What Patients Need to Know:
Medicare Drug Price Negotiation

Passed in 2022, the Inflation Reduction Act (IRA) contains several provisions which can adversely affect patients' access to lifesaving treatments, particularly to the newest innovative medicines, as well as to lower-cost biosimilars. One of these provisions is new authority for Medicare to "negotiate" (set) drug prices for costly drugs.

Why Medicare Didn't Negotiate Prices to Begin With?

When the Medicare Part D drug benefit program was designed and implemented in 2003, the negotiation of prescription drug prices was a contentious issue. Ultimately, the decision was made not to allow the federal government to negotiate drug prices directly, based on concerns that government-negotiated prices could potentially undermine innovation and limit patient access to new medicines.

Historical evidence has borne these concerns out. For example, in some European countries and Canada, government-negotiated drug prices have led to less innovation and fewer new medicines being developed. As a result, patients in these countries often don't have access to the latest life-saving treatments that are available in the United States.

By maintaining a system that encourages innovation and competition in the pharmaceutical industry, we can help ensure that patients like John have access to the most advanced, cutting-edge treatments that can potentially save or significantly improve their lives.

60% of new drugs are developed in the U.S.

In the 1970s, European companies developed most new drugs; however, since the implementation of price controls in Europe, **60% of new drugs are currently developed in the US**, compared to 13% in Switzerland, 8% in the United Kingdom (UK), and 6% in Germany and France.[1]

Of new cancer medications, **90% are available to US patients** within the first year of launch, whereas less than half of these are available to cancer patients in Germany, the UK, France, and Canada.[4]

90% of new medicines are available to U.S. patients within the first year of launch

About ASBM

The Alliance for Safe Biologic Medicines (ASBM) is a diverse group of stakeholders that includes physicians, pharmacists, patient advocates, researchers, and biopharmaceutical manufacturers. Since 2010, ASBM has worked closely with regulators worldwide as they develop and implement health policies, to ensure that these serve the best interests of patients.
Learn more at www.safebiologics.org

SafeBiologics
ALLIANCE for SAFE BIOLOGIC MEDICINES

What Patients Need to Know: Medicare Drug Price Negotiation

Of cancer medicines launched globally between 2011 and 2019, more than **96% are available to US patients** while only 65% are available in other developed nations such as Australia, Japan and the UK.[2] Furthermore, cancer death rates per 100,000 are **1.6 to 1.8 times higher** in Europe than those in the US.[3]

Cancer death rates are 1.6 to 1.8 times higher in Europe than those in the U.S.

400,000 MORE DEATHS EACH YEAR

Approximately 400,000 additional patients would die from cancer in the U.S. each year. This is greater than the number of deaths from COVID-19 during 2020, every year.

If U.S. Cancer patients had European cancer death rates...

Imagine a situation in the United States where European-style price controls are implemented. John, an American patient, is diagnosed with a rare form of cancer. If the government were to set drug prices as in certain European countries, it might discourage companies from investing in the research and development of new, innovative treatments for John's cancer. Consequently, John may be limited to older, less effective treatments, which could reduce his chances of survival or significantly impact his quality of life.

Controlling Costs Without Sacrificing New Drugs

There are proven ways to lower costs, including promoting competition from biosimilars: highly similar near-copies of innovator medicines used to treat many chronic conditions like rheumatoid arthritis, psoriasis, Crohn's disease, and cancer.

The cumulative savings in drug spend for classes with biosimilar competition is estimated to have been $21 billion over the past 6 years. Trends show an acceleration in savings per quarter, and in Q2 2022 alone, savings in drug spend due to biosimilar competition were estimated at $3.2 billion. As these products compete for market share, the average sales price (ASP) of biologics (both reference products and biosimilars) is declining. The prices of biosimilars have decreased at a negative compound annual growth rate (CAGR) of -9% to -24%; the prices of most reference products have decreased at a negative CAGR of -4% to -21%.[5] Unfortunately, the price negotiation scheme and other provisions in the IRA may jeopardize these successes by introducing new uncertainty into the market, and discouraging biosimilar development.

What Can Patients Do?

Over the next two years, the Centers for Medicare and Medicaid will be soliciting comment on how the IRA's provisions will be implemented. ASBM will keep patients informed about these comment periods and other opportunities to make their voices heard through patient advocacy organizations.

Scan the QR code to subscribe to ASBM's newsletter and stay up to date on developments with IRA implementation and other emerging issues that can negatively impact patient access to life-improving and life-saving medicines.

Follow ASBM on Twitter at @SafeBiologics.

SafeBiologics
ALLIANCE for SAFE BIOLOGIC MEDICINES

1 "Europe negotiates a poor vaccine rollout"; Forbes, April 2021
2 IQVIA Analytics, FDA, EMA, PMDA, and TGA data. New active substances approved by at least one of these regulatory agencies and first launched in any country from January 1, 2011 to December 31, 2019; June 2020.
3 "Democrat plan on drug costs will stifle innovation", San Antonio Express-News, May 12, 2021
4 IQVIA Analytics, FDA, EMA, PMDA, TGA, &w3 Health Canada data, April 2021.
5 Amgen 2022 Biosimilar Trends Report