



American Medical Manufacturers Association

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April 15, 2026

Jennifer Thornton

General Counsel, Office of the United States Trade Representative

600 17th Street NW, Washington, DC 20508

Re: Comments of the American Medical Manufacturers Association on the Initiation of Section 301 Investigations: Acts, Policies, and Practices of Certain Economies Relating to Structural Excess Capacity and Production in Manufacturing Sectors (Docket No. USTR-2026-0067)

Dear General Counsel Thornton:

The American Medical Manufacturers Association (AMMA) submits these comments in response to the Section 301 investigations initiated by the Office of the United States Trade Representative (USTR) on March 11, 2026. AMMA is the leading national trade association representing domestic manufacturers of personal protective equipment (PPE) and needles and syringes.

Our members are U.S. based companies that manufacture the gloves, masks, gowns, respirators, needles, and syringes upon which American hospitals, healthcare workers, and first responders depend every day. These essential supplies underpin the functioning and resilience of the U.S. healthcare system. Currently the U.S. faces a proven national security vulnerability as a significant amount of these goods are sourced from foreign manufacturers operating under government subsidies untethered from market economics.

AMMA strongly supports the initiation of these investigations. The acts, policies, and practices of China, India, Malaysia, Vietnam, Thailand, and other investigated economies have systematically hollowed out U.S. domestic PPE manufacturing through state-directed overproduction and predatory pricing. The harm is severe and ongoing. More importantly, the overconcentration of U.S. medical supply chains in a small number of foreign countries has created an active national security vulnerability. This vulnerability is one that foreign governments have already demonstrated a willingness to exploit.

AMMA urges USTR to pursue precise, targeted tariff remedies that are specifically focused on PPE products rather than broad-based sectoral tariffs. Targeted tariffs, calibrated to the specific PPE categories where foreign excess capacity is most damaging and where domestic manufacturing resilience is most critical, will allow remedies to achieve their maximum effect for addressing acts, policies, and practices that unfairly and unreasonably burden and restrict U.S. commerce. Broad tariffs applied across diverse manufacturing sectors risk dissipating their corrective impact. The Section 301 investigations should therefore focus their tariff recommendations on PPE product categories where the impact of unfair foreign acts, policies, and practices is clearest and the domestic manufacturing base most in need of relief.

Our comments below address the specific issues raised in this investigation as they apply to PPE and syringes and needles, a sector we urge USTR to designate as a priority.

I. THE STATE OF U.S. PPE MANUFACTURING

The United States now imports 80 to 90 percent of its total PPE supply. This is not a market outcome. It is the direct result of foreign government industrial policy that has priced domestic manufacturers out of their own market. ^[1] In 2024, more than 87 percent of U.S. medical gloves were imported from just three countries: Malaysia, China, and Thailand. ^[2] The United States still relies heavily on foreign sources for surgical masks



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and N95 respirators. Despite lessons from past supply shocks, PPE supplies remain dependent on overseas production, leaving the country vulnerable to supply shocks and geopolitical risk. ^[1]

Domestic dependence is similarly acute in surgical and isolation gowns, particularly in higher-barrier products required for moderate to high-risk procedures. These gowns are essential to maintaining sterile conditions and preventing the transmission of infectious agents in clinical settings. The North American surgical gowns market was valued at approximately \$2.78 billion in 2021 and is projected to reach approximately \$4.55 billion by 2027, reflecting sustained demand driven by surgical volume and infection control requirements. ^[20] Despite this demand, the U.S. market remains heavily reliant on imports, with approximately 80 to 90 percent of supply sourced from China and Southeast Asia. ^[20]

Half of U.S. nitrile glove manufacturers have been driven out of business in the past three years. ^[24] Domestic facilities that survived are operating well below viable utilization rates. This is not because of a lack of demand, but instead because subsidized imports undercut domestic pricing by margins that no unsubsidized U.S. producer can sustain.

AMMA's members have invested hundreds of millions of dollars in U.S.-based manufacturing infrastructure. Combined domestic capacity for nitrile gloves among AMMA members currently stands at approximately 4.8 billion units per year, scalable to over 30 billion annually by mid-2026 with two additional facilities coming online. ^[24] One member operates a 215-acre campus currently producing 200 million gloves per month with a build-out potential of 1.6 billion gloves per month. That capacity is not being fully realized, because subsidized imports make it commercially untenable to do so.

PPE Category	U.S. Import Dependence	Primary Source Countries
Nitrile Examination Gloves	>90%	Malaysia (65–70%), China, Thailand
Surgical Masks	95%	China, Southeast Asia
N95 Respirators	70%	China
Needles & Syringes	Significant and growing	China (dominant since 2021)
Isolation & Surgical Gowns	80–90%	China, Southeast Asia

[Data: AMMA member data; ITA; Census Bureau. Current figures can be verified via USITC Dataweb, HTS codes: 4015.12 (nitrile gloves), 6307.90 (respirators), 6210.10 (gowns), 9018.31 (syringes), 9018.32 (needles).]

