COUNCIL FOR AFFORDABLE
HEALTH COVERAGE

June 27, 2025

Ambassador Jamieson Greer
United States Trade Representative
Office of the United States Trade Representative
600 17th St NW
Washington, DC 20508

Re: Comment Regarding Foreign Nations Freeloading on American-Financed Innovation (Docket No. USTR-2025-0011)

Submitted electronically through www.comments.ustr.gov/s/.

Dear Ambassador Greer,

The Council for Affordable Health Coverage (CAHC) appreciates the opportunity to provide comments to the Office of the United States Trade Representative (USTR) regarding the request for comment pursuant to the Executive Order titled *Delivering Most-Favored-Nation Prescription Drug Pricing to American Patients*. As a broad-based coalition of employers, insurers, patient groups, and other stakeholders committed to expanding access to affordable coverage through market-based solutions, we commend the agency's recognition of foreign free loading on medical innovation. Our alliance (www.cahc.net) has a singular focus: ensuring all Americans have access to affordable coverage. We are pro-patient, pro-competition, and pro-innovation.

We have long supported lower drug costs and greater access to drug therapies for patients, while fostering innovation to expand competitive drug markets that lower drug prices. New therapies also help treat and cure diseases, which prevents more costly interventions in more expensive settings, like hospitals and emergency rooms.

We support the agency's efforts to investigate and address foreign practices that may impede competition and innovation in healthcare and thus shift costs of drugs onto American patients in the global pharmaceutical marketplace.

Foreign Country Concerns – France, United Kingdom, and Germany

Delayed Access

Before most patients can access a new medicine in Europe, it must be independently evaluated for effectiveness and safety, a process known as licensing or the 'marketing authorization decision'. If a product is approved, most European countries also assess a medicine for its cost-effectiveness to decide whether their health system will pay for the medicine. Foreign governments utilize strict price-setting systems to arbitrarily determine both the value of a new drug and the cost of the product to be available to the consumer. This process delays time to market for therapies.

The average time for a new medicine to reach European patients is now 578 days, with significant variation across countries, ranging from 126 days in Germany to 804 days in Poland. It also means certain products for serious conditions like cancer or rare diseases are simply not available at any given time. For example, in 2024, just 46 percent of innovative medicines approved centrally in the EU between 2020 and 2023 were

available to patients. This means that for every 100 new drugs approved, roughly 46 were accessible to patients in Europe.[1] Just 50 percent of new cancer treatments are available to Europeans. Patients may pay lower prices, but they also have less access to treatments and cures for dreaded diseases. That is a heavy price for patients to pay.

Price Controls

Government-run health systems in the United Kingdom (UK), Germany, and France dictate prices and fail to recognize the fair market value of innovator products. Clawbacks, rebates, and price-volume caps are common in countries with nationalized healthcare systems, which use their centralized government purchasing power to secure price concessions from pharmaceutical companies, which in turn delays market access for products that have already received regulatory approval. Concerning specific countries, cost assessments, often known as a health technology assessment (HTA), are used to varying degrees, but prominently in the UK, France, and Germany.

In the UK, prices are regulated by the Voluntary Scheme for Branded Medicines Pricing and Access, which uses the National Institute for Health and Care Excellence (NICE) to conduct the HTA and determine the binding price.[2] Manufacturers are forced to either enter the market at the undervalued price determined by NICE bureaucrats or choose not to make their product available. While the majority of prescription drugs in the UK are under the Voluntary Scheme, there are a small number of manufacturers that take part in the Statutory Scheme, which doesn't use NICE to set prices but instead sets a maximum price based on set factors, similar to Germany.[3] Earlier this month, the UK government doubled the repayment rate for newer branded medicines under the statutory scheme to a record 31.3 percent, meaning manufacturers must now pay back twice as much as before.[3] Medicines are often not funded under the national health budget for their full market authorization, restricting patients from treatments proven to be effective.

In Germany and France, while the price is considered nonbinding, it is used to set a maximum price for the product, limiting the manufacturer's ability to truly negotiate with the government. In Germany, they negotiate with the National Association of Statutory Health Insurance Funds, or "Sickness Funds", which also uses international reference pricing to set the maximum price.[3] In France, drug companies negotiate with the Comité Economique des Produits Santé (CEPS), the drug pricing authority, which uses international reference pricing as a consideration in its price-setting process.[4]

These aggressive cost-containment measures are not only a non-tariff trade barrier, but they are also a major reason why American patients pay more here for innovative products, while EU countries free-ride off US ingenuity and innovation.

