

June 27, 2025

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USTR-2025-0011

Ms. Jennifer Thornton
General Counsel
Office of the U.S. Trade Representative
600 17th Street, N.W.
Washington, DC 20508

Re: Request for Comments Regarding Foreign Nations Freeloading on American-Financed Innovation, 90 Fed. Reg. 23105 (May 30, 2025)

Dear Ms. Thornton:

The Pharmaceutical Research and Manufacturers of America (PhRMA) appreciates this opportunity to provide the following comments in response to the request by the Office of the U.S. Trade Representative (USTR). PhRMA and its members welcome efforts by USTR to address unfair foreign trade practices that devalue innovative medicines and important therapeutic research, while enabling foreign governments to enjoy the benefits of U.S. biopharmaceutical development without paying their fair share for the innovations and resulting health care advancements. PhRMA urges USTR to leverage ongoing trade negotiations to achieve the President’s objective to eliminate foreign government acts, policies and practices that have “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.”¹

The United States leads the world in the research and development of valuable new medicines. However, foreign government price controls and reimbursement delays are trade barriers that significantly threaten the ability of our member companies and their workers to develop, manufacture and export transformative medicines that include life-saving treatments and cures. The United States has long supported biopharmaceutical innovation through a system of robust intellectual property protections and market-based competition, while foreign governments have employed price controls and other barriers to avoid contributing their fair share to the research and development of new medicines. As USTR correctly identified in its 2025 Special 301 Report, U.S. trade policies should ensure that foreign governments “appropriately recognize the value of innovative medicines ... so that trading partners contribute their fair share to research and development of new treatments and cures.”²

¹ Trump, Donald J. *Delivering Most-Favored-Nation Prescription Drug Pricing to American Patients*. *Federal Register*, vol. 90, no. 95, May 15, 2025, pp. 20749–20751. Executive Order 14297 at Sec. 3, available at <https://www.federalregister.gov/documents/2025/05/15/2025-08876/delivering-most-favored-nation-prescription-drug-pricing-to-american-patients>.

² Office of the United States Trade Representative. *2025 Special 301 Report*. April 29, 2025, p. 29, available at https://ustr.gov/sites/default/files/files/Issue_Areas/Enforcement/2025%20Special%20301%20Report%20%28final%29.pdf.

The submission below provides the following information in response to USTR’s request for comments: (1) information regarding the innovative biopharmaceutical sector’s extensive U.S. economic footprint; (2) a brief overview of unfair and non-reciprocal trade practices that foreign governments use to set the prices of new innovative medicines³ below fair market value or to otherwise devalue U.S. biopharmaceutical innovation; (3) descriptions of the most egregious acts, policies and practices in high-income countries that devalue U.S. biopharmaceutical innovation; and (4) PhRMA’s views on trade policies and approaches that would be effective in eliminating these unfair and non-reciprocal trade practices.

1. The U.S. Innovative Biopharmaceutical Industry is a Major Economic Sector and Contributes Significantly to High-Standard U.S. Manufacturing and Employment

PhRMA member companies are devoted to inventing, manufacturing and distributing valuable medicines that enable people to live longer, healthier and more productive lives. The U.S. biopharmaceutical industry is the world leader in medical research – producing more than half the world’s new molecules in the last decade. Pioneering work by biopharmaceutical innovators in the United States contributes significantly to economic growth and supports high-paying, high-standard and diverse jobs in all 50 states. The U.S. biopharmaceutical industry supports over 4.9 million jobs across the economy, including more than one million direct jobs, and contributes more than \$1.65 trillion in economic output on an annual basis.⁴

Our sector also continues to be one of the most research-intensive, manufacturing-intensive and export-intensive in America, annually investing an estimated \$122.2 billion in researching and developing new medicines.⁵ With the right policies and incentives in place at home and abroad, our member companies can continue to bring valuable new medicines to patients around the world. In 2023, U.S. biopharmaceutical goods exports exceeded \$101 billion.⁶ The biopharmaceutical sector was the largest exporter of goods among the most R&D-intensive industries in 2023 – which in addition to biopharmaceuticals included navigational equipment, semiconductors and other electronic components, medical equipment and supplies, and communications equipment.⁷

The innovative biopharmaceutical industry is a global leader in U.S. manufacturing, producing \$388 billion of gross output in 2023, and supplying nearly two-thirds (by value) of all medicines

³ In this submission, “new innovative medicines” refers to global new active substances approved by the U.S. Food and Drug Administration (FDA), European Medicines Agency (EMA) and/or Japan’s Pharmaceuticals and Medical Devices Agency (PMDA) and first launched in any country in the past decade.

