Global Coalition on Aging

The Inflation Reduction Act & Small Molecule Development: Policy Brief

June 2025

The Global Coalition on Aging (GCOA) aims to reshape how global leaders approach and prepare for the 21st century's profound shift in population aging. GCOA, in collaboration with cross-sector stakeholders representing patient, provider, caregiver, policy, industry, and academic communities, launched the *Alliance for Health Innovation (Alliance)* with the mission to establish the importance of innovation in achieving healthy aging through policy reforms, investments, and strategic partnerships – both for the value to patients and health system sustainability.

This issue brief builds on two previous GCOA Alliance briefs – the first from October 2023 informed by a cross-sector conversation at Georgetown University on healthy aging and innovation, and the second from March 2024 based on a roundtable hosted jointly with the American Federation for Aging Research (AFAR) focused on the intersection of healthy aging, innovation, and oncology.[1,2] Those briefs underscored **the need for policies that ensure everyone can access the innovations that are allowing people to live longer and healthier than ever.**

The Inflation Reduction Act of 2022 (IRA) empowers Medicare to negotiate drug prices directly with pharmaceutical manufacturers through the establishment of the Medicare Drug Price Negotiation Program (MDPNP). While there are provisions within the IRA that will help support patients in accessing the treatments they need, **specific policies within the IRA will have disastrous impacts on patients and innovation by restricting access to life-saving treatment options and creating a chilling effect on drug research and discovery.** A policy within the MDPNP – known commonly as the "pill penalty" or "small molecule distinction" – is one such example.

Under the IRA, small molecule drugs, typically taken in pill, syrup, or inhaled form, will become subject to negotiated prices nine years after approval from the Food & Drug Administration (FDA). In contrast, large-molecule biologic drugs, most often injected or infused in a doctor's office or hospital setting, are subject to negotiated prices 13 years after FDA approval.

The arbitrary distinction between small and large molecule medicines in the IRA disincentivizes investment into discovering new small molecule drugs, negatively impacting patient access, healthy aging, and American innovation. Seven out of the ten drugs selected for the first round of drug price negotiations under the IRA and thirteen out of the fifteen drugs selected for the second round of negotiations are small molecule drugs.[3]

These policies are already impacting the development and future availability of small molecule treatments – there has been a 70 percent decrease in funding for these drugs since the drug price negotiation provisions in the IRA were first drafted in September 2021.[4]

For certain patient populations that rely on small molecule drugs to manage their symptoms, such as older adults and those impacted by cancer, limited access to existing treatments and negative impacts on future drug discovery can have significant adverse health impacts. Small molecule drugs provide increased flexibility to meet patient needs and reduce barriers to patient access and adherence. With the IRA disincentivizing the development of these treatments, efforts to advance patient access and healthy aging are threatened as patients are forced to rely on more costly and complex biologic treatment regimens.

Small molecules and biologics are both crucial to the future of medicine. The research and discovery of new treatments should be guided by scientific research and driven by medical needs.

The Ensuring Pathways to Innovative Cures (EPIC) Act offers a straightforward fix for the arbitrary distinction between when different types of drugs are subject to negotiated prices. First introduced in the 118th Congress and reintroduced in the 119th Congress, the federal legislation seeks to align the negotiation timelines of small and large molecule drugs, making all treatments eligible for negotiation eleven years after FDA approval.

In April 2025, President Trump issued an executive order signaling his administration's support for addressing the "pill penalty" within the MDPNP.[5]

> ***"The [MDPNP] imposes price controls on small molecule prescription drugs, usually in tablet or capsule form, 4 years earlier than on large molecule biological products. Known as the "pill penalty," this discrepancy threatens to distort innovation by pushing investment towards expensive biological products, which are often indicated to treat rarer diseases, and away from small molecule prescription drugs, which are generally cheaper and treat larger patient populations."*** **– President Donald Trump | Executive order on "Lowering Drug Prices by Once Again Putting Americans First" [6]**

The EPIC Act can play a critical role in safeguarding the future innovation of treatments, protecting access to critical small molecule drugs, and advancing healthy aging.

