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Public Citizen 2026 Special 301 Review Post-hearing Comment

February 25, 2026

Public Citizen is a nonprofit consumer advocacy organization with more than one million members and supporters. Public Citizen's Access to Medicines Program works with partners across the U.S. and around the world to make medicines available for all through tools in policy and law.

During the 2026 Special 301 public hearing, agency representatives asked three questions about our written comment. We reiterate one key point from our testimony and provide fuller answers to the panel's questions below.

The United States benefits from a trade agenda that allows other countries to protect health. In acknowledging the 2001 Doha Declaration, each Special 301 report since the declaration's adoption has recognized the need to support access to medicines. Despite this ostensible recognition, as we detail in our pre-hearing comment,[1] Special 301 has often failed to make these commitments real in action. It regularly elevates industry complaints that pressure other countries to remove or refrain from using health safeguards and implement policies that would restrict access to medicines.

Alarmingly, the consequences of this practice have now been further elevated in rapidly-signed U.S. trade deals, including those with Argentina and Indonesia. These deals adopt Special 301 report comments wholesale into binding agreements, without input from the public or Congress and without clear consideration of the laws and policies crafted under the judgment of experts and legislatures in each of our trading partners' national contexts.

In the past, USTR has articulated that the United States would refrain from criticizing other countries for exercising TRIPS flexibilities and would respect its trading partners' sovereign right to adopt measures in furtherance of legitimate public purposes.[2] We urge the committee to take forward this practice by omitting expressed or implied references to countries' public interest policies.

We firmly believe that this committee can execute its duty under statute with balance that can protect people's lives.

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[1] Public Citizen 2026 Special 301 Review Comment, https://www.citizen.org/wp-content/uploads/Public-Citizen_2026-Special-301_Review_Comment.pdf

[2] USTR Releases 2024 Special 301 Report on Intellectual Property Protection and Enforcement, https://ustr.gov/about-us/policy-offices/press-office/press-releases/2024/april/ustr-releases-2024-special-301-report-intellectual-property-protection-and-enforcement; 2024 National Trade Estimate Report on Foreign Trade Barriers, https://ustr.gov/sites/default/files/2024%20NTE%20Report.pdf

1. **USTR: Public Citizen states that the Special 301 report should not discuss pharmaceutical pricing issues because they do not constitute discriminatory non-tariff trade barriers that deny fair and equitable access to U.S. persons that rely upon intellectual property protection. However, other stakeholders have raised concerns that restrictive pricing policies constitute significant non-tariff trade barriers and do impact their ability to operate in the market. We would welcome a response to these concerns, including whether, in your assessment, there are any policies affecting pharmaceutical prices that would cause concern or constitute a non-tariff trade barrier.**

Countries use various methods to regulate spending and inform their negotiations for drug pricing and reimbursement.[3] This is sensible given rising drug prices and the need to manage costs while providing access to medical products.

In this year's Special 301 review process, pharmaceutical industry stakeholders target measures that are frequently used to regulate the cost of medicines, including health technology assessments, "mandatory price cuts and revenue clawbacks," international reference pricing, and "reimbursement delays."[4] They allege that these measures represent barriers to trade that unfairly limit market access.[5]

The Trade Act of 1974 provides no mandate for USTR to discuss non-discriminatory pharmaceutical pricing in the Special 301 report. The Special 301 report concerns, by statute, the denial of "adequate and effective protection of intellectual property rights" or the denial of "fair and equitable market access to United States persons that rely upon intellectual property protection."[6]

Regarding the denial of fair and equitable market access, the statute further clarifies that:

> A foreign country denies fair and equitable market access if the foreign country effectively denies access to a market for a product protected by a copyright or related right, patent, trademark, mask work, trade secret, or plant breeder's right, through the use of laws, procedures, practices, or regulations which—
> *(A) violate provisions of international law or international agreements to which both the United States and the foreign country are parties, or*
> *(B) constitute discriminatory nontariff trade barriers*. (emphasis added)[7]

Thus, as Professor Sean Flynn at American University has noted, "where a pricing program has the mere effect of reducing the rate of return of a patented product in a non-discriminatory way and violates no international agreement in doing so, then it is an inappropriate subject for listing under the Special 301 program."[8]

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[3] Iselin Dahlen Syversen et al, *A Comparative Analysis of International Drug Price Negotiation Frameworks: An Interview Study of Key Stakeholders*, Milbank Quarterly (Sept 17, 2024), https://pmc.ncbi.nlm.nih.gov/articles/PMC11654763/; https://www.oecd.org/content/dam/oecd/en/publications/reports/2008/09/pharmaceutical-pricing-policies-in-a-global-market_g1gh8df5/9789264044159-en.pdf.

