September 15, 2025

The Honorable John Thune
Senate Majority Leader
511 Dirksen Senate Office Building
Washington, DC 20510

The Honorable Mike Johnson
Speaker of the House
568 Cannon House Office Building
Washington, DC 20515

The Honorable Charles Schumer
Senate Minority Leader
322 Hart Senate Office Building
Washington, DC 20510

The Honorable Hakeem Jeffries
House Minority Leader
2267 Rayburn House Office Building
Washington, DC 20515

RE: Concerns Regarding the Impacts of the IRA on Older Americans and People Living with Chronic and Complex Conditions

Dear Majority Leader Thune, Speaker Johnson, Majority Leader Schumer, and Minority Leader Jeffries,

We, the undersigned organizations, representing a diverse group of stakeholders including patients, providers, and caregivers, are committed to preserving access to treatment and fostering innovation to ensure that all people, including those diagnosed with chronic and complex conditions, can live longer, healthier lives.

According to the most recent census data from 2020, 16.8% of the U.S. population are age 65 and older and, from 1920 to 2020, this age group grew five times faster than the general population – due, in part, to advancements in medicines that help to extend lifespans and improve quality of life.[1] As the U.S. population ages, it is essential to have policies and systems in place that support and promote healthy aging, resulting in improved outcomes for older adults. The discovery of new medicines will continue to play an essential role in our ability to live longer and healthier lives, especially as rates of chronic conditions in older Americans are projected to double by 2050.[2]

We recognize the need to make healthcare more affordable and accessible for Americans, including those who rely on prescription drugs to manage chronic and complex diseases. In 2022, one in five adults aged 65 and older skipped, delayed, or rationed prescription treatments due to concerns about the out-of-pocket costs they would incur at the pharmacy counter.[3] Those cost challenges have only been exacerbated in recent years as patients balance their healthcare needs against rising costs for other essential goods.

As the 119th Congress considers policy solutions to address the affordability of prescription treatments, we urge you to consider the impacts of such policies on the American healthcare innovation ecosystem and patient access, particularly for older Americans and people living with chronic and complex conditions.

[1] United States Census Bureau: The Older Population: 2020 (May 2023)
[2] Frontiers in Public Health: Projecting the chronic disease burden among the adult population in the United States using a multi-state population model (January 2023)
[3] JAMA Network: Cost-Related Medication Nonadherence and Desire for Medication Cost Information Among Adults Aged 65 Years and Older in the US in 2022 (May 2023)

Impact of the Inflation Reduction Act (IRA) on Older Americans

While some healthcare-related provisions of the Inflation Reduction Act (IRA) are beneficial to older Americans, such as the capping and smoothing of out-of-pocket costs for Medicare Part D enrollees, we remain concerned about how the Medicare Drug Price Negotiation Program (MDPNP) could impact access to medicines for senior and disabled populations, particularly given the complexities at the state level that can affect patient access to treatments they rely on. As outlined in a recently published Global Coalition on Aging (GCOA) policy brief, a concern identified by Congress in the passage of the IRA is the disparity in drug price negotiation timelines between small and large molecule drugs. Small-molecule drugs – often taken in pill, syrup, or inhaled form – are eligible for negotiation seven years after approval by the Food and Drug Administration (FDA). Large-molecule drugs – often administered by a health care professional – are eligible for negotiation eleven years after FDA approval. Negotiated prices for these medicines go into effect nine to thirteen years after FDA approval, respectively.

The IRA's unnecessary distinction between small and large molecule drugs – also known as the *Pill Penalty* – risks diverting time and investment away from developing small molecule drugs because they have a shorter period of exclusivity before negotiations start. Seven out of the ten drugs selected for the first round of drug price negotiations and thirteen out of the fifteen drugs selected for the second round of negotiations are small-molecule drugs.[4] Research predicts that, as the program progresses, the percentage of drugs selected that are small molecules will increase.[5] A recent study has shown that resources have already been diverted away from small-molecule drugs, resulting in a 70% decrease in funding since the IRA was drafted in September 2021.[6] Correspondingly, a leading national survey research company conducted a poll and found 86% of voters aged 55 and older fear that the *Pill Penalty* will slash investment in small-molecule drug research and development (R&D), limiting future treatment options.[7] A separate study found a 74% decrease in the median size of investments into indications specifically targeting the Medicare-aged population, with a significant decline in investments in the development of small molecules compared to large molecules since the introduction of the IRA.[8]