⁴ TEconomy Partners, “The Economic Impact of the U.S. Biopharmaceutical Industry: 2022 National and State Estimates,” May 2024, available at <https://phrma.org/-/media/Project/PhRMA/PhRMA-Org/PhRMA-Refresh/Report-PDFs/D-F/The-Econ-Impact-of-US-Biopharma-Industry-2024-Report.pdf>.

⁵ Research!America, “U.S. Investments in Medical and Health Research and Development, 2016-2020,” January 2022, available at https://www.researchamerica.org/wp-content/uploads/2022/09/ResearchAmerica-Investment-Report.Final_January-2022-1.pdf.

⁶ U.S. Bureau of Economic Analysis, International Accounts Products for Detailed Goods Trade Data, available at <https://www.bea.gov/international/detailed-trade-data>.

⁷ ndp analytics analysis of National Science Foundation and Business Research and Development Survey data, 2024.

consumed in the United States.⁸ In 2023, U.S. sales of finished biopharmaceuticals totaled \$393 billion, of which 64 percent (\$251 billion) was produced in the United States and 36 percent (\$143 billion) was imported.⁹ The U.S. biopharmaceutical industry also is among the top five employers of U.S. manufacturing jobs, with more Americans directly employed in biopharmaceutical manufacturing than in manufacturing in several other industries, including each of the following: iron and steel products, aerospace products and parts, petroleum and coal products, and electric equipment and appliances.¹⁰ In 2022, 34 percent of U.S. biopharmaceutical industry employees were engaged in manufacturing at more than 1,500 manufacturing plants across the country, 39 percent were engaged in biopharmaceutical R&D, 24 percent were engaged in distribution and three percent were engaged in corporate administration.¹¹

2. Foreign Governments Engage in Acts, Policies and Practices That Devalue U.S. Biopharmaceutical Innovation

To research, develop, manufacture and deliver new treatments and cures for patients who need them around the world, biopharmaceutical innovators must be able to secure and effectively enforce intellectual property rights, obtain timely marketing approval for new medicines and make those therapies available to patients according to reimbursement rules and procedures that are fair, transparent, reasonable and non-discriminatory, and that appropriately value and reward innovative medicines. These conditions are also necessary to facilitate U.S. exports and ensure that the innovative biopharmaceutical industry can continue to provide jobs and competitively advance the economic interests of the United States. Unfortunately, many foreign governments engage in unfair and non-reciprocal trade practices that deny basic intellectual property protections and market access to U.S. innovators.

In many countries outside of the United States, governments are the primary payer of medicines and in effect dictate the price of medicines and the extent and timing of patient access to medicines. This dominant position often results in U.S. trading partners failing to appropriately recognize the value of innovation in their pricing and reimbursement policies, instead engaging in actions that distort markets and artificially depress prices below what a competitive market would provide and delay patient access to medicines. Foreign governments increasingly employ a range of measures, including biased health technology assessments, mandatory price cuts and revenue clawbacks, international reference pricing, unreasonable reimbursement delays and erosion of intellectual property protections. These measures often are layered to exert maximum pressure to artificially devalue the medical innovation that these countries receive.

Government price controls and reimbursement delays are trade barriers that allow foreign governments to enjoy the benefits of U.S. biopharmaceutical development without paying their fair share for these innovations. Some countries have even resorted to threatening American

⁸ U.S. Department of Commerce Bureau of Economic Analysis, Gross Output by Industry, 2023.

⁹ Ernst & Young, “Impacts of Potential Tariffs on the US Pharmaceutical Industry,” April 2025.

¹⁰ U.S. Bureau of Labor Statistics, Current Population Survey (CPS) Labor Force Statistics, available at <https://www.bls.gov/cps/home.htm>.

