Andrea Durkin

Vice President,
International Policy

June 27, 2025

Jennifer Thornton
General Counsel
Office of the United States Trade Representative
Washington, DC 20230

Re: *USTR-2025-0011: Request for Comments Regarding Foreign Nations Freeloading on American-Financed Innovation*

Dear Ms. Thornton,

The National Association of Manufacturers is the largest manufacturing association in the United States, representing manufacturers of all sizes, in every industrial sector and in all 50 states. Manufacturing drives American prosperity—the industry employs nearly 13 million people, contributes $2.94 trillion annually to the U.S. economy and accounts for nearly 53% of all private-sector research in the nation.[1]

The NAM appreciates the opportunity to comment on the request for comments by the Office of the U.S. Trade Representative (USTR) regarding "any act, policy, or practice that may be unreasonable or discriminatory and that has the effect of forcing American patients to pay for a disproportionate amount of global pharmaceutical research and development, including by suppressing the price of pharmaceutical products below fair market value in foreign countries."

The NAM supports the administration's goal of addressing discriminatory trade barriers that allow foreign governments to enjoy the benefits of U.S. biopharmaceutical development without appropriately paying for this innovation. A significant share of U.S. pharmaceutical production is supported by export and global sales. However, foreign governments use price controls and reimbursement delays among other practices to, in effect, discount the innovation in U.S.-manufactured pharmaceuticals.

The NAM encourages USTR to seek to engage our trading partners to secure non-discriminatory and fair market access terms through changes to market access policies in foreign markets, along with pursuing robust intellectual property rights that are adequately enforced. This would level the playing field and ensure that U.S. patients are not bearing an unfair burden of funding global innovation. At the same time, domestic policies—such as making innovation incentives from the 2017 tax reforms permanent and instituting pharmacy benefit manager (PBM) reforms that prevent these unregulated actors from driving up health care costs—would support biopharmaceutical innovation here in the U.S.

[1] National Association of Manufacturers (2025), Press Releases, "Manufacturers to Trump and Congress: Act Now on Comprehensive, Commonsense Manufacturing Strategy as Tariffs Hit Manufacturing Industry," https://nam.org/manufacturers-to-trump-and-congress-act-now-on-comprehensive-commonsense-manufacturing-strategy-as-tariffs-hit-manufacturing-industry-33417/

Negotiating foreign market access and instituting much-needed domestic reforms—rather than imposing domestic price controls—are crucial to supporting U.S. biopharmaceutical innovation and ensuring that patients can access life-saving treatments and cures.

Pharmaceutical Manufacturers' Role in the U.S. Economy Is Large and Growing

The pharmaceutical and medicine manufacturing industry delivers $655 billion in U.S. economic output each year, underscoring its substantial role in the overall performance of the U.S. economy.[2] Pharmaceutical manufacturers in the U.S. range from multinational corporations that discover, develop, manufacture, and distribute a broad spectrum of prescription and over-the-counter medicines, to smaller firms that focus on biologics, vaccines, generic medications, and over-the-counter health products. The industry also includes manufacturers that specialize in producing active pharmaceutical ingredients (APIs) and other chemical inputs, as well as contract development and manufacturing organizations (CDMOs).

Pharmaceutical manufacturers directly employ around 341,800 workers nationwide.[3] At an average annual salary of $87,170, workers in the pharmaceutical sector earn higher salaries than the national average.[4] The industry generates $147 billion in labor income, illustrating its significant economic impact on workers, their families and their communities.[5] There are nearly 18,000 job openings in the industry across the country, which is projected to grow 7% over the next five years.[6]

U.S. Domestic Production is Strong, and Most Medicines Consumed in the U.S. Are Manufactured in the U.S.

By value, nearly two-thirds ($252 billion) of medicines taken by patients in the U.S. are manufactured domestically across more than 1,500 biopharmaceutical manufacturing facilities in the U.S.[7] APIs made in the U.S. accounted for a majority (53%) of the $85.6 billion of APIs in medicines consumed in the U.S. in 2021.[8] Building on decades and billions of dollars in existing U.S. investments, manufacturing expansion continues with numerous manufacturers having recently announced multi-billion-dollar investments in facilities in the U.S.

