

# The Art of the Trade: **UNDERSTANDING THE USTR**

The high cost of pharmaceutical drugs in the United States is once again making headlines, this time focusing on why the U.S. pays so much more for prescription drugs than other countries like the United Kingdom, Spain, and Germany. In response to this disparity, President Donald Trump issued an Executive Order titled *"Delivering Most-Favored Nation Prescription Drug Pricing to American Patients."*<sup>1</sup> Among its provisions, the Order directs the United States Trade Representative to take "all necessary steps to ensure foreign countries are not engaged in any act, policy, or practice that may be unreasonable or discriminatory or that may impair United States national security . . ."

For many patients, providers, and caregivers, the USTR is an unfamiliar federal office they likely haven't interacted with. This resource aims to inform stakeholders about the USTR's role, its influence on prescription drug affordability, and how consumers and advocates can effectively engage this office.

## **What is the Office of the United States Trade Representative (USTR)?**

The Office of the USTR is a Cabinet-level office that develops and coordinates U.S. international trade and investment policy, leads trade negotiations with other countries, and advises the President on trade matters. It is led by the U.S. Trade Representative, who is appointed by the President and serves as the President's principal advisor, negotiator, and spokesperson on trade issues.<sup>2</sup>

## What is the mandate of the Office of the USTR?

The USTR's primary mandate is to:

- Develop and coordinate U.S. trade policy;
- Negotiate trade agreements and resolve trade disputes;
- Monitor and enforce compliance with trade agreements; and
- Represent U.S. interests in international trade forums.<sup>3</sup>

This duty includes addressing practices that may be “unreasonable or discriminatory” and could impair U.S. national security or commerce.<sup>4</sup>

## When is a practice considered “unreasonable or discriminatory”?

A foreign act, policy, or practice is considered “unreasonable or discriminatory” by the USTR if it unfairly burdens or restricts U.S. commerce. Examples include:

- Denying fair opportunities to establish businesses or access markets (i.e., foreign equity restrictions, joint venture or local ownership requirements, and discriminatory licensing or approval procedure<sup>5</sup>);
- Failing to adequately protect intellectual property rights;
- Allowing anti-competitive practices that restrict U.S. goods or services (for example, USTR recently found China's predominant control of maritime shipping and logistics was depriving foreign U.S. companies from participating in this market);<sup>6</sup>
- Denying worker rights, such as collective bargaining or minimum labor standards.

The USTR has discretion to respond, including taking retaliatory action, when such practices are identified.<sup>7</sup>

In May 2025, USTR initiated an investigation into foreign acts, policies, or practices that may be “unreasonable or discriminatory” in the context of pharmaceutical pricing, particularly those forcing American patients to pay a disproportionate share of global research and development costs through price suppression abroad. The investigation invited public comments from interested parties, including details on specific foreign countries, practices, and their impacts, to identify those deemed unreasonable or discriminatory.<sup>9</sup>

As of October 2025, no final report from this investigation has been publicly released. However, the investigation remains part of ongoing efforts that could lead to trade actions if progress on implementing the Most-Favored-Nation pricing model under Executive Order 14297 stalls.<sup>10</sup>



## Has USTR engaged on trade issues related to health care before?

Yes, the USTR has engaged extensively on trade issues related to health care, **but its work has primarily focused outward, supporting U.S. industry interests abroad, rather than addressing international trade policies that impact U.S. patients or domestic access to care.**

For instance, USTR has worked to eliminate foreign tariffs and taxes on imported medicines that raise costs for patients abroad, strengthen IP protections to encourage U.S. innovation, and address opaque or discriminatory reimbursement systems that disadvantage U.S. pharmaceutical and medical device manufacturers. While these efforts promote fair competition and global access to U.S. products, they underscore that USTR's engagement has been largely outward.<sup>11</sup>

If the agency expands its efforts to focus more inward on domestic health care issues, USTR should strengthen engagement with U.S. stakeholders, including patient advocates, health care providers, and public health experts, to more effectively evaluate and address how international trade policies affect health care affordability and patient access in the United States.

## Does USTR monitor how trade issues impact consumers, or do they only focus on how trade impacts businesses?

USTR monitors the impacts of trade issues on consumers across various sectors, including the health care space, alongside its primary focus of advancing U.S. business interests and market access. Through annual reports like the Special 301 Report, a Congress-mandated review evaluating the adequacy and effectiveness of intellectual property protection and enforcement abroad, and the National Trade Estimate (NTE) on Foreign Trade Barriers, an annual survey documenting foreign trade barriers affecting U.S. goods, services, and investment, USTR identifies and addresses international practices that threaten U.S. commercial and innovation interests. From the consumer perspective, this can also include protecting consumers from counterfeit drugs that endanger consumer health and safety, as well as import restrictions that limit access to affordable generics.<sup>12</sup>

## What is the "Most-Favored Nation" Pricing Model?

The Most-Favored-Nation (MFN) pricing model is a prescription drug pricing policy that seeks to align U.S. drug prices with international prices. Introduced by President Trump through an Executive Order in May 2025, the MFN model directs manufacturers to offer American consumers the lowest international price or face potential enforcement actions by the Administration.<sup>13</sup> Under this framework, the MFN target price is set at the lowest price available to specific countries with a GDP per capita of at least 60 percent of that of the United States.<sup>14</sup> These reference countries could include Australia, Austria, Belgium, Canada, Czech Republic, Denmark, Finland, France, Germany, Iceland, Ireland, Israel, Italy, Japan, Korea, Luxembourg, the Netherlands, New Zealand, Norway, Poland, Slovenia, Spain, Sweden, Switzerland, and United Kingdom.<sup>15</sup>



