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Ways and Means Trade Subcommittee

Hearing: "TRADE, MANUFACTURING, AND CRITICAL SUPPLY CHAINS: LESSONS FROM COVID-19"

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Chairman Blumenauer, Ranking Member Buchanan, and Members of the Committee, my name is Prashant Yadav. I am a Senior Fellow at the Center for Global Development, Affiliate Professor at INSEAD, and Lecturer at Harvard Medical School. Over the last two decades my research/scholarly work has focused on global medical supply chains.

I appreciate this Committee's thoughtful consideration of the topic of medical supply chains, and I thank you for the opportunity to share my viewpoints as testimony to the Committee.

COVID-19 and Medical Supply Chains

The COVID-19 pandemic has exposed the vulnerabilities of supply chains across many industries, but nowhere has it caused more suffering than in the supply chain for medical products. Shortages of Personal Protective Equipment (PPE), testing supplies for SARS Cov2, and other medical products for COVID-19 have highlighted the grave challenges we face in our medical supply chain. Shortages of PPE have still not been resolved and continue to adversely impact front line health professionals throughout the US.

The challenges we have faced in the US medical supply chain have resulted from a combination of factors which vary depending on the type of medical products. PPE, test kits, medicines, and ventilators each have a different economic geography of manufacturing. For PPE there is a high geographic concentration of manufacturers in China. A huge surge in PPE demand in China in February 2020 followed by similar demand surges in the rest of the world led to demand far outstripping supply of PPE. Factory shutdowns, bans on PPE exports instituted by some countries, and international air cargo constraints put further strain on the PPE supply

chain. As the pandemic intensified, heightened global demand has led to shortages of the key starting material for N95 masks – nonwoven polypropylene. Insufficient stock of PPE in the Strategic National Stockpile (SNS) to meet the demand surge further hurt our ability to cope with the disruption in the global PPE supply chain. The supply chain for test kits is less dependent on production in China and depends more on production of key components in Europe. It has also come under significant stress due to manufacturing shutdowns, restrictions in air cargo, tariffs imposed by the US on select PPE items, and a huge mismatch between demand and supply.

Finally, transport and shipping constraints due to lower availability of air cargo contributed to the shortage across *all* categories of medical products.

Background to medical supply chains and trade

If we look 2019 data from the World Trade Organization(WTO) on US imports (by value) of all medical product, Ireland (17%), Germany (12%), Switzerland (9%), China(8%), and Mexico (6%) together account for more than half of all US imports (by value) of medical products.

Germany, the US, and Switzerland are also the leading exporters of medical products to the world. Approximately 35% of medical products globally come from these three countries. The US has a 12% share of global medical product exports, and medical exports constitute 7% of our total goods exports. Medical product exports comprise a significantly higher share of exports for other countries, most notably Ireland at 38% and Switzerland at 29%. In contrast, in China they account for less than 2% of total exports.

This picture looks different when we disaggregate by product categories. For example, China is the top exporter of face masks with 25% share of the global market. For PPE as a whole, China's share of the global export

market is 17%. For medicines, Germany, Switzerland, The Netherlands, and Ireland are the most significant exporters. If we focus only on generic medicines, then India contributes to approximately20% of global exports. Generic medicines manufactured in India constitute up to 40% of the US generic and over-the-counter (OTC) market. For Active Pharmaceutical Ingredients (API) – the key ingredients that go into finished formulations of medicines -- approximately 80% are produced in China.

While the geographical concentration varies by product category, overall the supply chains of medical products are highly global. There is a separation of production clusters from the consumption markets. The global production networks of medical products have evolved to their current state due to a variety of factors.

Medical supply chains are characterized by extremely high specialization across different production steps which enable the production of highly regulated products at the lowest cost. Lower labor costs have led firms to offshore production of face masks and some types of PPE to China and other regions with lower labor costs. For patented medicines and other medical products, the concentration of production in Germany, Switzerland, and Ireland stems from clustering advantages in technical know-how, tax incentives offered by those governments, complexity in manufacturing, and proximity to R&D hubs. For API, well designed and stringent environmental legislation in the US and EU was one of the factors which led to the shift of production to China and India. Irrespective of the original reasons for offshoring or concentrating production, over time comparative advantages in manufacturing efficiencies and economies of

scale have evolved in clusters where medical products are currently manufactured.

Considerations for US policy toward medical supply chains

Diversify production bases including (but not limited to) domestic manufacturing

Many of the policy proposals developed to address supply chain weaknesses exposed by the current pandemic call for greater US self-reliance in the production of medical products. It is tempting to think of having the production of all critical medical supplies within our national borders; in fact, it is safe to assume many policymakers in other countries are considering a similar approach. However, if implemented hastily this move towards supply chain autarky may further deteriorate the resilience of the global medical supply chain. If anything, COVID-19 shows that geographical concentration of critical medical supply production creates huge risks. We experienced some of the consequences of this approach when Hurricane Maria hit Puerto Rico. There was a concentration of manufacturing in Puerto Rico, especially saline bags, which led to shortages in hospitals across the US. By forcing medical products to be manufactured in the US, we will increase the cost of manufacturing but we will not necessarily make it more resilient or shock-proof. Also, reshoring production will not happen with the flip of a switch. Building new production plants for medical products takes time, sometimes several years to ensure the steps required for sterile manufacturing, regulatory approvals, and process efficiency are all steadfastly in place.