Importance of Small Molecule Drugs in Treating Chronic and Complex Conditions

Notably, small-molecule drugs have become an essential part of treatment regimens for many diagnoses, including cancer, neurological diseases, HIV, and others that disproportionately impact older Americans. Small-molecule drugs offer significant advantages for patients, particularly those living in rural areas. These oral therapies can be produced in different dosage forms to optimize convenience, increase adherence, and can be easily taken at home. Small-molecule drugs are the only medicines that can pass through the blood-brain barrier, making them critical treatment options for central nervous system disorders, such as Alzheimer's and Parkinson's disease.

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[4] Managed Healthcare Executive: Trump Impact on Medicare Drug Price Negotiations Uncertain (January 2025)
[5] Charles River Associates: Impact of Medicare Price "Negotiation" Program on small and large molecule medicines (May 2024)
[6] Information Technology & Innovation Foundation: The Inflation Reduction Act Is Negotiating the United States Out of Drug Innovation (February 2025)
[7] Real Clear Health: A Plea from Seniors: Eliminate the Biden Pill Penalty (March 2025)
[8] Vital Transformation: Inflation Reduction Act – Two Years On: Investor Behavior, R&D Impacts, & Proposed Solutions (April 2025)

Medical advancements in cancer diagnosis, treatment, and prevention efforts have contributed to a 34% decline in the cancer mortality rate from 1991 to 2022, averting approximately 4.5 million deaths in the United States.[9] However, in 2025, there is still projected to be 2,041,910 new cancer cases and 618,120 cancer deaths, the vast majority of those cases occurring in individuals over the age of 55.[8] Small molecule drugs offer particular advantages in cancer care due to their ability to target and easily enter cells and affect processes inside that allow tumors to grow and spread throughout the body.[10] Researchers are also experimenting with small-molecule drugs combined with other cancer therapies to achieve synergistic effects and improve treatment outcomes. Small-molecule medicines offer significant benefits to patients, not only because they target specific characteristics of cancer cells, but also because they can be taken orally, providing great convenience to patients who may otherwise be required to travel for regular infusions at a cancer care center.

Similar to cancer care, small-molecule drugs play a vital role in treating infectious diseases, such as HIV, as only small molecules can enter a cell and interfere with the viral replication cycle. HIV has turned from what was once a death sentence to a manageable chronic disease, and people with HIV are living longer than ever before. Of the nearly 1.1 million people living with HIV in the United States in 2022, an estimated 54% were over 50 years old, and this number is projected to increase to 70% by 2030.[11] Oral formulations are truly the backbone of HIV treatment and prevention, with the very first drug to treat HIV infection developed in pill form.[12] Competition in this space was critical to making the advancements that have moved HIV treatment from complex multi-pill daily regimens with significant side effects to single-tablet daily regimens with longer-acting treatment options on the horizon.

Between 2001 and 2021, 71% of drugs approved by the FDA to treat rare diseases were small molecules.[13] Innovation in this treatment class should be incentivized, not disadvantaged, to support the research and discovery of new treatments, as well as the incremental development of breakthrough therapies that improve health outcomes. Decreased innovation as a result of the MDPNP will be harmful for patients living with rare diseases because about 95% of rare diseases do not currently have a treatment option available.[14]

Ensuring Pathways to Innovative Cures (EPIC) Act

In February, Representatives Greg Murphy (R-NC), Don Davis (D-NC), and Richard Hudson (R-NC) reintroduced the Ensuring Pathways to Innovative Cures (EPIC) Act (H.R. 1492) in the U.S. House of Representatives. In March, Senators Thom Tillis (R-NC), Ted Budd (R-NC), Marsha Blackburn (R-TN), James Lankford (R-OK), and Steve Daines (R-MT) introduced companion legislation (S. 832) in the U.S. Senate. The legislation seeks to eliminate the unnecessary distinction between the negotiation timelines of small and large molecule drugs, making all treatments eligible for negotiation eleven years after FDA approval.

