

June 28, 2024

The Honorable Katherine Tai United States Trade Representative Office of the United States Trade Representative 600 17th Street, NW Washington, D.C. 20508

Re: Request for Comments on Proposed Modifications and Machinery Exclusion Process in Four-Year Review of Actions Taken in the Section 301 Investigation: China's Acts, Policies, and Practices Related to Technology Transfer, Intellectual Property, and Innovation; Docket ID No. USTR-2024-0007; 89 Fed. Reg. 46,252 (May 28, 2024)

Dear Ambassador Tai:

The Federation of American Hospitals (FAH) is the national representative of more than 1,000 leading tax-paying hospitals and health systems throughout the United States (US). The FAH's members provide patients and communities with access to high-quality, affordable health care in both urban and rural areas across 46 States, Washington DC, and Puerto Rico. Our members include teaching, acute, inpatient rehabilitation, behavioral health, and long-term care hospitals, and together they provide a wide range of inpatient, ambulatory, post-acute, emergency, children's, and cancer services to patients in diverse communities across the country.

The FAH appreciates this opportunity to submit comments to the US Trade Representative (USTR) regarding its Request for Comments on *Proposed Modifications and Machinery Exclusion Process in Four-Year Review of Actions Taken in the Section 301 Investigation: China's Acts, Policies, and Practices Related to Technology Transfer, Intellectual Property, and Innovation published in the Federal Register on May 28, 2024 (Tariff Modifications). The FAH supports the USTR's efforts to safeguard US technology, intellectual property, and innovation from potential interference by the Chinese government. However, the FAH is concerned with the immediate and detrimental implications that the Tariff Modifications may have on the healthcare sector, patient care, and safety, if implemented as proposed.*

¹ 89 Fed. Reg. 46,252 (May 28, 2024).

The US healthcare system is currently dependent on Chinese-manufactured medical supplies. This dependence is a result of decades of globalization and the optimization of supply chains to reduce costs. Chinese manufacturers have established themselves as reliable and cost-effective suppliers of essential medical goods, including personal protective equipment (PPE), e.g., masks, and essential items such as syringes. Our member hospitals and healthcare systems rely heavily on uninterrupted access to essential supplies, including medical equipment and devices, which are necessary to deliver effective and timely healthcare services. The Tariff Modifications propose to add substantial tariff costs to certain types of medical equipment, including syringes, medical needles, and PPE (Medical Necessities)² in an attempt to encourage reliance on domestic supplies and limit reliance on foreign produced materials. While we support this end goal, we are concerned that increasing tariffs on these goods will disrupt the supply of medical products on which American hospitals and medical facilities rely and impose cost increases for products with few, if any, alternative sources.

Unfortunately, as noted in more detail below, there currently is not enough domestic production of many of the types of Medical Necessities used by hospitals and the medical community. Further, American manufacturers, importers, and distribution companies have not had enough time to move their operations out of China or find alternative sources to the Chinese goods on which they rely before the Tariff Modifications go into effect on August 1 of this year. The FAH is concerned that the Tariff Modifications will substantially increase costs for Medical Necessities and disrupt the reliable supply of Medical Necessities, which will lead to supply chain shortages, which in turn will adversely affect patient care.

While the intention behind the Tariff Modifications is understandable, the potential negative impacts on American hospital medical supply chains cannot be overlooked. A more balanced approach that includes exclusion of all healthcare goods and products or Medical Necessities from the Tariff Modifications, or at a minimum, a multi-year delay in the imposition of the Tariff Modifications and/or lower tariffs for Medical Necessities would better serve the dual goals of reducing dependence on Chinese goods and ensuring the stability of the US healthcare system.

I. BACKGROUND

The COVID-19 pandemic highlighted the fragility of global supply chains, especially for medical supplies. During the height of the pandemic, many hospitals faced severe shortages of PPE, ventilators, and other critical supplies. Imposing additional tariffs on Chinese-made medical supplies could worsen these vulnerabilities. The healthcare system, and specifically the uninterrupted supply of medical supplies and equipment, has been further strained by recent environmental regulations placed on the industry.³ The Tariff Modifications may lead to a significant reduction in the importation of the medical supplies, which may further exacerbate

² Medical Necessities include all needles, syringes, PPE (including gloves) and all durable medical equipment (including crutches, canes, and walkers).

³ Notice of Proposed Rulemaking, Environmental Protection Agency; NESHAP Ethylene Oxide Emission Standards for Sterilization Facilities; Docket ID No. EPA-HQ-OAR-2019-0178; 88 Fed. Reg. 22,790 (April 13, 2023); see also, Pesticide Registration Review: Proposed Interim Decision and Draft Risk Assessment Addendum for Ethylene Oxide; Docket ID No. EPA-HQ-OPP-2013-0244; 88 Fed. Reg. 22,447 (April 13, 2023).

hospital shortages of healthcare supplies. In addition, domestic manufacturers likely will not be able to scale up production quickly enough to meet demand, especially for specialized items that require specific materials or manufacturing processes that are not currently available or economically viable in the US.

