UNITED STATES OF AMERICA

DEPARTMENT OF HEALTH AND HUMAN SERVICES

FOOD AND DRUG ADMINISTRATION

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CENTER FOR DEVICES AND RADIOLOGICAL HEALTH

MEDICAL DEVICES ADVISORY COMMITTEE

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VIRTUAL PUBLIC WORKSHOP - BUILDING MEDICAL DEVICE SUPPLY CHAIN RESILIENCE: A HEALTHCARE AND PUBLIC HEALTH ECOSYSTEM-WIDE COLLABORATION

DAY 1 - RESILIENCE DEFINED AND MEASURED

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M E E T I N G

(1:00 p.m.)

DR. NEWMAN: Good afternoon, and welcome to the FDA Center for Devices and Radiological Health Resilient Supply Chain Program Public Workshop on Building Medical Device Supply Chain Resilience: A Healthcare and Public Health Ecosystem-Wide Collaboration. My name is Carl Newman and I will be your emcee for today.

Since we don't have the luxury of seeing a packed conference hall, I'd like to share a sense of the participation for this workshop. Joining us over the next 3 days are over 820 registered participants representing over 200 medical device industry organizations, over 70 healthcare organizations and providers, over 20 universities and colleges, and 14 U.S. government departments and agencies.

Now, for an overview of the next several days and some workshop logistics, I would like to introduce Dr. Tammy Beckham, the Associate Director of the Resilient Supply Chain Program within the CDRH Office of Strategic Partnerships and Technology Innovation.

Tammy, the floor is yours.

DR. BECKHAM: Thank you, Carl. And good afternoon, everyone. Welcome and thank you for joining us for our workshop, Building Medical Device Supply Chain Resilience: A Healthcare and Public Health Ecosystem-Wide Approach. We are so excited to have you all here today and we look forward to hearing from speakers, panelists, breakout group participants, and from you, the audience, over the next few days. But before I get started today, please give me a minute to just thank everyone who spent so much time preparing for the workshop today and all the speakers and panelists and everyone that has joined us for this exciting event. Next slide.

The Center for Devices and Radiological Health is hosting this week's public workshop so that we can bring together participants from across the medical device

ecosystem to discuss opportunities for enhancing medical device supply chain resilience. We want to be able to explore opportunities and define mechanisms, that we can strengthen partnerships and collaborations between our public and private entities. And lastly, we want to introduce the new CDRH Resilient Supply Chain Program and hear your thoughts and feedback about the role that this program can have to your position in the supply chain sector. Next slide.

Each day the workshop will focus on a specific theme. Today's theme is Resilience Defined and Measured. We want to hear from you about what resilience means to you from your unique position in the supply chain. In tomorrow's session we're going to focus on innovative methods and mechanisms that collectively we can utilize to build and sustain resilience. And on the last day of the workshop we want to hear from you specifically about opportunities for collaborating and working together. Next slide

Our agenda today starts with a keynote address by Dr. Suzanne Schwartz and Dr. Mary Beth Kingston. This is going to be followed by a panel discussion moderated by Dr. Rob Handfield, and the panelists represent multiple sectors across the device supply chain to include patient groups, healthcare providers, healthcare systems, distributors, and group purchasing organizations. After our panel discussion we're going to move to breakout sessions. And for those of you that have been confirmed as breakout group participants, please locate your confirmation e-mail so that you can quickly enter your assigned breakout room when that comes. And then at the end of the day we're going to come back on the webcast and bring everyone back together to summarize the key takeaways from those breakout groups. Next slide.

And just a few reminders that you can send us your questions or comments through the webcast portal today using the text bubble located in the webcast window on the bottom right or through the workshop e-mail address that's shown on the slide. We will be

recording and transcribing the webcast today. Next slide.

The text bubble again is at the bottom right of the webcast screen, just type in your question or comment and hit send and we will receive that. Next slide.

And now without further delay, I'm really pleased to introduce our first keynote speaker this afternoon, Dr. Suzanne Schwartz, who is the Director of the Office of Strategic Partnerships and Technology Innovation.

Suzanne, the floor is yours.

DR. SCHWARTZ: All right, thank you so much. Thanks so much, Tammy, for your kind Introduction.

I consider my remarks as merely table setting for what promises to be a very exciting and productive series of discussions over the next few days. As we've embarked on building a novel program at our Center for Devices and Radiological Health for medical device supply chain resilience, your thoughtful vision and leadership have been extraordinary assets. Your passion and drive have been palpable to all of us with whom you've engaged both internal to our FDA organization, as well as to the universe of stakeholders externally.

And I want to start off merely by acknowledging that deep-felt appreciation to you and to your team for what you have already accomplished. Indeed, it is in every way emblematic of the approach we are advocating for today and in the coming days of the workshop. It is imperative for all of us across the ecosystem to lean forward together so that we can be best positioned to move from reactive posture towards a future state of medical device supply chain resilience. Why is this so important today? Let's move to the next slide, please. If you could just give me a moment.

Perhaps the administration's executive order on America's supply chain best encapsulates the moment we find ourselves in today and the unique opportunities it allows. To underscore key elements of this executive order, I want to replay a few excerpts of it.

The U.S. needs resilient, diverse, and secure supply chains to ensure our economic prosperity and national security. The potential sources of disruption are many. Pandemics and other biological threats, cyber attacks, climate shocks and extreme weather events, terrorist attacks, geopolitical and economic competition, and other conditions can reduce critical manufacturing capacity and the availability and integrity of critical goods, products, and services. And importantly, the close collaboration needed to build resilient supply chains will foster collective economic and national security and strengthen the capacity to respond to international disasters and emergencies. Next slide, please.

While vulnerabilities and dependencies in the global supply chain became amplified and most pronounced in the height of the pandemic, the reality is that we didn't get there overnight. The complexity, the fragility, and the challenges have been years in the making. Indeed, we've experienced a variety of events prior to the pandemic that have resulted in acute shortages of medical devices stemming from different causes and exacerbated by a host of factors.

For example, in times of stability and cheap transportation, it made sense to minimize inventory costs, but that has created systemic risk and reduced resilience. With increased consolidation in the supply base, critical components have become more dependent on either single or few suppliers. We have seen the impact from labor shortage and transportation bottlenecks. More frequent weather disruptions and natural disasters have impacted on raw materials, supplies, manufacturing, and shipments.

With trade conflicts, great power competition and the outbreak of war in Ukraine, for example, geopolitical issues can be a source of disruption and, as was observed during the pandemic, countries also limited exports of key materials and products to ensure their own domestic supply. Finally, the pandemic created sudden demand shocks for certain types of products such as PPE and of note, we may continue to see unpredictable increases

in demand as COVID-19 and post-COVID medical conditions continue to evolve and materialize as new pandemics or as epidemics emerge. Next slide.

These disruptions put our healthcare and public health critical infrastructure in jeopardy. This issue is one of public health and national security concern for the American public. Ultimately, it's patients and their providers who are the ones that suffer. Next slide.

No one entity, public or private sector, can resolve these complexities by themselves. We have to work collectively and collaboratively to put all the pieces together and to create that common picture leaning forward. Collaboration between industry and FDA is paramount to build resilience and mitigate shortages. Similarly, industry needs government as a partner to address system-wide barriers to increased resilience. All of this benefits the patient and U.S. public health. Next slide.

So why should FDA be involved? Well, there are three compelling reasons why the FDA can and really must have a role within the medical device supply chain. All three, when we take them together, form a substantive triad.

Number one, we are the only agency responsible for considering the patient perspective. And while multiple other agencies play important roles with supply chain efforts, the FDA is the only one responsible to patients as end users and to providers. We are concerned with the supply chain because our concern is for patient safety and wellbeing and their ability to receive the care that they need.

Number two, we bring technical knowledge of medical devices. We're best poised to convene industry and government to mitigate and prevent supply chain disruption because we understand devices and their clinical impact. We therefore conduct impact assessments that can then help inform other agencies in their decision making.

And finally, number three, understanding and supporting supply chain resilience is directly aligned with our FDA mission to protect and promote the public health. We

recognize that our regulatory role impacts the supply of medical devices and, where an action might impede product availability and have a potential adverse consequence for patients, we've also leveraged specific regulatory flexibilities to mitigate supply chain disruptions and to coordinate faster recovery. Next slide.

Experience and expertise has already shown us that leaning forward, that preparedness goes a long way in advancing us towards a future state of supply chain resilience. By being thoughtful and methodologic in our analyses, we can better anticipate that which lies around the curve and out of sight, and as such we can work together with stakeholders to implement preventative measures. After all, what's the alternative, being in a chronic or recurring state of firefighting?

Simply put, trying to address shortages after they've already become manifest leaves us in crisis mode. It does not advance the state of resilience. Let me state that again, it does not advance the state of resilience and actually, it puts our national security and critical infrastructure in grave jeopardy. The reactive stance of firefighting merely leaves destruction in its wake and requires, in fact, building new infrastructure to repair damage that's been done.

And so it's through this lens with this intent that we therefore share with you here our vision and mission for this new program, as stated here. We envision resilient public health supply chains that promote the availability of safe and effective medical devices for consumers, patients, and healthcare providers. Our mission is to strengthen public health supply chains by proactively monitoring, assessing, and communicating risks and vulnerabilities to prevent shortages of medical devices.. Next slide.

So what do we seek to accomplish through this program? What can stakeholders expect as tangible deliverables? And what are we asking of you, as our participants, during this workshop that's going to help inform this program build? Well, our programmatic goals

are, again, to promote availability of safe and effective medical devices, to build supply chain resilience, to use evidence-based data to drive regulatory mitigations, to develop risk-managed emergency response medical product plans. Our strategic objectives are to enable rapid intervention through proactive measures and partnerships, to develop and apply state-of-the-art supply chain intelligence for predictive modeling, early signal detection, and continuous surveillance, to foster a more resilient supply chain through investments in preventative measures.

