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A Reshoring Movement Spurred by the Pandemic

As supply chains fractured in 2020, U.S. companies and buyers quickly realized that the predominant outsourcing of entire industries and product groupings might not be the optimal strategy. All industries were impacted to some degree with limited access to goods, but none was hit harder than the medical sector when demand for protective equipment and testing supplies reached an all-time high. The U.S. Government quickly took note of this vulnerability and attempted to improve future readiness levels with actions led by the Department of Health and Human Services (HHS).

In late 2020, HHS leveraged the Administration for Strategic Preparedness & Response (ASPR) to establish and lead an "Industrial Base Expansion Portfolio". This platform initiated seed investments in approximately 60 companies across the following categories:

- PPE Capacity & Raw Materials ($1,284 Million)
- Therapeutic Supplies & Materials ($272 Million)
- Vaccine Supplies & Materials ($213 Million)
- Testing Capacity & Materials ($2,023 Million)

These investments were intended to kick-start reshoring and capacity expansion efforts to ensure at least a nominal amount of domestic production for critical medical supplies for future pandemic-like events or supply chain disruptions. In addition to initial government investments, a sizable amount of activity was mirrored by the private sector to establish manufacturing capabilities and reduce full reliance on imports.

An Emerging Production Base with an Uncertain Future

Early momentum appeared promising with the heightened activity around reshoring manufacturing for critical medical products. The overall vision was to solidify a nominal domestic production base that could be relied upon in times of greater need rather than to completely replace high-volume imported goods. However, as these operations have reached the point of commercial production, the appetite from larger U.S. buyers appears very questionable as most commercial buyers have fully reverted to the pre-pandemic model of purchasing low-cost imports that primarily originate from Southeast Asia.

For these nascent domestic manufacturers to truly gain traction and reach future levels of viability, additional support from the U.S. Government is needed. Support could come in the form of long-term purchase orders, additional support funding, tighter requirements to buy domestically-made products or increased tariffs against foreign-made goods. If support is not deployed within the next six months, the likelihood of this emerging production base disappearing as quickly as it formed is quite high.

Supply Chains Find Balance, Reliance on Imports Tilts

2023 marked a general return to normalcy for most supply chains, with inventories improving and lead times for products decreasing. The medical sector continued to grapple with periodic shortages of select products but the dire shortages of PPE and other products experienced during 2020-2022 were largely resolved.

Although access and inventories of critical products improved substantially, several interesting shifts in the background adversely affected critical products during this "recovery" period. As the U.S. was made painfully aware during the early stage of the pandemic, reliance on imported medical products from a hyper-centralized area of the world - Southeast Asia - was at an all-time high and the pendulum had shifted too far. Although this realization was made abundantly clear, the shifts referenced above do not reflect attempts at a course correction as evidenced by the points below:

- The majority of PPE products flow through medical, general and industrial distributors.
- These distributors source products at the lowest cost – the acquisition cost directly correlates to their margin structure.
- China and other Southeast Asia manufacturers have expanded PPE and related medical product production significantly over the past three years.
- As heightened awareness began to dull, these manufacturers increased their overall share of imports into the U.S. and our reliance has increased to an even greater level.

These "shifts" are supported by importation trends tracked through the U.S. International Trade Commission from 2020 through 2024. Below is supporting data and commentary for major PPE product categories such as nitrile gloves, face masks, N95 respirators and gowns.

