



June 28, 2024

PUBLIC VERSION

Amb. Katherine Tai
Office of the United States Trade Representative
600 17th Street NW
Washington DC 20508

Re: ***China's Acts, Policies, and Practices Related to Technology Transfer, Intellectual Property, and Innovation, 89 Fed. Reg. 46,252 (USTR May 28, 2024) (Request for Comments) – Docket ID USTR-2024-0007***

Dear Ambassador Tai:

The American Medical Manufacturers Association (“AMMA”) welcomes this opportunity to comment on the proposals developed by the Office of the U.S. Trade Representative (“USTR”) pursuant to the agency’s four-year review of the Section 301 investigation into unfair Chinese trade practices, and the President’s May 14, 2024 memorandum and directive to the agency.

EXECUTIVE SUMMARY

AMMA strongly supports the Administration’s commitment to increasing Section 301 tariffs on critical medical supplies such as face masks, medical gloves, syringes, and needles. USTR’s proposal is an important step in recognizing the importance of essential medical products as a strategic sector for national security. Addressing unfair trade practices enables the United States to achieve and protect a robust and healthy domestic supply chain for essential medical supplies, and is all the more critical given ongoing safety and quality concerns affecting imported plastic syringes and N95 face masks. However, further action must be taken to ensure that U.S. healthcare workers and patients have access to safe and reliable medical products, and to expand the United States’ ability to produce these crucial goods.

AMMA encourages the Administration to take the following actions in finalizing the proposed modification:

- The tariffs on all face masks, gloves, syringes, and needles of tariff subheadings 6307.90, 4015.12, 4015.19, 9018.31, and 9018.32 should be raised to a minimum of 100%.
- The effective date should be August 1, 2024 for all increases in tariffs on these critical medical supplies.
- The Administration should undertake a whole-of-government approach to support reshoring of America’s supply chains for critical medical supplies.

BACKGROUND ON AMMA

AMMA is an alliance of domestic manufacturers of essential medical supplies and partners, and is dedicated to the goal of creating a market environment that promotes, incentivizes, and helps sustain the domestic ownership and operation of essential medical products manufacturing. Our vision is a competitive, 21st century domestic supply chain that reduces shortages, bolsters our preparedness for future emergencies, and safeguards our nation's safety and security while supporting American jobs.

The COVID-19 pandemic highlighted significant flaws in the United States' supply chain for critical medical products, as the country encountered delayed shipments, counterfeit and used personal protective equipment ("PPE") products sold as new, and illegal and unethical forced labor. We must never again allow the United States to be so dependent on imported critical medical products. AMMA and its member companies are committed to providing a consistent supply of quality domestic medical supplies, including production and supply of raw materials to further strengthen the domestic supply chain.

CHANGES ARE NEEDED TO ENSURE THE MODIFICATIONS' SUCCESS

AMMA strongly supports USTR's proposal to increase Section 301 tariffs on essential medical products. As was made clear in President Biden's Executive Orders 14001 and 14017,¹ the National Strategy for a Resilient Public Health Supply Chain,² and the Make PPE in America Act,³ it is vital for the United States to secure a safe and reliable public health supply chain encompassing drugs, biological products, PPE, and medical devices—including diagnostic and testing devices—as well as ancillary supplies required to deliver these countermeasures, including syringes and needles.

Currently, the U.S. domestic public health supply chain faces strong headwinds in the form of foreign government subsidies affecting exporters' finished goods and raw material inputs,⁴ unfair labor practices abroad, and the costs associated with start-up production. Section 301 tariffs are an important tool for resolving these issues. In finalizing its proposed modifications, USTR should increase the Section 301 tariffs applicable to all face masks, gloves, syringes, and needles of tariff subheadings 6307.90, 4015.12, 4015.19, 9018.31, and 9018.32 to a minimum of 100%, implement tariff increases effective immediately, and engage with other agencies in a whole-of-government approach to support domestic

¹ *America's Supply Chains*, Executive Order 14017 (Feb. 24, 2021), 86 Fed Reg. 11,849 (Mar. 1, 2021); *A Sustainable Public Health Supply Chain*, Executive Order 14001 (Jan. 21, 2021), 86 Fed. Reg. 7,219 (Jan. 26, 2021).

² *National Strategy for a Resilient Public Health Supply Chain* (July 2021), available at <https://www.phe.gov/Preparedness/legal/Documents/National-Strategy-for-Resilient-Public-Health-Supply-Chain.pdf>.

³ *Infrastructure and Investment Jobs Act*, Public Law 117-58 (Nov. 15, 2021) at Sec. 70951-70953, 135 Stat. 429, 1312-1316, available at <https://www.congress.gov/117/plaws/publ58/PLAW-117publ58.pdf>.

