STATEMENT

OF

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# PROTECTING THE RELIABILITY OF THE U.S. MEDICAL SUPPLY CHAIN

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Chairman Grassley, Ranking Member Wyden, and distinguished Members of the Committee, thank you for the opportunity to speak with you today on a matter of utmost importance to the country: protecting the reliability of the U.S. Medical Supply Chain.

As the Senior Vice President, Chief Supply Chain and Logistics Officer for UC Health, my responsibilities include strategy and oversight for sourcing, acquiring and distributing all supplies and capital equipment within our health system. UC Health is an integrated healthcare system serving the Southwest Ohio and Northern Kentucky region, and one of 125 Academic Medical Systems in the country. In partnership with the University of Cincinnati, UC Health combines clinical expertise and compassion with research and teaching – a combination that provides patients with options for even the most complex situations.

The challenges that have emerged from the COVID-19 pandemic are unlike anything we have encountered in our lifetimes. The healthcare sector has been one of the hardest hit by this pandemic. Coronavirus-related disruptions to supply chains, combined with dramatic increases in global demand, are among one of the many challenges that hospitals and systems are facing in today's environment.

Our President and CEO, Dr. Rick Lofgren, is one of three health executives in Ohio serving in an advisory capacity to Governor DeWine on Ohio's response to the COVID19 pandemic. With leadership from state executives and the Ohio Hospital Association, the state created geographic regions in order to have a coordinated, regional approach to the pandemic. This geographic coordination, that includes active participation and engagement from regional and local leaders and public health experts, has created an environment of partnership and cooperation oftentimes not seen between hospitals or between hospitals sand public health. Through these communication pathways, we have been able to quickly identify and resolve barriers and challenges – oftentimes using unique and innovative solutions.

One such innovative solution is the "Virtual Stockpile", created by the Ohio Hospital Association in partnership with Governor DeWine, to guarantee that the hospital industry would contribute supplies to congregate living facilities, rural hospitals, health clinics, etc. so that Ohio's economy could open, and remain open. The Ohio Hospital Association coordinates this effort on behalf of their membership and, while it is in its infancy, shows the promise of what true collaboration could look like during any disruption to the medical supply chain.

In my role, I have participated in state-level conversations about the reliability of the supply chain, partnered with other academic and community hospitals to leverage the supply chain on state, regional and local levels, and coordinated an aggressive internal strategy to access supplies directly for our care teams and patients.

Today, I will provide a brief overview and background on healthcare supply chains. I will also highlight challenges, lessons learned and potential resulting strategies for moving forward post COVID-19. For each of these areas, I will segment my comments by focusing on perspectives

from both the Demand side and Supply side. Lastly, I will provide a summary of the impact that COVID-19 has had on out healthcare system and provide potential areas of improvement to the committee based on my insights and experiences in over 30 years in Operations and Supply Chain Management.

**Healthcare Supply Chain Background and Overview**

Traditional healthcare supply chains were typically transactional based departments which were focused on purchasing and distributing materials within the hospital or system. In recent years, as reimbursement models have shifted towards value based, patient centered care the hospital supply chain has shifted its focus and become more strategic and integrated with its clinical partners. Supplies are often the second largest expense within a healthcare system accounting for anywhere from 25% - 35% of total expenses – labor is the only category that is larger than supply expense. Value based reimbursement systems reward providers who decrease costs while improving quality and outcomes, creating an improved and more cost-effective system.

This change has shifted the focus of supply chain executives from transactional to an integrated model with a laser focus on Cost, Quality and Outcomes (CQO). This focus has forced better alignment with internal customers and led to improvements in cost, quality and outcomes through efforts such as product standardization. These efforts required improvements in infrastructure and systems that integrate pure purchasing data such as quantities and price with quality, outcomes and utilization patterns. Improved data capabilities have enabled physicians, clinicians and supply chain to start align purchasing decisions thereby driving improvements in CQO. Not all healthcare systems are fully integrated, but the vast majority are moving in this direction in order to more deeply understand demand, reduce waste, improve outcomes and lower the overall cost of healthcare.

