Comments on the Section 301 Investigation Regarding Germany's Persistent Underpayment for Innovative Pharmaceutical Products

Submission to the United States Trade Representative (USTR)

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INTRODUCTION

We welcome the opportunity to provide comments and analysis to the USTR inter-agency Section 301 committee on its investigation pursuant to the Trade Act of 1974, as amended (Trade Act), with respect to Germany's persistent underpayment for innovative pharmaceutical products.

Founded in 1980, the Mercatus Center at George Mason University is the world's premier university-based source for market-oriented ideas—bridging the gap between academic ideas and real-world problems. The Mercatus Center advances knowledge about how markets work by training graduate students, conducting research, and applying economics to offer solutions to society's most pressing problems. Our mission is to generate knowledge and understanding of the institutions that affect the freedom to prosper and to find sustainable solutions to overcome the barriers that prevent individuals from living free, prosperous, and peaceful lives. This comment, therefore, does not represent the views of any particular affected party or special interest group; it is intended to assist the USTR in its decision-making.

We wish to address the following: Acts, policies and practices of the German government related to persistent underpayment for innovative pharmaceutical products; why these practices are unreasonable, how these practices burden U.S. commerce and the nature and level of that burden; why these practices are actionable under Section 301(b) of the Trade Act; what actions the USTR should take in response; and the extent to which the policies, practices and acts result in the United States paying a disproportionate share of global R&D costs for innovative pharmaceuticals.

GERMANY'S PRICE SUPPRESSION POLICIES RESULT IN THE UNITED STATES PAYING DISPORPORTIONATELY MORE FOR GLOBAL R&D COSTS FOR INNOVATIVE PHARMACEUTICALS

Americans pay two to three times the average price that other developed countries' nationals pay for the same patented drugs, including US drugs,[1] with branded US drugs costing little under double what they cost on average in Germany.[2] The US market produces roughly 75% of profits from pharmaceutical sales globally even though the US produces just 25.82% of global Gross Domestic Product (GDP)[3] and

[1] Keyhani, Salomeh, Steven Wang, Paul Hebert, et al., 2010, "US Pharmaceutical Innovation in an International Context," *American Journal of Public Health* 2010(6): 1075–1080.
[2] See Frech, H.E. III, Mark Pauly, and William S. Comanor, 2024, "Are Drug Prices Abroad Too Low?" *Regulation* 47(3).
[3] "Percent of world GDP - Country rankings," TheGlobalEconomy.com (Accessed: 15 June 2026)

covers 5% of the world's population.[4] Although Germany is the second largest market for global pharmaceutical sales behind the US, it currently only yields 5% of global pharmaceutical profits,[5] a fifteenth of what the US market yields, even though its GDP and population are roughly a fifth of the US population[6] and GDP.[7]

Innovative medicines cost billions of dollars to research, develop and bring to market, and pharmaceutical companies typically rely upon expectations about the global revenue they will raise from sales of the drug during the patent exclusivity period when deciding how much to invest in R&D. Pharmaceutical innovation is thus a global public good and the price suppression policies of non-U.S. nations creates a classic 'free rider' problem as American taxpayers who fund the Centers for Medicare and Medicaid Services (CMMS) and private payors subsidize these nations' access to new cures that benefit their citizens and public health.

GERMANY'S PRICE SUPPRESSION POLICIES ARE UNREASONABLE, BURDENSOME FOR U.S. COMMERCE AND ACTIONABLE UNDER SECTION 301(b) OF THE TRADE ACT

Germany engages in various state policies that suppress pharmaceutical innovation below market value through direct price controls and through leveraging their government's buyer monopsony power. U.S. antitrust law considers "monopsony" to be the "mirror image" of monopoly.[8] Monopoly power refers to the ability that a powerful seller has to harm competition and consumers by maintaining the ability to raise prices and restrict output compared to an efficient competitive market. Similarly, monopsony power is the ability of a powerful buyer in a market to suppress output by underbidding their suppliers' prices to lower levels than those that would exist under competitive market conditions. Even if a monopsonist buyer passes on its cost savings to consumers in a secondary market through lower prices, those consumers may still be worse off than they would be in a competitive market as they may face reduced supply, fewer choices, and fewer innovative or new products than they would in a competitive market.