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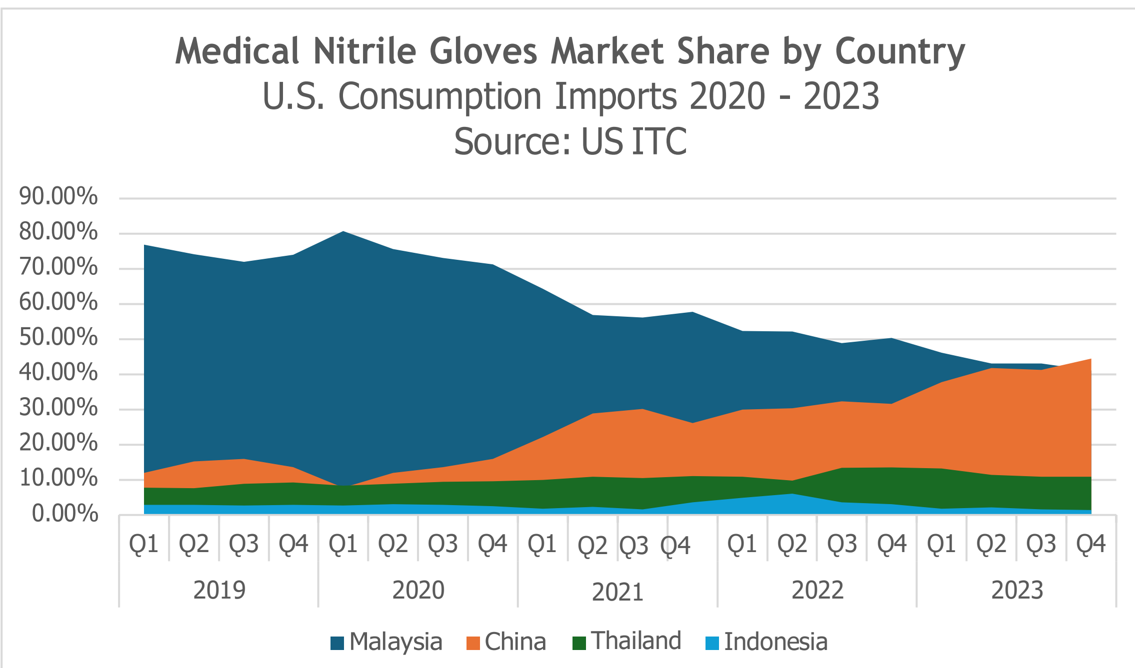
Nitrile Glove Importation Trends

The U.S. consumes approximately 110-120 billion units (individual gloves) of nitrile gloves annually. There is no significant domestic production of these products currently and approximately 98% of this volume is imported each year with roughly 65%-75% being medical grade and the balance on non-medical/industrial.

These disposable medical products were one of the scarcest PPE items during the heights of the pandemic due to their high utilization in most care settings. Historically, the largest manufacturer of these goods was Malaysia which controlled about 70% of the global market. China was a nominal player but invested significantly during the early stages of the pandemic to expand production and increase market share. As shown by U.S. importation trends below, this strategy was well executed and China has risen from a fractional provider to the U.S. to the dominant supplier.



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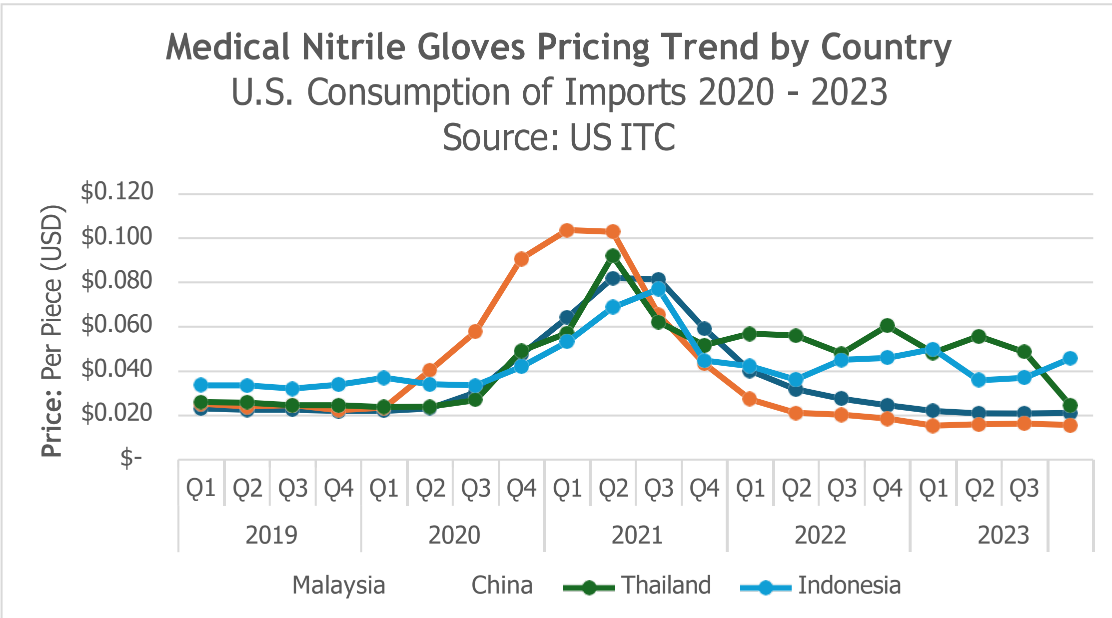
This meteoric rise in market share was the result of increased capacity combined with aggressively low prices. As shown in the chart below, China began to use price as a strategic level in late 2021 to undercut other countries and accelerate their market share consolidation.