We need to create sufficient reactive capacity in the US to be able to rapidly respond to surges in demand for medical products. Such manufacturing

capacity will not necessarily be a replacement for the entire volume of medical products for which we currently rely on global supply chains. Instead, it will be supplemental to the more routine global supply. For such capacity to be sustainable in the long term, we need investments in medical product manufacturing platforms which are efficient at smaller scale, and which can be scaled up and down in operation without incurring significant cost or time. We also need purchasers of medical products -- both private health systems and federal purchasing programs -- to provide adequate incentives for the creation of such capacity. Large purchasers must be willing to pay the extra costs of having reactive capacity that most of the time will never be utilized.

We should also enable US medical product companies to diversify their supplier base internationally. Many medical product companies have now recognized the vulnerability of their supply chains due to geographical concentration of suppliers. As they consider expanding their supplier base to additional countries, they will face difficult economic tradeoffs. Developing a supplier base in a new country requires significant investments. Transferring the know-how, building human capital, and achieving the required manufacturing productivity require time and money which companies by themselves may be hesitant to commit. Through the new US International Development Finance Corporation (DFC), we can provide capital for US-based medical product companies to expand and diversify their supplier bases to additional countries, especially for PPE. In addition to creating greater resilience in our medical supply chain, it will also allow us to contribute to industrialization in countries in Africa, Latin America, and some parts of Asia which are currently not well integrated into global supply chains.

Mandatory Stress Testing to Ensure Resilience

In the wake of the COVID-19 pandemic, medical product companies will try to enhance resilience in their supply chain by building redundancy, diversifying their manufacturing base locations, and creating greater supply chain visibility. However, setting up alternative manufacturing sites and keeping spare capacity and diversified suppliers costs money. If left to their own devices it is unclear if all companies in the medical supply chain will invest sufficiently in resilience. A federal program run by the Department of Health and Human Services could ask manufacturers of critical medical products to demonstrate that their supply chain can meet significant demand surges and weather supply disruptions (including supply disruptions resulting from export controls). Although in a different context and with very different variables, such stress testing is now routine in the banking sector and carried out by the Federal Reserve Board. At the very least the federal government should require medical product manufacturers registered in the US to provide information about their production locations, production capacity at each location, and component and raw material suppliers. Such information provided to a designated federal agency will be kept confidential for proprietary reasons. It will be important to design such a stress testing and reporting mechanism in a way that does not lead to high costs for companies, which would create barriers for smaller firms to compete in the market.

Expanded strategic stockpiling

Keeping adequate quantities of critical medical supplies in the SNS is by far the most robust way to ensure we have enough supplies to meet emergency needs. Stockpiles support much-needed slack into tight global supply

chains and are a rapid response mechanism to help cope with unanticipated demand surges or supply disruptions. The federal government can also leverage its purchasing of medical products for the SNS to incentivize resilience in the medical supply chain. Purchasing for the stockpile can be prioritize manufacturers with reactive manufacturing capacity in the US in order to keep their supply lines running.

Inadequate stocks and operational management challenges prevented the SNS from guaranteeing medical supplies during the initial COVID-19 crisis. But that does not have to be the case in the future. We need a congressionally mandated National Academy of Medicine expert committee to reevaluate the governance and technical design of the SNS. The SNS is not only a device for emergency preparedness but also a vital buffer for the medical supply chain which can help create resilience without compromising global trade.

Conclusion

The COVID-19 pandemic has exposed the vulnerabilities of our medical supply chains and shown us how poorly performing supply chains result in additional suffering for patients and expose health professionals and emergency workers to unwarranted risks. We all now recognize that the US medical supply chain is subpar in terms of resilience. Building a resilient medical supply chain which is ready to weather a future shock therefore requires concerted effort and planning. Such efforts must understand the key organizing principles of global medical supply chains and the specialization of tasks and *not* focus on domestic manufacturing alone. As we prepare for the massive supply chain that will be necessary to manufacture and distribute potential vaccines for COVID-19, we are

reminded of the global nature of the vaccine supply chain in which glass vials, adjuvants, and other items come from a supply chain with a global footprint. The US faces a national imperative to assure supply chain security to meet needs at home. But the US also has a national interest in preserving trading partners and growing economies and well-being around the world. We need not frame supply chain security as a zero-sum game. Instead, by focusing on diversification of the supply base of medical product manufacturing, the US would gain supply chain resilience, expanded trade opportunities, and goodwill. That combined with routine stress testing of the medical supply chain for resilience and building a larger national buffer in our stockpile would enable our medical supply chains to be more robust to future shocks.

Thank you for the opportunity to present this testimony. I hope you find it useful, and I welcome any opportunity to work with the Committee in the future as you consider legislative avenues to build resilient medical supply chains to protect and save more lives.