II. THE CASE FOR TREATING PPE AS A PRIORITY SECTOR

The concentration of U.S. medical supply chains in a small number of foreign countries is the result of unreasonable, discriminatory practices that burden and restrict U.S. commerce. Foreign governments control the pricing and availability of products on which American healthcare workers and patients depend. They have shown they will use that control when their own interests require it.



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A. Foreign Governments Have Restricted Medical Supply Exports As a Weapon of Trade

The risk of foreign supply weaponization is not theoretical. It has already been exercised in practice. Several investigated economies have already acted on this vulnerability, restricting medical supply exports to serve their own needs and leaving U.S. hospitals scrambling for supply:

- China introduced documentation and licensing requirements that materially delayed outbound PPE shipments at the moment of peak global need.^[3]
- India's Directorate General of Foreign Trade restricted PPE exports for months, easing restrictions only through export quotas.^[4]
- Malaysia regulates origin certification for glove exports and limits transshipped foreign production, giving it direct regulatory leverage to throttle supply under any national policy shift. With 65 to 70 percent of U.S. medical glove imports now projected to originate from Malaysia, this represents a single point of failure.^[5]

The supply chain disruptions that resulted from these actions were not isolated incidents. They reflected a structural vulnerability that was decades in the making. The concentration of global PPE manufacturing in a small number of countries creates systemic risk that cannot be mitigated by stockpiling alone.

B. China's Use of Supply Chain Control as a Strategic Instrument

China's record in other critical industries shows the dangers of letting a single adversarial nation dominate key U.S. supply chains. In 2023, China imposed export bans on gallium and germanium, materials critical to U.S. semiconductor manufacturing. **These export bans were direct retaliation for U.S. export controls.** This established a clear template: supply chain dominance is a geopolitical tool, and Beijing is willing to use it.^[6]

The Congressional Select Committee on the Chinese Communist Party has documented that China uses state subsidies and civil-military fusion policies to deliberately dominate global medical, biotech, and critical mineral supply chains as a matter of explicit national strategy.^[7] China's syringe and needle exports to the United States increased dramatically between 2018 and 2023, and China became the top global exporter of syringes by 2021. This was driven by state subsidies, not market efficiency.^[8, 9]

China is also actively working to preserve its market dominance in the face of U.S. tariff actions. Chinese manufacturers have migrated production capacity to Vietnam, Indonesia, and Thailand specifically to circumvent tariff enforcement. This shift is corroborated by public statements from Hartalega CEO Kuan Mun Leong, who confirmed in September 2025 that Chinese rubber manufacturers had established plants in Vietnam and Indonesia expressly to export to the U.S. under lower-tariff country-of-origin labels.^[18] The scale of this capacity migration is significant: a separate federal proceeding (BIS-2025-0258) references a new Vietnamese glove facility with 8 billion units of annual capacity coming online in Q4 2025.^[19] Tariff actions targeting China alone are therefore insufficient.

C. The Broader Pattern of Supply Chain Instability

Geopolitical events consistently demonstrate that supply chains concentrated in foreign countries and that depend on global maritime chokepoints are inherently fragile. The ongoing Strait of Hormuz disruption is one recent example. The petrochemical feedstocks for nitrile rubber production flow through the same disrupted corridors as Middle East energy exports, placing additional upstream pressure on Malaysian and Thai glove manufacturers and on the South Korean NBR latex suppliers that U.S. domestic manufacturers depend on for their own raw materials.^[24] We raise this example as the most recent illustration of a recurring pattern: when geopolitical conditions shift, U.S. access to foreign-manufactured medical supplies is at risk, and there is no domestic industrial base left to fill the gap.

China's purchase of discounted Iranian crude through shadow fleet operations, including ship-to-ship transfers conducted in Malaysian waters, has been documented by researchers tracking Iran's oil sanctions evasion networks.^[22, 23] These arrangements further illustrate how the supply chains feeding 90 percent of U.S. medical gloves are embedded in networks of sanctioned trade and geopolitical instability. The energy subsidies this arrangement provides to Malaysian and Chinese glove manufacturers are themselves a product of sanctions evasion, compounding the unfair trade advantage these producers hold over U.S. manufacturers.

D. Circumvention and Illicit Trade Practices

The effects of unreasonable and discriminatory foreign acts, policies, and practices are compounded by active circumvention of U.S. trade law. CBP enforcement of the Uyghur Forced Labor Prevention Act has resulted in the detention of nearly \$1 billion in goods since 2022.^[10] Chinese PPE has been entered under misclassified HTS codes, and reports of double-invoicing, undervaluation schemes, and counterfeit or reused products reaching U.S. hospitals underscore that the United States cannot rely on foreign supply chains to deliver safe, compliant products at any price.