With these goals and objectives in mind, we can shift from reactive to proactive. You'll hear from Tammy and others about performing cross-cutting supply chain illumination and data analysis to increase visibility across product categories and to identify key risks and vulnerabilities. We can convene stakeholders for information sharing and to coordinate efforts. We can increase resilience with actions to mitigate disruptions and explore prevention. And we do this by promoting regulatory prioritizations and expediting for resilience building and shortage resolution. We can provide information and support to proactively mitigate counterfeit or fraudulent medical devices and increase trust in device authenticity. And finally, we can streamline government engagement as a central coordinator to help medical device stakeholders engage the right federal partners. Next slide, please.

From our perspective, this workshop serves two purposes: number one, to formally announce and introduce the Resilient Supply Chain Program; and secondly, to serve as a call to action to stakeholders across the ecosystem to work together with us to strengthen the supply chain. After all, our vision cannot be achieved by FDA alone. We need your input on how to design an effective program that helps prevent future challenges. We also must hear from a diverse group of stakeholders from across the ecosystem, especially patients and healthcare providers. And finally, the last slide.

Thank you in advance for your participation, your feedback, and your support in this workshop. As you participate in the sessions over the next few days, remember, our mission, front and center, is ultimately to improve public health.

With this goal in mind I look forward to turning the meeting back over to Dr. Carl Newman, who will introduce our next speaker, Dr. Mary Beth Kingston, who will share more on how shortages of medical devices have impacted providers and their ability to deliver care for patients. Thank you.

DR. NEWMAN: Thank you, Suzanne, for setting the table and for the call to action and collaboration.

We're fortunate, as Suzanne mentioned, I have a twofer for our keynotes today and it's my honor to introduce our next speaker, Dr. Mary Beth Kingston. Dr Kingston is a chief nursing officer for Advocate Aurora Health, where she serves as a member of the executive leadership team and is responsible for nursing practice and standards and patient experience. Dr Kingston is also on the board of trustees and is an executive committee member of the American Hospital Association, and previously served on the board and was president of the American Organization of Nurse Executives.

She's a recipient of the American Assembly for Men in Nursing's inclusion and diversity award, a Robert Wood Johnson Executive Nurse Fellow, and a recipient of the Pennsylvania Nightingale Award for Nursing Administration. Dr. Kingston is a fellow in the American Academy of Nursing, was named one of *Modern Healthcare's* 50 most influential clinicians of 2021, and is a longtime advocate for healthy and safe work environments.

Dr. Kingston, the floor is yours.

DR. KINGSTON: Thank you so much for that kind introduction and thank you for having me here today to very briefly discuss the importance of the supply chain integrity, not only from the perspective of healthcare providers, but also from our patients and all of

those that we serve. I applaud the efforts of everyone participating in this discussion today and look forward to the actions related to the Resilient Supply Chain Program workshop. Dr. Schwartz did a great job of describing the critical importance of this issue, as well as many of the factors that must be considered. If you could go to the next slide, please.

So to underscore the importance, I'd like to briefly discuss this impact, again, from the point of care. A few key thoughts, and I'm speaking to the choir here. Disruptions are not new, but the pandemic certainly highlighted these occurrences, specifically around the issue of protective personal equipment and initially around ventilator availability and distribution. And now, of course, as mentioned, seeing global disruptions, China, Ukraine, the impact of single-source suppliers, etc. Not to mention weather issues, of course. But the pandemic issues, specifically PPE, had a direct impact on healthcare workers and I think this was to a degree that we had not seen before.

Now, on the plus side, one thing that happened that I'm very pleased about is that the connections between our supply chain team, team members, really, and clinical operations improved dramatically during this time. We just developed a greater appreciation of each other's roles. In fact, I spoke with our supply chain leader just a few weeks ago and he was saying to me that his supply chain team, they always knew they served a crucial role, but they truly felt the connection with what they were doing and what was happening in our hospitals and other healthcare sites.

On the other hand, I had the opportunity to serve as the clinical co-lead for our incident command and I never thought I'd wake up in the morning wondering if the plane from China had arrived with supplies that we needed. It really connected us in a way that had not happened before. And we have taken that improved connection, that improved communication, that improved understanding to respond more quickly and comprehensively when issues do arise. One example I would provide is with our contrast,

the recent issue with contrast. Our supply chain leader said to me in prior years he would not have been able to quickly identify who needed to be engaged, mobilize, implement a plan, and do whatever he could to bring the needed supplies and issues to our patients and particularly to our healthcare providers. So that's one of the silver linings, I think, is that connection and the lessons learned. Next slide, please.

I want to talk a little bit about the impact on healthcare workers and this impact was profound. They experienced fear, fear for their own safety and the safety of their family. And this is something I really had not seen, I've been in health care for over 40 years, even a little more than 40, 45 years to be exact. The frequently changing guidelines, it felt to them at times that we were basing our decisions on what was available or on what was convenient as opposed to evidence-based information. And this is the theme that I'd like to share and that is, this resulted in a lack of trust in our processes and our leadership.

For those of us that practice in multi-state systems, there is often confusion about guidelines coming from the CDC versus the state, down to our local public health departments. We saw this in many areas, but I would mention testing algorithms, and this was often based on a lack of supply of testing equipment. And as a result, there was fear for all of these issues, there was fear of harming patients, whether we felt not enough people were getting tested or whether people were reusing N95s, but that harm was there and people were feeling that. Next slide, please.

What that resulted in is something that we term moral distress. And I'm not going to say that this was limited to direct healthcare providers, because I think many of our supply chain colleagues felt this, as well. But moral distress is really knowing what needs to be done or what is the right thing to do, but not being able to for whatever reason to pursue the right course of action. We saw this on so many levels during the pandemic, unrelated many times to supply chain; for example, the visiting restrictions. But in supplies, it was

often related to PPE. So this disruption that we're talking about today and what we can do to move forward really impacts healthcare workers in a big way. Next slide, please.

And then, of course, we have the impact on those that we serve. Of course, in terms of safety, and the specifics depend on the device, on the disruption, but I have to say that what we do know about patient safety is that when healthcare team members, when healthcare workers do not feel safe, they are not able to concentrate and focus as strongly as we would like on the safety of patients. So it did affect patients, as well. Also, it contributed to a negative patient experience because that anxiety that healthcare workers feel is then transmitted to patients, not to mention the news reports, etc.

It also had a true impact, has a true impact -- and an example of this, again, would be contrast -- on our ability to care for patients depending on the specific issue, whether it's our ability to diagnose quickly or treat appropriately.

And then there are the ethical dilemmas that arise and this was particularly notable during the pandemic. You know, no one wants to go to scarce resource protocols, but I did find myself in meetings where we were going through this and I had been an ED nurse manager many years ago, I'm very familiar with triage protocols and prioritizing in times when you are under what we would term battle conditions. This was so prolonged, though, and the thought of determining protocols for who would receive a certain treatment or not was really so difficult.

And so I think that the ethical pieces that arise when we have these types of disruptions is important both for patients and the outcomes, but also for those who are providing care and then again, the resulting lack of trust that occurred not just with healthcare workers but with patients and families when they're not aware of all the specifics, but all they know is our current systems and processes are not working as well as they would expect it to. Next slide, please.

And so in summary, I hope I've shed a little bit of light on the impact that occurs directly at the point of care. The work you are doing is so critically important and I believe it will help us do what is the major theme of what I'd like to communicate today and that is the work of rebuilding trust in our processes, in our systems, with our healthcare teams, with our patients and our communities.

I know we have taken these lessons in our own organization and we are actively assessing risk and we are working with our vender partners to understand more and I know that people are at different points, but many times we don't understand the downstream supply effects. And so that lesson has hit home for us, we are working with all of our vendors to truly understand their downstream supplies and how that impacts us.

But I will say the most important lesson today of everything, and Dr. Schwartz mentioned this, is that it will take all of the sectors, it will take each one of us to be committed to this to be able to move forward to ensure that we mitigate and reduce disruptions to our supply chain.

Thank you so much for your time today and I really am looking forward to a very productive workshop. Thank you.

DR. NEWMAN: Next slide, please. Thanks much, Mary Beth, for articulating the point-of-care perspectives and underscoring the importance of resilient medical device supply chains to patients and providers.

Before we begin the panel discussion for today, let me introduce the panel moderator, Dr. Robert Handfield, who will also have a few brief opening remarks. Dr. Handfield is a Bank of America University Distinguished Professor of Supply Chain Management at North Carolina State University, and the Executive Director of the Supply Chain Resource Cooperative. He is considered a thought leader in the field of supply chain management and is an industry expert in the field of strategic sourcing, supply market

intelligence, and supplier development. Dr. Handfield served on the Department of Defense Joint Acquisition Task Force providing market intelligence and analysis for the supply of PPE needed for the domestic response during the COVID-19 pandemic. He also led a National Institute for Innovation and Manufacturing biopharmaceuticals research team to study the distribution of test kits during the pandemic. Dr. Handfield has worked with many companies through the Supply Chain Resource Cooperative, and in January of this year was invited to serve on the Biden White House Council of Economic Advisers.

Dr. Handfield, the floor is yours.

DR. HANDFIELD: Thank you very much, Carl. Next slide, please.

So this is definitely an interesting time to be a professor of supply chain management and I've been studying supply chains for about 35 years, but never have I seen the term "supply chain" more in the news or more in the media or have I been contacted by so many media.

You know, I think what we're seeing today with this panel and the speakers today is the fact that we really were not fully prepared for a pandemic when this occurred and like many others on the panel today, I witnessed this firsthand on the task force, not only seeing the shortages, but certainly the impact on our healthcare providers, as was so eloquently described by Mary Beth, and the plight of nurses during this time frame. Not only were there shortages of PPE, but in the testing environment there was a shortage of tests and that was very well described also in Scott Gottlieb's book on controlled spread where he talks about the shortages of testing that enabled us to address this issue.

