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August 10, 2026

Public Citizen Comments re: "Request for Comments on the Section 301 Investigation Regarding Germany's Persistent Underpayment for Innovative Pharmaceutical Products"
USTR-2026-0463

Public Citizen is a nonprofit consumer advocacy organization with more than one million members and supporters. The Access to Medicines program advocates for access to prescription drugs in the United States and internationally.

Section 302(b)(1)(A) of the Trade Act authorizes the U.S. Trade Representative to initiate an investigation to determine whether an act, policy, or practice of a foreign country is actionable under Section 301 of the Trade Act. Actionable conduct under Section 301 includes acts, policies, and practices of a foreign country that are unjustifiable, unreasonable or discriminatory, and burden or restrict U.S. commerce. An act, policy, or practice is unreasonable if, while not necessarily in violation of, or inconsistent with, the international legal rights of the United States, it is otherwise unfair and inequitable.[1]

On June 18, 2026, the U.S. Trade Representative initiated a "Section 301" investigation focusing on "the extent to which Germany engages in acts, policies, and practices that have the effect of suppressing the prices of pharmaceuticals in its market below fair market value, thereby forcing American patients to underwrite a disproportionate amount of global pharmaceutical R&D."[2]

Our comment will focus on three points:

1. **Germany's drug price negotiation framework informed the United States' efforts to lower drug costs; USTR should not attack country practices that the U.S. uses or would consider using to lower drug costs;**
2. **Germany's pharmaceutical pricing policies are not unjustifiable, unreasonable or discriminatory; and**
3. **Germany's prices are not "suppressed" and do not burden or restrict U.S. commerce.**

Based on these points, Public Citizen urges USTR to drop its investigation.

1. Germany's drug price negotiation framework informed the United States' efforts to lower drug costs; USTR should not attack country practices that the U.S. uses or would consider using to lower drug costs.

The United States pays the highest drug prices in the world for prescription drugs because the patent-based pharmaceutical industry operates largely without government negotiations as a check on price. But now that is changing, precisely because the U.S. is implementing policies more similar to those used in other countries to address high drug prices. The U.S. government should not attack legitimate policies that countries the world over use to make medicines more accessible and affordable.

[1] https://www.federalregister.gov/documents/2026/06/24/2026-12671/initiation-of-section-301-investigation-hearing-and-request-for-public-comments-germanys-persistent
[2] https://www.federalregister.gov/documents/2026/06/24/2026-12671/initiation-of-section-301-investigation-hearing-and-request-for-public-comments-germanys-persistent

Until recently, and in contrast to many other countries, the largest drug purchaser in the United States was barred from negotiating drug prices. The Medicare Drug Price Negotiation Program established in 2022 is projected to save taxpayers billions of dollars.[3] Negotiated prices from the first and second rounds of negotiations are estimated to save Medicare $6 billion and $8.5 billion, and patients $1.5 billion and $685 million, respectively, in the first year prices take effect.[4] The program is also hugely popular — 88% of Americans say it's important for the government to negotiate drug prices and two-thirds of Americans want to see the program expanded.[5] Several components of Germany's negotiation framework were informative for our own system.

Many new drugs add little clinical value but come at great expense (so-called 'me-too' drugs, that piggy back on related innovations). An analysis of 216 drugs entering the German healthcare system between 2011 and 2017 found that over half showed no proof of added benefit over existing therapies.[6] Another found that fewer than half of approved first indications for new drugs in the U.S. and Europe between 2011 and 2020 add substantial therapeutic value over existing treatments.[7]

To help ensure prices reward genuine innovation, price negotiation frameworks in the U.S. and Germany assess clinical value compared to existing treatments. In Germany, a health technology assessment body evaluates added clinical value over a therapeutic alternative based on data submitted by the drug's manufacturer.[8] If the assessment shows no evidence of added benefit, statutory health insurers will only cover a certain amount of the cost, based on a price comparable to existing drugs, where applicable.[9] If the drug is determined to offer minor, considerable, or major added benefit, the manufacturer and statutory health insurers' body negotiate a higher reimbursement price.[10] When making price offers in the Medicare Drug Price Negotiation Program, the Centers for Medicare and Medicaid Services (CMS) is required to consider evidence of therapeutic value, including the extent to which selected drugs represent a therapeutic advance as compared to existing therapeutic alternatives and the costs of those alternatives, as well as the comparative effectiveness of selected drugs and therapeutic alternatives, among other factors.[11] In contrast to Germany's process independent from negotiations that relies on a standardized