Domestic Reforms Will Increase Affordability of Medicines for U.S. Patients

To achieve the President's goal of providing greater affordability of medicines to U.S. patients, the U.S. needs to address distortions in the U.S. market, including middlemen. In the U.S., pharmaceutical manufacturers, PBMs, and health insurance companies all play a role in how drug prices are set. PBMs are underregulated middlemen in the prescription drug system, contributing to the skyrocketing cost of health care by tying patient cost-sharing to list prices, pocketing manufacturer rebates, limiting patient access to lower-cost generic and biosimilar medicines, and obscuring their concerning business models. Reforms to their business practices would lower health

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[2] National Association of Manufacturers (2023), *"Creating Cures, Saving Lives: The Urgency of Strengthening U.S. Pharmaceutical Manufacturing"*.
[3]U.S. Bureau of Labor Statistics, "May 2023 National Industry-Specific Occupational Employment and Wage Estimates: NAICS 325400 - Pharmaceutical and Medicine Manufacturing," U.S. Department of Labor.
[4]Ibid.
[5] National Association of Manufacturers (2023), *"Creating Cures, Saving Lives: The Urgency of Strengthening U.S. Pharmaceutical Manufacturing"*.
[6] Lightcast, "Industry Snapshot: Pharmaceutical and Medicine Manufacturing," April 2025, lightcast.io (Subscription)
[7]PhRMA, "Biopharmaceutical manufacturing companies continue to expand their economic footprint across the United States," March 24, 2023.
[8]Avalere Health report, "U.S. Makes Majority of API by Dollar Value in U.S.-Consumed Medicines," October 14, 2023.

care costs and provide much needed transparency for patients and other stakeholders within the U.S. healthcare system.

Manufacturers also strongly support making President Trump's 2017 tax reforms permanent and more competitive through the One Big Beautiful Bill Act. Pharmaceutical companies depend on a competitive tax code to support life-saving innovation. Congress and the administration should preserve crucial innovation and investment incentives—including immediate R&D expensing, the FDII deduction, full expensing for capital equipment purchases, and more—and maintain the reduced corporate rate instituted in 2017 in order to empower the industry to innovate and grow in the U.S.

The Pharmaceutical Industry Invests More Than $100 Billion Annually to Develop New Medicines

In addition to the value that pharmaceuticals deliver to patients, society, and the healthcare system, drug pricing also reflects the risks and costs inherent in drug innovation as well as the investments required to bring a product to market through rigorous regulatory processes. Innovation in the pharmaceutical sector is a complex, lengthy and cost-intensive process. R&D investments in the U.S. drive breakthrough discoveries and the development and commercialization of new drugs and therapies not only for American patients but for patients worldwide.

In the drive for continual innovation, pharmaceutical companies make up the largest share of all private-sector R&D in the nation, accounting for 36.1% of spending at $146.1 billion in 2023.[9, 10] It typically takes 10 to 15 years of research, clinical trials and regulatory approval before a new drug can be brought to market.[11] The industry today invests 20 times more than it did in the 1980s; over the last 40 years, pharmaceutical R&D investment has compounded at over 9% a year.[12] In fact, when compared to other countries, U.S. business R&D expenditures are substantially more than R&D expenditures in other countries.

R&D Business Expenditures by Country
Millions of U.S. PPP* Dollars and Percent of Total Business Enterprise[13]

	United States (2018)	France (2017)	Germany (2018)	United Kingdom (2018)	China (2018)	Japan (2018)	South Korea (2018)
Pharmaceuticals, medicinal chemical, and botanical products	$74,592	$1,079	$7,094	$658	$13,741	$13,545	$1,825
	16.9%	2.5%	7.2%	1.8%	3.8%	9.9%	2.3%

*Purchasing Power Parity

[9] U.S. Bureau of Economic Analysis, "Table 5.6.5. Private Fixed Investment in Intellectual Property Products by Type," U.S. Department of Commerce".
[10] National Association of Manufacturers, "Facts About Manufacturing".
[11] Derep, Maxime, N-Side, "What is the Average Time to Bring a Drug to Market in 2022?" 2022.
[12] National Association of Manufacturers (2023), "Creating Cures, Saving Lives: The Urgency of Strengthening U.S. Pharmaceutical Manufacturing".
[13] Ibid.

