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FOSTERING HIGHER FOREIGN CONTRIBUTIONS TO PHARMA R&D THROUGH TRADE DEALS, DEREGULATION, AND INCENTIVE ALIGNMENT

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ABSTRACT

The United States globally leads in developing new, innovative drugs. American taxpayers and private payors also pay far more for patented drugs than foreign counterparts do. The Trump Administration is seeking to require pharmaceutical firms to lower US drug prices while it threatens sanctions against foreign countries unless they pay more for US-produced drugs. Drug price controls, however, would undermine innovation, thereby harming both drug producers and consumers. Fortunately, political economy considerations incentivize foreign governments to lift patented drug prices when agreements support their domestic industrial policies and life sciences ambitions. Replacing coercive price-fixing and regulatory friction with reciprocal trade and regulatory synergy would foster a robust, equitable innovation ecosystem that sustainably finances future medical cures. The 2025 US–UK agreement on pharmaceutical pricing demonstrates the achievability of such agreements. This paper outlines frameworks for future agreements aimed at increasing foreign contributions to pharmaceutical innovation and applies them to the European Union (EU).

METADATA

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Fostering Higher Foreign Contributions to Pharma R&D Through Trade Deals, Deregulation, and Incentive Alignment

Introduction

Americans pay two to three times as much for the same patented drugs as people in other developed countries,¹ with the United States contributing roughly 75% of global pharmaceutical profits despite accounting for just 5% of the global population² and 25.82% of global GDP.³ Relative to other nations, the United States thus delivers an outsized contribution to the public good of global pharmaceutical research, creating new cures that benefit everyone. The current per-capita contribution levels of non-US countries fall significantly below that of the US and thus undersupply the public good, constituting “free riding” on American taxpayers and private payors who make up the shortfall.

To address this issue, President Trump signed Executive Order 14297, “Delivering Most-Favored-Nation Prescription Drug Pricing to American Patients,” on May 15, 2025.⁴ It directs the US Secretary of Commerce and the United States Trade Representative to “take all necessary and appropriate action to ensure foreign countries are not engaged in any act, policy, or practice 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.” Conversely, however, the order’s other main stipulation is that pharmaceutical companies lower the prices they charge Americans since Americans are “the [world’s] largest purchaser of pharmaceuticals” and should thus “get the best deal” as they “deserve low-cost pharmaceuticals on the same terms as other developed nations.”

To achieve lower domestic drug prices, the order threatens drugmakers with punitive sanctions unless they accept lower drug prices from the US government’s Medicare and Medicaid programs, and private payors such as patients and employer-sponsored health plans. These sanctions include but are not limited to revocation of Food and Drug Administration (FDA) approval for drugmakers’ products, significant tariffs, export restrictions and targeted antitrust investigations and lawsuits. Leaving aside questions of legal authority,⁵ the administration’s actions and order create significant uncertainty around revenue projections and thus disincentivize investments in future research and development in a sector characterized by long and uncertain timelines and high upfront capital commitments that hinge on expected future profits.⁶

¹ Salomeh Keyhani, Steven Wang, Paul Hebert, Daniel Carpenter, and Gerard Anderson, “US Pharmaceutical Innovation in an International Context,” *American Journal of Public Health* 100, no. 6 (2010): 1075–80.

² James C. Robinson, “‘Most Favored Nation’ Drug Pricing Is an Idea Whose Time Has Come,” *Health Affairs* 45, no. 4 (2026): 350–55.

³ “Percent of world GDP – Country rankings,” TheGlobalEconomy.com, accessed June 15, 2026, https://www.theglobaleconomy.com/rankings/gdp_share/.

⁴ Exec. Order No. 14297, 90 Fed. Reg. 20749 (May 15, 2025).

⁵ For instance, conditioning FDA approval to market a drug on its price, with the aim of influencing that price, would likely violate federal law. See Lars Noah, “Governance by the Backdoor: Administrative Law(lessness?) at the FDA,” *Nebraska Law Review* 93 (2014): 129.

⁶ Frech et al. (2024) note that “[p]ast R&D costs are already paid, so they do not influence the prices charged for existing pharmaceuticals. Instead, R&D efforts depend on the anticipated profits to be gained from future new pharmaceuticals, taking

This paper argues that rather than trying to equalize foreign and domestic drug prices, the administration ought to focus on reducing “free riding” by increasing foreign contributions to pharmaceutical innovation through trade deals. Section I explains why equalizing US and foreign patented drug prices is not economically desirable or practically achievable. Section II outlines how and why Americans and foreign nations alike would benefit from higher foreign contributions, including through lower long-term healthcare costs. Section III considers the US–UK agreement on pharmaceutical pricing as a case study in achieving higher foreign contributions to drug innovation. Section IV outlines principles for achieving higher foreign contributions to drug prices through trade deals with other nations and applies this framework to the European Union (EU).

I: Should Americans Pay the Same Lower Price that Foreigners Pay for Patented Drugs?

The order’s central premise is that Americans pay more for drugs than foreign nationals and that this means that Americans should pay the same price that foreign nationals do for patented drugs to ensure fairness. However, this argument is flawed: Lower US generic prices offset higher patented drug prices, differences in patented drug prices can be economically efficient and deliver offsetting benefits to Americans, and globally uniform drug prices are unrealistic and unfeasible.

A. Americans pay less for prescription drugs when counting generics

Recent research finds that a favorable regulatory climate and the relatively large US market drive faster generic drug entry, resulting in average Medicare and Medicaid drug prices 18% below those in the UK, Japan, Germany, France and Canada when both branded drugs and generics are considered.⁷ Over 90% of US drug prescriptions by volume are for generics, significantly more than in comparable developed economies,⁸ and US unbranded generics are priced 43% lower on average than in those economies.⁹ US drug prices decrease by approximately 50% on average with two generic competitors, approximately 70% with five, and approximately 90% with 15 or more.¹⁰ The Centers for Medicare and Medicaid Services (CMS) serves over 160 million Americans and is one of the country’s largest drug buyers.¹¹ And since the prices CMS generally pays for drugs are legally pegged to the lowest private market price under Medicaid and the

account of the long-run sunk cost of inventing, testing, obtaining approval for, and promoting new pharmaceuticals.” See H. E. Frech III, Mark Pauly, and William S. Comanor, “Are Drug Prices Abroad Too Low?,” *Regulation* 47, no. 3 (2024): 26.

⁷ Tomas J. Philipson, Deyu Zhang, and Qi Zhao, “International Comparison of Prices for Drug Prescriptions,” University of Chicago, Policy Brief, June 7, 2025. The authors note that “[l]ower average prescription prices in the United States are driven not just by the high volume of generics, but also by the negotiating power of private Medicare plans and mandatory discounts in Medicaid, both of which reduce net prices for brand-name prescriptions.”

⁸ “Unbranded generics made up 90% of US prescription volume, compared with 41% of volume [on average] in the other [Organisation for Economic Cooperation and Development (OECD) member countries].” See “Comparing Prescription Drugs in the US and Other Countries: Prices and Availability: Contractor Project Report,” NIH National Library of Medicine, February 2024, <https://www.ncbi.nlm.nih.gov/books/NBK611301/>.

⁹ “Comparing Prescription Drugs in the US and Other Countries.”

¹⁰ Olivier J. Wouters, Panos G. Kanavos, and Martin McKee, “Comparing generic drug markets in Europe and the United States: prices, volumes, and spending,” *The Milbank Quarterly* 95, no. 3 (2017): 572.

¹¹ Elizabeth Ann Scruth, Robin Betts, and Kevin P. Worth, “Centers for Medicare and Medicaid Services: The Patient Safety Structural Measure,” *Clinical Nurse Specialist* 39, no. 5 (2025): 200–202.

average private market price under Medicare Part B, public sector prices also reflect prescription drug costs for US health plans and patients buying directly.¹²

The US private health plan market also incentivizes competition from generics to lower prices. Many health plans and their Pharmacy Benefit Managers (PBMs) place cheaper generics in the lowest-cost tier of their formularies (the drugs the plan covers)¹³ and/or encourage pharmacies to substitute lower-cost generics by reimbursing pharmacies with a maximum allowable cost (MAC) above the drugs' cost.¹⁴ State laws also encourage lower-cost generic substitution by allowing (or requiring) pharmacies to substitute equivalent generic products.¹⁵ With these incentives, newly launched US generics capture around 50% of the brand-name drug's market share within six months and a supermajority thereafter.¹⁶

Importantly, the larger US customer base is not the only reason it is more lucrative for generic producers to enter the market sooner than in smaller economies. Higher patented-drug prices also contribute: Where foreign governments suppress them, generic entry upon patent expiration is less lucrative. Every additional \$140 million in yearly revenue for a branded drug is associated with approximately one additional generic manufacturer entering the market.¹⁷

A recent University of Chicago study finds that for the 25 drugs that have been selected for government-negotiated price caps under the US Inflation Reduction Act (IRA),¹⁸ average lifetime drug prices would actually rise by approximately 19% even though average net prices of the branded drugs would fall by 37%.¹⁹ This is because capping the branded drug's price would

¹² See Satya Marar and Jacob James Rich, "How America Subsidizes the World's Medicine," *Discourse*, July 12, 2024, <https://www.discoursemagazine.com/p/how-america-subsidizes-the-worlds>.