One of the things I want to talk about today, and I think what we want to focus on in this session today, is really understanding what we even mean by resilience. And one definition here is simply having the right product at the right time and at the right place for healthcare providers to be able to provide what they need, the right medical device for the

right individual.

Another definition that I've introduced in a recent book I've written called *Flow*, is the term of supply chain immunity. And this is a more organizational capability to deal with sudden and uncontrolled disruptions of products and services within the supply chain. And the idea of immunity, I think, is an appealing one because it appeals to the idea of not just vaccination, but using our innate T cells and so forth to be able to develop the right data access, the right level of governance in our response, developing a playbook that can also develop those roles and responsibilities on how to respond and then, of course, establishing the right supply network and the right supply intelligence to enable an effective response.

So I think today what we would like to do is explore this idea a little bit further and try to understand, with our panel, what do we actually mean by resiliency or immunity. How do we measure it? How do we know we have it? And finally, what are the economics? I think that's a piece that everyone is talking about, is what does it mean to have all of these items in stockpile? And I think that seems to be sort of the knee jerk reaction I've observed, is everybody is stockpiling a lot of stuff, but it may not be the right response.

So let me maybe jump to the next slide, if possible.

We did a study recently with a group called SMI Supply Chain and we interviewed providers, a number of hospital providers around the country, as well as a number of suppliers of manufactured product including med devices, and we asked them what are the key priorities in establishing your resilience program. And you can see here that some of the common ones that we saw involved developing a playbook. Certainly stockpiles are part of that. Building out increased sourcing options, looking at more domestic options, and we're starting to see a little bit of that today, I'm observing more sourcing is beginning to go to Mexico, which is closer than China. Also, some domestic providers of like PPE and other products are also springing up. But I think it's important that the government be part

of this response that we enable and support some of these domestic capabilities. Analytics is a big piece, knowing what we have, as Mary Beth was saying, knowing what to allocate, how to allocate, needing data to be able to make those decisions. And then, of course, building our team, building the right competencies of a team to develop better intelligence, better analytics, and better understanding of what we can do..

So these are all different types of things, but I don't want to suggest them before we go to our panel and I think we'd be better off if we start our panel and introduce some of these questions to them directly. Next slide.

So our panel today. Eric Gascho is Vice President of Policy and Government Affairs at the National Health Council. Mr. Gascho leads the National Health Council's advocacy efforts working with member organizations to develop policy positions to improve the lives of people with chronic diseases and disabilities, and advocating these policies on Capitol Hill and within the executive branch.

We're also joined by Deborah Haywood. Deborah is Vice President of Government Solutions for McKesson and has 31 years in the extended care market, recently received the McKesson leadership award for her pandemic response work of working directly with Operation Warp Speed and the COVID-19 vaccine and ancillary kit distribution with HHS and ASPR -- ASPR is the Assistant Secretary of Pandemic Response -- as well as the Strategic National Stockpile.

Dr. Erin Kyle is editor in chief of the guidelines for preparatory -- I'm sorry, perioperative practice at the Association for periOperative Registered Nurses, a membership organization representing more than 200,000 perioperative nurses in the United States, and Dr. Kyle oversees the development of evidence-based practice recommendations and professional expertise on perioperative nursing practice for members of perioperative nurses, regulator bodies, acccreditors, and professional

organizations.

Andrew Lam is here with us. Andrew is Vice President of Procure to Pay at Kaiser Permanente, and his work with the supply chain services team spans from demand and supply planning to the end-to-end digitization of supply chain management. He's recognized for assuring and optimizing supply and for developing processes that streamline operations and enhance margin performance.

Linda Rouse O'Neill is Vice President of Government Affairs for the Health Industry Distributors Association, or HIDA. Linda brings over 25 years of healthcare-based lobbying on Capitol Hill and member services experience to her role overseeing the government affairs team as they meet with key federal agencies and Congress on healthcare issues important to HIDA members, such as pandemic preparedness and response, diversified sourcing, and supply chain resilience.

And finally, Soumi Saha is both a pharmacist and a lawyer. She's the Vice President of Advocacy at Premier and is responsible for developing and implementing the supply chain advocacy strategy for one of the nation's largest GPOs. Dr. Saha advances proactive legislation and regulatory actions to address supply chain vulnerabilities, and leads Premier's efforts to pass legislation addressing drug and device shortages to solve future crises.

Thank you all for joining us here today on this panel.

So let's kick it off, and what we've done is asked we've asked two panelists to address each of the questions and then we'll hopefully have a little time at the end for some questions from the audience, as well.

So let's start with a very basic question. What is resilience or how do you define resilience?

And Deborah, I'll start with you.

MS. HAYWOOD: Sure. Good afternoon, everybody. So resilience, you know, when we think about what it has been and what it is today, is just the ability to achieve sustained operational supply chain excellence through transparent public-private partnerships. True resiliency means that providers can consistently deliver critical medical supplies at differentiated points of care; we have a lot of different points of care today, especially here in the United States. Resiliency is overcoming the obstacles so that our citizens' and our healthcare providers' safety is maintained. At McKesson, we truly approach resiliency through a readiness lens, being adequately prepared and making sure that we're forecasting with analytics, ensuring stockpiles are maintained and related to product, is ready to use in a ready-to-use state.

DR. HANDFIELD: Thank you, Deborah.

And Erin, do you have something different or similar in terms of your definition of resilience?

MS. KYLE: Yeah, I couldn't agree more with what Deborah has shared with us and I would also add that resilience means that there really is a capacity that is either innate or developed in any person, group, process or system that allows for seamless recovery from adversity and challenges. And for a system like our medical supply chain in the U.S., that means that every part of the system is not vulnerable to things like being locked in to a single source or strategy for supplies, supply components, packaging, sterilization capability, transportation, and purchasing processes.

Resilience means that the system has mechanisms built in that create the capacity for the flexibility and adaptability to shift one or more of the parts of the system in a way that keeps essential medical devices and supplies in the hands of clinicians delivering care to patients without disruption.

So what does that look like in today's world? Well, with known challenges such as

global conflict, the effects of the COVID-19 pandemic, and climate change, it looks like global cooperation to face these issues, but it also looks like the United States having contingency plans to anticipate and respond proactively to vulnerabilities that are outside of our control.

We know that global sourcing of supply components is necessary and that international manufacturing of supplies is ingrained in the system today. We need to continually study and monitor each part of the supply chain system with domestic resilience as a top priority when planning for what we know could happen, as we've seen in recent years.

And having said all of that, it's also important that strategies to address vulnerabilities in each part of the supply chain are developed in a way that delivers quality devices and supplies to clinicians that are both effective and affordable for our patients and healthcare institutions.

DR. HANDFIELD: Thanks Erin, that's a great, great set of definitions. I can't help but think of this issue of single sources and our vulnerabilities in supply chain. You know, if we shift our focus to the medical device supply chain, certainly one of the big vulnerabilities there, believe it or not, has been resin. Resin comes from petrochemical plants and petrochemical plants were shut down in the Texas freeze back in February of 2021 and never really recovered. And so we're still seeing a lot of shortages of resins and in the manufactured medical supply chains.

But let's turn to another panelist. Eric, why is there a focus on resilience needed for this medical device supply chain that we're in today?

MR. GASCHO: Thank you for the question and thank you to the FDA for hosting such a critical workshop at such a critical point in time.

So as we are currently kind of having a national conversation about supply chains

broadly, I think it's really important to remember that the types of supply chain issues and potential shortages within the FDA's sphere of influence really can be a matter of life and death for many people with chronic diseases and disabilities. We'll talk a little bit later about some of the clinical outcomes and what that means, but I really want that to be sort of framing throughout this conversation.

We're also obviously coming out of a time where the healthcare system has been stretched further than we've ever seen in our lifetime and you heard a lot about that already. And as others have mentioned, the pandemic maybe didn't cause a lot of the gaps in the supply chain that we've seen, but it certainly did exacerbate and illuminate them. There's a lot of lessons learned that are coming out of the pandemic about some of the lack of resiliency within the supply chain and potential need for improvement and just on the direct impact that we've seen on patients.

Some of the ones that we've seen that had a very direct impact that I've heard a lot about from the patient organizations within our membership kind of fall in a couple different areas. You know, obviously we're speaking about devices today, but the one I heard a lot about within the drug space was hydroxychloroquine for people with lupus and arthritis, we saw a big shortage of that as that product was being hoarded by folks who were using it to treat COVID.

Within the device space we've seen some more things happen, as well. We saw a shortage of albuterol inhalers as many of the inhalers were being used in the clinical setting for COVID which further exacerbated asthma within patients, saw a shortage of contrast agents which has led to delayed diagnosis, and then certainly we've heard a lot about and we'll continue to hear a lot about the lack of access to PPE and to testing, which have probably the most direct impact on people with chronic diseases and disabilities who are more susceptible to severe COVID disease. So the further perpetuants of the pandemic

really had a very direct impact on people with chronic conditions.

At the end of the day, I think what I really want the takeaway to be from my being here is that device shortages are going to have a disproportionate impact on 160 million people with chronic diseases and disabilities in this country and if we don't have resiliency within the supply chain, what we're asking patients to do is be resilient themselves and make very difficult choices and really put themselves at risk. So again, a really important conversation we're having here today and I look forward to continuing it.

DR. HANDFIELD: Thank you Eric, and those are some great points about the impact on patients and certainly, especially patients with disabilities.

Andrew, let's hear from you. What does a focus on resilience look like in the medical supply chain from your perspective?