¹¹ TEconomy Partners, “The Economic Impact of the U.S. Biopharmaceutical Industry: 2022 National and State Estimates,” May 2024, available at <https://phrma.org/-/media/Project/PhRMA/PhRMA-Org/PhRMA-Refresh/Report-PDFs/D-F/The-Econ-Impact-of-US-Biopharma-Industry-2024-Report.pdf>.

intellectual property rights when reimbursement “negotiations” fall short of extracting the desired price concessions. These actions deny American inventors and workers the ability to compete on fair and reciprocal terms, and, as highlighted by USTR in its recent Special 301 Report, defeat the expected benefit of intellectual property protections, specifically the ability of “U.S. owners of IP [to] have a full and fair opportunity to use and profit from their IP”¹² Moreover, these measures exacerbate the U.S. trade deficit by inappropriately lowering and delaying payments in their own markets while taking advantage of U.S. investments in innovation. Examples of policies that devalue U.S. innovation and harm U.S. competitiveness, jobs and exports include:

- **Biased health technology assessments:** Foreign governments use frameworks that deliberately ignore health benefits from innovative medicines to arbitrarily set low prices. Some countries benchmark prices against older inferior medicines and generics or devalue life years based on outdated thresholds that have never been indexed to inflation.
- **Mandatory price cuts and revenue clawbacks:** Instead of adequately funding health care budgets, foreign governments impose price cuts and revenue clawbacks that shift financial burdens onto biopharmaceutical companies.
- **International reference pricing:** Many foreign governments set drug prices in their own country based on the prices paid in other countries that have much lower gross domestic product (GDP) per capita or that devalue innovation.
- **Unreasonable patient access delays and restrictions:** Many foreign governments have protracted pricing and reimbursement processes that significantly delay and restrict patient access, resulting in lost marketing time and potential use during the expected and otherwise legally required period of intellectual property protection for the product.
- **Compulsory licensing threats:** Nearly all foreign governments have implemented powers to override patents, too often on ambiguous and overly broad grounds that include pricing.
- **Exploitation of regulatory data protection:** The European Union (EU) is finalizing legislative options that would erode the current regulatory data protection (RDP) term unless companies commit to supply requirements in EU member states. In turn, companies would be forced to accept the prices set by each government and the resulting spillover from international reference pricing or relinquish an important intellectual property protection.

As a result of these policies that devalue U.S. innovation, other high-income countries do not contribute their fair share to the research and development of new treatments and cures. Ending damaging pricing policies and erosion of intellectual property protections in these markets and others could add billions of dollars to research and development of new medicines that prevent, treat and cure costly diseases, thereby reducing the need for more costly interventions that drive

¹² Office of the U.S. Trade Representative, 2025 Special 301 Report at p. 29, available at [https://ustr.gov/sites/default/files/files/Issue_Areas/Enforcement/2025%20Special%20301%20Report%20\(final\).pdf](https://ustr.gov/sites/default/files/files/Issue_Areas/Enforcement/2025%20Special%20301%20Report%20(final).pdf).

overall health care costs in the United States and around the world, while supporting U.S. competitiveness and jobs.¹³

3. USTR Should Prioritize Addressing Acts, Policies and Practices of High-Income Countries That Devalue U.S. Biopharmaceutical Innovation

This submission identifies the most egregious acts, policies and practices that devalue U.S. biopharmaceutical innovation in the following economies: **Australia, Canada, France, Germany, Italy, Japan, Korea, Spain, the United Kingdom** as well as the EU. Together, these nine countries account for more than 70 percent of spending on new innovative medicines by high-income countries outside the United States. These practices are highlighted because foreign government price controls and reimbursement delays allow foreign governments to enjoy the benefits of U.S. biopharmaceutical development without proportionately paying for these innovations (i.e., these countries spend a much smaller share of GDP per capita on new innovative medicines than the United States). U.S. government engagement to eliminate these practices would yield the greatest benefit in promoting fair and reciprocal trade and ensuring that high-income countries contribute their fair share toward the cost of global biopharmaceutical research and development. PhRMA's annual National Trade Estimate and Special 301 Report submissions to USTR provide a more comprehensive and detailed overview of significant trade barriers facing the U.S. innovative biopharmaceutical industry, including for these markets and others not highlighted in this submission.

The Table below reports (1) country spending on new innovative medicines as a share of GDP per capita,¹⁴ (2) the percentage of these medicines reimbursed by public insurance,¹⁵ and (3) the average delay from country regulatory approval to public reimbursement.¹⁶

¹³ See Council of Economic Advisers, "Reforming Biopharmaceutical Pricing at Home and Abroad," February 2018, available at <https://trumpwhitehouse.archives.gov/wp-content/uploads/2017/11/CEA-Rx-White-Paper-Final2.pdf>; and U.S. Department of Commerce, International Trade Administration, "Pharmaceutical Price Controls in OECD Countries: Implications for U.S. Consumers, Pricing, Research and Development, and Innovation," December 2004, available at <https://web.archive.org/web/20190414170009/https://2016.trade.gov/td/health/DrugPricingStudy.pdf>.