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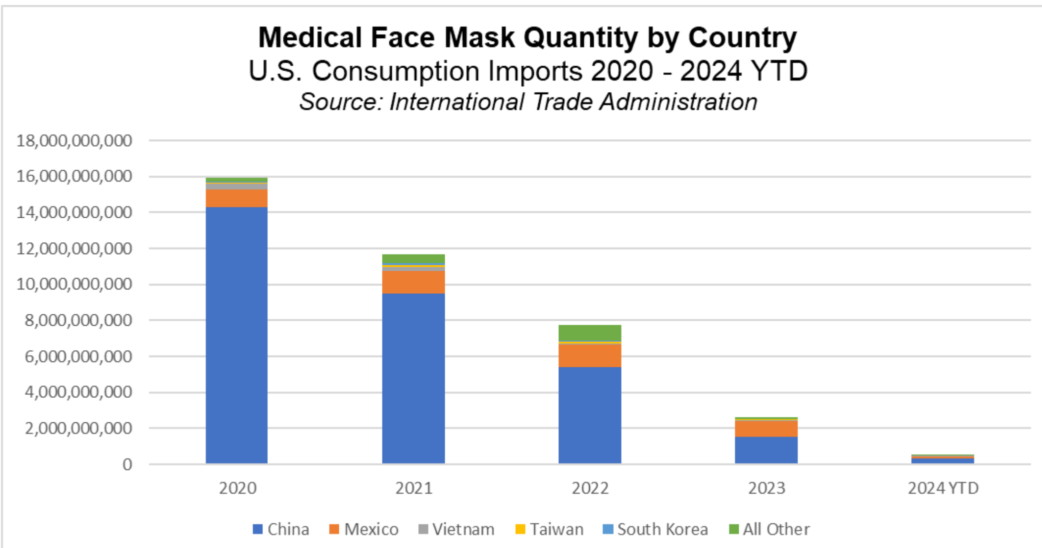
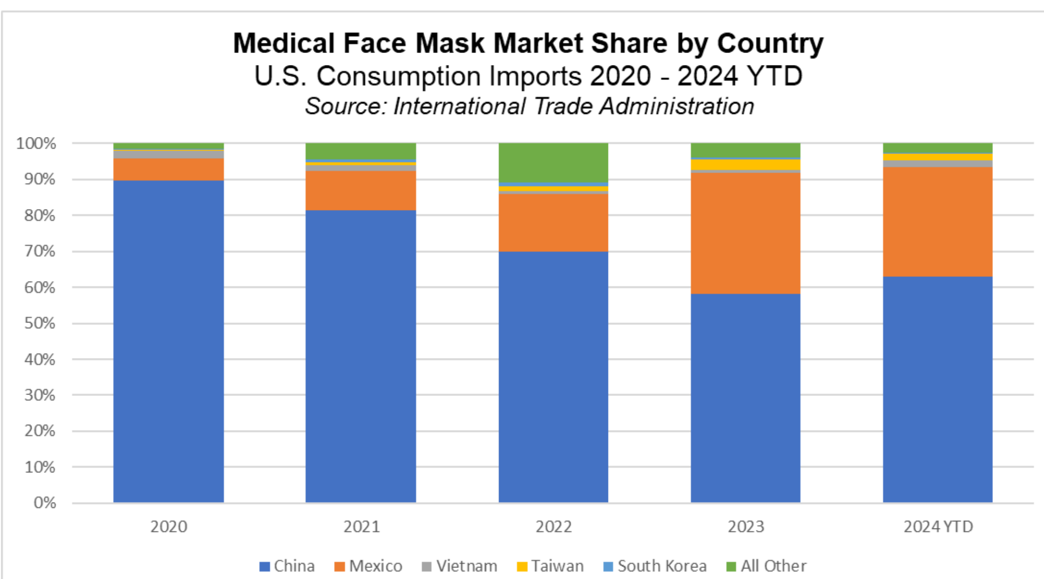
Face Mask Importation Trends

Unlike Nitrile Gloves which are used at high volumes during non-pandemic periods, demand for Medical Facemasks has dropped considerably since 2020 and 2021. Progress has been made with diversification by country of origin with Mexico establishing market share in the ~25% range. China remains a dominant player in this product category with upwards of 60% market share while reported sales from U.S. Manufacturers appears miniscule.