MR. LAM: Yeah. Good morning, here in California. But it's been said a little earlier this morning that when you look at the challenges in the medical device supply chain even before the pandemic, I mean, it's been years of vendor consolidation and there's been a focus on cost reduction and that focus on cost reduction has really reduced the barriers in that end-to-end supply chain, a lot of just-in-time, a lot of reliance on overseas manufacturing. And then when you look at it today, and I just looked at this yesterday, at Kaiser Permanente we were dealing with 9,000 individual unique items on back order. Pre-pandemic, that list was still in the thousands, but it's just exacerbated over time. You mentioned plastic resin shortage, right? That's just been something that's ongoing and it hits the far reaches of things you wouldn't expect. You know, I heard plastic resin shortage used as a reason for a tourniquet cuff shortage and it's just been ongoing.

And what I would add in terms of why it's so important to focus on it is, it's just really any small issue today leads to a complete back order in a full category: pandemic, geopolitical issue, a natural disaster, a recall, right? A lot of news today around the

pediatric nutritional products. For many of us on the call, we've been dealing with that since December of this year (sic), not a new issue. It just happened to hit the news cycle and become the bigger issue.

But what I will also say, that also causes downstream effects. For example, that lack of communication, transparency, trust in the supply chain, that leads to hoarding, it leads to over-ordering, it just becomes a self-fulfilling prophecy. So you may have had enough in the network for the whole country, let's just say, but now it's all sitting in one place or sitting in one area and there's not a resilient supply chain to move that around or even know where it is.

And then finally, the last thing I would say in terms of why we need to focus on that is, from my experience in medical devices, the supplier community still has been a little bit lacking in their demand in supply planning capabilities. It really lags retail capabilities when you look at like an Amazon or a Walmart in comparison, and their ability to proactively identify, combat, communicate, and plan on recovery has been lacking and it just really came to hit us, particularly, with the pandemic.

DR. HANDFIELD: Thank you, Andrew. And I think you're referring to the challenges of really looking upstream, you know, in some cases multiple tiers, to identify where these disruptions are occurring.

Let's hear from Linda Rouse O'Neill, as well. I know you've had some experience in this, in the distributor world.

MS. O'NEILL: Yes. Well, first, thanks so much for having HIDA come and participate in the workshop, it's so important, the work and the conversation that we're all having, and I think we're going to finally go somewhere and learn from COVID and move the ball forward, at least that's my hope. So HIDA represents medical product distributors, so to your question of why we need to focus resiliency on the medical product supply chain, I

think, as I was listening to everybody, from Dr. Schwartz and Dr. Kingston this morning and the rest of the panel, I was like, in a nutshell, because we're critical to any sort of pandemic response or emergency response going forward, everyone's talking about supplies, which was not always talked about in the past and because we are such a critical partner to our provider customers and the patients they serve, as well as our federal agencies, looking at medical supply chain through a resiliency lens going forward is truly needed.

We used to be just in time and there were a lot of reasons for that and traditionally, pre-COVID, the rule of thumb in the industry was you probably had 20 to 30 days of supply of products at any one time and as we've come out of post-COVID, the spotlight is we really need a more robust supply chain and we need more diversified sourcing, but I don't think it can be in any one place. If you think about the resin example, you can't put all the eggs in one basket. We really need a strategic blend of domestic and near-shored and global product sourcing going forward.

And we really need to think about supply chain in a way that's communicated so all the end users, whether that's the public, whether that's our provider customers, whether it's retail, everybody understands and at the end of the day, if we're in this situation again, had access to the product they need and who they're going to get that from and I think that communication going forward is really important.

DR. HANDFIELD: Just kind of as a follow-up to that question, Linda, how would you sort of measure resilience? How would you measure the effectiveness of communication or the ability to react? Is it lead time or what are some of the key measures, even?

MS. O'NEILL: That's tough. Deborah might have some different thoughts. I'll probably take a big picture and then if anybody else on the panel would comment. So when I started at HIDA 12 years ago, the focus was just in time, the right product at the right time for the right customer and I think, to your question, when we're talking about

communication, I think it's the right information about the right product and the availability to the right partner so that decisions can be made. But when you look forward, think forward to true resiliency, I thought Deborah said it well, we've got to have that cushion in the supply chain so that our customers can use who they are used to dealing with on a regular basis. Whoever their distributor is should have the product that they need to be able to support them and that behind the scenes that communication needs to be happening, if the shortage is in one place, so that we can move things through the chain.

DR. HANDFIELD: Thanks. Deborah, do you have any ideas also on how to measure resiliency in McKesson's supply chain, for instance?

MS. HAYWOOD: Sure, I'd be glad to weigh in here. And Linda knows me well, we've worked close together for a long period of time here with HIDA support, and I would just add I think where it really starts is just incorporating that public-private partnership. I will say, coming through COVID, that has improved. The experience that we've all had, the communication, the collaboration, has certainly improved but we have to make sure that the known amount and forecasted levels of product that is approved by the U.S. government, approved by the FDA to be used at the site of care, especially in the particular healthcare setting that it's being used in, so that the appropriate device is being used and is a product supported by FDA governance.

I think the other thing is just measuring that resiliency, it starts with the collaboration with manufacturers, the distributors work very closely to understand the amount of shipments, the expectations of shipments coming in, the accountability for where that products goes, all the way through to the end user. That will prevent the hoarding. It also makes sure the product is in the place that it's needed most whenever, at the time of an emergency, and that's critical. I think another part of the reporting that is really critical, and it started with the supply control tower, now many distributors are

reporting that information, which is great, it gives a holistic view, but just continuing those IT enhancements to increase, really, that overall transparency. So to me the key to success and measuring resiliency is just making sure that IT enhancements continue to improve, that resiliency is established by the known forecasted amount of U.S. government product that's approved by the FDA, being used in the healthcare setting and it protects the citizens and the healthcare providers that are actually using the product. So for me, I would say in McKesson's approach, it starts just with transparency and reporting and ensuring the product is in a ready-to-use state.

DR. HANDFIELD: That's a great concept and I think that can also be enhanced by doing different kinds of war gaming, you know, looking at potential threats that might occur and what kinds of clinical requirements would that mean in terms of FDA-approved medical devices.

Let's turn to the clinical impacts of disruptions. Maybe, Erin, you can talk about what you see on your end in terms of the clinical impacts of these disruptions.

MS. KYLE: You know, this is really such a far-reaching question that has so many answers. The most obvious one is that when supplies that are necessary for healthcare delivery are not available, healthcare delivery, including diagnosis and treatment, doesn't happen the way it should and patients suffer. It means that even the most basic healthcare needs like specialized nutrition for infants might not be met.

When medical supplies are not available, clinicians do what is necessary to continue to care for patients as best they can with what they have. They may be forced to improvise and compromise when there are no other choices. That means that they can shift their practice to something outside of the standard of practice. Good clinicians want what's best for their patients and are very uncomfortable when they're in a position to practice outside of what they consider best practice or even just safe practice. This creates moral distress,

just like Dr. Mary Beth Kingston mentioned earlier in her keynote today. And this moral distress can produce things like burnout, like we're seeing today amongst so many clinicians at a very alarming rate.

Another problem with supply scarcity when it involves personal protective equipment and technologies is that clinicians not only have to make do without needed medical devices and supplies, but they also are in a position where they feel unprotected and unsafe while delivering that care. And again, as we've seen, this contributes to burnout among clinicians.

And finally, and perhaps not as obvious, is that supply chain disruptions that persist for an extended time can shift the idea about what is acceptable practice from the former standard of care to something less and will inevitably contribute to worse outcomes for patients. An example of this in the perioperative setting could be an increase of surgical site infections or an increased rate of wrong site surgeries. And I know I've only touched on a very few of these, so there's so many more, but these are the ones that I really wanted to highlight today.

DR. HANDFIELD: Thanks, Erin, great insights.

Eric, what are your thoughts on this question?

MR. GASCHO: Yeah. First of all, I completely agree with Erin. Also love the points that Mary Beth Kingston raised on that slide she had on the patient impacts. I think, as both mentioned, this is a really big question. I would probably argue that this is an entire workshop in and of itself and it's really difficult to answer in a sort of disease agnostic way, but at a high level, the direct clinical impacts and delays in care can be significant. It will vary from condition to condition but certainly, as you think about it with someone who has a life-threatening diagnosis or a chronic condition that has disease progression, delays in care can very significantly impact patient care. As you think about disruptions in any

diagnostic tools, as we heard, delayed diagnosis of cancer, for example, can have immense consequences. So I think it is really important that we think about what the clinical and patient impacts are.

You know, one other way that you could potentially be oversimplifying this, but one way to look at it would be if you have disruptions in the supply chain, they're entirely disrupting the triple aim, which is the right care for the right patient at the right time. And if it's not at the right time, it really can have a lot of significant impacts.

And then finally, I'd like to sort of build on the comment that Erin raised about a lot of difficult decisions that providers are forced to make. I completely agree, but would also add that patients likewise have to make similar decisions. One would hope that that's being done in tandem with a practicing clinician, but that assumes that everyone has a clinician who they have a good relationship with, who they have trust in. And I know we'll talk about it throughout the day, but the topic of health equity certainly comes to mind here in thinking about the lack of those relationships with many patients. What are the decisions that patients will be making potentially on their own? Will they ration their care? Will they think about changing their regimen with or without the guidance of a clinician? Will we see hoarding? So I think there's a lot of things to really think about in terms of what the patient decision making is, as well.

DR. HANDFIELD: Thanks, Eric. Great insights from someone who's very close to the patient care world.

Let's shift now more to the health operations impact of disruptions in terms of how we manage inventory, capacity, workforce and of course, the supply chain. Andrew, maybe you can talk about your experience, what have been some of the health operations impacts of not just the pandemic but potentially other disruptions, as well.