¹⁴ Ernst & Young, "High-Income Country Spending on Innovative Medicines," June 2025.

¹⁵ PhRMA analysis of IQVIA MIDAS®, Global Data, NAVLIN and country regulatory authority data for new active substances approved by FDA, EMA and/or PMDA and first launched in any country between January 1, 2014, and December 31, 2023, April 2025. Note: A medicine is considered publicly reimbursed in Canada if 50 percent or more of the population lives in a province where it is publicly reimbursed. In several markets, patient access barriers remain when public reimbursement of medicines is restricted to only some of the approved indications and uses.

¹⁶ *Id.*

Country	Percentage of GDP per Capita Spent on New Innovative Medicines	Percentage of New Innovative Medicines Reimbursed by Public Insurance	Average Delay from Country Regulatory Approval to Public Reimbursement
United States	0.78%	87%	0 months
Australia	0.26%	25%	10 months
Canada	0.32%	19%	28 months
France	0.29%	44%	18 months
Germany	0.36%	55%	4 months
Italy	0.46%	45%	19 months
Japan	0.40%	50%	3 months
Korea	0.09%	20%	23 months
Spain	0.53%	39%	20 months
United Kingdom	0.28%	43%	24 months

Australia undervalues new innovative medicines by setting prices based on older inferior medicines and generics and through use of low and outdated monetary thresholds per year of life gained from clinically proven treatments. When recommending coverage of new medicines, the Pharmaceutical Benefits Advisory Committee examines a broad group of existing treatments and then selects the medicine with the lowest price as the comparator, even if that medicine is seldom used versus newer therapies. In addition, government assessments often restrict access to a small subset of the patient population for which the regulator determines the product to be safe and effective and additionally create considerable patient access delays through unnecessary data requirements and other administrative hurdles.

Canada sets ceiling prices for all patented medicines sold to public or private payers by referencing prices in other countries, followed by restrictive health technology assessments that inform additional discounts. In 2021, Canada removed the United States and Switzerland from the Patented Medicine Prices Review Board (PMPRB) reference basket to ensure that it referenced more countries with lower incomes and lower drug prices. When assessing new medicines, Canada’s Drug Agency uses low and outdated monetary thresholds per life year gained for clinically proven treatments to make coverage recommendations that are contingent on price cuts of 70-90 percent for some new cancer and rare disease products.¹⁷ Public insurance plans run by each province require further price cuts and impose bureaucratic requirements that considerably delay patient access.¹⁸

France combines price cuts, rebates, revenue clawbacks and pharmaceutical-specific taxes to drive net prices on innovative medicines to be among the lowest in Europe. When setting prices,

¹⁷ Balijepalli, Chakrapani et al., “The Impact of Willingness-to-Pay Threshold on Price Reduction Recommendations for Oncology Drugs: A Review of Assessments Conducted by the Canadian Agency for Drugs and Technologies in Health,” *Journal of Comparative Effectiveness Research* 13(5), 2024, available at <https://doi.org/10.57264/cer-2023-0178>.

¹⁸ Rawson, Nigel, “Health Technology Assessment and Price Negotiation Alignment for Rare Disorder Drugs in Canada: Who Benefits?,” *Orphanet Journal of Rare Diseases* 17(218), 2022, available at <https://doi.org/10.1186/s13023-022-02390-x>.

France asserts that 60 percent of new innovative medicines provide no added benefit over current treatments. Older inferior medicines and generics are often used as price benchmarks, and increasingly excessive rebates are required by the statutory health insurance system – annual rebates grew from €0.5B in 2012 to €7.1B in 2024.¹⁹ New innovative medicines supposedly awarded “price stability” are still subject to excessive rebates that can push net prices far below the agreed-to price floors. Revenue clawbacks and pharmaceutical-specific taxes further reduce spending (a reduction of €2.5B in 2024) on already devalued medicines with calls for additional reductions.²⁰