Under the status quo, countries that suppress drug prices through monopsony buying are partially able to insulate their citizens from monospony's negative, anti-competitive effects. This comes at the cost of U.S. companies having to accept disproportionately lower revenues overseas to fund innovations for the same drugs that are supplied in the U.S. market. As these policies serve to lower expected and actual overseas royalties on U.S. pharmaceutical patents, they also serve to compromise the IP rights of American citizens and companies.

The 2011 German Pharmaceutical Market Restructuring Act (Arzneimittelmarktneuordnungsgesetz, or AMNOG), allows drug manufacturers to freely set the prices of newly authorized drugs during their first year on the German market. During this time, Germany's Institute for Quality and Efficiency in Health

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https://www.theglobaleconomy.com/rankings/gdp_share/

[4] Robinson, James C. "'Most Favored Nation' Drug Pricing Is An Idea Whose Time Has Come" *Health Affairs* 45, no. 4 (2026): 350-355.

[5] See Frech, H.E. III, Mark Pauly, and William S. Comanor, 2024, "Are Drug Prices Abroad Too Low?" *Regulation* 47(3).

[6] https://worldpopulationreview.com/countries/germany.

[7] Farrag, Omar, and Patrice Robitaille. "India and the Global Economy." U.S. Federal Reserve (2026) https://www.federalreserve.gov/econres/notes/feds-notes/india-and-the-global-economy-20260408.html.

[8] See Roger Noll, "Buyer Power" and Economic Policy, 72 ANTITRUST L.J. 2 (2005), 589; *Weyerhaeuser Co. v. Ross-Simmons Hardwood Lumber Co.*, 549 U.S. 312 (2007).

Care (IQWiG) estimates the therapeutic benefit that the medicine provides above and beyond existing therapies and this assessment is used in price negotiations between manufacturers and Germany's statutory health insurance (GKV). This process results in negotiated prices for GKV that are typically 24.5% lower than the market price at the drug's launch.[9] However, as the request for comments from USTR notes, "Germany conditions the confidentiality of manufacturers' pharmaceutical pricing on certain criteria, including acceptance of a 9 percent price discount and payment of additional administrative costs." Furthermore, "In 2026, Germany's Ministry of Health introduced draft legislation designed to reduce pharmaceutical spending. This legislation would impose an additional mandatory rebate for patented medicines starting in 2027. The current proposal envisions a fixed rate at 3.5 percent for the first half of 2027 and would thereafter change into a variable rate based on the difference between actual and target expenditures of the health insurance funds for all medicines, divided by sales of innovative medicines. According to one estimate, this dynamic rebate will reach 20 percent by 2030."

The threat of publicly disclosing the prices negotiated between the Germany government and pharmaceutical companies effectively forces companies to lower their prices and accept the 9% discount, as several nations use international reference pricing models that would lower the prices they pay for the same patented medicines if a lower price in Germany was publicly disclosed.[10] Of the 19 Organisation for Economic Cooperation and Development (OECD) member countries with a GDP per-capita that is at least 60% of the United States (Austria, Belgium, Denmark, Finland, Iceland, Ireland, Israel, Germany, Luxembourg, the Netherlands, New Zealand, Norway, Sweden, Australia, Canada, France, Japan, the United Kingdom and Switzerland), 12 apply an international reference pricing model for pharmaceuticals that includes Germany. Drugmakers are thus compelled to accept this discount below negotiated prices purely because it would mean less loss of expected global revenue than the alternative. Compelled rebates for German public health insurance similarly leverage the German government's buyer monopsony power, as 90% of the German population is covered by the GKV and refusal to pay the rebate would lead to a significant loss of market access. Additionally, once a market price is set during the first year of the newly approved drug's German launch, and once a negotiated price is reached between SKV and the drug manufacturer, German law applies price freezes that prevent manufacturers from raising this price to account for inflation without incurring financial penalties.[11] Such threats of penalties and compelled rebates and discounts undermine the claim that the prices that Germany pays for U.S. patented medicines are based on objective assessments of the medicine's therapeutic benefit above existing therapies, as these assessments are made by IQWiG prior to the application of mandatory discounts and rebates.