Impact on Key Populations

While the development of new and innovative treatments is critical for all patients, some populations stand to be disproportionately impacted by a lack of access to and future development of small molecule treatments. With their lower cost and easier administration compared to large molecules or biologics, **small molecule drugs help to meet patients where they are and ensure they can access the treatments they need to manage symptoms and achieve healthier aging.**

CASE STUDIES: THE IMPORTANCE OF SMALL MOLECULE DRUGS			
Supporting Brain Health in Aging Adults	**Managing Infectious Diseases**	**Fighting Cancer**	**Supporting Rural Communities**
Small molecule medications provide **immeasurable benefits for age-related neurodegenerative conditions** due to their ability to cross the blood-brain barrier.	Small molecule medicines play a **vital role in HIV treatment** as only small molecules can enter a cell and interfere with the viral replication cycle, suppressing the ability of the virus to spread.	Small molecule medicines have become a **critical part of treatment for cancer** due to their ability to reach medicine targets inside cells, where cancer originates.	Small molecule medicines are **accessible from nearby community pharmacies while many biologics must be administered by specialists** that require longer and often more expensive travel.
6.5 million Americans have Alzheimer's disease (AD), including 1 in 9 people over the age of 65. Small molecules could have significant benefits for individuals affected by AD and other neurodegenerative diseases.[7]	Due to effective small molecule medicines for treatment and prevention, HIV has turned from what was once a death sentence to a manageable chronic disease. People with HIV are living longer than ever before.[8]	Small molecule medicines in cancer contributed to a 34 percent decline in the cancer mortality rate from 1991 to 2022, averting ~ 4.5 million deaths in the United States.[9]	77 percent of community pharmacies serve population areas of 50,000 or fewer.[10]

An estimated 129 million people in the U.S. – over one third of the country's population – have at least one major chronic disease as defined by the Department of Health & Human Services (HHS).[11] These rates skyrocket for older adults, with nearly 95 percent of Americans age 60 and older living with at least one chronic condition and nearly 79 percent living with two or more chronic conditions.[12] According to census data from 2020, 16.8 percent 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.[13] Rates of chronic conditions in older Americans are set to double by 2050. As the U.S. population ages and faces increasing incidence of chronic disease, we must have policies and systems in place that support and promote healthy aging and better outcomes for aging populations.[14]

> *"Small molecules, which are typically administered in pill form, are often preferred by older adults based on cost and lessened need to travel outside the home for administration. Creating disincentives for the development of one category of drugs over another without any medical or scientific rationale does not make sense."*
> **– Sue Peschin | Alliance for Aging Research**[15]

Most older adults in the U.S. rely on at least one prescription medicine to maintain their health and older adults have strong preferences for medicines they can take in the comfort of their home.

91% A survey found that **91 percent of respondents** felt that being "able to take the medicine at home" was important or extremely important when considering the benefits of a new medicine to meet an unmet need.[16]

The ability to take medicine at home provides those who rely on treatments to stay healthy, including older adults, with more independence, eliminates the need for transportation to a hospital or infusion center, and reduces the financial burden associated with logistical and administration costs. For the needs of many older adults, frequent visits to specialists' offices and hospitals can create additional physical or psychological barriers to treatment that can impact adherence. One study suggests that patients are 1.8 times more likely to be non-adherent to their medications if faced with transportation-related challenges to access treatment.[17] Responsibilities at home – including care for children or other family members – may also create barriers that make it more difficult for older adults to leave their homes to seek office-based care.

The availability of small molecule drugs significantly decreases the strain of these challenges by allowing patients to manage symptoms and treat their conditions from their own homes – saving time, money, and resources that could be allocated elsewhere.

Cancer & Rare Diseases

For cancer, small molecule drugs have an efficacy advantage compared to biologics and other treatment types. Small molecules are smaller in size, simpler in structure, and have a lower molecular weight than other treatment types, making it easier to pass through the blood-brain barrier – the body's natural shield against foreign substances entering the brain and nervous system. This enables the medicines to reach their therapeutic targets in order to facilitate clinical benefit. For cancer, these medicines reach directly inside of cells – where cancer originates – to deliver medicine.

