The Evidence Does Not Support Positive Determination in Section 301 Investigation of Germany's Pharmaceutical Policies

Oral Testimony of:
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for

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Hearing on Initiation of Section 301 Investigation of Germany's Alleged Persistent Underpayment for Innovative Pharmaceutical Products (Docket USTR-2026-0463)

Thank you to the Office of the US Trade Representative (USTR) and the Section 301 Committee for organizing this hearing and for the opportunity to present on the initiation of the Section 301 Investigation of Germany's pharmaceutical pricing system.

My name is Prof. Thomas Hwang. I am a physician-researcher, Director of the Cancer Innovation and Regulation Initiative, and faculty at the Program On Regulation, Therapeutics, And Law at Harvard Medical School and the Brigham and Women's Hospital in Boston. My research focuses on the evaluation and regulation of new medicines and other interventions in cancer care. All views are my own.

Our systematic review of the evidence does not support claims that Germany's pharmaceutical pricing system is unreasonable or discriminatory within the meaning of Section 301, or that they burden or restrict US commerce. In fact, our recent research on the Administration's Most-Favored-Nation pricing models in Medicaid and Medicare underscore the importance of the German system for delivering lower prices for medicines for public programs and taxpayers in the US.[1]

My testimony calls for USTR to not make a positive determination in the Section 301 investigation of the German pharmaceutical pricing system. If USTR proceeds with action in this investigation, we urge USTR to not impose tariffs or other restrictions on imports of German-origin medicines.

After a brief background, my comments are structured around five key considerations. I will also share findings from our research on the geographic origin of medicines in the US health care system; these findings form part of a manuscript submitted for scientific publication.

[1] Hwang TJ, et al. *JAMA* 2026;336(6):514-517; Hwang TJ, et al. *Lancet* 2026:S0140-6736(26)01555-2.

Background

New medicines entering the German market undergo a two-stage process for reimbursement. All new medicines are reimbursed at launch. Then, price negotiations are conducted based on evidence-based assessments of added clinical benefit (with final evaluation conducted by the Federal Joint Committee).[2]

This transparent and rigorous benefit assessment in Germany rewards therapeutically important innovations. It also serves as a model for other countries around the world. Our research has leveraged the German scoring system to assess the therapeutic value of medicines approved by FDA.[3] And our current study indicates that Germany is among the top three countries of origin for innovative medicine imports into the US by value, underscoring its importance for access to medicines by US patients.

Key Considerations

The USTR's notice of initiation of Section 301 investigation highlights two policies of concern to the Committee: (1) a proposed dynamic or variable pharmaceutical rebate, and (2) conditions on confidentiality of prices. **The first of these policies of concern is no longer applicable (not enacted in recent legislation), and the second is not discriminatory and does not burden US commerce.**

1. **Variable pharmaceutical rebates cited by USTR were excluded from final enacted legislation.**

   The first of two cited reasons supporting the initiation of Section 301 investigation is no longer relevant: variable rebates were excluded from the final text of the GKV Stabilization Act (SHI Contribution Rate Stabilization Act; GKV-BStabG) as adopted on July 10, 2026.

   The final German legislative text instead includes an increased statutory rebate (15.5%), which applies to all pharmaceutical companies regardless of domicile and is not unreasonable or discriminatory within the meaning of Section 301. In fact, this statutory rebate level in the German system is lower than comparable minimum statutory rebate rates in the US: for example, 23.1% for Medicaid, 24% for the VA and other federal purchasers, and 25-60% for Medicare under the Inflation Reduction Act. The German government is in discussion with industry on reduced statutory rebates.

2. **The second policy of concern, the price confidentiality mechanism, is not discriminatory and is rarely applied, therefore not burdening US commerce.**

   As amended in 2024, German law permits confidentiality of prices for innovative medicines (following price negotiations) under certain conditions: a 9% discount, documentation of research and development activity in Germany, and certain administrative costs. This voluntary mechanism is available to both domestic and foreign manufacturers – and ultimately rarely used. Since its entry into

[2] The Federal Joint Committee may delegate the benefit assessment to the Institute for Quality and Efficiency in Health Care (IQWiG), but the final assessment by the G-BA is binding.
[3] Hwang TJ et al., *BMJ* 2020;m3434; Vokinger KN et al., *BMJ* 2023;e074166; Vokinger et al., *JAMA Health Forum* 2022;3(8):e222685.

force in 2025, manufacturers have elected to apply this provision for only 3 drugs. Given how rarely this provision has been invoked, there is no evidence that this provision has burdened US commerce.

3. **The German price confidentiality mechanism is not unique to Germany: similar price confidentiality policies are widely used in the US and in other countries.**

   In the US system, confidentiality of negotiated prices is a common condition of pricing across public and private payers. The expectation is that confidential final prices reflect additional discounts provided to such payers (e.g., Medicaid supplemental rebates) that are not available to the broader market. In the Medicare program, the Centers for Medicare and Medicaid Services said that it needed confidentiality to "increase the chances of effective and successful negotiation" with pharmaceutical companies. The President's nominee for Deputy Secretary of the Department of Health and Human Services said in his recent US Senate confirmation hearing that confidential negotiations were needed for the government's ability to negotiate with other countries. The conditions on confidentiality in the German system are therefore neither novel nor uniquely burdensome for US commerce.

4. **Conditions on price confidentiality incentivize price transparency, which benefits US public programs and taxpayers.**

   The required discount for price confidentiality may serve as a deterrent against confidential prices, which benefits US public payers and taxpayers. Following Executive Order 14297 announced by President Trump in May 2025, the administration has implemented or proposed Most-Favored-Nation pricing models in Medicaid and Medicare, all of which include Germany as a reference country. To the extent that final negotiated prices in Germany are transparent, and that industry is disincentivized against shielding German prices from US payers' MFN models, this provision of the German system allows the US federal government and taxpayers to benefit from lower prices in Germany.

5. **The evidence does not support a positive determination in this Section 301 investigation. Nonetheless, if USTR adopts a positive determination, we urge USTR to not impose tariffs on German-origin innovative medicines.**

   Our research suggests that most German-origin pharmaceutical imports are exempted from separate Section 232 pharmaceutical tariffs due to company-specific agreements with the Administration. We recommend that USTR not stack any Section 301 tariffs on existing Section 232 duties.

In summary, we recommend that USTR not make an affirmative determination in its Section 301 investigation and instead allow the administration to continue bilateral negotiations with the German government for policies that could result in lower prices for innovative medicines in both countries.

Our team is available to discuss these issues at any time, and we welcome further engagement with USTR on issues relating to pharmaceutical trade policy. ■