Prescription Drug Production

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[1] https://efpia.eu/news-events/the-efpia-view/statements-press-releases/new-data-shows-no-shift-in-access-to-medicines-for-millions-of-europeans/#:~:text=The%20W.A.I.T.,down%20from%2048%25%20in%202019.
[2] Nagar, S., Rand, L.Z., & Kesselheim, A.S. (2022). What Should US Policymakers Learn From International Drug Pricing Transparency Strategies. AMA Journal of Ethics.
[3] Citeline Regualtory Pink Sheet. Pharma's Protests Fall Flat as UK Locks In High Rebate Rates. June 2025.
[4] Raimond, V.C., Feldman, W.B., Rome, B.N., & Kesselheim, A.S. (2021). Why France Spends Less Than the United States on Drugs: A Comparative Study of Drug Pricing and Pricing Regulation. The Milbank Quarterly.

Pharmaceutical development and production are capital-intensive and front-loaded, with the majority of costs incurred during the research and development (R&D) phase, particularly during clinical trials, which are both lengthy and costly. This process, on average, takes ten to 15 years before a product reaches the market. To recoup these investments and sustain future innovation, manufacturers rely on access to global markets. However, many foreign governments leverage centralized pricing mechanisms to mandate below-market prices, knowing companies must participate in those price-fixing schemes to access those markets.

The United States remains the global engine of biopharmaceutical innovation, conducting the majority of early-stage research and clinical trials. As a result, US patients and taxpayers effectively underwrite the global drug development pipeline. This dynamic underscores the need for thoughtful, balanced policy approaches that protect innovation while addressing affordability.

Non-Tariff Trade Barrier

Non-tariff barriers are regulations, policies, or practices other than tariffs that restrict or impede international trade. They include quotas, licenses, standards, and price controls that deny competition on fair and equitable terms. The United States is the leader of pharmaceutical R&D, but because the drug supply chain is global, and the US is the freest market for prescription drugs, the country is at a major disadvantage. There is a significant imbalance in the system that allows foreign countries to rely on American investment and production, get the product at a lower cost, and do little to reinvest in the market.

European drug companies can sell their products in the US at competitive, market prices, but American companies must sell theirs in Europe at much lower, government-controlled prices. Additionally, these companies also get to take advantage of American innovation contributions by moving their R&D headquarters to the United States, allowing for quicker drug development and market access.

Pharmaceutical R&D is successful in America because current policies and regulations promote innovation and competition. Since these foreign nations don't value treatments and patient outcomes as highly as the US, they aren't concerned with delaying patient access. For example, research from RAND found more than 50 percent of new drugs were first launched in the United States, whereas France, Germany, and the UK didn't launch these products until a year later.[5]

This dynamic not only undermines the sustainability of American pharmaceutical leadership but also distorts fair trade by allowing foreign governments to impose non-tariff barriers that shield their markets while exploiting the openness of the US system. Addressing this imbalance is essential to ensure that innovation is rewarded equitably and that global access to medicines is both fair and sustainable.

Conclusion

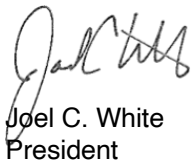
The United States continues to lead in prioritizing patient health by supporting access to innovative treatments and using forward-looking health value assessments. In contrast, many other countries rely on outdated valuation models that often restrict access to modern therapies and fail to reflect the true value of improved

[5] Mulcahy, A.W. (2024). Comparing New Prescription Drug Availability and Launch Timing in the United States and other OECD Countries. The RAND Corporation.

health outcomes. This underscores the importance of maintaining a policy environment that rewards innovation and puts American patients first.

The Council for Affordable Health Coverage strongly supports the USTR's efforts to address foreign freeloading on American-financed innovation. We urge continued collaboration and thoughtful policy development to ensure American patients are not unfairly burdened with the costs of global pharmaceutical research and development.

Sincerely,



Joel C. White
President