¹³ Dennis W. Carlton et al., "PBMs and Prescription Drug Distribution: An Economic Consideration of Criticisms Levied Against Pharmacy Benefit Managers" (Compass Lexecon, October 2024), 13, <https://compass-lexecon.files.svcdn.com/production/files/documents/PBMs-and-Prescription-Drug-Distribution-An-Economic-Consideration-of-Criticisms-Levied-Against-Pharmacy-Benefit-Managers.pdf?dm=1728503869>.

¹⁴ Patricia M. Danzon, "Pharmacy Benefit Management: Are Reporting Requirements Pro- or Anticompetitive?," *International Journal of the Economics of Business* 22 (2015): 249.

¹⁵ Danzon, "Pharmacy Benefit Management: Are Reporting Requirements Pro- or Anticompetitive?."

¹⁶ David Walters and Matthew Sauter, Generic Launch Market Entry Study (Wakely for the Pharmaceutical Care Management Association, March 2026), 3.

¹⁷ M. Whittington, "The Price of Lower Drug Prices," Center for Pharmacoeconomics, MEDACorp, May 22, 2026, <https://leerink.com/article/the-price-of-lower-drug-prices/>.

¹⁸ The IRA, which became law in 2022, allows the CMS to use its buyer monopsony power and the threat of penalties to negotiate (effectively set) drug prices. See Inflation Reduction Act of 2022, Pub. L. No. 117-169, § 11001, 136 Stat. 1818, 1833–53 (codified at 42 U.S.C. §§ 1320f–1320f-7); Satya Marar, "The Federal Government's Drug Price Negotiation Program Would Likely Violate Its Own Antitrust Laws," *IPWatchdog*, January 26, 2026, <https://ipwatchdog.com/2026/01/26/federal-governments-drug-price-negotiation-program-likely-violate-own-antitrust-laws/>. Under its "Medicare Drug Price Negotiation Program," CMS identifies a new round of drugs each year for negotiation. Price setting on the first round of drugs took effect in 2026. See Sally Pipes and Wayne Winegarden, "The Rise—and Potential Fall—of America's Drug Industry: How to Avoid the Road to Serfdom" (Issue Brief, Pacific Research Institute, July 2025), https://www.pacificresearch.org/wp-content/uploads/2025/07/N_CMEI_DrugIndustry_SP_F.pdf; Tricia Neuman and Juliette Cubanski, "Explaining the Prescription Drug Provisions in the Inflation Reduction Act," KFF, March 6, 2024, <https://www.kff.org/medicare/issue-brief/explaining-the-prescription-drug-provisions-in-the-inflation-reduction-act/>; Kristi Martin, "Medicare Drug Price Negotiations: All You Need to Know," Commonwealth Fund, May 15, 2025, <https://www.commonwealthfund.org/publications/explainer/2025/may/medicare-drug-price-negotiations-all-you-need-know>. Since the IRA passed, drugmakers have discontinued 26 drugs and shuttered 51 research programs, according to a database operated by Incubate, a coalition of early-stage life sciences investors. See "Life Sciences Investment Tracker: Incubate Coalition," Incubate Investment Tracker, July 9, 2025, <https://lifesciencetracker.com/>.

¹⁹ Tomas J. Philipson, Deyu Zhang, Noah Fisher, and Cyrus Seyrafi, "The Impact of Price Controls on Longterm Prescription Drug Prices," Initiative on Enabling Choice and Competition in Health Care, University of Chicago, August 16, 2026.

disincentivize generic and biosimilar entry, reducing it by an estimated 37% and leading to a 45% increase in average generic and biosimilar prices after the branded drug's exclusivity period ends. Changing US policy settings to contain short-term patented drug costs in the vein of foreign governments would thus produce savings that are likely more than offset by higher long-term drug prices after the capped branded drug's market exclusivity ends.

Furthermore, under the US Hatch–Waxman Act, the first generic manufacturer to successfully challenge a branded drug's patent through a "Paragraph IV certification" receives a 180-day monopoly on the generic market, creating revenues that incentivize multimillion dollar patent challenges.²⁰ In other countries, other generic manufacturers can capture those revenues without paying for the litigation.

Thus, importing foreign caps on patented drug prices will likely slow US generic entry and reduce price competition by weakening these incentives, increasing rather than reducing the long-term costs of drugs for private and public payors alike. Furthermore, differences in patented drug prices between countries are not evidence of unfair or inefficient markets.

B. Price discrimination between national markets promotes efficiency and medicine access

Selling drugs at different prices across geographic markets is also not necessarily unfair or anticompetitive. Besides reflecting sellers' different costs of serving different countries, economists recognize that price discrimination between markets can optimize resource allocation and boost net output and social welfare by accounting for differences in demand.²¹ The pharmaceutical sector has high fixed costs as a percentage of sales²² because it is research-intensive and requires significant upfront costs before new products are brought into existence.²³ Industries with this feature are more likely to attract socially optimal investment when sellers can price discriminate between markets. The ability to capture more profits by charging higher prices where demand is less elastic incentivizes upfront investment or attracts start-up capital to overcome high fixed costs, thereby enabling socially desirable investments that may not otherwise occur.²⁴

Demand for pharmaceuticals is higher in larger economies because GDP correlates with a country's total pharmaceutical consumption.²⁵ GDP per capita correlates with higher monetary value for health improvement, demand for health improvement rises with income, and larger

²⁰ Elizabeth Stotland Weiswasser and Scott D. Danzis, "The Hatch-Waxman Act: History, Structure, and Legacy," *Antitrust LJ* 71 (2003).

²¹ See S. Cowan, "When Does Third-Degree Price Discrimination Reduce Social Welfare, and When Does It Raise It?," Department of Economics Discussion Paper Series no. 410, University of Oxford, October 2008, http://www.economics.ox.ac.uk/index.php/papers/details/when_does_third_degree_410/.

²² Susan O. Schweitzer, *Pharmaceutical Economics and Policy*, 2nd ed. (Oxford University Press, 2007).

²³ See Aylin Sertkaya, Trinidad Beleche, Amber Jessup, and Benjamin D. Sommers, "Costs of Drug Development and Research and Development Intensity in the US, 2000–2018," *JAMA network open* 7, no. 6 (2024): e2415445 <https://jamanetwork.com/journals/jamanetworkopen/fullarticle/2820562>.

²⁴ See Frank R. Lichtenberg, "Pharmaceutical Companies' Variation of Drug Prices Within and Among Countries Can Improve Long-Term Social Well-Being," *Health Affairs* 30, no. 8: 1542 and Tomas J. Philipson and Anupam B. Jena, "Who Benefits from New Medical Technologies? Estimates of Consumer and Producer Surpluses for HIV/AIDS Drugs," *Forum for Health Economics & Policy* 9, no. 2 (2006): article 3.

²⁵ See Frech III, Pauly, and Comanor, "Are Drug Prices Abroad Too Low?," 28–29. The authors found that differences in national GDP explained 83% of the variation between countries' contributions to global pharmaceutical R&D, and that a country with a GDP five times that of another country is likely to contribute 6.45 times more to pharmaceutical R&D.

populations mean more people can benefit from a new medicine.²⁶ Price uniformity across countries would thus lower global revenue and incentives to fund drug development, leading to fewer new cures and lower medicine supply and uptake as limited supply cannot go where it is most valued.²⁷

Despite the “fairness” rationale for equalizing US drug prices to those overseas, this would not be a fair outcome for American patients who would lose access to existing and new medicines even if they see short-term reductions in drug prices. Of 104 new oncology drugs introduced between 2017 and 2021, 83 were launched in the US while only 58 were launched in Europe.²⁸ Since new drugs reduce future hospitalizations,²⁹ and since hospitalization costs impose a burden on the federal budget that is three times that of drug prices,³⁰ price uniformity across countries could also leave American taxpayers worse off in the long run.