MR. GASCHO: Yeah, when I think of disruptions, the first thing that comes to my

mind, which still affects us today, is that it's a huge, massive administrative burden when you're managing shortages, disruptions, back orders, and it's an administrative burden for many reasons.

One is (1) you're researching for alternate products, you're researching for alternate practices, alternate vendors; you're working on communication, you're working on is there going to be a patient impact, do I need to cancel a procedure, do I need to communicate that to the patient. And when you do that you have to include all facets of the operation. It's not just supply chain in the back looking for an alternative product and bringing it in.

Products even, if they look the same or maybe operate the same, they're not. And so that requires physician time, clinician time, nursing time, infection prevention, employee health, clinical technology, it includes all of those groups for every single disruption to review if this is an alternative practice or product that is suitable for the patient. And all that does is it takes away from patient care. And we mentioned the pandemic, it's still ongoing and we still have people, and staffing is challenged for multiple facets. And so you have this huge administrative burden working on that and it just takes away from patient care, that's one.

It was mentioned earlier -- in particular, Kaiser Permanente -- we're a multi-hospital, multi-region, multi-state system and with that product availability, that answers differently across all those different regions. And so you have a reduction of standardization of care across even a health system because of that. One hospital may be able to get product A, the other hospital can only get product B, so now you inherently introduce a lack of standardization into the process.

And then finally, cost -- right -- cost inflation, not just from the product perspective, but you've got transportation, you've got maybe the product requires a different practice, so that introduces new costs, staffing costs. And one of the biggest impacts, obviously, is

cost and that's impacting our operations on a day-to-day basis.

DR. HANDFIELD: Thanks, Andrew. Yeah, great points. I think as we start talking about standardization of care it will be interesting to see if there is some availability of products at different locations. And I think you noted that hoarding is a big problem in our healthcare system today -- people stockpiling material while others are running short -- creating greater visibility in that would be one idea.

Soumi, we haven't heard from you yet, so I'd love to hear your point of view from a representative of a GPO.

DR. SAHA: Of course, thank you. So to add to the points that Andrew raised around the operational impact, I think one of the biggest challenges we had early on in the pandemic is that we were really dealing with a fragmented, siloed approach. It was an "every man for themselves" type of approach where each individual was trying to track down products on their own.

We didn't really have a unified holistic manner of nationally acquiring many of these critical medical supplies and drugs needed for treating the pandemic, which also unfortunately meant that we all quickly became experts in the gray market offers, our inboxes were all flooded with supposed suppliers who had magical products that appeared out of nowhere and there was no centralized way to truly vet those offers to determine which were authentic versus which were counterfeit products because the last thing we wanted to do was impact the integrity of the supply chain and how that would impact patient care downstream, as well.

I also want to hit on this burden point. You know, one of the biggest challenges to date is we can't tell you what is on U.S. soil when it comes to critical medical supplies and drugs, we don't have a true transparent and visible way to say this is what is in supplier, distributor, and hospital markets universally. And that creates challenges, too, because that

lack of visibility means we don't know, many times, what to say to suppliers who raise their hand and say how can I help. It means we're not really moving products to the area of greatest need and really leveraging a dynamic allocation process. It means we don't know how to help some of our non-acute providers who were left with no supply during the pandemic.

And what happened during the pandemic is we, as a country, started asking hospitals and other providers to start manually reporting their inventory on hand via a fancy Excel file at the end of the day and talk about needing your providers to be front and center for patient care. We can't burden folks with manual processes like that in the future, so we really need to leverage technology, to that first point, build out those IT infrastructures so we can automate that type of necessary data collection and then action in the future.

And the other thing I would point out is that the operational impact continues to change day to day. The shortages of today are so different than the shortages of 2 years ago. We're no longer talking about shortages of PPE, we're now talking about shortages of contrast media, suction canisters, items that no one was talking about 24 months ago, and that is just to the point that this is going to continue to evolve, we're going to have to remain flexible and nimble, but also continue to innovate in how we solve these problems. The whack-a-mole approach of we're going to fix this one product category is not going to work, we're going to have to really look at it universally across the entire medical supply chain.

DR. HANDFIELD: Yeah, those are excellent points. Thank you, Soumi. And I know during COVID I had firsthand experience of how difficult it was to get information on inventory at hospitals, and hospitals often aren't always too keen on sharing that information or may not have access to it for one reason or another.

DR. SAHA: Well, I think one of the big challenges, too, is there was this intense fear

throughout the pandemic that if you had product because let's say you were in a hurricane zone and you should have a stockpile, that you were going to be punished and product was going to be confiscated from you.

DR. HANDFIELD: Yeah.

DR. SAHA: So as we also think about the future, it's not about just building the transparency, it's also about building the assurances that if you appropriate level of inventory to meet your demand, that you will not be punished for having such.

DR. HANDFIELD: Yeah. And I think that brings up the next question, is how do all of the different parties in the supply chain engage together to create resilience? I think you can't do it alone, clearly. You know, you can't create your own little leased warehouse full of stockpile and inventory and say well, I'm good. You know, we do rely on providers, we rely on distributors, we rely on GPOs and of course, manufacturers. How do these parties work together to create alignment in resilience?

Soumi, we will start with you again and then go to Deborah.

DR. SAHA: Yeah, I think the key moving forward is going to be continued public-private collaboration. No sector can do it on their own and no individual entity within the supply chain can do it on their own. We really have to continue to work together. One wonderful thing that came out of the pandemic is that public-private collaboration that allowed us to be transparent with one another, share data with one another, innovate together on how to do better, and that has to continue as we move forward. So as we think about the FDA's role moving forward, I think it's not just what is the FDA's role, it is what is the FDA's role working alongside the private sector to address medical device supply chain resiliency, we have to work together and each entity needs to have a seat at the table to really effect change for the future.

DR. HANDFIELD: Absolutely, couldn't agree more.

Deborah, what are your thoughts?

MS. HAYWOOD: Oh, I completely agree with everything Soumi said. I mean, it's really that transparency and that collaboration, and one of the benefits, like I said a little earlier, was the federal agencies partnering with and working, much like Soumi just said, alongside. That has to continue if we're going improve this for the duration and that it's just saying that it's not just something that's done for today and then we don't continue to upgrade it and look at it as the different events can possibly change and go forward.

I think the data sharing, to me, the transparency is what's most important and that has to happen between our providers, our manufacturers, our distributors, and understanding what is going to be critical for that is just really how are we going to continue to innovate and that innovation is going to have to be something that can be used by all entities so that it can be aligned, so that the data is correct and that it can be shared and that it is a U.S. government owned or U.S. government approved product. I think that is one of the biggest things, we had that influx of gray product come into the market and now trying to still either get that out or understand where it was. We've got many providers that are left holding some of that product that simply cannot be used, and so that's not something that can be sustained.

You know, I think in just looking at -- looking just in addition, it's making sure distributors can continue to add that resiliency to get it to the point of care where it's needed the most, to prohibit some of the hoarding that providers feel like they have to do to protect themselves. It's just a natural feeling, they're going to try and take care of their own entity or their own establishment and so that they can go out and deliver that patient care, but making sure that we have reserves in place and that we're checking the expiration date. So it's fine to have stockpile, it's fine to have product, but if the expiration of that product or device is not maintained with preventative maintenance or the supplies that go

with the device are not there to be used whenever that device must be used, you know, really your system will fail. So I think we've all learned a lot, but moving forward it just really comes down to operational excellence. It has to happen within the supply chain, the providers have to be able to depend on it, the citizens need to know that the product is there and that they're going to receive the care they need most at the time that they need it, and the distributors and manufacturers are going have to be transparent with their data so that supply excellence can be expected for smooth execution.

DR. HANDFIELD: Yeah. Thanks, Deborah. I think that we really need to have hospitals that don't have to worry about having product available. It should just be there, as you say.

MS. HAYWOOD: Agreed.

DR. HANDFIELD: The last question we have is kind of an interesting one and I think I'm going to direct it to Eric, and it has to do with how do we factor in health equity into supply chain resilience and how do we make sure that when there are shortages that we promote health equity and reduce disparities in the availability of medical devices. And I think we've seen -- you know, as a result of COVID, we've seen a lot of shortages and we've seen a lot of delayed care, especially for some assessments. What do you think is a future state in terms of what we can do to promote health equity in the future?

MR. GASCHO: Thanks, I will try my best to answer this question, just given how important and sort of all encompassing it is and certainly does not lend itself well to brevity, but I will attempt to be brief.. So I think we've heard a few times today that the pandemic did not cause many of the supply chain shortages that we've seen but really exacerbated and eliminated them. I think the same thing can be said about health disparities. Certainly, the pandemic did not cause the health disparities we saw, but absolutely the health disparities did have a massive impact on the outcomes that we saw within marginalized

populations. I think you can make a similar argument as it relates to supply chain resiliency and integrity. I think if we do have shortages, I think that the second question is a very key one because without active planning, I think it's pretty easy to assume that there will be a disproportionate impact of supply chain shortages on marginalized populations probably for at least two reasons, but kind of the two that are most apparent to me, certainly as we see that a shortage of any supply is only going to increase demand, which will make it easier for people of means to be able access them, and I think we want to make sure we're thinking about equitable distribution.

Secondly, as I mentioned in my opening statement, lack of supply chain resiliency is really going to have a disproportionate impact on people with chronic diseases or disabilities, and black and brown populations are disproportionately affected by chronic diseases and disabilities. So thinking about where the biggest need is going to be is really important.