For example, there are no US-based manufacturing alternatives of enteral feeding syringes (with ENFit connections) and virtually all of the supply of global enteral feeding syringes, regardless of brand, is produced in China. Enteral feeding syringes are medical devices used to provide nutrition to individuals who cannot obtain nutrition orally, cannot swallow properly, and/or need nutritional supplementation. Enteral feeding syringes are routinely used in neonatal care units to provide lifesaving nutrition to children born prematurely or who are suffering from other medical complexities requiring their use. While some US companies may plan to develop, or are in the process of developing, a new manufacturing infrastructure outside of China, they certainly will not be able to do so before August 1, 2024, as it takes years to establish new manufacturing locations, obtain US regulatory approvals, and increase sterilization capacity which is required for the syringes before use. The Tariff Modifications, which propose to place a 50 percent tariff increase on syringes, represent the first time the USTR plans to subject syringes to the imposition of a tariff. US-based healthcare companies have simply not had enough prior notice or time to react to such a substantial change.

Additionally, higher tariffs on medical supplies would translate to higher costs for hospitals and other medical facilities. This increase in healthcare costs could have a broader economic impact, placing financial strain on financially distressed hospitals and healthcare systems already stretched thin by the pandemic and other health crises, such as the Change Healthcare cyberattack.

The Tariff Modifications' potential for market disruptions and impacts to the medical community is reminiscent of the baby formula shortage crisis that occurred in 2022. That crisis was precipitated by the COVID-19 pandemic and associated supply chain issues and was exacerbated when the Food and Drug Administration, for safety reasons, shut down a manufacturing facility after several infants were sickened by one of the formulas produced at the facility. The facility made nearly half of the US supply of certain types of baby formula, including for babies with allergies and other health conditions requiring a specialized diet. The repercussions of the facility shutdown were felt for months afterwards and severely impacted American families' access to certain types of baby formula. The FAH is concerned that the Tariff Modifications could have similar negative impacts in that they could force certain US companies that rely on Chinese manufactured materials to shut down or slow down production if they do not have access to, or cannot afford, the foreign produced materials necessary to manufacturer their US products.

II. COMMENTS

The FAH strongly supports the development of domestic manufacturing and supply of Medical Necessities and other medical devices and equipment and the healthy competition amongst US manufacturing companies to support the same. Yet, we are very concerned about the impact the Tariff Modifications will have on the medical community and patients across the

country immediately after these tariffs are imposed. Thus, we urge USTR to adopt the solutions presented in our comments below.

a. The USTR Should Exempt All Healthcare Goods and Products from the Tariff Modifications

As noted above, healthcare providers depend on a steady and reliable supply of medical goods. The Tariff Modifications could lead to shortages and delays, making it challenging to maintain adequate stock levels of essential items such as PPE, diagnostic tools, and life-saving equipment. Tariffs will lead to higher costs for importing critical medical supplies and equipment. The combined effect of supply chain disruptions and higher costs could limit access to essential medical care. Further, in times of crisis, such as pandemics or natural disasters, the need for prompt and unhindered access to medical supplies is paramount. The Tariff Modifications could hinder the rapid response required to address such emergencies, putting public health at risk.

For these reasons, the FAH requests that the USTR exempt all healthcare goods and products from the Tariff Modifications. Alternatively, the FAH requests that the USTR exempt all Medical Necessities from the Tariff Modifications.

b. Alternatively, the USTR Should Implement a Multi-Year Delay in Tariff Imposition For Medical Necessities

The FAH supports development of domestic and other manufacturing sources, but those sources currently do not exist, and the medical community must rely on foreign manufacturing and products to serve our patients. If the goal of the tariffs is to reduce dependence on Chinese-manufactured medical supplies, the FAH urges the USTR to adopt a more gradual approach to ensure supply chain availability for these critical medical supplies. If an exclusion for all healthcare goods/products or Medical Necessities is not granted, the FAH requests a delay in the imposition of tariffs. A multi-year delay would provide sufficient time for American manufacturers to begin producing a domestic supply of these products or find alternatives to Chinese sources. Specifically, additional time would allow for necessary investments in manufacturing infrastructure, workforce training, and regulatory approvals to ensure that the quality and quantity of domestically produced products meet the needs of the healthcare system.

c. Lower Tariff Rates if Immediate Imposition is Necessary

In the event that tariffs are imposed immediately, the FAH urges that the tariffs on critical medical supplies, including the Medical Necessities, be set at a substantially lower rate and phased in. This would help mitigate the impact on supply chain availability and healthcare costs, ensuring that hospitals can continue to provide high-quality care without facing significant disruptions to supply of critical medical supplies. Imposing lower tariff rates over several years would give manufacturers time to scale up domestic production and ensure that quality and supply can meet demand. This phased in approach would also provide hospitals with the necessary time to adjust their procurement strategies and budgets.

The FAH appreciates the opportunity to submit these comments. If you have any questions or wish to discuss these comments further, please contact me or any member of my staff at (202) 624-1500.

Sincerely,