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COMMENTS OF ITIF

to the

Office of the United States Trade Representative

Washington, D.C.

In the Matter of: Section 301 Investigation of Germany's Persistent Underpayment for Innovative Pharmaceutical Products	)	MB Docket No. USTR-2026-0463

August 10, 2026

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INTRODUCTION AND SUMMARY

The Information Technology and Innovation Foundation (ITIF)—an independent, nonprofit, nonpartisan research and educational institute focused on the intersection of technological innovation and public policy—appreciates the opportunity to provide information to the Office of the U.S. Trade Representative (USTR) regarding its Section 301 investigation of "Germany's Persistent Underpayment for Innovative Pharmaceutical Products."

Biopharmaceutical innovation constitutes a key pillar of economic growth and requires global investment to ensure that new products are brought to market, deliver meaningful patient benefits, and help address the shared global threat posed by disease. Countries that fail to recognize the value of innovative medications and implement price-control policies inhibit the pharmaceutical research and development (R&D) ecosystem and put an undue burden on other nations. Germany's pricing policies have perpetuated harm not only to its own biopharmaceutical innovation ecosystem and German patients, but also to those of the United States and the global community. Germany's drug price controls furthermore cause U.S. companies to experience reduced return on their investments to create novel medicines, which diminishes their capacity to engage in high-risk medical research, leading to slower progression in producing fewer scientific breakthroughs and addressing major global health challenges. The global biopharmaceutical innovation ecosystem is only effective if every country bears the costs of producing novel medicines, as reflected through paying prices for drugs that reflect what those innovative medications are worth. However, as this filing explains, there are steps the United States can take to prevail on allied nations to pay more of their fair share for innovative drugs.

PRICING POLICIES CAN HARM BIOPHARMACEUTICAL INNOVATION

Biopharmaceutical innovation is unusually dependent on expected future returns.[1] Developing a medicine commonly requires a decade or more of laboratory work, clinical testing, regulatory review, and manufacturing preparation before a product can be brought to market. On average, this requires approximately $2.7 billion to successfully bring one drug to the market.[2] Most compounds that enter human

[1] Daron Acemoglu and Joshua Linn, "Market Size in Innovation: Theory and Evidence from the Pharmaceutical Industry," *The Quarterly Journal of Economics* Vol. 119, No. 3 (August 2004): 1049–1090, https://doi.org/10.1162/0033553041502144.

[2] Sally Pipes, "Germany Wants Cheaper Drugs-And Americans To Pay The Difference," *Forbes*, May 7, 2026, https://www.forbes.com/sites/sallypipes/2026/05/07/germany-wants-cheaper-drugs-and-americans-to-pay-the-difference/.

testing never receive approval, while successful products must recoup not only their development costs but also the costs of failed programs.[3] In fact, fewer than 10 percent of compounds entering human testing ultimately receive regulatory approval.[4] Firms therefore must decide whether to begin, continue, expand, or terminate research programs by comparing risk-adjusted expected revenues with the capital and scientific resources required.[5]

Biopharmaceutical companies must be able to earn sufficient revenues so that they can reinvest in future generations of biomedical innovation and cover the cost of failed drug development efforts. Indeed, virtually all academic assessments find strong links between drug industry profits and R&D investments. For instance, the Organization for Economic Cooperation and Development (OECD) has found that "there exists a high degree of correlation between pharmaceutical sales revenues and R&D expenditures."[6] In fact, there exists an almost 1:1 correlation (0.97) between R&D expenditures and sales in the OECD study. Related academic research shows a statistically significant relationship between a biopharma enterprise's profits from the previous year and its R&D expenditures in the current year.[7] Likewise, Gambardella found that sales revenue from previous periods have a significant, positive impact on current-period biopharma R&D.[8] Lastly, research by Dubois et al. makes this dynamic crystal clear, finding that every $2.5 billion of additional biopharmaceutical revenue leads to one new drug approval.[9]

This explains why academic studies consistently reveal that a reduction in current drug revenues leads to a decrease in future research and the number of new drug discoveries.[10] For instance, one study found that a real 10 percent decrease in the growth of drug prices would be associated with an approximately 6 percent

[3] Eungdo Kim et al., "Factors Affecting Success of New Drug Clinical Trials," *Therapeutic Innovation & Regulatory Science* Vol. 57, No. 4 (July 2023): 737–750, https://doi.org/10.1007/s43441-023-00509-1.