I also want to challenge us to think more broadly about health equity, certainly to think about it from a racial/ethnic perspective, very important, but also really thinking about what are some of the unique needs of other populations, such as those with disabilities. I was really struck by a point that was raised by Mary Beth earlier about equitable distribution of devices, and one that immediately came to mind was something that we really struggled with early on in the pandemic with ventilator shortages. You know, a lot of the disability groups within our membership were very concerned about the crisis standards of care and what that would mean for people with disabilities. Thankfully, we did not see any of them get implemented or if they were, they were modified to be more respectful of people with disabilities. But really thinking about, sort of broadly speaking, what does that ethical distribution mean, whether it be in black and brown populations, whether it be in areas that may have -- are underfunded or fewer options for medical

facilities and then certainly within the disability community, as well?

DR. HANDFIELD: Thank you. Great, great response. So we do have some time for questions from the audience and Marina has been doing a great job of capturing some of these.

Our first question has to do with complexity of product disruption, the escalating complexity of product disruption affects the organization's ability to provide the best care. What would you recommend to centrally communicate manufacturer disruptions, acquisitions, product line reductions, shortages and other things that might occur? How do we make people aware of these potential disruptions for certain kinds of products, given our complex supply chains today?

Who would want to take that on? Andrew, do you want to start, start us off maybe with that?

MR. LAM: Yeah, I mean, personally, I'd advocate for some sort of central database or communication platform where manufacturers are required to put that information, early warning systems and such. You know, the FDA helps with, from a recall quality perspective, the quality perspective. I would love to see some sort of extension where we have something where the manufacturer is doing a discontinuation of a product and it's coming up in a period of time. The information and communication is a bit disjointed, and I do think there's some -- I would even say maybe some equity questions or concerns there in terms of who they're telling first, when they're telling them, because you can see, as I mentioned, when there's hoarding, product can be pooled based off of communication and alert.

DR. HANDFIELD: Yeah. And I think that's the problem. Very often you don't hear about it until it's too late, right? And I've heard that if you had early warning, at least you'd be able to put in some conservation measures or identify substitutes or do other things and

I think that that early warning is really important.

Linda, do you have any thoughts on that issue, as well?

MS. O'NEILL: Sorry, I think I was on mute. I think it will probably take a little bigger picture and kind of hearken back to some of the discussion earlier about communicating, and Deborah was mentioning all the distributors and manufacturers were in constant communication together and we do a lot at HIDA, they have a supply chain collaboratively with people in kind of that bigger picture of stakeholders as manufacturers and distributors, GPOs and providers.

And we kind of talked through some of those more like industry pain points, if you will, and we've done some best practices when we talk around allocation and coming up with some industry best practices. We've been talking about that same thing, too, on how you communicate amongst the supply chain in a more uniform way about back orders and shortages so that our customers, our provider customers are getting the same information from everybody and people are being consistent. So it's something that we've been tackling and working on, as well.

DR. HANDFIELD: Soumi, you have your hand raised, as well. And Erin. I'll let Soumi go first.

DR. SAHA: Great. Thanks, Robert. So one of the things I do want to point to is new authority that FDA received in March of 2020, right at the beginning of COVID, around collecting supply chain disruption information and discontinuation information as it relates to medical devices, and FDA has since stood up a device shortage list, if you will. The key though, is that being able to collect that information and communicate that information out is currently contingent upon the public health emergency. And so one thing that Premier has been working on is looking at how we ensure that those authorities are extended beyond just the public health emergency so FDA can continue to grow their work in the

device shortage realm and continue to be more robust with their communications. However, speaking of burden, burden goes both ways. Burden can be on a provider, but burden can also be on a supplier from a regulatory perspective. So we're also mindful that much of this reporting can't increase the burden on the supplier to a level where it's no longer feasible for them to do so, where it requires increasing prices to a point where providers can't absorb those costs. So there are nuances that we want to be able to work through, but we do think that FDA does play a critical role in being that centralized collector of supply chain disruption information and a broad communicator. They started that work, it can grow, and it can be further refined.

DR. HANDFIELD: I couldn't agree more. I think the FDA is certainly the right agency to be able to coordinate that kind of a response.

Erin, love to hear your thoughts, as well.

MS. KYLE: Yeah, I just agree with what everyone has said already and would like to just add on to that, that collecting information in a centralized location really is essential in a way that every person who hears the information can trust it, they can take it to the bank. And I would also add that, from the perspective of clinicians on the front lines, what we've found through surveys at AORN is that many times clinicians don't really know what the supply chain climate is like and how it's going to affect their practice until they arrive for work that day.

So I'm going to approach this question a little bit differently and answer it in terms of how the organization can take information that's shared broadly from an agency like FDA and get it to the hands of the people who really need it on the front lines when it's essential that they know. And I would offer that the best way to do this is to build in a communication strategy that's part of their standard daily work every day. So we communicate in the hospital and in a clinician setting, how many beds are available, what

sorts of admissions we expect, what discharges look like. Why not also include information about supply chain disruptions or solving supply chain problems as also part of those daily communications?

DR. HANDFIELD: Yeah.

(Cross-talk.)

DR. HANDFIELD: Yeah. No, that's a great idea and I've seen that done very well working with, for instance, Flex, where they have people's mobile phones and they can alert individuals based on what is going on in the supply chain and where the shortages are occurring, and there's no reason that couldn't be deployed at a healthcare level.

Let's go to our next question, and this is one that I've seen before, how do the panelists assess the tradeoff between lean and resilience? Lean, of course, is often interspersed with the JIT concept. And you know, it's funny, I worked in Michigan for a while with the automotive sector and I observed JIT very well and the difference with JIT, I think, is that you have suppliers that are local, that are delivering right to your facility, and in health care, unfortunately, a lot of our suppliers are across the ocean. But is there a tradeoff and what does that look like?

Who wants to take that one? Deborah, go ahead.

MS. HAYWOOD: Yeah, I think the tradeoff begins with just a supply chain that has product that is both domestic and international. I think you have to make sure that you have enough sustained product. Just because its domestic doesn't mean that you couldn't have an emergency that actually took out that plan, as well, so we have to think proactively in a manner that was really not done before. So I think there's a balance there. I think also that the FDA is almost the source of truth, whether you're a distributor, manufacturer or a provider, you look to the FDA to play a key part of that communication, much to what Erin was just saying.

And so when you think about how do you maintain that or how do you establish that just in time, there are tradeoffs. The tradeoff is going to be the cost of the product, depending on where the product comes from. The pricing is certainly always a conversation that needs to take place, but what are we willing to do for future success for sustainability so that just in time becomes just in time of the need?

So we've looked at you run a 7 to 10-day or a 15-day, depending on the type of care setting that you are, as far as inventory, because you only have so much space and there is reordering that takes place between the distributor and the manufacturer to resupply that. So that cost is the space to contain the product, as well as the cost of the product, so maybe being nearer at times domestically or have international support, as well. So I think just in time needs to become just in time of the need and think forward of what that need is going to be.

DR. HANDFIELD: Unlike the Amazon model, you can get it in 2 days, but to do that they've had to build distribution centers in every major city, right?

MS. HAYWOOD: Right, cost.

DR. HANDFIELD: The next question has to do with accuracy of communicated data and I think a big problem with communication is the accuracy of the data or the lack of that data. We saw that certainly during COVID and even during the current period, the volume of shortages that's continued to impact us and we've seen this with -- you know, I mentioned resins but also baby formula, of course, and a number of other areas. And finding out who has what, where the inventory is, what the demand is can be a real challenge. What do we need to do to get more accurate data or how do we think about getting more accurate data? Is that something the FDA should manage?

DR. SAHA: I don't know that it has to be FDA that manages it, but I think it goes back to that prior conversation about transparency regarding what's actually in the supply chain

from the supplier down to the hospital or healthcare provider, what's actually out there in the provision of patient care. But part of that is also making sure we have a standardized data nomenclature. One thing that was quickly apparent during the pandemic is how I refer to a box is probably different than how you referred to a box or a unit, and so there's some work that needs to be done behind the scenes to standardize that nomenclature, make sure we're comparing apples to apples so that as we're reporting out supply chain data, there is consistency in how that reporting occurs.

DR. HANDFIELD: Yeah, great point. And I've seen that, as well, just in terms of data standardization, data accuracy, the importance of having similar coding schemes or at least ways to crosswalk data so that you can look at it in different ways and be looking at it.

We've heard a lot on this panel about the topic of collaboration and this is a consistent theme, that everybody needs to collaborate. And this individual notes that this isn't going to happen unless something changes. So what do you think is going to be -- is this the triggering event that is going to make collaboration happen or is there something else? You know, we don't want to have to regulate collaboration, but what is the right approach to driving this level of collaboration within the supply chain today?

Erin, maybe you have any thoughts?

MS. KYLE: Yes, I think that you just have to build it into the system, just like any other system. If you decided now that we're going to shift focus from the way that we've done things always to the way that we want to do things into the future, it does require a huge shift in mindset. And I think we're all there right now. I think that across the board, everyone is really in a place where it's the right time to make the change for a more collaborative and communication-rich environment to move forward. I think that the most critical thing that we need to do right now is to figure out what the structure of that communication looks like so that collaboration is sustainable.

DR. HANDFIELD: Right. And I think the issue at hand also is competition, right? That's always the issue with sharing information and collaboration, how do we maintain competitiveness and how do we ensure competitors don't have access to our information and be able to use that against us?

Linda, I'm sure you maybe deal with that all the time with HIDA, right? So what do you think might work in this environment?

MS. O'NEILL: I'd probably take it back a step, I would almost argue there's been a lot of collaboration already happening. We've been doing work with the Strategic National Stockpile, especially, for years as distributors, doing roundtable discussions with them and I think one of the things that doesn't get talked about a lot is we wouldn't have gotten done what we did during COVID, not that there hasn't been a lot of lessons learned, if we hadn't already had some collaboration and trust and some initial leg work being done. It was the distributors, as our members, that were first to the table to submit data to the supply chain control tower and that's something I don't think would've happened 5 years ago.