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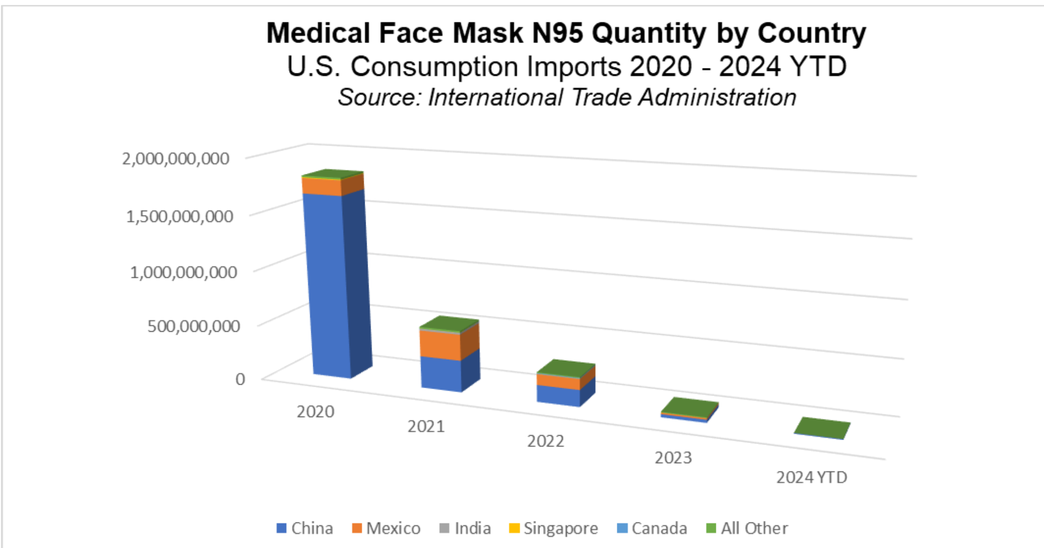
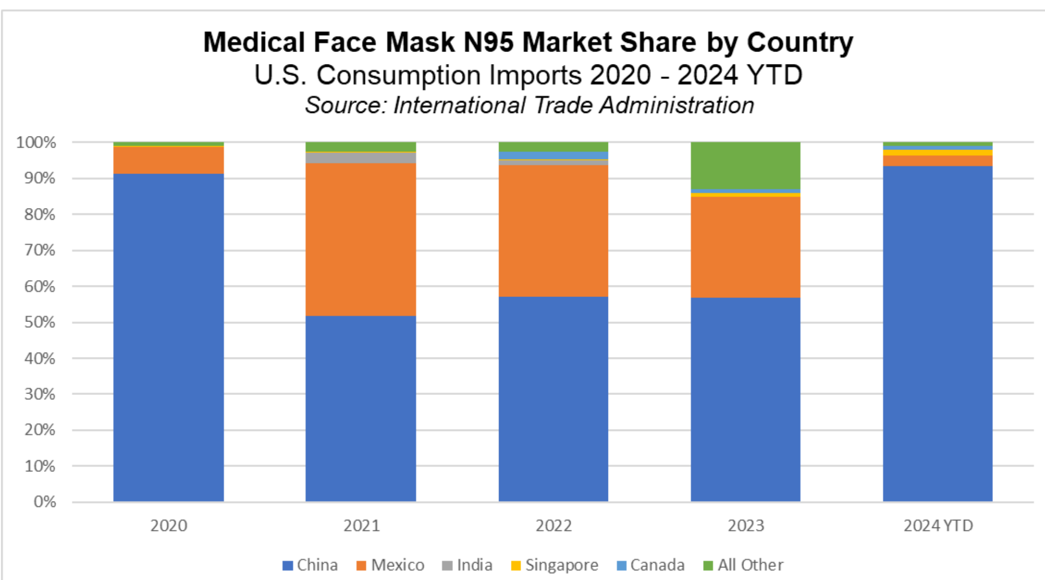
N95 Respirator Importation Trends

Similar to Medical Facemasks, overall volumes of N95 usage and importation have declined significantly since reaching peaks in 2020. Purchases showed signs of diversification in 2021 with increased volumes from Mexico and other countries. However, reliance upon imports from China appears to have resumed in 2023 with overall market share climbing back to ~90%.