[4] 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* Vol. 47 (2016): 20–33; Christopher P. Adams and Van V. Brantner, "Estimating the Cost of New Drug Development," *Health Economics* Vol 19, No. 2 (2010): 130–141; Christopher H. Wong, Kien Wei Siah, and Andrew W. Lo, "Estimation of Clinical Trial Success Rates and Related Parameters," *Biostatistics* Vol. *20*, No. 2 (2019): 273–286.

[5] DiMasi, Grabowski, and Hansen, "Innovation in the Pharmaceutical Industry: New Estimates of R&D Costs."

[6] Organization for Economic Cooperation and Development, *Pharmaceutical Pricing Policies in a Global Market* (OECD, September 2008), 190, http://www.oecd.org/els/pharmaceutical-pricing-policies-in-a-global-market.htm.

[7] Destrina Grace Simanjuntak and Raymond R. Tjandrawinata, "Impact of Profitability, R&D Intensity, and Cash Flow on R&D Expenditure in Pharmaceutical Companies" (Social Science Research Network, April 29, 2011), http://papers.ssrn.com/sol3/papers.cfm?abstract_id=1824267.

[8] Alfonso Gambardella, *Science and Innovation: The US Pharmaceutical Industry During the 1980s* (Cambridge University Press, 1995).

[9] Pierre Dubois, "Market size and pharmaceutical innovation," *The Rand Journal of Economics* Vol. 46, Issue 4 (October 2015): 844–871, https://onlinelibrary.wiley.com/doi/full/10.1111/1756-2171.12113.

[10] Joe Kennedy, "The Link Between Drug Prices and Research on the Next Generation of Cures" (ITIF, September 2019), https://itif.org/publications/2019/09/09/link-between-drug-prices-and-research-next-generation-cures.

decrease in pharmaceutical R&D spending as a share of net revenues.[11] Likewise, Golec and Vernon show that if the United States had used a European Union (EU)-like drug pricing system from 1986 to 2004, this would have resulted in a decline in firms' R&D expenditures of up to 33 percent and the development of 117 fewer new medicines.[12] More recently, 2021 research by Philipson and Durie at the University of Chicago estimate that a 1 percent reduction in pharmaceutical industry revenue leads on average to a 1.54 percent decrease in R&D investment.[13]

Conversely, research by Schwartz et al. found that if government price controls in non-U.S. OECD countries were lifted, the number of new treatments available would increase by 9 to12 percent by 2030, equivalent to 8 to 13 new drugs in that year. This could potentially increase the life expectancy of someone 15 years old today by 0.6 to 1.6 years on average.[14]

Recent work by Ho and Pakes further confirms that pharmaceutical innovation generates global benefits while being financed disproportionately by U.S. consumers. Modeling a counterfactual in which prices converge internationally, they find that U.S. prices could fall substantially only if pharmaceutical prices in other high-income countries increased markedly, with prices rising to approximately 148 percent of current levels in Germany, 197 percent in France, 263 percent in Italy, and 287 percent in Spain. Their analysis highlights the extent to which current global pharmaceutical innovation depends on cross-country differences in pricing and suggests that the U.S. pricing premium functions as an important source of financing for worldwide biopharmaceutical R&D.[15]

Indeed, the required incentive to develop new medications is the expected global revenue stream after discounts, rebates, taxes, launch delays, and the risk that one country's price will affect another's due to international reference pricing.[16] Reference pricing is the practice of collecting information about what other countries pay for drugs to inform domestic pricing decisions. Reference pricing is practiced by the majority of EU and OECD countries.[17] This lamentable practice, which the United States should not emulate, has the

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[11] Carmelo Giaccotto, Rexford E. Santerre, and John A. Vernon, "Drug Prices and Research and Development Investment Behavior in the Pharmaceutical Industry," *The Journal of Law & Economics* Vol. 48, Issue 1 April 2005, https://www.jstor.org/stable/10.1086/426882.

