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Via Electronic Submission

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USTR-2025-0011

Jennifer Thornton
General Counsel
Office of the United States Trade Representative
Executive Office of the President
600 17th Street NW
Washington, D.C. 20509

Re: Request for Comments Regarding "Foreign Nations Freeloading on American-Financed Innovation," Federal Register Docket Number USTR-2025-0011

Dear Ms. Thornton:

The Part B Access for Seniors and Physicians (ASP) Coalition, which represents more than 300 patient and provider organizations across the country, offers this submission in response to the request for comments regarding the "Foreign Nations Freeloading on American-Financed Innovation," pursuant to the May 12, 2025, Executive Order (EO) 14297 "Delivering Most-Favored-Nation (MFN) Prescription Drug Pricing to American Patients."

The ASP Coalition has long raised concerns about the imposition of proposals such as 'foreign reference pricing systems,' including the 'most favored nation' or MFN pricing proposals outlined in EO 14297 and the intent to impose policies made by foreign countries onto millions of physicians and the patients they care for in America. Efforts by the Administration to reevaluate these policies put patient access to innovative treatments at risk.

We strongly believe that linking U.S. health care policy to other countries, that artificially suppress prices through access restrictions and subjective controls, ties the hands of providers in the U.S. by narrowing available treatments due to the threat of foreign trade barriers and market forces outside of their control. At a time when providers are grappling with a challenging reimbursement environment, they nor their patients can afford to be forced to navigate policies based on socialized medicine systems which are at times antithetical to our American values. These policy changes would not only impose price controls under Medicare, Medicaid, and in the private market, but would significantly harm providers' ability to deliver patient-centric care and upend the future development of innovative medicines.

As detailed below, our submission highlights the risks associated with said policies, offers surveys highlighting international physician opposition to government intrusion in health care decisions, and identifies other actions that indicate strong opposition among patients and provider organizations.

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History of MFN-type Proposals and Demonstrations in the U.S., Policy Opposition, & Risks Associated with Patients and Provider Organizations

On November 20, 2020, the Centers for Medicare & Medicaid Services (CMS) released an interim final rule creating the seven-year MFN Model on a nationwide, mandatory basis, set to begin on January 1, 2021.

In response to the MFN Model, the ASP Coalition expressed concerns that Medicare patients with cancer, and other serious and complex chronic conditions such as rheumatologic, autoimmune and inflammatory conditions; and those with blinding eye diseases, Crohn's disease and ulcerative colitis, rare chronic diseases, and serious mental illnesses would have faced massive hurdles in accessing critical therapies. The ASP Coalition sent a letter in December 2020, backed by 355 patient and provider organizations, urging Congressional action to delay the MFN Model and hold patients harmless from its policies.

CMS acknowledged repeatedly that the model would force beneficiaries to "forego" care; in fact, the CMS Office of the Actuary (OACT) predicted 19% lower utilization of these drugs due to "no access." Specifically, CMS reported the following in their MFN Model [CMS-5528-IFC] interim final rule:

- A portion of the MFN model "savings is attributable to beneficiaries not accessing their drugs through the Medicare benefit, along with the associated lost utilization;" and added that beneficiaries may "experience access to care impacts" by being forced to use an "alternative therapy that may have lower efficacy or greater risks, or postponing or forgoing treatment," et al. if MFN participants choose not to provide Model drugs or prescribe alternative therapies instead.
- CMS further noted that the OACT estimated $85.5 billion in savings, "net of the associated change in the Part B premium, in Medicare Part B spending," partly due to patients foregoing treatments.

In November 2020, the Coalition conducted surveys of physicians in the U.K., Germany, Australia, and France – four of the 22 OECD countries the MFN Model calculations derived from. The physicians – who treat complex conditions such as cancer, rheumatoid arthritis, and diabetes – all agreed that such payment structures put patients at risk. Our findings showed just how harmful MFN policies would be to patients.

