

ISSUE BRIEF | Center for a Healthy America

Put Americans First by Ending Global Freeloading

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TOPLINE POINTS

- ★ Patients with chronic conditions and other debilitating diseases can access lifesaving prescription drugs because drug manufacturers and American health agencies invest billions of dollars to develop new medicines.
- ★ Other wealthy countries pay artificially lower prices for prescription drugs, which deprives drug manufacturers of billions of dollars that are critical to developing lifesaving medications to treat chronically ill patients. Other countries pay just 24 percent of the price that Americans pay for brandname prescription drugs.
- ★ Policymakers can expand access to pharmaceutical treatments for sick patients by pressuring wealthy countries to end freeloading practices. Greater pharmaceutical options would also lower costs for Americans by increasing competition and helping sick patients avoid costly hospital visits.

Overview

Patients rely on drug manufacturers and federal health agencies to develop high-quality, effective drugs to treat chronic conditions and other debilitating diseases. However, wealthy countries around the world freeload off American innovation when they institute price controls that reduce global drug sales revenue. These price controls stifle the development of critical pharmaceutical breakthroughs needed to treat and save sick patients.

Policymakers could accelerate drug development and enhance patient health by



implementing reforms that discourage other countries from freeloading off American drug innovation. Implementing reforms that end price-setting policies abroad would ensure other countries more equitably contribute to global drug development and increase the availability of lifesaving medications that improve millions of lives. This would lower patient costs by increasing competition and reducing unnecessary hospital visits and would provide U.S. policymakers with greater flexibility to lower drug prices without harming innovation.

Drug Research and Development Benefits Patients

Among the largest healthcare threats facing patients in the United States is chronic diseases. Chronic diseases, such as cancer, diabetes, and heart disease, are long-lasting conditions that impair a person's daily activities and require ongoing medical care. In 2018, 129 million Americans were diagnosed with at least one chronic condition (Boersma et al., 2020). For every 10 dollars Americans spend on health care each year, nine dollars goes to treat individuals with chronic diseases (Buttorff et al., 2017). In 2022, these illnesses claimed the lives of 1.9 million Americans, accounting for eight out of the 10 leading causes of death (Centers For Disease Control, 2024).

High-quality and widely available drugs play a major role in improving the health of patients who suffer from chronic diseases. Prescription drugs can reduce the severity of patients' conditions so they can more easily work, travel, and perform daily activities (<u>Lichtenberg, 2002</u>). These drugs also increase the chance that patients can live longer lives instead of dying prematurely (<u>Lichtenberg, 2003</u>). Overall, prescription drugs were responsible for 66 percent of the increase in longevity in the United States and 73 percent of the increase in longevity in other wealthy countries between 2006 and 2016 (<u>Lichtenberg, 2022</u>).

Drug manufacturers and government health agencies recognize the critical need for patients to access new drugs. Both pour billions of dollars into research and development (R&D) to discover and produce new drugs (Congressional Budget Office, 2021). Drug R&D requires investigating the origin of diseases, inventing new chemical compounds or biologic agents, turning the compound or agent into a pill, injection, or inhalable medication, and performing clinical trials.

Given the enormous need to advance scientific breakthroughs, lawmakers task the National Institutes of Health (NIH) to fund basic research through grants to research centers at universities (Congressional Budget Office, 2021). Basic drug research is the scientific exploration of the origin of diseases and how they interact with the human body (Cleary et al., 2018). This research paves the way for drug manufacturers to develop therapies to treat these diseases. As for-profit companies, drug manufacturers have little incentive to invest in



basic research that does not directly translate into a commercial product. Therefore, the NIH fills this research gap. Research funded by the NIH contributed to developing 354 of the 356 drugs that the Food and Drug Administration (FDA) approved between 2010 and 2019 (Cleary et al., 2023).

After NIH grant recipients complete basic research, drug manufacturers invest billions of dollars to translate basic R&D advancements into commercial products. A study by the Brookings Institution estimated that every \$1 billion that drug manufacturers invested in R&D produced 0.7 to 4.5 new drugs in 2018 (Conti et al., 2021).