⁴ See, e.g., Alexander Brown, et al., *Investigating state support for China's medical technology companies*, MERCATOR INSTITUTE FOR CHINA STUDIES (Nov. 2023), available at <https://merics.org/en/report/investigating-state-support-chinas-medical-technology-companies>.

production. These actions are necessary to (1) adequately address unfair Chinese trade practices affecting PPE and other critical medical supplies, (2) avoid the use of unsafe and unreliable medical supplies by U.S. healthcare workers and patients, and (3) maintain and grow the domestic industrial base for critical medical products.

A. The Proposed Tariff Increases are Insufficient and Will Leave the United States Vulnerable

In its May 28, 2024 *Federal Register* notice, USTR proposes to increase the tariffs on tariff provisions 6307.90.9845,⁵ 6307.90.9850, 6307.90.9875, and 4015.12.10, pertaining to respirators, non-disposable masks, and medical/surgical gloves to 25%, while increasing the tariffs on provisions 9018.31.00 and 9018.32.00, pertaining to syringes and needles to 50%. U.S. import statistics confirm that these increases will not be sufficient to eliminate or counteract unfair Chinese practices. At the proposed levels, they will also do little to secure the U.S. supply chain for PPE and other critical medical supplies.

(1) U.S. import statistics confirm that at the proposed levels, the increased tariffs will be ineffective in counteracting unfair Chinese practices

- **Respirators and Other Non-Disposable Face Masks:** The Chinese respirators and other non-disposable face masks covered by USTR's proposal are imported at extremely low prices. For example, according to data obtained from the U.S. International Trade Commission ("ITC"), January-April 2024 imports from China under tariff codes corresponding to respirators (6307.90.9842, 6307.90.9844, and 6307.90.9850) had an average unit value of 19 cents. [\[\[Confidential Information Redacted\]\]](#). China has also significantly increased the quantity of its respirator exports to the United States in 2024 relative to 2023 levels. For non-respirator, non-disposable masks, the situation is similar, with China representing the greatest source of imports, at average unit values well below those of other meaningful import sources. Given China's aggressive pricing, a 25% tariff is likely to have little effect on China's practices or on purchasing choices in the U.S. market.
- **Medical or Surgical Gloves:** The situation is similar for these goods. Official import statistics maintained by the ITC show that Chinese imports have fallen in average unit value from 53 cents per dozen pairs in 2022 to 37 cents per dozen pairs in January-April 2024. China has become the United States' largest source of imported medical/surgical gloves, outstripping Malaysia, which has an average import value of 62 cents per dozen pairs.
- **Syringes and Needles:** ITC data shows that China is the lowest-priced source of imports under the codes identified in USTR's notice, with a 2023 average unit value of just 10 cents per unit. The average unit value for other top-ten import sources was 75

⁵ AMMA notes that provision 6307.90.9845 has not been in use since 2022, after which it was split into two distinct subheadings numbered 6307.90.9842 (for surgical N95 respirators) and 6307.90.9844 (for all other N95 respirators). AMMA understands USTR as proposing to increase tariffs on all goods corresponding to former provision 6307.90.9845.

cents per unit in 2023. China is also by far the largest source of imports, with nearly 2 billion units shipped to the United States last year. Worryingly, China has substantially stepped up its imports in 2024 relative to 2023 levels, even as it offers rock-bottom prices.

The low prices of Chinese imports, coupled with China's aggressive targeting of the U.S. market, indicate that China will simply ship through the proposed 25% tariff for certain face masks and gloves, and the 50% tariff for syringes and needles. The proposed tariffs are therefore insufficient to fulfill the goals of the Section 301 investigation. Tariffs of a minimum of 100% would better fulfill the Administration's goal of altering China's practices.

(2) At the proposed levels, the increased tariffs will be ineffective in securing the U.S. supply chain for PPE and other critical medical products

China is not a reliable backstop for U.S.-based manufacturing of critical medical supplies. [\[\[Confidential Information Redacted\]\]](#). Reliance on China for critical medical products is also inadvisable due to the unique safety risks that Chinese products pose. These risks are underscored by the U.S. Food & Drug Administration's recent announcements and subsequent recalls stemming from quality and performance issues affecting Chinese syringes.⁶

B. The Proposal Leaves Out Critical Products

USTR's proposed modification would affect Chinese goods imported under six tariff codes identified in Annex A of the agency's May 28, 2024 notice.⁷ But while it is crucial for the United States to increase Section 301 tariffs on goods corresponding to these codes, the proposal should include all face masks of tariff subheading 6307.90, as well as all gloves of tariff subheadings 4015.12 and 4015.19. Going forward, AMMA also encourages USTR to continue assessing the effective rate of tariffs on the full range of products identified in the Make PPE in America Act,⁸ as well precursors and raw materials for PPE and other critical medical supplies like syringes and needles.