Hospital supply chains differ from their industry counterparts in that they are much more reliant on Group Purchasing Organizations (GPOs) and Prime Distributors to assist with day-to-day activities. Even with the most rigorous standardization efforts, many systems still have thousands of parts they are trying to contract, purchase, inventory and distribute. The sheer magnitude of this number of products often necessitate the use of these strategic third party partners to assist with contracting, purchasing and distributing of materials for health systems. In fact, many systems are looking towards these strategic partners to help drive costs out of the internal healthcare supply chain. Examples of this include the utilization of GPO price contracts to eliminate the need for local contracting and utilizing prime distributors and converting to a Just in Time (JIT) delivery model which eliminates the need for bulk warehousing and storage onsite.

While healthcare supply chains have become increasingly efficient in helping to drive out cost and inefficiencies, they have also become heavily inward focused. The use of strategic vendors to perform critical functions can be a very cost-effective approach, however, it adds another layer or touchpoint within the overall supply chain and can lead to neglect and a lack of understanding

into where there may be supply risks upstream. The lack of integrated systems or tools to help track utilization and forecast demand also impacts the overall supply chain and its ability to quickly react to changes.

**Healthcare Supply Chain Challenges**

***Demand***

1. The increased demand spike for COVID-19 related medical supplies was unprecedented. Demand for supplies such as PPE, testing equipment, testing supplies, ventilators, physical plant resources (monitors/beds) and ventilator related drugs started to climb in March.
2. Low volume products, such as PPE, became high volume overnight. Allocations from prime distributors were based on historically low usage of these supplies, thus allocated supply was inadequate to meet healthcare system needs.
3. Unknown usage and shifting usage patterns caused anxiety and stockpiling of supplies as they were available.
4. The increase in demand spike for certain essential drugs with increased off label use stressed areas within the pharmaceutical supply chain.
5. An increase in demand from non-traditional customers such as first responders, nursing homes and others contributed to the rapid increase in demand for PPE products worldwide.

***Supply***

1. A large percentage of manufacturing capabilities for both raw materials and manufacturing are located in the Asia-Pacific region. This includes both PPE and a large number of Active Pharmaceutical Ingredients (API's) required for many medicines and drugs.
2. Existing manufacturing facilities around the world were disrupted due to closures and lockdowns to prevent the spread of COVID-19.
3. Export restrictions were imposed by many countries to protect domestic supplies during the height of the crisis.
4. Distribution and logistics capacity constraints were affected by workforce issues. Sickness and travel bans have had an effect on commercial air and ocean freight carriers. Many suppliers were chartering private planes to help expedite shipments.
5. There was a significant increase in counterfeit PPE products and gray market suppliers.
6. A lack of transparency and communication across the medical supply chain network slowed and confused responses from health systems.
7. The global impact of COVID-19 was unparalleled. In a more typical disaster, such as a hurricane, supply chains can redirect resources from one geography to another. The global impact of this pandemic did not allow for shifting of resources – all areas were hit equally throughout the world.

**Healthcare Supply Chain Lessons Learned and Responding Strategies**

***Demand***

1. Implementing preservation and reuse policies, to protect and preserve limited supply resources, were a necessity. A great deal of effort went into preservation policies with strong collaboration between healthcare providers, infection control and supply chain leaders. All efforts were coordinated to ensure healthcare workers were protected while trying to preserve supplies in the face of scarcity.
2. New businesses were created to assist with the shortage of supplies. Decontamination efforts for N95 masks were fast tracked. Battelle in Columbus, OH, was granted the approval by the FDA and awarded a contract by HHS and FEMA and funded up to $400 million to assist healthcare facilities with decontamination of masks.
3. Innovation labs were mobilized quickly at universities like the University of Cincinnati to research and look for alternative solutions to supply issues. 3D printing of masks, swabs and respirators were among the first innovations that were presented to healthcare systems. Additionally, innovative solutions to re-tool and re-use non-standard equipment was also at the forefront of innovation.
4. Data collection and reporting on daily PPE usage (by department and site) was critical to monitor demand spikes and to ensure that preservation efforts were being followed.
5. Local and state organizations (e.g., Ohio Hospital Association) mobilized and helped to facilitate dialogue and solution sharing among members.
6. Strong collaboration and communication networks between health systems has become commonplace. Sharing of ideas and supplies has become standard practice as everyone is learning and adapting to this pandemic.