[4] PhRMA 2026 Special 301 Review Notice of Intent to Testify and Hearing Statement at 20.

[5] *See*, PhRMA 2026 Special 301 Review Notice of Intent to Testify and Hearing Statement at 20; US Chamber of Commerce 2026 Special 301 Review Comment at 15-16.

[6] 19 U.S. Code § 2242(a)(1)(A)-(B).

[7] 19 U.S. Code § 2242(d)(3)(A)-(B).

[8] *See,* Sean Flynn, *Special 301 Post-Hearing Submission, Responding to Questions from the Committee* (Mar. 7, 2016), available at http://infojustice.org/archives/35820.

Pharmaceutical industry stakeholders allege broadly that pricing policies in Australia, Canada, Denmark, France, Germany, Italy, Japan, Korea, Spain, Switzerland and the United Kingdom are "unreasonable and discriminatory."[9] However, the majority of pricing complaints for these countries do not allege discrimination, but rather claim a denial of market access that is inconsistent with the Special 301 mandate.

Additionally, a closer inspection of complaints that do allege discrimination is warranted. A law cannot be said to be discriminatory if it is equally applicable to all entities within a market. Even laws or policies having the effect of imposing measures on single entities or entities from a particular sector or country cannot *ipso facto* be considered to constitute discrimination. In pharmaceuticals, it is far more likely that countries are making negotiation offers appropriately informed by the therapeutic value of products or other factors, as does the United States. No country should overpay.

For example, the Pharmaceutical Research and Manufacturers of America (PhRMA) claims that France's pricing and reimbursement policies have "discriminated against innovative companies" by classifying many new drugs as providing little or no added clinical value, which impacts their pricing.[10]

In France, a designated health technology assessment body performs value assessments based on evidence regarding a drug's clinical effects and performance compared to existing alternatives.[11] Medicare price negotiations in the United States are informed by similar factors, including comparison to therapeutic alternatives. Following the value assessment in France, another committee then negotiates prices, considering the value assessment and prices in comparator countries.[12] Drugs assessed to offer moderate to high therapeutic value over existing therapies are typically reimbursed at a higher price.[13] Standards are not applied differently to different products. The mere fact that innovative medicines deemed to be less clinically beneficial according to these standards are then subjected to different price parameters does not imply that the standards are discriminatory. In fact, countries are doing exactly what they should in a market: paying for value. Many new drugs add little clinical value but come at great expense (so-called 'me-too' drugs, that free-ride on related innovations). PhRMA's complaint amounts to a lament that its members' products are not more innovative. Pharmaceutical industry stakeholders' claims are underpinned by the desire to increase profits, not reduce credible barriers to trade.

2. **HHS: Regarding Public Citizen's point that the Special 301 report should not single out countries for medicine pricing practices that the U.S. is considering domestically, could you expand on which country practices you're referring to and how these practices are being considered by the United States?**

The reason the U.S. has the highest drug prices in the world — three times as high as other OECD countries — is because unlike in many other countries, the patent-based pharmaceutical industry

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[9] PhRMA 2026 Special 301 Review Comment at 2.
[10] PhRMA 2026 Special 301 Review Comment at 132.
[11] Kerstin N. Vokinger & Huseyin Naci, *Negotiating Drug Prices in the US—Lessons From Europe*, JAMA (Dec. 22, 2022), https://jamanetwork.com/journals/jama-health-forum/fullarticle/2799713.
[12] Marc A. Rodwin, *What Can the United States Learn from Pharmaceutical Spending Controls in France?*, The Commonwealth Fund (Nov. 2019), https://www.commonwealthfund.org/sites/default/files/2019-11/Rodwin_pharma_cost_control_France_ib_v2.pdf
[13] Iselin Dahlen Syversen et al, *A Comparative Analysis of International Drug Price Negotiation Frameworks: An Interview Study of Key Stakeholders*, Milbank Quarterly (Sept 17, 2024), https://pmc.ncbi.nlm.nih.gov/articles/PMC11654763/.

operates largely without government negotiations as a check on price.[14] But that is changing. The 2022 Inflation Reduction Act for the first time allowed Medicare to negotiate drug prices directly with manufacturers.