Section 301(b) of the U.S. Trade Act stipulates that unreasonable (i.e., unfair or inequitable) or discriminatory practices by U.S. trading partners that burden or restrict U.S. commerce are actionable. Germany's price suppression policies outlined above are unreasonable as they result in prices that are

[9] See Lauenroth, Victoria D., Aaron S. Kesselheim, Ameet Sarpatwari, and Ariel D. Stern. "Lessons from the impact of price regulation on the pricing of anticancer drugs in Germany" *Health Affairs* 39, no. 7 (2020): 1185-1193 https://pubmed.ncbi.nlm.nih.gov/32634355/.

[10] See Rand, Leah Z., and Aaron S. Kesselheim. "International reference pricing for prescription drugs: a landscape analysis." *Journal of Managed Care & Specialty Pharmacy* 27, no. 9 (2021): 1309-1313 https://pmc.ncbi.nlm.nih.gov/articles/PMC10391192.

[11] Section 130a Abs. 3a of the German Social Code, SGB V. See https://go.pharmazie.com/blog/german-pharma-pricing-reform-2026.

divorced from both competitive market rates as well as objective benefit assessments, and because they result in prices that are approximately half of what Americans pay for the same branded drugs,[12] even though Germany's purchasing power parity (PPP)-adjusted GDP per-capita is only 16.24% lower than that of the United States.[13] They thus result in Americans paying disproportionately more to fund the global public good of pharmaceutical innovation and are thus inequitable and unfair towards American taxpayers, health plan customers and private patients. They are also unfair and inequitable towards U.S. pharmaceutical companies, as they burden U.S. commerce by devaluing returns on U.S. IP (and thus devaluing the IP itself) and by inhibiting the operation of competitive markets for U.S. medicines.

ABOLISHING PHARMACEUTICAL PRICE SUPPRESSION POLICIES WOULD BENEFIT GERMANY'S ECONOMY AND PATIENTS

Anti-Competitive Market Distortions (ACMDs) are government-backed regulations or practices that distort prices, weaken market competition and reduce economic efficiency compared to a competitive market.[14] These can include anti-competitive regulations, regulations that arbitrarily discriminate between market competitors and practices and regulations that devalue or fail to safeguard property rights, including IP.[15] Since ACMDs are backed by state power, they cannot be remedied through market processes and often deter market actors from addressing market demand. As Germany's rebate/discount mandates, price freezes and monopsony buying for pharmaceuticals deflate patented drug prices below what would exist in a competitive market and thereby suppress pharmaceutical innovation to sub-competitive levels, they are ACMDs. And since these policies restrict, distort and create costs for international trade by suppressing prices on U.S. drugs and returns on U.S. IP to sub-competitive levels, they are also Non-Tariff Barriers (NTBs) to trade.

Abolishing ACMDs unlocks latent economic energy while mitigating political risks linked to stagnation and misallocation of capital.[16] 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 German market upon patent expiration. This would allow for similar benefits to foreign governments and patients as those reaped by the U.S. public sector. Recent research finds that the US Medicare and Medicaid programs pay 18% less for prescription drugs on average compared to what the UK, Japan, Germany, France and Canada pay when both branded drugs and generics are considered.[17] Over 90% of US drug prescriptions by volume are for generics, a significantly higher figure than in comparable developed economies,[18] and unbranded generics in the U.S. are priced

