Written Testimony of Cathy Denning, RN, MSN
Group SVP, Sourcing Operations, Analytics & Center of Excellence
Vizient, Inc.

The United States Senate Committee on Finance

Part 2: Protecting the Reliability of the U.S. Medical Supply Chain During the COVID-19 Pandemic

July 30, 2020

Good morning, Chairman Grassley, Ranking Member Wyden, and members of the Committee. Thank you for holding this critically important hearing and for giving me the opportunity to testify today. My name is Cathy Denning, and I am the Group Senior Vice President of Sourcing Operations, Analytics and the Center of Excellence at Vizient and a registered nurse. Prior to joining Vizient 20 years ago, I practiced in the clinical arena working in both the acute care and home care settings.

Before we get started today, I'd like to tell you a little bit more about Vizient. Headquartered in Irving, Texas – so if I may, I'd like to say a special "hello to you, Senator Cornyn"– Vizient is the nation's largest member-owned, member-driven, health care performance improvement company.

You'll hear me use the word "member" a lot today. When we say member, we mean the health care providers that participate in our organization's services and choose to work with us every day. Vizient members include more than half of all the acute-care health care systems, including pediatric facilities, community hospitals, integrated health delivery networks and approximately 95% of the nation's academic medical centers. We also serve approximately 20% of the non-acute care market as well.

Most people know us for our supply chain expertise, also known as group purchasing or "GPO" expertise, which is what I will focus on today. Our group purchasing business is predicated on the idea of negotiating prices and terms and conditions for drugs, devices, and other medical products and services on behalf of our member healthcare providers. In other words, we help providers realize savings and efficiencies by aggregating their purchasing volume and using that to negotiate discounts and other value, such as clinical and utilization support, with suppliers, resulting in larger savings and greater value than individual hospitals can typically negotiate on their own. Our members purchase approximately $100 billion of goods and services off of our contracts annually.

Beyond this supply chain support, we also offer an array of consulting services, collaboration services, analytic tools and clinical expertise – all designed to ultimately improve patient outcomes and lower the cost of health care. We see ourselves as extensions of, and advocates

for, the health care members we serve. We strive every day to be their indispensable partner – to help them achieve efficiencies, lower costs, and improve patient outcomes – with the goal of improving the health care system for all.

Important for today's discussion - Vizient holds a unique position in that we work closely with both healthcare providers and suppliers. We act as a liaison, advocating on behalf of the member providers we serve and sometimes acting as their lifeline in times of disaster.

That brings us to why we are here today – focusing on the critical issue of counterfeit PPE, the so-called "grey market" of brokers and supplies, and how at a time of grave need there were, and are, individuals and organizations looking to exploit healthcare providers, the patients they serve, and the government with their false and often harmful claims of having appropriate medical supplies to offer.

But before I go into more detail regarding our experience, and our members' experiences, with counterfeit product, I think it's important that I provide some context regarding the perfect storm that led to the current situation.

First – it is my strong belief, having spent my entire career either working in a healthcare setting or for a GPO, that the supply chain is not "broken" as some have claimed. We've certainly seen that there are ways that the private sector, including Vizient, can work better with other private and public sector stakeholders to make improvements – and I'll get to those later – but generally speaking, even in times of previous disasters like hurricanes, floods, and others – the health care supply chain represents a great example of different stakeholders working together for a common purpose. Previously, manufacturers, distributors, GPOs, hospitals and others have been able to quickly put protocols and processes in place to help guide critical supplies and services to areas most in need. We are proud of the work we do on a daily basis – but surely in times of crisis.

That said – yes – when COVID-19 hit the United States, everything seemed to change overnight. And it is important to understand how the unprecedented nature of this pandemic impacted the supply chain and made it nearly impossible for anyone to fully prepare.

I realize that word – unprecedented – has been used often in describing the last several months here in the United States and across the world. But, truly, this pandemic was. As you all know, the health care industry has been looking for ways to reduce costs for more than 20 years. Lean practices to streamline clinical processes, just-in-time inventory, and tightly managing inventories of medical supplies have become more commonplace in hospitals across the country. Additionally, more manufacturing has been moved off-shore as suppliers sought to lower prices and looked for ways to achieve cost savings.