[12] Joseph Golec and John A. Vernon, "Financial Effects of Pharmaceutical Price Regulation on R&D Sending by EU Versus US Firms," *Pharmacoeconomics*, Vol. 28, Issue 8 (2010), 625, https://pubmed.ncbi.nlm.nih.gov/20617857/. All cost estimates were converted to 2019 dollars using the consumer price index.

[13] Tomas J. Philipson and Troy Durie, "Issue Brief: The Impact of HR 5376 on Biopharmaceutical Innovation and Patient Health" November 9, 2021, https://cpb-us-w2.wpmucdn.com/voices.uchicago.edu/dist/d/3128/files/2021/08/Issue-Brief-Drug-Pricing-in-HR-5376-11.30.pdf.

[14] Taylor T. Schwartz et al., "The Impact of Lifting Government Price Controls on Global Biopharmaceutical Innovation and Population Health" (Precision Health Economics, 2018), https://tools.ispor.org/research_pdfs/58/pdffiles/PHP216.pdf.

[15] Kate Ho and Ariel Pakes. "Policy options for the drug pricing conundrum," *Proceedings of the National Academy of Sciences*, Vol. 122, Issue 9 (February 25, 2025), https://www.pnas.org/doi/10.1073/pnas.2418540122.

[16] Dubois et al., "Market Size and Pharmaceutical Innovation."

[17] Christen Linke Young, Richard G. Frank, and Rachel Sachs, "International reference pricing for prescription drugs," (Brookings, July 9, 2025), https://www.brookings.edu/articles/international-reference-pricing-for-prescription-drugs/.

effect of cross-referencing the below market drug prices a basket of countries pay, creating a "lock-in" effect of underpaying for innovative drugs. **Instead of creating a global interlocking network of countries underpaying for innovative drugs, it's important that countries—particularly countries with the means—pay their fair share for efforts to develop innovative new drugs.**

Pricing policy also affects where and when medicines become available. International reference pricing and parallel trade link to international markets, so if a firm accepts a low price in one jurisdiction, this can lower allowable prices elsewhere or create arbitrage risk.[18] Manufacturers consequently may sequence launches, delay entry, or decline to market a product where the expected price would impair returns in larger markets.[19]

GERMANY UNDERPAYS FOR INNOVATIVE MEDICINES

In a 2023 report (using 2018 data), ITIF found that, of the 32 OECD countries with available data, all had lower prescription drug prices than the United States (and that even after adjusting for gross domestic product (GDP) per capita, 30 countries still had lower prescription drug prices than the United States).[20] Overall, the average price of brand-name originator drugs for these 32 countries was 177.9 percent lower than in the United States.[21] Germany paid an average price 187.3 percent less than the United States for these brand-name originator drugs.[22] ITIF's report finds that if just five wealthy nations—Japan, Germany, France, Italy, and the United Kingdom—paid their fair share, the world would benefit from 12 new drugs every year, with Germany's drug price controls costing humanity 3.4 new drugs each year.[23]

Moreover, other nations' extensive drug price controls are a significant contributing factor explaining why other countries tend to have access to the most-innovative drugs long after in America. Indeed, for the United States, which has historically relied more heavily on market-based pharmaceutical pricing than most OECD countries, innovative medicines have generally become available earlier than in countries with more extensive price regulation. Among 290 new medicines introduced between 2011 and 2018, 89 percent were available in the United States, compared with 62 percent in Germany, 57 percent in Denmark, 56 percent in the Netherlands, 50 percent in Japan, and 48 percent in France and Switzerland. Comparable differences are also observed for oncology therapies: of 82 new cancer medicines introduced during the same period, 96 percent

[18] Margaret K. Kyle, "Pharmaceutical Price Controls and Entry Strategies," *The Review of Economics and Statistics* Vol. 89, No. 1 (February 2007): 88–99, https://doi.org/10.1162/rest.89.1.88.

