



June 25, 2025

Ms. Catherine Gibson
Deputy Assistant U.S. Trade Representative
for Monitoring and Enforcement
Office of the U.S. Trade Representative
The Winder Building
600 17th Street, NW
Washington, DC 20508

IN RE: Docket Number USTR-2025-0011 - Request for Public Comments Regarding Foreign Nations Freeloading on American-Financed Innovation

Dear Deputy Assistant USTR Gibson,

The Center for American Principles is a 501(c)(4) non-profit issue advocacy organization that advances policy solutions based on American core principles to tackle the country's most critical challenges. Our mission is to protect and promote individual freedoms, free enterprise, limited government, the rule of law, and a strong national defense. We appreciate the opportunity to share our views on foreign price controls that contribute, along with domestic middlemen and abuse of government-mandated subsidy programs, to inflation of U.S. prices for biopharmaceutical products.

What's At Stake for the U.S.

Thanks to free enterprise, world-class research institutions, robust capital markets, constitutionally protected intellectual property rights, and a strong rule of law environment, the United States enjoys the world's most successful ecosystem for biopharmaceutical innovation. Within this ecosystem, moderate levels of federal funding for early-stage scientific research prime the pump of the American innovation engine, and the U.S. private sector drives it forward through much larger investments in applied research, product development, testing, regulatory approvals, and commercialization¹.

This success cannot be taken for granted. Prior to 1980, Europe, not the United States dominated global pharmaceutical production. According to economic consultancy

¹ Congressional Research Service, U.S. Research and Development Funding and Performance: Fact Sheet, <https://www.congress.gov/crs-product/R44307>

Vital Transformation: “Between 1961 and 1980, firms based on the European continent invented and brought to market over sixty percent of new therapeutic molecules.”²

The “Innovation Engine” report from the Eira Initiative at the Berkeley Policy Institute explains that three critical events taking place in the early 1980s, “created the legal infrastructure for today’s biopharmaceutical industry: (1) the Supreme Court’s extension of patent protection to biotechnological inventions (and the USPTO’s willingness to grant patents for such inventions), (2) the establishment of the Court of Appeals for the Federal Circuit and judicial decisions that restored robust levels of patent protection, and (3) enactment of the Bayh-Dole Act.”³ These consequential assertions of innovation leadership propelled the United States over the next decades to the forefront of the world’s biotech revolution, a lead it has maintained ever since.

The result has been a steady stream of new therapies—and even cures⁴. According to the Eira Initiative, during the period 2010-2019, “38 new drugs were approved each year on average by the U.S. Food and Drug Administration, representing a 60% increase relative to the previous decade. ... The United States as of 2021, was the source of approximately 40% of new drugs released worldwide, as compared to 25% for Europe... [and] approximately 60% of new U.S. drugs were developed by small biotech companies, whereas new drugs originating in Europe were principally developed by large pharmaceutical companies⁵” – a key indicator of the health and resilience of the U.S. ecosystem. These new therapies have generally been available to American patients sooner than those of any other country in the world. A 2024 report from RAND noted, “[M]ore than half of new drugs were sold first in the United States. The gap between U.S. launch and sales in other countries was about one year on average⁶.”

U.S. biopharmaceutical dominance has delivered broader economic benefits, as well. According to the National Association of Manufacturers, the industry’s direct contribution to GDP in 2021 was \$192 billion, up 24% from just two years earlier, and pharmaceutical-related economic activity supported nearly 1.5 million American jobs⁷. The industry’s leading role in U.S. R&D activity accelerated its impact: “Every year since 2004, publicly traded pharmaceutical companies have exhibited the highest rate of R&D intensity

² Vital Transformation, The Historical Impact of Price Controls on the Biopharma Industry, citing Arthur Daemmrigh. <https://vitaltransformation.com/wp-content/uploads/2022/04/The-Historical-Impact-of-Price-Controls-on-the-Biopharma-Industry.pdf>

³ Eira Initiative at the Berkeley Policy Institute, Innovation Engine, <https://eirainitiative.org/wp-content/uploads/2024/11/Eira-Report-nov-12.pdf>

⁴ Gilead Sciences, Gilead Sets Sights on Hepatitis C Elimination as it Marks 10 Years of Curative Therapies, <https://www.gilead.com/stories/gilead-sets-sights-on-hepatitis-c-elimination-as-it-marks-10-years-of-curative-therapies>

⁵ Eira Initiative, Innovation Engine

⁶ RAND, New Prescription Drugs Typically Sold First in U.S., Reach Other Wealthy Nations Within a Year, <https://www.rand.org/news/press/2024/02/01/index2.html>

⁷ National Association of Manufacturers, Creating Cures, Saving Lives, https://documents.nam.org/COMM/NAM-Creating%20Cures,%20Saving%20Lives_FINAL3.pdf

(R&D expenditures as a percentage of net revenues) among all major U.S. tech industries—averaging about 19% during this period and approaching 25% since 2017.”⁸ Altogether, private sector investment in U.S. biopharmaceutical R&D approaches \$150 billion per year, constituting 55% of all global R&D, according to another recent study.⁹

Challenges Loom – Foreign and Domestic

Today, however, a confluence of challenges threatens the U.S. leadership position and the enormous benefits it has delivered to U.S. patients and the U.S. economy. The result of forfeited U.S. leadership will inevitably be increased costs to the American public in terms of health outcomes, health expenditures, and technological leadership.