Then COVID-19 hit. No one knew how it was transmitted, where it came from, or how to treat it – only that it presented with a complicated mix of symptoms and appeared to be respiratory in

nature. This meant that providers were facing an unknown, highly contagious infection and the public was panicked here and simultaneously across the globe. It was the perfect storm.

At the same time, other challenges exacerbated the problem. For example, here in the U.S. we were coming off of two spikes of influenza Type A and Type B. We were already facing critical shortages of surgical gowns due to manufacturing issues in China. Then, when COVID-19 spread across the globe, suppliers that manufacture in Asia could not get their PPE out of the country due to the sequester of those products for in-country use. In addition, although we've known for quite some time that a lack of a diverse and redundant manufacturing locations is problematic, it became acutely problematic during this crisis. To give you a specific example, the EU epicenter for COVID-19 was the Lombardy region in Italy – but that's also exactly where the overwhelming majority of the nasal swabs needed to test for COVID-19 are manufactured. While manufacturing was increased and deemed an essential business by the Italian government, it exposed a vulnerability in the supply of these critical products.

To add to the challenges, virtually overnight, hospitals were using roughly ten times their usual amount of PPE products and those in the hardest hit areas were using ten to fifteen times their usual amount of N95 respirators at the peak of their surge. To provide context, these products are normally used only for known highly infectious respiratory illnesses during surgery and procedures that produce aerosol. Now many members are using these as universal precautions for all patients.

Bottom line – in the pre-COVID-19 environment, there was simply no way for anyone to have adequately planned for this unprecedented and ongoing spike in worldwide demand for PPE.

Which brings us to why we are here today – to expose the predatory practices of those looking to exploit this vulnerability by making false promises and offering unsafe, exorbitantly priced medical supplies to healthcare providers throughout the country, and to work together to collectively find ways to prevent these practices in the future.

One of the first things we did to help our members respond to the COVID-19 outbreak was establish a dedicated "war room" to ensure rapid responses to member needs. These dedicated staff began fielding more than 1,000 member inquiries each week. Some of these inquiries included requests to vet products that members were considering purchasing from non-traditional manufacturers or brokers – and to provide an opinion on whether an offered product was what someone claimed it was.

The war room staff, along with our sourcing and clinical staff, and our Quality Assurance and Regulatory Affairs (QARA) professionals, quickly determined that the best way to assist our members, and have the biggest impact, would be to focus on the actual manufacturers of the products. Our QARA team has the expertise to help members understand the regulatory environment and the registration and approval requirements for manufacturers – so that is where we focused our efforts. We did not actually examine or "touch" the products

themselves. We emphasized to members that our process was simply a necessary first step; if they wanted to move forward with purchasing any of these items, they would need to feel comfortable with the seller, and review samples of the products themselves to ensure the products met their internal infection control or other protocols.

Starting in mid-March, as the number of requests to vet products became more numerous, we realized that many of the requests were duplicates – either because the same broker had reached out to multiple end-points, or because multiple brokers were claiming to have product from the same original manufacturers. For example – we received 38 separate submissions purporting to be from brokers who represented a product from a single manufacturing site in China. The site IS a legitimate manufacturer of respirators, but brokers were claiming this manufacturer could supply members with additional products including surgical masks, gloves and surgical gowns – yet we could not find any such device listings with the FDA. At least 26 brokers claimed to have access to this single manufacturer's products. Submissions like these started in mid-March and continue to be submitted by new brokers as recently as last week.

Given these complexities, we quickly stood up a workflow management tool and database to help manage the influx of requests and to help us track where the duplications were occurring. To give you a better sense of the sheer volume – from March 29 through July 13, we received 2,385 total requests to review products with 1,320 of these being unique requests for a unique manufacturer and product. Ultimately, we found that only 788 of these products could be validated as potentially appropriate based on the applicable FDA or NIOSH standards.