III. ACTS, POLICIES, AND PRACTICES OF THE INVESTIGATED ECONOMIES

A. China

China's structural excess capacity in PPE and medical apparatus is the product of deliberate government strategy, not competitive trade and free market forces. China's government deploys low-interest state lending, subsidized energy, preferential land allocation, export incentives, and currency management to enable Chinese manufacturers to produce nitrile gloves for as little as \$0.015 per glove before tariffs. This is a price that no U.S. producer operating under American labor law and without comparable state support can approach. China's global medical apparatus surplus is large, persistent, and growing. Its dominance in syringes, masks, and PPE raw materials reflects the same state-directed industrial strategy that has generated China's \$1.2 trillion global goods trade surplus.^[11] AMMA urges USTR to find China's acts, policies, and practices with respect to PPE and medical apparatus unreasonable, discriminatory, and actionable under Section 301(b).^[11]

A central but underappreciated dimension of China's cost advantage is its access to petrochemical feedstocks, including polypropylene and other petroleum derivatives. China sources these resources from sanctioned nations at far below international market prices. Chinese manufacturers have previously procured these inputs through trade arrangements with Iran and Venezuela, paying a fraction of the global benchmark indices that U.S. manufacturers must pay. AMMA members purchasing polypropylene on international markets pay prevailing global spot prices; their Chinese counterparts do not. This structural input cost advantage is not the result of superior efficiency or scale. It is the product of sanctions evasion, and it artificially suppresses Chinese production costs in ways that are invisible to standard trade remedy analyses focused solely on output pricing.

The effect of these combined subsidies, including state lending, currency management, forced labor, and below-market petrochemical inputs, is not merely to lower Chinese production costs. It is to establish an artificial floor on market pricing that has anchored global expectations for what PPE should cost. Chinese glove producers have used this manufactured cost base to set global reference prices well below levels any unsubsidized producer can match, conditioning procurement officers, hospital systems, and group purchasing organizations to treat artificially low prices as the market norm. This distortion cascades throughout the global supply chain: as Chinese prices suppress global benchmarks, Malaysian, Indonesian, Indian, and Vietnamese producers operate on thinner margins and under pressure to compete. These countries are then compelled to match or approach Chinese price levels, often by overcapitalizing their own production and operating at sustained losses. The



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downward price spiral that has devastated U.S. domestic manufacturing does not originate in Malaysia or Vietnam. It originates in Beijing.

It is also critical to note that China's PPE production growth is not organic. Capacity was constructed, subsidized, and sustained by government direction, not by genuine market demand signals. The COVID-19 pandemic served as a policy accelerant: China expanded production capacity dramatically during 2020 and 2021, supported by state subsidies, while the global market was disrupted and domestic competitors in the United States and elsewhere were sidelined. The result was a market entry environment in which new U.S. domestic manufacturers began operations already at a severe structural disadvantage. The domestic U.S. glove manufacturing industry is young and was built under conditions where China had already captured procurement relationships and anchored buyer expectations to subsidy-enabled prices. It has never competed on a level playing field.

B. Malaysia

Malaysia is currently the single most consequential source of excess glove capacity threatening U.S. medical glove manufacturers, accounting for a projected 65 to 70 percent of U.S. medical glove imports by end of 2025, up from 25 to 30 percent in 2024. ^[16, 17] Unlike China, Malaysia's overcapacity originated primarily as a private-sector market response to the COVID-era demand surge and China's own aggressive capacity buildout, not state-directed industrial policy. Government supports, including natural gas subsidies, technology grants, and export marketing assistance, have nonetheless cushioned Malaysian manufacturers from the market discipline that would otherwise have forced faster capacity rationalization. The result is glove prices that collapsed from \$0.04 to \$0.06 per unit in 2023 to \$0.02 to \$0.035 by 2025, making U.S.-priced production commercially untenable. ^[16, 17] Malaysia's situation also differs from Vietnam and Indonesia, where large-scale transplanted Chinese capacity reflects deliberate tariff circumvention. No comparable Chinese manufacturing footprint has been documented in Malaysia.

AMMA urges USTR to apply precise, targeted tariff remedies calibrated specifically to the medical glove sector in Malaysia, focused on nitrile examination gloves and surgical gloves. This will allow remedies to achieve their maximum effect for national security and domestic manufacturing resilience purposes, without generating unintended consequences in product categories where Malaysia's market conditions differ.

C. Vietnam

Vietnam's bilateral goods trade surplus with the United States reached \$178 billion in 2025 and has been previously found by USTR to reflect, in part, unreasonable currency undervaluation. ^[12, 13] For U.S. PPE manufacturers, Vietnam is the primary destination for Chinese capacity migration designed to circumvent tariff enforcement, including through the 8-billion-glove facility that opened in late 2025. Chinese-origin production and Chinese government subsidies enter the U.S. market under Vietnamese origin labels. AMMA urges USTR to find Vietnam's practices, including currency undervaluation, transshipment facilitation, and accommodation of Chinese capacity migration, actionable under Section 301.