[12] Frech, H.E. III, Mark Pauly, and William S. Comanor, 2024, "Are Drug Prices Abroad Too Low?"
[13] Based on 2025 World Bank International Comparison Program (ICP) GDP per capita, PPP (current international $) figures for the United States ($90,026.50) and Germany ($75,406.70). See https://data.worldbank.org/indicator/NY.GDP.PCAP.PP.CD?locations=DE
[14] Singham, Shanker A., and U. Srinivasa Rangan. "Anti-competitive market distortions: a typology." *Economic Affairs* 38, no. 3 (2018): 339.
[15] Singham, Shanker. *Trade Policy in the Trump Administration: Advancing Reduction of Anti-Competitive Market Distortions*. White Paper. London: Competere and The Growth Commission, August 2025, 6.
[16] Singham, Shanker. *Trade Policy in the Trump Administration: Advancing Reduction of Anti-Competitive Market Distortions*. White Paper. London: Competere and The Growth Commission, August 2025, 6.
[17] Philipson, Tomas J., Deyu Zhang, and Qi Zhao, 2025, "International Comparison of Prices for Drug Prescriptions," University of Chicago, June 7.
[18] "Unbranded generics made up 90 percent of U.S. prescription volume, compared with 41 percent of volume [on average] in the other [Organisation for Economic Cooperation and Development (OECD) member countries]." See Comparing Prescription Drugs in the U.S. and Other Countries: Prices and Availability: Contractor Project Report.

43% lower on average in the U.S. relative to their average price in those economies.[19]

In 2004, the U.S. Departments of Commerce and Health and Human Services found that that if prices of patented drugs rose to competitive market levels in non-U.S. OECD countries, then more competitive generic markets could significantly, or even completely, offset any extra costs.[20] 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 Germany by supporting its domestic generic and non-generic pharmaceutical industry, including 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, correlate with successful innovation economies.[21]

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.[22] At the start of the 1990s, pharmaceutical industry investment in Europe was approximately 50 percent greater than in the United States.[23] However, by 2004, Europe's share of global pharmaceutical innovation had fallen to 18% while the U.S. share rose to 62%.[24] During the 1990-2017 period, pharmaceutical research and development investment in the United States grew by twice the European rate.[25] Half of all new therapies introduced between 2014 and 2018 originated in the United States, while only about 25% originated in Europe.[26] Reversing or scaling back these ACMDs would thus help drive significant economic and public health gains for Germany and other 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.

2024 Feb. https://www.ncbi.nlm.nih.gov/books/NBK611301/.

[19] Ibid.

[20] Hassett, Kevin A. "Pharmaceutical Price Controls in OECD Countries." *Testimony before the Department of Commerce, International Trade Administration* 2 (2004).

[21] See, e.g., Jonathan M. Barnett, Patent Tigers: The New Geography of Global Innovation, 2 CRITERION J. INNOVATION 429 (2017); Stephen Haber, Patents and the Wealth of Nations, 23 GEO. MASON L. REV. 811 (2016).

[22] Specifically, "[b]eginning in the 1980s, many European nations implemented a broad array of pharmaceutical price control tools, including international (and regional) reference pricing systems, cost-focused health technology assessments, global prescribing budgets that held provider organizations accountable for exceeding spending budgets, profit controls that capped what insurers could pay for groups of similar drugs, and rules limiting the use of higher-priced medicines to hospitals." See Barbosu, Sandra, Stephen Ezell, and Esther Serger. *Lessons From Europe's Loss of Biopharma Leadership, and Its Attempts to Recover*. Washington, DC: Center for Life Sciences Innovation, Information Technology and Innovation Foundation, March 2026.

[23] See European Federation of Pharmaceutical Industries and Associations (EFPIA), "The Research Based Pharmaceutical Industry: A Key Actor for a Healthy Europe," (EFPIA, 2006) cited in Barbosu, Ezell, and Serger, *Lessons From Europe's Loss of Biopharma Leadership*, 3-5.