Germany rejects clinical trial evidence to assert, when setting prices, that 55 percent of new innovative medicines provide no added benefit over current treatments.²¹ The Federal Joint Committee (G-BA) selects comparators for these required benefit assessments, often using older inferior medicines and generics as price benchmarks (in 74 percent of assessments).²² New innovative medicines are often priced 10 percent lower than older patent-protected medicines deemed to offer the same benefit and new medicines deemed to offer a minor added benefit are often not priced higher than older medicines offering less benefit. An additional 20 percent rebate is imposed on all patent-protected medicines used in combination therapies. In addition, Germany mandates a seven percent rebate and price freeze for all medicines reimbursed by the statutory health insurance system since 2010.²³

Italy imposes revenue clawbacks, driven by underfunded hospital budgets, that have rapidly become unsustainable for biopharmaceutical manufacturers. In 2024, manufacturers were required to pay back approximately €2B of €17B in hospital medicine revenues.²⁴ The Italian Medicines Agency (AIFA) deems only a third of new innovative medicines as “fully innovative,” which means many new medicines are not exempted from revenue clawbacks nor placed immediately on regional formularies. Pricing and reimbursement processes at the national level already delay patient access to new medicines, which is exacerbated by further unnecessary delays and uncertainty in listing products on regional formularies.

¹⁹ Economic Committee for Health Products (CEPS). Note: 2024 rebates are not yet published.

²⁰ Leem, “Economic Assessment of Pharmaceutical Companies - 2024 Edition,” March 2025, available at https://www.leem.org/sites/default/files/2025-03/Bilan%20Eco%202024_0.pdf; Social Security Accounts Commission (CCSS) Report, June 2025, available at https://www.securite-sociale.fr/files/live/sites/SSFR/files/medias/CCSS/2025/Rapport%20CCSS%20juin_BAT_%20avec%20couverture.pdf.

²¹ AMNOG-Monitor, “Early Benefit Assessment: Detailed Analysis of All G-BA Resolutions,” June 2025, available at <https://www.amnog-monitor.com>. Note: 55 percent of assessed medicines were deemed to not provide an added benefit for any indication. Note: This analysis excludes orphan drugs with sales below a threshold that makes them ineligible to receive a rating of offering no added benefit.

²² AMNOG-Monitor, “Early Benefit Assessment: Detailed Analysis of All G-BA Resolutions,” June 2025, available at <https://www.amnog-monitor.com>. Note: The G-BA defines at least one generic comparator in 74 percent of subpopulation assessments. Analysis excludes assessments with non-drug comparators (e.g., surgery).

²³ German Bundestag, “Financial Reform of Statutory Health Insurance Approved,” October 20, 2022, available at <https://www.bundestag.de/dokumente/textarchiv/2022/kw42-de-gkv-finanzierungsstabilisierungsgesetz-916742>.

²⁴ Italian Medicines Agency (AIFA), “Monitoring of National and Regional Pharmaceutical Expenditures,” April 2025, available at https://www.aifa.gov.it/documents/20142/2505785/Monitoraggio_Spesa_gennaio-dicembre-2024.pdf.

Japan devalues new innovative medicines through draconian rules that set low prices of patented medicines at launch and then exacerbates this problem by aggressively cutting prices throughout the patent period. Following National Health Insurance price listing, Japan applies a growing number of re-pricing rules in a highly unpredictable and arbitrary manner that significantly erode prices and expected revenues of patented medicines. Overall, half of patented medicines launched in Japan are subjected to annual price cuts. In addition, for new innovative medicines that receive a price premium at launch for demonstrating clinical superiority over a comparator, Japan then cuts the price premium by up to 90 percent using low and outdated monetary thresholds per life year gained. By June 2025, 32 of 42 innovative medicines that completed these mandatory assessments had their prices cut.²⁵ In recent years, Japan has become overly dependent on these price cuts to fund non-biopharmaceutical spending. While medicines represent just 10 percent of overall social security spending, price cuts to medicines have accounted for 70 percent of social security budget reductions since 2018.²⁶

Korea sets prices of new innovative medicines through a combination of referencing the lowest price among OECD countries and using low and outdated monetary thresholds per life year gained from clinically proven treatments.²⁷ Two government agencies, the Health Insurance Review and Assessment (HIRA) service and the National Health Insurance Service (NHIS), force companies through a gauntlet of assessments to access the market, resulting in lengthy patient access delays following marketing authorization. The monetary threshold per life year was originally set equal to Korea's GDP per capita in 2007, and has not been updated even though Korea's GDP per capita has since more than doubled.²⁸ As a result of these practices that suppress prices below fair market value, Korea spends a lower share of its pharmaceutical budget on new innovative medicines than any other high-income OECD country.²⁹