But I think that's a testament to the fact that we've been caring about preparedness for a long time, just like a lot of people here do. And so behind the scenes there is a lot of work already being done with folks in the industry and with some of the other federal agencies. And so I think adding FDA's workshop, which is perfect timing on top of that, there's a lot to build on, there's already been a lot of collaboration, a lot of discussions, and I think there are more agencies that have a role in that, like FDA, and more partners that have a role in that beyond just manufacturers and distributors and some of the initial work that's being done. But I would say I think my biggest takeaway from discussions today is there's trust, there is an element of trust there that, for my distributors who are submitting data to the supply chain control tower, they know what they're submitting, they know what it's getting used for, and some of that is a two-way street. I think Deborah talked about

that bi-directional communication. And I think it will be important going forward for federal agencies to really make sure that they're communicating what they're going to do with that data, how they're going to make decisions so that the commercial market is willing to keep doing that and to keep building on it. So I don't think anybody wants to go back to ground zero and start over again and have this happen. So I would hate to see a lot of the good work that we've done go away and I think kind of moving forward and keep building on that trust and keep building on some of the successes. We keep talking lessons learned, but there are also a lot of great successes that we can build on.

DR. HANDFIELD: Great, thanks. Thanks, Linda.

Cost is always a critical decision and I've seen this so often in the N95 mask market where a lot of domestic manufacturers sprung up after COVID and then post-COVID, a lot of healthcare providers are going back to China, of course, because of the economics. So we have to address the cost issues at some point if we're going to go with a near-shoring or on-shoring solution. What incentives can be created to enable on-shoring or near-shoring to address the cost issues? Is there some government policies that should be enacted, do you think?

Soumi, I don't know, maybe you have thoughts on this?

DR. SAHA: I do. So I think there's two realities, you know, you're absolutely right, the fact of the matter is that domestically sourced product will be more expensive. There is opportunity to invest in automation, for example, to help bring down some of those costs, use more of an automated process. But there are two options here. The conversation that needs to occur is (1) how do we pay for resilience? CMS, right now in their inpatient rule, is contemplating reimbursing providers at a higher rate for domestically made N95 masks. That's one way to think about it, but we also need to think about how we pay for resilience beyond just N95s and other critical medical supplies and drugs and how do we pay for it

beyond just CMS. We need the private payers at the table, as well, to have that conversation. Option number 2 is how do you potentially offset the higher cost of domestically made product to create price parity so that there isn't a difference in pricing? And that's where we need to think about tax incentives, trade partners, other opportunities of that nature. So option 1 is either you have to pay for that resilience and figure out a way to pay at a higher cost, or 2 is figure out a way to create price parity between domestically sourced product and globally sourced product.

DR. HANDFIELD: Thank you. And the other solution, I think, is when you start looking at transportation costs from Asia, they are significantly higher, so there's -- along with fuel cost, so there may be some transportation savings, obviously, from domestic sourcing, as well.

Question 6 is around information sharing, and several people have suggested some type of a centralized information hub. What do you think are the incentives that would need to be offered to different firms to truthfully report supply chain information?

And maybe, Eric and Andrew, you can address this, because ultimately I think people want to know what's going on inside of hospitals and what's the consumption rate and how much inventory there is and so forth.

MR. GASCHO: I would actually like to pose a question to the panel, as well, or maybe this is something to be discussed during the breakout session.

DR. HANDFIELD: Yeah.

MR. GASCHO: I think one thing that kind of appears to me from this and the collaboration question, as well, is are the barriers to collaboration and data sharing well established? So this might be one of them, maybe it's a sort of lack of trust in how the information is going to be used. We heard competition. I would love to know if we even know what those barriers are to begin to address them. If not, I think that's a really

important first step to think about.

DR. HANDFIELD: Great point. Maybe that's a great breakout discussion point.

Andrew, your thoughts?

MR. LAM: Yeah. I mean, I would actually say the exact same thing, which is understanding those barriers, I mean, trust of what the data is going to be used for and then more importantly, not what is it going to be used for, how is it going to help the situation. You know, what we saw a lot in the pandemic, there was a lot of reporting requirements, both state, local government, federal, in terms of how much PPE do you have and they were asking for that daily.

And in certain cases, it's what are you doing with that information. Is it just being consolidated, are we reallocating inventory, are we trying do something like that or are we trying to get a sense for how much additional capacity is needed. So if that was happening, it's not being communicated, it wasn't being shared and in some cases it just felt like an administrative burden because of -- you know, for political reasons.

DR. HANDFIELD: I agree, and I think it's important to understand what we're going to do and how we're going to -- you know, how we're going to -- trying to use that information, as you said.

Let's kind of finish up, I think we have time for one more. For working on emergency preparation with U.S. government leaders for many years prior to COVID, what are some of the big lessons learned out of this?

And Linda, maybe we can hear from you about what were the big lessons learned.

MS. O'NEILL: I think the big lessons learned really are to continue building our public-private partnership. Really, I think folks have been saying that and we keep coming back to that and I think, from our perspective as distributors is yeah, nobody can do it alone and we've said that, but I think that our membership, you've got 500-plus distribution

centers, 76 million square feet of warehouse storage space, they use distributors for what we do well, managing inventory, rotating it, for the products that make sense, PPE, testing supplies, things that are used every day in healthcare. And we can help support, whether it's state stockpiles, the federal SNS, to be able to augment and really create a cushion so that when we get back to measuring that resiliency, if we've got a big enough cushion, then our provider customers are going to be able to get what they need and Deborah said it well, that just-in-time becomes just in time for whatever they need or whatever that demand is at that time.

So I think the biggest lesson for me is really building on that partnership and creating a cushion from our perspective in the supply chain, utilize us for what we do well, as well as diversified sourcing, I think that's really become an eye opener for a lot of folks. We can't be overly dependent on one thing. And I think going forward, we need -- I thought Soumi said it very well, we got to figure out a way for it to be sustained, right? You can't just have an initial incentive to produce here, you've got to have buy-in from that commercial market and it can't just be Medicare, although I think I love that CMS is looking at it from that perspective. Soumi said well, you need more, you need that continued and that sustained demand to be able to support any sort of domestic production going forward. I think it gives me a lot of hope, though. I think more and more people care about it and I think more and more people are listening to what we have to say.

DR. HANDFIELD: Well, thank you. I think that's a great summary. You know, I think we talked about a lot of really important things here, the public-private partnerships, the importance of creating capacity and availability, thoughtful allocation and equity when shortages do occur, having stockpiles of the right kinds of things and ongoing data monitoring and so forth. So a really good first panel discussion to kick off our day and I want to thank all the panelists for their time today and their thoughtful comments and

taking time on your very busy day for participating in this.

Carl, over to you.

DR. NEWMAN: Thanks, Rob. And thanks to our distinguished panelists, a really great conversation and great discussion. Yeah, it was a pleasure to actually follow along.

So next up we're going to have a quick break before our breakout groups. For those following along at home or wherever, if you signed up for our breakout groups today, you should have received an e-mail from the RSCP workshop address with a link to join. There was tremendous interest in the breakout groups but unfortunately, even in a virtual sphere, we still have limited space available in these sessions. So we're going to start the breakout groups at 2:45, that's a little less than 10 minutes from now. For those of you in the general audience, it's time for a station break. Please return back at 3:30 p.m. Eastern time, when we'll continue our programming with some key takeaways from the breakout sessions and close out the day. See you at 3:30.

(Off the record at 2:38 p.m.)

(On the record at 3:36 p.m.)

DR. NEWMAN: All right. Welcome back, everyone. Hope everyone had a nice little break. We had some really lively discussion during a series of breakout groups and we'll report out from some of the highlights from those groups. We'll probably get to all of them, probably, but I think what we'll hear from the reporters, it will probably be summative of the ones we don't get to hear from today.

Let's start with Breakout Group Number 6. Taylor, I think you were leading that one.

MR. WILKERSON: Yeah. Thank you, Carl. So we had a really good discussion around how you define and measure resilience. I think a couple of the key things that came out of that, one is the importance of it being proactive and that extended not just from how you define resilience, but also the measurement, including a lot of predictive measures into

that. The other aspect that really came out is that resilience has to include that ability to recover or rebound after a disruption and how quickly can you go from being disrupted to back to normal operations.

A couple of the other key things that came out, one is the importance of building relationships and relationships going everywhere from helping with that proactive, predictive aspect to the recovery and then the end-to-end perspective of resilience from raw material back to especially the patients, we heard that this morning, as well -- or earlier today, as well, really understanding resilience across that entire supply chain and tailoring resilience to the specific attributes of the product, the environment, etc., so it's not necessarily a one-size-fits-all. So again, a really good discussion around all of that. Look forward to hearing what the other groups had discussed.

DR. NEWMAN: Great, great. Thanks, Taylor.

Joel, do you want to share some highlights from Breakout Group Number 7?

MR. COHEN: Yes, thank you. Good afternoon, everyone.

Carrying on with what Taylor said, the idea that there's no one-size-fits-all approach, we heard talk about a focus on flexibility, of developing the capability to develop new relationships and make different choices more quickly. At the same time, there are investments being made in enhancing the reliability of the relationships that currently exist and that includes enhanced verification of stated capabilities, it includes writing and agreeing to much longer-term contracts. So you have the present-day forecast capability actualized through these long-term relationships that aren't meant to achieve flexibility, they are meant to guarantee that the relationships and the reliance that is in place will be there when you need it. Moving into the idea that supply chains are ultimately evaluated on a complex and dynamic risk model that itself continues to evolve even if individual relationships are increasing their longevity and the forecast that's applied there, there is a

holisticism that continues to be revised, so the importance of flexibility to your approach even as individual relationships are invested in for more of a reliable capability.

DR. NEWMAN: Great, thanks.

MR. COHEN: And a lot of other good conversation besides, so really appreciate folks being here today.