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

[25] Nathalie Moll, "Would the last pharmaceutical investor in Europe please turn the lights out," *European Federation of Pharmaceutical Industries and Associations*, January 3, 2020, https://www.efpia.eu/news-events/the-efpia-view/blog-articles/would-the-last-pharmaceutical-investor-in-europe-please-turn-the-lights-out/ cited in Barbosu, Ezell, and Serger, *Lessons From Europe's Loss of Biopharma Leadership*, 3-5.

[26] Ibid.

Researchers from the University of Southern California Leonard D. Schaeffer Center for Health Policy & Economics find that if European drug prices rose by 20 percent, then this would lead to substantially more discovery of drugs that lengthen lives and increase quality of life worldwide.[27] The resulting increased innovation would produce an estimated $10 trillion in welfare gains for Americans, and $7.5 trillion for Europeans over the next five decades.[28]

RECOMMENDED USTR RESPONSE

Under Section 301 of the Trade Act of 1974,[29] if the United States Trade Representative (USTR) determines that a foreign country's act, policy, or practice violates a trade agreement or is "unjustifiable, unreasonable, or discriminatory" and burdens U.S. commerce, then the USTR has statutory authority to impose retaliatory or remedial actions subject to direction from the President. These may include the suspension, modification or withdrawal of existing trade concessions, imposition of tariffs or import quotas on the foreign nation's products, or restrictions or withdrawal of market access for foreign goods and services exporters. Notably, however, such penalties would cause economic harm to U.S. consumers and the U.S. economy by increasing the prices of and/or reducing access to imports. American businesses that rely upon imported product inputs would suffer as well and would become less competitive relative to their foreign peers at a time when the cost of living ranks high among the American public's most significant concerns.

For these reasons, we would recommend that the USTR negotiate with Germany for that country to pay more for U.S. drugs and for the rollback of the ACMD policies that it applies to pharmaceuticals through targeted "carrots". This can include greater access to the U.S. market for German exporters in both pharmaceutical and non-pharmaceutical sectors through the rollback of tariffs and NTBs that currently affect them. This would also help increase competition in U.S. markets while benefiting Americans through lower prices. The U.S. government might also consider regulatory and deregulatory measures that would help achieve this result, such as expedited approval pathways through the FDA for pharmaceuticals that are approved in Germany or originate from German manufacturers. Deregulatory measures can also help combat domestic ACMDs in the United States and would be consistent with President Trump's executive order on "Unleashing Prosperity through Deregulation."[30] They would also be 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 U.S. ACMDs to boost economic growth.[31]

Importantly, the use of "carrots" rather than "sticks" in negotiating higher contributions to U.S. and global pharmaceutical innovation from Germany would also be more likely to achieve favorable outcomes for the United States. It would allow the German government and its political leadership to more easily present any diplomatic/trade agreements with the United States that result as a win and benefit to the German voting public. Although the benefits to Germans of contributing more for global

[27] Goldman, Dana, and Darius Lakdawalla, "The Global Burden of Medical Innovation," USC Schaeffer Center for Health Policy & Economics Working Paper, 2018 https://schaeffer.usc.edu/wp-content/uploads/2024/10/01.2018_Global20Burden20of20Medical20Innovation.pdf.
[28] Ibid.
[29] 19 U.S.C. § 2411.
[30] Trump, D. "Executive Order 14192, Unleashing Prosperity Through Deregulation." *Federal Register* 90 (2025): 9065-9067.
[31] Singham, *Trade Policy in the Trump Administration*, 4.

pharmaceutical innovation may not be immediately visible and the positive results of such a policy change (such as expedited access to new cures) could take years to manifest, the benefits of lower trade and regulatory barriers with the United States for German consumers and businesses would be more immediately apparent. This is especially important where Germany's ability to comply with any negotiated concessions would depend upon its legislature passing new or amended laws to ratify the rollback of their ACMDs. USTR could also use these negotiations and the prospect of trade concessions for Germany to secure the rollback of German ACMDs in non-pharmaceutical sectors that burden U.S. businesses and exporters. Such a result would promote Trump Administration economic policy goals.