D. Thailand and Indonesia

Thailand's manufacturing sector is operating below 60 percent capacity utilization, and its bilateral surplus with the United States totaled \$51 billion in 2025, up from \$35 billion in 2024. ^[14] Thai producers benefit from labor costs under \$10 per day compared to \$20 to \$25 per hour for U.S. workers. Indonesia maintains a \$31 billion global goods trade surplus and is an emerging transshipment site for Chinese PPE manufacturers. ^[14] In documented cases, Chinese manufacturers have not merely relocated operations to Indonesia, they have physically transplanted entire production facilities, including structural steel, equipment, and manufacturing lines, from China. This is not investment in new capacity; it is the geographic relocation of Chinese-subsidized overcapacity to jurisdictions with lower tariff exposure, preserving the same cost structures and government-backed advantages that made the original Chinese production uncompetitive under U.S. trade law. AMMA urges USTR to monitor both countries closely as Chinese producers continue to diversify away from tariff-targeted

locations, and to treat transplanted Chinese capacity under Indonesian or Vietnamese origin as presumptively subject to the same remedies applied to Chinese-origin production.

IV. BURDEN ON U.S. COMMERCE

The pricing gap between subsidized imports and domestic production costs is the most direct evidence of the burden these investigations must address. Before the U.S.-Iran conflict, foreign-sourced nitrile gloves from Malaysia, Thailand, and other producing countries landed in the U.S. at approximately \$0.013 to \$0.034 per pair^[16, 24]. One AMMA member has confirmed a domestic production floor of approximately \$0.055 to \$0.060 per glove, with the lower end of that range applying to lighter glove specifications. This is the minimum sustainable price for a product compliant with the Make PPE in America Act. This price differential persists because foreign producers across the investigated economies operate within structural cost environments that U.S. manufacturers cannot replicate. These include volume-based preferential utility pricing schemes that, while nominally market-driven, are shaped by government policy and available at scale only to producers running at the kind of high-volume utilization rates that artificially suppressed import pricing makes commercially untenable for U.S. facilities. The cumulative effect of these structural advantages establishes an import price floor that reflects policy outcomes, not genuine market efficiency.

The consequences of this pricing gap for domestic producers are severe and direct. The experience of one domestic glove manufacturer that entered the U.S. market with a genuine commitment to competitive pricing illustrates the dynamic precisely. Despite the company's efforts to offer market-competitive prices, it was ultimately forced to close its production lines. The cause was not operational failure, but rather that Chinese producers were selling at prices no manufacturer could match while paying international market rates for raw materials, U.S. wages, and compliant overhead. This example is not an isolated case; it is a pattern. Every domestic manufacturer that has attempted to enter or scale the U.S. glove market in the past five years has faced the same structural handicap: a market where the dominant price reference was established by a foreign government's industrial policy, not by supply and demand.

The mask market provides another concrete illustration of the cost differential and the inadequacy of current tariff levels as a corrective. A domestic manufacturer's cost to produce an earloop face mask, including cost of goods, labor, and overhead, is approximately \$0.06 per unit, translating to a commercially viable sale price of \$0.07 to \$0.09 per mask. A Chinese producer, drawing on forced labor, below-market petrochemical inputs from sanctioned nations, government subsidies, and currency management, can produce and export the same mask FOB at approximately \$0.015. This represents less than one-quarter of the U.S. production cost.

Even with the current 50 percent Section 301 tariff rate that took effect January 1, 2026, a Chinese mask enters the United States at approximately \$0.0225. This is still far below what a domestic manufacturer must charge to remain solvent. For large-scale distributors purchasing at volume, the economic calculus is not close. The tariff, as currently structured and applied, does not close the gap in any meaningful way.^[15]

The surgical gown market reflects the same structural pricing distortions. Higher-barrier gowns (AAMI Level 3 and Level 4), which are required for fluid-intensive and high-risk procedures, represent the most clinically critical segment of the market and are subject to stringent performance standards for liquid and viral penetration resistance.^[20]

Imported gowns, primarily sourced from Asia, enter the U.S. market at prices that reflect lower input costs and large-scale production environments, while domestic production must absorb higher labor, regulatory, and compliance costs. At the same time, distribution and procurement channels are highly concentrated, limiting access for domestic producers and reinforcing price-based competition anchored to imported supply.^[21]

As with gloves and masks, the result is that domestic manufacturing capacity exists but cannot be economically utilized. Market pricing is anchored to imported production costs shaped by foreign industrial policy rather than sustainable domestic cost structures.

Even with the current 10 percent Section 122 global surcharge compounded with increased costs surrounding the U.S.-Iran Conflict, Malaysian gloves still enter the U.S. at \$0.025 to \$0.044 per unit, well below the domestic threshold. The pricing effect has varied: brand owners passed costs through quickly; private label manufacturers absorbed the burden until contracts could be renegotiated; and some held prices to protect market share. The result is a mixed picture, not a uniform pricing strategy.