C. Practical difficulties in setting an optimal “global price”

Beyond the economic case for allowing different patented drug prices across markets, there is no practical method for determining a single global price.

One method would divide the fixed costs of researching, developing, testing, and approving a drug among nations to estimate a single price, adjusted for each nation’s purchasing power parity (PPP). However, pharmaceutical research involves “trial and error,” and the sunk costs of failed trials and projects must be accounted for to enable optimal investment in new drug discovery and development. The Congressional Budget Office finds that drugmakers need an average 62.2% profit margin on successful drugs to achieve just a 4.8% overall return on assets.³¹ In recent years, these costs have risen even further due to higher failure rates and increased research costs.³² Apportioning the costs of failed projects among successful ones in a nonarbitrary, demand-based way that enables optimal investment thus poses a significant technical challenge.

The “high-powered incentive” to invest in pharmaceutical research is also based on maximizing expected future profits instead of the mere desire to cover fixed costs with additional monetary reward.³³ This links drug research to societal demand for specific types of drugs, cures,

²⁶ Frech III, Pauly, and Comanor, “Are Drug Prices Abroad Too Low?,” 28–29.

²⁷ Frank Lichtenberg studied the relationship across drugs between total output growth and increasing differentiation in prices over a decade using sales data for almost 6,500 drugs in 38 nations. He found that, as differences in the price of a drug in different national markets rose, so too did the drug’s supply and its uptake. See Frank R. Lichtenberg, “Pharmaceutical Companies’ Variation of Drug Prices Within and Among Countries Can Improve Long-Term Social Well-Being,” *Health Affairs* 30, no. 8 (2011): 1540–41.

²⁸ Global Innovation Policy Center, *The True Cost of Price Controls: Patient Access Report 2024* (US Chamber of Commerce, 2024), 15, <https://www.uschamber.com/assets/documents/GIPC-2024-Patient-Access-Report.pdf>.

²⁹ For instance, treating obesity can lower or prevent future hospitalizations and the need to treat cardiovascular and other ailments. See L. A. McKeown, “Could Pricey GLP-1 Drugs Cut Healthcare Costs? The Math Isn’t Simple,” *tctMD*, December 9, 2024, <https://www.tctmd.com/news/could-pricey-glp-1-drugs-cut-healthcare-costs-math-isnt-simple>.

³⁰ Prescription drugs accounted for approximately 9% of the federal health budget in 2022. Hospitalization costs accounted for 30%. See CMS.gov, “National Health Expenditures 2022 Highlights,” December 13, 2023, <https://www.cms.gov/newsroom/fact-sheets/national-health-expenditures-2022-highlights>.

³¹ Congressional Budget Office, “How Taxes Affect the Incentive to Invest in New Intangible Assets,” November 15, 2018.

³² Joseph A. DiMasi, Henry G. Grabowski, and Ronald W. Hansen, “Innovation in the Pharmaceutical Industry: New Estimates of R&D Costs,” *Journal of Health Economics* 47 (May 2016): 20–33.

³³ Margaret K. Kyle, “Incentives for Pharmaceutical Innovation: What’s Working, What’s Lacking,” *International Journal of Industrial Organization* 84 (September 2022): 102850.

or innovations, enabling socially optimal and economically efficient investments, assuming drug prices reflect public demand rather than arbitrary or extraneous incentives.

It is also impossible to know in advance exactly how profitable a drug will or ought to be, and an estimate based on market demand rather than technocratic global price-setting exercise would better approximate optimal investment incentives. Moreover, expected profits support technology transfer, market entry, and funding for new investment in manufacturing facilities and supply chains.

II: Why Foreign Nations Should Pay More for US Drugs

Even though price uniformity across international jurisdictions may not be desirable, optimal or realistic, there is still a strong case for foreign countries to increase their current contributions to pharmaceutical R&D, both to reduce the degree to which American patients, health plans and taxpayers subsidize their healthcare systems, and to spur the creation of new cures. It would also be of benefit to the economies and domestic pharmaceutical industries of these countries.

Philipson and Jena (2006) considered over 200 previous studies on different patented drugs and their cost effectiveness. They found that drug companies capture under 7% of societal surplus in 25% of the studies and over 25% in another 25% of the studies.³⁴ For example, even though HIV/AIDS therapies that entered the market since the late 1980s were found to raise social welfare by nearly \$1.4 trillion, they generated just \$62.9 billion in profits for the companies that created them, which represents less than 5% of the total welfare.³⁵ This suggests that current global drug sales generate insufficient revenue to optimally supply the public good of pharmaceutical innovation, as optimal market outcomes occur when all of the societal surplus can be captured through profits.³⁶

Unlike the United States, foreign governments also actively suppress patented drug prices below market levels using either direct price controls, buyer monopsony power, or both. US law considers “monopsony” to be the “mirror image” of monopoly.³⁷ Monopoly power refers to the ability of a powerful seller to curb competition and harm consumers by raising prices and restricting output without losing market share to competitors. Similarly, monopsony power refers to the ability of a powerful buyer to suppress output by underbidding suppliers’ prices below competitive market levels. Even if the monopsonist buyer partially passes on its cost savings to consumers in a secondary market through lower prices, those consumers may still be worse off than in a competitive market, as they may face reduced supply, fewer choices, or fewer innovative or new products.

Foreign governments and their public insurers are typically the biggest purchasers of drugs in those markets, and act as monopsony buyers by controlling drugmakers’ access to virtually all or a large proportion of those countries’ citizens. This is especially true under single-payer public healthcare systems. These governments leverage access to virtually entire national markets in

³⁴ Tomas J. Philipson and Anupam B. Jena, “Surplus Appropriation from R&D and Health Care Technology Assessment Procedures,” NBER Working Paper no. 12016 (National Bureau of Economic Research, February 2006).

³⁵ Philipson and Jena, “Surplus Appropriation from R&D and Health Care Technology Assessment Procedures.”

³⁶ See Joe Kennedy, “The Link Between Drug Prices and Research on the Next Generation of Cures,” *Information Technology and Innovation Foundation*, September 9, 2019.

³⁷ See Roger Noll, “‘Buyer Power’ and Economic Policy,” *Antitrust Law Journal* 72, no. 2 (2005): 589; *Weyerhaeuser Co. v. Ross-Simmons Hardwood Lumber Co.*, 549 U.S. 312 (2007).

negotiations with drugmakers, forcing them to accept lower prices than would exist in a competitive market.

This is not to say that foreign public insurers use their monopsony power to secure patented drug prices that are just above marginal production cost. Instead, many foreign governments use quantitative assessments and models to estimate the value of a drug and use their buying power and control of market access to secure this price from drugmakers. This demonstrates at least tacit acknowledgment that new cures deliver significant societal benefits and are costly to research and develop even if they can be produced cheaply.³⁸ For example, Healthcare Technology Assessments (HTAs) are systematic and multidisciplinary evaluations of the medical, economic, social and ethical impacts of medicines, treatments and medical devices, using metrics such as the Quality-Adjusted Life Years (QALYs) a drug is expected to add to estimate cost-effectiveness.³⁹

In practice, however, these systems are manipulated through government policy to deflate prices. This may be done through spending caps and budgetary claw-backs. For instance, Australia implements a claw-back mechanism whereby drugmakers must return all expenditures in excess of the cap to the government, and requires drugmakers to cut their prices if a generic or biosimilar competitor does not enter the market by certain stages regardless of inflation, production costs, or the drug's ongoing therapeutic value.⁴⁰ Similarly, Canada devalues US patented medicines by excluding the US and Switzerland from the basket of comparison countries that its Patented Medicine Prices Review Board (PMPRB) uses to determine whether drug prices are "excessive" and need to be cut.⁴¹

Even the metrics and assumptions used in HTAs are often manipulated. For instance, the UK government's National Institute for Health and Care Excellence (NICE) values a QALY at between \$33,389 and \$46,745, with a higher figure only for ultra-rare and end-of-life treatments.⁴² This figure is a December 2025 revision that only slightly modifies an estimate of \$26,711 to \$40,067 per QALY set in 1999 and left unadjusted for inflation. By contrast, the American Institute for Clinical and Economic Review (ICER) values an additional year of life at \$100,000–\$150,000 and up to \$200,000 for treatment of severe cases—well over three to four times the UK figure.⁴³

Defenders of HTA-based pricing would respond that such assessments are not intended to disguise protectionism or shift the costs of global pharmaceutical innovation onto US patients. On this view, HTAs provide a disciplined and transparent method for allocating finite public healthcare budgets among competing health needs, comparing a medicine's incremental clinical benefits and costs with available alternatives, and preserving access for the greatest number of

³⁸ See Comanor, William S., "Why Are (Some) US Drug Prices So High?," *Regulation* 44, no. 4: 18–23; Frech III, Pauly, and Comanor, "Are Drug Prices Abroad Too Low?," 26–29.