It's important to note that this "vetted" list has morphed week after week as guidance from the federal agencies continues to be refined. For example – the FDA issued an emergency use authorization (or EUA) for certain filtering face piece respirators on April 3rd but then, as part of their continuous quality assessment and working with the CDC and NIOSH, revised this EUA just over a month later. More than 65 filtering face piece respirators that had previously been authorized by the original EUA, many of which had appeared on our validated list, were no longer authorized. This just goes to show how complex and evolving this situation has been over the last few months – and it continues to evolve even today.

This vetting and validation process was only one piece of our overall response efforts to the pandemic. It continues to be laborious – but critical – and between these bad actors, unsafe products, demand needs of our provider members and consistent with our dedication to leaving no stone unturned to get our members what they needed, we also explored other ways to help bring more supplies to market.

Vizient has partnered with multiple suppliers to expand capacity of PPE and other vital supplies, including putting our own capital at risk with some North American suppliers to start or expand PPE manufacturing lines, thus increasing overall production capacity. Our relationship with Standard Textile, where we guaranteed purchases if they converted manufacturing lines, has helped to create more than 2 million reusable isolation gowns and more than 700,000 reusable

surgical masks and face shields. With the company, Encompass, we helped to reopen their North American production line to produce 19 million level 3 disposable isolation gowns. These are just a few specific examples of how we have helped to source new product. Working with nearly a dozen more manufacturers we have helped to source Level 2 disposable gowns, nasal swabs, nitrile gloves, medical masks, and N95 sterilization processors for our healthcare provider members.

Despite our efforts, as I mentioned, counterfeit product continued – and continues – to be a problem that our provider members face. The overwhelming demand that I highlighted earlier has continued as hospitals are still facing actual or possible surges in COVID-19 cases. Although suppliers, GPOs, and the government have all taken innovative and big steps forward to meet this demand, we don't expect that the overall supply will begin to even out until 2021. Bad actors continue to reach out to providers in need, and our members continue to try and find whatever safe supplies they can. Unfortunately, it often times does not end well. I'd like to highlight a few specific examples of the types of situations our members have found themselves in – and, as such, bring attention to just one of the many challenges they are facing throughout this crisis.

First, our member, Yale New Haven Health in Connecticut, experienced an ongoing issue with N95 respirators. In late March they became aware that there may be counterfeit Dasheng KN95 respirators. Combing through donations they had received, they found a significant number of these counterfeit respirators. Of course, they also had open orders at the time for these Dasheng KN95s so they immediately cancelled those. Yale later learned that most of the PPE vendors with whom they had been engaging were not actually dealing directly with factories in China but, rather, third party distributors or grey market brokers. Their concern around these counterfeit products led them to cancel orders they had placed directly with the Dasheng factory. Throughout this crisis, Yale discovered that many vendors had sent false test results, prompting Yale to send some of their KN95s out to a third party testing lab – turns out they were barely 85% efficient – leading Yale to become even more skeptical of these vendors and their product.

Second – a regional acute care facility in Florida engaged with a broker to obtain N95 respirators supposedly manufactured by 3M. The hospital's internal review process caught that the broker was not actually licensed to sell those 3M masks so they did not contract for or end up paying for the products. They did, however, have additional purchase pending for masks but the shipments were continually delayed. Their bank got concerned that the activity was fraudulent so although they did receive some product, they cancelled the remaining order and, thankfully, got their money back. But this hospital ended up losing out on two different shipments of critically needed product due to counterfeiting concerns.

Finally – one last example I'll highlight for you – but I'll note that these three examples are representative of stories we've heard from many more of our provider members. A large acute-care provider in the Pacific Northwest is currently in the middle of sorting out a questionable

situation in which they were sent small sized Halyard-manufactured N95s from a company that claimed to have sourced them in South Carolina. However, when they arrived they were in plastic bags and sealed with a sticker – not the original Halyard boxes, as would normally be expected. When this provider pressed the third-party company on this, they were told that they had a process for "reallocation" of the respirators – but would not share what this actually meant with the provider. The company in question is a sterilizer solutions firm in its normal course of business – so you can draw your own conclusions on that one – but they have been very unresponsive since our member began to question them about this incident.