Malaysia's pricing competitiveness rests on decades of accumulated scale, quality leadership, and a dense supply chain ecosystem that cannot be quickly replicated. Labor is no longer an advantage. Malaysia loses significantly on wages to Vietnam, Thailand, and Indonesia, and has responded with rapid automation in the most labor-intensive production steps. The industry has also undergone real consolidation and facility closures as Chinese oversupply eroded margins. The gap U.S. producers face is not primarily a product of government support. It reflects decades of industrial infrastructure that most U.S. manufacturers, having entered the market only in the last five years, have not had time to replicate.

Product	Foreign Import Price	U.S. Production Floor	Gap After 25% Tariff
Nitrile Gloves (per 1,000)	\$20–\$44 (Malaysia/Thailand - +10%)	\$60 (MPPEIA compliant)	~\$11–\$35 below domestic floor
N95 Respirators (per unit)	~\$0.375 (mostly China - +50%)	\$0.50–\$0.70 (domestic)	~1.3–1.9x differential
Surgical/Procedure Masks (each)	\$0.01–\$0.0225 (China FOB - +50%)	\$0.05–\$0.07 (domestic)	2.2-7x at production level
Surgical Gowns (Level 3&4, each)	~\$1.10-\$2.75 (imported - +10/50%)	~\$4.00-\$7.00 (domestic estimate)	~1.5-6.5x differential

[Data: AMMA member cost data; UOB Kay-Hian Research, July 2025; MARGMA Q1 2025 Newsletter. For N95 respirator differentials, see Section IV of AMMA's March 30, 2026 CMS ANPRM comments. Surgical gown market size and segmentation derived from Mordor Intelligence [20]; market structure and distribution dynamics derived from Grand View Research [21].]

V. DOMESTIC CAPACITY EXISTS — POLICY SUPPORT IS THE MISSING INGREDIENT

AMMA's members have demonstrated that large-scale domestic PPE production is entirely feasible. The constraint is not industrial capability. It is the commercial environment created by foreign government subsidies, which has made domestic manufacturing economically unviable without a countervailing policy framework.



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Category	Current Domestic Output	Surge Capacity (with demand signal)
Nitrile Gloves	4.8 billion units/yr	31 billion units/yr
Surgical Masks	2.1 billion units/yr	5.1 billion units/yr
N95 Respirators	435 million units/yr	1.5 billion units/yr
Medical Gowns	93 million units/yr	725 million units/yr
Needles & Syringes	3+ billion units/yr	Scalable with automation investment

One AMMA member's facility can triple output within 90 days and quintuple within a year if procurement commitments are in place. Another can surge production by 20 to 40 percent within 120 days under emergency protocols, drawing on pre-positioned finished goods inventory. These manufacturers are not asking for market protection. They are asking for the market certainty that justifies deploying the capital they are ready and willing to invest.

The most visible evidence that unused domestic capacity is suppressed by foreign pricing can be found in hospital procurement behavior. American hospitals are the natural anchor buyers for domestic PPE. However, hospitals are currently purchasing foreign gloves and masks **not** because domestic products are unavailable, but because it is cheaper to purchase foreign products. The price differential engineered by Chinese and Chinese-influenced supply chains has conditioned U.S. healthcare purchasing departments to view the foreign price as the reference price. Until that artificial price difference is corrected through meaningful trade remedies, domestic capacity will remain underutilized regardless of how much manufacturers invest, not because the supply is inadequate, but because the demand has been distorted by state-subsidized foreign competition.

The single most important constraint remaining is upstream raw material availability. No meaningful domestic production capacity for Nitrile Butadiene Rubber (NBR) latex currently exists in the United States. Domestic sources of this critical input are effectively nonexistent for purposes of commercial glove production. As a result, U.S. glove manufacturers must source NBR from TAA-compliant foreign suppliers, primarily in South Korea and Italy. Current U.S. glove production cannot yet achieve full domestic content independence, through no fault of domestic manufacturers. AMMA urges USTR and relevant agencies to recognize this structural constraint in designing tariff remedies: where critical inputs are not available from domestic sources, trade policy should affirmatively support sourcing from TAA-compliant countries rather than applying tariff structures that inadvertently penalize U.S. manufacturers.

AMMA emphasizes that this is not a permanent condition. Significant private investment in onshore NBR production capacity is underway, and AMMA urges USTR to coordinate with relevant agencies to support federal co-investment in domestic NBR reactor capacity as a necessary complement to trade remedies targeting finished glove imports.



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VI. CONCLUSION

The structural excess capacity of the investigated economies has inflicted deep and sustained harm on U.S. PPE manufacturers and created an active national security vulnerability. Foreign governments have already demonstrated both the willingness to restrict medical supply exports and the capability to use supply chain dominance as geopolitical leverage. ^[3, 4, 6] Foreign excess capacity has produced a dangerous supply chain concentration. Over 90 percent of PPE supplies now flow from a handful of countries and needles and syringes remain vulnerable to low-cost imports eroding the existing domestic manufacturing base. This cannot be allowed to continue. ^[1]

AMMA and its members stand ready to supply the PPE and needles and syringes that American healthcare workers and first responders need. The capacity exists. The workforce is here. What is required is USTR action that levels the playing field against state-subsidized foreign overproduction and provides the policy conditions for domestic manufacturing to survive and scale.