³⁹ See P. Murphy, S. Griffin, S. Walker, et al., "Cost-Effectiveness Thresholds in Policy and Practice: Do HTA Guidelines Align with Estimates of Health Opportunity Cost?," *Health Economics, Policy and Law* (2026).

⁴⁰ United States Trade Representative, 2025 Special 301 Report (Office of the United States Trade Representative, 2025), 26, <https://ustr.gov>.

⁴¹ United States Trade Representative, 2025 Special 301 Report, 26.

⁴² The official figure as of December 1, 2025, is £25,000 to £35,000/QALY gained associated with using a medicine, which revises the original figure of £20,000 to £30,000/QALY gained, which was set in 1999. See UK National Institute for Health and Care Excellence, "Changes to NICE's Cost-Effectiveness Thresholds Confirmed," December 1, 2025, <https://www.nice.org.uk/news/articles/changes-to-nice-s-cost-effectiveness-thresholds-confirmed>.

⁴³ P. Thokala, J. J. Carlson, and M. Drummond, "HTA'd in the USA: A Comparison of ICER in the United States with NICE in England and Wales," *Journal of Managed Care & Specialty Pharmacy* 26, no. 9 (2020): 1162–70.

patients. Differences in QALY thresholds could reflect legitimate differences in national income, disease burdens, fiscal capacity, and democratic judgments about the value of extending life or improving its quality. Foreign governments might further argue that their bargaining power is necessary to counterbalance pharmaceutical companies' patent-based market power and that higher prices would increase short-term healthcare costs without any guarantee that the resulting additional revenues would be invested in socially valuable research. These are serious considerations, and HTAs can provide useful information about the relative value of treatments. Nevertheless, they do not establish that governments should use their purchasing power to impose prices that systematically undercompensate innovation or free ride on returns generated in the United States. When QALY thresholds remain far below levels that reflect income growth, inflation, or the value of life in comparable markets, and when spending caps and claw-backs prevent prices from responding to demand, HTAs cease to be merely neutral budgeting tools and become instruments for suppressing the market signals on which future pharmaceutical investment depends.

These arbitrarily large differences between US and overseas estimates of a QALY's value illustrate how technocratic assessments serve as a veneer of objectivity as foreign governments leverage buyer monopsony to lower drug spending while purporting to pay fair prices for funding research and development. In so doing, these governments take advantage of the higher US public and private drug prices and spending that disproportionately fund the development and supply of new drugs.

A. Foreign price controls as anti-competitive market distortions (ACMDs) and non-tariff barriers (NTBs) to trade

ACMDs are government-backed regulations or practices that distort prices, weaken market competition and reduce economic efficiency relative to a competitive market.⁴⁴ These can include anticompetitive regulations, regulations that arbitrarily discriminate between competitors and practices and regulations that devalue or fail to safeguard property rights, including IP.⁴⁵ Since ACMDs are backed by state power, they cannot be remedied through market processes and often deter market actors from addressing market demand. Because foreign governments' price controls, budgetary claw-backs, manipulated HTAs and patented drug valuations, and monopsony buying deflate patented drug prices below competitive levels and thereby suppress pharmaceutical innovation to subcompetitive levels, they are ACMDs. And since these policies restrict, distort and create costs for international trade by suppressing prices on US drugs and returns on US IP to subcompetitive levels, they are also non-tariff barriers (NTBs) to trade.

For foreign nations, abolishing ACMDs would unlock latent economic energy while mitigating political risks linked to stagnation and misallocation of capital.⁴⁶ For instance, scaling back price controls and other distortionary pricing policies on patented drugs would increase financial incentives for generic drug manufacturers to challenge patents and enter the market upon patent expiration. This would provide foreign governments and patients benefits similar to those enjoyed by the US public sector, which pays less on average for prescription drugs than public

⁴⁴ Shanker A. Singham and U. Srinivasa Rangan, "Anticompetitive Market Distortions: A Typology," *Economic Affairs* 38, no. 3 (2018): 339.

⁴⁵ Shanker A. Singham, *Trade Policy in the Trump Administration: Advancing Reduction of Anti-Competitive Market Distortions* (Competere and the Growth Commission, August 2025), 6.

⁴⁶ Singham, *Trade Policy in the Trump Administration: Advancing Reduction of Anti-Competitive Market Distortions*, 6.

payors in Canada, Japan, Germany and the UK. In 2004, the US Departments of Commerce and Health and Human Services found that if prices of patented drugs rose to competitive market levels in non-US OECD countries, then more competitive generic markets could significantly, or even completely, offset any extra costs.⁴⁷ Replacing arbitrary price controls with market-driven demand signals would also drive sustainable revenue streams that incentivize private investment in life-saving cures, technology transfers, and resilient global supply chains.

Abolishing these ACMDs would also spur economic growth and innovation in foreign economies by supporting the domestic generic and nongeneric pharmaceutical industry. This includes domestic research into new drugs which would be incentivized by the prospect of returns from the domestic market that are closer to competitive levels. Studies show that securing reliable and effective property rights for inventors, including by eliminating price controls that devalue or reduce returns on patents, correlates with successful innovation economies.⁴⁸ In 2018, University of Southern California researchers found that if European drug prices rose by 20%, then this would lead to substantially more discovery of drugs that lengthen lives and increase quality of life globally.⁴⁹ The resulting increased innovation would produce approximately \$10 trillion in welfare gains for Americans, and \$7.5 trillion for Europeans over the next five decades.⁵⁰

Conversely, drug-price ACMDs have led to European nations ceding global leadership in pharmaceutical research and development to the United States. Such policies were introduced in Europe starting in the 1980s.⁵¹ At the start of the 1990s, pharmaceutical industry investment in Europe was approximately 50% greater than in the United States.⁵² By 2004, Europe's share of global pharmaceutical innovation had fallen to 18% while the US share rose to 62%.⁵³ Half of all new therapies introduced between 2014 and 2018 originated in the United States, while only about 25% originated in Europe.⁵⁴ Reversing or scaling back these ACMDs would thus help drive economic and public health gains for foreign economies while raising wages, fostering patient access to medicine, increasing consumer choice, creating significant numbers of high-paying research jobs, and increasing fiscal capacity to meet public spending needs.

Additionally, reliable offers to reduce drug-price ACMDs could incentivize the US government to lower its own trade and regulatory barriers, including through tariff reductions, thereby benefiting foreign economies and industries through greater access to the lucrative US market. This would provide a stronger incentive for these nations to increase the prices they pay for US drugs, since domestic polities feel the benefits of increased trade and competition across

⁴⁷ Kevin A. Hassett, "Pharmaceutical Price Controls in OECD Countries," testimony before the Department of Commerce's International Trade Administration, 2004, 2.

⁴⁸ Jonathan M. Barnett, "Patent Tigers: The New Geography of Global Innovation," *Criterion Journal of Innovation* 2 (2017): 429; Stephen Haber, "Patents and the Wealth of Nations," *George Mason Law Review* 23 (2016): 811.

⁴⁹ Dana Goldman and Darius Lakdawalla, "The Global Burden of Medical Innovation," USC Schaeffer Center Working Paper, 2018, https://schaeffer.usc.edu/wp-content/uploads/2024/10/01.2018_Global20Burden20of20Medical20Innovation.pdf.

⁵⁰ Goldman and Lakdawalla, "The Global Burden of Medical Innovation."

⁵¹ See Sandra Barbosu, Stephen Ezell, and Esther Serger, "Lessons from Europe's Loss of Biopharma Leadership and Its Attempts to Recover" (Center for Life Sciences Innovation, Information Technology and Innovation Foundation, March 2026).