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[3] https://www.cbo.gov/system/files/2026-07/62549-Medicare-Part-D.pdf (showing the Congressional Budget Office's recent adjustments to projected savings regarding drug provisions in the 2022 Inflation Reduction Act).
[4] https://www.cms.gov/files/document/fact-sheet-negotiated-prices-initial-price-applicability-year-2026.pdf; https://www.cms.gov/files/document/fact-sheet-negotiated-prices-ipay-2027.pdf
[5] https://www.arnoldventures.org/resources/national-targeted-cd-registered-voter-surveys
[6] https://www.bmj.com/content/366/bmj.l4340
[7] https://www.bmj.com/content/382/bmj-2022-074166
[8] https://www.iqwig.de/en/presse/in-the-focus/new-drugs-approval-benefit-assessment-coverage/1-drug-approval-and-early-benefit-assessment-in-germany/
[9] https://www.commonwealthfund.org/sites/default/files/documents/___media_files_publications_issue_brief_2013_oct_1711_schlette_early_benefit_assessment_rx_germany_intl_brief.pdf; https://www.g-ba.de/english/benefitassessment/
[10] https://www.iqwig.de/en/presse/in-the-focus/new-drugs-approval-benefit-assessment-coverage/1-drug-approval-and-early-benefit-assessment-in-germany/; https://www.commonwealthfund.org/sites/default/files/documents/___media_files_publications_issue_brief_2013_oct_1711_schlette_early_benefit_assessment_rx_germany_intl_brief.pdf; https://www.g-ba.de/english/benefitassessment/
[11] https://www.kff.org/medicare/key-facts-about-medicare-drug-price-negotiation/; 42 U.S. Code § 1320f-3(e)(1)–(2) (stating that, alongside evidence about therapeutic alternatives [including therapeutic advancement compared to existing alternatives and the cost of those alternatives, prescribing information for a selected drug and its therapeutic alternatives, comparative effectiveness, and the extent to which a drug and its therapeutic alternatives address unmet medical needs not addressed adequately by available therapy], CMS is required to consider manufacturer-specific data, including research and development costs; production and distribution costs; data on patent applications, regulatory exclusivities, and FDA applications and approvals; and market data, revenue, and sales volume data).

value assessment and categorization system, CMS considers factors itself without clear guidance on how to weigh the degree of benefit over alternatives. However, approaches used in Germany and other countries continue to inform ongoing policy debates in the United States regarding how more systematic clinical evidence appraisal could inform pricing decisions.[12]

Another aspect of Germany's price negotiation framework, called binding arbitration, was among proposals put forward for Medicare's negotiation framework.[13] In Germany, if a drug manufacturer and the statutory health insurance body cannot agree, an arbitration board determines the final price.[14] The board includes representatives from the statutory health insurers' body and the pharmaceutical industry, among others.[15] Legislators in the United States ultimately opted for a less conservative approach. Instead of deferring final price determinations to a third party, CMS retains the power to make final price offers it deems appropriate, including in circumstances where negotiations fail because pharmaceutical companies are not negotiating in good faith. As leverage to encourage the successful resolution of price negotiations, the Medicare negotiation program penalizes manufacturers that fail to reach a final price by subjecting them to a tax equal to a percentage of the drug's sales, or allowing them to avoid the tax by withdrawing all of their drugs from Medicare and Medicaid.[16] The strategies in both Germany and the U.S. have had success. In the five years after Germany instituted its negotiation system, drugs with no added therapeutic benefit were more likely to be withdrawn from the market than those with added benefit (25% vs 2%).[17] In the United States, courts have upheld the Medicare Drug Price Negotiation Program in each of myriad lawsuits raised by the pharmaceutical industry, including those targeting the financial penalty for refusing to complete negotiations with CMS.[18]

2. Germany's pharmaceutical pricing policies are not unjustifiable, unreasonable or discriminatory.

Governments have the right and the responsibility to manage healthcare costs to protect the public and steward taxpayer resources. Governments also recognize that expansive patent monopolies enable high drug prices, which contribute to rising healthcare costs. National policies targeting patented products are often readily explained by the reasonable need to manage healthcare costs, informed by the local context.