***Supply***

1. Production expansion with existing traditional manufacturers quickly increased but was also insufficient to meet increased demand. Companies such as 3M and Medline quickly ramped up production worldwide at existing manufacturing facilities.
2. Modification of existing production lines to run additional or new product was also enabled as quickly as possible to increase output of much needed supplies.
3. Extended hours of operation and overtime was used wherever possible to increase output in existing manufacturing facilities.
4. Nontraditional manufacturers entered the space quickly to assist the country with the need for PPE. Athletic and apparel companies were among many who quickly pivoted operations to assist with products like protective eyewear and simple masks. Procter &Gamble is an example of a Cincinnati company who quickly pivoted operations to manufacture critical supplies and donate to local and regional health systems.

5. In addition to the university 3D printing efforts, industry 3D printing leaders also quickly looked for ways to partner with universities to find expedited solutions that worked for the medical community.
6. Many companies also pivoted to make ventilators, however, retooling manufacturing lines in addition to longer lead times for this type of manufactured equipment did not provide immediate relief.
7. Sourcing expansion of both raw materials and finished products happened quickly from both the supplier and customer side of the equation. Suppliers were looking for alternative solutions to meet the increased need while end users were looking to source product from non-standard suppliers in order to secure product as quickly as possible.
8. Supply Chain transparency platforms have been created to assist with communication across entire supply chains. Vizient and One Network Enterprises are a great example of this much needed improvement in the U.S. medical supply chain.
9. Logistics providers partnered with both the private sector and the government to expedite shipments and increase logistics service capacity.
10. Supply allocation was quickly put in place by domestic manufacturers and distributors alike, thus ensuring that products were available for "hotspots" that were hit the hardest.
11. From a global perspective, export restrictions were put in place to keep scarce medical resources in the United States.

**UC Health - Fiscal Impact**

The unanticipated healthcare supply chain costs due to COVID-19 have been staggering; the long-term impact to the U. S. healthcare system remains to be seen. With the prohibition on elective procedures, the impact of COVID-19 from a fiscal perspective was a loss of approximately $110 million in April/May. This represents a 5-6% loss of total annual revenue over this two-month period. Expenses during this same period increased by approximately $10 million largely due to buildup of inventories for PPE.

While hospitals are no longer prohibited from providing elective procedures for patients, FY21-22 will continue to see an increase in expenses and overall reduced revenue for the system. Expenses will continue to be larger than historical levels due to many new developments as a result of COVID-19. A few examples include increased utilization of supplies, new expenses such as screening stations at hospital entrances, increased lab testing, and investment in additional infrastructure such as telehealth. This increased utilization of supplies is coupled with higher than normal pricing. The chart below provides data on a small sample of UC Health PPE utilization and pricing (Pre-COVID and current):

| | Pre-COVID-19 | | COVID-19 | | Average Price | | |
|---|---|---|---|---|---|---|---|
| | Avg Daily Usage | Avg. Price (ea) | Avg Daily Usage | Max Price (ea) | April | May | June |
| Exam Glove | 9,405 | $ 0.06 | 47,876 | $ 0.06 | $ 0.06 | $ 0.06 | $ 0.06 |
| Impervious Plastic Gown | 2,886 | $ 0.27 | 5,996 | $ 2.34 | $ 1.20 | $ 2.30 | $ 0.32 |
| Level 1 Mask | 2,280 | $ 0.11 | 8,343 | $ 1.95 | $ 1.12 | $ 0.06 | $ 0.07 |
| N95 Mask | 159 | $ 0.64 | 382 | $ 6.50 | $ 3.21 | $ 1.69 | $ 1.50 |
| Face Shield | 52 | $ 0.96 | 128 | $ 6.00 | $ 3.65 | $ 0.96 | $ 0.96 |

**UC Health - Supply Chain Impact and Experiences**

***Demand***

While Southwest Ohio was not an initial hotspot, and that allowed us the benefit of learning from others, it also meant that the region was not prioritized in terms of obtaining limited resources. As resources were distributed to national hotspot areas, we often needed to engage our elected leaders to intervene on our behalf with federal leaders and/ or the manufacturer in order to obtain the items we needed to provide a stable and ongoing COVID19 response in Southwest Ohio.