H.R. 1492 would implement the change in negotiation timelines immediately upon passage, while S. 832 proposes implementing the change in negotiation timelines starting in the initial price applicability year (IPAY) 2028. While we are supportive of any action to correct the unnecessary distinction between small

[9] American Cancer Society: Cancer Statistics Center
[10] American Cancer Society: How Targeted Therapies Are Used to Treat Cancer (January 2021)
[11] National Institutes of Health: HIV and Older People (March 2024)
[12] National Institute of Allergy and Infectious Diseases: Antiretroviral Drug Discovery and Development
[13] Value in Health Regional Issues: Exploring the Potential Challenges for Developing Generic Orphan Drugs for Rare Diseases: A Survey of US and European Markets (May 2023)
[14] The Lancet Global Health: The landscape for rare diseases in 2024 (March 2024)

and large molecule drugs, immediate action is crucial to ensure that patients are not further impacted by lack of access to their treatments. We commend these members of Congress for recognizing the need for a legislative solution to the arbitrary distinction between small and large molecule drugs.

In April 2025, President Trump issued an executive order signaling his administration's support for addressing the "pill penalty," noting that the "discrepancy threatens to distort innovation."[15] Moreover, recent legislation passed by Congress and signed by President Trump has recognized the need to amend the MDPNP to ensure it does not stunt innovation and create additional barriers to access vital treatments. A policy within the One Big Beautiful Bill Act (H.R. 1) excludes orphan drugs from selection for negotiation within the MDPNP, an important step to safeguarding access to current and future innovative treatments for patients living with rare diseases within Medicare.

We must eliminate policies that hinder the development of new treatments, especially when many patients currently lack a treatment option for their condition. A thriving biomedical innovation environment in the United States underpins our ability to age well and maintain our health.

We urge you to support efforts to advance the EPIC Act to safeguard future innovation of treatments and protect access to critical small-molecule drugs for our aging population and people living with chronic and complex conditions.

On behalf of the healthcare communities that we serve, we thank you for your leadership and urgent attention to this issue. We are happy to discuss our concerns further or answer any questions you may have.

Sincerely,

Global Coalition on Aging
Alliance for Aging Research

60 Plus Association
ADAP Advocacy Association
Aging Life Care Association
AiArthritis
Alliance for Women's Health and Prevention
American Association of Senior Citizens
American Behcet's Disease Association
American College of Clinical Pharmacy
American Foundation for Women's Health
American Society of Consultant Pharmacists (ASCP)
American Urological Association (AUA)
Autoimmune Association
Biomarker Collaborative
Bone Health and Osteoporosis Foundation
Cancer Support Community
Caregiver Action Network
Caring Ambassadors Program

[15] The White House: Executive Order: Lowering Drug Prices By Once Again Putting Americans First (April 2025)

CaringKind, The Heart of Alzheimer's Caregiving
Cervivor, Inc.
Chronic Care Policy Alliance
Coalition of State Rheumatology Organizations
Color of Gastrointestinal Illnesses
Community Liver Alliance
COPD Foundation
Cutaneous Lymphoma Foundation
Depression and Bipolar Support Alliance (DBSA)
Exon 20 Group
GJPI INC.
Global Healthy Living Foundation
Health Hats
Healthcare Leadership Council
Healthy Men Inc
HealthyWomen
Heart Valve Voice US
Hepatitis C Mentor and Support Group-HCMSG
HIV+Hepatitis Policy Institute
ICAN, International Cancer Advocacy Network
International Pemphigus & Pemphigoid Foundation
LUNGevity Foundation
Lupus and Allied Diseases Association, Inc.
Mental Health America
MET Crusaders
National Association For Continence
National Black Nurses Association
National Grange
National Hispanic Health Foundation
National Menopause Foundation
National Minority Quality Forum
National Transitions of Care Coalition (NTOCC)
Neuropathy Action Foundation
Organic Acidemia Association
Partnership to Fight Chronic Disease (PFCD)
Patient Empowerment Network
Patients Rising
PD-L1 Amplifieds
Pioneer Institute
PlusInc
Prevent Blindness
Pulmonary Hypertension Association
Red Hot Mamas North America Inc.
RetireSafe
Second Wind Dreams, Inc.
Spondylitis Association of America
StopAfib.org
The Bonnell Foundation: Living with Cystic Fibrosis

The Mended Hearts, Inc.
Tigerlily Foundation
Vasculitis Foundation
Voices of Alzheimer's
Washington Health Innovation Council
WHAM (Women's Health Access Matters)
ZERO Prostate Cancer