[19] Patricia M. Danzon, Y. Richard Wang, and Liang Wang, "The Impact of Price Regulation on the Launch Delay of New Drugs—Evidence from Twenty-Five Major Markets in the 1990s," *Health Economics* Vol. 14, No. 3 (March 2005): 269–292, https://doi.org/10.1002/hec.931.

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

[21] Ibid.; US Health and Human Services, International Prescription Drug Price Comparisons (Appendix C: Table C.1. Calculated US Versus Other-Country Price Indices, 2018; The World Bank, GDP per capita, PPP.

[22] Long and Ezell, "The Hidden Toll of Drug Price Controls: Fewer New Treatments and Higher Medical Costs for the World."

[23] Ibid.

were available in the United States, compared with just 73 percent in Germany; 66 percent in Denmark, France, and the Netherlands; 62 percent in Switzerland; and 54 percent in Japan.[24]

GERMANY'S PHARMACEUTICAL PRICE CONTROLS

The Goldwater Institute, an Arizona-based think tank, characterizes Germany's pharmaceutical pricing approach as that of a "freeloader," concluding that "American patients and taxpayers finance a disproportionate share of the research that produces new medicines, while German price controls allow Berlin to demand the benefits of innovation without bearing its share of the cost."[25] Indeed, Germany's system relies on centralized benefit assessments, reimbursement negotiations, and reference pricing to regulate pharmaceutical prices.[26] As noted, the negative impacts of these approaches have already been felt, as fewer new medications launched globally are reaching the German market.[27] The following lists several policies and regulations that have acted to reduce the prices Germany pays for drugs.

Germany's Health Reform Act of 1989 introduced a national reference-pricing system for reimbursable medicines. The reform grouped medicines into three classes and established reimbursement ceilings for each class. Under this system, a medicine reference price was calculated using the prices of that medicine and therapeutically similar products.[28] Germany also implemented across-the-board price reductions for medicines outside the reference-pricing system and reduced prices for nonprescription medicines.[29] A U.S. Government Accountability Office (GAO) report found that, in 1993, Germany implemented across-the-board price cuts on drugs not covered by the reference price system, as well as a reduction in nonprescription drug prices.[30] A study that examined the average prices per Defined Daily Dose (DDD)—the average daily dose for a drug—across eight therapeutic classes found that, as expected, each therapeutic class's average price per DDD decreased immediately after the introduction of reference prices.[31]

Subsequently, Germany's "Act on the Reform of the Market for Medicinal Products" (Arzneimittelmarktneuordnungsgesetz, or AMNOG) took effect on January 1, 2011.[32] It replaced unrestricted long-term launch pricing for new active ingredients with an early benefit assessment followed by

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[24] Doug Badger, "Examination of International Drug Pricing Policies in Selected Countries Shows Prevalent Government Control over Pricing and Restrictions on Access," (Galen Institute, March 2019), https://galen.org/assets/Badger-Report-March-2019.pdf.

[25] Victor Riches, "Germany's Freeloader Drug Policy," Goldwater Institute, June 3, 2026, https://www.goldwaterinstitute.org/germanys-freeloader-drug-policy/.

[26] Ibid.

[27] Ibid.

[28] Giovanni Giuliani, Gisbert Selke, and Livio Garattini, "The German Experience in Reference Pricing," *Health Policy* Vol. 44, No. 1 (April 1998): 73–85, https://doi.org/10.1016/S0168-8510(98)00012-8.

[29] U.S. General Accounting Office (GAO), "Prescription Drugs: Spending Controls in Four European Countries" (GAO, May 1994), 56, https://www.gao.gov/assets/hehs-94-30.pdf.

[30] Ibid.

[31] Giuliani, Selke, and Garattini, "The German experience in reference pricing."