> *"Small molecule drugs are essential for the treatment of many cancers and are more accessible for patients due to their cost and convenience of taking them at home. Innovative oral cancer drugs are bringing improved efficacy and reduced side effects to patients, improving their treatment and lives. The EPIC Act would eliminate the unnecessary distinction between small and large molecule drugs in the IRA, allowing both to be eligible for negotiation eleven years after FDA approval."* – **Sally Werner | Cancer Support Community**[18]

Moreover, patients going through treatment for cancer prefer small molecules as part of their treatment regimen – these oral therapies can be taken at home, without the additional time and cost frequently associated with the administering of infusion treatments.

88% After having received both types of treatment, **88 percent of patients** who were randomized to receive oral chemotherapy first preferred oral medicine over IV therapy.[19]

While they may seem simple in their pill form, researchers and scientists are finding innovative ways to leverage the unique nature of small molecules to support breakthrough treatments. As scientists and experts continue to learn more in the fight against cancer, the clinical application of a combination of small molecule drugs and biologics continues to evolve and demonstrate efficacy.

Consider one treatment type that combines biologics with small molecules. Antibody drug conjugates (ADCs) are a class of anti-cancer drugs made up of monoclonal antibodies – some of the most complex biologics – and a small-molecule cytotoxic agent. ADCs are a treatment regimen that can help overcome certain limitations of other treatments options such as chemotherapy due to their ability to selectively target cancer cells.[20,21]

The arbitrary distinction in the IRA does not only disincentivize small molecule research and discovery, but the incremental development of new and breakthrough therapies and treatment regimens that improve patient quality of life and health outcomes.

> *"By supporting the EPIC Act, we're advocating for the discovery and accessibility of new cancer treatments that can meet patients where they are—whether at home, in treatment centers, or in underserved areas."* – **Tigerlily Foundation**[22]

The risks of a treatment being deprioritized in the pipeline because of disincentives in the IRA are even more significant for patients with rare diseases. While about 95 percent of rare diseases currently do not have treatments available, 71 percent of orphan drugs approved by the FDA between 2001 and 2021 were small molecules. In the U.S., a designated orphan drug is one that treats rare conditions that affect fewer than 200,000 patients.[23,24]

71% **71 percent of drugs** approved by the FDA and the European Medicines Agency to treat rare diseases between 2001 and 2021 were small molecules.[25]

Bringing any treatment to market is costly, risky, and challenging – but these issues can be exacerbated when the treatment is for a rare disease. Further disincentivizing the development of such medicines by arbitrarily disadvantaging small molecule drugs – which make up the majority of existing treatments for rare diseases – will only compound the challenges facing those biopharmaceutical companies working to bring such treatments to market. Innovation in this treatment class should be incentivized, not disadvantaged by a policy that lacks support from evidence or science.

HIV

Small molecule drugs are indispensable in the fight against infectious diseases, particularly HIV. Unlike other forms of treatment, only small molecules can penetrate cells and disrupt the viral replication cycle, making them uniquely effective. The discovery and development of these therapies has transformed HIV from a fatal diagnosis into a manageable chronic condition. As a result, individuals living with HIV are living longer, healthier lives. In the United States alone, nearly 1.1 million people were living with HIV in 2022, with an estimated 54 percent over the age of 50. By 2030, this figure is expected to rise to 70 percent, highlighting the growing population of aging individuals living with HIV.[26]

Advancing research into small molecule drugs is vital not only for discovering breakthroughs but also for moving closer to an eventual cure. New small molecule treatment approaches, such as single-tablet regimens and long-acting therapies, provide both convenience and improved adherence to medication schedules. This adherence is a cornerstone of effective HIV management, as it ensures viral suppression, reduces the risk of drug resistance, prevents further transmission, and drives efforts to end the HIV epidemic.[27]

> *"The HIV community is just beginning to unpack the enormous potential of long-acting antiretroviral medications for HIV treatment and prevention...,"* – **National Institute of Allergy and Infectious Diseases Director Jeanne Marrazzo, M.D., M.P.H.**[28]

Medical progress is equally critical for the aging population living with HIV, who often face multiple health conditions and intricate medication regimens. A recent national survey on aging with HIV revealed that 81 percent of respondents take medications for chronic conditions other than HIV, and 17 percent have had to modify their HIV treatments due to interactions with medications for age-related issues.[29] These complexities underscore the need for continued innovative and adaptable treatment options to meet the needs of the aging population with HIV.

