Dear Members of the House of Representatives Committee on Oversight and Accountability,

The Inflation Reduction Act of 2022 (IRA) includes changes to improve medication affordability for some Medicare beneficiaries, such as capping annual out-of-pocket spending, increasing low-income subsidy eligibility, spreading out-of-pocket costs over time, and capping copayments for insulin products under Medicare Part D. Lowering financial barriers will help millions of people reliant on Medicare—particularly those living with one or more chronic conditions—to improve and maintain their health. As we commend these aspects of the IRA, however, we also call for changes to the law to avoid the negative, unintended consequences of provisions that will undermine the progress made on access.

In particular, we are concerned about the provisions in the IRA that treat small-molecule medicines--drugs that often come in simple to use forms, such as pills, tablets, and patches--as less important by subjecting them to government pricing 9 years after FDA approval instead of the 13 years afforded to biologics. Accordingly, the Partnership to Fight Chronic Disease and the _____ undersigned organizations urge you to amend the IRA's Medicare Drug Price Negotiation Program and establish the timeframe for government pricing at 13 years post-approval for both biologics and small-molecule drugs.

Biologics are complex therapeutics derived from living cells or through biological processes. Their large, complex structures make biologics more sensitive to physical conditions, which often requires them to be administered in a physician's office via an infusion or injection. In contrast, small-molecule medicines have simpler chemical structures and tend to be more stable, meaning they often come in pill or tablet form and therefore can be picked up by patients at their local pharmacy and taken at home. Additionally, because of their simpler structures, small-molecule medicines can be more easily genericized once patent protections expire.

Most older adults in the U.S. rely on prescription medicines to maintain their health. Among U.S. adults aged 65 and older, 87.5 percent take at least one prescription medicine a month. Almost 40 percent of these adults take more than five.***[1]*** Not surprisingly, older adults have strong preferences for medicines they can take at home. When asked to rank the importance of benefits that a new treatment offers, 91 percent of respondents to a recent survey indicated that being "able to take the medicine at home" was important or extremely important to them.***[2]*** A

review of oncology studies found that people undergoing chemotherapy also prefer oral over IV therapies.***[3]***

Being able to take a medicine at home facilitates greater independence, eliminates transportation needs and expenses, removes caregiving needs associated with transportation or administration, and reduces expenses associated with the drug and administration costs. For people living with disabilities, the ability to self-administer a medication at home also alleviates the need to overcome physical barriers to access and limits physical and emotional stressors associated with leaving home, transportation, and time spent in a medical environment to receive an infusion. Moreover, many offices and hospitals are also often ill-equipped to respond to the needs of older people or those living with disabilities, creating additional treatment barriers. Travel costs, lack of transportation, housing and food insecurity, and the need to secure care for children or aging parents are regular challenges made more burdensome as the duration or frequency of office-based treatment increases.

Small-molecule drugs also facilitate greater access for underserved populations and support health equity. Medically underserved populations have less access to specialty care often associated with biologics. The recurring need to travel to a healthcare facility for ongoing treatment is more than an inconvenience, and access issues relating to social determinants of health fall hardest on people of color, people living in rural areas, and people with lower incomes. People living in rural areas also face shortages of specialists like oncologists, neurologists, and rheumatologists, which adds another barrier for patients who are limited to office-based treatment. Given that more than one in five older adults live in rural areas,***[4]*** the unmet need for alternate routes of administration for infused medicines for Medicare beneficiaries is urgent. In contrast, nearly 90 percent of U.S. residents live within 5 miles of a community pharmacy.***[5]***

Prior to the IRA, long-standing federal policies and patent protections allowed drug developers 14 years, on average, to earn a return on their significant investments in research and development. One analysis found that roughly half of this return occurs in years 9 through 13 post-launch.***[6]*** As a result of the significantly truncated timeline created by the IRA, there is evidence that investment in research and development is already shifting away from small-molecule medicines, including those that would treat rare diseases, cancers, and other conditions.***[7]***

The smaller size and simpler structure of small-molecule medicines allows them unique opportunities for treating chronic conditions. Because of their ability to easily

penetrate cellular walls, they can deliver medicine directly to the therapeutic cellular target, which is particularly important in the treatment of many cancers. Additionally, while the blood-brain barrier presents challenges for the delivery of medicines to therapeutic targets in the brain, small-molecule medicines are capable of crossing this barrier and are therefore particularly important in the treatment of many neurological conditions, including mental illnesses, epilepsy, stroke, and Alzheimer's disease. We are concerned that the earlier price-setting timeline for small-molecule medicines compared to biologics creates a significant disincentive for investments into these medicines. As a result, the patients we represent will experience reduced access to new treatments, increased non-medical barriers to care, and worsening health disparities.

Thankfully, the fix is straightforward: remove this disincentive by supporting bipartisan efforts to set the eligibility for IRA drug pricing at 13 years post-FDA approval for both small-molecule and biologic medications. We urge you to work together to enact reforms that preserve access to small molecule medicines before implementation of this program begins in earnest. Without change, the chilling effect on investments today will accelerate with serious consequences for Medicare beneficiaries now and in the future.

Sincerely,

AiArthritis
Alliance for Aging Research
Applied Pharmacy Solutions
Autoimmune Association
Colorectal Cancer Alliance
Council for Affordable Health Coverage
Derma Care Access Network
Healthcare Leadership Council
Neuropathy Action Foundation
Nevada Chronic Care Collaborative
No Patient Left Behind
Partnership to Advance Cardiovascular Health
Partnership to Fight Chronic Disease
Rural Minds

[1] Health, United States, 2019. ***https://www.cdc.gov/nchs/data/hus/2018/fig14.pdf***

[2] Defining Unmet Medical Need in the Inflation Reduction Act for the Maximum Fair Price: Reflecting Patient Input. June 2023. ***http://www.fightchronicdisease.org/sites/default/files/Defining%20Unmet%20Medical%20Need%20062323%20FINAL%20.pdf***

[3]Eek D, Krohe M, et al. Patient-reported preferences for oral verses intravenous administration for the treatment of cancer: a review of the literature. Patient Prefer Adherence. 2016 Aug 24;10:1609-21 ***https://www.ncbi.nlm.nih.gov/pmc/articles/PMC5003561/#:~:text=Specifical...***.

[4] Smith AS and Trevelyan E. In Some States, More than Half of Older Residents Live in Rural Areas. Oct. 22, 2019. ***https://www.census.gov/library/stories/2019/10/older-population-in-rural...***.

[5] Berenbrok L, Tang S, et al. Access to community pharmacies: A nationwide geographic information systems cross-sectional analysis. JAPhA 2022 Jul 12;62(6): p1816-1822. ***https://www.japha.org/article/S1544-3191***(22)00233-3/fulltext

[6] Nine Years is Too Short to Generate a Return for Many Biopharma Companies. ***https://nopatientleftbehind.docsend.com/view/qekzsg4mbpp2ajct***

[7] D Goldman, J Grogan, et al. Mitigating the Inflation Reduction Act's Adverse Impact on the Prescription Drug Market. Apr 13, 2023. ***https://healthpolicy.usc.edu/research/mitigating-the-inflation-reduction...***