⁵² See European Federation of Pharmaceutical Industries and Associations, "The Research-Based Pharmaceutical Industry: A Key Actor for a Healthy Europe," 2006, cited in Barbosu, Ezell, and Serger, "Lessons from Europe's Loss of Biopharma Leadership," 3–5.

⁵³ Kimberly Cleaves, "Imbalanced Innovation," *Modern Drug Discovery*, July 2004, 23–24, cited in Barbosu, Ezell, and Serger, "Lessons from Europe's Loss of Biopharma Leadership," 3–5, <http://pubsapp.acs.org/subscribe/archive/mdd/v07/i07/pdf/704business3.pdf>.

⁵⁴ Cleaves, "Imbalanced Innovation," 3–5.

industries more immediately than those of new drug development and innovation. Securing greater US market access through increasing foreign contributions to US and global pharmaceutical innovation is also consistent with current US government policy under the Trump administration as reflected in the executive order on Most-Favored Nation (MFN) drug pricing, “Unleashing Prosperity through Deregulation.”⁵⁵ It is also consistent with the Trump tariff doctrine, which intends to use access to the US market to drive countries into deals that lower their ACMDs, and the Trump economic doctrine, which intends to lower US ACMDs to boost economic growth.⁵⁶ Finally, it is consistent with the 2026 US Trade Representative (USTR)’s Section 301 Special Report on Intellectual Property Protection and Enforcement, which identifies foreign ACMDs on drug pricing as a priority for mitigation through trade negotiations and singles out such ACMDs in Australia, Japan, South Korea, the UK and Canada.⁵⁷ And the 2025 US–UK agreement on pharmaceutical pricing demonstrates that such agreements are achievable.

III: US–UK Case Study

In December 2025, the US and UK governments reached a pharmaceutical pricing agreement under which the United States would waive tariffs on UK drug exports for at least three years in return for the UK’s National Health Service (NHS) paying 25% more for new US drugs.⁵⁸ This is the first major price increase in over 20 years and was implemented from April 2026 through an upward revision of the NHS’s QALY thresholds for assessing new medicines.⁵⁹ The deal also caps the claw-back rate, that is the percentage of annual NHS sales revenue that drugmakers are required to return to the agency, at 15% for the next three years. The current rate is 23.5%.⁶⁰ The Association of the British Pharmaceutical Industry and the UK government are required to negotiate a new, more sustainable payment scheme by 2029. The share of UK GDP spent on branded drugs will increase by 17% between 2026 and the end of 2028 and double by 2036,⁶¹ from 0.3% to 0.6% under the deal.⁶²

Favorable conditions for negotiating this agreement included the centralized procurement policies of the single-payer UK NHS, the vulnerability of the UK’s life sciences sector to America’s Section 232 tariffs,⁶³ and benefits to British healthcare access and innovation from

⁵⁵ Trump, D, “Executive Order 14192, Unleashing Prosperity Through Deregulation,” *Federal Register* 90 (2025): 9065–9067.

⁵⁶ Singham, Trade Policy in the Trump Administration, 4.

⁵⁷ United States Trade Representative, 2025 Special 301 Report, 24–28.

⁵⁸ Jacqui Wise, “UK–US Pharmaceutical Deal: NHS Will Pay Billions More for New Drugs,” *British Medical Journal (Online)* 391 (2025): r2538.

⁵⁹ Office of the United States Trade Representative, US Department of Health and Human Services, and UK Department of Health and Social Care, “Agreement in Principle on Pharmaceutical Pricing: US–UK Economic Prosperity Deal,” press release, December 1, 2025, <https://www.ustr.gov/about/policy-offices/press-office/press-releases/2025/December>.

⁶⁰ Wise, “UK–US Pharmaceutical Deal.”

⁶¹ Sally Gainsbury and James Lomas, “The UK Government Must Publish a Detailed Impact Assessment of the Costs and Benefits of the US–UK Medicines Partnership,” *British Medical Journal (Online)* 393 (2026).

⁶² Wise, “UK–US Pharmaceutical Deal.”

⁶³ 19 U.S.C. § 1862. The US is the single largest destination for UK pharmaceutical exports. See Office for National Statistics, “UK Trade with the United States: 2023,” January 17, 2025, <https://www.ons.gov.uk/economy/nationalaccounts/balanceofpayments/articles/uktradewiththeunitedstates2023/2023>.

higher drug prices.⁶⁴ The UK government expects that the deal will increase and expedite British patients' access to groundbreaking treatments. The National Institute for Health and Care Excellence (NICE) estimates that three to five more new medicines or treatments will be approved annually.⁶⁵ The UK government also expects that it will support economic growth and the domestic life sciences sector,⁶⁶ which accounted for 17% of all British business R&D in 2023.⁶⁷ It thus supports the UK government's 2025 10-year Life Sciences Sector Plan, which aims to make the UK a global life sciences leader by 2035.⁶⁸ Under that plan, the UK government has committed \$698.97 million to support domestic production of diagnostics and drugs through the Life Sciences Innovative Manufacturing Fund (LSIMF), and \$115.6 billion for public R&D through 2030, focusing on clinical trial infrastructure and AI-aided drug discovery.⁶⁹ The US–UK pharmaceutical pricing deal will enhance returns on these investments. This demonstrates that winding back drug price ACMDs can complement domestic life sciences investment.

Importantly, the US–UK deal lays the groundwork for other developed nations to increase their contributions to global pharmaceutical R&D. Of the 19 Organization for Economic Cooperation and Development (OECD) members with per capita GDP at least 60% of the US level, 15 use International Reference Pricing (IRP) for pharmaceuticals and all but two include the UK in their basket of comparison countries.⁷⁰ This means that a 25% increase in NHS drug prices will also likely increase prices paid by other foreign governments.

The US–UK deal also demonstrates that successful agreements with foreign nations to eliminate drug price ACMDs or increase contributions to pharmaceutical innovation are more likely to eventuate when they complement or bolster existing governmental initiatives. For instance, like the UK, Sweden, the Netherlands, France and Germany have also implemented medium and/or long-term national life sciences sector strategies and already host government-supported life sciences clusters. The EU has its own life sciences strategy, which includes a \$346 million commitment through the Competitiveness Compass to drive procurement in life sciences, including in critical areas like cancer care and new vaccines,⁷¹ and \$404 million+ in

⁶⁴ Morgan, Lewis & Bockius LLP, "UK–US Pharmaceutical Trade Deal: Impact on UK Drug Pricing, Tariffs, and Investment," LawFlash, December 4, 2025, <https://www.morganlewis.com/pubs/2025/12/uk-us-pharmaceutical-trade-deal-impact-on-uk-drug-pricing-tariffs-and-investment>.

⁶⁵ Wise, "UK–US pharmaceutical Deal."

⁶⁶ Wise, "UK–US pharmaceutical Deal."

⁶⁷ Association of the British Pharmaceutical Industry, "Creating the Conditions for Investment and Growth," December 10, 2025, <https://www.abpi.org.uk/publications/creating-the-conditions-for-investment-and-growth/>.

⁶⁸ UK Department for Business and Trade et al., Life Sciences Sector Plan (UK Government, July 16, 2025), <https://www.gov.uk/government/publications/life-sciences-sector-plan/life-sciences-sector-plan>.

⁶⁹ Barbosu, Ezell, and Serger, "Lessons from Europe's Loss of Biopharma Leadership," citing UK Government, "Life Sciences Innovative Manufacturing Fund (LSIMF): Expression of Interest," <https://www.gov.uk/government/publications/life-sciences-innovative-manufacturing-fund-lsimf>.

⁷⁰ See Leah Z. Rand and Aaron S. Kesselheim, "International Reference Pricing for Prescription Drugs: A Landscape Analysis," *Journal of Managed Care & Specialty Pharmacy* 27, no. 9 (2021): 1309–13, <https://www.jmcp.org/doi/full/10.18553/jmcp.2021.27.9.1309>; Mauro Iannopolo, "US Most-Favored-Nation Drug Pricing and European Reference Pricing: Transmission Mechanisms and Policy Implications for Italy," manuscript under review, 2026.

⁷¹ European Commission, "Commission Launches New Strategy to Make Europe a Global Leader in Life Sciences by 2030," press release, July 1, 2025, https://ec.europa.eu/commission/presscorner/detail/en/ip_25_1686.

biomanufacturing and biotechnology investments under the Horizon Europe EIC portfolio.⁷² These initiatives would yield greater returns under higher global and domestic drug prices.⁷³

IV: Achieving Higher Foreign Drug Prices Through Bilateral and Multilateral Deals

This section will outline general principles for achieving optimal trade deals and analyze how these apply to the EU, which represents several of the world's top pharmaceutical-exporting nations.