Working together, drug manufacturers and the NIH generate new cures for Americans. One study estimated that every dollar that the NIH provides in grants for basic R&D generates \$8.38 in R&D investments from drug manufacturers after eight years (Toole & Hathorn, 2007). The new drugs developed by public and private drug R&D investments have improved the lives of millions. Between 2006 and 2016, new antiretroviral drugs increased the average life expectancy of patients with HIV by 10 years (Antiretroviral Therapy Cohort Collaboration, 2017). New Hepatitis C drugs can cure patients in 90 percent of cases (O'Kane, 2023). Advances in disease-modifying treatments for multiple sclerosis have also helped patients suppress the disease (National Institute of Neurological Disorders and Stroke, n.d.).

Global Freeloading Harms Sick Americans

It is vitally important that policymakers accelerate the development of prescription drugs to treat chronic diseases. Between 2015 and 2030, the number of Americans with three or more chronic diseases is expected to increase from 30 million to 83 million. These illnesses also threaten to cost the United States \$2.8 trillion between 2016 and 2030 in increased healthcare spending and lost productivity (<u>Partnership To Fight Chronic Disease</u>, 2016).

Unfortunately, many countries undermine the development of prescription drugs that treat these diseases. Many countries leverage their national health programs to negotiate steep discounts from drug manufacturers. An analysis by the RAND Corporation found that the list prices of brand-name drugs were, on average, 4.22 times higher in the United States than in other wealthy countries in 2022. To put it another way, other countries paid just 24 percent of the list price that American patients and taxpayers were charged for drugs (Mulcahy et al., 2024).

This phenomenon, known as global freeloading, allows other wealthy countries to have their cake and eat it too—to get lifesaving drugs for their citizens without paying the necessary costs to develop them. As a result, these countries are failing to adequately



fund the development of new prescription drugs that are crucial for treating sick patients, especially those with chronic conditions.

Many countries use a policy known as external reference pricing (ERP) to determine how their national health programs pay for a drug. ERP sets a drug's price based on how much other countries pay for the same drug. A country's health program will typically choose a list of similar countries, evaluate the drug's price in those countries, and set the price of the drug in their own country at the average price, the lowest price, or another benchmark. Twenty of the 27 countries within the European Union (EU) and 24 of the 30 countries within the Organisation for Economic Co-operation and Development (OECD) use ERP (World Health Organization, 2013).

Wealthy countries also apply a range of other policies to pay lower prices for prescription drugs. Internal reference pricing, for example, determines the maximum price for a drug based on the average price of other drugs that are therapeutically similar in the same country (Carone et al., 2012). Some countries impose "payback" provisions that require drug manufacturers to refund some of their revenue to the government if the country spends more than a predetermined amount on prescription drugs.

This freeloading extends beyond price-setting policies to government R&D funding. Other countries freeload off American innovation by investing fewer public dollars in drug R&D relative to the United States. An analysis by the OECD found that America's federal government invested 0.19 percent of its gross domestic product (GDP) in drug R&D in 2021. European governments, however, invested just 0.07 percent of their GDP in drug R&D (Organisation For Economic Co-operation and Development, 2023). Partly because of other nations' price-setting and R&D policies, the vast majority of drug research is performed in the United States. Between 1998 and 2022, 78 percent of global drug R&D was conducted within the United States (Pharmaceutical Research and Manufacturers of America, 2024).

Other countries' freeloading policies have dramatically reduced the capacity of drug manufacturers to develop new products. On average, every \$2.5 billion increase in global drug sales to treat a specific disease incentivizes drug manufacturers to develop an additional new drug for the same condition (<u>Dubois</u>, et al, 2015).

When other countries enforce price-setting policies that reduce drug sales revenue, they withhold billions of dollars that are critical to developing new treatments for sick patients. The Information Technology and Innovation Foundation estimates that price controls in other wealthy countries reduced global drug sales by 77 percent, or \$254 billion, in 2018 (Long & Ezell, 2023). In other words, drug manufacturers had \$254 billion less



available to invest in developing new treatments.

Ending Global Freeloading Accelerates Treatments and Cures

Americans shoulder the global burden of developing new drugs because other countries have ignored their responsibility to do so. The United States accounts for 67 percent of global sales of new brand-name drugs approved since 2018 (European Federation of Pharmaceutical Industries and Associations, 2023). By contrast, drug manufacturers collected only 15.8 percent of their sales revenue in Europe's five largest economies (European Federation of Pharmaceutical Industries and Associations, 2023). Another analysis from the Brookings Institution estimates that American consumers accounted for up to 78 percent of global profits for drug manufacturers in 2016. Manufacturers generated only 22 percent of their profits outside of the United States (Goldman & Lakdawalla, 2018).

