

GOVERNMENT-MANDATED PRICE CONTROLS HARM PATIENTS AND UNDERMINE INNOVATION

America leads the world in medical innovation, with a market-based health care system, strong protections for intellectual property and other policies that promote investment in new discoveries. We are in a new era of medicine where breakthrough science is transforming patient care and achieving tremendous progress against some of the most complex and difficult to treat diseases of our time. A record number of 65 medicines were approved in the United States last year alone.^{i,ii} And the future has never been brighter with about 8,000 medicines in clinical development globally with the potential to impact U.S. patients.ⁱⁱⁱ In fact, across the pipeline, 74% have the potential to be first-in-class treatments, representing entirely different approaches to treating disease.^{iv}

Competitive market conditions are the most effective way to meet the needs of patients, address society's demand for better medical treatment, maximize value and reward innovation. In contrast, government-mandated price controls can lead to reduced patient access and less investment in research and development that drives future therapeutic advances for patients. Price control policies differ from country to country. The common result, however, is that patients and innovators lose.

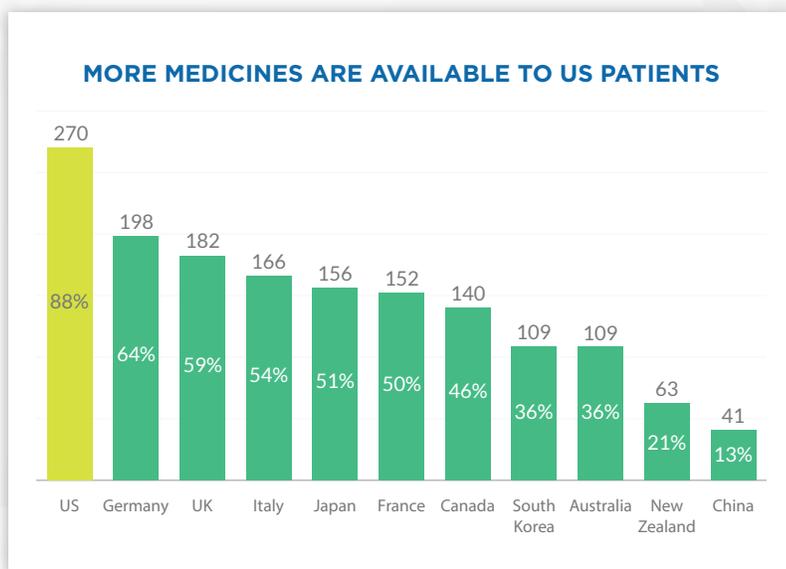
International reference pricing—one form of price control—is where a government uses medicine prices in other countries to set prices in its own country. This is not a market-based approach to health care policymaking, and it ultimately harms patient access and discourages future research and development. The Department of Commerce found that international reference pricing and other foreign price controls result in, on average, 11% to 16% less private R&D investment worldwide, causing fewer new medicines to be launched.^v And further research estimates that lifting government price controls in OECD countries would result in 8 to 13 additional new medicines launching globally every year by 2030.^{vi}

The US market-based system protects, rewards and values the ongoing discovery of much-needed medicines to treat the most challenging and debilitating diseases facing patients today. For that, we get access to the newest treatments and the best outcomes.

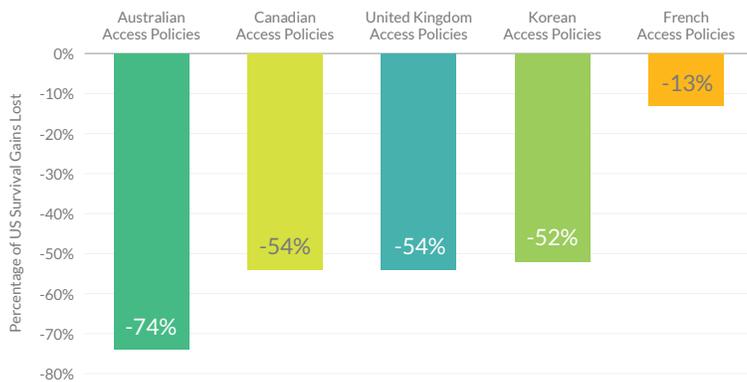
HOW PRICE CONTROLS HARM PATIENT ACCESS

Americans get access to new medicines years earlier, on average, than other wealthy nations, and they have access to more medicines than patients in any other country.

Nearly 90% of new medicines launched since 2011 are available in the United States, compared to just 64% in Germany, 59% in the United Kingdom, 51% in Japan, 50% in France and 46% in Canada.^{vii} And the medicines available in these countries take years longer, on average, to reach patients. On average, patients must wait at least 14 months longer in Canada and 19 months longer in France than in the United States.



LUNG CANCER PATIENTS EXPERIENCE BETTER SURVIVAL UNDER THE MARKET ACCESS POLICIES IN THE UNITED STATES



When foreign governments set artificially low prices for medicines, patients in those countries face significant restrictions in accessing those medicines. For example, if U.S. patients diagnosed with the most common form of lung cancer had the lower levels of access experienced in other wealthy countries, aggregate survival gains from 2006 to 2017 would have been cut in half.^{VIII}

There are right ways and wrong ways to ensure patients can afford their medicines. Importing price controls from countries that restrict access to medicines will harm patient access here in the United States and reduce biopharmaceutical companies' ability to invest in the next generation of treatments and cures. Instead, we need to enhance the competitive marketplace, ensure more of the \$166 billion in negotiated rebates and discounts in

the biopharmaceutical supply chain are used to lower costs for patients at the pharmacy counter, address misaligned supply chain incentives, and promote value-based contracts and innovative payment models that lower out-of-pocket costs and improve predictability for patients.

I US FDA. 2018 Novel Drugs Summary. January 2019.

II US FDA. 2018 Biological License Approvals

III Adis R&D Insight Database. May 2019.

IV Analysis Group. The Biopharmaceutical Pipeline: Innovative Therapies in Clinical Development, July 2017. http://www.analysisgroup.com/uploadedfiles/content/insights/publishing/the_biopharmaceutical_pipeline_report_2017.pdf.

V U.S. Department of Commerce. Pharmaceutical Price Controls in OECD Countries: Implications for U.S. Consumers, Pricing, Research, & Development, & Innovation. 2004.

VI T Schwartz, A Ward, X Xu and J Sullivan. The Impact of Lifting Government Price Controls on Global Pharmaceutical Innovation and Population Health. 2018.

VII PhRMA analysis of IQVIA Analytics Link and FDA, EMA and PMDA data on new active substances first launched globally between 2011 and 2018, May 2019.

VIII IHS Markit. Comparing Health Outcome Differences Due to Drug Access: A Model in Non-Small Cell Lung Cancer. December 2018. <https://ihsmarkit.com/research-analysis/populationhealth-outcomes-american-patients.htm>