[32] Federal Joint Committee (G-BA), "The Benefit Assessment of Medicinal Products in Accordance With the German Social Code, Book Five (SGB V), Section 35a," https://www.g-ba.de/english/benefitassessment.

a national reimbursement negotiation. AMNOG requires medicines with new active ingredients to undergo an assessment of their added clinical benefit. Manufacturers may set the launch price for six months, after which the Federal Joint Committee's assessment informs a nationwide reimbursement negotiation between the manufacturer and the statutory health insurance system.[33] When a manufacturer cannot demonstrate added benefit relative to the government-selected comparator, reimbursement is generally capped at—or set below—the comparator's treatment cost. Although AMNOG can better align prices with demonstrated clinical value, its comparator rules, evidence requirements, and statutory pricing constraints can undervalue incremental advances, rare-disease treatments, and transformative therapies supported by nontraditional evidence.[34]

Mandatory manufacturer discounts are another significant feature of the German system. Manufacturers of covered medicines must provide a mandatory discount in addition to the AMNOG negotiation. The baseline discount for covered patent-protected products is 7 percent of the manufacturer's ex-factory price before value-added tax.[35] Pharmacies provide the discount to health insurance funds and are subsequently reimbursed by the manufacturer. The discount applies even after the reimbursement amount has been negotiated based on the medicine's assessed benefit. After AMNOG's implementation, 29 medications were removed from the German market, harming pharmaceutical companies and patients between 2011 and 2018.[36]

Germany also has a time-limited mechanism that allows a manufacturer to keep the reimbursement amount from standard public disclosure. To qualify, the manufacturer must document that it maintains a pharmaceutical research department in Germany and conducts relevant company projects and collaborations with German public institutions in preclinical or clinical research. Even when these localization conditions are satisfied, the confidential reimbursement amount is automatically reduced by an additional 9 percent until data exclusivity expires.[37]

In practice, **a manufacturer must therefore accept a 9 percent discount and maintain specified research operations in Germany to obtain confidentiality**. Confidentiality has significant economic value because it can reduce spillovers through international reference pricing. The first condition effectively converts

[33] Federal Joint Committee (G-BA), "AMNOG – Nutzenbewertung von Arzneimitteln gemäß § 35a SGB V," https://www.g-ba.de/themen/arzneimittel/arzneimittel-richtlinie-anlagen/nutzenbewertung-35a/.

[34] Andrea Lebioda et al., "Relevance of Indirect Comparisons in the German Early Benefit Assessment and in Comparison to HTA Processes in England, France and Scotland," *Health Economics Review* Vol. 4 (2014): 31, https://doi.org/10.1186/s13561-014-0031-5; Jörg Tomeczkowski et al., "Challenges and Criteria for Single-Arm Trials Leading to an Added Benefit in German Health Technology Assessments," *PharmacoEconomics* Vol. 43, No. 10 (October 2025): 1223–1233, https://doi.org/10.1007/s40273-025-01524-w.

[35] Sozialgesetzbuch (SGB) Fünftes Buch (V)—Gesetzliche Krankenversicherung, § 130a(1), https://www.gesetze-im-internet.de/sgb_5/__130a.html.

[36] Riches, "Germany's Freeloader Drug Policy."

[37] Sozialgesetzbuch (SGB) Fünftes Buch (V)—Gesetzliche Krankenversicherung, § 130b(1c), https://www.gesetze-im-internet.de/sgb_5/__130b.html.

confidentiality into a statutory price concession, while the second ties reimbursement treatment to the geographic location of research rather than the medicine's clinical value.