## How could an MFN model be implemented?

The Executive Order does not specify how an MFN would be implemented, but outlines a phased approach to identify and adopt an MFN pricing model for prescription drugs.<sup>16</sup> Within 30 days, the Secretary of Health and Human Services (HHS), working with the White House, Centers for Medicare & Medicaid Services (CMS), and other agencies, must communicate MFN price targets to manufacturers to align U.S. drug prices with those in other developed nations. This step was completed by June 11, 2025, initiating voluntary negotiations with manufacturers.<sup>17</sup>

If these voluntary efforts are deemed insufficient, the EO directs the Secretary to propose rulemaking for mandatory MFN pricing in government programs like Medicare, allow case-by-case importation of lower-cost drugs via FDA certifications, and coordinate with the Attorney General, FTC, and other agencies to address anti-competitive practices, export-related price disparities, and unsafe or improperly marketed drugs.<sup>18</sup> In early October 2025, the administration escalated demands, requiring manufacturers to align all brand product pricing with MFN targets or face further regulatory and trade consequences, including regulatory and enforcement action.<sup>19</sup> On November 6, 2025, CMS announced a voluntary CMMI "(GENEROUS) Model" under which Medicaid programs enrolled the pilot will be able to purchase prescription drugs at prices aligned with those paid in select other countries.<sup>20</sup> However, this program requires relies on pharmaceutical manufacturers voluntary participation.

While the Order outlines a phased framework for developing and implementing an MFN pricing model, beginning with voluntary targets, progressing to negotiated agreements, and escalating to mandatory measures, if necessary, it leaves several key issues unresolved. It raises potential conflicts with existing federal frameworks such as the Inflation Reduction Act( (IRA), which established a Medicare Drug Price Negotiation Program, allowing Medicare to negotiate prices for certain high-cost drugs and requiring manufacturers to pay rebates if prices increase faster than inflation.<sup>21</sup> If the MFN price is applied to drugs also subject to Medicare price negotiations, conflicts could arise if the MFN price exceeds the IRA's negotiated ceiling, potentially complicating the HHS Secretary's ability to set a Maximum Fair Price based on the criteria established under the IRA.<sup>22</sup>

Questions have also been raised regarding the executive branch's authority to impose mandatory pricing without congressional approval and the lack of key definitions within the Order.<sup>23</sup> In addition, stakeholders have raised concerns about potential adverse effects on pharmaceutical innovation and how this could impact access for patients abroad if companies change how they launch treatments in other countries.<sup>24</sup>



## Are tariffs and an MFN model the same thing?

No, tariffs and an MFN pricing model are not the same. A tariff is a tax imposed on goods imported into the U.S.,<sup>25</sup> whereas an MFN pricing model determines what certain U.S. payers, such as Medicaid and Medicare, pay for prescription drugs.

On September 15, President Trump announced a new 100% tariff on branded pharmaceutical drugs, unless the manufacturer has a production facility actively under construction in the United States.<sup>26</sup> The tariffs were set to take effect on October 1, however, the Administration paused implementation to allow time for negotiations with pharmaceutical manufacturers.<sup>27</sup> On September 30, 2025, the administration announced its first voluntary agreement with a pharmaceutical company to provide MFN-priced drugs to U.S. patients.<sup>28</sup> Other companies have begun to announce additional agreements with the White House, but it is unclear if these singular arrangements will pause the development of a mandated MFN.<sup>29</sup>

## When would an MFN impact consumers, caregivers, or health care providers?

The impact of an MFN policy is difficult to predict due to its complexity and interaction with existing programs such as the Inflation Reduction Act, 340B, and current reimbursement and supply chain systems.<sup>30</sup> In the short term, MFN may primarily pressure pharmaceutical companies to lower the list price of certain prescription drugs or ensure domestic production of pharmaceutical products; however, unless deeper reforms are implemented patients are unlikely to see immediate changes at the pharmacy counter.<sup>31</sup> This is largely because existing negotiations focus on pharmaceutical companies matching the "list price" of a prescription drug to its MFN price. However, the list price is not what consumers pay for a drug, or what payers pay for a drug, as this is the cost of the drug before discounts and rebates are applied. Therefore, for an MFN to impact consumers, there must be a mandate that any savings derived from an MFN be passed down to consumers.

Over time, however, MFN could influence drug prices, patient access, and innovation.<sup>32</sup> For example, pharmaceutical manufacturers may adjust global market plans, prioritizing high-value U.S. markets, delaying or scaling back launches in other regions, and reassessing research and development (R&D) investments based on perceived market risks.<sup>33</sup> Patients, caregivers, and healthcare professionals may encounter new clinical and operational challenges as formulary designs, reimbursement models, and supply chains shift in response to the policy.<sup>34</sup> For example, there is a risk that high-cost or specialized therapies could become less accessible, potentially leaving some patient populations underserved.<sup>35</sup> Ultimately, the effects of MFN will likely take time to materialize, with short-term impacts limited and long-term outcomes unclear, and dependent on if, how, and when the policy is implemented, making the impacts and benefits difficult to predict.<sup>36</sup>



## Who should I contact if I am concerned about an MFN and how it could impact me or my organization?

If you are concerned about the impact of an MFN policy, contact the USTR at [contactustr@ustr.eop.gov](mailto:contactustr@ustr.eop.gov) or via mail at 600 Seventeenth St. NW, Washington, D.C. 20506. You can also contact your federal representatives in the U.S. House of Representatives and U.S. Senate and ask them to ensure any MFN policy does not negatively impact access, innovation, and consumer affordability. While Congress has limited authority over international trade, it still has a powerful voice, and Members can share your concerns with the White House and USTR.



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1455 Pennsylvania Ave, NW, Suite 400, Washington, DC 20004

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