We view the current medical supply chain (from PPE to testing supplies to machinery) as "comfortable, not confident", and we continue to advocate for a national and state distribution strategy (public and private) that allows resources to be distributed to all geographic areas.

As a standing member of our Incident Command Center, collaboration between clinical leaders, infection control and supply chain was vital to developing a plan and understanding what future demand for critical supplies would look like. Broad communication of appropriate PPE use, re-use and storage was a critical component that helped supply chain to better understand and develop a strategy for sourcing these scarce resources. Collaborative planning helped to provide appropriate protection to UC Health employees while ensuring that usage data was collected and monitored on a daily basis. Daily reports from Supply Chain helped to alleviate clinical concerns about the supply of PPE for the system. All sourcing decisions and activities were centralized and supplies were strategically placed in work areas with nursing leaders playing a vital role in monitoring and dispensing as appropriate. These interventions did not happen overnight, but constant communication between all parties helped facilitate a better understanding and less fear among all stakeholders.

***Supply***

With critical supply on allocation from our prime distributor due to their inability to meet demand, UC Health had to quickly pivot and source PPE from non-standard suppliers. This change in activity was dramatic and shifted from a supply that was on automatic replenishment with one vendor to reaching out and making over 500 new sourcing inquiries in a 30-45 day period to vendors we had no prior experience with. This presented a unique challenge with respect to balancing the urgent need for product and the inherent risk in dealing with unknown third parties. UC Health relied on a strong network of contacts and collaboration with peer academic medical centers across the country to work with credible vendors and weed out bad actors.

UC Health's strategy was to focus on known or existing vendors and, if at all possible, to steer clear of new vendors entering the market. We mitigated risk by spreading multiple smaller orders through various vendors versus trying to rely on singular large purchases to cover all of

our needs. The vendors we utilized were already in the business of supplying either the healthcare industry in another capacity or a different industry in a similar capacity. For example, we used a vendor who had previously focused on supplying material handling bins to the healthcare industry, but was able to utilize their network of logistics and suppliers to quickly enter the PPE space. Another vendor we found supplied PPE into a different industry than healthcare but was able to pivot and start selling industrial respirators into healthcare as the CDC and NIOSH released expanded lists of approved N95 masks. As UC Health and others started to have success with non-standard vendors, we quickly shared successes with our counterparts to build an alternative supply network.

In Southwest Ohio, there was tremendous cooperation among health systems and even some attempts to combine our purchasing power and look for large scale opportunities to purchase simple masks and N95 masks. While I believe there eventually was some limited success with this approach, we learned that there were many scams and promises of large quantities of supplies coming in from outside the United States. These scams involved large sums of money being placed in escrow or cash in advance purchases for goods that did not materialize. UC Health relied on our internal legal team to vet potential sellers and was fortunate that we did not lose any money despite our involvement, albeit limited, with some of these transactions. UC Health quickly moved away from this approach and continued to place smaller orders with more reliable vendors.

***Product Vetting***

A majority of the product we successfully sourced came from China or other Asian-Pacific countries. A great deal of time and resources were spent vetting these products before we moved forward with purchasing. Our standard approach required a potential vendor to submit material specification sheets, FDA Certificates of Approval, Third Party Testing Certification and samples that were reviewed by our infection control team. A significant percentage of the information we reviewed did not prove to be authentic. FDA certificates were submitted that did not match what we could find online at the FDA website and Third Party testing certificates were submitted that could not be verified. If a product made it past these initial checkpoints, our team then tested the product to ensure that all materials received matched specification sheets. Using the methodology described above, UC Health was fortunate that we did not purchase or receive any non-standard or counterfeit products.

***Supplier Communications***

During the initial months of the pandemic, UC Health had several shipments delayed and our suppliers communicated to us that this was due to the supplies being either purchased or seized by the federal government. Shipments were often delayed for 2-4 weeks until another shipment arrived from overseas. In order to circumvent product being held or seized at the port of entry, our suppliers communicated that they were labeling packages as “not for medical use”. We received product labeled as such and they met all specifications and testing criteria. We were not

direct recipients of this communication from the manufacturer and can only attest to what we were told by our suppliers.