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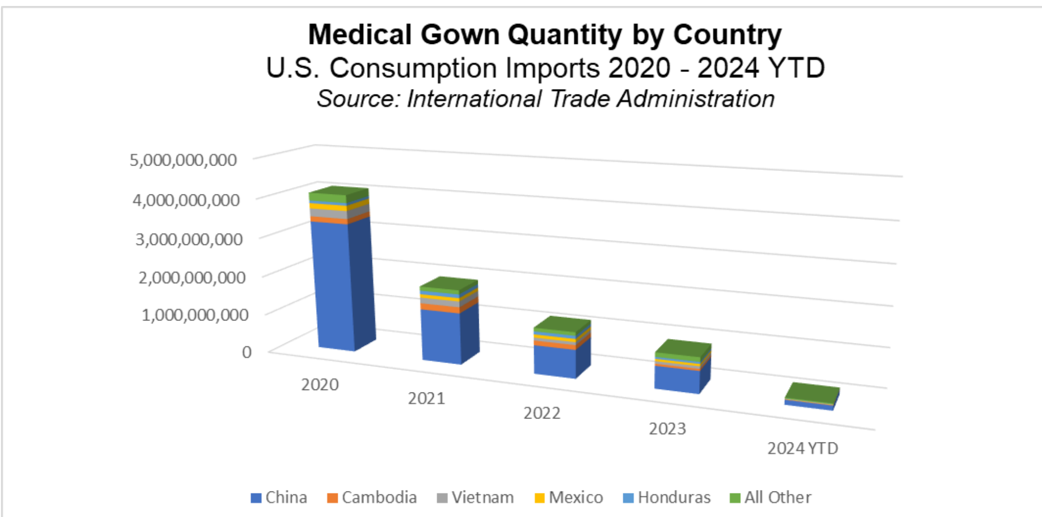
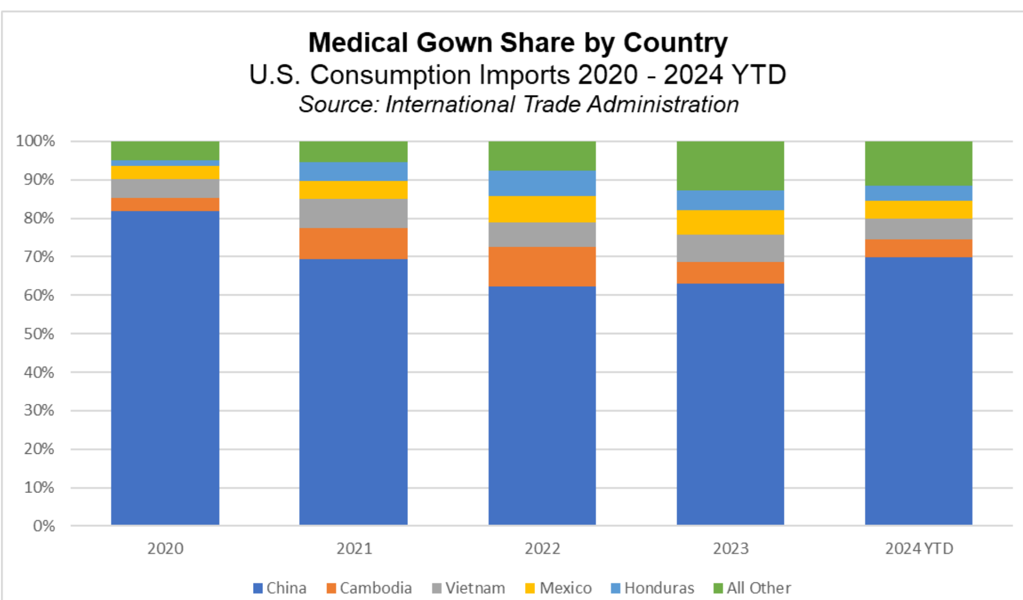
Medical Gowns Importation Trends

The decreased demand trend continues when analyzing Medical Gowns which is a product category which has shown little activity on the domestic production front due to the more labor intensive production when compared to other PPE products. These heightened labor requirements increase the pricing disparity between U.S. and foreign producers which likely accounts for the limited progress on the domestic side. The key point to highlight here is that these products are still used in significant quantities and China's dominant market share remains at 70% or higher.