AMMA urges USTR to prioritize PPE as a priority sector in these investigations. AMMA further urges that the tariff remedies emerging from these Section 301 investigations be precision based and targeted. Specifically, remedies should focus on PPE product categories, including nitrile gloves, surgical masks, N95 respirators, isolation gowns, and needles and syringes, rather than being applied as broad sectoral remedies across all manufacturing. Targeted tariffs allow remedies to have their maximum corrective effect for national security and supply chain resilience. Broad-based tariffs dilute the focused pressure needed to rebalance the pricing environment in the specific product categories that matter most for frontline American workers. The investigations should prioritize remedies that are precisely calibrated to the PPE products and country-specific subsidy practices driving the greatest harm to domestic manufacturers and the greatest risk to U.S. national security. We thank you for the opportunity to comment on these investigations and welcome the opportunity to provide more feedback.

Respectfully submitted,

Eric Axel

Executive Director

American Medical Manufacturers Association



APPENDIX: REFERENCES

Note: Capacity data and cost differential estimates cited in the body of these comments are drawn from confidential submissions by AMMA member manufacturers and are not attributed to specific companies herein. All other factual claims are supported by the publicly available sources listed below.

I. U.S. PPE Import Dependence

1. American Hospital Association / Healthcare Brew. (2025, August 12). Despite Covid-19 Pandemic Efforts, the US Still Mostly Imports PPE. Healthcare Brew. Retrieved from <https://www.healthcare-brew.com/stories/2025/08/12/pandemic-efforts-us-mostly-imports-ppe>. Referenced throughout for the finding that the U.S. imports 80–90% of its total PPE supply.
2. JT Medtech. (2025, October 17). Comments on Bureau of Industry and Security rulemaking, Docket No. BIS-2025-0258. Retrieved from https://downloads.regulations.gov/BIS-2025-0258-0341/attachment_1.pdf. Referenced for U.S. nitrile glove import source composition (approximately 42% Malaysia, 40% China, 12% Thailand in 2024) and related market dynamics.

II. Foreign Government Export Restrictions on PPE

3. U.S. Congressional Research Service. (2020). COVID-19: China Medical Supply Chains and Broader Trade Issues (R46304). Retrieved from <https://www.congress.gov/crs-product/R46304>. Referenced for China's March 2020 imposition of NMPA registration and documentation requirements that materially delayed outbound PPE shipments and disrupted established supply chains for importing countries, including the United States.
4. India Directorate General of Foreign Trade. (2020, January 31; June 22; June 29). Notifications Nos. 44/2015-2020 and subsequent amendments. Global Trade Alert. Retrieved from <https://www.globaltradealert.org/intervention/78825>. Referenced for India's prohibition and subsequent quota-based restriction on PPE exports, eased only through formal licensing under the DGFT quota system beginning June 2020.
5. Malaysian Rubber Glove Manufacturers Association (MARGMA). (Q1 2025). MARGMA Quarterly Newsletter. Retrieved from <https://margma.com.my>. Referenced for Malaysia's regulatory framework governing glove origin certification and export controls, and for the projected increase in Malaysia's share of U.S. medical glove imports to 65–70% by end of 2025.

III. China's Use of Supply Chain Control and Export Restrictions

6. Center for Strategic and International Studies (CSIS). (2024, December 11). China Imposes Its Most Stringent Critical Minerals Export Restrictions Yet Amidst Escalating U.S.-China Tech War. Retrieved from <https://www.csis.org/analysis/china-imposes-its-most-stringent-critical-minerals-export-restrictions-yet-amidst>. Referenced for China's July 2023 imposition of licensing restrictions on gallium and germanium exports as retaliatory measures against U.S. semiconductor export controls, establishing a documented precedent for use of supply chain dominance as geopolitical leverage.
7. U.S. House Select Committee on Strategic Competition between the United States and the Chinese Communist Party. (2023, December 12). Reset, Prevent, Build: A Strategy to Win America's Economic



Competition with the Chinese Communist Party. Retrieved from <https://chinaselectcommittee.house.gov/sites/evo-subsites/selectcommitteeontheccp.house.gov/files/evo-media-document/reset-prevent-build-scc-report.pdf>. Referenced for the Committee's documentation that China deploys state subsidies and civil-military fusion policies to deliberately dominate global medical, biotech, and critical mineral supply chains.