Spain sets prices of new innovative medicines by using older inferior medicines and generics in Spain and other countries as price benchmarks. The Spanish government selects the comparators from a broad group of treatments and then chooses from the drugs with the lowest prices as the comparator. When recommending coverage of new medicines, the Inter-Ministerial Commission on Medicine Prices (CIPM) examines a broad group of existing treatments and then selects the medicine with the lowest price as the comparator. Regional authorities often require additional assessments, rebates and price cuts that further undervalue new innovative medicines and further restrict and delay patient access. In addition, Spain requires mandatory discounts of 7.5 percent for all innovative medicines and a revenue clawback of 2 percent on all retail pharmacy sales to further reduce spending on already devalued medicines.

²⁵ C2H, "Targeted Medicines and Results of Cost-Effectiveness Evaluation After April 2019," June 2025, available at <https://c2h.niph.go.jp/en/results/item.html>.

²⁶ PhRMA analysis of Japan Ministry of Finance data, March 2025.

²⁷ HIRA references prices from eight countries, but NHIS subsequently references prices from any of the 38 OECD member countries.

²⁸ World Bank National Accounts Data, GDP per Capita (current LCU) for Korea, available at <https://data.worldbank.org/indicator/NY.GDP.PCAP.CN?locations=KR>.

²⁹ Yu, Seung-Rae and Sooyoung Choi. "New Drug Expenditure by Therapeutic Area in South Korea: International Comparison and Policy Implications," February 2025, available at <https://doi.org/10.3390/healthcare13050468>.

The United Kingdom uses low and outdated monetary thresholds per life year gained from clinically proven treatments, which have not been updated for inflation since 1999 (depreciating a life year by more than 47 percent over the past 25 years).³⁰ The National Health Service (NHS) requires excessive price discounts (£3.4B in 2025, among the highest in the world) based on these biased valuations before agreeing to fund new treatments. These same valuations are also used as a reason to restrict access to only a small subset of the population for which the regulator deems the product to be safe and effective and to deny access completely for many treatments. While the United Kingdom claims that the NHS funds 84 percent of new treatments, only 14 percent of all new innovative medicines are funded without access restrictions and for all approved uses.³¹ In addition, revenue clawbacks have increased dramatically over the past several years (now 23 percent in 2025), further reducing spending on already devalued medicines.³²

European Union member states routinely exceed the 180-day EU deadline³³ for pricing and reimbursement decisions of new innovative medicines (instead requiring over 700 days on average³⁴), with no corresponding mechanism to restore lost patent and RDP terms. Compounding this problem, the EU is finalizing revisions to the General Pharmaceutical Legislation that would reduce the current RDP term and condition restoration of the lost term on commitments to supply EU member states (which is beyond the control of the manufacturer), the conduct of local clinical trials or submission of the EU marketing application within 90 days of first global submission. This approach emulates China’s discriminatory proposal to condition the full RDP term on seeking approval in China before first global approval. The EU is also proposing to inappropriately expand the scope of its existing “Bolar” exemption to patent infringement to include currently inapplicable commercial activities, including conducting pricing and reimbursement processes and procurement tender applications. No other country allows for such commercial activities during the patent term. This approach would undermine patent enforcement because price listing is a trigger in many member states to seek injunctive relief from patent infringement. Finally, the EU recently reached a provisional agreement on legislation that would establish an additional and unnecessary pan-European compulsory licensing mechanism for “crisis” management that targets the biopharmaceutical sector.

³⁰ U.K. Government Accredited Official Statistics, available at <https://www.gov.uk/government/statistics/gdp-deflators-at-market-prices-and-money-gdp-march-2025-spring-statement-quarterly-national-accounts>; Bank of England Inflation Calculator, available at <https://www.bankofengland.co.uk/monetary-policy/inflation/inflation-calculator>.

³¹ McKeown, Sarah and Richard Kane, “Measuring Impact of HTA on Patient Access to New Medicines in NHS England: A Comparison of Public Health Insurance Funding Restrictions and Patient Uptake for New Medicines Across England, France, Germany, and the United States,” December 2024, available at <https://www.ispor.org/heor-resources/presentations-database/presentation/euro2024-4015/144637>.