There are myriad ways to review and analyze the importation data and trends relating to PPE and other medical products but the common theme can be summarized in three points:

1. **Overall demand for PPE and related products is down significantly from pandemic highs**
2. **China continues to control the majority of imports and market share, and in some cases has increased their dominance**
3. **The Domestic Production Base will by stymied by low cost imports if price is the only preference**

The Buying Model – Price Outweighs Resiliency

As is typically the case, the buying model within the medical industry is slightly more complicated than one would initially assume. There are sellers - manufacturers and importers - and buyers - hospitals, clinics, etc. - but there are other key participants as well which control the overall market dynamics. With the exception of specialized products and services, Hospitals, Physicians Offices, Dentists, and other healthcare providers do not typically purchase products directly from a manufacturer – they purchase through their designated medical products distributor. Additionally, these hospital systems and healthcare providers typically align with a Group Purchasing Organization (GPO) who negotiates pricing on behalf of their members and determines what products and manufacturers will be available or "on contract".

To fully understand the impact these other parties have on the overall model, you must look at the incentives and strategies for each:

Distributors - Margins Fueled by Private Label Portfolios

Medical distributors sell a wide range of branded products from companies such as 3M, Becton Dickinson, and others but they do not set prices for these products (the GPO's do) and their service fees for distribution alone are quite low. To offset this, all distributors have established large private-label product portfolios that focus on commodity products such as gauze, incontinence products, sutures - and PPE. These products are produced by contract manufacturers under the distributors brand and the goal is to find the lowest acquisition price possible. This is the reason all the leading distributors have large sourcing offices in teams located in China or Southeast Asia.

The Takeaway: Healthcare end users are limited by what their main distributors offer and the distributors will aggressively drive purchases to their private label options. These private-label portfolios are massive profit centers and will continue to preference imports - for margin reasons - over domestic options.

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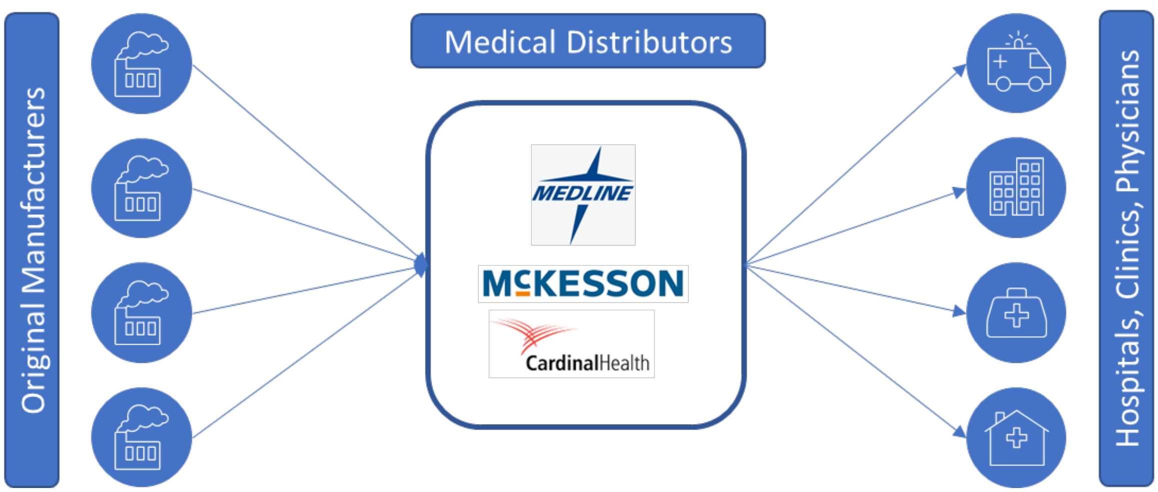
Group Purchasing Organizations - Driven by Price and Compliance

GPO's leverage an organized base of members (associated health systems) to negotiate favorable pricing on a wide range of products. This is beneficial for hospital members who do not have the bandwidth or expertise to monitor and negotiate pricing across thousands of individual products. In exchange, the GPO's receive a small fee for all transactions between their members and the product manufacturers they have negotiated pricing with. Additionally, hospital members are incentivized to funnel more purchases through their GPO - also known as "compliance" - because they will be rewarded with a rebate or additional discount. The products that ultimately end up within the GPO offering are the lowest price options that meet the required quality levels - there is no preference for domestic or more resilient options.