Germany's 2026 Statutory Health Insurance Contribution Rate Stabilization Act (GKV-BStabG),[19] referenced in the Section 301 investigation notice, includes several measures intended to respond to the budget shortfall (EUR15 billion by 2027, rising to EUR40 billion by 2030) facing public insurers' funds which would lead to higher costs for the 90% of Germans that rely on statutory health insurance.[20]

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[12] https://www.sciencedirect.com/science/article/abs/pii/S1098301526001038; https://www.commonwealthfund.org/publications/issue-briefs/2026/apr/international-lessons-pricing-and-financing-high-cost-medicines; https://pmc.ncbi.nlm.nih.gov/articles/PMC10906446/

[13] https://www.kff.org/wp-content/uploads/2019/07/Issue-Brief-Whats-the-Latest-on-Medicare-Drug-Price-Negotiations.pdf; https://www.fiercehealthcare.com/payer/medpac-debates-reference-pricing-arbitration-to-bring-down-prices-part-b (noting that the Medicare Payment Advisory Commission also suggested binding arbitration related to negotiation of Medicare Part B drugs).

[14] https://www.g-ba.de/english/benefitassessment/

[15] https://www.commonwealthfund.org/blog/2019/how-drug-prices-are-negotiated-germany

[16] https://www.kff.org/medicare/key-facts-about-medicare-drug-price-negotiation/; https://www.healthaffairs.org/content/forefront/ira-litigation-pharma-s-failed-challenges-medicare-drug-pricing

[17] https://www.healthaffairs.org/doi/full/10.1377/hlthaff.2018.05142

[18] https://www.healthaffairs.org/content/forefront/ira-litigation-pharma-s-failed-challenges-medicare-drug-pricing

[19] https://www.recht.bund.de/bgbl/1/2026/228/VO.html

[20] https://www.dw.com/en/how-to-fix-germanys-costly-health-care-system/a-76597471

Among other suggestions, Germany's Health Finance Commission recommended an adjustment to the statutory rebate imposed on patented pharmaceutical products in order to "sustainably stabilize expenditures for patented pharmaceuticals."[21] The Commission identified pharmaceutical spending among the areas where costs have increased since 2024. Spending on patented pharmaceuticals, which averaged an eight percent increase annually over five years, drove costs for the category.[22] The report also noted that spending was driven by higher prices of new patented drugs, rather than prescription volumes.[23]

The proposed "dynamic," or "variable," which was referenced in the Section 301 investigation notice, was not included in the final law. Instead of the proposed expenditure-linked rebate, which would have adjusted rebates based on spending growth for patented drugs and the financial capacity of the statutory health insurance system, the law includes a fixed rebate set at 8.5% of a company's sales price.[24] This is in addition to the existing rebate of 7%.

These changes are not unreasonable, but national efforts to respond to a key driver of rising costs and impending funding shortfalls in the health system. Notably, in response to pharmaceutical company concerns, the German government changed from the proposed variable rebate to a static rebate to be less burdensome to the industry.[25]

Germany's Federal Constitutional Court has previously ruled that an increase in the mandatory rebate is constitutional. The court rejected pharmaceutical company complaints, noting that the rebate "serves the legitimate purpose of ensuring the financial stability of the statutory health insurance system," the financing of which "constitutes an exceptionally significant interest of the common good."[26]

Thus, the rebate policy is justified by a rational public policy goal. It is also not discriminatory: it is equally applicable to foreign and domestic entities.