To put this in perspective, the average American household paid drug manufacturers \$616, which was subsequently invested in R&D in 2021 (<u>Pharmaceutical Research and Manufacturers of America, 2024</u>). By contrast, the average household in Canada paid drug manufacturers just \$59, which was ultimately invested in R&D (<u>Patented Medicine Prices Review Board, 2022</u>).

Drug manufacturers could demand other wealthy countries pay higher prices and more equitably contribute to drug innovation. Instead, they allow these countries to evade their responsibility to support pharmaceutical development. It is unfair for American patients, including seniors, to pay such high prices to subsidize drug development, while other wealthy nations refuse to contribute.

Policymakers should encourage other wealthy countries to abandon price-setting policies that undermine drug development. If other countries paid higher prices for brand-name prescription drugs, drug manufacturers could generate significantly more revenue from global sales. In 2020, the White House Council of Economic Advisors estimated that if other wealthy countries ended policies that artificially lowered their drug prices, global revenue for drug manufacturers would increase by \$194 billion, a 42 percent increase (The Council of Economic Advisors, 2020).

If other countries paid higher drug prices, drug manufacturers could invest in more R&D to develop additional medications or could lower prices for American patients. A 2018 study in the *Value in Health* journal estimates that every 1 percent increase in drug sales revenue leads to a 3.5 percent increase in new drug approvals. Therefore, removing drug price controls in other wealthy countries could cause drug manufacturers to produce eight to 13 additional drugs per year by 2030 (Schwartz, 2018).

Patients in the United States and around the world would benefit long-term if foreign





governments spend more on prescription drugs. As drug manufacturers develop more drugs, chronically ill patients could access these products to treat their conditions and live longer, healthier lives. The *Value in Health* journal study estimated that the increased availability of new drugs would increase life expectancy in OECD countries by up to nearly one year (Schwartz, 2018). Another 2018 study by the Brookings Institution estimated that if European prices for prescription drugs increased by 20 percent, Americans would experience a \$10 trillion increase in welfare gains over the next 50 years. Europeans would also experience a \$7.5 trillion increase in welfare gains over this same period through new drug discovery that would alleviate the health conditions of future generations (Goldman & Lakdawalla, 2018). For example, dementia cost Europeans \$438 billion in medical expenses and lost productivity in 2019 (World Health Organization, 2021). Slightly higher drug prices in Europe could provide additional revenue for drug manufacturers to develop new, innovative treatments, which would improve the quality of European patients' lives.

Less freeloading by other countries could also lower costs for Americans. As other countries pay higher prices, manufacturers could develop more brand-name drugs to compete against one another. When drug manufacturers compete to develop drugs that treat the same condition, these companies have an incentive to offer larger discounts to health plans to cover their products. This would lower the net price of drugs, resulting in lower premiums for patients (Lakdawalla & Li, 2021). In addition, newly developed drugs could potentially reduce the need for chronically ill patients to spend money on other health care services, such as expensive hospital stays and numerous doctor's office visits (Congressional Budget Office, 2012).

Policymakers in the United States would also have additional opportunities to lower American drug prices if other countries abandoned freeloading policies. Since manufacturers currently generate such a large share of their revenue from American patients, measures to reduce American drug prices artificially potentially threaten the ability of drug manufacturers to innovate. Policymakers would have greater latitude to enact such initiatives if drug manufacturers generated a larger share of their global sales from other countries.

Policy Options To End Global Freeloading

Policymakers can consider a range of options to end global freeloading.

Establish Most-Favored Nation Pricing In Government Health Programs: One option is to align the prices drug manufacturers charge Americans with the prices they charge in other wealthy countries through a reform known as the Most Favored Nation (MFN) Model (42 C.F.R. Part 513, 2020). In 2020, the Centers for Medicare and Medicaid Services (CMS) under President Trump proposed this policy as a demonstration program under



the agency's Center for Medicare and Medicaid Innovation (CMMI) (42 U.S.C. 1315a, 2010). The MFN Model would limit how much Medicare and Medicaid spend on certain high-cost drugs based on the drug's lowest price in other wealthy countries. The countries selected to calculate the MFN price would be countries within the OECD with a GDP per capita that is at least 60 percent of America's GDP per capita. However, President Biden's CMS rescinded the MFN Model in December 2021 (42 C.F.R. Part 513, 2021).