- **Disposable Face Masks:** Annex A to USTR's proposal does not identify tariff provision 6307.90.9870, covering disposable, non-respirator textile face masks. But the President's May 14, 2024 memorandum directed USTR to increase the Section 301

⁶ See *UPDATE: Evaluating Plastic Syringes Made in China for Potential Device Failures: FDA Safety Communication*, U.S. Food and Drug Administration (June 20, 2024), available at <https://www.fda.gov/medical-devices/safety-communications/update-evaluating-plastic-syringes-made-china-potential-device-failures-fda-safety-communication>.

⁷ As noted previously, one of the codes identified in USTR's notice, 6307.90.9845, is no longer in the Harmonized Tariff Schedule of the United States ("HTSUS"), having been split at the beginning of 2023 into two new codes numbered 6307.90.9842 and 6307.90.9844. AMMA understands USTR as proposing to increase tariffs on all goods corresponding to former provision 6307.90.9845.

⁸ The Act defines PPE as: "surgical masks, respirator masks and powered air purifying respirators and required filters, face shields and protective eyewear, gloves, disposable and reusable surgical and isolation gowns, head and foot coverings, and other gear or clothing used to protect an individual from the transmission of disease."

tariffs on face masks generally. USTR's decision to exempt provision 6307.90.9870 from the scope of increased tariffs is at odds with the President's direction.

Further, face masks of the kind covered by provision 6307.90.9870 have a vital role to play in protecting U.S. healthcare workers and patients. It is imperative that existing domestic production of these goods remains competitive, and that the Administration encourage additional U.S. manufacturing. While Chinese imports under this code have fallen over time, China remains the United States' top import source for these important products. Moreover, Chinese import prices are absurdly low – just 2 cents per mask in January-April 2024, compared with a value of 8 cents per mask from Mexico, the next largest import source. [\[\[Confidential Information Redacted\]\]](#). AMMA urges USTR to include provision 6307.90.9870 in the final modification, at a duty rate of at least 100%.

- **Gloves**⁹: Annex A to USTR's proposal does not identify codes pertaining to nitrile gloves for dental or veterinary use, or such gloves for industrial and commercial purposes. While gloves for purely medical/surgical use are of unique concern in the context of U.S. supply chain resiliency, nitrile gloves are also widely used in the dental and veterinary sectors. They are also needed in manufacturing operations for sensitive technologies like semiconductors, as well as in public safety, food preparation, and sanitation contexts that are independently critical to U.S. national and economic security. USTR should therefore extend the proposed tariff modifications to cover all gloves of tariff subheadings 4015.12 and 4015.19. Failure to do so will encourage import misclassification of Chinese medical/surgical gloves as gloves of other types in order to avoid Section 301 tariffs. Further, should another pandemic or other crisis implicating national security arise, securing an adequate and reliable supply of gloves for non-medical/surgical use will be critical to maintaining U.S. industrial and economic capacity.

Finally, Annex A to USTR's proposal lists certain tariff codes for face masks, gloves, and syringes/needles, but does not identify other goods listed in the Make PPE in America Act. Nor does it identify precursors and raw materials for production of critical medical supplies including such as PPE, syringes, and needles. But these products have also suffered from unfair Chinese import competition, and they should not be ignored as America seeks a robust and healthy domestic supply chain for essential medical supplies. Going forward, AMMA encourages USTR to consider the effective rate of tariffs on these products, with the goal of diversifying the global supply chain for a wide range of critical PPE, medical supplies, and inputs away from China and ideally into the United States.

C. The Effective Date of the Tariff Increases Should Be August 1, 2024 for All PPE and Critical Medical Supplies

USTR proposes to delay any increase in tariffs on gloves of tariff line 4015.12.10 until 2026. There is no reason to delay increased Section 301 tariffs on gloves, given the United States' increasing ability to produce gloves domestically, and the headwinds for domestic production that China's artificially low prices create. Without the tariffs in place, the

⁹ Annex A identifies tariff line 4015.12.10, corresponding to medical or surgical gloves of vulcanized rubber other than hard rubber. Within this tariff line are two ten-digit provisions: one corresponding to medical gloves and a second corresponding to surgical gloves.

domestic industry will continue to struggle with demand, and demand signals are critical for ramping up production. Delay will only subject the United States' industry to additional harm from China's relentless low pricing, without advancing the goal of securing a safe and reliable supply for healthcare workers, patients, and others. AMMA also notes that new domestic glove production lines are scheduled to come online in 2024. [\[\[Confidential Information Redacted\]\]](#). Rather than allow continued low-priced imports from China to imperil this production and other U.S. interests, USTR should impose new tariffs on gloves immediately, at the rate of at least 100%. Indeed, AMMA believes that increased Section 301 tariffs at a rate of at least 100% should apply to all face masks, gloves, syringes, and needles of tariff subheadings 6307.90, 4015.12, 4015.19, 9018.31, and 9018.32 effective August 1, 2024.

