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Thursday, July 2, 2020

House Small Business Committee

Subcommittee on Economic Growth, Tax, and Capital Access

Hearing: Supply Chain Resiliency

Testimony of Chris Fagnani

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Thank you, Chairwoman Velazquez, Chairman Kim, Ranking Member Chabot, Ranking Member Hern and distinguished members of the Committee for the opportunity to testify today.

My name is Chris Fagnani and I am co-owner and vice president of Lynn Medical. Established in 1966, my company is a second generation, family-owned medical product distributor with 30 employees located in a suburb of Detroit, Michigan. Lynn Medical is a cardiology and imaging Specialty Distributor. We represent over 100 manufacturers of medical equipment and disposable supplies related to procedures such as ultrasounds, ECG's, patient monitoring and a host of other healthcare issues. Our products find application nationally in hospitals, doctors' offices, and clinics. For this hearing, it is important to note, a significant part of our medical customers are also small businesses as they are owned and operated by the physician or groups of physicians.

I also have the pleasure of appearing before you today as the current Board Chair of the Health Industry Distributors Association (HIDA). HIDA is the industry association that represents 100 distribution companies operating 500 medical distribution centers across the care continuum nationwide. HIDA members such as Lynn Medical deliver medical products and supplies, manage logistics, and offer customer services to virtually every provider in the country. What is important to share with the Committee is that small businesses are a key segment of the distribution industry as 73 percent of members are small businesses.

Challenges

COVID-19 created several challenges for Lynn Medical—both as a small business and as a distributor in the healthcare market. As is with any small business, human resources are limited. Most of our departments have a staff of one and most employees wear multiple hats. At the start of COVID-19, we had to quickly focus on technology and navigate how to set our employees up to work remotely due to the shelter in place requirements that occurred in many states, including my home state of Michigan. We were not set up to work remotely and did not have an IT Department to create and deploy the plan. We had to purchase hardware for our employees and tweak software capabilities to create the ability to communicate internally and remotely to serve our customers. This was a significant cost and resource drain to the company.

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Another challenge we had to deal with was significant product shortages and disruptions to the healthcare supply chain. Representing quality products is a pillar of our organization. As demand was in many cases three times the capacity from our traditional manufacturer partners, we found ourselves having to vet new sources. Again, we do not have a regulatory department whose main role is to solely navigate through information to determine the FDA's current and shifting guidance recommendations on the status on various products under Emergency Use Authorizations (EUAs).

However, we felt strongly it was our responsibility to understand, comply and educate our customers on these topics. An example is KN95 masks. Initially, according to the CDC website, 80 factories overseas were granted EUA status for KN95 masks, but that was quickly reduced to 14 factories. Once a factory was removed from the CDC list, any product from that factory was immediately stopped at US customs. What happened to my company was we had product that left China that was on the approved list, but by the time it made it to the US border had to be returned to China due to a change in labeling on the box that needed to be made. This required change from federal agencies occurred while our product was on the water. The bottom line was the product was ok, but the box was not. We had already presold the product to customers, but were now faced with a 6-week delay, which added costs to our business for the extra shipping. . We then had to educate our customers for the reason there were delays and shifts in EUA status.

Another example that highlights the challenges is the COVID-19 Antibody tests. We had shipped product that was allowed as the manufacturer had filed for an EUA and the EUA was pending based on a March 16, 2020 FDA guidance document that deemed the product allowable while EUA approval was pending. However, a subsequent FDA guidance on May 4, 2020 stated it was not allowable to ship the product until the EUA was formally granted. It was very difficult to obtain clear answers from regulatory agencies and very difficult to explain to medical facilities. There was significant hardship in searching for clear documentation to ensure we were compliant.

Challenges were also present in finding, staying up to date, and implementing the information pertaining to assuring our workplace was following all the necessary and prudent guidelines to stay operational, serve our customers and protect the health of our employees. As a distribution center we had essential workers that needed to come to work for us to maintain operations and get needed products to providers. Many of

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these resources are now readily available but in mid-March when we needed to act swiftly this information was almost nonexistent from local or national sources.

Currently, we are concerned about payables from our healthcare customers. As I mentioned, many of our customers are small businesses that have been closed for months because of COVID-19. As these offices reopen, they are also having to purchase personal protective equipment (PPE) for their employees—something that is necessary but was not in their budgets. While our physician customers are beginning to see patients, it is not at pre-COVID volumes, which means their cash flow is not at normal levels. They need Lynn Medical to support them and provide longer payment windows. At the same time, with product shortages many vendors required pre-payment which is not customary.

Opportunities

My company did apply and receive approval for the Paycheck Protection Program (PPP). It was an easy and painless process for us and I want to thank you for including this program in the CARES Act. This assistance is critical to Lynn Medical's financial health. It allowed us to stay whole and maintain our commitment to our employees as we support our customers to the best of our ability.

While the regulatory environment was confusing, we utilized the flexibility and agility small business has to become adept at vetting new suppliers and becoming a resource for our customers. We found ourselves partnering with other small manufacturing businesses whose primary products were deemed non-essential but wanted to keep their employees working and assist in the COVID-19 response.

We partnered with a family owned business in Michigan that was primarily a cut and sew shop for the automotive industry. They made seat covering and arm rests for cars. We collaborated with them, so they could transition to isolation gowns and fill a critical need for the COVID-19 response. We also partnered with a drum making business in New Jersey who retooled to make face shields. We found in the small business community innovation, a willingness to shift priorities and take risks to keep their businesses relevant and employees working.

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Recommendations

I am proud of my company and of our industry. We have never stopped working to secure product and support our customers and communities during the COVID-19 response.

I would like to thank this Committee for its leadership on small business issues and the policies Congress included in previous stimulus packages. Those policies, such as PPP, have been critical to our financial health and commitment to our employees.

As the Committee considers future opportunities to support small business, I would like to offer a couple of recommendations:

1. Streamlined information source for small business. Small businesses do not have regulatory and legal departments to assist them in navigating the shifting guidance and emergency use authorizations from federal agencies. Clear and simple communications for small businesses would be of great value.
2. Enactment of the Medical Supplies for Pandemics Act of 2020 (H.R. 6531): This bipartisan legislation was introduced by Representative Dingell (D-MI) and Walorski (R-IN) and was included in the House-passed HEROE's Act. On behalf of Lynn Medical and our industry, I urge you to ensure it is included in the final stimulus package agreed to by House and Senate.

This legislation is important for the medical supply chain and preparedness efforts. Critical to its success is including **all medical product distributors** as their diversity in size and geography offers different perspectives and customer bases. Healthcare is a local business. Many privately-owned medical practices utilize small business medical distributors to gain access to their medical products. Not including small business distributors in the solution for emergency preparedness would create a gap in service to the local medical facilities.

Specifically, the Medical Supplies for Pandemics Act of 2020 directs the Strategic National Stockpile to work with the supply chain to enhance supply chain elasticity by:

- Creating incentives for manufacturers of critical medical supplies to diversify production, increase emergency stock and increase capacity; and

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- Working with distributors of medical supplies to manage domestic reserves of critical products such as PPE, infection prevention products, ancillary products and testing supplies. This reserve is intended to be owned by the SNS but would be stored and managed by the commercial supply chain where it would be refreshed and replenished by medical product distributors.

Thank you again for the opportunity to testify before you today. I look forward to any questions you may have.