As I mentioned previously – these are just three stories – there are countless other stories, and many of our members were reluctant to come forward with their stories due to reputational concerns, liability risks, or other issues. At a bare minimum, these counterfeit products and grey market brokers have taken vital resources away from our provider members and wasted hundreds of hours of time – time they could have been spending elsewhere.

In fact, some of the biggest issues our members faced throughout the country are not necessarily with respect to counterfeit product, but with grey market third parties seeking to exploit our members' needs by offering these critical products at excessive prices. Brokers, and sometimes suppliers, sought to charge hospitals $8.50 for AAMI Level 2 and 3 non-sterile isolation gowns, when those same gowns typically go for as low as $0.84 per gown. Similarly, brokers were trying to sell masks for as much as $11 (with the median price being $4.50) when they normally sell for approximately $0.80.

Despite the contemptible actions of these bad actors and the overall challenges presented by COVID-19, I think it's important that I end my remarks today with a hopeful outlook to the future.

We are learning from our experience going through COVID-19 that vulnerabilities do exist – and therefore there are opportunities for improvement. Specifically – our supply chain needs to be more resilient, through enhanced transparency, redundancy, and diversification. We also need to take the lessons we learned regarding the Strategic National Stockpile and do better to ensure that it truly is a resource to states and providers.

In order to further build a resilient supply chain, more transparency is needed. Transparency into the location of manufacturing, including raw materials, as well as storage locations. And I don't just mean transparency with the FDA and other government officials – this information should be shared with private sector partners as well so that we can aid in the diversification efforts I'm going to speak to.

Redundancy – whether it be in the PPE space or in the pharmaceutical space, where Vizient is also extremely active in helping to source product for members – we have long advocated that the best way to achieve availability and cost savings is to encourage competition. But competition is also necessary to mitigate disruption. It is critical that we have multiple

manufacturers who produce the same products so that a shutdown or negative impact on one company doesn't ripple throughout the supply chain broadly.

Regarding diversification of the supply chain – I've touched on this already – but the fact that so many of our medical supplies are manufactured overseas is not the singular reason for the problems we are facing now. Similarly, onshoring all manufacturing would not solve these problems either. We need a diversified supply chain – one that is global in nature. By having multiple manufacturing locations spread across the globe, we mitigate the risk of having all manufacturing of an essential product in one location wiped out by a single event. That said, I think we can all agree that more needs to be done to create a much stronger domestic footprint.

Finally, there has been a lot of discussion regarding the federal stockpile – we strongly believe that the stockpile does need to be bolstered and be accessible to healthcare providers in need. We believe the stockpile should have at least 90 days of supplies for key items (including the essential medications list that my Vizient colleagues in pharmacy have put together – drugs without which you would be unable to provide life-sustaining care). These items, however, need to be rotated and managed as appropriate. This means that the government should continue to engage private sector stakeholders, like Vizient, manufacturers, health care systems and others to help provide feedback on which products should be included, how much, and how they should be stored and managed. And, again I'll emphasize the importance of transparency – which is much needed in the stockpile as well. Health care systems and states need to be able to quickly access these products during a disaster and all participants in the supply chain need to understand the consumption of these products and overall need. That said – whether it be the federal or state stockpiles – usage should be limited to times of emergencies, not as a regular course of business. Stockpiles are meant to supplement needs and serve a very specific, and critical purpose.

I would like to close by saying that Vizient has enjoyed a collaborative working relationship with the federal government and Capitol Hill for many years – but especially over these last few months. I have been pleased with how officials from FEMA, FDA, CDC, DOD, and others have been proactive in their outreach to me, our leadership team, and others throughout Vizient – and especially the outreach and support to our provider members.

With that, I want to thank you again for the opportunity to testify today. I appreciate being able to be here to share my, and Vizient's, experiences regarding counterfeit PPE products and other supply chain challenges over the last few months. As you can tell, I am passionate about these issues and strongly believe that we can all do better, working together, to help health care providers and the patients they serve get through this crisis. I would also like to offer my sincere appreciation for all of the front line health care workers who have given of themselves tirelessly throughout the pandemic.

I look forward to your questions.