The Section 301 investigation notice also states that "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" as one of the claimed "means and tools that Germany uses to implement its unfair pricing policies and practices."[27]

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[21] https://www.bundesgesundheitsministerium.de/fileadmin/Dateien/3_Downloads/F/FinanzKommission_Gesundheit/FinanzKommissionGesundheit_Erster_Bericht_20260330.pdf, at 276.
[22] https://www.bundesgesundheitsministerium.de/fileadmin/Dateien/3_Downloads/F/FinanzKommission_Gesundheit/FinanzKommissionGesundheit_Erster_Bericht_20260330.pdf, at 276.
[23] https://www.bundesgesundheitsministerium.de/fileadmin/Dateien/3_Downloads/F/FinanzKommission_Gesundheit/FinanzKommissionGesundheit_Erster_Bericht_20260330.pdf, at 269-71.
[24] https://www.insideeulifesciences.com/2026/07/29/what-does-the-gkv-bstabg-reform-change-for-pharma-pricing-reimbursement-in-germany/
[25] https://www.bundesgesundheitsministerium.de/presse/pressemitteilungen/bundestag-beschliesst-gkv-beitragssatzstabilisierunggesetz-pm-10-07-2026 ("The originally planned dynamic manufacturer's discount will be replaced by a legally mandated increase in the static manufacturer's discount to 15.5 percent. This is intended to address the legitimate interest of companies in planning certainty and at the same time ensure that the pharmaceutical industry makes a direct contribution to containing expenditures.").
[26] https://www.bundesverfassungsgericht.de/SharedDocs/Pressemitteilungen/EN/2025/bvg25-061.html?nn=68112
[27] https://www.federalregister.gov/documents/2026/06/24/2026-12671/initiation-of-section-301-investigation-hearing-and-request-for-public-comments-germanys-persistent

This is misleading. Germany's new law offers drugmakers a new advantage: confidentiality.[28] Under the usual system, drugmakers are obligated to report prices, as they should be.[29]

Pharmaceutical corporations defend price secrecy to avoid scrutiny of their pricing practices.[30] This impedes the public's interest in fair prices by preventing accountability, cross-market comparison, and potentially fostering high, unreasonable prices.[31] Countries across the globe, including the United States, recognize that health price transparency can support affordability and healthy markets, and are implementing transparency rules to that end.[3233]

Far from being unfair to drugmakers, Germany's law is creating more flexibility for them by letting them opt out of price reporting requirements. Public Citizen would prefer Germany apply a much tougher standard. If anything, Germany is overly generous in allowing drugmakers to elect to conceal their prices, even if they are asked to choose between rebates and secrecy.

3. Germany's prices are not "suppressed" and do not burden or restrict U.S. commerce.

The statute defines an "unreasonable" act, policy, or practice as one that "while not necessarily in violation of, or inconsistent with, the international legal rights of the United States, is otherwise unfair and inequitable."[34] Such policies include those that deny "fair and equitable [...] nondiscriminatory market access opportunities for United States persons that rely upon intellectual property protection," including "restrictions on market access related to the use, exploitation, or enjoyment of commercial benefits derived from exercising intellectual property rights in protected works or fixations or products embodying protected works."[35]

Insulated by patents and other exclusivities, pharmaceutical companies charge prices beyond what would be seen in a competitive market. This market power is reflected in rising launch prices for new drugs in both Germany and the United States. In Germany, launch prices increased by an average of six percent per year between 2011 and 2022.[36] Between 2008 and 2021, U.S. launch prices increased by 20 percent per year, or 11 percent after accounting for rebates.[37] Drugmakers also regularly hike prices after market launch. Between 2022 and 2023, among drugs with price increases, changes in list prices averaged out to an additional $590 per product, driven by increases in already expensive medicines.[38] Among drugs already on the market between 2007 and 2018, net prices increased every year by an average of 4.5 percentage points.[39] U.S. prices are not more fair because they take place in a supposedly "free market" — nor are they influenced by prices in other countries, as the Department of Commerce found in its 2004