In August 2021, CMS proposed to rescind the MFN Model in a notice of proposed rulemaking; CMS later published a final rule in the *Federal Register* on December 27, 2021, rescinding the November 2020, MFN Model interim final rule with comment period and removing the associated regulatory text at 42 CFR part 513 (these actions withdrew the MFN Model), effective February 28, 2022.

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Introducing MFN-type Policies in the U.S. & Risks Associated with Patients and Provider Organizations

Building on the evidence above/patterns of opposition towards similar MFN-type policies, physician and patient organizations have specifically expressed concerns that these policies would:

- ***Reduce Access to Innovative Medicines*** – the ASP Coalition believes that MFN-type policies would delay investment in R&D for innovative medicines, including new cures and therapies for diseases such as Alzheimer's and cancer. In fact, a 2018 report for the Department of Commerce found that international reference pricing and other foreign price controls suppress worldwide private research and development investment by 11-16% annually, impacting the number of new and innovative medicines brought to market. Additionally, according to the Biotechnology Innovation Organization (BIO), adopting foreign price controls would jeopardize access to new, innovative medicines for patients in need:
  - Nearly 90% of new medicines launched since 2011 are available in the U.S., compared to just 50% in France, 48% in Switzerland, and 46% in Canada.
  - 74 cancer drugs launched between 2011 and 2018, 95% are available in the United States, compared with 74% in the United Kingdom, 49% in Japan, and 8% in Greece.
- ***Jeopardize the U.S. Pharmaceutical Pipeline*** – the ASP Coalition believes these proposals (e.g., the IPI Model) would risk American medical innovation, citing reports, offered by BIO, that:
  - Price controls in OECD countries reduced global R&D spending by between $5 billion and $8 billion, enough to fund the discovery of three to four new drugs per year.
  - Prior to adopting price controls, European companies invested 24% more on prescription drug R&D than U.S.-based companies. By 2015, European-based companies had fallen behind their U.S. counterparts by 40%.
  - A 2018 study by researchers with Precision Health Economics found that eliminating price controls in OECD countries would lead a 12% increase in R&D and the development of 13 new drugs per year.
- ***Disrupt Patient Access*** – Though CMS and the Administration in the past have argued that MFN policies would "lower drug payment amounts for the most costly Medicare Part B drugs, thereby lowering program expenditures and out-of-pocket costs for beneficiaries," CMS has noted that there is "significant uncertainty with the potential effects of the MFN Model;" the ASP Coalition maintains that any 'foreign reference pricing' proposals would reduce patient access to current and future innovative treatments.

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Foreign Trade Policies that Undermine American Innovation & Harm Patient Access

Beyond MFN-type proposals and demonstrations offered by U.S. Administration's in the past, it is our concern that moving forward with the current EO would undermine and undervalue the current and future U.S. R&D pipeline.

As mentioned above, many countries employ discriminatory and restrictive drug pricing policies that systematically undervalue American medical innovation. For one, these practices disproportionately harm small biotechnology companies that often rely on attracting investors based on potential future revenue from a single or limited number of products to support their entire business and future R&D pipeline. Therefore, the U.S. risks allowing foreign governments to benefit from American-funded innovation, while simultaneously weakening the global competitiveness of the U.S. biotechnology sector. Instead of pursuing MFN price-setting policies that would harm U.S.-based innovation and erode access to innovative medicines, we should use trade agreements to encourage our trade partners to pay their fair share and increase their investment in global medical innovation.

Conclusion

If MFN drug pricing proposals are implemented, patients could face significant new barriers accessing the vital care they have come to rely on through Medicare Part B, including access to new and innovative therapies. This harmful policy would wreak havoc on the patient-provider relationship among those who rely on the critical Part B program specifically. The ASP Coalition urges the Administration to address these policies in its trade agreements to protect the most vulnerable beneficiaries and their access to lifesaving therapies.

Rather than institute policies that would hurt patient and providers, the ASP Coalition maintains that the Administration should support policies intended to improve the coordination, quality, and efficiency of health care services. The ASP Coalition looks forward to working with USTR to advance a trade agenda that reinforces and protects provider-patient relationships and the high-quality care that our country has consistently been able to offer.