The harms of ACMDs to domestic and foreign competition and consumers alike demonstrate that their repeal offers a compelling political incentive for both parties to enter into bilateral trade agreements between the US and non-US nations. The US–UK trade deal demonstrates that agreements on higher foreign contributions toward US pharmaceutical innovation are realistically achievable through tariff exemptions and the promise of lower frictions and greater cooperation in pharmaceutical trade and supply chains. This blueprint rests on two complementary ideas. First, agreements should create reciprocal economic benefits that make higher pharmaceutical prices attractive to both parties. Second, they should be designed to create durable political and economic constituencies that reinforce those agreements over time. Reciprocal regulatory cooperation advances both objectives.

Reciprocal ACMD abolition and mutual recognition of regulatory approvals or processes offer simple and mutually beneficial ways to reduce trade frictions, foreign and domestic business costs, and consumer prices while increasing access to goods and services (including medicines) on both sides of trade deals. Mutual and reciprocal stipulations make it harder for foreign opponents of trade agreements with the US to portray the agreements as one-sided or unfair. They also eliminate regulatory duplication that serves no legitimate consumer welfare or protection purpose. By facilitating additional cross-border supply chains and cooperative alliances, they can provide a hedge against future disruptions of both domestic and existing foreign supply chains, especially in critical areas like medicines, medical supplies and food products.⁷⁴

Simultaneously, reciprocal ACMD abolition and mutual recognition of approvals or stages of the approval process facilitate cross-border trade and supply chains. This provides a hedge against future political threats to the trade deals, as reversing them would risk the jobs, companies and economic growth they facilitate. This mirrors the “transitional gains trap” described by economist Gordon Tullock, whereby the conferral of special privileges leads to an increase in the costs of joining the beneficiary group that matches the expected profits.⁷⁵ Thus, removing those benefits will face opposition from existing beneficiaries, including those incurring losses from the investments they made to join the group.

However, unlike special privileges, mutual recognition of regulatory processes and reciprocal abolition of ACMDs remove existing costs and abolish privileges for special interest groups benefiting from trade and competition barriers. They also encourage firms to allocate resources

⁷² European Commission, “EIC Impact Report 2023: Accelerating Deep Tech in Europe,” news release, March 25, 2024, <https://ec.europa.eu/newsroom/eisma/items/824162/en>.

⁷³ Barbosu, Ezell, and Serger, “Lessons from Europe’s Loss of Biopharma Leadership.”

⁷⁴ A globally diverse network of suppliers buffers against localized shocks at home or abroad, including natural disasters, labor strikes and factory shutdowns. For instance, the American baby formula industry collapse of 2022 was driven by highly nationalized domestic supply chains that created localized chokepoints. See Scott Lincicome, Gabriella Beaumont-Smith, and Alfredo Carrillo Obregon, “Formula for a Crisis: Protectionism and Supply Chain Resiliency—The Infant Formula Case Study,” Cato Institute Briefing Paper no. 146, January 11, 2023, <https://www.cato.org/briefing-paper/formula-crisis>.

⁷⁵ Gordon Tullock, “The Transitional Gains Trap,” *Bell Journal of Economics* 6 (1975): 671–78.

toward productive activities and investments that benefit consumers through innovation or lower prices, rather than lobbying or investing purely to secure privileges.

A range of synergies under this framework make the EU a favorable candidate for trade negotiations.

A. The European Union as a potential negotiating partner

In 2025, the United States represented 53% of global pharmaceutical list price sales,⁷⁶ while the EU accounted for between 15.66% and 19.58% (2024).⁷⁷ However, among continents, European nations exported \$456.3 billion or 81.5% of the global total for pharmaceuticals.⁷⁸ This makes the EU, which includes four of the top five pharmaceutical exporters,⁷⁹ an ideal United States negotiating partner for a drug pricing agreement. European nations would also benefit from increased access to medicines by curbing price control policies and increasing their pharmaceutical revenue contributions to levels closer to the US. 40% of medicines launched in the US never make it to major European markets,⁸⁰ and European price controls are estimated to lower worldwide pharmaceutical R&D by over \$56 billion yearly, preventing the creation of approximately 25 new medicines every year.⁸¹ Other favorable conditions for a drug pricing agreement include the importance of life sciences for Europe's economies, US negotiating leverage due to the importance of US market access for Europe's pharmaceutical industry, and the strong increase in global pharmaceutical revenues obtainable through securing higher drug prices from all EU countries.

EU institutions cannot mandate what member states pay for pharmaceuticals, as this is the purview of their national governments and regulatory authorities.⁸² However, the European Commission (EC) or Council can adopt nonbinding recommendations,⁸³ and the European Parliament (EP) can pass nonbinding resolutions calling upon member states to increase patented drug prices by a negotiated percentage. The US and EU can adopt an agreement under which US commitments take effect upon the assent or ratification by all or a specified number of EU member states. Because the agreement could not itself set national prices, its operative mechanism

⁷⁶ IQVIA, "IQVIA Early Bird: 2025 Revealed—The Trends Shaping Pharma's Future," IQVIA blog, March 11, 2026, <https://www.iqvia.com/blogs/2026/03/iqvia-early-bird-2025-revealed>.

⁷⁷ Europe cornered between 20% and 25% of global pharmaceutical sales by revenue in 2024. The EU estimate of between 15.66% and 19.58% was calculated by subtracting the shares of non-EU European nations (approximately 79.6% of European sales revenue came from EU countries), including Switzerland, Norway and the UK, and expressing this as a percentage of global sales. See Proxima Research, "Review of Global Trends in the Pharmaceutical Business. Part I—USA and Europe," February 20, 2026, <https://proximaresearch.com/kz/en/news/review-of-global-trends-in-the-pharmaceutical-business-part-i-usa-and-europe-2/>.

⁷⁸ Daniel Workman, "Drugs and Medicine Exports by Country," World's Top Exports, last modified June 6, 2026, <https://www.worldstopexports.com/drugs-medicine-exports-country/>.

⁷⁹ Workman, "Drugs and Medicine Exports by Country." Germany, Italy, Ireland and Belgium are EU member states that are among the top global drug exporters.

⁸⁰ Trelysa Long and Stephen Ezell, "The Hidden Toll of Drug Price Controls: Fewer New Treatments and Higher Medical Costs for the World" (Information Technology and Innovation Foundation, July 17, 2023), <https://itif.org/publications/2023/07/17/hidden-toll-of-drug-price-controls-fewer-new-treatments-higher-medical-costs-for-world/>.

⁸¹ IQVIA Institute for Human Data Science, Global Trends in R&D 2026: Advancing Innovation in a Changing Landscape (Parsippany, NJ: IQVIA Institute for Human Data Science, 2026), <https://www.iqvia.com/insights/the-iqvia-institute/reports-and-publications/reports/global-r-and-d-trends-2026>.

⁸² European Union, "Consolidated Version of the Treaty on the Functioning of the European Union," *Official Journal of the European Union*, C 202, June 7, 2016, art. 168(7), <https://eur-lex.europa.eu/legal-content/EN/TXT/?uri=CELEX:12016E168>.

⁸³ European Union, "Consolidated Version of the Treaty on the Functioning of the European Union."

would be conditionality: US tariff, regulatory, or market-access concessions would take effect only after participating member states adopted the specified pricing or reimbursement measures, with EU-level recommendations and political coordination helping secure that assent.