The Takeaway: GPO's assist healthcare members lower purchasing costs but they also control the available options. Domestic manufacturers will struggle to find a position on most GPO offerings due to price disparities between U.S. manufactured goods and low-cost imports. Additionally, healthcare buyers will be hesitant to purchase directly from domestic manufacturers because it will negatively impact their overall "purchasing compliance" with their GPO partner.



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A Solution Requires a Multi-prong Approach

In order to increase domestic production of PPE and additional critical medical products, we must implement a multi-pronged approach. Each of the following strategies will play a critical role in bolstering domestic PPE production. When implemented in harmony, these changes create a smooth and clear path for a robust production base.

Raise Tari) Levels Against Low-Cost Imports

Current Situation: At this time, tariffs have been leveraged against China at a rate of only 7.5% for PPE-related medical products, compared to 25% for similar non-medical PPE products. Meanwhile, some tariffs have been lifted since the start of the pandemic. Even with these nominal tariffs in place, China continues to consolidate market share with aggressive pricing, rendering these tariffs useless. These small and ineffective tariffs against China combined with the lack of tariffs against other Southeast Asia exporters result in incentivization for large US buyers to continue purchasing products from Southeast Asia, and ignoring increased domestic options.

Required Actions: It is critical that the Biden Administration increase tariffs for PPE-related medical products to reflect the same rates as non-medical PPE products. Specifically the tariff schedule should match the 25% rate in the industrial industry. With the industry grappling with tariff inversions on products like nitrile butadiene rubber (NBR) this adjustment is more critical than ever. Tariffs serve as a clear incentive for PPE consumers to purchase domestically manufactured products.

Anticipated Benefits: Although increasing tariffs cannot close the gap between Asian exports and domestically produced goods, it can reduce the disparity between the two. Additionally, the revenue generated by these increased tariffs can be redirected to fund additional programs and incentives to further support domestic manufacturing. For example, the US imports approximately 70 billion medical-grade nitrile gloves per year. Roughly one-half of those gloves come directly from China. Raising the tariff level to 25% for these products would yield approximately $110 million - money that could fund incentive programs for hospital systems, distributors and other leading buyers of these products.

Encourage & Enforce Government Purchasing from Domestic Manufacturers

Current Situation: While the U.S. Government and its agencies are not the largest purchasers of PPE related products, they contribute significantly to the industry. For example, the Veterans Administration Hospital System buys large amounts of PPE and medical products, FEMA buys substantial amounts of PPE for regional disasters and the Defense Logistics Agency purchases PPE-related goods to support troops. Although these agencies have publicly committed to preferring domestic suppliers when available and limiting purchases from unfriendly trading countries, their actions prove otherwise. For instance, the government has implemented a process allowing for the purchase of medical PPE products from foreign countries through a system of waivers. In the process of approving these waivers, other preferences outweigh "domestic" in the purchasing hierarchy and there are no penalties for non-compliance.

Required Actions: The Biden Administration needs to mandate that all government agencies procure certain categories of products from domestic manufacturers – especially in sectors that the Government is actively working to reshore. The Made in America Office was recently established to accelerate that very cause, but progress has been slow.

Anticipated Benefits: Increasing purchasing from domestic manufacturers has the power to strengthen the U.S. manufacturing industry. Although recent momentum for reestablishing production of critical medical supplies in the U.S. has been faltering, a firm purchasing commitment from Government agencies would likely provide the necessary foothold for these manufacturers to ensure production capabilities when needed in the future. This would draw domestic manufacturing of critical medical supplies back into the U.S., strengthening America's self-sufficiency.

Incentivize the Private Market Buyers

Current Situation: If the domestic production base for critical medical supplies is to have long-term viability, there must be support from buyers in the private commercial market. Currently, large hospital systems are the biggest purchasers of medical PPE products by far. They buy these products from leading medical distributors, who often have strong "private label" operations. These distributors acquire commodity goods from overseas manufacturers and sell them under their own brand names at higher prices. However, since most medical PPE items are commodity goods that fall within these private label portfolios, distributors prioritize sourcing the cheapest options,

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primarily from Southeast Asia, rather than supporting domestic manufacturers. This production environment rewards distributors for sourcing the lowest cost options possible, while domestic manufacturers take the hit.