IV. China's Dominance in Syringes and Medical Apparatus Exports

8. Mercator Institute for China Studies (MERICS). (2023, November). Investigating State Support for China's Medical Technology. Retrieved from https://merics.org/sites/default/files/2023-11/MERICS_Report_MedTech%20State%20Support_November%202023_final.pdf. Referenced for China's emergence as the top global exporter of medical syringes by 2021, and for MERICS's documentation of the state subsidies and industrial policy mechanisms underpinning China's rise in medical technology exports.
9. American Affairs Journal. (2024, February). Foreign Government Subsidies and FDA Regulatory Failures Are Causing Drug Shortages in the United States: Here's How to Fix It. Retrieved from <https://americanaffairsjournal.org/2024/02/foreign-government-subsidies-and-fda-regulatory-failures-are-causing-drug-shortages-in-the-united-states-heres-how-to-fix-it>. Referenced for data showing that shipments of Chinese-made syringes to the United States increased 51 percent in 2023 alone, and for context on China's dominance in the U.S. needle and syringe market since 2021.

V. UFLPA Forced Labor Enforcement and Transshipment

10. CNBC. (2023, April 17). Since June, Feds Have Seized Nearly \$1 Billion in Goods Tied to Forced Labor. Retrieved from <https://www.cnbc.com/2023/04/17/feds-seize-goods-tied-to-forced-labor.html>; U.S. Customs and Border Protection (CBP). UFLPA Enforcement Statistics Dashboard. Retrieved from <https://www.cbp.gov/newsroom/stats/trade/uyghur-forced-labor-prevention-act-statistics>. Referenced for CBP enforcement of the Uyghur Forced Labor Prevention Act, including the total value of detained goods and the documented pattern of transshipment through Malaysia, Vietnam, and other Southeast Asian countries.

VI. China's Global Goods Trade Surplus and Excess Capacity

11. Office of the United States Trade Representative (USTR). (2026, March 11). Initiation of Section 301 Investigations: Acts, Policies, and Practices of Certain Economies Relating to Structural Excess Capacity and Production in Manufacturing Sectors. Federal Register, 91 FR 12888. Retrieved from <https://www.federalregister.gov/documents/2026/03/17/2026-05214>. Referenced for China's global goods trade surplus exceeding \$1.2 trillion in 2025, representing a record high and approximately 70 percent of global goods trade surpluses.

VII. Vietnam Trade and Currency Practices

12. Office of the United States Trade Representative (USTR). Vietnam Country Page. Retrieved from <https://ustr.gov/countries-regions/southeast-asia-pacific/vietnam>. Referenced for the U.S. goods trade deficit with Vietnam of \$178.2 billion in 2025, a 44.3 percent increase over 2024.

13. Office of the United States Trade Representative (USTR). (2021, January 15). Report on Vietnam's Acts, Policies, and Practices Related to Currency Valuation. Retrieved from https://ustr.gov/sites/default/files/enforcement/301Investigations/Vietnam_Currency_301_Actionability_Report_Jan_15_21.pdf. Referenced for USTR's prior affirmative finding that Vietnam's exchange rate practices, including persistent foreign exchange market interventions, have contributed to undervaluation of the Vietnamese dong and burdened U.S. commerce.

VIII. Thailand and Indonesia: Trade Data and Excess Capacity

14. Office of the United States Trade Representative (USTR). (2026, March 11). Initiation of Section 301 Investigations: Acts, Policies, and Practices of Certain Economies Relating to Structural Excess Capacity and Production in Manufacturing Sectors. Federal Register, 91 FR 12888. Retrieved from <https://www.federalregister.gov/documents/2026/03/17/2026-05214>. Referenced for Thailand's bilateral goods trade surplus with the United States of \$51 billion in 2025 (up from \$35 billion in 2024), and for the USTR's finding that Thailand's manufacturing sector has operated below 60 percent capacity utilization for two consecutive years. Also referenced for Indonesia's role as an emerging transshipment site for Chinese production.

IX. Section 301 Tariff Structure and Effectiveness

15. U.S. Trade Representative. (2024). Section 301 Tariffs on Products from China — Four-Year Review. Office of the United States Trade Representative. Retrieved from <https://ustr.gov/issue-areas/enforcement/section-301-investigations/section-301-china>; White & Case LLP. (2024, September 13). United States Finalizes Section 301 Tariff Increases on Imports from China. Retrieved from <https://www.whitecase.com/insight-alert/united-states-finalizes-section-301-tariff-increases-imports-china>. Referenced for the structure of Section 301 tariffs as applied to FOB prices and for the tariff escalation schedule applicable to PPE categories including syringes, needles, gloves, and masks.