³² ABPI, “Delivering a Voluntary Scheme for Health and Growth,” March 2025, available at <https://www.abpi.org.uk/publications/delivering-a-voluntary-scheme-for-health-and-growth/>.

³³ The EU Transparency Directive (Directive 89/105/EEC) requires EU member states to make national pricing and reimbursement decisions within 180 days of receiving an application from the marketing authorization holder, provided that all necessary information was provided.

³⁴ PhRMA analysis of IQVIA MIDAS®, Global Data, NAVLIN and country regulatory authority data for new active substances approved by FDA, EMA and/or PMDA and first launched in any country between January 1, 2014, and December 31, 2023, April 2025.

4. USTR Should Leverage Ongoing Trade Negotiations to Secure the Elimination of Unfair and Non-Reciprocal Foreign Trade Practices That Devalue U.S. Biopharmaceutical Innovation

The Administration is currently engaged in trade negotiations with multiple partners to “remedy non-reciprocal trade arrangements” as envisioned in President Trump’s April 2, 2025, Executive Order.³⁵ PhRMA urges USTR to use these ongoing trade negotiations to secure the elimination of foreign government acts, policies and practices that devalue and undermine biopharmaceutical innovation that the United States enables for the world, prioritizing engagement with the economies listed in this submission. To effectively address these acts, policies and practices, USTR should require high-income countries to adopt binding and enforceable trade commitments to achieve an appropriate level of spending on new innovative medicines, including through the implementation of specific reforms to the policies described in Section 3 above. USTR also should establish mechanisms for bilateral consultation with trading partners to ensure implementation and sustained compliance with these obligations.

PhRMA welcomes recent efforts by the Administration to ensure that the United Kingdom “improve[s] the overall environment for pharmaceutical companies operating in the United Kingdom.”³⁶ To fulfill this important commitment, the United Kingdom must take immediate steps to reform the policies described in Section 3 above and commit to an appropriate level of spending on new innovative medicines. Securing and enforcing such commitments from the United Kingdom and the other economies identified in this submission would fulfill President Trump’s directive to ensure that foreign nations contribute their fair share toward biopharmaceutical innovation, while also significantly furthering the President’s goal to promote fair and reciprocal trade.

PhRMA members are committed to advancing public policies that promote U.S. leadership in biopharmaceutical research and manufacturing, support American jobs and ensure that innovative medicines are accessible and affordable for U.S. patients. As the Administration works to counter unfair and non-reciprocal trade practices abroad, it should ensure that any trade measures are carefully crafted to avoid adverse impacts on U.S. patients, health care systems and the global competitiveness of the U.S. innovative biopharmaceutical industry. Most importantly, the Administration should refrain from imposing tariffs on imports of innovative medicines and the ingredients used to produce innovative medicines in the United States, as these actions would be detrimental to U.S. competitiveness and increase health care costs at home.³⁷ PhRMA urges USTR to ensure that trade enforcement actions are calibrated to avoid these adverse

³⁵ Trump, Donald J. *Regulating Imports with a Reciprocal Tariff to Rectify Trade Practices that Contribute to Large and Persistent Annual United States Goods Trade Deficits*, April 2, 2025, pp. 15041-15109. Executive Order 14257 at Sec. 4(c), available at <https://www.federalregister.gov/documents/2025/04/07/2025-06063/regulating-imports-with-a-reciprocal-tariff-to-rectify-trade-practices-that-contribute-to-large-and>.

³⁶ General Terms for the United States of America and the United Kingdom of Great Britain and Northern Ireland Economic Prosperity Deal, May 8, 2025, available at https://ustr.gov/sites/default/files/files/Press/fs/US%20UK%20EPD_050825_FINAL%20rev%20v2.pdf.

³⁷ See Pharmaceutical Research and Manufacturers of America, Comment on Notice of Request for Public Comments on Section 232 National Security Investigation of Imports of Pharmaceuticals and Pharmaceutical Ingredients, Docket No. BIS-2025-0022, May 6, 2025, available at <https://www.regulations.gov/comment/BIS-2025-0022-0070>.

consequences for patients and the global competitiveness of the U.S. innovative biopharmaceutical industry.

Sincerely,

A handwritten signature in black ink, reading "Kevin Haninger". The signature is written in a cursive, flowing style with a large, stylized "K" and "H".

Kevin Haninger
Vice President, International