Germany's most recent health reform, "GKV-Beitragssatzstabilisierungsgesetz" (GKV-BStabG), entered into force on July 30, 2026, with the aim of addressing rising costs across the German healthcare system.[38] Section 130a of GKV-BStabG requires an additional manufacturer markdown of 8.5 percent of a company's sale price on top of the current 7 percent amounting to a total 15.5 percent compulsory manufacturer markdown for patent protected medicines, meaning that pharmaceutical companies are required to pay 15.5 percent of their sale prices to payer health insurances.[39] There are some exceptions to the additional markdown, such as dosage forms and formulations needed to treat children or certain reserve antibiotics.[40] The GKV-BStabG also requires an additional 9 percent markdown, starting on January 1, 2027, for patent-protected or regulatory data-exclusive vaccines.[41] In addition to these markdown requirements, GKV-BStabG extends the reimbursements price freeze until the end of 2030, limiting manufacturer's ability to adjust prices for inflation and cost changes impacting production.[42] Through December 31, 2030, health insurance funds may also conclude tender-style rebate contracts for patented medications.[43] This recent change is not fully aligned with AMNOG and shifts prescribing decisions toward cost considerations rather than clinical value. Medications that are therapeutically comparable are not always medically interchangeable, and GKV-BStabG builds on policies that already harm biopharmaceutical development. Despite these changes, the German Parliament has adopted a resolution, Entschließungsantrag, which asks the German government to expand Pharma and MedTech dialogue with the goal of enhancing pharmaceutical production, investment, and value creation in Germany allowing for the government to address cost containment policy challenges.[44]

While GKV-BStabG was being finalized, Eli Lilly and Boehringer Ingelheim reduced their planned investments in Germany's pharmaceutical industry by at least $1 billion.[45] Following reduced investment, pharmaceutical makers Eli Lilly, AstraZeneca, Pfizer, and Merck have argued that the GKV-BStabG reform sends the wrong message for Europe's ability to compete with the United States and China in the life sciences, arguing that Germany's pharmaceutical environment undervalues innovation and threatens the country's

[38] Dr. Adem Koyuncu and Maximilian Aretz, "Reimbursement in Germany? And the Reforms are Not Over: What to Expect From the New German Minister of Health and the Pharma Dialogue?" *Global Policy Watch*, August 3, 2026, https://www.globalpolicywatch.com/2026/08/what-does-the-gkv-bstabg-reform-change-for-pharma-pricing-reimbursement-in-germany-and-the-reforms-are-not-over-what-to-expect-from-the-new-german-minister-of-health-and-the-pharma-dialogue/.

[39] Ibid.

[40] Ibid.

[41] Ibid.

[42] Ibid.

[43] Ibid.

[44] Ibid.

[45] Kevin Dunleavy, "Lilly, Boehringer to slash at least $1B each from planned investments in Germany," *Fierce Pharma*, June 3, 2026, https://www.fiercepharma.com/pharma/lilly-boehringer-plan-slash-investment-germany-report.

competitiveness.[46] Germany's long-standing policies and recent policy changes place a continued and unstable burden on biopharmaceutical innovation. USTR therefore appropriately identified the risk of persistent underpayment for biopharmaceutical innovation when pursuing its Section 301 investigation.

THE U.S.–UK PHARMACEUTICAL PRICING ARRANGEMENT PROVIDES A WORKABLE PRECEDENT

The April 2026 U.S.–UK pharmaceutical pricing arrangement demonstrates that it is mutually desirable and feasible for countries to address pharmaceutical burden sharing through negotiated, measurable commitments without undermining national health systems.[47] The arrangement recognizes that countries should contribute a fair share toward the cost of pharmaceutical innovation and links improved reimbursement to patient access, R&D, investment, supply-chain resilience, and mutually beneficial trade.

The arrangement establishes concrete commitments. The United Kingdom agreed to double spending on new medicines as a share of GDP from 0.3 percent in 2026 to 0.6 percent by 2036, with interim targets of 0.35 percent by 2028 and 0.40 percent by 2030.[48] It also agreed to increase UK National Health Service (NHS) net prices for prospective new medicines by 25 percent beginning in April 2026, raise UK National Institute for Health and Care Excellence's (NICE) standard cost-effectiveness range from £20,000–£30,000 per quality-adjusted life year to £25,000–£35,000, which analysts estimate will allow the United Kingdom to approve an additional three to five new medicines or indications annually.[49] The agreement will also increase medicines' share of the NHS budget from 10 percent to 12 percent by 2036.[50]