Drug manufacturers would face a choice under the MFN Model: Raise their prices in other countries so they can maintain their prices in the United States or lower their American prices to match the lowest price they offer other countries. These incentives would encourage drug manufacturers to reduce or even terminate the discounts they offer other countries and lead these countries to contribute more funding to pharmaceutical innovation. The Office of the Assistant Secretary for Planning and Evaluation estimated that drug prices in other countries would increase in reaction to the MFN Model, potentially up to the drug's average price in the United States (42 C.F.R. Part 513, 2020). Higher prices abroad would empower drug manufacturers to invest significantly more resources into developing new cures and treatments for sick patients.

Policymakers could re-promulgate the MFN Model through CMMI. When policymakers decide what international drug pricing information to measure, they could use net drug prices to fully account for the discounts and rebates drug manufacturers provide other countries. When deciding which drugs the MFN Model would regulate, policymakers could consider selecting the top 50 brand-name drugs without therapeutically similar competitors that account for the greatest share of Medicare's drug spending. Policymakers could also consider implementing the MFN Model on drugs that treat the most expensive health conditions. Another option would be to implement the MFN Model on drugs that were developed through federal funding from the NIH.

Policymakers could also promulgate the MFN Model in the Federal Employees Health Benefits (FEHB) program. The agency that oversees the FEHB program, the Office of Personnel Management (OPM), sets the program's policies through letters they issue to health insurers that administer the program's health benefits. OPM could issue a letter to participating health insurers that it will limit how much it spends on brand-name drugs based on the lowest price established by the MFN Model (U.S. Office of Personnel Management, n.d.). To implement this reform, policymakers could consider how to ensure drug manufacturers continue to participate in the program so that products remain widely available to the program's beneficiaries at a new lower cost.

Establish MFN Pricing Under the Inflation Reduction Act: Another option is to implement the MFN Model through CMS' drug price negotiation program. In 2022, Congress enacted the Inflation Reduction Act (IRA). The IRA directed CMS to





establish a program to determine a "maximum fair price" for 60 brand-name drugs that Medicare Part B and Part D cover. The law requires CMS to consider the top 50 drugs that account for the greatest share of Medicare's drug spending (42 U.S.C. 1320f-3, 2022).

The law gives CMS broad authority to decide how to determine the maximum fair price of these drugs. The IRA directs the agency to consider the drug's R&D costs, whether the drug faces competition from other brand-name drugs, and other relevant information to determine the price of drugs selected for CMS's price-setting program. However, the law leaves it up to the agency to determine how much to weigh these factors. In June 2023, CMS issued guidance on how the agency will set the maximum fair price for selected high-cost prescription drugs (Centers for Medicare & Medicaid Services [CMS], 2023).

Policymakers could issue revised guidance stating that CMS would consider the price of the program's drugs in other wealthy countries when determining their maximum fair price. Specifically, the agency would consider the drug's lowest international price as outlined in the MFN Model.

Focus MFN Pricing on Future Drugs: Policymakers could also introduce the MFN Model exclusively for new brand-name drugs that are approved after a certain date rather than drugs that already exist on the market. Focusing the MFN Model on new products would make sure drug manufacturers could recoup their R&D investments in drugs that are already on the market. At the same time, it would give companies ample time to negotiate higher prices from other countries for future drugs currently in development. To enforce this proposal, the MFN Model would apply to a new drug once a certain number of similar countries decided to cover the new drug under their national health program.

To provide relief to seniors who use expensive drugs already on the market, this proposal could establish options to reduce their costs. One option is to eliminate cost-sharing for patients for certain brand-name drugs that reduce their overall health expenses when patients adhere to the drug's treatment regimen. Alternatively, this proposal could apply an across-the-board discount to the most expensive brand-name drugs that are already on the market. For example, policymakers could apply an across-the-board discount that is proportionate to how much more Americans are spending on drugs compared to prior years. On a per capita basis, Americans spent roughly 18 percent more on retail prescription drugs in 2021, after accounting for inflation, than they did in 2011 (Wager et al., 2023). Policymakers could use this metric to apply an 18 percent cut to the most expensive brand-name drugs for seniors.

Apply the MFN Model to Commercial Health Plans: Policymakers could also implement the MFN Model on certain drugs in the commercial market, including for





plans in the individual and employer markets. Senator Rick Scott (R-FL) and Senator Josh Hawley (R-MO) introduced the Transparent Drug Pricing Act (S. 977, 2019), a proposal to establish the MFN Model for all consumers, regardless of their coverage status. This bill would prohibit drug manufacturers from charging a list price for any drug approved by the FDA that exceeded the lowest list price of the same drug in Canada, France, the United Kingdom, Japan, or Germany.