D. A Whole-of-Government Approach is Required

While tariffs have an important role to play in counteracting unfair Chinese practices and securing the U.S. supply chain for PPE and other critical medical supplies, government-wide coordination both within and outside the context of Section 301 is required to ensure that the United States has safe, reliable, and adequate supply of critical medical products.

The necessary, multi-pronged approach includes strong enforcement of the tariffs by U.S. Customs & Border Protection, reduction of waivers from domestic purchasing requirements, and incentives for healthcare providers to procure domestically produced critical medical supplies. As explained in AMMA's April 24, 2024 white paper on the state of the U.S. PPE industry,¹⁰ the Administration should accelerate firm domestic purchase commitments from U.S. agencies, standardize "Made in America" parameters and definitions government-wide, and implement domestic preferences for the Strategic National Stockpile. Likewise, the government should incentivize private purchasing of U.S.-made products by, for example, creating payment adjustments through the Centers for Medicare & Medicaid Services to address cost disparities between American-made and foreign goods, building on the precedent set for surgical N95 respirators.

Other countries are taking strategic action to secure their supply lines in the wake of the pandemic and the global supply chain weaknesses that it exposed. Certainly, as the Section 301 investigation has demonstrated and as highlighted in a recent report issued by the Mercator Institute for Chinese Studies,¹¹ the Chinese Government displays no hesitation in backing domestic production of medical goods through diverse forms of direct subsidies, tax concessions, and financing. China uses these and other forms of support not only to further production in China, but to expand China-owned/controlled production in third countries. Brazil has raised import duties on syringes/needles to more than 140%, thereby shielding its domestic industry from unfair trade practices like China's. The United States should be no less aggressive in taking strong, whole-of-government steps to ensure

¹⁰ AMERICAN MEDICAL MANUFACTURERS ASSOCIATION, *A Reshoring Movement Spurred by the Pandemic* (Apr. 24, 2024), available at <https://www.ammaunited.org/2024/a-reshoring-movement-spurred-by-the-pandemic/>.

¹¹ Alexander Brown, et al, *Investigating state support for China's medical technology companies*, MERCATOR INSTITUTE FOR CHINA STUDIES (Nov. 2023), available at <https://merics.org/en/report/investigating-state-support-chinas-medical-technology-companies>.

its access to safe, reliable, and sufficient supply of critical medical supplies, including but not limited to the specific products identified in USTR's proposal.

Finally, USTR and the Administration should be wary of the potential for partial and hesitant action to create perverse results. Tariffs on Chinese goods, without other strategic actions, are likely to result in supply shifting to other low-cost countries. This is a particular concern with nitrile gloves. Malaysia is a top producer of these goods and a significant source of U.S. imports. But it is no more useful, from the perspective of U.S. supply chain resiliency, for the United States to depend overwhelmingly on Malaysia for access to nitrile gloves than it is for the United States to depend on China for these crucial products. The example of nitrile gloves illustrates the importance of a coordinated and, above all, strategic, whole-of-government approach to ensuring that the United States counteracts unfair practices and secures a safe and reliable domestic public health supply chain.

CONCLUSION

AMMA and its member companies are heartened by the Administration's willingness to take concrete action with respect to the pernicious effects of unfair Chinese trade practices on the United States' supply chain for PPE and other critical medical supplies, such as syringes and needles. However, as discussed above, additional action will increase the effectiveness of USTR's current proposal, allowing the proposed modifications to better serve the goals of the Section 301 investigation, support provider and patient safety, and reorient global supply chains to support U.S. PPE and critical medical supplies production.

Specifically, AMMA encourages the Administration to take the following actions in finalizing the proposed modification:

- The tariffs on all face masks, gloves, syringes, and needles of tariff subheadings 6307.90, 4015.12, 4015.19, 9018.31, and 9018.32 should be raised to a minimum of 100%.
- The effective date should be August 1, 2024 for all increases in tariffs on these critical medical supplies.
- The Administration should undertake a whole-of-government approach to support reshoring of America's supply chains for critical medical supplies.

Respectfully submitted:



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