One such challenge is the healthcare subsidy that U.S. patients and taxpayers provide to much of the rest of the world, according to the Center for Medicare Services: “The United States spent approximately \$535.3 billion, or \$1,615 per capita, on prescription drugs in 2019, which is roughly twice as much as any other major industrialized nation. The prescription market in the United States represents approximately 50% of the global drug sales (in US dollars), and the United States generally pays greater prices for branded prescription medications, which makes the prescription market an attractive target for policies to reduce branded medication costs¹⁰”. A fact sheet from the U.S. Department of Health and Human Services adds, “Overall, [the Medicare Part B program] pays 2.11 times the non-U.S. OECD average price for the included drugs and 2.05 times the average for the nineteen OECD higher income countries.”¹¹

CAP agrees with President Trump, who said in his recent Executive Order, “Americans should not be forced to subsidize low-cost prescription drugs and biologics in other developed countries and face overcharges for the same products in the United States.” However, not all the price challenges American patients face are foreign-sourced. Unforced domestic policy errors also add to the U.S. cost of medicines.

Through a convoluted and opaque healthcare delivery infrastructure, pharmacy benefit managers (PBM’s) and the insurance companies to whom they are closely related, have been empowered to force high list prices on pharmaceutical innovators in order to exact exorbitant middleman profits. The rapidly expanding, government mandated 340B regime sees healthcare providers receiving medicines from pharmaceutical manufacturers

⁸ Eira Initiative, [Innovation Engine](#)

⁹ Nature, Chandri, et al. [Comprehensive measurement of biopharmaceutical R&D investment, https://www.nature.com/articles/d41573-024-00131-2](https://www.nature.com/articles/d41573-024-00131-2)

¹⁰ National Institutes of Health, [International reference pricing of pharmaceuticals in the United States: Implications for potentially curative treatments, Sullivan et al., https://pmc.ncbi.nlm.nih.gov/articles/PMC10373031/](https://pmc.ncbi.nlm.nih.gov/articles/PMC10373031/)

¹¹ HHS Issue Brief, [MEDICARE FFS PART B AND INTERNATIONAL DRUG PRICES: A COMPARISON OF THE TOP 50 DRUGS, https://aspe.hhs.gov/sites/default/files/migrated_legacy_files/197401/Part-B%20Drugs-International-Issue-Brief.pdf](https://aspe.hhs.gov/sites/default/files/migrated_legacy_files/197401/Part-B%20Drugs-International-Issue-Brief.pdf)

at deep discounts and then re-selling them to patients at a mark-up to subsidize unrelated costs of care. Adding further to the cost of medicines, and to a reduction in the availability of new breakthrough medicines to those who need them most, is the increasing legal uncertainty facing U.S. innovators from unwarranted attacks on the patent system that underwrites private sector capital investment.

A recent article¹² by the group No Patients Left Behind summarizes well both the benefits accruing to the United States from its leadership in biotechnology and many of the challenges facing that leadership from foreign and domestic policy errors:

- “Spending on novel medicines represents only about 8% of total U.S. healthcare expenditures.”
- “U.S. market prices for innovative medicines offer approximately a 70% discount compared to their full societal benefits, including better health outcomes, increased productivity, and reduced healthcare system costs.”
- “U.S. Pharmacy Benefit Managers (PBMs), acting as intermediaries between drug manufacturers, insurers, and pharmacies, often retain a disproportionate share [of drug costs] – more than 50% of brand medicine spending goes to someone other than the drug manufacturers.”
- “[W]ealthy nations are effectively paying only about 30% of U.S. net prices for innovative medicines, despite having economies that justify paying substantially more.”

¹² No Patient Left Behind, Time to End Foreign Free Riding and Fix the Global Imbalance in Biomedical Innovation, <https://www.linkedin.com/pulse/time-end-foreign-free-riding-fix-global-imbalance-k1huf/>

Figure 1: The Freerider Index – how much wealthy countries underpay for medicines