Another frequent communication from our suppliers in the first 4-6 weeks of the pandemic was the inability to get shipments into the country due to the lack of available capacity with commercial airfreight companies. Suppliers used multiple methods of transport to overcome this constraint including private charters, smaller and more numerous shipments on Fed Ex or UPS, and ocean freight, which delayed availability by 2-4 weeks.

***Regional and Strategic National Stockpile Assistance***

Starting in February, the Ohio Department of Health (ODH) surveyed hospitals in order to ascertain our PPE levels and to prepare for statewide stockpile resource allocation.
In partnership with the ODH, the Ohio Hospital Association and the Regional Healthcare Coordinators, we monitored ongoing PPE needs and inventories in order to inform distribution allocations. Additionally, this network of communication allowed for sharing of guidelines and recommendations for PPE conservation, and regional and state cache limitations due to expired or destroyed supplies. Hospitals were asked to utilize the limited regional and state cache prior to the Strategic National Stockpile (SNS) as they continued to distribute PPE from our regional cache to healthcare providers, EMS, law enforcement and hospitals through EMA request processes.

In early March, UC Health received our first supplies from our regional cache and in late March we received our first shipment of PPE from SNS. We continued to receive shipments of supplies in the months of April and May.

**Opportunities for Improvement**

I would like to go on record that the cooperation I have witnessed both internally and externally to UC Health has been in a word - remarkable. This includes but is not limited to government officials, healthcare leaders, and industry leaders from the non-healthcare sector, physicians, nursing, and supply chain. Supply chain disruptions continue to be more frequent as geopolitical events, weather events, and other outside forces continue to impact all industries. If we can continue to have an open dialogue and learn from our collective experiences and other industries, we will be in a much better position when the next supply disruption happens.

Specific to the healthcare industry, I would offer the following specific examples of areas that can continue to be strengthened and improved:

1. Communication and transparency along the entire supply chain must be improved. Genuine transparency from demand forecasting to supply and raw material availability is crucial and builds trust along the supply network. Improved data capabilities and

infrastructure should be adopted across the healthcare supply chain to help facilitate these efforts.

2. Create a more diverse and possibly regionalized approach for critical supplies. Supply chain resiliency should be favored over low cost for critical supply items.
3. Require manufacturers of critical supplies to report raw materials and manufacturing capacities to the government to provide insight into the most important supply chains. This would be similar to how pharmaceutical manufacturers are required to report to the government.
4. Require health systems or hospitals to carry a minimum days on hand supply of critical supplies. This would be similar to the CMS requirement for facilities to maintain enough fuel, potable water, etc. to operate for a minimum of 96 hrs. My suggestion would be to mandate a minimum of 30 days inventory on critical PPE for all health systems.
5. Improve transparency and communication on the national stockpile. This would include details on the supplies and quantities that are being stockpiled and how these will be allocated during a time of need.
6. Build a larger national stockpile of critical supplies. This would eliminate the competition for supplies when and if a crisis strikes again. We should avoid scenarios where government and industry are trying to secure the same resources and competing against one another.
7. Improve domestic capabilities and capacities for the manufacturing of critical raw materials and supplies. On February 26, US Health and Human Services (HHS) Secretary Alex Azar told the House Appropriations Committee that the country had a stockpile of 12 million N95 masks, but according to HHS estimates, it needs 300 million to cover an emergency. The estimated annual production capacity in the US and Mexico is 65 million masks.

**Conclusion**

Thank you for the opportunity to share my insights on this very important subject. COVID-19 has provided yet another example of the vulnerability of critical healthcare supply networks and the need to look for new creative solutions to overcome these disruptions. I believe we have already learned many valuable lessons that can be used to improve our healthcare supply chain resiliency and ultimately improve outcomes during future supply disruptions. I look forward to working with the Committee and others to offer my thoughts and help to strengthen our healthcare supply chain from end to end and create greater transparency and resiliency in the process.

I am happy to answer any questions from the Committee.