The EU prioritizes the development of its life sciences sector, which supports 29 million EU jobs and generates \$1.74 trillion for the EU economy.⁸⁴ For instance, the “Choose Europe to Start and Scale” initiative aims to lower barriers for biotech start-ups, its “Choose Europe” plan aims to draw foreign researchers, and the proposed EU Biotech Act would generate faster market-access pathways while funding multinational clinical trials through its “One Health” approach.⁸⁵ The Act would also modernize and harmonize biomanufacturing and biotechnology patent and data-use rules in order to raise the EU’s global competitiveness by fostering interoperability among member states and regulatory predictability.⁸⁶

Reductions in US market barriers, lower regulatory overheads and higher EU member pharmaceutical revenue contributions would support these efforts. They would also complement the \$289.36 million the EU has committed under its life sciences strategy for cross-sectoral technology development, including novel approach methodologies, new molecules, increased biomanufacturing efficiency and advanced materials.⁸⁷ Major EU member states similarly prioritize life sciences in industrial policy. For instance, Germany’s intergovernmental Future Research & Innovation (R&I) Strategy facilitates start-up pathways;⁸⁸ Sweden’s national life sciences strategy supported a 5% increase in public R&D between 2024 and 2025;⁸⁹ and the Dutch National Growth Fund (NGF) committed \$1.47 billion in 2025 alone for national biotech innovation.⁹⁰

Greater regulatory harmonization with the US FDA and lower US ACMDs would also mirror and support the European Medicines Agency (EMA)’s regulatory efficiency improvement efforts, including expedited drug reviews and postapproval modification, stronger frameworks for nonstandard drug categories, and more efficient use of drug developer resources.⁹¹ In exchange

⁸⁴ Directorate-General for Communication, “Making Europe a Global Leader in Life Sciences,” news release, July 2, 2025, https://commission.europa.eu/news-and-media/news/making-europe-global-leader-life-sciences-2025-07-02_en.

⁸⁵ Barbosu, Ezell, and Serger, “Lessons from Europe’s Loss of Biopharma Leadership” citing Directorate-General for Communication, “Making Europe a Global Leader in Life Sciences”; Thomas Gabrielczyk, “EU Set to Improve Investment for Biotech Start-Ups and Scale-Ups,” *European Biotechnology Magazine*, May 30, 2025, <https://european-biotechnology.com/latest-news/eu-set-to-improve-investment-for-biotech-start-ups-and-scale-ups/>; European Commission, “Choose Europe,” accessed August 18, 2026, https://commission.europa.eu/topics/research-and-innovation/choose-europe_en.

⁸⁶ Barbosu, Ezell, and Serger, “Lessons from Europe’s Loss of Biopharma Leadership”; Gabrielczyk, “EU Set to Improve Investment for Biotech Start-Ups and Scale-Ups”; European Commission, “Choose Europe.”

⁸⁷ European Commission, “Commission Launches New Strategy to Make Europe a Global Leader in Life Sciences by 2030,” press release, July 1, 2025, https://ec.europa.eu/commission/presscorner/detail/en/ip_25_1686.

⁸⁸ The Federal Government, Future Research and Innovation Strategy (Berlin: The Federal Government, 2023), https://www.aufstiegs-bafoeg.de/SharedDocs/Publikationen/de/bmbf/FS/747580_Zukunftsstrategie_Forschung_und_Innovation_en.pdf.

⁸⁹ Barbosu, Sandra, Stephen Ezell, and Esther Serger, “Lessons From Europe’s Loss of Biopharma Leadership.”

⁹⁰ Government of the Netherlands, Government’s Vision on Biotechnology 2025–2040 (Amsterdam: Government of the Netherlands, May 2025), <https://www.government.nl/documents/reports/2025/04/11/dutch-vision-on-biotechnology-2025–2040>.

⁹¹ Barbosu, Sandra, Stephen Ezell, and Esther Serger, “Lessons From Europe’s Loss of Biopharma Leadership, and Its Attempts to Recover,” citing European Medicines Agency (EMA), “EMA welcomes political agreement on new EU pharmaceutical legislation,” EMA, December 2025, <https://www.ema.europa.eu/en/news/ema-welcomes-political-agreement-new-eu-pharmaceutical-legislation>; GMDP Academy, “Streamlining Change: New EU Guidelines Simplify Medicines Lifecycle Management,” October 2025, <https://gmdpacademy.org/news/streamlining-change-new-eu-guidelines-simplify-medicines-lifecycle-management/>.

for higher EU contributions to US pharmaceutical innovation, existing US government programs can be reformed to complement EU life sciences policy by increasing US-EU cooperation and creating opportunities for EU member state economic growth without further expanding US industrial policy.

An agreement for higher EU contributions to global drug development is more likely to succeed when it prioritizes concessions and stipulations that minimize internal political opposition. Zero-tariff guarantees on EU pharmaceutical exports, including under Section 232 national security tariffs, are a compelling incentive, as demonstrated by the US-UK drug pricing agreement. This should be conditional on the domestic and European Parliament ratifications necessary for higher drug prices to take effect.

Cross-sector tariff offsets for other key EU export sectors, including green technologies, automobiles, luxury goods and specialized machinery, could also offset the budgetary impact of higher drug prices through broader EU economic growth.⁹² These exemptions and reductions would benefit US consumers through lower prices. However, tariff reductions or exemptions for green technologies and specialized machinery would also benefit American manufacturers through cheaper production inputs, making them more internationally competitive.

The US can also reduce US–EU regulatory friction by raising export-control thresholds and streamlining export licensing pathways for EU countries to comply with US International Traffic in Arms Regulations (ITAR) and Export Administration Regulations (EAR).⁹³ These apply to dual-use commercial technologies, including robotics, software and advanced sensors.⁹⁴ This would benefit American and European exporters by reducing licensing delays and helping keep production costs low.

Similarly, the US can offer to exempt EU member states from Section 301 investigations targeting their health sector practices, including manipulated HTAs, in return for paying higher drug prices.⁹⁵ This would resolve EU member states’ use and manipulation of HTAs without formally overriding metrics conceived by European health agencies, making the agreement more politically palatable.

Reducing duplicative regulatory approval processes between the US FDA and EU and member-state agencies such as the EMA would also incentivize higher EU drug prices by lowering overhead for EU pharmaceutical exporters. If made conditional on EU reciprocity, it would also benefit US drug exporters. Importantly, this could produce consumer savings without impacting government budgets and revenue. It would also expedite access to innovative medicines for both Americans and Europeans.

⁹² Eurostat records “Machinery & transport equipment” (SITC 7) and “Chemicals & manufactured products” as the largest EU export categories by value. Vehicles, parts, and accessories, which are grouped under “Road vehicles” (SITC 78 / HS 87), are among the most significant manufactured good export categories for Germany–US, Italy–US and Sweden–US trade. See Eurostat, “EU Trade with the United States—Latest Developments,” Statistics Explained, European Commission, accessed August 20, 2026, https://ec.europa.eu/eurostat/statistics-explained/index.php?title=EU_trade_with_the_United_States_-_latest_developments.

⁹³ See US Department of State, International Traffic in Arms Regulations, 22 C.F.R. pts. 120–130 (2024); Export Administration Regulations, 15 C.F.R. pts. 730–774 (2024).

⁹⁴ See e.g. 15 C.F.R. pt. 774, supp. no. 1; 22 C.F.R. § 121.1.

⁹⁵ Section 301 of the US Trade Act (19 U.S.C. § 2411) permits the US Trade Representative (USTR) to investigate and address foreign government policies that “restrict, discriminate against, or unfairly burden,” US commerce. The USTR may pursue remedies including tariff retaliation, abolishing existing trade concessions, or negotiated settlements. See Scott Lincicome, Inu Manak, and Alfredo Carrillo Obregon, “Unfair Trade or Unfair Protection? The Evolution and Abuse of Section 301” (Cato Institute, 2022).

Although the US FDA generally approves the same medicines before overseas counterpart agencies in developed countries, over 20% of all new active substances approved stateside in 2023 were approved first or within a month of FDA approval by counterpart agencies in Australia, Canada, Japan, Switzerland or the EU.⁹⁶ Congress is already considering such reciprocity under the Reciprocity Ensures Streamlined Use of Lifesaving Treatments (RESULT) Act.⁹⁷ The Act would amend the Federal Food, Drug, and Cosmetic Act to require the FDA to decide on requests for reciprocal marketing approval within 30 days of a drug, biological product, or medical device's authorization in a qualifying foreign country and allow Congress to overturn FDA denials by joint resolutions.⁹⁸ Enactment of the RESULT Act could be included as a trade deal stipulation with the EU.

With legislative direction from Congress, the US FDA could also enter into cooperative agreements with EU agencies to participate in the EU's "One Health" multinational clinical trial framework initiative proposed under its Biotech Act. This would address discrepancies in clinical trial endpoint requirements, pediatric investigation plans and dossier formats. Clinical-trial framework harmonization could also be achieved by establishing a unified transatlantic dossier (eCTD) accepted by agencies in both jurisdictions without localization through the International Council for Harmonisation (ICH).⁹⁹ These moves would also reduce overheads and trade barriers while speeding up market entry for American and European medicines. Importantly, these benefits would flow without compromising the bottom lines of US and EU pharmaceutical sectors and government budgets, making them politically saleable on both sides of the Atlantic.