[28] Sozialgesetzbuch (SGB) V [Social Code Book V] §130b(1c) (providing pharmaceutical companies the option to keep reimbursement prices for new drugs confidential if they give evidence that they are conducting research in Germany. In exchange for confidentiality, the company agrees to a nine percent discount on the reimbursement price).
[29] Sozialgesetzbuch (SGB) V [Social Code Book V] §131(4) (showing the requirements for price data transmission).
[30] https://yjolt.org/sites/default/files/22_yale_j.l._tech._61_naked_price.pdf
[31] https://www.citizen.org/article/open-letter-to-medical-procurers-say-no-to-secrecy-in-medical-product-agreements/
[32] https://cdn.who.int/media/docs/default-source/essential-medicines/intellectual-property/gspa/a72_r8-en.pdf?sfvrsn=8ecefe84_3&download=true
[33] https://www.whitehouse.gov/presidential-actions/2025/02/making-america-healthy-again-by-empowering-patients-with-clear-accurate-and-actionable-healthcare-pricing-information/
[34] 19 U.S. Code § 2411(d)(3)(A)
[35] 19 U.S. Code § 2411(d)(3)(B), (F)(ii)
[36] https://jamanetwork.com/journals/jama-health-forum/fullarticle/2827325
[37] https://jamanetwork.com/journals/jama/fullarticle/2792986
[38] https://aspe.hhs.gov/sites/default/files/documents/e24f630a33f0a0585337c65745904487/aspe-drug-price-tracking-brief.pdf
[39] https://jamanetwork.com/journals/jama/fullarticle/2762310

drug pricing investigation.[40] Rather, shielded by monopoly protections, companies set prices based on what the market will bear.[41]

Pharmaceutical companies do not have a right to these pricing excesses. Patents grant the right to exclude competitors, a consequence of which is significant market power to set high prices; patents do not confer the right to a particular price or pricing authority. U.S. courts have affirmed this, noting that while patent rights "permit greater profits during a product's exclusivity period," they do not "create any affirmative right to make, use, or sell anything."[42] Where "federal patent laws do not confer a right to sell at all, they do not confer a right to sell at a particular price."[43] Based on this, courts have rejected claims that the Medicare Drug Price Negotiation Program infringes property rights by limiting companies' ability to sell products at "market rates," concluding, "[t]here is no protected property interest in selling goods to Medicare beneficiaries [...] at a price higher than what the government is willing to pay when it reimburses those costs."[44]

In the absence of typical competitive constraints, and in response to high prices that do not reflect "fair value" but the market power of the industry, Germany's pricing policies help ensure they do not overpay.

This does not mean that German prices do not support research and development (R&D). As previously mentioned, Germany's drug price negotiation framework is designed to reward innovation.

Indeed, patented drug prices are not reflective of R&D costs. Research finds no association between R&D costs and prices.[45] Top drug companies receive 163% of their global R&D costs from just the excess revenue generated in the United States,[46] underscoring that these companies earn well beyond their R&D spending and don't need to raise prices to maintain R&D investments. Exorbitant U.S. prices are not necessitated by R&D costs and there is no evidence to support the claim that lower prices in other countries burden the United States with higher costs.

This investigation should not conflate revenue with R&D. The vast majority of company revenue is not spent on R&D. Large pharmaceutical manufacturers often spend more enriching shareholders than they do developing new drugs. Over the past four years (2022 to 2025), the 15 publicly traded companies whose drugs were selected for the first and second rounds of Medicare drug price negotiations collectively spent $4.4 billion more on stock buybacks and dividends than on research and development.[47] Moreover, pharmaceutical companies regularly overstate claims that pricing regulations will harm innovation. For example, despite research showing that high-spend drugs approved for one or more orphan (affecting fewer than 200,000 U.S. patients) indications recover R&D costs at rates comparable to or faster than other high-spend drugs, pharmaceutical industry stakeholders continue to lobby for and win lucrative carve-outs for these drugs from price negotiations.[48][49]

Allowing high prices and revenues alone to guide R&D discussions can actually undermine innovation as the industry shifts investments to high margin products. For example, one study found that clinical trials