X. Malaysian Glove Sector: Market Share and Pricing Data

16. UOB Kay Hian Research. (2025, July 23). Malaysia Glove Sector: Adopting to a New Equilibrium (Glove Sector Report). Jack Goh, analyst. Available via UOB Kay Hian research portal at <https://research.uobkayhian.com/> and summarized at <https://www.minichart.com.sg/2025/07/31/malaysia-glove-sector-faces-pressure-from-us-tariffs-china-competition-2025-outlook-top-stock-picks-earnings-forecasts/>. Referenced in Section III.B for the projection that Malaysia's share of U.S. medical glove imports would rise to 65–70% in 2025 (from 25–30% in 2024), for glove average selling price data showing a collapse from \$0.04–\$0.06 per unit in 2023 to \$0.02–\$0.035 by 2025, and for the finding that Malaysian manufacturers absorbed tariff impacts rather than passing them through to U.S. buyers.
17. Malaysian Rubber Glove Manufacturers Association (MARGMA). (2025). Industry Statistics and Market Share Data. Retrieved from <https://margma.com.my>. Cited in The Star and The Straits Times (February 2025) for the finding that Malaysia held approximately 44–45% of global rubber glove market share in 2024, and for corroboration of U.S. import composition data. Referenced in Section III.B for Malaysia's global production standing and for the baseline 2024 market share figures from which the 2025 projections are derived.



XI. Chinese Capacity Migration to Southeast Asia

18. The Malaysian Reserve / The Sun. (2025, September 2). Hartalega Gains US Market Share as Tariffs Hit Chinese Glove Makers. The Malaysian Reserve; The Sun (Malaysia). Retrieved from <https://themalaysianreserve.com/2025/09/02/hartalega-gains-us-market-share-as-tariffs-hit-chinese-glove-makers/> and <https://thesun.my/business-news/hartalega-malaysia-s-share-of-us-glove-market-has-increased-to-56-EM14815274>. Referenced in Section II.B for public statements by Hartalega CEO Kuan Mun Leong at the company's September 2025 AGM press conference confirming that Chinese rubber manufacturers had established production plants in Vietnam and Indonesia specifically to export to the U.S. market under lower-tariff country-of-origin designations, and that Chinese producers who lost the U.S. market "have come out into South-East Asia to build capacity."
19. American Armor Gloves (Nephron Nitrile, LLC). (2025, October 17). Comments on Bureau of Industry and Security Rulemaking, Docket No. BIS-2025-0258. Retrieved from https://downloads.regulations.gov/BIS-2025-0258-0347/attachment_1.pdf. Referenced in Section II.B for the identification within that federal proceeding of a new Vietnamese glove manufacturing facility with 8 billion units of annual production capacity coming online in Q4 2025, attributed to Chinese manufacturers relocating to lower-tariff jurisdictions to circumvent U.S. Section 301 enforcement.

XII. Surgical Gown Market Data

20. Mordor Intelligence. (2023). North America Surgical Gowns Market — Growth, Trends, COVID-19 Impact, and Forecasts (2022–2027). Proprietary research report; industry analyses. Referenced for U.S. surgical gown market size projections (\$2.78 billion growing to \$4.55 billion), demand drivers, and AAMI Level 3 and Level 4 product segmentation data.
21. Grand View Research. (2025). U.S. Surgical Gowns Level 3 and Level 4 Market — Company Share Analysis, 2024. Proprietary research report; industry analyses. Referenced for market concentration among dominant suppliers, distribution structure, and competitive dynamics in high-barrier gown categories.

XIII. Iran Shadow Fleet and Sanctioned Oil Trade

22. Kozhanov, N. (2026, January 28). Sanctions Without Shock? United Nations Snapback and Iran's Oil Exports. Clingendael Institute. Retrieved from <https://www.clingendael.org/publication/sanctions-without-shock-united-nations-snapback-and-irans-oil-exports>. Referenced in Section II.C for documentation that Iran-to-China oil exports routinely involve ship-to-ship transfers in grey zones near Malaysia, that China purchases the substantial majority of Iran's shipped crude through these shadow logistics networks, and that this arrangement provides Chinese and Malaysian manufacturers with below-market petrochemical input costs derived from sanctioned trade.
23. Anonymous. (2025, October 2). Iran's Oil Exports: Resilience Amid Sanctions and 'Snapback.' Stimson Center, Middle East Perspectives Project. Retrieved from <https://www.stimson.org/2025/irans-oil-exports-resilience-amid-sanctions-and-snapback/>. Referenced in Section II.C for the finding that Iran maintains oil exports through subsidized pricing, shadow fleets, and established buyer networks, including facilities on Kharg Island that supplied more than 268.5 million barrels between January 2023



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and March 2025, primarily to China, Malaysia, and Singapore—routing that intersects directly with the supply chains feeding U.S. medical glove imports.

XIV. AMMA Member Data

24. Confidential operational and cost data submitted by AMMA member manufacturers in connection with these comments. AMMA members also provided specific market insights. Specific figures include: the share of U.S. nitrile glove manufacturers that have exited the market in the past three years; upstream raw material sourcing dependencies (NBR latex, South Korea and Italy); domestic production cost floors for nitrile gloves (approximately \$0.055–\$0.060 per glove); and the impact of Strait of Hormuz disruptions on petrochemical feedstock supply chains. Per the note at the head of this Appendix, these submissions are not attributed to specific member companies herein. Where member data is cited alongside publicly available sources, both are noted.