Required Actions: A financial incentive or offset could further equalize the cost disparity between foreign and U.S. products to the point where distributors and health systems would increase support. This incentive could be in the form of an increased CMS reimbursement to hospital systems that increase purchases of domestically manufactured goods or in the form of a tax credit or reimbursement to distributors who begin sourcing from domestic manufacturers. This can be accomplished either through passage in Congress or through a rulemaking adjustment in the annual CMS reimbursement schedule.

Anticipated Benefits: If the pricing disparity can be neutralized, the market preference should tilt towards domestic options, resulting in a more stable supply chain for all parties.

Standardize "Made in America" Parameters

Current Situation: At this time, the only subset of buyers that prefer domestically manufactured medical products are buyers within the various government agencies included in the "Make PPE in America Act." These agencies include the VA Hospital System, Defense Logistics Agency, Department of Homeland Security and many others. However, the definition for "Made in America" remains murky, leading to confusion and inaction. For example, certain agencies define "Made in America" as "wholly manufactured in the United States." This includes the manufacturing process, key raw materials and supporting materials. However, realistically for certain products, this compliance is unattainable because select raw materials are not currently manufactured in the U.S. This minor level of non-compliance opens the door for increased purchase waivers, thus directing purchases back to imports. Additionally, some programs that pre-date the "Make PPE in America Act," such as the set asides in the Ability One and Service-Disabled Veteran-Owned Small Business (SDVOSB) often take precedence.

Required Actions: It is critical to create a more direct connection between government buyers and emerging domestic manufacturers. This will provide a much-needed level of traction for these manufacturers, as well as create a dependable demand signal. In order to do this the "Made in America" parameters must be standardized. The Made in America Office also must make waivers less easily obtained, and instead direct applicants to exhaust domestic options before turning to foreign manufactured products.

Anticipated Benefits: Having some level of guaranteed purchases will not only provide a nominal level of revenue to these manufacturers but it will solidify their outlook which will improve their chances of securing private investment to improve operations, create more jobs and reach a level of efficiency which is more competitive with foreign producers.

Align SNS Replenishment with Domestic Network

Current Situation: Annual demand of PPE from Government purchasers represents a small portion (approximately 5-7%) of the overall market. Additionally, purchase volumes are fragmented between groups such as the VA Hospital System, Homeland Security, Defense Logistics Agency and others. On the other hand, the Strategic National Stockpile represents large, consolidated purchasing volumes for PPE products such as masks, gloves and gowns. Yet, currently the contracting process with the Strategic National Stockpile (SNS) is extremely opaque and there is no preference for domestic providers. This results in the stockpile being predominantly reliant upon imported goods.

Required Actions: At this stage, it is critical for HHS and ASPR to pivot to begin preferencing or mandating the SNS to be replenished from domestically produced goods when available. Additionally, government agencies should reevaluate product portfolios and add new products to the SNS, such as reusable respirators. This process will be facilitated by a request for additional funding in order to support adequate replenishment and purchasing of domestically produced goods.

Anticipated Benefits: Aligning SNS purchases with the domestic PPE manufacturing base is beneficial on multiple fronts. First, stockpile orders provide some degree of firm demand to domestic manufacturers which will help to support these emerging businesses. Next, having a more proximal production base provides more flexibility to the SNS by allowing it to adjust upwards or downwards in times of need, or to make adjustments to product specifications as demands fluctuate. Finally, a partnership style model with domestic manufactures (as opposed to a transactional model) opens the door to collaboration regarding solutions such as vendor managed inventory and product innovation.

Future Resilience Requires Timely Engagement

The mobilization of multiple entities focused on reshoring or establishing manufacturing of critical medical products has been impressive. Having these manufacturing capabilities domestically is both good for U.S. medical supply chains and overall national security. However, this nascent production base is at a tipping point and the outlook remains uncertain as purchasing practices have reverted to decision-making based wholly upon price with no consideration of country of origin.

Crafting a better, more sustainable solution requires "whole of government" support as evidenced by the range of recommendations shared here. The American Medical Manufacturers Association (AMMA) is fully engaged and committed to this effort and will continue to review additional recommendations to strengthen this production base.