Global Coalition on Aging

Executive Summary: Impact of the IRA on Patient Access & Discovery of Small Molecule Drugs

Overview

The Inflation Reduction Act of 2022 (IRA) allows Medicare to negotiate drug prices directly with pharmaceutical manufacturers through the Medicare Drug Price Negotiation Program (MDPNP). One policy within the IRA, known commonly as the "pill penalty," disincentivizes investment into research and discovery of new small molecule drugs, negatively impacting patient access, healthy aging, and American innovation.

Small molecule drugs provide increased flexibility to meet patient needs and reduce barriers to patient access and adherence. The IRA disincentivizes the development of small molecule treatments, which may force patients to rely on more costly and complex biologic treatment regimens, threatening efforts to improve patient access and healthy aging.

Small Molecule Drugs: Drugs that can enter cells easily due to their low molecular weight and are typically taken in pill, syrup, or inhalant form to manage patient symptoms. Under the **Inflation Reduction Act** (IRA), small molecule drugs become subject to Medicare price negotiation **nine years after approval** by the U.S. Food and Drug Administration (FDA).

Large Molecule Drugs: Treatments that are injected or infused in a doctor's office or hospital setting. Under the **Inflation Reduction Act** (IRA), large molecule drugs – also called biologics – become subject to Medicare price negotiation **thirteen years after approval** by the U.S. Food and Drug Administration (FDA).

By The Numbers: The Impact of Small Molecule Drugs	
80%	20 of the first 25 drugs – or 80% of treatments – selected for drug price negotiations under the IRA are small molecule drugs.[I]
71%	71% of drugs approved by the FDA and European Medicines Agency (EMA) to treat rare diseases between 2001 and 2021 were small molecules.[II]
70%	Since the IRA was introduced, there has been a 70% reduction in early-stage funding for the development of small molecule treatments.[III]

I Managed Healthcare Executive: Trump Impact on Medicare Drug Price Negotiations Uncertain (January 2025)
II Science Direct: Exploring the Potential Challenges for Developing Generic Orphan Drugs for Rare Diseases: A Survey of US and European Markets (May 2023)
III Vital Transformation: Inflation Reduction Act – Two Years On Investor Behavior, R&D Impacts, & Proposed Solutions (April 2025)

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> "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."
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> – Cancer Support Community + 60 Healthcare Organizations (Source)

Impact of Small Molecule Drugs for Key Patient Populations

Unique Clinical Benefit: Small molecule drugs are the only medicines that can pass through the blood-brain barrier, making the innovation of these treatments critical for cancer, HIV, central nervous system disorders, and more.

Accessible Treatment Options: Due to their form and the availability of different dosages, patients can easily take small molecule drugs at home, eliminating the need to travel to a health care provider, reducing burdens of receiving treatment, and increasing treatment adherence.

Patient Affordability: Small molecule drugs typically have lower costs associated with treatment compared to other treatment options, such as infusions.

A Straightforward Policy Solution to the "Pill Penalty"

The Ensuring Pathways to Innovative Cures (EPIC) Act aims to eliminate the harmful and unnecessary "pill penalty" by aligning the negotiation eligibility timelines of small and large molecule drugs. A commonsense solution, the EPIC Act would:

- Ensure that research and development of small molecule drugs is not disincentivized by an arbitrary policy distinction that lacks a scientific basis.
- Support the critical supply chain that ensures access to treatment and the continued leadership of the U.S. innovation ecosystem on the global stage.
- Establish a strong precedent for pharmaceutical research and development for years to come.

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. Patients, including those impacted by rare and chronic conditions, older Americans, and people living in rural communities, rely on the continued innovation of new treatments and cures to stay healthy, remain active in the workforce, and contribute to our nation's economy – and that all starts with an unimpeded supply chain and robust American healthcare ecosystem.

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For more information about this policy brief please reach out to:

Melissa Gong Mitchell, Executive Director, Global Coalition on Aging (mmitchell@globalcoalitiononaging.com)
Michiel Peters, Head of Advocacy Initiatives, Global Coalition on Aging (mpeters@globalcoalitiononaging.com)