In order to determine the government's initial price offer before entering negotiations with manufacturers, CMS considers several factors, including information about therapeutic alternatives and their prices.[15] Many of the same factors are considered in other countries' pricing regulations, which pharmaceutical stakeholders criticize in their Special 301 comments.

The "most-favored nation" pricing models advanced by the Trump administration — GLOBE, GUARD, and GENEROUS — are reference pricing, the same practice drugmakers complain about in their Special 301 comments.[16] CMS will weigh the prices paid by other OECD countries and assess rebates, in order to ensure that Americans do not pay more for particular drugs. The Trump administration is expected to back legislation codifying this practice.[17]

Members of Congress and health experts increasingly propose the U.S. adoption of further, similar pricing measures used in other countries. For example, evaluating the value of new treatments through health technology assessments and using comparative effective research to inform reimbursement, as well as levying penalties for excessive prices and revenues, are all proposals with significant mainstream U.S. support that may become law or practice in coming years.

Ultimately, the result of deregulating pricing or otherwise limiting the ability to address medicine affordability, as pharmaceutical corporations request, is higher prices, access barriers, and greater cost burdens on governments and people. When the U.S. government puts pressure on others for their pricing regulations, it undermines legitimate policies that countries the world over, including our own, use or may consider using in the future to make medicines more accessible and affordable.

3. **PTO: Public Citizen's submission cites data from the government of Brazil on patent pendency period for biopharmaceutical patents. Can you please provide more context about the cited data, including whether it describes statistics for only patent applications with decisions issued between October and December 2025?**

In our pre-hearing comment, we clarified that while PhRMA states that Brazil has an average patent pendency of 9.5 years for pharmaceutical patents (based on an average between 2020 and 2024), more

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[14] Andrew W. Mulcahy et al, *International Prescription Drug Price Comparisons* (Feb. 1, 2024), https://www.rand.org/pubs/research_reports/RRA788-3.html.

[15] Juliette Cubanski, *FAQs about the Inflation Reduction Act's Medicare Drug Price Negotiation Program*, KFF (Jan. 23, 2025), https://www.kff.org/medicare/faqs-about-the-inflation-reduction-acts-medicare-drug-price-negotiation-program/; Kate Meyer & Jeremy Sharp, *Determining the Right Offer Price in Medicare Drug Negotiations,* The Commonwealth Fund (Sept. 22, 2023), https://www.commonwealthfund.org/blog/2023/determining-right-offer-price-medicare-drug-negotiations.

[16] Kristi Martin & Rachel Sachs, *Administration Releases Proposed Medicare International Drug Reference Pricing Models*, Health Affairs Forefront (Dec. 24, 2025), https://www.healthaffairs.org/content/forefront/administration-releases-proposed-medicare-international-drug-reference-pricing-models.

[17] Lauren Gardner, *Trump touts MFN deals, prods GOP leaders to codify them*, Politico (Feb. 24, 2026), https://subscriber.politicopro.com/article/2026/02/trump-touts-mfn-deals-prods-gop-leaders-to-codify-them-00797195.

recent data from the government of Brazil show an average patent pendency period of 4.8 years for biopharmaceutical patents (and five years for biotechnology patents).[18] This refers to the average decision time from the date of examination request for decisions completed during the quarter.

In this year's hearing, despite apparent improvements in patent review timelines in recent years, PhRMA noted that it is seeking extended patent terms.

We reiterate that variance in review periods is a normal part of patent examination. Indeed, U.S. patent terms already were extended from 17 to 20 years concomitantly with the adoption of the TRIPS Agreement in 1995 in order to accommodate concerns from drugmakers. Extending patent terms beyond that 20-year period due to perceived delays in examination represents a windfall for drugmakers, legislatively, financially and against the public interest in timely access to affordable generics.

We support efforts to ensure patent offices worldwide are fully funded and staffed so that examination can proceed efficiently. However, USTR should ensure that it does not seek less rigorous patent reviews or the adoption of patent term adjustments for patent office or other administrative delays, which are not required under the TRIPS Agreement, would punish countries improving patent backlogs, and delay access to affordable medicines.

[18] INPI, Indicadores Tempo de Decisão Técnica e Número de Decisões (Oct/Dec 2025), https://www.gov.br/inpi/pt-br/servicos/patentes/relatorios-gerenciais/TempoDecisao_Trimestr_OUTDEZ2025.pdf.