If such stipulations face political opposition over ceding regulatory independence, that opposition could be mitigated by mutually recognizing overlapping procedures rather than final approvals. For instance, factory inspections undertaken by European agencies can be recognized by the FDA without obviating the FDA's role in final drug approvals. If European agencies reciprocate, then US drug exporters would benefit too.

The US Government Accountability Office (GAO) reported in 2022 that the FDA faced chronic backlogs in preapproval inspections (PAIs).¹⁰⁰ Such backlogs delay generic and biosimilar approvals when overseas manufacturing facilities cannot be inspected. Although the FDA and EU have collaborated on frameworks to rely on PAI reports, automatic PAI waivers do not exist.¹⁰¹ There is already an FDA–EU agreement for mutual recognition of Good

⁹⁶ Centre for Innovation in Regulatory Science, R&D Briefing 93, "New Drug Approvals in Six Major Authorities, 2014–2023: Changing Regulatory Landscape and Facilitated Regulatory Pathways" (Centre for Innovation in Regulatory Science, 2024), <https://cirs-ci.org/publications/cirs-rd-briefing-93-new-drug-approvals-by-six-major-authorities-2014-2023/>.

⁹⁷ Office of Senator Ted Cruz, "Sen. Cruz, Rep. Roy Reintroduce RESULT Act to Increase Access to Life-Saving Medical Care," press release, February 26, 2025, <https://www.cruz.senate.gov/newsroom/press-releases/sen-cruz-rep-roy-reintroduce-result-act-to-increase-access-to-life-saving-medical-care>.

⁹⁸ US Congress. Senate. Reciprocity Ensures Streamlined Use of Lifesaving Treatments Act of 2025. S. 3081, 119th Cong., 1st Sess. (2025), <https://www.congress.gov/bill/119th-congress/senate-bill/3081>.

⁹⁹ International Council for Harmonisation, Electronic Common Technical Document (eCTD) v4.0 Implementation Guide (Geneva: International Council for Harmonisation of Technical Requirements for Pharmaceuticals for Human Use, 2021). Although ICH Modules 2 through 5 (Quality, Nonclinical, Clinical) are already internationally harmonized, Module 1 remains region-specific (e.g., FDA-specific forms vs. EU-specific administrative data). Module 1 requirements can be replaced with a fully standardized global administrative envelope under ICH eCTD v4.0 and ICH M11.

¹⁰⁰ US Government Accountability Office, Drug Safety: FDA Should Take Additional Steps to Improve Its Foreign Inspection Program, GAO-22-103611 (2022), <https://www.gao.gov/products/gao-22-103611>.

¹⁰¹ Covington & Burling LLP, "FDA and European Union Extend Mutual Recognition Agreement for Pharmaceutical Good Manufacturing Practice Inspections to Animal Drugs," News & Insights, June 2, 2023, <https://www.cov.com/en/news-and->

Manufacturing Practices (GMP) for postapproval inspections for animal and human drugs.¹⁰² This agreement could be expanded to include PAIs and vaccines, Advanced Therapy Medicinal Products (ATMPs), gene and cell therapies. The US could also expedite reviews by using assessment reports from the FDA’s European counterparts in marketing authorization decisions in return for reciprocal use of FDA reports by those agencies. This would mirror the Australian Therapeutic Goods Administration (TGA)’s comparable health authority pathway.¹⁰³

Another model for multilateral drug evaluations is the FDA’s Project Orbis, a collaborative framework for concurrent submission and near-simultaneous reviews of oncology products across international regulatory authorities.¹⁰⁴ The EMA’s inclusion and the expansion of Project Orbis to include all new medicines can be included as a mutually beneficial stipulation of a US–EU drug pricing agreement. The US can also offer to reciprocally expand existing waivers on chemical batch-testing requirements for EU drug imports,¹⁰⁵ for instance by formalizing standard multijurisdiction release protocols for biologics and instituting automatic (rather than case-by-case) waivers for ATMPs, vaccines, and cell and gene therapies.

Securing commitments from a critical mass of EU countries to raise the prices they pay for patented drugs would create substantial pressure on countries outside of these agreements to raise their own prices. This would occur through external political pressure, the threat of losing current priority in accessing innovative medicines, and through direct mechanisms such as where EU countries are included in IRP models of non-EU nations. By fostering US–EU supply chains and life sciences cooperation on both sides of the Atlantic, it could also form the basis for transatlantic coordination on similar agreements with non-EU countries.

V. Conclusion

The disproportionate reliance on American patients, health plans, and taxpayers to fund the high fixed costs of global pharmaceutical innovation is structurally inefficient and economically and politically unsustainable. However, importing or replicating foreign price controls, as envisaged by the Trump administration’s Executive Order 14297, or imposing domestic price constraints through measures such as the Biden administration’s IRA, threatens to stifle generic entry, undermine dynamic market incentives, and ultimately slow the global pipeline for life-saving cures. Rather than flattening global prices through a “race to the bottom,” true fairness and long-

insights/insights/2023/06/fda-and-european-union-extend-mutual-recognition-agreement-for-pharmaceutical-good-manufacturing-practice-inspections-to-animal-drugs.

¹⁰² US Food and Drug Administration, “FDA and European Union Announce Mutual Recognition Agreement for Pharmaceutical Good Manufacturing Practice Inspections of Animal Drugs,” CVM Updates, May 31, 2023, <https://www.fda.gov/animal-veterinary/cvm-updates/fda-and-european-union-announce-mutual-recognition-agreement-pharmaceutical-good-manufacturing>.

¹⁰³ See Alina Yoffe, Johnson Liu, Greg Smith, and Orin Chisholm, “Regulatory Reform Outcomes and Accelerated Regulatory Pathways for New Prescription Medicines in Australia,” *Therapeutic Innovation & Regulatory Science* 57, no. 2 (2023): 271–86.

¹⁰⁴ See US Food and Drug Administration, “Project Orbis,” 2026; Medicines and Healthcare products Regulatory Agency, “Guidance: Project Orbis,” GOV.UK, 2026, <https://www.gov.uk/guidance/project-orbis>.

¹⁰⁵ Reciprocal import batch testing waivers were established under the Pharmaceutical Sectoral Annex of the US–EU Mutual Recognition Agreement (MRA). See Council of the European Union, “Council Decision 1999/78/EC of June 22, 1998, on the Conclusion of an Agreement on Mutual Recognition Between the European Community and the United States of America,” Official Journal of the European Communities, L 31, February 4, 1999, 1–2. <https://eur-lex.europa.eu/legal-content/EN/TXT/?uri=CELEX:31999D0078>; Food and Drug Administration Safety and Innovation Act, Pub. L. No. 112-144, § 712, 126 Stat. 993, 1069–70 (2012) (codified as amended at 21 U.S.C. § 384e); Testing and Release for Distribution, 21 C.F.R. § 211.165 (2026).

term public health resilience can be achieved by elevating foreign contributions to competitive market levels while dismantling ACMDs and NTBs.

As demonstrated by the 2025 US–UK agreement on pharmaceutical pricing, foreign governments can be successfully incentivized to raise patented drug prices when agreements align with their domestic industrial policies and life sciences ambitions. By pairing commitments to higher drug reimbursement with strategic, cross-sector benefits—such as pharmaceutical tariff exemptions, targeted Jones Act waivers, and streamlined export licensing—the United States can negotiate bilateral and multilateral deals that deliver tangible economic growth to trading partners. This would offset domestic political resistance to higher healthcare expenditures while benefiting American consumers and businesses through lower prices and greater access to goods and production inputs, thereby easing cost-of-living concerns.

Central to the success of future agreements, particularly with major trading partners like the European Union, is transatlantic regulatory modernization. Integrating mutual recognition of pre-approval inspections, establishing unified electronic Common Technical Dossiers (CTDs), expanding import batch testing waivers, and scaling multilateral review models like Project Orbis, eliminate costly redundancies without compromising clinical standards. These regulatory efficiencies lower overheads for manufacturers, accelerate patient access to breakthrough treatments on both sides of the Atlantic, and create an enduring framework for cross-border cooperation. By replacing coercive price-fixing and regulatory friction with reciprocal trade and regulatory cooperation, the United States and its allies can foster a robust, equitable innovation ecosystem that sustainably finances the next generation of global medical cures.