[40] https://web.archive.org/web/20190414170009/https:/2016.trade.gov/td/health/DrugPricingStudy.pdf
[41] https://jamanetwork.com/journals/jama/article-abstract/2545691
[42] https://litigationtracker.law.georgetown.edu/wp-content/uploads/2024/05/AstraZeneca_2025.05.08_OPINION.pdf
[43] *Id.*
[44] https://litigationtracker.law.georgetown.edu/wp-content/uploads/2024/05/AstraZeneca_2025.05.08_OPINION.pdf
[45] https://jamanetwork.com/journals/jamanetworkopen/fullarticle/2796669; https://www.cbo.gov/publication/57126
[46] https://www.healthaffairs.org/content/forefront/r-d-costs-pharmaceutical-companies-do-not-explain-elevated-us-drug-prices
[47] https://www.citizen.org/article/false-choice-between-affordability-and-innovation/
[48] https://www.healthaffairs.org/doi/10.1377/hlthaff.2026.00209
[49] https://www.citizen.org/article/hundreds-of-lobbyists-hired-to-undermine-drug-price-negotiations/

for cancer medicines made up 46.6% of all trials assessed, indicating seemingly disproportionate levels of research compared to other disease areas.[50] Pharmaceutical corporations also sometimes neglect investments in products that would serve patients' needs but not profit motives, such as research into new antibiotics (the pipeline of new antibiotics from large research-based pharmaceutical companies has shrunk by 35% since 2021)[51] and neglected diseases (private industry contributed just 15% of the global funding for neglected diseases in 2023).[52]

This dynamic also fails to take into account the massive public-sector contributions to innovation. In the United States, the National Institutes of Health (NIH) plays a critical role in basic research and drug development. NIH research contributed to virtually every new drug approved from 2010-2019.[53] While omitting public-sector contributions to drug development from their pricing decisions, the pharmaceutical industry is also not transparent with its R&D costs, and industry-reported R&D costs per new drug are twice as much or more than figures from independent researchers.[54]

In the best case, monopolies and extreme pricing behaviors they enable are an inefficient way to pay for research. Instead of focusing innovation support through these indirect means, policymakers should consider other mechanisms—such as grants and prizes—to incentivize private sector investment and help deliver products at affordable prices.[55] In the worst case, such as continuing a monopoly-based system but limiting pricing policies that would help moderate it, this approach can harm patients.

As people in the United States know well, higher prices raise costs and make needed medicines harder to access. Four-in-ten Americans struggle to afford their medicines.[56] The U.S. pharmaceutical pricing agreement with the U.K. underscores the risks posed to patients, with the deal expected to redirect billions in health spending toward patented drugs over other health services, leading to an estimated 229,000 excess deaths over ten years, according to a recent study.[57]

In sum, there is no evidence that the U.S. bears a higher cost burden due to lower drug prices in other countries. U.S. prices are not reflective of fair value or justified by R&D costs. Drug prices are lower in other countries compared to the United States because those countries have systems in place to moderate the monopoly pricing excesses of prescription drug corporations. The United States is now implementing domestic policies, including the Medicare Drug Price Negotiation Program, to address these pricing excesses, which is reasonable considering the need to ensure medicines are affordable for patients and taxpayers. We urge USTR to take no action and to drop its investigation.

[50] https://iris.who.int/server/api/core/bitstreams/7a5517d6-1077-4ecd-bf32-d6d664add439/content
[51] https://accesstomedicinefoundation.org/in-the-media/antibiotic-innovation-shrinks-as-drug-resistant-infections-rise-globally-says-new-report
[52] https://cdn.impactglobalhealth.org/media/G-FINDER%202024_Full%20report.pdf
[53] https://doi.org/10.36687/inetwp133
[54] https://pmc.ncbi.nlm.nih.gov/articles/PMC7054832/; https://pmc.ncbi.nlm.nih.gov/articles/PMC11704977/
[55] https://www.keionline.org/book/prizes-to-stimulate-innovation
[56] https://www.kff.org/health-costs/public-opinion-on-prescription-drugs-and-their-prices/
[57] https://www.bmj.com/content/394/bmj-2026-340588