Importantly, pharmaceutical R&D efforts are tied to and bolstered by revenue for the manufacturers in the U.S. that are making these substantial investments. Reductions in revenue translate into reduced rates of innovative effort. The USC Schaeffer Center has estimated that for every 10% reduction in expected U.S. revenues, pharmaceutical innovation — such as clinical trial starts or new drug approvals — is expected to ultimately fall by 2.5% to 15%.[14] This makes efforts by USTR to address unfair pricing practices overseas vital to R&D in the U.S.

Addressing Unfair and Discriminatory Market Access Policies in Foreign Markets

The NAM is encouraged by the administration's focus on addressing unfair market access and IP policies by foreign trading partners. A large portion of U.S. pharmaceutical production is supported by global sales and exports. In 2023, $101 billion of pharmaceuticals were exported from the U.S.[15] U.S. pharmaceutical production activity supported approximately 1.7 million total U.S. jobs in 2023, of which an estimated 490,000 were related to export sales.[16]

In its submission on the Section 232 national security investigation of imports of pharmaceuticals and pharmaceutical ingredients, the NAM urged the Commerce Department not to recommend broad-based tariffs on pharmaceutical inputs that would increase production costs for U.S. manufacturers, risk supply chain disruptions, and contribute to escalating costs and shortage risks to U.S. patients. Trade policy and current negotiations with U.S. trading partners can instead be leveraged to ensure that foreign countries adopt fair policies while also ensuring our trading partners adopt and enforce high intellectual property protections to protect R&D and innovation by manufacturers in the U.S.

Many countries, however, have government policies that fail to properly value innovation, including clawback and other revenue return mechanisms. For decades, some of the largest markets for U.S. innovative medicines, including Canada, Europe, Japan and South Korea, have imposed discriminatory and nontransparent policies that undervalue American innovation, limiting the resources available to support U.S. R&D and jobs associated with manufacturing in the U.S. For example, Canada has removed the U.S. from its list of reference countries, resulting in cuts to the prices of patented biopharmaceutical products. Japan introduced off-year drug pricing revision resulting in continuous price reduction during patent periods. Japan has also applied market-expansion repricing rules which are outdated for innovative modalities (*e.g.,* for regenerative medicines) and which discriminate against foreign companies. South Korea uses unreasonably low and outdated cost-effectiveness thresholds in its pricing assessments while imposing excessive and repeated price cuts that fail to recognize the value of patented pharmaceutical products. South Korea's Innovative Pharmaceutical Company accreditation, under which companies are eligible for R&D tax credits and more favorable pricing, is discriminatory as it requires domestic investments to prove "innovativeness."

In Europe, countries use a variety of mechanisms that limit patient access to medicines as well as aggressive cost-containment measures and revenue controls (based on arbitrary budget ceilings), such as outdated assessments, rebates and industry clawbacks. The UK, for example, maintains two pricing schemes: a voluntary scheme for branded medicine pricing and access (VPAG) as well as a similar statutory scheme which have adversely impacted U.S. innovators. The current VPAG clawback for 2025 is 23% of revenue, which is more than double the average rate of the last decade.

[14] USC Schaeffer Center white paper, "The Elasticity of Pharmaceutical Innovation: How Much Does Revenue Drive New Drug Development?" Feb. 18, 2025.
[15] EY report, "Impacts of Potential Tariffs on the U.S. Pharmaceutical Industry," April 22, 2025
[16] Ibid.

Italy imposes discriminatory clawbacks on a select group of companies, many of them foreign-owned, to address broader healthcare budgetary shortfalls. France layers price cuts, rebates, and industry-wide revenue clawbacks to achieve savings goals. Other nations limit the benefits of market exclusivity through protracted regulatory delays that lead to lost marketing time and access delays for patients.

As a result of the complexity and variability of these policies, USTR should undertake detailed bilateral negotiations using a common set of principles to ensure U.S. innovation is properly valued.

Conclusion

The NAM welcomes the administration's commitment to addressing unfair trading practices and ensuring that countries that benefit from U.S. R&D pay their fair share towards global innovation. Foreign drug pricing and reimbursement policies are complex. We encourage the administration to engage industry to better understand the intricacies and implications of these policies on the U.S. market. The NAM appreciates the opportunity to comment on this important topic and would be happy to support further engagement with its members.

Sincerely,

Andrea Durkin
Vice President, International Policy