81% 81% of respondents to a national survey on aging with HIV reported taking medications for chronic conditions other than HIV.[30]

Rural Communities

The small molecule distinction within the IRA also threatens to deepen health disparities and access issues for Americans living in rural communities. The one in five Americans who live in rural areas face unique health challenges compared to those living in urban areas, particularly around the five leading causes of death – heart disease, cancer, unintentional injury, chronic lower respiratory disease, and stroke.[31] Moreover, as rural Americans tend to be older and sicker than those in urban areas, ensuring their access to new and innovative treatments is particularly critical.[32]

> *"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."- Partnership to Fight Chronic Disease (PFCD) + 19 Healthcare Groups*[33]

Patients in rural areas may be burdened with increased travel time and expenses to receive treatment in care settings such as infusion centers rather than take medications, such as pills, in the convenience of their home.[34] Small molecule drugs dispensed by local pharmacies provide a more accessible option for these patients, rather than facing the long distances and additional costs to receive office-based care. More than half of pharmacists (55 percent) work in a community-based setting and 77 percent of community pharmacies serve populations of 50,000 or fewer.[35,36]

Pharmacies are a vital entity in healthcare delivery – serving as the primary healthcare resource for many patients, particularly those in rural communities where other resources may be further away or otherwise less available.

96.5% Across the overall U.S. population, **96.5 percent** lived within 10 miles of any pharmacy.[37]

In rural areas, access to treatments at independent pharmacies is particularly critical. A study showed that in large metropolitan areas, nearly 63 percent of pharmacies were chains; however, in rural areas, 76.5 percent of pharmacies were franchises or independent pharmacies.[38] For these patient populations and many other patients who rely on access to innovative treatments, addressing the small molecule distinction is critical.

The Risk and Reward to Innovate

Studies have estimated that the cost of research and development for a new drug range from $314 million to $4.46 billion.[39] An economic evaluation study estimated that the mean cost of developing a new drug from 2000 to 2018 was $172.7 million.[40] With the additional cost considerations of drug development failure and capital costs, the mean cost of developing just one new drug rose to $879.3 million.

Pharmaceutical manufacturers take on significant risk when developing medicines – just 12 percent of new molecular entities that enter clinical trials eventually receive approval from the FDA.[41] Given that risk, manufacturers rely on the period of market exclusivity to recoup the costs spent on developing treatments that ultimately reach the market, as well as those that failed to reach commercialization.

As the IRA allows for small molecule drugs to be eligible for negotiation within Medicare two years earlier than large molecule drugs, biopharmaceutical manufacturers have two fewer years to recoup the significant investments they made into the development, marketing, and distribution processes for these vital treatments. Since the IRA was introduced, there has been a nearly 70 percent reduction in early-stage funding for the development of small molecule treatments.[42] Not only does this limit the availability of treatments to reach patients in need, but also the ability for manufacturers to reinvest in the research and discovery of future treatments and cures.

The development of medicines should be driven by patient need and advances in science, not an arbitrary policy that disincentivizes innovation in a class of treatments vital to treating individuals with complex and costly conditions such as cancer and HIV.

> ***"...[The] IRA creates an incentive to shift resources toward developing drugs that benefit from a longer horizon of pricing independence. Policies that favor one group over another undermine efforts to ensure that patients can benefit from the best characteristics of each group. Biopharmaceutical manufacturers can serve patients best by identifying therapeutics that will work best for them, regardless of whether the products are small molecules or biologics."*** – Cencora [43]

The IRA & American Innovation

American leadership in drug development and the current supply chain gives our nation an advantage in providing patients and their loved ones with innovative treatments. Between 2014 and 2018, businesses with U.S. headquarters produced almost two times more new chemical or biological entities than those in Europe and nearly four times as many as in Japan.[44] This leadership threatens to be upended by IRA policy that disincentivizes the development of small molecule drugs. These treatments represent as much as 90 percent of global sales, making the law's impact on their revenue in the U.S. significant.[45] One analysis showed that IRA price controls could reduce future revenues of small molecule medicines subject to negotiation under the MDPNP by as much as 28 percent. In turn, this will discourage investment into the future development of such treatments.[46]

