication processes. When coupled with the law's broad restrictions on judicial and administrative review, these proposals stifle any opportunity for accountability, program integrity, or recourse for aggrieved parties.

We urge you to work diligently and quickly to address these and other issues as you begin implementing this far-reaching new price control program. The preliminary decisions made through this initial guidance process, if carried out without greater reflection and input from the public, will have dire consequences for American patients for decades to come.

If you have questions about this request, please contact Conor Sheehey of the Senate Finance Committee staff, Alec Aramanda of the House Committee on Energy and Commerce, and Patrick Dumas of the House Committee on Ways and Means.

Sincerely,

Mike Crapo
Ranking Member
Committee on Finance

Cathy McMorris Rodgers
Chair
House Committee on Energy and Commerce

Jason Smith
Chairman
House Committee on Ways and Means