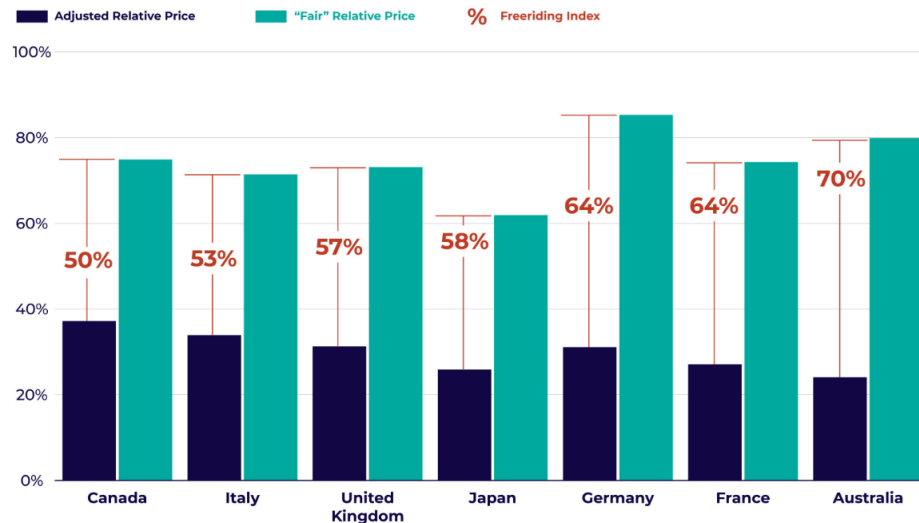


Figure 1 plots adjusted relative price vs “Fair” relative price, sorted by increasing GDP per capita PPP, and tracks our basket of branded drugs only. SOURCE: RAND, CIA, RA Capital Management. The Freeriding Index is shown for each country and measures the percent by which the Adjusted Relative Price is lower than the “Fair” Relative Price.

13

No Free Lunch

The U.S. pharmaceutical industry bears the lion’s share of the cost and risk associated with the research and development of new medicines. Even where U.S. federal funding of early-stage scientific research plays an important role in the discovery of a potential new disease therapy, industry licensees pay an arms-length, market price for the rights to develop that research further and they assume all of the risk of its subsequent success or failure. The price of successful new medicines—nine in ten fail by most counts—emerging from this innovation lifecycle must ultimately cover the costs associated with the R&D pipeline that produced them for the ecosystem to be sustainable.

The United States, with its commitment to free enterprise and inherent distrust of price controls, has provided a market where biopharmaceutical innovators have had a fair opportunity to re-coup the costs of research and development from that small percentage of medicines entering clinical trials that actually succeed. Other countries, including the wealthiest, have chosen to impose artificial prices that largely do not help compensate for the sunk costs of drug development.

This situation leaves the U.S. industry in an unenviable position. Political pressure mounts as policymakers see foreign governments acquiring innovative medicines at a steep discount to the U.S. price. Faced with foreign price controls, innovators have a

¹³ Peter Kolchinsky and Richard Xie, [No More Freeriding on the Great American Drug Deal](https://rapport.racap.com/all-stories/no-more-freeriding-great-american-drug-deal), <https://rapport.racap.com/all-stories/no-more-freeriding-great-american-drug-deal>

choice between selling at a discount or losing the sale. Since the investment in R&D represents a sunk cost, with respect to these foreign sales any price that exceeds the marginal cost of manufacturing and delivering the medicine makes economic sense. However, if every country including the United States demanded a sale at the marginal cost of production, there would be no more private sector innovation of new medicines.

Biopharmaceutical innovators have very little leverage in this equation. If they refuse to sell to foreign governments, they not only lose any marginal profit from the sale, but they also face the imminent threat of the compulsory licensing of their patented technologies, which have already been publicly disclosed through both the patent application process and regulatory disclosures required by governments to demonstrate the safety and efficacy of their products. Moreover, each company must fight its own battle in its commercial relationship with each government, since they would rightly be charged with collusion should they attempt to come together to hold the line on foreign prices.

Foreign free-riding is real and should be a priority for the U.S. government - the only entity, public or private, with the wherewithal to force a reckoning with foreign price controls. Pharmaceutical companies simply can't do it on their own. Our rightful distaste for foreign freeriding, however, should not blind us to the threat from unforced domestic policy errors, which don't require any help from foreigners to raise the price of medicines in the United States.

Indeed, when the U.S. government seeks to raise the price of medicines overseas, it should remain mindful of the advantage that accrues from being the safe haven for innovative industry, a place where the rules are the rules, and markets set prices, not governments. If foreign prices were to rise at the same time that the United States puts downward pressure on prices at home, the R&D investment which has concentrated in the United States since 1980 will erode. That will be especially true if middlemen continue to be allowed to exact rents at the expense of both innovators and patients, or if misguided attempts to wrest constitutionally protected patent rights from innovators continue to receive positive policy attention.

There is too much work left to be done for American patients who are still waiting for the treatment that will give them hope and life. Every Cure, a non-profit organization that provides research grants for drug re-purposing, notes that, "[L]ess than 22% of the 18.5K recognized diseases in the world have FDA-approved treatments¹⁴. Thanks to the robust biopharmaceutical innovation ecosystem in the United States, we continue to make progress towards addressing these unmet medical needs. That ecosystem is the envy of the world – and in all honesty it has subsidized the world's cost of medicines to a significant degree. What will not help is doing harm to our own ecosystem by following a failed foreign price control model.

¹⁴ Every Cure, The Problem, <https://everycure.org/the-problem/>

Thank you for your attention to these views.

Respectfully,

A handwritten signature in black ink, reading "Patrick J. Wilhite". The signature is written in a cursive style with a large, stylized "P" and "W".

Policy Fellow
Center for American Principles