> ***"...the IRA's Medicare Drug Price "Negotiation" Program might have been a sensible policy if the price intervention was focused on wasteful or useless medicines. But it isn't; price controls can target some of the most valuable drugs. By doing so the policy will reduce investment in clinical development of drugs most likely to be price controlled."*** **– Kirsten Axelsen | American Enterprise Institute[47]**

One study found that by the end of 2022, the U.S. had more total new drugs sold (74 percent of all new drugs) compared with any other individual country in the study.[48] The country with the second-highest share of new drugs available – Germany – was 22 percentage points behind the U.S. Ensuring quicker and better treatment access for American patients is vital to ensuring that our country stays healthy, can contribute to the workforce and economy for longer, and is able to age healthily.

The benefits and value of the American innovation ecosystem extend beyond access to more drugs. American innovation also translates into a better understanding of what American patients need and where there are unmet population needs to improve our country's health. If there is a large unmet medical need in the U.S. that may not be as prevalent or urgent for another nation, the U.S. economy – driven by consumerism and capitalism – will lead to a prioritization of innovation for that condition.

From a national security and geopolitical perspective, ceding strength in innovation to other nations is detrimental to American global leadership – particularly as China grows its presence in the medical innovation sector. As the U.S. has passed policies that hinder the economic contributions of a vital American sector, China is emerging as a fierce competitor in the drug development ecosystem. In the past five years, China's share of global clinical trials has increased by 57 percent.[49]

10→15% China's share of clinical trials has jumped from **10 to 15 percent** of the global total in the past five years.[50]

Moreover, pharmaceutical companies now source approximately one-third of in-licensed molecules from China – and that reliance continues to grow.[51] This American industry, and the patients it supports, cannot afford to be hindered by policies that disincentivize the research and development of new treatments.

Conclusion

Across America, we see people living longer and healthier lives than in decades prior. Disrupting recent progress and advancements toward healthier aging, threatens health outcomes and American economic and geopolitical leadership.

Imposing price controls on large and small molecule drugs on differing timelines was an arbitrary decision that is not based on scientific evidence. Aligning the negotiation eligibility timelines for large and small molecule drugs will rectify misaligned incentives that the IRA created and ensure that small molecules can continue to enjoy the robust investment of the past.

The EPIC Act is a concrete policy solution that the 119th Congress can advance to ensure strength for American patient health outcomes, healthy aging, and the ongoing leadership of a vital national industry.

American patients, including those impacted by cancer and rare conditions, older individuals, and those living in rural communities, rely on an unimpeded supply chain and robust American healthcare innovation to stay healthy, remain active in the workforce and society, and contribute to our nation's economy. Passage of the EPIC Act will support the critical supply chain that ensures access to treatment and foster the continued leadership of the U.S. innovation ecosystem on the global stage.

> ***"We cannot take steps that will stunt the progress made in medical advancements, particularly for cancer and other difficult diagnoses. We must continue to ensure that all patients have access to the treatment best suited for them and prescribed by their trusted medical professionals, and that policies accurately reflect the needs and input of patients who will be most impacted by them." – Cancer Support Community + 60 Healthcare Organizations***[52]

About the Global Coalition on Aging and the Alliance for Health Innovation

The Global Coalition on Aging (GCOA) aims to reshape how global leaders approach and prepare for the 21st century's profound shift in population aging. Through research, public policy analysis, advocacy and strategic communications, GCOA is advancing innovative policy and market solutions and working to ensure global aging is a path to health, productivity, and economic growth.

GCOA, in collaboration with cross-sector stakeholders representing patient, provider, caregiver, policy, industry, and academic communities, launched the *Alliance for Health Innovation (Alliance)* with the mission to establish the importance of innovation in achieving healthy aging through policy reforms, investments, and strategic partnerships – both for the value to patients and health system sustainability.

The Alliance advocates for policy solutions that support a robust, thriving innovation sector that enables people to live longer – and healthier – lives and welcomes the perspective and engagement of stakeholders across communities to support and advance solutions that drive innovation and better outcomes for aging populations.

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