The arrangement also includes robust safeguards against circumvention. The United Kingdom committed not to offset the net-price increase through stricter access restrictions, higher discounts, retrospective payment demands, or other concessions. It capped the Voluntary Scheme for Branded Medicines Pricing, Access, and Growth (VPAG) repayment rate at 15 percent for the duration of the scheme and established a work program for a successor framework that could include outcomes-based payments and differentiated thresholds.[51] These

[46] Andreas Rinke, Maria Martinez, and Maggie Fick, "German lawmakers approve healthcare shake-up aimed at taming costs," *Reuters*, July 10, 2026, https://www.reuters.com/business/healthcare-pharmaceuticals/germanys-lower-house-parliament-passes-healthcare-reform-2026-07-10/.

[47] UK Department for Science, Innovation and Technology, "Arrangement Between the Government of the United States of America and the Government of the United Kingdom of Great Britain and Northern Ireland on Pharmaceutical Pricing," April 2, 2026, sections I–II, https://www.gov.uk/government/publications/uk-us-arrangement-on-pharmaceutical-trade-and-pricing/arrangement-between-the-united-states-of-america-and-the-united-kingdom-on-pharmaceutical-pricing-html; Office of the U.S. Trade Representative, "Successful Conclusion of the United States–United Kingdom Arrangement on Pharmaceutical Pricing," news release, April 2, 2026, https://ustr.gov/about/policy-offices/press-office/press-releases/2026/april/successful-conclusion-united-states-united-kingdom-arrangement-pharmaceutical-pricing.

[48] Ibid.

[49] National Institute for Health and Care Excellence, "Changes to NICE's cost-effectiveness thresholds confirmed," News, December 1, 2025, https://www.nice.org.uk/news/articles/changes-to-nice-s-cost-effectiveness-thresholds-confirmed.

[50] UK Department for Science, Innovation and Technology, "Arrangement Between the Government of the United States of America": Office of the U.S. Trade Representative, "Successful Conclusion of the United States–United Kingdom Arrangement."

[51] Ibid.

safeguards are essential because a nominal price increase provides little economic value if another part of the reimbursement system immediately recaptures it and prevents real benefits from being realized.[52]

Considering Germany's institutions differ from those of the United Kingdom, a U.S.–Germany arrangement would not mechanically replicate every provision, of course. For instance, AMNOG assesses comparative added benefits rather than applying an explicit NICE-style cost-per-Quality-Adjusted Life Years (QALY) threshold. In addition, German statutory health insurance funds operate through a system of statutory self-government rather than a single NHS budget. Nevertheless, the critical components of the precedent established by the U.S.-UK agreement are its overall negotiating architecture, including quantified commitments, measurement of net rather than list prices, anti-circumvention provisions, protection of patient access, staged implementation, and continued bilateral oversight.

CONCLUSION

Instead of copying other OECD countries in a "reference-price-race-to-the-bottom," U.S. policy should instead encourage peer countries to appropriately value innovative medicines. The USTR Section 301 Investigation exploring "Germany's Persistent Underpayment for Innovative Pharmaceutical Products" is crucial for America's biopharmaceutical innovation ecosystem. Every country has unique medical, regulatory, and pricing institutions that require a tailored approach to maximally benefit innovation and the development of new pharmaceuticals. Differences in institutions that impact health policy create difficulties in determining fair payment and adequate R&D investment. Affordability also remains at the heart of pharmaceutical policy discussions, and a priority of nations globally. However, affordability must be balanced with high-value new pharmaceuticals that can improve the lives of patients and help address the global burden of disease. The U.S.-UK pharmaceutical pricing agreement serves as a strong example of what a balance between economic investment and pharmaceutical development can look like in practice. This agreement has also revealed the necessary tools and provisions that must be utilized to ensure wealthy nations adequately contribute to the sustained development of new medications. Without additional intervention, Germany's drug-pricing changes, including those newly implemented under GKV-BStabG, could further harm both the German and U.S. biopharmaceutical ecosystems, and interests of patients on both sides of the Atlantic.

Thank you for your consideration.

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[52] Ibid.