Establish the International Pricing Model: Policymakers could also limit Medicare and Medicaid spending on prescription drugs to the average price in other wealthy countries. In 2018, CMS proposed this policy for Medicare Part B, known as the International Pricing Index (IPI) Model, as a demonstration program under CMMI (CMS, 2018). CMS estimated this policy would reduce Medicare and Medicaid spending on prescription drugs by \$19.7 billion between 2020 and 2025. The agency also estimated premiums for seniors would decrease by \$6 billion.

Setting Medicare and Medicaid's prices based on average international prices, rather than the MFN price, could give drug manufacturers more predictability when they seek to sell medication to Medicare and Medicaid beneficiaries. Setting both programs' prices based on a drug's lowest foreign price could introduce sudden shifts in the MFN price of the drug when individual countries change their policies. This could threaten the ability of manufacturers to earn revenue and invest in new drugs. Using average prices under the IPI Model, by contrast, could insulate drug manufacturers from sudden price changes year to year, while providing price relief to patients.

Prohibit Global Discounts as a Condition of Medicare Coverage: Another option is to use Medicare's bargaining power to encourage drug manufacturers to terminate the discounts that they offer other wealthy countries. Policymakers could prohibit drug manufacturers from participating in Medicare if they charge other countries lower prices for their products than they charge to Medicare. If drug manufacturers fail to raise their prices abroad to meet this requirement, policymakers could require manufacturers to rebate the difference to Medicare beneficiaries.

Use American Trade Authority to End Freeloading: Policymakers could also use America's negotiating power in trade relations to pressure other countries to abandon freeloading policies. Section 301 of the Trade Act of 1974 empowers the Office of the United States Trade Representative (USTR) to investigate other countries' policies that "burden or restrict" American commerce (19 U.S.C. 2411, 1974). If the USTR determines that another country is enforcing policies that undermine American commerce, the office can impose tariffs and other trade restrictions to retaliate against them. If the other country chooses to rescind these harmful policies in response to USTR's tariffs, both countries could establish a new



trade agreement in which the United States stops enforcing its trade restrictions on the condition that the other country refrains from reimposing its harmful policies (<u>Congressional Research Service</u>, 2023).

USTR can play an effective role in encouraging other countries to reverse policies that burden Americans. In 2017, USTR initiated an investigation into China's policy of requiring American companies that sell goods in the country to surrender their intellectual property and proprietary technology to Chinese companies (Office of the United States Trade Representative [USTR], 2017). One year later, USTR concluded that China's policies were discriminatory and burdened American companies (USTR, 2018). The agency subsequently imposed tariffs on Chinese goods entering the United States. Following these tariffs, China and the United States signed a trade agreement that committed China to end its technology transfer abuses in exchange for the United States lowering its tariffs (USTR, 2020). However, the Biden Administration failed to adequately enforce the conditions of the agreement against China (Ways & Means Committee, 2022).

Despite Biden's enforcement failures, USTR's actions demonstrate a proof-of-concept that Section 301 tariffs can encourage countries to end policies that threaten America's interests. The agency could similarly investigate other countries' price-setting policies that undermine drug access and development. Drug manufacturers require billions in revenue to invest in R&D and develop drugs that raise the living standards of Americans. Because other countries impose price-setting policies that deny drug manufacturers this necessary revenue, these companies develop fewer treatments for American patients with chronic diseases and other conditions.

Conclusion

Patients in every country benefit when drug manufacturers develop new medications to treat and cure diseases. However, many wealthy countries enforce price-setting policies that undercompensate drug manufacturers that sell products to their citizens. These countries are potentially withholding billions of dollars from drug manufacturers, which could invest those dollars to develop lifesaving treatments or lower prices for American patients.

Policymakers should put patients first and end global freeloading off American drug innovation. They could use the regulatory authority available to CMS and USTR to encourage other countries to pay higher prices for prescription drugs. This would provide drug manufacturers with billions of dollars to develop new medications. In turn, patients in the United States and abroad would live longer and healthier lives due to these newly available drugs. Reducing freeloading abroad would also allow U.S. policymakers to lower American drug prices while ensuring sustained investment in pharmaceutical innovation and the development of lifesaving therapies.



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