DR. NEWMAN: Fantastic. Thanks, Joel. I know there was some lively conversation in your group and I was able to stop in and sort of peek behind the curtain.

Pam, do you want to share highlights from your group?

MS. DOUGLAS: Of course, yeah. We also had a very energetic conversation and I think we covered topics like the others have just debriefed, but we also discussed that having resilience enables the sprint capacity and ability to respond, and it's a strategy around readiness to supply as opposed to the failure to supply. And so some of the strategies that were used by our participants included diversity of sourcing, adaptive strategies on how to manage inventory, raw materials, work and process planning, lead time and logistics. They also protected the supply chain by having some of the right inventory in the right places and planned ahead to get approval from the FDA for ultimate components, in cases if a key component was not available or a key resin or other type of product that's used.

But one of the messages that came through very, very clearly was that communication, trust, and transparency are really critical and that working with the suppliers and the recipients of the products is very important and that having communication at the right level that is timely and of the -- you know, it helps build the trust and the transparency between the organizations is key.

And then there were also some conversations about managing the short and long-term resilience measures and approaches because there are some differences in reacting to

a shortage versus planning to have resilience for something that might happen in the future. And that concludes our group.

DR. NEWMAN: Great, thanks. It sounds like a very robust discussion happened there.

Let me see. Jon, are you able to share a little bit about the discussion from your group?

MR. DAVIS: Yes, absolutely. We had a great discussion in our breakout group. First of all, I think we heard a great definition from one person, you know, resilience ultimately is about being able to keep product on the shelf when it's needed to care for patients.

We heard a few different elements around resiliency. One thing we heard about there, resiliency is directly tied to innovation and there's this balancing act between innovation, flexibility, which is inherently risk taking, versus quality and certainty, and a corresponding concern about the response from the FDA when it comes to those kinds of risks that are being taken.

We heard an opportunity around secondary suppliers, the importance of having dual-source suppliers, but also looking for collaboration with the FDA to streamline and define criteria or a pathway for adding secondary suppliers. We also heard from individuals who were including that in their initial regulatory filing so that they had that plan for multiple suppliers and multiple components and raw material suppliers up front.

And finally, back to what others said, organizing sessions like this is important. We heard a great need for collaboration across industry and even this idea that serving patients and making sure that if there's a shortage, you know, as one person said, my company may not be able to serve our customer and supply the demand, but my competitor might. And so how do we make sure that there is a way to for us to communicate and collaborate to ensure that the product gets where it's needed in order to serve the patient outcomes?

That's it for our group.

DR. NEWMAN: Great, thank you. Let me see.

Mary, any highlights from yours?

MS. MORIARTY: Hi. Thanks, Carl. We had a great discussion, as well, with our group members. I would say that many of the themes discussed by other report-outs I can echo from our group, as well, with regard to being very proactive in the ecosystem, having strong communication and collaboration systems to help get the messages out.

Some things that our group discussed that may not have been related from the other report-outs include such things as having a regional capability to understand resilience at the regional level. So I thought that was a pretty interesting conversation, as well.

They discussed that really needing help from FDA and other federal agencies in getting the messages out about resiliency, worried about medical device companies perhaps not having necessarily the clout or the volume and when compared to other industries like, for example, the auto industry, in terms of getting the help they need to build resilience and get the products where they need to be.

And they discussed a little bit about the types of systems, both quality systems and risk management systems that really can help identify and define the suppliers who are maybe not providing the products at the time and in the numbers that are needed. So I think those are some differences that we heard in our group.

DR. NEWMAN: Great, thanks so much. A couple of times it sounds like transparency and communication came up across the groups. Was there any discussion on what that might look like, because that transparency with the government, for example, or transparency across individual stakeholders in a sector or like manufacturers or trade organizations, any discussion on what that transparency and communication might, should, or could look like?

MR. WILKERSON: So this is Taylor, I can jump in a little bit there. I mean, as I discussed, part of our discussion was around the building of relationships throughout the supply chain and I think that was a key component that was not just working with people a long time, but being transparent and sharing data and that was both upstream in the supply chain as well as sharing information with your customers, with the people using your products, so that they are aware of anything that's going on. So a lot of our discussion really focused on that aspect of sharing the information within the supply chain for the different devices, different products.

DR. NEWMAN: Thank you.

MS. DOUGLAS: This is Pam. I can add in that, for us, our group also took the form of ensuring that there was good, trusted communication between the suppliers and with tier one and tier two suppliers and the company, so that they had timely updates so that there were no surprises, so that they were able to kind of assess risks early and come up with mitigations and that sometimes the conveying of information that was identified in those conversations, it was like you reported to a group up the chain in a more, I guess, unidentified way or in a more ambiguous way, but that was part of both making sure that people got the message, but also that there could be more specifics in the trust at the level that's important to protect and be able to have those kind of open conversations.

DR. NEWMAN: Thanks.

MR. COHEN: Excuse me. A related topic that came up in our group had to do with the importance of the conversation carrying on between the FDA and other regulatory agencies around the world and the importance of those dialogues being in place and being sustained and being supported so that as market actors within the medical device ecosystem adapt to circumstances and to work along their networks or to build out their networks, to make these the relationships, to meet their production requirements, that the

necessary relationships and understandings exist between government entities who do so much to sustain the framework within which the market ultimately operates. So there was a good bit of conversation about that within our group.

DR. NEWMAN: That's an interesting point.

Jon, you mentioned something as part of the takeaways from your group about innovation and risk taking. I'm wondering, was there any elaboration on where that innovation and risk taking should take place first or thoughts on how it could take place?

MR. DAVIS: Yeah, there was some really robust conversation. One participant shared how they were -- they really took a deep-dive look at their own manufacturing process that they had for producing N95 masks. They found it was incredibly antiquated and that they worked with their engineers and created a whole new production machine and equipment to have an incredibly expedited production of those materials. So there was a lot of internal look at innovation.

Subsequent to innovation, though, is also how do we make sure that we've got multiple different suppliers. So there was a diagnostic group and they were looking at well, how do we have multiple suppliers, but then that brings complexity, that brings multiple different lots from multiple different suppliers that increases the complexity of testing to ensure what the quality is. It's much easier and simpler to have a single-source supplier for things like that. So innovation comes with consequences and it's a balancing act from that standpoint around that risk taking, as well.

DR. NEWMAN: In some of the other groups, was there a similar discussion about the balance between complexity and simplicity? So you've got, on the one hand, with complexity there is redundancy and robustness, but with simplicity there is that risk of a single point of failure. Did that concept come up in any other groups, as well?

(Pause.)

DR. NEWMAN: All right.

MR. WILKERSON: I think, Carl, the way it came up in our group is again going back to how you define resilience, and it may be almost sort of flipping that on its head a little bit, that being too simplistic in how you define resilience for saying resilience this for everything actually leads to more of a problem, that there is a need to go a layer or two deeper and define resilience a little more nuanced depending on the individual product or the individual environment it's going into but again, that balancing act between saying resilience is this and being able to make it applicable to what's actually going on in the supply chain and in the organization.

DR. NEWMAN: Excellent. Pam?

MS. DOUGLAS: I'd also add that our group thought about resilience as going beyond just the given product, but that it also included the individuals who could -- you know, whether they were clinicians or others that were needed to use the device and that absent any of these things, like it was not -- the resilience wasn't there unless you had everything needed to provide that care to the patient. So it was also mentioned that things can -- you know, getting stuck in transit, let's say on a ship. You might have been able to manufacture it but If you can't actually get it, then that's not meeting the need.

DR. NEWMAN: So resilience across the spectrum. Great.

Any other last-minute highlights that we didn't touch on already?

MR. COHEN: I think we touched on this a little, but one of the things our group appreciated was that it's important to think about resilience, it's important to invest in resilience. A lot of actors within the ecosystem are still currently primarily focused on a reactive posture, on responding to the ongoing disruptions of this current environment, and I think it's something that we've heard a number of folks talk about in the preludes to this workshop event, that resilience is a really important thing that we have to be working on

alongside everything else that's really important that we need to be working on and just appreciating sort of the ranked prioritization of some of these challenges that are staring us in the face.

DR. NEWMAN: Great, thank you. Thank you all for leading those panels, as well. I know there are several other panels that happened concurrently and I'm sure that there's a lot of similar themes that came out of those. Next slide, please.

So thanks, everyone in virtual land, for joining along today for the first day of our 3-day workshop. I hope that for those who were able to join the breakout groups, I really appreciate, and I know everyone else does, your thought and your participation and your creativity. Everyone, please keep in mind, this is a 3-day workshop and this is just the first day.

So tomorrow I'll be pulling the thread a little more and talking about building and sustaining resilience, and I'm sure that we'll have more and continued robust conversations in the form of the breakout groups. Sorry, my cat is kind of going nuts behind me. I can only hold him at bay for so long. But I hope everyone is able to join us again tomorrow for Day 2 and then again for Day 3, when we're going talk a little bit more about how do we do this kind of collaboration thing, anyway. Thank you all for your attendance and your time and patience and this is, I think, a great first day and the first kickoff for this workshop.

(Whereupon, at 3:55 p.m., the meeting was adjourned, to be continued the following day, Wednesday, June 8, 2022 at 1:00 p.m.)

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C E R T I F I C A T E

This is to certify that the attached proceedings in the matter of:

VIRTUAL PUBLIC WORKSHOP - BUILDING MEDICAL DEVICE SUPPLY CHAIN RESILIENCE: A HEALTHCARE AND PUBLIC HEALTH ECOSYSTEM-WIDE COLLABORATION

June 7, 2022

Via Zoom Videoconference

were held as herein appears, and that this is the original transcription thereof for the files of the Food and Drug Administration, Center for Devices and Radiological Health, Medical Devices Advisory Committee.

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